

# 最終報告書

表　題：イソトリデシル＝ステアラートのラットにおける反復投与毒性・生殖発生毒性

併合試験

試験番号：S R 0 9 2 0 7

株式会社 化合物安全性研究所

## 陳述書

表題：イソトリデシル=ステアラートのラットにおける反復投与毒性・生殖発生毒性  
併合試験

試験番号：SR09207

1. 本試験は、「新規化学物質等に係る試験を実施する試験施設に関する基準について」(平成23年3月31日薬食発0331第8号・平成23・03・29製局第6号・環保企発第110331010号厚生労働省医薬食品局長・経済産業省製造産業局長・環境省総合環境政策局長連名通知)に従い、試験方法は、OECD試験法ガイドライン(OECD Guideline for Testing of Chemicals; Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (422), 1996.03.22)に基づいて実施したものであります。
2. 本試験は、試験計画書に従って実施し、試験成績の信頼性に影響を及ぼしたと思われる環境要因は認められませんでした。

株式会社 化合物安全性研究所

試験責任者

2014年1月9日

## 信頼性保証書

表題：イソトリデシル＝ステアラートのラットにおける反復投与毒性・生殖発生毒性併合試験

試験番号：S R 0 9 2 0 7

本試験は、株式会社 化合物安全性研究所 QAU によって、下記のとおり査察された。

査 察 段 階	査 察 日	試 験 責 任 者 へ の 報 告 日	運 営 管 理 者 へ の 報 告 日
試験計画書	2011年 1月 26日	2011年 1月 26日	2011年 1月 26日
試験計画書変更書 (No. 1)	2011年 3月 2日	2011年 3月 2日	2011年 3月 2日
試験計画書変更書 (No. 2)	2011年 3月 14日	2011年 3月 14日	2011年 3月 14日
試験計画書変更書 (No. 3)	2011年 3月 23日	2011年 3月 23日	2011年 3月 23日
試験計画書変更書 (No. 4)	2011年 7月 11日	2011年 7月 11日	2011年 7月 11日
試験計画書変更書 (No. 5)	2011年 10月 3日	2011年 10月 3日	2011年 10月 3日
試験計画書変更書 (No. 6)	2012年 1月 17日	2012年 1月 17日	2012年 1月 17日
被験物質の受入・表示・保存	2011年 1月 26日	2011年 1月 26日	2011年 1月 26日
投与液の調製	2011年 2月 3日	2011年 2月 3日	2011年 2月 3日
	2011年 2月 18日	2011年 2月 18日	2011年 2月 18日
動物受入・検疫・馴化	2011年 1月 26日	2011年 1月 26日	2011年 1月 26日
群分け	2011年 2月 7日	2011年 2月 7日	2011年 2月 7日
投与	2011年 2月 9日	2011年 2月 9日	2011年 2月 9日
一般状態観察	2011年 2月 9日	2011年 2月 9日	2011年 2月 9日
体重測定	2011年 2月 9日	2011年 2月 9日	2011年 2月 9日
摂餌量測定	2011年 2月 9日	2011年 2月 9日	2011年 2月 9日
詳細な状態観察	2011年 2月 15日	2011年 2月 15日	2011年 2月 15日
機能検査	2011年 3月 17日	2011年 3月 17日	2011年 3月 17日
尿検査	2011年 3月 20日	2011年 3月 22日	2011年 3月 22日
	2011年 3月 21日		
性周期検査	2011年 2月 9日	2011年 2月 9日	2011年 2月 9日
生殖能検査（交配）	2011年 2月 22日	2011年 2月 23日	2011年 2月 23日
	2011年 2月 23日		
分娩および哺育状態観察	2011年 3月 17日	2011年 3月 17日	2011年 3月 17日
剖検・器官重量測定	2011年 3月 23日	2011年 3月 23日	2011年 3月 23日
血液学的検査	2011年 3月 23日	2011年 3月 23日	2011年 3月 23日
血液化学的検査	2011年 3月 23日	2011年 3月 24日	2011年 3月 24日
	2011年 3月 24日		
	2011年 7月 11日	2011年 7月 11日	2011年 7月 11日
	2012年 2月 1日	2012年 2月 2日	2012年 2月 2日
新生児の剖検	2011年 3月 22日	2011年 3月 22日	2011年 3月 22日
病理組織学的検査（標本作製）	2011年 3月 24日		
	2011年 3月 31日	2011年 4月 7日	2011年 4月 7日
	2011年 4月 7日		
病理組織学的検査（鏡検）	2011年 5月 26日	2011年 5月 26日	2011年 5月 26日

査 察 段 階	査 察 日	試 験 責 任 者 へ の 報 告 日	運 営 管 理 者 へ の 報 告 日
生データ	2013年 2月 12日 2013年 2月 13日 2013年 2月 20日 2013年 2月 21日 2013年 2月 22日	2013年 2月 22日	2013年 2月 22日
最終報告書（草案）：図表	2013年 2月 12日 2013年 2月 13日 2013年 2月 20日 2013年 2月 21日 2013年 2月 22日	2013年 2月 22日	2013年 2月 22日
最終報告書（草案）：図表*	2013年 3月 6日	2013年 3月 6日	2013年 3月 6日
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最終報告書（草案）：本文*	2013年 3月 6日	2013年 3月 6日	2013年 3月 6日
最終報告書	2014年 1月 9日	2014年 1月 9日	2014年 1月 9日

\* : 改善内容の確認

1. 本試験は、「新規化学物質等に係る試験を実施する試験施設に関する基準について」(平成 23 年 3 月 31 日 薬食発 0331 第 8 号・平成 23・03・29 製局第 6 号・環保企発第 110331010 号 厚生労働省医薬食品局長・経済産業省製造産業局長・環境省総合環境政策局長連名通知) および OECD 試験法ガイドライン (OECD Guideline for Testing of Chemicals; Combined Repeated Dose Toxicity Study with the Reproduction/ Developmental Toxicity Screening Test (422), 1996. 03. 22) に従い実施された。
2. 本試験は、試験計画書に従って実施され、また、本報告書には当該試験に使用した方法および手順が正確に記載されており、試験成績には当該試験の実施過程において得られた生データが正確に反映していることを確認した。

株式会社 化合物安全性研究所

Q A U責任者

[REDACTED] [REDACTED] 2014年 1月 9日

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表題：イソトリデシル=ステアラートのラットにおける反復投与毒性・生殖発生毒性

併合試験

試験番号：SR09207

試験目的：この試験は、イソトリデシル=ステアラートを雌雄ラットに反復経口投与してその毒性ならびに性腺機能、交尾行動、受胎および分娩等の生殖に及ぼす毒性を検討するために行われた。

#### 試験実施基準 (GLP) および試験法ガイドライン

試験実施基準 (GLP)：「新規化学物質等に係る試験を実施する試験施設に関する基準について」  
(平成 23 年 3 月 31 日薬食発 0331 第 8 号・平成 23・03・29 製局第 6 号・環  
保企発第 110331010 号厚生労働省医薬食品局長・経済産業省製造産業局  
長・環境省総合環境政策局長連名通知)

試験法ガイドライン：OECD 試験法ガイドライン(OECD Guideline for Testing of Chemicals;  
Combined Repeated Dose Toxicity Study with the Reproduction/  
Developmental Toxicity Screening Test (422), 1996. 03. 22)

#### 動物愛護

本試験は試験施設の動物実験倫理委員会の承認を得、かつ、標準操作手順書（動物実験倫理規定）に準拠した。

法規および基準等：「動物の愛護及び管理に関する法律」(昭和 48 年 10 月 1 日 法律第 105 号、  
最終改正 平成 18 年 6 月 2 日 法律第 50 号)  
「実験動物の飼養及び保管並びに苦痛の軽減に関する基準」(平成 18 年 4  
月 28 日 環境省告示第 88 号)  
「動物実験に関する指針」(昭和 62 年 5 月 22 日承認 社団法人 日本実験動  
物学会)

**試験委託者**

名称 : 厚生労働省 医薬食品局  
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**試験従事者およびその業務分担**

被験物質管理 : [REDACTED]  
動物管理 : [REDACTED]  
検疫・馴化 : [REDACTED]  
投与・観察・測定 : [REDACTED]  
臨床検査 : [REDACTED]  
病理検査 : [REDACTED]

**試験期間**

試験開始日 : 2011 年 1 月 26 日  
被験物質受入 : 2010 年 4 月 26 日  
動物受入 : 2011 年 1 月 26 日  
実験開始(投与開始)日 : 2011 年 2 月 9 日  
交配開始 : 2011 年 2 月 22 日  
新生児剖検開始 : 2011 年 3 月 21 日  
母動物剖検開始 : 2011 年 3 月 23 日  
雄動物および回復群雌動物投与終了 : 2011 年 3 月 22 日  
雄動物投与終了時剖検 : 2011 年 3 月 23 日  
回復群雌雄動物剖検 : 2011 年 4 月 6 日  
病理組織学的検査終了 : 2011 年 6 月 22 日  
ホルモン測定終了(実験終了) : 2012 年 2 月 2 日  
試験終了日 : 2014 年 1 月 15 日

## 要 約

イソトリデシル=ステアラートを、0 (媒体: トウモロコシ油)、100、300 および 1000 mg/kg/day の用量で、1 群雌雄各 12 匹の Cr1:CD (SD) ラットに、雄に対しては交配前、交配期間および交配後を含む計 42 日間、雌に対しては交配前、交配および妊娠期間、ならびに分娩後 5 日までの 42 ~ 46 日間経口投与し、雌雄動物への反復投与による影響、雌雄動物の生殖および新生児の発生に及ぼす影響について検討した。また、0 および 1000 mg/kg について、雄動物は各 5 匹を選抜し、雌動物は各 5 匹を別に設け、42 日間の投与終了後 14 日間の回復を行い、回復性についても併せて検討した。

### 1. 反復投与毒性

一般状態観察、詳細な一般状態観察、機能検査、体重、摂餌量、尿検査、血液学的検査、ホルモン測定、剖検において、雌雄とも 1000 mg/kg までの用量では被験物質の影響は認められなかった。

雄では、300 mg/kg/day 以上で腎臓に近位尿細管上皮の好酸性小体 ( $\alpha$ 2u-グロブリン抗体陽性) の発現頻度の増加、1000 mg/kg で腎臓重量の増加が認められた。これらの変化は可逆性のあるものであった。

雌では、1000 mg/kg/day でトリグリセライドおよびクレアチニンの高値および肝臓重量の高値が認められた。

以上のことから、本試験条件下におけるイソトリデシル=ステアラートの雄に対する無影響量 (NOEL) は 300 mg/kg/day 以上で雄の  $\alpha$ 2u-グロブリン腎症の発生頻度に増加が認められたことから 100 mg/kg/day、雌に対する無影響量 (NOEL) は、1000 mg/kg/day で雌の肝臓重量、トリグリセライドおよびクレアチニンに高値が認められたことから、300 mg/kg/day と考えられた。また、雄で認められた  $\alpha$ 2u-グロブリンはラット特有の蛋白であり、ヒトでは存在しないことから、雄に対する無毒性量 (NOAEL) は 1000 mg/kg/day、雌では肝臓重量、トリグリセライドおよびクレアチニンの高値が認められたことから無毒性量 (NOAEL) は 300 mg/kg/day と考えられた。

### 2. 生殖発生毒性

主試験群の生殖能検査および新生児の検査では、1000 mg/kg 群まで、いずれの項目にも被験物質投与に関連する変化はみられなかった。

以上のことから、本試験条件下における イソトリデシル=ステアラートの反復投与による親動物の生殖に対する無影響量および無毒性量 (NOEL および NOAEL) および新生児の発生に対する無影響量および無毒性量 (NOEL および NOAEL) はいずれも 1000 mg/kg/day と考えられた。

## 緒 言

イソトリデシル=ステアラートを、0 (媒体: トウモロコシ油)、100、300 および 1000 mg/kg/day の用量で、1 群雌雄各 12 匹の Cr1:CD (SD) ラットに、雄に対しては交配前、交配期間および交配後を含む計 42 日間、雌に対しては交配前、交配および妊娠期間、ならびに分娩後 5 日までの期間経口投与し、雌雄動物への反復投与による影響、雌雄動物の生殖および新生児の発生に及ぼす影響について検討した。また、0 および 1000 mg/kg について、雄動物は各 5 匹を選抜し、雌動物は各 5 匹を別に設け、42 日間の投与終了後 14 日間の回復を行い、回復性についても併せて検討した。

## 材料および方法

### 1. 被験物質

名称	: イソトリデシル=ステアラート
英名	: Isotridecyl stearate
別名	: オクタデカン酸イソトリデシル <sup>1)</sup> ステアリン酸イソトリデシルエステル <sup>2)</sup> Octadecanoic acid isotridecyl ester <sup>1)</sup>
CAS No.	: 31565-37-4
化審法官報公示整理番号	: 2-2489
分子式	: C <sub>31</sub> H <sub>62</sub> O <sub>2</sub>
構造式 <sup>3)</sup>	:
分子量	: 466.835 <sup>1)</sup> 、466.82278 <sup>4)</sup>
物理化学的性質 <sup>2)</sup>	: 外観 ; 液体(30°C)、淡黄色透明 臭い ; 特有臭気 沸点 ; データなし 融点 ; データなし 引火点 ; 240°C 蒸気圧 ; データなし 爆発限界 ; データなし

蒸気密度；データなし  
 比重；約 0.86  
 溶解度；水溶解性のデータなし。低級アルコールに難溶、エーテル等の溶剤類に可溶。試験施設において、トウモロコシ油を用いて調製確認を行った。

n-オクタノール／水分配係数；データなし  
 発火点；データなし  
 自然発火温度；データなし  
 分解温度；データなし

ロット番号 : 00119  
 純度 : 71% (ステアリン酸とイソトリデカノールのエステル化物)。現状を純度 100% (ステアリン酸とイソトリデカノールのエステル化物 71% + パルミチン酸とイソトリデカノールのエステル化物 29%) として試験に使用した。(Appendix 1-1)

使用原料の成分比率：1) 脂肪酸原料成分(パルミチン酸 30%、ステアリン酸 69%、その他脂肪酸 1%)  
 2) アルコール原料成分[イソトリデカノール(異性体混合物)99%以上]

製造者 : [REDACTED]

入手量 : 750 g×2 (関連試験と共に一括受入)  
 安定性 : 通常の取扱いにおいては、光、熱、衝撃に対して化学的に安定<sup>2)</sup>。試験操作の終了後、使用した被験物質に関する分析成績を入手し、被験物質の試験期間中の安定性を確認した(Aappendix 1-2)。

保存条件<sup>2)</sup> : 直射日光の当たらない通気のよい場所で容器を密閉し保存する。火気、熱源より遠ざける。

保存場所 : 株式会社 化合物安全性研究所の被験物質保存室(実測範囲: 21~25°C)

保存期間 : 2010 年 4 月 26 日(入手)~2011 年 3 月 23 日(最終回調製)

取り扱い上の注意<sup>2)</sup> : 保護手袋、保護眼鏡、保護面、保護衣を着用し、飛沫等が皮膚に付着したり、粉塵、ガスを吸入しないようにする。

サンプリング : 被験物質サンプルとして、約 5 g を採取し、試験施設の資料保存室に保存した。

残余被験物質の処置 : 関連試験を含め、すべての試験操作終了後、製造者に返却する。

## 2. 媒体

名称	: トウモロコシ油
ロット番号	: VOH3633、VOT4896
製造者	: ナカライトスク株式会社
保存条件	: 室温
取り扱い上の注意	: 特になし

## 3. 投与液の調製および化学分析

調製方法	: 被験物質を精量し、所定の濃度となるように媒体を添加後、スターラーを用いて溶解させた。
調製頻度	: 8日間に1回以上。
保存条件	: 遮光気密容器に入れた。
保存場所	: 株式会社 化合物安全性研究所の被験物質保存室(実測範囲: 22~24°C)
保存期間	: 2011年2月3日(初回調製)~2011年4月1日(最終回投与)
使用期限	: 調製液の安定性の保証されている期間内に使用した。
調製上の注意	: 被験物質はクリーンベンチ内で取扱い、調製の際にはゴム手袋およびマスクを着用し、吸い込んだり、眼、皮膚および衣類に触れないようとした。
残余調製液の処置	: 残余の投与液は、焼却処分するために産業廃棄物として回収した。
投与液の安定性	: 0.1および200 mg/mLの調製液について調製後室温保存で10日間安定であることが確認された(Appendix 2)。
調製液の濃度確認	: 被験物質の全濃度に関する投与液中における濃度を、雄の初回調製時および雌の最終回調製時の計2回確認した。投与液は試験施設で調製後、(株) 日曹分析センターに送付した。分析は(株) 日曹分析センターで実施し、各濃度液は設定濃度に調製されていることを確認した(Appendix 3)。
濃度分析方法	: Appendix 3に示す(試験計画書番号 10-198)。

## 4. 試験方法

### (1) 試験系

種・系統	: ラット、Cr1:CD (SD)
微生物統御	: SPF
生産業者	: 日本チャールス・リバー株式会社 厚木飼育センター
微生物モニタリング	: 動物生産業者よりデータ入手した。
動物選定理由	: ラットはこの種の試験で通常用いられている動物種であり、繁殖成績が

安定していることと当研究所における背景対照データが利用できることから、この系統を選定した。

発注動物数	: 雄 52 匹、雌 62 匹
受入動物数	: 雄 54 匹、雌 64 匹
発注動物週齢	: 雌雄各 8 週齢
出荷体重基準	: 雄は 240～330 g、雌は 160～230 g
受入時体重範囲	: 雄は 251～288 g、雌は 177～219 g
投与開始時週齢	: 雌雄各 10 週齢
群数	: 雌雄各 6 群(主試験群 雌雄各 4 群、回復群 雌雄各 2 群)
各群動物数	: 主試験群 雌雄各 12 匹、回復群 雌雄各 5 匹

#### (2) 検疫および馴化

検疫方法	: 一般状態を 1 日 1 回観察し、体重を受入時(馴化 1 日)および馴化期間終了日(投与開始 2 日前)を含め約 1 週に 1 回の頻度となるように計 3 回測定した。検疫および馴化期間中、いずれの動物にも異常はみられなかった。
性周期検査	: 雌動物について、性周期検査を膣垢スメア塗抹法により群分け日までの 10 日間に行った。検査の結果、性周期の異常は認められなかった。
期間	: 雌雄とも、馴化 1 日(受入日)から馴化 13 日までの 12 日間。

#### (3) 群分け

検疫および馴化期間中に実施した一般状態観察および体重測定ならびに雌の性周期検査の結果を参考にして、動物の使用の適否を決定した。群分けは、投与開始 2 日前の体重に基づいて層化無作為抽出法により、各群の平均体重が均一になるように行った。雌雄別に各個体の体重が平均体重の±20%を超えないことを確認した。なお、選抜から外れた動物は群分け日に試験から除外して、標準操作手順書に従って取扱った。選択された動物について、投与開始前日に一般状態に異常がないことを確認した。

#### (4) 動物およびケージの識別

動物	: 群分け前は油性フェルトペンで尾部に印を付け、個体識別を行った。 群分け後は耳介に動物番号を入れ墨し、個体識別を行った。 新生児については、個体の識別は行わなかった。
飼育ケージ	: 群分け前は性別毎に色分けしたラベルに試験番号および受入時の動物番号を明記し、各ケージの前面に標示した。

群分け後は性別毎に色分けしたラベルに試験番号、試験群および群分け後の動物番号を明記し、各ケージの前面に標示した。

### (5) 動物飼育

#### 1) 飼育環境

飼育室番号	: 302 号室
温度・湿度	: $22 \pm 3^{\circ}\text{C}$ , $50 \pm 20\%$ (実測範囲 $20 \sim 23^{\circ}\text{C}$ , $43 \sim 53\%$ )
換気回数	: 10~15 回／時間
照明時間	: 人工照明 12 時間 (8:00~20:00)

#### 2) 飼育器材および飼育方法

ケージの種類 : ブラケット式金属製金網床ケージ ( $260\text{W} \times 380\text{D} \times 180\text{H}$ , mm)  
 ただし、交尾成立雌動物については妊娠 17 日から哺育 4 日まで同ケージの金網床を小型受皿に代えて実験動物用床敷（ホワイトフレーク、日本チャールス・リバー株式会社）を使用した。

1 ケージあたりの収容動物数 :

検疫および馴化期間中は 2 匹、群分け後は 1 匹、交配期間中は雌雄各 1 匹、分娩後は 1 腹を収容した。

ケージおよび給餌器の交換 :

群分け時、その後は 2 週に 1 回の頻度で交換した。ただし、交尾成立雌動物については妊娠 0 日および 14 日に実施した。

受皿交換 : 週 2 回実施した。

自動給水装置の水抜き : 週 1 回実施した。

給水器の交換 : 尿検査時にのみ用いた。

小型受皿の交換 : 妊娠 20 日に実施した。

室内の清掃および清拭消毒 :

1 日 1 回実施した。清拭消毒に際しては、塩素系消毒薬およびヨウ素系消毒薬を 1 週間単位で交互に使用した。

#### 3) 飼料

種類・名称	: 固型飼料、CRF-1
ロット番号	: 101005、101207、110106
製造業者	: オリエンタル酵母工業株式会社
給餌方法	: 金属製給餌器を用いて自由に摂取させた。 ただし、剖検前日の夕刻からは全例を絶食させた。

汚染物質および微生物検査 :

試験に悪影響を及ぼす恐れのある汚染物質の分析あるいは微生物検査を、使用した各ロットの飼料について実施した。汚染物質の分析は Eurofins Analytics 社（分析報告書：AR-10-JP-001107-01、AR-10-JP-001322-01、AR-11-JP-000301-02）が、微生物検査は飼料製造業者（分析試験報告書：No. 10G03-153、10G03-186、11G03-004）がそれぞれ行った。分析データを飼料製造業者からロット毎に入手した。分析項目と許容値は株式会社 化合物安全性研究所の標準操作手順書に準拠した。分析の結果、いずれの項目にも規定された許容値を超える値は認められなかった。

#### 4) 飲料水

種類	: 札幌市水道水
給水方法	: 自動給水装置を用いて自由に摂取させた。ただし、尿検査時は給水器を用いた。
汚染物質検査	: 試験に悪影響を及ぼす恐れのある汚染物質の分析を、2011年1月4日、2011年4月1日および2011年7月1日に、当該飼育室と同系統配管の最末端（301号室）から試料を採取して実施した（水質検査結果表：No. A224281、A230001、A231007）。分析は日本衛生株式会社において行い、分析データを入手した。分析項目と許容値は株式会社 化合物安全性研究所の標準操作手順書に準拠した。分析の結果、いずれの項目にも規定された許容値を超える値は認められなかった。

#### (6) 被験物質の投与

##### 1) 投与量の設定

投与量	: 0 (媒体のみ)、100、300 および 1000 mg/kg/day とした。
設定理由	: 先に実施した予備試験（S R 0 9 2 0 7 P）(投与量 0、8、40、200 および 1000 mg/kg/day、雌雄各 3 匹/群、2 週間反復経口投与) の結果 <sup>5)</sup> 、1000 mg/kg/day の雄でアルカリホスファターゼ(ALP) の高値傾向、雌で平均赤血球ヘモグロビン(MCH) の有意な低値が認められた。一般状態、体重、摂餌量、剖検所見、器官重量、性周期において、1000 mg/kg/day の用量までイソトリデシル=ステアラートの影響は認められなかった。以上のことから、本試験では 1000 mg/kg/day を最高用量とし、以下公比約 3 で除して 300 および 100 mg/kg/day をそれぞれ中用量および低用量に設定した。

## 試験群の構成

: 試験群の構成と各群の動物番号は以下の通りとした。

試験群	投与量 (mg/kg)	濃度 (mg/mL)	投与容量 (mL/kg)	動物数(動物番号)	
				雄	雌
<主試験群>					
対照群	0	0	5	12 (101～112)	12 (151～162)
低用量群	100	20	5	12 (201～212)	12 (251～262)
中用量群	300	60	5	12 (301～312)	12 (351～362)
高用量群	1000	200	5	12 (401～412)	12 (451～462)
<回復群>					
対照群	0	0	5	5 (101～112)*	5 (163～167)
高用量群	1000	200	5	5 (401～412)*	5 (463～467)

对照群の動物には、被験物質投与群と同様の方法で媒体のみを投与した。

\*: 主試験群から交配期間終了後に選抜した。投与 28 日の体重に基づいて、各群の平均値に近似するようにそれぞれ 5 匹(動物番号 103、107、109、110、111、401、403、407、409、410)ずつ選抜した。

## 2) 投与

投与方法および投与経路：ディスポーザブル胃ゾンデおよびディスポーザブルシリンジを用いて強制的に胃内に経口投与した。

投与回数 : 1 日 1 回、連日投与した。

投与時刻 : 9:00～11:58 (分娩中の 1 例については分娩終了後 13 時 23 分に投与した。)

投与期間 : 雄；交配 14 日前より 42 日間  
雌；交配前 14 日間および交尾成立までの交配期間、さらに交尾成立例は妊娠期間および分娩後 5 日（哺育 0 日を分娩後 0 日として起算）までの期間

交尾不成立例は交配期間終了後 23 日までの 51 日間、不妊例は妊娠 25 日までの 52 日間

回復群については 42 日間

回復期間 : 投与期間終了後 14 日間

投与液量 : 各個体の投与液量は投与日に最も近い測定日の体重に基づいて算出した。

投与方法、投与経路、投与回数および投与期間の選定理由：

試験法ガイドラインを参考にした。

## (7) 観察、測定および検査項目

## I. 反復投与毒性

投与開始日を投与 1 日と起算し、さらに、主試験群の雌は交尾成立日を妊娠 0 日、分娩終了日を哺育 0 日、回復群の雌雄は投与 42 日の翌日を回復 1 日と起算した。

## 1) 一般状態観察

例数	: 全例
期間	: 投与 1 日から剖検日まで。
頻度	: 投与期間中は投与前および投与後の 1 日 2 回、回復期間中は午前および午後の 1 日 2 回、剖検日は午前中に 1 回観察した。
観察方法	: 個々の動物の生死、外観、行動等について観察した。異常が認められる場合は、その症状ならびに症状の持続期間を記録した。

## 2) 詳細な一般状態観察

例数	: 全例
時期	: 投与開始前ならびに投与 7、14、21、28、35 および 42 日。 回復群の動物については、回復 7 および 14 日。
観察方法	: あらかじめ定めたスコアリング基準を用いてスコア化した観察結果を記録した。 観察項目およびその方法： ①体位・姿勢、呼吸状態、振戦・痙攣、常同行動（回転・旋回）、異常行動（自咬）をケージ外から観察した。 ②取り出し易さ、取扱い易さ、筋収縮性、立毛、被毛の状態、皮膚、眼・眼球および粘膜の外観、瞳孔径、流涙、流涎、その他分泌物の有無について、ケージから取り出す時に観察した。 ③歩行、運動協調性、環境刺激に対する反応、探索行動、排泄状態（排尿・排糞）、常同行動（身づくろい・くびふり）、異常行動（後ずさり・異常発声）、攻撃性について、オープンフィールド内で観察した。
3) 機能検査	

例数	: 各群 5 例（主試験群雄は各群の体重の平均値に近似するように、主試験群雌は分娩日の早い動物順に選抜した）
時期	: 投与 6 週および回復 2 週。 主試験群の雌は哺育 4 日。
観察／測定方法	: あらかじめ定めたスコアリング基準を用いてスコア化した観察結果あるいは測定機器による測定値を記録した。

観察項目およびその方法：

- ①刺激に対する感覚運動反応：検査台上で以下を観察した。  
視覚刺激、触覚刺激、聴覚刺激、痛覚刺激、固有受容器刺激、空  
中正向反射
- ②握力：CPU ゲージ（アイコーエンジニアリング株式会社）を用い  
て前肢および後肢について各 3 回測定し、1 g 単位で記録した。
- ③自発運動量：自発運動量測定装置（スーパー・メックスおよび  
CompACT、室町機械株式会社）を用いて測定した。上記に引き続き、  
10 分間隔で 1 時間測定した。

4) 体重測定

- |      |   |
|------|---|
| 例数   | : 全例  |
| 測定日  | : 投与 1、3、5、7、10、14、21、28、35 および 42 日の投与前、回復<br>7 および 14 日ならびに剖検日。<br>主試験群の雌は投与 1、3、5、7、10、14 日の投与前、妊娠 0、1、3、<br>5、7、10、14、17 および 20 日の投与前、哺育 0、1 および 4 日の投<br>与前ならびに分娩後 6 日の剖検日。なお、交尾不成立例は投与 21、<br>28、35、42、49 日の投与前および 51 日の翌日の剖検日。 |
| 測定方法 | : 電子式上皿天秤（GX-2000、株式会社エー・アンド・デイ）を用い<br>て測定し、1 g 単位で記録した。  |

体重増加量および体重増加率：

以下の式により算出した。

〈雄および回復群の雌〉

投与期間；

$$\text{体重増加量(g)} = \text{投与 42 日体重(g)} - \text{投与 1 日体重(g)}$$

$$\text{体重増加率(%)} = \frac{\text{体重増加量(g)}}{\text{投与 1 日体重(g)}} \times 100$$

回復期間；

$$\text{体重増加量(g)} = \text{回復 14 日体重(g)} - \text{投与 42 日体重(g)}$$

$$\text{体重増加率(%)} = \frac{\text{体重増加量(g)}}{\text{投与 42 日体重(g)}} \times 100$$

〈主試験群の雌〉

妊娠前投与期間；

$$\text{体重増加量(g)} = \text{投与 14 日体重(g)} - \text{投与 1 日体重(g)}$$

$$\text{体重増加率(%)} = \frac{\text{体重増加量(g)}}{\text{投与 1 日体重(g)}} \times 100$$

妊娠期間；

$$\text{体重増加量(g)} = \text{妊娠 20 日体重(g)} - \text{妊娠 0 日体重(g)}$$

$$\text{体重増加率(%)} = \frac{\text{体重増加量(g)}}{\text{妊娠 0 日体重(g)}} \times 100$$

哺育期間；

$$\text{体重増加量(g)} = \text{哺育 4 日体重(g)} - \text{哺育 0 日体重(g)}$$

$$\text{体重増加率(%)} = \frac{\text{体重増加量(g)}}{\text{哺育 0 日体重(g)}} \times 100$$

## 5) 摂餌量測定

- 例数 : 全例
- 測定日 : 雌雄とも剖検日および交配期間を除き、体重測定と同じ日に実施した。ただし、主試験群の雌については、妊娠 20 日は残量、哺育 0 日は給与量のみを測定した。
- 測定方法 : 電子式上皿天秤 (GX-2000、株式会社エー・アンド・ディ) を用いて測定し、1 g 単位で記録した。投与開始前日に適当量を測定後ケージ毎に給与し、その後は測定日に残量および給与量を測定した。ただし、最終回の測定は残量のみとした。  
以下の式により、摂餌量 (g/rat/day) を算出した。

$$\text{摂餌量(g/rat/day)} = \frac{\text{給与量(g/rat)} - \text{残量(g/rat)}}{\text{測定日間の日数(day)}}$$

## 6) 尿検査

- 例数 : 雄は機能検査と同一の各群 5 例について、雌は回復群全例(各群 5 例)
- 時期 : 投与 6 週および回復 2 週
- 採尿方法 : ラット用代謝ケージ (KN-646、B-1 型、株式会社夏目製作所) を用いて採尿し、投与直後から約 3 時間の蓄尿で①～⑧を、また約 21 時間の蓄尿で⑨および⑩を実施した。採取した尿は検査終了後廃棄した。

検査項目および検査方法：

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① 尿 pH	試験紙法
② 蛋白 (Protein)	試験紙法
③ 尿糖 (Glucose)	試験紙法
④ 尿ケトン体 (Ketone body)	試験紙法
⑤ ウロビリノーゲン (Urobilinogen)	試験紙法
⑥ ビリルビン (Bilirubin)	試験紙法

⑦ 潜血 (Occult blood)	試験紙法
⑧ 色調(Color)	肉眼観察
⑨ 尿量(Urine Volume)	容量測定
⑩ 比重(Specific gravity)	屈折計法
⑪～⑭ マルティスティックス、シーメンスヘルスケア・ダイアグノスティクス	
⑮ 尿比重屈折計ユリコン-S、アタゴ	

## 7) 血液学的検査

例数 : 各群 5 例 (主試験群の雄は機能検査に用いた動物以外から動物番号の若い順に選抜した。主試験群の雌は機能検査と同一例、回復群は全例。)

時期 : 剖検時(主試験群の雄は投与 42 日の翌日、主試験群の妊娠雌は分娩後 6 日、回復群の雄および雌は回復 14 日の翌日)に採血した。なお、交尾不成立雌および不妊雌については採血しなかった。

採血方法 : 16～22 時間の絶食下でラットをペントバルビタールナトリウム溶液(ソムノペンチル、共立製薬株式会社)の腹腔内注射により麻酔し、腹部大動脈より採血した。検査項目のうち、①～⑩については EDTA・2K (ベノジェクト II 真空採血管、テルモ株式会社) で処理した血液約 1 mL を用い、⑪および⑫については 3.8% クエン酸ナトリウムで処理した血液約 2 mL を、3500 回転/分で 10 分間の遠心分離して得られた血漿を用いた。得られた血液および血漿は検査終了後廃棄した。なお、白血球塗抹標本 (May-Grünwald-Giemsa 染色) を作製し、保存した。白血球の分布異常はみられなかったため、白血球塗抹標本の鏡検は行わなかった。

## 検査項目および検査方法 :

①赤血球数(RBC)	電気抵抗検出法
②ヘマトクリット値(HCT)	電気抵抗検出法
③ヘモグロビン濃度(HGB)	SLS ヘモグロビン法
④平均赤血球容積(MCV)	RBC, HCT 値より算出
⑤平均赤血球血色素量(MCH)	RBC, HGB 値より算出
⑥平均赤血球血色素濃度(MCHC)	HCT, HGB 値より算出
⑦血小板数(Platelet)	電気抵抗検出法
⑧白血球数(WBC)	フローサイトメトリー法
⑨網赤血球数(Reticulocyte)	フローサイトメトリー法
⑩白血球分画 (Differential count of WBC)	フローサイトメトリー法
⑪プロトロンビン時間(PT)	トロンボプラスチン法
⑫活性化部分トロンボプラスチン時間(APTT)	エラジン酸法

⑪～⑭ 自動血球分析装置 XT-2000 iV、シスメックス

⑮⑯ 血液凝固自動測定装置 KC4 デルタ、トリニティ・バイオテック

## 8) 血液化学的検査

例数 : 血液学的検査と同一の各群 5 例

時期 : 剖検時に採血した。

採血方法 : 16~22 時間の絶食下でラットをペントバルビタールナトリウム溶液（ソムノペンチル、共立製薬株式会社）の腹腔内注射により麻酔し、腹部大動脈より採血した。検査項目のうち、(1) および(5)について  
は、血液 1 mLあたりヘパリンナトリウム（ヘパリンナトリウム注  
N「味の素」、1000 単位/mL、味の素株式会社）約 20 単位で処理後、  
3500 回転/分で 10 分間の遠心分離で得られた血漿を用いて検査した。  
他の項目については分離剤入り試験管（セパクリーン A、栄研器材  
株式会社）に血液を採取し、3500 回転/分で 10 分間の遠心分離で得  
られた血清を用いて検査した。また、得られた血清の一部は(20) ~  
(22) 測定用としてポリプロピレン製チューブ 4 本に約 150  $\mu$ Lずつ分  
注し、測定に供するまで超低温フリーザー（-80°C 設定）に保存し  
た。これらのうち 1 本は (20) 測定用として三菱化学メディエンス  
株式会社に送付し、測定結果を入手した。得られた血漿および血清  
は検査終了後-20°C以下で凍結保存し、試験終了日に廃棄した。

## 検査項目および検査方法 :

(1) AST	JSCC 法
(2) ALT	JSCC 法
(3) アルカリホスファターゼ(ALP)	JSCC 法
(4) $\gamma$ -GTP	L- $\gamma$ -グルタミル-3-カルボキシ-4-ニトロアニリド 基質法
(5) グルコース(Glucose)	ヘキソキナーゼ法
(6) 総コレステロール(T-Chol)	酵素法
(7) トリグリセライド(TG)	遊離グリセロール消去法
(8) 総ビリルビン(T-Bil)	アゾビリルビン法
(9) 尿素窒素(UN)	ウレアーゼ・GLDH 法
(10) クレアチニン(Crea)	Jaffé 法
(11) ナトリウム(Na)	イオン選択電極(ISE)法
(12) カリウム(K)	イオン選択電極(ISE)法
(13) クロール(Cl)	イオン選択電極(ISE)法
(14) カルシウム(Ca)	OCPC 法
(15) 無機リン(IP)	Fiske-Subba Row 法
(16) 総蛋白(TP)	ビウレット法
(17) 蛋白分画(Protein fraction)	セルロースアセテート膜電気泳動法
(18) A/G 比(A/G ratio)	蛋白分画より算出
(19) アルブミン(Albumin)	総蛋白と蛋白分画より算出
(20) 甲状腺刺激ホルモン(TSH)	RIA 法(三菱化学メディエンス株式会社で測定)
(21) T3	ELISA 法
(22) T4	ELISA 法

- (1) ~ (16) 自動分析装置 7080 形、日立ハイテクノロジーズ
- (17)~(19) 自動電気泳動装置 AES320、三島オリンパス
- (21)(22) ウェルリーダーSK601、株式会社 サイニクス

## 9) 剖検

例数	: 全例
時期	: 主試験群の雄(投与終了時剖検例)は投与 42 日の翌日、主試験群の雌は分娩後 6 日、回復群の雄および雌は回復 14 日の翌日に剖検した。主試験群の交尾不成立例は投与 51 日の翌日、不妊例は妊娠 26 日(投与 52 日の翌日)に剖検した。
検査方法	: 体外表を観察し、ペントバルビタールナトリウム溶液(ソムノペンチル、共立製薬株式会社)の腹腔内注射による麻酔下で採血後、放血により安楽死させ、全身の器官・組織を肉眼的に観察した。検査終了後、以下の器官・組織を 10% 中性緩衝ホルマリンに固定・保存した。なお、眼球およびハーダー腺はデビッドソン液で固定・保存し、精巣および精巣上体はブアン液で固定、70% エタノールに保存した。肺については固定液を注入後浸漬固定した。左右のある器官については原則として左右とも固定・保存した。
器官・組織名	: 脳(大脳、小脳および脳橋)、脊髄、下垂体、胸腺、甲状腺(上皮小体を含む)、副腎、脾臓、心臓、食道、胃、肝臓、胰臓、十二指腸、空腸、回腸(パイエル板を含む)、盲腸、結腸、直腸、気管、肺、腎臓、膀胱、精巣、精巣上体、前立腺、精嚢(凝固腺含む)、卵巣、子宮(角部および頸部)、眼球およびハーダー腺、乳腺(雌のみ、右腹部)、大腿骨(骨髓を含む、右)、腸間膜リンパ節、頸下リンパ節、坐骨神経および肉眼的異常部位(正常組織との境界部含む)。

## 10) 器官重量測定

例数	: 各群 5 例(雄は血液学的検査、雌は機能検査とそれぞれ同一動物)
時期	: 剖検時
測定方法	: 電子式上皿天秤(ER-180A、株式会社エー・アンド・デイ)を用いて以下の器官について重量を測定した。左右のある器官については、左右併せて測定した。
検査器官	: 脳、下垂体、甲状腺(上皮小体含む)、心臓、肝臓、腎臓、脾臓、副腎、胸腺、精巣、精巣上体、卵巣
相対重量の算出	: 以下の式から相対重量を算出した。

$$\text{相対重量(%)} = \frac{\text{絶対重量(g)}}{\text{剖検日体重(g)}} \times 100$$

### 11) 病理組織学的検査

- 例数 : 剖検時に固定・保存した全例の全器官・組織について標本作製を実施し、対照群および高用量群の5例について鏡検した。また、雄の精巣の精子形成について精査した。腎臓は全群全例について鏡検した。また、剖検で異常がみられた部位の検査を実施した：100 mg/kg 群；精巣および精巣上体小型化(動物番号 202、206)、精巣上体尾部黄白色腫瘍(動物番号 210)、300 mg/kg 群；ハーダー腺出血、精巣および精巣上体小型化(動物番号 311)、前肢第3指欠損(動物番号 355)、腺胃粘膜黒色斑(動物番号 356)、1000 mg/kg 群；胃境界縁白色腫瘍(動物番号 464)、肺前葉黄緑色斑(動物番号 452)。
- 検査方法 : パラフィン包埋後薄切し、ヘマトキシリン・エオジン染色標本を作製して鏡検した。腎臓でみられた好酸性小体は、代表例(動物番号 105、111、207、302、402)について  $\alpha$  2u-グロブリン染色を実施した。

## II. 生殖発生毒性

### 1) 性周期検査

- 例数 : 雌の全例
- 期間 : 投与開始日から主試験群は交尾成立まで、回復群および交尾不成立例は剖検日までの連日。
- 方法 : ギムザ染色による膣垢塗抹標本を作製し、光学顕微鏡下で性周期段階を観察した。
- 判定 : 性周期の各段階(発情前期、発情期、発情後期および発情休止期)を4日から6日の間隔で繰返すものを正常と判定し、発情期間隔を算出した。発情休止期が7日以上継続してみられる例は連続非発情とし異常と判定した。

### 2) 生殖能検査

- 例数 : 主試験群の雌雄の全例
- 時期、方法 : 投与14日を交配開始日、交配開始日の翌日を交配1日とし、交配開始日の夕刻から、同試験群内の雌雄1対を交尾が確認されるまで14日間を限度として連続同居させた。
- 交配組み合せ : 無作為組み合せ
- 交尾成立の判断基準 : 膣内膣栓、あるいは膣垢スメア標本中の精子が認められた場合を交尾

成立と判断した。交尾成立日を妊娠 0 日とした。

次式から群毎に交尾率を算出した。

$$\text{交尾率} (\text{Copulation index, \%}) = \frac{\text{交尾した雄/雌の数}}{\text{同居させた雄/雌の数}} \times 100$$

受胎能 : 妊娠の確認を分娩の有無および剖検時に子宮内の着床痕の有無により行った。

次式から群毎に受胎率を算出した。

$$\text{受胎率} (\text{Fertility index, \%}) = \frac{\text{受胎動物数}}{\text{交尾した雄/雌の数}} \times 100$$

### 3) 分娩および哺育状態観察

例数 : 受胎した雌の全例

分娩観察 : 交尾が確認された雌動物は全例自然分娩させた。

分娩状態を妊娠 21 日から 25 日まで、毎日少なくとも 3 回 (9:00、13:00 および 17:00) 観察した。

分娩終了の確認 : 9:00 に母動物が児を巣の中に集めて腹の下に抱え込んでいるのが観察された場合に分娩終了とし、その日を哺育 0 日 (生後 0 日) とした。1 匹以上の生存児を出産したものを正常出産とした。

次式から群毎に出産率を算出した。

$$\text{出産率} (\text{Gestation index, \%}) = \frac{\text{生児出産雌数}}{\text{妊娠雌数}} \times 100$$

出産児の観察 : 生後 0 日に正常に出産した腹毎に生存児数と死亡児数とを計数し、それらの合計を出産児数とした。

次式から腹毎に出生率を算出した。

$$\text{出生率} (\text{Live birth index, \%}) = \frac{\text{出産時生存児数}}{\text{出産児数}} \times 100$$

出産児の性比の算出 : 生後 0 および 4 日に個々の児動物の性を肛門と生殖突起の間の長さで判定した。死亡児も含めた生後 0 日の全出産児、死亡例を含めない生後 0 日の生存児ならびに生後 4 日の生存児を対象として腹毎に以下を算出した。

$$\text{生後 0 日の全出産児の性比} (\text{Sex ratio}) = \frac{\text{雄出産児数}}{\text{雄出産児数} + \text{雌出産児数}}$$

$$\text{生後 0 日の生存児の性比} (\text{Sex ratio}) = \frac{\text{雄生存児数}}{\text{雄生存児数} + \text{雌生存児数}}$$

$$\text{生後 4 日の生存児の性比(Sex ratio)} = \frac{\text{雄生存児数}}{\text{雄生存児数} + \text{雌生存児数}}$$

妊娠期間の算出 : 妊娠 0 日から哺育 0 日までの期間の日数を計数した。

分娩率の算出 : 剖検時に各雌の子宮内の着床痕を肉眼的に計数した。

次式から腹毎に分娩率を算出した。

$$\text{分娩率(Delivery index, \%)} = \frac{\text{出産児数}}{\text{着床数}} \times 100$$

着床率の算出 : 剖検時に各雌の卵巣の黄体数を計数した。

次式から腹毎に着床率を算出した。

$$\text{着床率(Implantation index, \%)} = \frac{\text{着床数}}{\text{黄体数}} \times 100$$

哺育 4 日の哺育率の算出 : 次式から群毎に算出した。

$$\text{哺育率(Nursing index, \%)} = \frac{\text{哺育 4 日に生存児を持つ雌数}}{\text{生児出産雌数}} \times 100$$

#### 4) 新生児の一般状態観察および生存率

例数 : 全例

頻度 : 1 回／日

期間 : 生後 0 日から生後 4 日（剖検日）までとした。

観察方法 : 生存または死亡を確認し、一般状態および外観について観察した。  
なお、死亡例は発見後速やかに剖検し、Whole body を 10% 中性緩衝ホルマリン液で固定・保存した。

生後 4 日の新生児生存率の算出 : 次式により 1 腹単位で算出した。

$$\text{新生児生存率(Viability index, \%)} = \frac{\text{生後 4 日の生存児数}}{\text{出産時生存児数}} \times 100$$

#### 5) 新生児の体重測定

例数・時期 : 生存児全例について、生後 0、1 および 4 日に実施した。

測定方法 : 電子式上皿天秤（GX-2000、株式会社エー・アンド・デイ）を用いて雌雄別に腹毎に測定し、0.1 g まで記録した。  
雌雄毎に腹当たりの平均体重を求めた。

#### 6) 新生児の剖検

時期・例数 : 生後 4 日に全例について実施した。

検査方法 : 体外表（口腔内を含む）を観察し、二酸化炭素吸入法により安樂死させ、全身の器官・組織を肉眼的に観察した。異常例については、Whole body を 10% 中性緩衝ホルマリン液に固定・保存した。

## 5. 統計学的方法

握力、自発運動量、体重、体重増加量および増加率、摂餌量、尿量、血液学的検査、血液化学的検査、器官の絶対重量および相対重量、発情期間隔、黄体数、着床数および着床率、出産児数、出産時の生存児数および死亡児数、分娩率、出生率、性比、妊娠期間、生後4日の生存児数および新生児生存率の成績について平均値および標準偏差を算出し、Bartlettの検定法を行い、等分散性を解析した。等分散の場合は一元配置分散分析法で解析し、不等分散の場合は Kruskal-Wallis の検定法で解析した。一元配置分散分析の結果、有意差がみられた場合は Dunnett の検定法を用いて対照群との比較を行った。Kruskal-Wallis 法の解析の結果、有意差がみられた場合は Mann-Whitney の U-検定法を用い対照群との比較を行った。新生児の出生率、性比、新生児生存率および雌雄別体重については、1腹を標本単位として処理した。

詳細な一般状態観察および機能検査の観察項目、尿検査の定性的項目、尿比重ならびに病理組織学的検査のうち2段階以上のグレードが認められた所見については、群毎の傾向を Kruskal-Wallis の検定法で解析し、有意差がみられた場合は Mann-Whitney の U-検定法を用いて対照群との比較を行った。

正常性周期の雌の出現率、交尾率、受胎率、出産率、哺育4日の哺育率、ならびに病理組織学的検査のうち1段階のグレードが認められた所見については、多試料カイ二乗検定を行い、その結果有意差が認められた場合には2試料カイ二乗検定で対照群との比較を行った。ただし、2試料カイ二乗検定に不適合の場合には Fisher の直接確率検定法を用いた。

対照群との比較検定については、有意水準は5%とした。統計学的方法に関する表示方法を INDIVIDUAL DATA の前に示す。

## 成 績

### I . 反復投与毒性

#### 1. 一般状態

一般状態の成績を Table 1 および 2、 INDIVIDUAL DATA 1-1-1～1-3-2 に示す。

##### (1) 主試験群雄

投与期間中、対照群を含むいずれの群の動物にも異常はみられなかった。

回復期間中、対照群および 1000 mg/kg 群の動物には異常は認められなかった。

##### (2) 主試験群雌

投与期間中(交配前、妊娠期間、哺育期間を通じて)、いずれの群の動物にも被験物質投与に起因した異常は認められなかった。なお、300 mg/kg 群の 1 例で妊娠 6 日からケージ内での事故による前肢第 3 指の欠損、その周囲の腫張が認められた。

##### (3) 回復群雌

投与期間中および回復期間中を通じて、対照群および 1000 mg/kg 群のいずれの動物にも異常は認められなかった。

### 2. 詳細な一般状態観察

詳細な一般状態観察の成績を Table 3-1～3-3 および 4-1-1～4-2-3、 INDIVIDUAL DATA 2-1-1～2-18-6、スコアリングの基準を INDIVIDUAL DATA 2-1-1 の前に示す。

##### (1) 主試験群雄

投与期間中の観察において、いずれの項目にも各被験物質投与群と対照群の間に有意な差は認められなかった。

回復期間中の観察において、いずれの項目にも 1000 mg/kg 群と対照群の間に有意な差は認められなかった。

##### (2) 主試験群雌

投与期間中の観察において、いずれの項目にも各被験物質投与群と対照群の間に有意な差は認められなかった。

##### (3) 回復群雌

1000 mg/kg 群の投与期間および回復期間中の観察では、いずれの項目にも対照群との間に有意な差はみられなかった。

### 3. 機能検査

機能検査の成績を Table 5 および 6、INDIVIDUAL DATA 3-1-1～3-10-2、スコアリングの基準を INDIVIDUAL DATA 2-1-1 の前に示す。

#### (1) 主試験群雄

投与 6 週の検査では、いずれの項目にも各被験物質投与群と対照群の間に有意な差はみられなかった。

回復 2 週の検査では、いずれの項目にも 1000 mg/kg 群と対照群との間に有意な差はみられなかった。

#### (2) 主試験群雌

哺育 4 日の検査では、いずれの項目にも各被験物質投与群と対照群の間に有意な差はみられなかった。

#### (3) 回復群雌

投与 6 週の検査では、いずれの項目にも 1000 mg/kg 群と対照群の間に有意な差はみられなかつた。

回復 2 週の検査で、1000 mg/kg 群における前肢の握力に対照群と比較して有意な高値が認められた。しかし、投与期間中および回復 2 週の雄ならびに主試験群の雌において、握力の増強の傾向は認められていないことから、被験物質投与に起因した変化ではないと考えられた。

### 4. 体重推移

体重推移を Figure 1～3、Table 7～11、INDIVIDUAL DATA 4-1-1～4-5-2 に示す。

#### (1) 主試験群雄

投与期間中および回復期間中の体重、体重増加量および体重増加率において、各被験物質投与群と対照群の間に有意な差は認められなかった。

#### (2) 主試験群雌

投与期間中(交配前、妊娠期間、哺育期間を通じて)の体重、体重増加量および体重増加率において、各被験物質投与群と対照群の間に有意な差はみられなかった。

#### (3) 回復群雌

投与期間中および回復期間中の体重、体重増加量および体重増加率において、1000 mg/kg 群と対照群の間に有意な差はみられなかった。

### 5. 摂餌量

摂餌量を Figure 4～6、Table 12～16、INDIVIDUAL DATA 5-1-1～5-5-2 に示す。

#### (1) 主試験群雄

投与期間中の摂餌量において、被験物質投与に起因する変動は認められなかった。なお、1000

mg/kg 群の投与 21～28 日および 28～35 日の摂餌量に対照群と比較して有意な高値が認められたが、この群の平均体重は投与 1 日から対照群より若干高く投与期間中はそのままの推移を示していることから、摂餌量増加は身体に応じた変動であり、被験物質投与に起因する変化ではないと考えられた。

回復期間中の摂餌量には 1000 mg/kg 群と対照群の間に有意な差はみられなかった。

#### (2) 主試験群雌

交配前、妊娠期間中および哺育期間中の摂餌量において、被物質投与に起因した変動はいずれの被験物質投与群にも認められなかつた。なお、哺育期間中、100 mg/kg 群で哺育 1～4 日の摂餌量に対照群との間に有意な高値が認められたが、用量依存性のない偶発的変動であった。

#### (3) 回復群雌

投与期間および回復期間中の摂餌量には、1000 mg/kg 群と対照群の間に有意な差はみられなかつた。

### 6. 尿検査

尿検査の成績を Table 17～20、INDIVIDUAL DATA 6-1-1～6-4-2 に示す。

#### (1) 主試験群雄

投与 6 週の検査では、いずれの項目にも各被験物質投与群と対照群の間で有意な差はみられなかつた。

回復 2 週の検査では、いずれの項目にも 1000 mg/kg 群と対照群の間に有意な差はみられなかつた。

#### (2) 回復群雌

投与 6 週および回復 2 週の検査では、いずれの項目にも 1000 mg/kg 群と対照群の間に有意な差はみられなかつた。

### 7. 血液学的検査

血液学的検査の成績を Table 21～24、INDIVIDUAL DATA 7-1-1～7-4-4 に示す。

#### (1) 主試験群雄

投与期間終了時の検査では、いずれの検査項目においても各被験物質投与群と対照群の間で有意な差は認められなかつた。

回復期間終了時の検査では、1000 mg/kg 群で被験物質投与に起因する変動は認められなかつた。なお、1000 mg/kg 群で好酸球数に対照群と比較して有意な高値が認められたが、投与期間終了時にはいずれの検査項目にも高値傾向は認められなかつたことから、被験物質投与の影響ではないと考えられた。

## (2) 主試験群雌

投与期間終了時(分娩後 6 日)の検査では、いずれの検査項目においても各被験物質投与群と対照群の間で有意な差は認められなかった。

## (3) 回復群雌

回復期間終了時の検査では、1000 mg/kg 群で被験物質投与に起因する変動は認められなかつた。なお、1000 mg/kg 群で単球数および好酸球数に対照群と比較して有意な高値が認められたが、投与期間終了時にはいずれの検査項目にも高値傾向は認められなかつたことから、被験物質投与の影響ではないと考えられた。その他の項目では 1000 mg/kg 群と対照群の間に有意な差はみられなかつた。

## 8. 血液化学的検査

血液化学的検査の成績を Table 25~28、INDIVIDUAL DATA 8-1-1~8-4-4 に示す。

### (1) 主試験群雄

投与期間終了時の検査では、いずれの検査項目においても各被験物質投与群と対照群の間で有意な差は認められなかつた。

回復期間終了時の検査では、1000 mg/kg 群で  $\alpha_2$  グロブリンに対照群と比較して有意な低値が認められたが、投与期間終了時の検査では対照群との間に差はなく、回復時の対照群の値がわずかに高かったことによる偶発変動と考えられた。

### (2) 主試験群雌

投与期間終了時(分娩後 6 日)の検査では、1000 mg/kg 群でトリグリセライドおよびクレアチニンに対照群と比較して有意な高値が認められた。なお、300 mg/kg 群で尿素窒素に対照群と比較して有意な高値が認められたが、用量依存性のない偶発的変動であった。その他の検査項目には各被験物質投与群と対照群の間で有意な差はみられなかつた。

### (3) 回復群雌

回復期間終了時の検査では、対照群と比較して 1000 mg/kg 群で  $\beta$  グロブリンの有意な高値、尿素窒素の有意な低値が認められたが、投与終了時に 1000 mg/kg 群で同傾向の変動は認められていないことから、被験物質投与に起因した変動ではないと考えられた。

## 9. ホルモン測定

ホルモン測定の成績を Table 29~32、INDIVIDUAL DATA 9-1-1~9-4-2 に示す。

### (1) 主試験群雄

投与期間終了時の検査では、T3、T4 および TSH に被験物質投与に関連した変動は認められなかつた。なお、100 mg/kg 群の T4 に対照群と比較して有意な高値が認められたが、用量依存性はなく、偶発的な変動であった。

回復期間終了時の検査では、T3、T4 および TSH に 1000 mg/kg 群と対照群との間に有意な差は認められなかった。

#### (2) 主試験群雌

投与期間終了時(分娩後 6 日)の検査では、T3、T4 および TSH に各被験物質投与群と対照群との間に有意な差はみられなかった。

#### (3) 回復群雌

回復期間終了時の検査では、T3、T4 および TSH に 1000 mg/kg 群と対照群との間に有意な差は認められなかった。

### 10. 剖検所見

剖検所見を Table 33～35、INDIVIDUAL DATA 10-1-1～10-4-2 に示す。

#### (1) 主試験群雄

投与期間終了時の剖検では、被験物質投与に関連した所見はいずれの群にも認められなかった。なお、100 mg/kg 群の 2 例および 300 mg/kg 群の 1 例で精巣および精巣上体の小型化、100 mg/kg 群の他の 1 例に精巣上体尾部に黄白色腫瘍、300 mg/kg 群の 1 例にハーダー腺出血が認められた。しかし、いずれの変化も用量関連性のないことから、被験物質投与に関連したものではないと考えられた。

#### (2) 主試験群雌

投与期間終了時(分娩後 6 日)の剖検では、被験物質投与に関連した所見はいずれの群にも認められなかった。なお、300 mg/kg 群の 1 例で腺胃粘膜に黒色斑、1000 mg/kg 群の 1 例で肺前葉に黄緑色斑が認められたが、いずれも少数例であり、用量依存的な発生ではないことから、被験物質投与に起因したものではないと考えられた。

#### (3) 回復群雌

回復期間終了時の剖検では、1000 mg/kg 群の 1 例で胃境界縁白色腫瘍が認められたが、1 例のみの変化であり、投与期間終了時の雌雄ともにみられていない変化であることから、被験物質投与との関連性はないと考えられた。

### 11. 器官重量

器官の絶対重量および相対重量の成績を Table 36～39、INDIVIDUAL DATA 11-1-1～11-4-4 に示す。

#### (1) 主試験群雄

投与期間終了時に、1000 mg/kg 群で腎臓の絶対重量に対照群と比較して有意な高値が認められた。なお、100 mg/kg 群で心臓および甲状腺の絶対重量に対照群と比較して有意な高値が認められたが用量関連性のない偶発変動であった。

回復期間終了時では、1000 mg/kg 群で腎臓の絶対重量に対照群と比較して有意な高値が認め

られた。

### (2) 主試験群雌

投与期間終了時では、1000 mg/kg 群で肝臓の絶対重量および相対重量に対照群と比較して有意な高値が認められた。なお、100 mg/kg 群で心臓の絶対重量、副腎の絶対重量および相対重量に対照群と比較して有意な高値が認められたが用量関連性のない偶発変動であった。

### (3) 回復群雌

回復期間終了時では、1000 mg/kg 群の胸腺の相対重量に対照群と比較して有意な低値が認められた。

## 12. 病理組織学的検査

病理組織学的検査の成績を Table 40～43、INDIVIDUAL DATA 12-1-1～12-4-2 に示す。

### (1) 主試験群雄

投与期間終了時、全例の検査を実施した腎臓では、近位尿細管上皮の軽度な好酸性小体( $\alpha$  2u-グロブリン染色を実施したすべての動物が陽性を示した)が対照群で 7 例中 2 例、100 mg/kg 群で 12 例中 1 例、300 mg/kg 群で 12 例中 8 例、1000 mg/kg 群で 7 例全例にみられ、300 mg/kg 以上の群でその発生頻度に対照群と比較して増加傾向が認められた。軽度な硝子円柱が 300 および 1000 mg/kg 群の各 1 例、尿細管上皮の軽度な再生が 100 および 300 mg/kg 群の各 1 例で認められた。

なお、1000 mg/kg 群で肝臓に小肉芽腫、心臓の限局性心筋変性、前立腺の炎症性細胞浸潤、下垂体前葉囊胞、眼球網膜委縮が軽度で認められたが、対照群にも散見された変化であり、被験物質投与との関連性はないものと考えられた。その他、対照群で下垂体中間葉に軽度囊胞が認められた。剖検で異常がみられた 100 mg/kg 群の 3 例、300 mg/kg 群の 1 例の精巣および精巣上体の検査では、軽度～重度の精細管委縮、軽度～中等度の精巣上体精子数減少、軽度の管腔内細胞残屑、中等度の精子肉芽腫、軽度の精巣間質の水腫が認められた。また、300 mg/kg 群のハーダー腺の検査では軽度な炎症性細胞浸潤が認められた。これらの変化は 1000 mg/kg 群で認められず、用量関連性のないことから、被験物質投与によるものではないと考えられた。

回復期間終了時、腎臓では 1000 mg/kg 群の 1 例に軽度な硝子円柱が認められ、近位尿細管上皮に好酸性小体、尿細管上皮に軽度な再生が対照群にのみ認められた。なお、1000 mg/kg 群で肺動脈鉱質沈着、肝臓に小肉芽腫、前立腺に炎症性細胞浸潤が少数例認められたが、対照群でも散見される変化であり、被験物質投与との関連性はないものと考えられた。対照群のみ肺胞内マクロファージ集簇、下垂体中間葉に軽度囊胞が認められた。

### (2) 主試験群雌

全例の検査を実施した腎臓では、尿細管上皮に軽度な再生が対照群で 11 例中 1 例、1000 mg/kg 群で 11 例中 2 例、軽度な硝子円柱が 1000 mg/kg 群の 1 例、腎盂粘膜に軽度な炎症性細胞浸潤

が 100 および 1000 mg/kg 群で各 1 例、皮質に軽度な鉱質沈着が 100 mg/kg 群の 1 例に認められた。

なお、1000 mg/kg 群で肝臓に軽度小肉芽腫、肺に肺胞内マクロファージ集簇および肉芽腫性炎が認められたが、これらの変化は対照群でも認められていることから、被験物質投与との関連性はないものと考えられた。肉眼的に変化の認められた 300 mg/kg 群の 1 例の腺胃に軽度なびらんが認められた。

### (3) 回復群雌

回復期間終了時の検査において、被験物質投与による変化は認められなかった。なお、1000 mg/kg 群で肝臓の小肉芽腫、胃境界縁に扁平上皮囊胞が認められたが、対照群にもみられる変化あるいは 1 例のみの変化であり、被験物質投与との関連性はないものと考えられた。その他対照群に肺の骨化生が認められた。

## II. 生殖発生毒性

### (1) 生殖能検査

生殖能検査の成績を Table 44 および 45、INDIVIDUAL DATA 13-1-1～13-2-2 および 14-1～14-4 に示す。

正常性周期を示す雌の出現率、発情期間隔、交尾率、受胎率、出産率、妊娠期間および哺育 4 日の哺育率には、被験物質投与群と対照群の間に有意な差はみられなかった。

### (2) 妊娠、分娩、哺育状態および新生児生存率

妊娠、分娩、哺育状態および新生児生存率の成績を Table 46、INDIVIDUAL DATA 15-1～15-4 に示す。

黄体数、着床数、着床率、分娩率、出産児および生存児の性比、出産時の生存児数および死亡児数、出生率、生後 4 日の生存児数および新生児生存率には、被験物質投与群と対照群の間に有意な差はみられなかった。

### (3) 新生児の一般状態

新生児の一般状態の成績を Table 47、INDIVIDUAL DATA 16-1～16-4 に示す。

100、300 および 1000 mg/kg 群において、生後 0 日から生後 4 日までの期間の死亡児が、雄または雌に少数例にみられた。また、300 mg/kg 群において、授乳の証拠としてのミルクバンドのみられない児が、生後 1～2 日に雌 1 例に認められた。これらの新生児死亡は少数例であり、用量関連性はないことから被験物質投与の影響ではないと考えられた。

### (4) 新生児の体重推移

新生児の体重推移を Figure 7、Table 48、INDIVIDUAL DATA 17-1～17-4 に示す。

いずれの被験物質投与群も対照群と比較して有意差は認められなかった。

### (5) 新生児の剖検

新生児の剖検の成績を Table 49、INDIVIDUAL DATA 18 および 19-1～19-4 に示す。

死亡児の剖検では、異常はみられなかった。生後 4 日の生存児の剖検では、被験物質投与に起因した変化は認められなかった。なお、1000 mg/kg 群の雄 1 例に肝臓中葉に黄白色斑、対照群の雄 1 例に肝臓に多巣性の黄緑色斑が認められた。

## 考 察

### 1. 反復投与毒性

腎臓において、1000 mg/kg 群の雄に重量増加が認められ、病理組織学的検査では、近位尿細管上皮の好酸性小体( $\alpha$ 2u-グロブリン抗体陽性)が対照群を含めすべての群で認められ、300 mg/kg 以上の群でその発生頻度が用量依存的に増加し、硝子円柱も認められた。このような変化は  $\alpha$ 2u-グロブリン腎症として知られており、特に雄ラットに特徴的に認められる変化である<sup>6)</sup>。300 mg/kg 以上の群で認められた発生頻度の増加は、被験物質投与に起因したものと考えられた。回復期間終了時では硝子円柱が 1 例に認められたのみであり、回復性のある変化と考えられた。なお、雌の少数例でみられた硝子円柱、雌雄ラットで散見された尿細管上皮の再生、腎孟粘膜の炎症性細胞浸潤、皮質の鉱質沈着は、発生頻度も低く、対照群でも観察され、当施設の背景データでも認められた変化であり、自然発生的な変化と考えられた。

雌の投与期間終了時(分娩後 6 日)に、1000 mg/kg 群でトリグリセライドの高値が認められ、肝臓重量の増加が認められた。この変化は被験物質の原料が脂肪酸であることから、大量の被験物質投与により、加水分解によってトリグリセライドの成分である脂肪酸が生じたことにより、その代謝に影響を与えたものと考えられた。しかし、肝臓の病理組織学的検査では脂肪蓄積に関連した変化はみられず、毒性学的には軽微な変化と考えられた。また、1000 mg/kg 群のクレアチニンに高値が認められたが、腎臓に被験物質投与に関連した器質的変化は認められなかつたことから、毒性学的には軽微なものと考えられた。

一般状態、詳細な一般状態観察、機能検査、体重、摂餌量、尿検査、血液学的検査、剖検および甲状腺ホルモン測定において、雌雄とも被験物質投与に関連すると考えられる変化は認められなかつた。

以上のことから、本試験条件下におけるイソトリデシル=ステアラートの雄に対する無影響量(NOEL) は 300 mg/kg/day 以上で雄の  $\alpha$ 2u-グロブリン腎症の発生頻度に増加が認められたことから 100 mg/kg/day、雌に対する無影響量 (NOEL) は、1000 mg/kg/day で雌の肝臓重量、トリグリセライドおよびクレアチニンに高値が認められたことから、300 mg/kg/day と考えられた。また、雄で認められた  $\alpha$ 2u-グロブリンはラット特有の蛋白であり、ヒトでは存在しないことから、雄に

に対する無毒性量(NOAEL)は 1000 mg/kg/day、雌では、肝臓重量およびトリグリセライドの高値が認められたことから無毒性量(NOAEL)は 300 mg/kg/day と考えられた。

## 2. 生殖発生毒性

生殖能検査では、1000 mg/kg 群まで、性周期には異常はなく、発情期間隔、交尾率、受胎率、黄体数、着床数、着床率、出産率、妊娠期間、哺育率、分娩率、出産児数、性比、生存児数および死亡児数、出生率、生後 4 日の生存児数および新生児生存率には、被験物質投与に関連する変化は認められなかった。

新生児の体重、一般状態および剖検では、1000 mg/kg 群まで、被験物質投与に関連する変化はみられなかった。

以上のことから、本試験条件下における イソトリデシル=ステアラートの反復投与による親動物の生殖に対する無影響量および無毒性量 (NOEL および NOAEL) および新生児の発生に対する無影響量および無毒性量 (NOEL および NOAEL) はいずれも 1000 mg/kg/day と考えられた。

## 参考文献

- 1) 日本化学物質辞書 Web. 化学物質情報詳細. 独立行政法人 科学技術振興機構
- 2) 製品安全データシート
- 3) 化学物質総合情報提供システム Chemical Risk Information Platform (CH RIP). 独立行政法人 製品評価技術基盤機構.
- 4) 化審法データベース (J-CHECK)
- 5) 最終報告書：イソトリデシル=ステアラートのラットにおける反復投与毒性・生殖発生毒性併合試験(用量設定試験)(試験番号 S R 0 9 2 0 7 P), 2011 年.
- 6) Peter Greaves, Histopathology of Preclinical Toxicity Studies. Forth Edition, 2012, pp. 562–566.

## 試験成績の信頼性に影響を及ぼしたと思われる環境要因

最終被験物質投与液の調製時に使用した媒体のロット番号が試験計画書に規定されていたロット番号と異なっていた。媒体は市販薬であることから、被験物質投与による毒性評価に影響はないと考えられた。また、生殖能検査において、14 日間の交配期間中交尾が確認されなかつた対照群の雌 1 例(動物番号 162)について、試験計画書では既に交尾が確認された同群の雄とさらに交配させることになっていたが、その後の交配は行わなかつた。生殖機能を評価できる例数は確保できたことから、試験評価に影響を及ぼすものではないと判断された。

## 資料の保存

以下の試験関係資料を試験終了後 10 年間、株式会社 化合物安全性研究所の資料保存室に保存する。その後の保存については試験委託者との協議により決定する。

- ① 試験計画書および試験計画書変更書
- ② 生データその他の記録文書
- ③ 最終報告書
- ④ 標本：膿垢塗抹標本
  - 血液塗抹標本
  - 固定器官・組織
  - 病理組織標本(パラフィン包埋ブロックおよび光顯標本)
- ⑤ 被験物質サンプル

## 試験責任者の記名なつ印

試験責任者

  2014 年 1 月 9 日

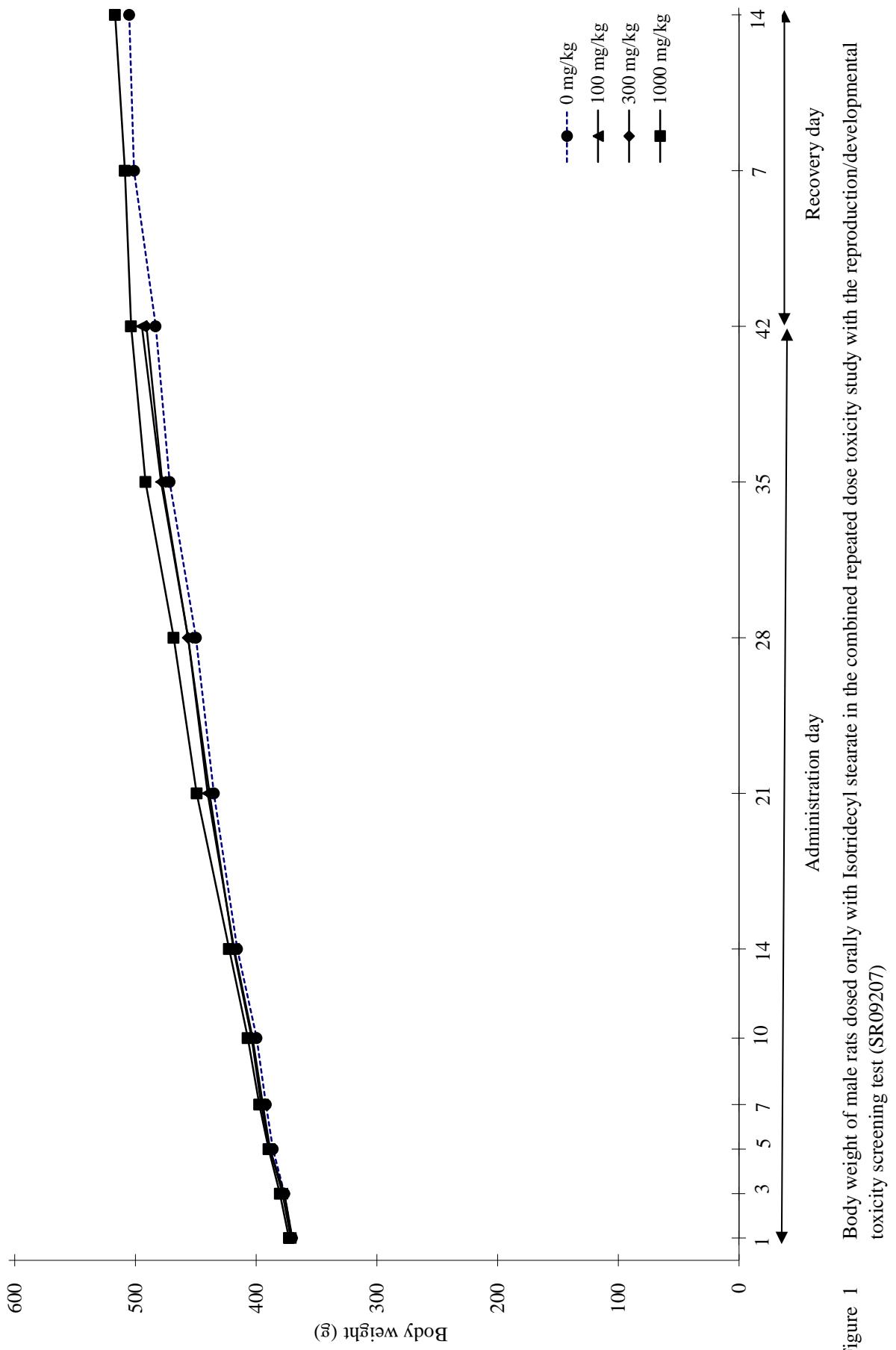


Figure 1 Body weight of male rats dosed orally with Isotriacyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

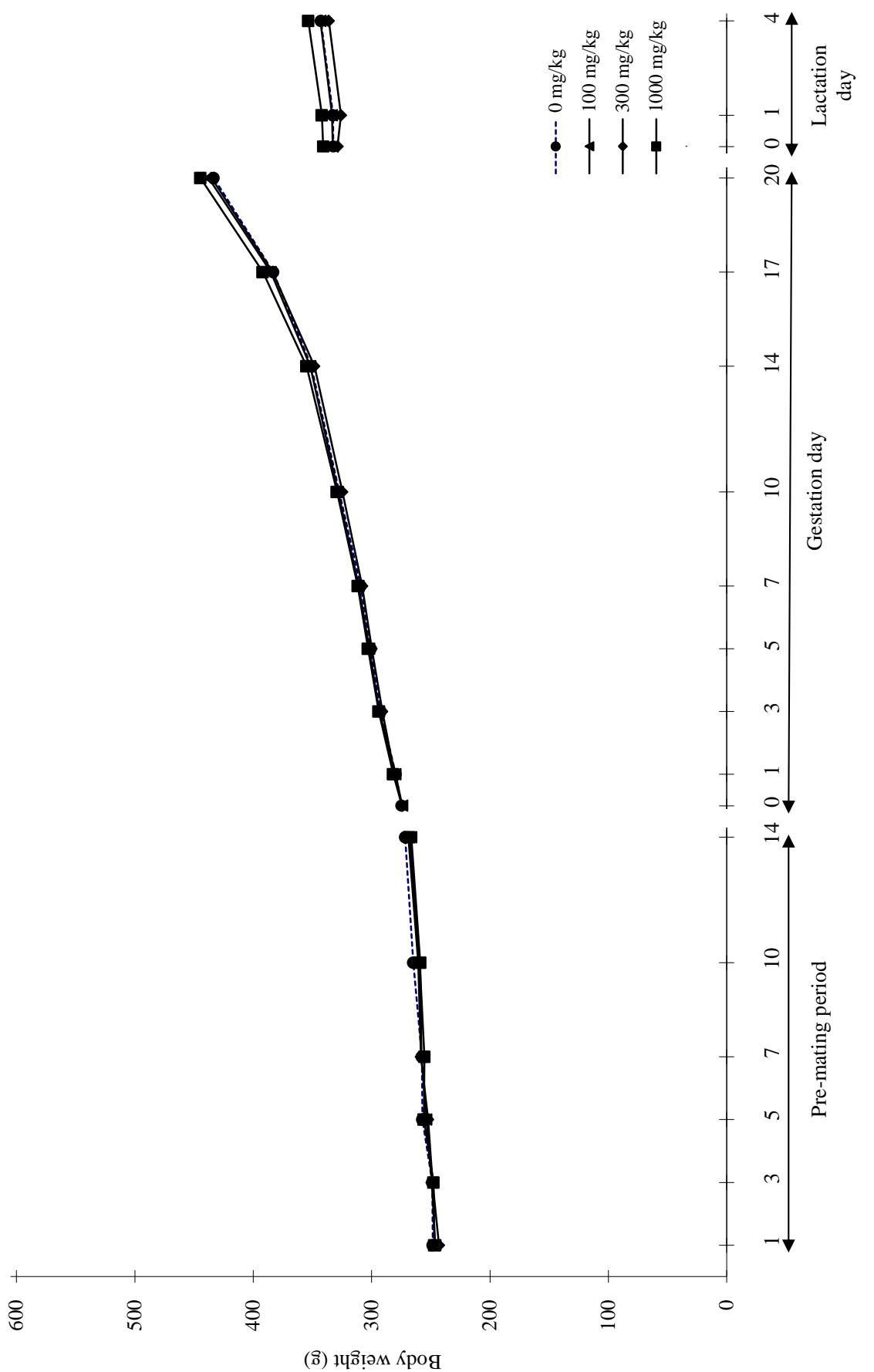


Figure 2 Body weight of female rats dosed orally with Isotriacyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)



Figure 3

Body weight of female rats in 14-day recovery test following 42-day repeated oral dose with Isotriacyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

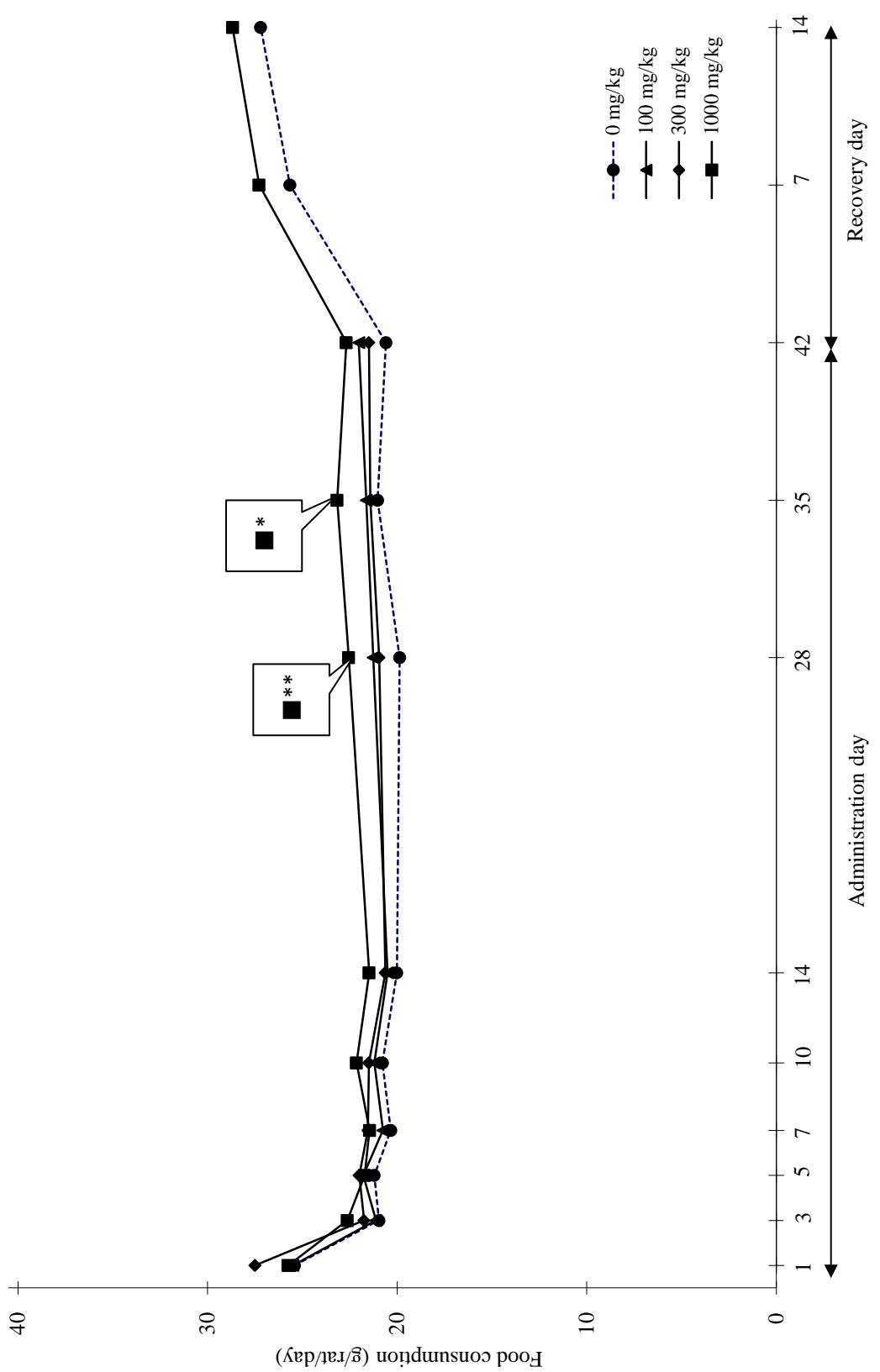


Figure 4

Food consumption of male rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

\* : Significantly different from the 0 mg/kg group at  $p \leq 0.05$  (Dunnett's test).

\*\* : Significantly different from the 0 mg/kg group at  $p \leq 0.01$  (Dunnett's test).

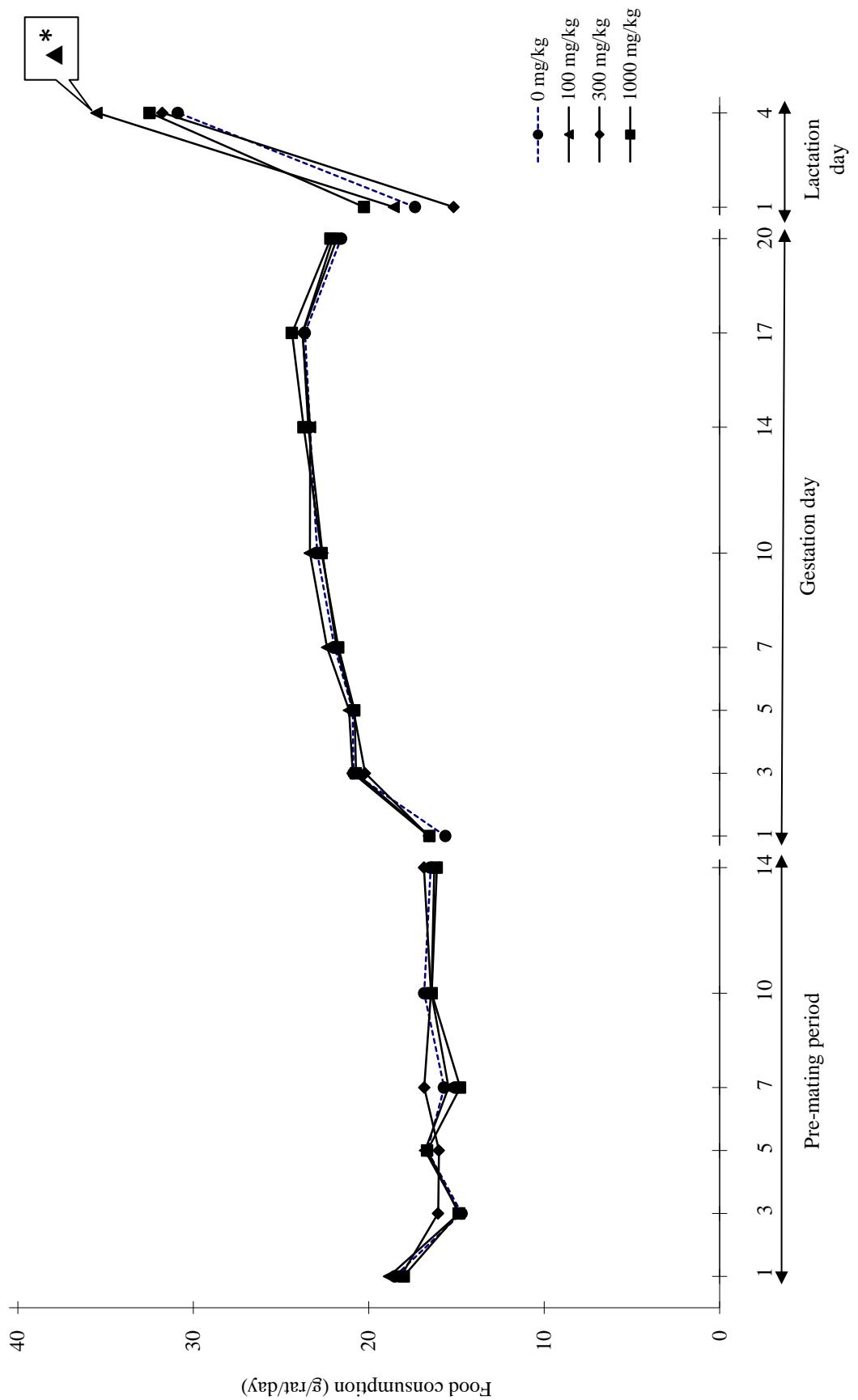


Figure 5 Food consumption of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

\* : Significantly different from the 0 mg/kg group at  $p \leq 0.05$  (Dunnett's test).

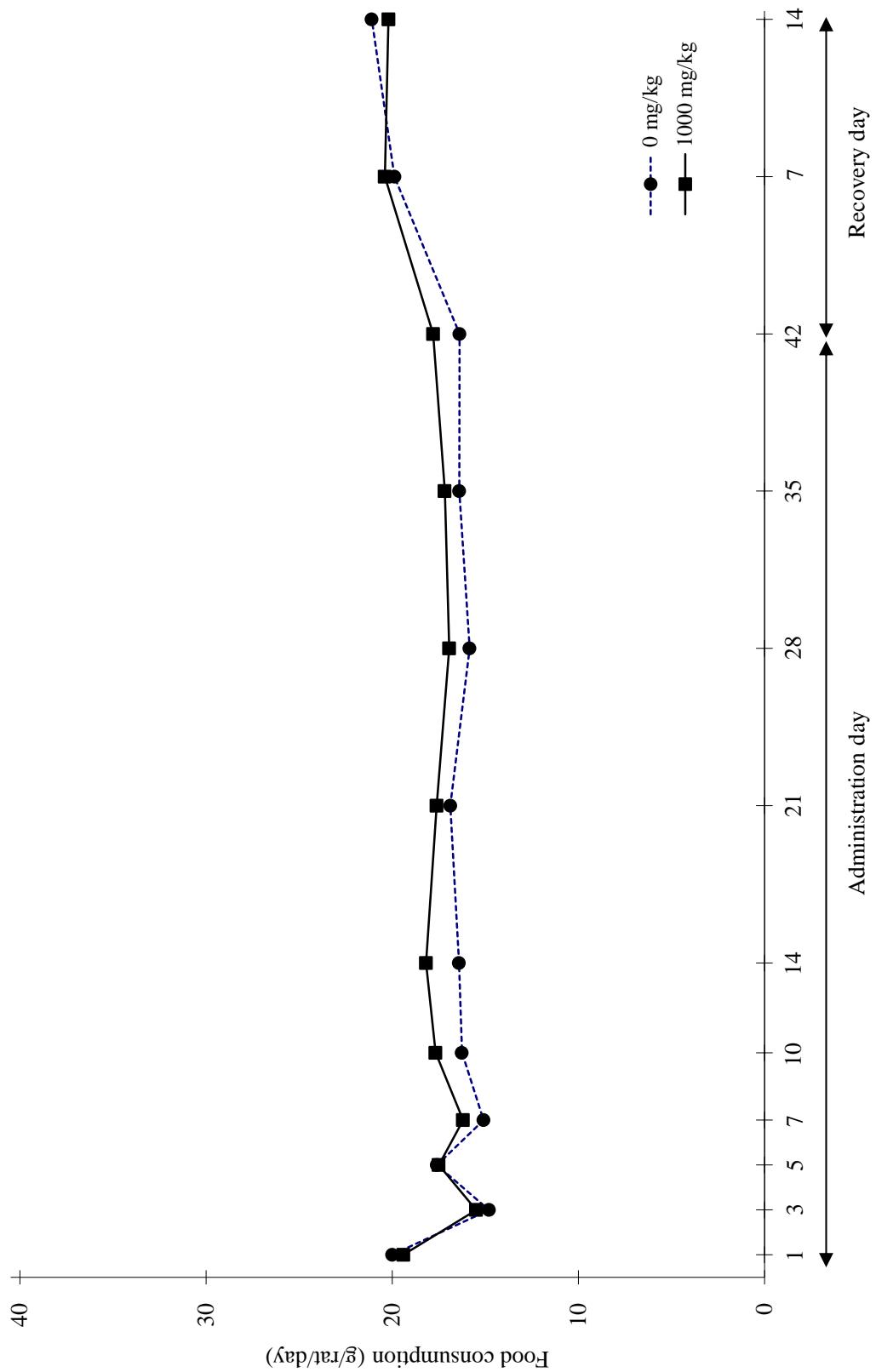


Figure 6 Food consumption of female rats in 14-day recovery test following 42-day repeated oral dose with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

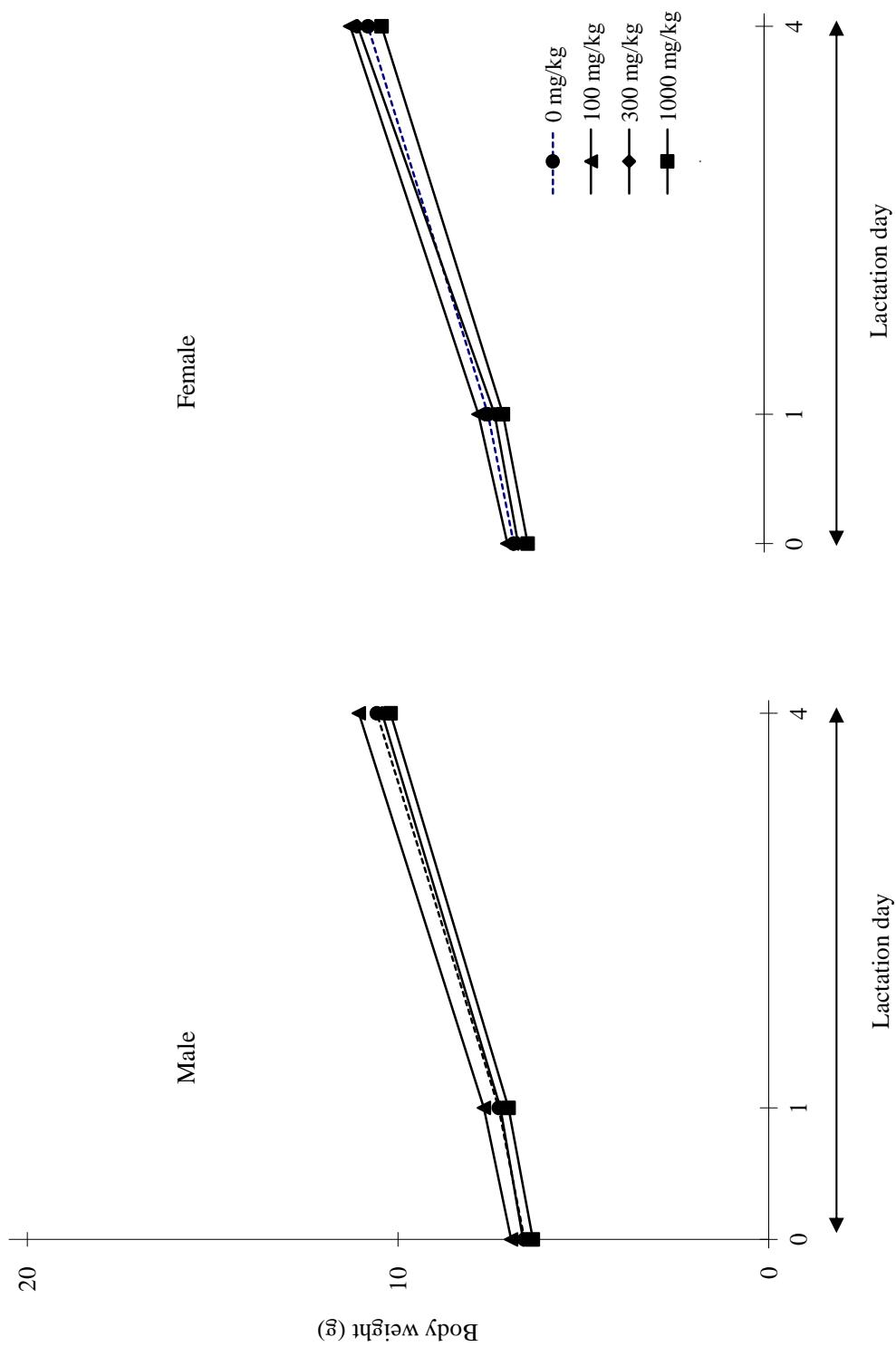


Figure 7 Body weight of pups in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test of Isotriacyl stearate (SR09207)

Table 1 General appearance of male rats dosed orally with Isotriidecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Findings	Administration day		Autopsy day
		1-42	1-42	
0 mg/kg	Number of animals examined	12	7	7
	No abnormal findings	12	7	
100 mg/kg	Number of animals examined	12	12	12
	No abnormal findings	12	12	
300 mg/kg	Number of animals examined	12	12	12
	No abnormal findings	12	12	
1000 mg/kg	Number of animals examined	12	7	7
	No abnormal findings	12	7	

Group	Findings	Recovery day		Autopsy day
		1-14	1-14	
0 mg/kg	Number of animals examined	5	5	5
	No abnormal findings	5	5	
1000 mg/kg	Number of animals examined	5	5	5
	No abnormal findings	5	5	

Values are number of animals with findings.

Table 2 General appearance of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Findings	Administration day		Mating day				Autopsy day	
		1-14	Pre-mating day	15	16	17	18-26	27,28	29-51
0 mg/kg	Number of animals examined	12	8	4	4	1	1	1	1
	No abnormal findings	12	8	4	4	1	1	1	1
100 mg/kg	Number of animals examined	12	9	8	6	-	-	-	-
	No abnormal findings	12	9	8	6	-	-	-	-
300 mg/kg	Number of animals examined	12	10	6	3	-	-	-	-
	No abnormal findings	12	10	6	3	-	-	-	-
1000 mg/kg	Number of animals examined	12	8	5	4	1	-	-	-
	No abnormal findings	12	8	5	4	1	-	-	-

Values are number of animal with findings.  
- : Not applicable.

(to be continued)

Table 2 General appearance of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)  
(continued-1)

Group	Findings	Gestation day				
		0-5	6-10	11-21	22	23-26
0 mg/kg	Number of animals examined	11	11	11	3	-
	No abnormal findings	11	11	11	3	-
100 mg/kg	Number of animals examined	12	12	12	6	-
	No abnormal findings	12	12	12	6	-
300 mg/kg	Number of animals examined	12	12	12	3	-
	No abnormal findings	12	11	11	3	-
1000 mg/kg	Swelling of left forelimb	0	1	0	0	-
	Loss of 3rd digit in left forelimb	0	1	1	0	-
	Number of animals examined	12	12	12	2	1
	No abnormal findings	12	12	12	2	1

Values are number of animal with findings.

- : Not applicable.

Day 26 of gestation : Autopsy day.

(to be continued)

Table 2 General appearance of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)  
 (continued-2)

Group	Findings	Lactation day		Autopsy day
		0.5	1	
0 mg/kg	Number of animals examined	11	11	11
	No abnormal findings	11	11	11
100 mg/kg	Number of animals examined	12	12	12
	No abnormal findings	12	12	12
300 mg/kg	Number of animals examined	12	12	12
	No abnormal findings	11	11	11
	Loss of 3rd digit in left forelimb	1	1	1
1000 mg/kg	Number of animals examined	11	11	11
	No abnormal findings	11	11	11

Values are number of animal with findings.

(to be continued)

Table 2 General appearance of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)  
 (continued-3)

Group	Findings	Administration day		Recovery day		Autopsy day
		1-42	1-14	1-14	1-14	
0 mg/kg	Number of animals examined	5	5	5	5	5
	No abnormal findings	5	5	5	5	
1000 mg/kg	Number of animals examined	5	5	5	5	5
	No abnormal findings	5	5	5	5	

Values are number of animal with findings.

Table 3-1 Detailed clinical observation of male rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Period	Group	Number of animals	Category No.	Body position/ Posture	Respiratory pattern	Tremor/ Convulsion	Stereotype		Bizarre behavior	
							1	0	Repetitive circling	12
Pre	0 mg/kg	12		12	12	12	12	0	0	12
	100 mg/kg	12		12	12	12	12	0	0	12
	300 mg/kg	12		12	12	12	12	0	0	12
	1000 mg/kg	12		12	12	12	12	0	0	12
Day 7	0 mg/kg	12		12	12	12	12	0	0	12
	100 mg/kg	12		12	12	12	12	0	0	12
	300 mg/kg	12		12	12	12	12	0	0	12
	1000 mg/kg	12		12	12	12	12	0	0	12
Day 14	0 mg/kg	12		12	12	12	12	0	0	12
	100 mg/kg	12		12	12	12	12	0	0	12
	300 mg/kg	12		12	12	12	12	0	0	12
	1000 mg/kg	12		12	12	12	12	0	0	12
Day 21	0 mg/kg	12		12	12	12	12	0	0	12
	100 mg/kg	12		12	12	12	12	0	0	12
	300 mg/kg	12		12	12	12	12	0	0	12
	1000 mg/kg	12		12	12	12	12	0	0	12
Day 28	0 mg/kg	12		12	12	12	12	0	0	12
	100 mg/kg	12		12	12	12	12	0	0	12
	300 mg/kg	12		12	12	12	12	0	0	12
	1000 mg/kg	12		12	12	12	12	0	0	12

Category No. : The category number observed in each item.

Pre : Pre-administration.

Day 7, 14, 21 and 28 : Day 7, 14, 21 and 28 of administration.

(to be continued)

Table 3-1 Detailed clinical observation of male rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)  
(continued)

Period	Group	Number of animals	Category No.	Body position/ Posture	Respiratory pattern	Tremor/ Convulsion	Stereotype		Bizarre behavior	
							1	1	0	0
Day 35	0 mg/kg	12		12	12	12	12	12	12	12
	100 mg/kg	12		12	12	12	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	12	12
	1000 mg/kg	12		12	12	12	12	12	12	12
Day 42	0 mg/kg	12		12	12	12	12	12	12	12
	100 mg/kg	12		12	12	12	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	12	12
	1000 mg/kg	12		12	12	12	12	12	12	12
Recovery	0 mg/kg	5		5	5	5	5	5	5	5
	day 7 1000 mg/kg	5		5	5	5	5	5	5	5
Recovery	0 mg/kg	5		5	5	5	5	5	5	5
	day 14 1000 mg/kg	5		5	5	5	5	5	5	5

Category No. : The category number observed in each item.

Day 35 and 42 : Day 35 and 42 of administration.

Recovery day 7 and 14 : Day 7 and 14 of recovery.

Table 3-2 Detailed clinical observation of male rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Period	Group	Number of animals	Category No.	Ease of Removal	Ease of				Fur	Eyes 1	Mucous 1	Skin 1	Pupil size 1	Lacration 1	Salivation 1	Secretions/Excretions 0
					1	2	1	0								
Pre	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12	12
	100 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12	12
	1000 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12	12
Day 7	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12	12
	100 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12	12
	1000 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12	12
Day 14	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12	12
	100 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12	12
	1000 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12	12
Day 21	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12	12
	100 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12	12
	1000 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12	12
Day 28	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12	12
	100 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12	12
	1000 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12	12

Category No. : The category number observed in each item.

Pre : Pre-administration.

Day 7, 14, 21 and 28 : Day 7, 14, 21 and 28 of administration.

(to be continued)

Table 3-2 Detailed clinical observation of male rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)  
(continued)

Period	Group	Number of animals	Category No.	Ease of				Fur	Eyes	Mucous	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
				Removal	Handling	Muscle tone	Piloerection								
Day 35	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	100 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	1000 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
Day 42	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	100 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	1000 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
Recovery	0 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5	5
day 7	1000 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5	5
Recovery	0 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5	5
day 14	1000 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5	5

Category No. : The category number observed in each item.

Day 35 and 42 : Day 35 and 42 of administration.

Recovery day 7 and 14 : Day 7 and 14 of recovery.

Table 3-3 Detailed clinical observation of male rats dosed orally with Isotriacyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Period	Group	Number of animals	Category No.	Gait	Co-ordination of movement	Reactivity to environmental stimuli	Stereotype			Bizarre behavior		
							1	0	1	0	1	1
Pre	0 mg/kg	12		12	12	12	10	2	11	1	12	12
	100 mg/kg	12		12	12	12	9	3	9	3	12	12
	300 mg/kg	12		12	12	12	11	1	10	2	12	12
	1000 mg/kg	12		12	12	12	11	1	9	3	12	12
Day 7	0 mg/kg	12		12	12	12	11	1	9	3	12	12
	100 mg/kg	12		12	12	12	11	1	11	1	12	12
	300 mg/kg	12		12	12	12	12	0	11	1	12	12
	1000 mg/kg	12		12	12	12	9	3	9	3	12	12
Day 14	0 mg/kg	12		12	12	12	10	2	11	1	12	12
	100 mg/kg	12		12	12	12	12	0	12	0	12	12
	300 mg/kg	12		12	12	12	12	0	11	1	12	12
	1000 mg/kg	12		12	12	12	12	0	12	0	12	12
Day 21	0 mg/kg	12		12	12	12	10	2	10	2	12	12
	100 mg/kg	12		12	12	12	11	1	11	1	12	12
	300 mg/kg	12		12	12	12	12	0	12	0	12	12
	1000 mg/kg	12		12	12	12	11	1	11	1	12	12
Day 28	0 mg/kg	12		12	12	12	12	0	12	0	12	12
	100 mg/kg	12		12	12	12	11	1	11	1	12	12
	300 mg/kg	12		12	12	12	12	0	12	0	12	12
	1000 mg/kg	12		12	12	12	11	1	12	0	12	12

Category No. : The category number observed in each item.

Pre : Pre-administration.

Day 7, 14, 21 and 28 : Day 7, 14, 21 and 28 of administration.

(to be continued)

Table 3-3 Detailed clinical observation of male rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)  
(continued)

Period	Group	Number of animals	Category No.	Gait	Co-ordination of movement	Reactivity to environmental stimuli	Reactivity to			Stereotype			Bizarre behavior		
							1	1	1	0	1	0	1	1	1
Day 35	0 mg/kg	12		12	12	12	12	9	3	12	0	12	12	12	12
	100 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12
	1000 mg/kg	12		12	12	12	12	11	1	12	0	12	12	12	12
Day 42	0 mg/kg	12		12	12	12	12	11	1	12	0	12	12	12	12
	100 mg/kg	12		12	12	12	12	11	1	12	0	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12
	1000 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12
Recovery day 7	0 mg/kg	5		5	5	5	5	5	0	5	0	5	5	5	5
	1000 mg/kg	5		5	5	5	5	4	1	5	0	5	5	5	5
Recovery day 14	0 mg/kg	5		5	5	5	5	5	0	5	0	5	5	5	5
	1000 mg/kg	5		5	5	5	5	5	0	5	0	5	5	5	5

Category No. : The category number observed in each item.

Day 35 and 42 : Day 35 and 42 of administration.

Recovery day 7 and 14 : Day 7 and 14 of recovery.

Table 4-1-1 Detailed clinical observation of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Period	Group	Number of animals	Category No.	Body position/ Posture	Respiratory pattern	Tremor/ Convulsion	Stereotype		Bizarre behavior	
							1	1	0	0
Pre	0 mg/kg	12		12	12	12	12	12	12	12
	100 mg/kg	12		12	12	12	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	12	12
	1000 mg/kg	12		12	12	12	12	12	12	12
Day 7	0 mg/kg	12		12	12	12	12	12	12	12
	100 mg/kg	12		12	12	12	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	12	12
	1000 mg/kg	12		12	12	12	12	12	12	12
Day 14	0 mg/kg	12		12	12	12	12	12	12	12
	100 mg/kg	12		12	12	12	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	12	12
	1000 mg/kg	12		12	12	12	12	12	12	12
Day 21	0 mg/kg	12		12	12	12	12	12	12	12
	100 mg/kg	12		12	12	12	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	12	12
	1000 mg/kg	12		12	12	12	12	12	12	12
Day 28	0 mg/kg	12		12	12	12	12	12	12	12
	100 mg/kg	12		12	12	12	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	12	12
	1000 mg/kg	12		12	12	12	12	12	12	12

Category No. : The category number observed in each item.

Pre : Pre-administration.

Day 7, 14, 21 and 28 : Day 7, 14, 21 and 28 of administration.

(to be continued)

Table 4-1-1 Detailed clinical observation of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)  
 (continued)

Period	Group	Number of animals	Category No.	Body position/ Posture	Respiratory pattern	Tremor/ Convulsion	Stereotype			Bizarre behavior	
							1	1	0	0	12
Day 35	0 mg/kg	12		12		12				12	12
	100 mg/kg	12		12		12				12	12
	300 mg/kg	12		12		12				12	12
	1000 mg/kg	12		12		12				12	12
Day 42	0 mg/kg	12		12		12				12	12
	100 mg/kg	12		12		12				12	12
	300 mg/kg	12		12		12				12	12
	1000 mg/kg	12		12		12				12	12
Day 49	0 mg/kg	1		1		1				1	1
	1000 mg/kg	1		1		1				1	1

Category No. : The category number observed in each item.  
 Day 35, 42 and 49 : Day 35, 42 and 49 of administration.

Table 4-1-2 Detailed clinical observation of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Period	Group	Number of animals	Category No.	Ease of				Mucous membranes	Skin size	Pupil	Lacration	Salivation	Secretions/ Excretions
				1	2	Muscle tone	Piloerection						
Pre	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12
	100 mg/kg	12		12	12	12	12	12	12	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	12	12	12	12	12
	1000 mg/kg	12		12	12	12	12	12	12	12	12	12	12
Day 7	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12
	100 mg/kg	12		12	12	12	12	12	12	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	12	12	12	12	12
	1000 mg/kg	12		12	12	12	12	12	12	12	12	12	12
Day 14	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12
	100 mg/kg	12		12	12	12	12	12	12	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	12	12	12	12	12
	1000 mg/kg	12		12	12	12	12	12	12	12	12	12	12
Day 21	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12
	100 mg/kg	12		12	12	12	12	12	12	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	12	12	12	12	12
	1000 mg/kg	12		12	12	12	12	12	12	12	12	12	12
Day 28	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12
	100 mg/kg	12		12	12	12	12	12	12	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	12	12	12	12	12
	1000 mg/kg	12		12	12	12	12	12	12	12	12	12	12

Category No. : The category number observed in each item.

Pre : Pre-administration.

Day 7, 14, 21 and 28 : Day 7, 14, 21 and 28 of administration.

(to be continued)

Table 4-1-2 Detailed clinical observation of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)  
(continued)

Period	Group	Number of animals	Category No.	Ease of			Mucous membranes	Skin size	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
				Removal	Handling	Muscle tone						
Day 35	0 mg/kg	12		12	12	12	12	12	12	12	12	12
	100 mg/kg	12		12	12	12	12	12	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	12	12	12	12
	1000 mg/kg	12		12	12	12	12	12	12	12	12	12
Day 42	0 mg/kg	12		12	12	12	12	12	12	12	12	12
	100 mg/kg	12		12	12	12	12	12	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	12	12	12	12
	1000 mg/kg	12		12	12	12	12	12	12	12	12	12
Day 49	0 mg/kg	1		1	1	1	1	1	1	1	1	1
	1000 mg/kg	1		1	1	1	1	1	1	1	1	1

Category No. : The category number observed in each item.  
Day 35, 42 and 49 : Day 35, 42 and 49 of administration.

Table 4-1-3 Detailed clinical observation of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Period	Group	Number of animals	Category No.	Gait	Co-ordination of movement	1	1	Reactivity to environmental stimuli			Searching	Urination	Defecation	Stereotype			Bizarre behavior		
								0	1	0				0	1	0	1	0	1
Pre	0 mg/kg	12		12	12			12	12	8	4	12	0	12	12	12	12	12	12
	100 mg/kg	12		12	12			12	12	11	1	12	0	12	12	12	12	12	12
	300 mg/kg	12		12	12			12	12	9	3	12	0	12	12	12	12	12	12
	1000 mg/kg	12		12	12			12	12	0	12	0	12	12	12	12	12	12	12
Day 7	0 mg/kg	12		12	12			12	12	0	12	0	12	12	12	12	12	12	12
	100 mg/kg	12		12	12			12	12	11	1	11	1	12	12	12	12	12	12
	300 mg/kg	12		12	12			12	12	0	12	0	12	12	12	12	12	12	12
	1000 mg/kg	12		12	12			12	12	0	12	0	12	12	12	12	12	12	12
Day 14	0 mg/kg	12		12	12			12	12	0	12	0	12	12	12	12	12	12	12
	100 mg/kg	12		12	12			12	12	11	1	12	0	12	12	12	12	12	12
	300 mg/kg	12		12	12			12	12	0	12	0	12	12	12	12	12	12	12
	1000 mg/kg	12		12	12			12	12	0	12	0	12	12	12	12	12	12	12
Day 21	0 mg/kg	12		12	12			12	12	0	12	0	12	12	12	12	12	12	12
	100 mg/kg	12		12	12			12	12	0	12	0	12	12	12	12	12	12	12
	300 mg/kg	12		12	12			12	12	0	12	0	12	12	12	12	12	12	12
	1000 mg/kg	12		12	12			12	12	0	12	0	12	12	12	12	12	12	12
Day 28	0 mg/kg	12		12	12			12	12	0	12	0	12	12	12	12	12	12	12
	100 mg/kg	12		12	12			12	12	11	1	12	0	12	12	12	12	12	12
	300 mg/kg	12		12	12			12	12	0	12	0	12	12	12	12	12	12	12
	1000 mg/kg	12		12	12			12	12	0	12	0	12	12	12	12	12	12	12

Category No. : The category number observed in each item.

Pre : Pre-administration.

Day 7, 14, 21 and 28 : Day 7, 14, 21 and 28 of administration.

(to be continued)

Table 4-1-3 Detailed clinical observation of female rats dosed orally with Isotriacyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)  
(continued)

Period	Group	Number of animals	Category No.	Gait	Co-ordination of movement	Reactivity to environmental stimuli			Searching	Urination	Defecation	Stereotype			Bizarre behavior		
						1	1	1				0	1	0	1	0	1
Day 35	0 mg/kg	12		12	12	12	12	12	0	12	0	12	0	12	12	12	12
	100 mg/kg	12		12	12	12	12	12	0	12	0	12	0	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	0	12	0	12	0	12	12	12	12
	1000 mg/kg	12		12	12	12	12	12	0	12	0	12	0	12	12	12	12
Day 42	0 mg/kg	12		12	12	12	12	12	0	12	0	12	0	12	12	12	12
	100 mg/kg	12		12	12	12	12	12	0	12	0	12	0	12	12	12	12
	300 mg/kg	12		12	12	12	12	12	0	12	0	11	1	12	12	12	12
	1000 mg/kg	12		12	12	12	12	12	0	12	0	12	0	12	12	12	12
Day 49	0 mg/kg	1		1	1	1	1	1	0	1	0	1	0	1	1	1	1
	1000 mg/kg	1		1	1	1	1	1	0	1	0	1	0	1	1	1	1

Category No. : The category number observed in each item.  
Day 35, 42 and 49 : Day 35, 42 and 49 of administration.

Table 4-2-1 Detailed clinical observation of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Period	Group	Number of animals	Category No.	Body position/ Posture	Respiratory pattern	Tremor/ Convulsion	Stereotype		Bizarre behavior	
							1	1	0	0
Pre	0 mg/kg	5		5	5	5	5	5	5	5
	1000 mg/kg	5		5	5	5	5	5	5	5
Day 7	0 mg/kg	5		5	5	5	5	5	5	5
	1000 mg/kg	5		5	5	5	5	5	5	5
Day 14	0 mg/kg	5		5	5	5	5	5	5	5
	1000 mg/kg	5		5	5	5	5	5	5	5
Day 21	0 mg/kg	5		5	5	5	5	5	5	5
	1000 mg/kg	5		5	5	5	5	5	5	5
Day 28	0 mg/kg	5		5	5	5	5	5	5	5
	1000 mg/kg	5		5	5	5	5	5	5	5

Category No. : The category number observed in each item.

Pre : Pre-administration.

Day 7, 14, 21 and 28 : Day 7, 14, 21 and 28 of administration.

(to be continued)

Table 4-2-1 Detailed clinical observation of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)  
(continued)

Period	Group	Number of animals	Category No.	Body position/ Posture	Respiratory pattern	Tremor/ Convulsion	Stereotype			Bizarre behavior	
							1	0	0	0	1
Day 35	0 mg/kg	5		5	5	5	5	5	5	5	5
	1000 mg/kg	5		5	5	5	5	5	5	5	5
Day 42	0 mg/kg	5		5	5	5	5	5	5	5	5
	1000 mg/kg	5		5	5	5	5	5	5	5	5
Recovery day 7	0 mg/kg	5		5	5	5	5	5	5	5	5
	1000 mg/kg	5		5	5	5	5	5	5	5	5
Recovery day 14	0 mg/kg	5		5	5	5	5	5	5	5	5
	1000 mg/kg	5		5	5	5	5	5	5	5	5

Category No. : The category number observed in each item.

Day 35 and 42 : Day 35 and 42 of administration.

Recovery day 7 and 14 : Day 7 and 14 of recovery.

Table 4-2-2 Detailed clinical observation of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Period	Group	Number of animals	Category No.	Ease of										Secretions/ Excretions
				Removal	Handling	Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	
1	1	2	1	1	1	0	1	1	1	1	1	1	1	0
Pre	0 mg/kg	5	5	5	5	5	5	5	5	5	5	5	5	5
	1000 mg/kg	5	5	5	5	5	5	5	5	5	5	5	5	5
Day 7	0 mg/kg	5	5	5	5	5	5	5	5	5	5	5	5	5
	1000 mg/kg	5	5	5	5	5	5	5	5	5	5	5	5	5
Day 14	0 mg/kg	5	5	5	5	5	5	5	5	5	5	5	5	5
	1000 mg/kg	5	5	5	5	5	5	5	5	5	5	5	5	5
Day 21	0 mg/kg	5	5	5	5	5	5	5	5	5	5	5	5	5
	1000 mg/kg	5	5	5	5	5	5	5	5	5	5	5	5	5
Day 28	0 mg/kg	5	5	5	5	5	5	5	5	5	5	5	5	5
	1000 mg/kg	5	5	5	5	5	5	5	5	5	5	5	5	5

Category No. : The category number observed in each item.

Pre : Pre-administration.

Day 7, 14, 21 and 28 : Day 7, 14, 21 and 28 of administration.

(to be continued)

Table 4-2-2 Detailed clinical observation of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)  
(continued)

Period	Group	Number of animals	Category No.	Ease of		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacration	Salivation	Secretions/Excretions	
				Removal	Handling											
Day 35	0 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5	5	5
	1000 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5	5	5
Day 42	0 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5	5	5
	1000 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5	5	5
Recovery day 7	0 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5	5	5
	1000 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5	5	5
Recovery day 14	0 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5	5	5
	1000 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5	5	5

Category No. : The category number observed in each item.

Day 35 and 42 : Day 35 and 42 of administration.

Recovery day 7 and 14 : Day 7 and 14 of recovery.

Table 4-2-3 Detailed clinical observation of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Period	Group	Number of animals	Category No.	Gait	Co-ordination of movement	Environmental stimuli	Searching	Urination	Defecation	Stereotype			Bizarre behavior		
										Excessive grooming		Unusual head movement	Walking backward	Vocalization	Aggression
										0	1	0	1	0	1
Pre	0 mg/kg	5		5	5	5	5	5	0	5	0	5	5	5	5
	1000 mg/kg	5		5	5	5	5	5	0	5	0	5	5	5	5
Day 7	0 mg/kg	5		5	5	5	5	4	1	4	1	5	5	5	5
	1000 mg/kg	5		5	5	5	5	5	0	5	0	5	5	5	5
Day 14	0 mg/kg	5		5	5	5	5	5	0	5	0	5	5	5	5
	1000 mg/kg	5		5	5	5	5	5	0	5	0	5	5	5	5
Day 21	0 mg/kg	5		5	5	5	5	4	1	5	0	5	5	5	5
	1000 mg/kg	5		5	5	5	5	5	0	5	0	5	5	5	5
Day 28	0 mg/kg	5		5	5	5	5	4	1	5	0	5	5	5	5
	1000 mg/kg	5		5	5	5	5	5	0	5	0	5	5	5	5

Category No. : The category number observed in each item.

Pre : Pre-administration.

Day 7, 14, 21 and 28 : Day 7, 14, 21 and 28 of administration.

(to be continued)

Table 4-2-3 Detailed clinical observation of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)  
(continued)

Period	Group	Number of animals	Category No.	Gait	Co-ordination of movement	Reactivity to environmental stimuli	Searching	Urination	Defecation	Stereotype		Bizarre behavior	
										grooming	Excessive head movement	Walking backward	Vocalization
Day 35	0 mg/kg	5	5	5	5	5	5	5	5	5	5	5	5
	1000 mg/kg	5	5	5	5	5	5	5	5	5	5	5	5
Day 42	0 mg/kg	5	5	5	5	5	5	5	5	5	5	5	5
	1000 mg/kg	5	5	5	5	5	5	5	5	5	5	5	5
Recovery day 7	0 mg/kg	5	5	5	5	5	5	5	5	5	5	5	5
	1000 mg/kg	5	5	5	5	5	5	5	5	5	5	5	5
Recovery day 14	0 mg/kg	5	5	5	5	5	5	5	5	5	5	5	5
	1000 mg/kg	5	5	5	5	5	5	5	5	5	5	5	5

Category No. : The category number observed in each item.

Day 35 and 42 : Day 35 and 42 of administration.

Recovery day 7 and 14 : Day 7 and 14 of recovery.

Table 5 Functional test of male rats dosed orally with Isotriacyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Period	Group	Number of animals	Category No.	Reactivity				Righting reflex
				Visual	Touch	Auditory	Pain	
Week 6	0 mg/kg	5		5	5	5	5	5
	100 mg/kg	5		5	5	5	5	5
	300 mg/kg	5		5	5	5	5	5
	1000 mg/kg	5		5	5	5	5	5
Recovery week 2	0 mg/kg	5		5	5	5	5	5
	1000 mg/kg	5		5	5	5	5	5

(to be continued)

Category No. : The category number observed in each item.  
Values are expressed as the number of animals.

Visual reactivity : approach response.

Touch reactivity : touch response.

Auditory reactivity : response to Galton's whistle.

Pain reactivity : tail pinch response.

Proprioceptive reactivity : returning from enforced posture.  
Righting reflex : landing performance from 30 cm above.

Week 6 : Week 6 of administration.

Recovery week 2 : Week 2 of recovery.

Table 5 Functional test of male rats dosed orally with Isotriacyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207) (continued)

Period	Group	Number of animals	Grip strength		Motor activity measurements (count)					
			Forelimb (g)	Hindlimb (g)	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'
Week 6	0 mg/kg	5	Mean 1072.28 S.D. 98.76	455.02 15.33	701.2 147.4	437.6 144.2	308.6 141.8	173.0 136.1	151.4 145.4	177.6 130.4
100 mg/kg	5	Mean 1145.20 S.D. 202.67	469.38 23.11	517.0 137.7	318.4 102.7	155.4 23.1	101.6 52.6	121.4 67.6	84.4 23.2	1949.4 766.2
300 mg/kg	5	Mean 1035.38 S.D. 128.32	478.52 39.25	599.6 188.6	358.4 124.1	231.8 128.6	126.8 129.4	100.8 71.4	103.8 60.2	1298.2 298.1
1000 mg/kg	5	Mean 1111.96 S.D. 101.95	416.86 86.29	592.0 256.4	305.0 189.6	228.6 196.8	143.4 225.1	143.8 132.1	127.4 135.8	1521.2 511.8
Recovery week 2	0 mg/kg	5	Mean 1353.60 S.D. 161.66	570.16 45.17	484.4 186.2	388.2 129.9	471.0 338.8	363.4 251.1	291.6 220.7	1540.2 1178.4
	1000 mg/kg	5	Mean 1429.40 S.D. 230.59	579.12 28.73	368.4 191.5	309.0 109.1	237.8 79.0	226.8 83.4	192.0 37.3	1445.6 401.3

Week 6 : Week 6 of administration.

Recovery week 2 : Week 2 of recovery.

Table 6 Functional test of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Period	Group	Number of animals	Category	Reactivity					Righting reflex
				Visual	Touch	Auditory	Pain	Proprioceptive	
			4	2	1	2	1		
Week 6	0 mg/kg	5		5	5	5	5	5	5
	1000 mg/kg	5		5	5	5	5	5	5
Recovery week 2	0 mg/kg	5		5	5	5	5	5	5
	1000 mg/kg	5		5	5	5	5	5	5
Lactation day 4	0 mg/kg	5		5	5	5	5	5	5
	100 mg/kg	5		5	5	5	5	5	5
	300 mg/kg	5		5	5	5	5	5	5
	1000 mg/kg	5		5	5	5	5	5	5

Category No. : The category number observed in each item.  
Values are expressed as the number of animals.

Visual reactivity : approach response.

Touch reactivity : touch response.

Auditory reactivity : response to Galton's whistle.

Pain reactivity : tail pinch response.

Proprioceptive reactivity : returning from enforced posture.  
Righting reflex : landing performance from 30 cm above.

Week 6 : Week 6 of administration.

Recovery week 2 : Week 2 of recovery.

Lactation day 4 : Day 4 of lactation.

Table 6 Functional test of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207) (continued)

Period	Group	Number of animals	Grip strength		Motor activity measurements (count)					
			Forelimb (g)	Hindlimb (g)	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'
Week 6	0 mg/kg	5	Mean 810.80 S.D. 83.20	366.86 36.61	944.6 412.9	632.6 324.8	589.4 404.1	495.4 327.5	232.8 216.2	209.2 190.9
	1000 mg/kg	5	Mean 961.40 S.D. 157.90	404.74 77.58	531.0 189.9	374.8 121.5	276.0 110.3	223.0 106.6	74.4 30.2	3104.0 1619.2
Recovery week 2	0 mg/kg	5	Mean 1077.46 S.D. 60.24	447.46 22.08	743.0 413.5	502.8 353.9	456.2 391.0	365.2 361.7	80.0 345.0	1559.2 498.5
	1000 mg/kg	5	Mean 1247.32* S.D. 143.04	432.88 22.75	527.6 134.8	383.2 120.9	265.2 133.6	248.8 183.7	233.8 139.6	2713.8 1999.9
Lactation day 4	0 mg/kg	5	Mean 1122.88 S.D. 58.87	528.74 127.17	565.4 332.2	274.0 222.2	172.2 195.4	76.2 71.2	125.8 152.5	1832.8 50.5
	100 mg/kg	5	Mean 1169.12 S.D. 71.46	522.50 152.31	686.0 197.4	359.4 262.2	138.6 135.4	122.0 125.9	68.8 55.5	1248.0 915.3
	300 mg/kg	5	Mean 1057.86 S.D. 93.03	472.60 33.57	505.8 169.0	287.6 285.3	168.8 263.4	107.6 177.5	154.4 129.9	1529.2 733.7
	1000 mg/kg	5	Mean 1047.20 S.D. 98.51	432.06 60.86	529.8 153.5	248.6 85.4	182.6 141.0	155.4 233.3	72.6 166.9	1303.0 1056.2
										1506.4 729.4

Week 6 : Week 6 of administration.

Recovery week 2 : Week 2 of recovery.

Lactation day 4 : Day 4 of lactation.

\* : Significantly different from the 0 mg/kg group at p ≤ 0.05 (Dunnett's test).

Table 7 Body weight of male rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR092/07)

Group	Number of animals	Administration day			Body weight (g)					Body weight gain (%)		
		1	3	5	7	10	14	21	28	35	42	
0 mg/kg	12	Mean	370.4	376.7	386.2	391.9	399.7	415.8	435.1	450.0	471.8	483.3
		S.D.	16.7	18.9	18.2	21.1	24.7	27.1	28.5	32.4	39.6	46.0
100 mg/kg	12	Mean	371.3	378.3	388.7	394.5	403.1	418.3	440.3	456.6	478.8	494.8
		S.D.	14.3	13.8	13.7	13.9	14.5	15.0	13.9	14.7	17.2	22.1
300 mg/kg	12	Mean	370.2	376.7	388.8	395.8	403.8	418.9	438.7	456.4	477.8	490.9
		S.D.	15.0	16.1	17.6	18.9	21.5	22.1	22.2	25.4	28.2	27.7
1000 mg/kg	12	Mean	372.8	380.4	389.8	397.5	407.0	422.5	449.3	468.4	491.8	503.7
		S.D.	15.0	16.6	17.1	19.0	19.3	20.3	20.5	21.3	24.2	29.9

Group	Number of animals	Recovery day		Body weight gain (%)	
		7	14	42-R14	%
0 mg/kg	5	Mean	501.2	505.2	21.2
		S.D.	31.3	38.2	4.302
1000 mg/kg	5	Mean	508.8	517.0	25.4
		S.D.	13.9	14.0	5.172
				7.6	1.568

Body weight gain (%) = (body weight gain / body weight on day 1 or day 42) x 100.

R14 : Recovery day 14.

Table 8 Body weight during pre-mating period of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals	Body weight(g) on pre-mating period						Body weight gain (g)
		1	3	5	7	10	14	
0 mg/kg	12	Mean S.D.	248.3 12.3	248.8 12.5	257.2 14.5	257.4 14.4	264.8 13.3	271.6 14.0
100 mg/kg	12	Mean S.D.	246.2 13.4	249.3 13.0	253.8 14.4	257.9 14.0	258.9 15.2	266.4 16.5
300 mg/kg	12	Mean S.D.	243.1 14.4	248.6 14.0	252.3 14.9	258.3 15.1	260.6 15.2	268.9 16.7
1000 mg/kg	12	Mean S.D.	247.0 12.2	247.8 13.6	255.9 13.5	255.3 15.2	259.3 13.9	267.9 13.5

Body weight gain (%) = (body weight gain / body weight on day 1) x 100.

Table 9 Body weight during gestation period of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals	Gestation day						Body weight (g)				Body weight gain (g)		
		0	1	3	5	7	10	14	17	20	0-20		%	
0 mg/kg	11	Mean	274.8	279.5	292.4	300.7	309.3	327.5	351.0	383.1	433.5	158.6	57.825	
		S.D.	12.4	14.0	14.8	16.2	17.0	18.8	20.3	22.1	26.1	22.6	8.564	
100 mg/kg	12	Mean	274.2	279.8	293.6	301.9	311.0	328.4	351.8	385.3	437.7	163.5	59.688	
		S.D.	13.3	14.8	15.0	15.0	13.7	14.9	17.8	18.7	21.8	13.2	4.614	
300 mg/kg	12	Mean	274.4	280.7	290.9	299.9	308.0	324.7	348.3	383.8	435.3	160.8	58.898	
		S.D.	17.9	15.6	17.1	15.4	16.5	16.0	19.5	19.0	17.9	10.4	6.060	
1000 mg/kg	11	Mean	274.4	281.7	294.0	303.0	311.6	329.3	354.9	391.9	444.5	170.2	62.202	
		S.D.	18.1	17.2	17.9	18.2	19.1	21.7	24.7	26.1	27.4	17.5	6.889	

Body weight gain (%) = (body weight gain / body weight on day 0) x 100.

Table 10 Body weight during lactation period of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals	Lactation day		Body weight gain (g)		
		0	1	4	0-4	%
0 mg/kg	11	Mean S.D.	332.4 20.9	332.5 19.7	342.8 16.8	10.5 9.7
100 mg/kg	12	Mean S.D.	332.8 26.1	333.4 22.5	343.2 17.9	10.3 12.6
300 mg/kg	12	Mean S.D.	328.8 18.3	325.9 18.3	336.3 19.4	7.5 13.8
1000 mg/kg	11	Mean S.D.	341.0 26.7	342.0 26.5	353.5 27.0	12.5 10.8

Body weight gain (%) = (body weight gain / body weight on day 0) x 100.

Table 11 Body weight of female rats in 14-day recovery test following 42-day repeated oral dose with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals	Administration day			Body weight (g)						Body weight gain (g) %			
		1	3	5	7	10	14	21	28	35	42			
0 mg/kg	5	Mean	251.0	251.4	258.8	259.0	261.8	269.2	284.2	288.2	294.8	297.4	46.4	18.408
		S.D.	6.6	8.4	7.4	11.3	10.3	14.0	17.3	20.1	23.9	23.9	19.7	7.537
1000 mg/kg	5	Mean	250.2	250.8	258.4	258.4	265.8	276.0	287.8	291.8	301.6	315.4	65.2	25.954
		S.D.	9.0	8.3	9.5	10.2	5.1	9.0	13.4	14.5	18.2	25.0	18.1	6.616

Group	Number of animals	Recovery day			Body weight gain (g)			% R14-R14
		7	14	42-R14	7	14	42-R14	
0 mg/kg	5	Mean	307.6	315.2	17.8	5.946		
		S.D.	25.6	29.0	11.5	4.056		
1000 mg/kg	5	Mean	321.6	320.8	5.4	1.740		
		S.D.	27.6	24.1	4.6	1.522		

Body weight gain (%) = (body weight gain / body weight on day 1 or day 42) x 100.

R14 : Recovery day 14.

Table 12 Food consumption of male rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals	Food consumption (g/rat/day)									
		Administration day		3~5	5~7	7~10	10~14	21~28	28~35	35~42	
-1~1		1~3									
0 mg/kg	12	Mean	25.42	20.96	21.21	20.33	20.78	20.02	19.86	21.03	20.59
		S.D.	2.19	1.97	1.97	1.86	2.02	1.93	1.72	2.47	2.96
100 mg/kg	12	Mean	25.50	21.13	21.79	20.75	21.21	20.51	21.27	21.63	22.03
		S.D.	1.83	1.43	1.25	1.45	1.19	1.13	1.27	1.47	1.87
300 mg/kg	12	Mean	27.50	21.75	22.00	21.54	21.49	20.63	20.95	21.42	21.49
		S.D.	2.58	1.94	1.72	2.02	1.88	1.34	1.51	1.68	1.61
1000 mg/kg	12	Mean	25.75	22.63	21.71	21.46	22.14	21.48	22.55**	23.17*	22.68
		S.D.	2.56	2.04	1.42	1.57	1.56	1.35	1.30	1.32	1.88

Group	Number of animals	Food consumption (g/rat/day)					
		Recovery day		42~R7	R7~R14		
0 mg/kg	5	Mean	25.66	27.20			
		S.D.	2.74	3.32			
1000 mg/kg	5	Mean	27.28	28.68			
		S.D.	1.78	1.52			

R7 : Recovery day 7, R14 : Recovery day 14.

The number in the parenthesis is the number of animals used for the measurement.

a : Not measured in 1 male because this animal was in the course of mating.

\* : Significantly different from the 0 mg/kg group at  $p \leq 0.05$  (Dunnett's test).

\*\* : Significantly different from the 0 mg/kg group at  $p \leq 0.01$  (Dunnett's test).

Table 13

Food consumption during pre-mating period of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals	Food consumption (g/rat/day) on pre-mating period						
		Administration day		-1~1	1~3	3~5	5~7	7~10
0 mg/kg	12	Mean	18.50	14.71	16.67	15.71	16.83	16.48
		S.D.	2.35	1.97	2.00	1.63	1.20	1.11
100 mg/kg	12	Mean	18.83	14.83	16.79	15.46	16.43	16.26
		S.D.	2.33	1.90	1.78	1.41	1.68	1.34
300 mg/kg	12	Mean	18.17	16.04	16.00	16.83	16.46	16.85
		S.D.	2.33	2.03	2.80	3.13	2.24	1.89
1000 mg/kg	12	Mean	18.00	14.88	16.67	14.79	16.42	16.12
		S.D.	2.30	1.81	1.61	1.74	1.24	1.79

Table 14 Food consumption during gestation period of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals	Gestation day	Food consumption (g/rat/day)					
			0~1	1~3	3~5	5~7	7~10	10~14
0 mg/kg	11	Mean S.D.	15.64 2.54	20.86 1.99	20.91 2.06	21.95 1.72	22.94 1.97	23.35 2.18
100 mg/kg	12	Mean S.D.	16.58 3.09	20.92 1.72	21.13 1.85	22.38 1.64	23.36 1.70	23.78 2.03
300 mg/kg	12	Mean S.D.	16.58 3.00	20.21 2.08	20.88 1.97	21.83 2.46	22.64 3.27	23.43 2.78
1000 mg/kg	11	Mean S.D.	16.55 1.69	20.73 1.77	20.82 1.31	21.73 1.62	22.68 1.78	23.71 1.85
								24.37 1.80
								22.17 1.60

Table 15 Food consumption during lactation period of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals	Food consumption (g/rat/day)			
		Lactation day		0~1      1~4	
0 mg/kg	11	Mean S.D.	17.36 4.30	30.88 4.59	
100 mg/kg	12	Mean S.D.	18.58 3.92	35.51+ 5.03	
300 mg/kg	12	Mean S.D.	15.17 4.57	31.77 4.60	
1000 mg/kg	11	Mean S.D.	20.27 3.10	32.49 1.98	

+ : Significantly different from the 0 mg/kg group at  $p \leq 0.05$  (Mann-Whitney's U-test).

Table 16

Food consumption of female rats in 14-day recovery test following 42-day repeated oral dose with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals	Administration day		Food consumption (g/rat/day)					
		-1~1	1~3	5~7	7~10	10~14	14~21	21~28	28~35
0 mg/kg	5	Mean	20.00	14.80	15.10	16.26	16.42	16.88	15.84
		S.D.	4.00	1.52	1.24	2.04	1.90	1.19	1.97
								2.15	2.87
									16.38
									2.22
1000 mg/kg	5	Mean	19.40	15.50	17.50	16.20	17.68	18.18	17.62
		S.D.	2.30	1.54	1.77	1.60	1.36	1.41	1.29
								1.19	0.97
									17.80
									1.57

Group	Number of animals	Recovery day		Food consumption (g/rat/day)						
		42~R7	R7~R14	42~R7	R7~R14	42~R7	R7~R14	42~R7	R7~R14	
0 mg/kg	5	Mean	19.88	21.10						
		S.D.	2.78	2.82						
1000 mg/kg	5	Mean	20.40	20.20						
		S.D.	1.88	0.79						

R7 : Recovery day 7 , R14 : Recovery day 14.

Table 17 Urinary findings of male rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals	pH				Protein		Glucose	Ketone body	Urobilinogen	Bilirubin	Occult blood	Color	Specific gravity		Urine volume (mL/21hr, mean±S.D.)			
		7.0	7.5	8.0	8.5	±	1+							-	±	A			
0 mg/kg	5	0	0	3	2	0	3	2	5	5	5	5	4	1	5	0	1	4	7.40 ± 1.95
100 mg/kg	5	0	0	2	3	1	3	1	5	5	5	5	0	5	0	0	2	3	8.80 ± 1.89
300 mg/kg	5	1	0	1	3	0	4	1	5	5	5	5	0	5	0	0	0	5	7.60 ± 2.48
1000 mg/kg	5	1	2	0	2	0	3	2	5	5	5	5	0	5	1	0	4	9.00 ± 4.37	

Values are number of animals with findings.

-, Normal ; ±, Slight ; 1+, Moderate ; 2+, Severe.

Color : A = Pale yellow or yellow

Table 18 Urinary findings of male rats in 14-day recovery test following 42-day repeated oral dose with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals	Urine			Urobladder			Blood			Urine			
		pH	Protein	Glucose	Ketone	Urobilinogen	Bilirubin	Occult blood	Color	Specific gravity	volume (mL/21hr, mean±S.D.)			
	7.5	8.0	8.5	1+ 2+	-	-	0.1 EU/dL	- 2+	-	A	1.030 1.050			
0 mg/kg	5	1	3	2	3	5	5	5	0	5	0	1	4	9.60 ± 1.64
1000 mg/kg	5	1	0	4	3	2	5	5	5	4	1	5	1	13.60 ± 6.90

Values are number of animals with findings.

- Normal ; 1+, Moderate ; 2+, Severe.

Color : A = Pale yellow or yellow

Table 19 Urinary findings of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals	pH			Protein		Glucose	Ketone body	Urobili- nogen	Bili- rubin	Occult blood - ±	Color A	Specific gravity $1.021\text{--}1.031\text{--}1.041\text{--}1.050<$	Urine volume (mL/21hr, mean±S.D.)				
		7.5	8.0	8.5	-	±								1.030	1.040	1.050		
0 mg/kg	5	0	1	4	4	1	0	5	5	5	4	1	5	0	3	1	11.20 ± 3.42	
1000 mg/kg	5	1	2	2	3	1	1	5	5	5	5	0	5	1	0	3	1	13.60 ± 12.33

Values are number of animals with findings.  
 -, Normal ; ±, Slight ; 1+, Moderate.  
 Color : A = Pale yellow or yellow

Table 20 Urinary findings of female rats in 14-day recovery test following 42-day repeated oral dose with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals	pH				Protein		Ketone body	Urobili- nogen	Bili- rubin	Occult blood	Color	Specific gravity		Urine volume (mL/21hr, mean±S.D.)	
		6.0	6.5	7.5	8.0	8.5	-						1.031- 1.041- 1.050<	1.040 1.050		
0 mg/kg	5	1	1	1	1	2	0	3	5	5	5	5	5	0	2	3
1000 mg/kg	5	0	1	0	2	2	0	3	2	5	5	5	5	2	0	3

Values are number of animals with findings.

- Normal ; ±, Slight ; 1+, Moderate.

Color : A = Pale yellow or yellow

Table 21 Hematological findings of male rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals	WBC $10^2/\mu\text{L}$	RBC $10^4/\mu\text{L}$	HGB g/dL	HCT %	MCV fL	MCH pg	MCHC g/dL	Platelet $10^4/\mu\text{L}$
0 mg/kg	5	Mean S.D.	75.48 23.45	904.0 29.2	16.00 0.42	45.84 1.50	50.74 1.91	17.70 0.25	34.92 0.94
100 mg/kg	5	Mean S.D.	67.44 19.93	884.8 40.5	15.34 0.42	44.14 1.11	49.96 2.68	17.36 0.69	34.76 0.67
300 mg/kg	5	Mean S.D.	74.12 12.42	890.8 33.7	15.64 0.69	44.76 1.48	50.24 1.06	17.56 0.45	34.92 0.54
1000 mg/kg	5	Mean S.D.	54.60 14.19	874.4 54.7	15.32 0.65	43.92 1.69	50.34 2.55	17.54 0.89	34.86 0.15

(to be continued)

Table 21 Hematological findings of male rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207) (continued)

Group	Number of animals	Reticulo- cyte			APTT sec	Differential count of WBC ( $10^3/\mu\text{L}$ )		
		%	PT sec	Neutrophil		Lympho- cyte	Monocyte	Eosinophil
0 mg/kg	5	Mean S.D.	2.878 0.458	20.00 2.50	24.74 1.89	11.46 4.84	61.48 20.69	1.70 0.16
100 mg/kg	5	Mean S.D.	3.328 0.233	18.70 0.63	24.90 1.16	13.26 4.52	51.68 16.63	1.68 0.64
300 mg/kg	5	Mean S.D.	3.194 0.128	20.48 2.36	26.48 2.59	11.30 3.87	60.36 14.33	1.38 0.37
1000 mg/kg	5	Mean S.D.	3.336 0.573	26.34 5.08	27.60 2.66	10.56 2.82	41.82 11.51	1.40 0.25

Table 22

Hematological findings of male rats in 14-day recovery test following 42-day repeated oral dose with Isotriacyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals	WBC 10 <sup>7</sup> /μL	RBC 10 <sup>4</sup> /μL	HGB g/dL	HCT %	MCV fL	MCH pg	MCHC g/dL	Platelet 10 <sup>4</sup> /μL
0 mg/kg	5	Mean S.D.	64.08 15.69	924.0 43.8	15.88 0.33	44.68 1.36	48.48 3.45	17.20 0.98	35.54 0.53
1000 mg/kg	5	Mean S.D.	83.30 18.06	929.4 26.7	15.96 0.46	44.52 1.26	47.92 1.80	17.18 0.35	35.88 0.76
<hr/>									
Group	Number of animals	Reticulo- cyte %	PT sec	APTT sec	Neutrophil	Lympho- cyte	Monocyte	Eosinophil	Basophil
0 mg/kg	5	Mean S.D.	2.642 0.730	21.92 3.16	26.40 2.56	12.78 8.53	48.80 12.12	1.68 0.90	0.82 0.34
1000 mg/kg	5	Mean S.D.	3.128 0.368	23.04 1.99	25.52 0.91	13.04 4.03	66.36 17.62	2.00 0.78	1.90+ 1.20

+ : Significantly different from the 0 mg/kg group at  $p \leq 0.05$  (Mann-Whitney's U-test).

Table 23 Hematological findings of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals	WBC 10 <sup>2</sup> /μL	RBC 10 <sup>4</sup> /μL	HGB g/dL	HCT %	MCV fL	MCH pg	MCHC g/dL	Platelet 10 <sup>4</sup> /μL
0 mg/kg	5	Mean S.D.	67.54 13.84	739.6 52.4	14.12 0.70	41.64 1.56	56.44 3.24	19.14 0.99	33.90 0.45
100 mg/kg	5	Mean S.D.	52.72 5.32	770.6 56.9	14.72 0.64	43.72 1.66	57.00 4.95	19.16 0.97	33.68 1.21
300 mg/kg	5	Mean S.D.	51.70 10.75	777.8 47.3	14.70 0.36	43.18 0.56	55.66 3.09	18.94 0.77	34.02 0.51
1000 mg/kg	5	Mean S.D.	63.98 6.92	749.6 38.4	14.22 0.39	41.90 1.65	55.94 2.15	19.00 0.61	33.94 0.63
									130.66 14.68
									120.38 19.67
									127.24 13.47

(to be continued)

Table 23 Hematological findings of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207) (continued)

Group	Number of animals	Reticulo- cyte			APTT sec	Neutrophil	Differential count of WBC ( $10^3/\mu\text{L}$ )		
		%	PT sec	Lympho- cyte			Monocyte	Eosinophil	Basophil
0 mg/kg	5	Mean S.D.	10.100 2.547	18.34 0.50	19.38 1.75	20.86 5.27	42.52 14.77	3.20 0.92	0.96 0.47
100 mg/kg	5	Mean S.D.	11.282 3.595	17.98 0.69	19.66 1.20	16.22 3.23	32.36 1.89	3.42 1.11	0.72 0.22
300 mg/kg	5	Mean S.D.	9.140 2.252	17.36 1.21	18.90 1.07	13.92 4.60	34.48 7.30	2.52 0.41	0.78 0.28
1000 mg/kg	5	Mean S.D.	9.566 2.400	17.28 0.54	17.36 1.24	17.98 3.31	42.54 8.58	2.78 1.01	0.68 0.24

Table 24 Hematological findings of female rats in 14-day recovery test following 42-day repeated oral dose with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR0207)

Group	Number of animals	WBC $10^7/\mu\text{L}$		RBC $10^4/\mu\text{L}$		HGB g/dL		HCT %		MCV fl		MCH pg		MCHC g/dL		Platelet $10^4/\mu\text{L}$	
		Mean	S.D.	Mean	S.D.	Mean	S.D.	Mean	S.D.	Mean	S.D.	Mean	S.D.	Mean	S.D.	Mean	S.D.
0 mg/kg	5	42.14	8.57	15.80	0.53	45.24	2.00	52.86	3.14	18.44	0.83	34.94	0.62	110.46	15.86		
1000 mg/kg	5	61.16	17.71	836.0	32.8	15.28	0.53	42.94	1.57	51.38	1.72	18.30	0.50	35.60	0.32	119.02	21.00
<hr/>																	
Group	Number of animals	Reticulo- cyte %		PT sec		APTT sec		Neutrophil		Lympho- cyte %		Monocyte		Eosinophil		Basophil	
																Differential count of WBC ( $10^3/\mu\text{L}$ )	
0 mg/kg	5	Mean	3.022	17.54	17.64	5.68	34.96	0.88	0.62	0.00							
		S.D.	0.519	0.86	1.16	1.84	11.12	0.11	0.27	0.00							
1000 mg/kg	5	Mean	2.676	17.56	18.26	7.68	51.06	1.34+	1.08*	0.00							
		S.D.	0.452	1.43	2.11	2.63	18.68	0.46	0.26	0.00							

+ : Significantly different from the 0 mg/kg group at  $p \leq 0.05$  (Mann-Whitney's U-test).

\* : Significantly different from the 0 mg/kg group at  $p \leq 0.05$  (Dunnett's test).

Table 25 Biochemical findings of male rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%)			AST IU/L	ALT IU/L	ALP IU/L	$\gamma$ -GTP IU/L	T-Bil mg/dL			
					Albumin	$\alpha_1$	$\alpha_2$								
0 mg/kg	5	Mean S.D.	5.22 0.22	2.672 0.138	1.050 0.072	51.16 1.80	20.76 2.80	7.64 0.79	15.86 0.95	4.58 0.80	62.6 6.0	30.8 4.3	400.2 120.8	0.26 0.05	0.058 0.013
100 mg/kg	5	Mean S.D.	5.24 0.15	2.594 0.034	0.980 0.043	49.48 1.08	23.00 1.28	7.32 0.40	15.58 0.46	4.62 0.72	60.6 5.9	30.4 3.8	382.8 76.3	0.36 0.17	0.052 0.008
300 mg/kg	5	Mean S.D.	5.08 0.29	2.576 0.104	1.034 0.049	50.80 1.24	21.70 1.68	7.68 0.43	15.58 0.72	4.24 0.44	75.2 42.4	31.2 15.7	376.0 76.1	0.40 0.16	0.052 0.015
1000 mg/kg	5	Mean S.D.	4.88 0.16	2.522 0.134	1.076 0.085	51.80 1.90	20.86 2.03	7.30 0.27	15.30 0.64	4.74 0.63	63.4 13.4	28.4 4.2	392.4 155.4	0.24 0.17	0.040 0.012

(to be continued)

Table 25 Biochemical findings of male rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207) (continued)

Group	Number of animals	Glucose mg/dL	T-Chol mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
0 mg/kg	5	Mean S.D.	160.4 5.0	55.0 11.3	22.0 9.2	13.40 2.03	0.532 0.030	145.4 0.5	4.262 0.199	106.2 1.3	9.62 0.30
100 mg/kg	5	Mean S.D.	146.8 17.3	48.8 3.7	32.0 17.8	13.36 0.86	0.540 0.019	146.0 1.4	4.332 0.107	105.8 1.3	9.80 0.12
300 mg/kg	5	Mean S.D.	150.4 22.8	48.8 12.6	25.6 8.6	12.82 1.48	0.520 0.066	145.4 1.8	4.456 0.241	106.2 1.1	9.72 0.22
1000 mg/kg	5	Mean S.D.	152.0 18.0	49.8 11.6	32.6 16.8	14.28 1.63	0.558 0.043	146.2 1.6	4.266 0.173	107.0 2.0	9.42 0.31

Table 26 Biochemical findings of male rats in 14-day recovery test following 42-day repeated oral dose with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%)			AST IU/L	ALT IU/L	ALP IU/L	$\gamma$ -GTP IU/L	T-Bil mg/dL					
					Globulin												
					$\alpha_1$	$\alpha_2$	$\beta$										
0 mg/kg	5	Mean S.D.	5.34 0.27	2.542 0.147	0.912 0.077	47.64 2.09	22.32 2.45	7.98 0.29	16.44 1.11	5.62 0.19	25.4 3.7	289.8 2.2	0.36 72.5	0.072 0.17	0.018		
1000 mg/kg	5	Mean S.D.	5.34 0.25	2.624 0.203	0.964 0.076	49.04 1.97	22.54 2.30	7.48* 0.33	16.10 0.51	4.84 0.99	59.6 2.9	27.0 5.4	303.0 57.4	0.26 0.05	0.058 0.008		
Group	Number of animals	Glucose mg/dL	T-Chol mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL						
0 mg/kg	5	Mean S.D.	150.0 31.0	57.6 15.9	25.8 13.9	16.28 1.30	0.506 0.021	146.0 1.2	4.286 0.133	106.8 0.8	9.52 0.8	7.42 0.32	0.39				
1000 mg/kg	5	Mean S.D.	153.4 8.1	55.4 17.9	35.6 10.1	15.22 1.80	0.484 0.024	144.6 1.1	4.720 0.681	106.6 1.7	9.76 0.39	7.98 1.19					

\* : Significantly different from the 0 mg/kg group at  $p \leq 0.05$  (Dunnett's test).

Table 27 Biochemical findings of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%)			AST IU/L	ALT IU/L	ALP IU/L	$\gamma$ -GTP IU/L	T-Bil mg/dL					
					Albumin												
					$\alpha_1$	$\alpha_2$	$\beta$										
0 mg/kg	5	Mean S.D.	5.88 0.63	3.010 0.404	1.048 0.075	51.10 1.85	18.72 0.97	7.52 1.30	18.16 1.65	4.50 0.35	75.6 7.7	29.0 6.4	235.4 89.7	0.70 0.14	0.048 0.011		
100 mg/kg	5	Mean S.D.	5.80 0.42	2.914 0.251	1.014 0.053	50.26 1.25	19.64 1.81	8.24 0.61	17.96 0.58	3.90 0.46	74.8 14.2	25.6 4.0	175.6 43.8	0.78 0.19	0.046 0.005		
300 mg/kg	5	Mean S.D.	5.78 0.36	2.942 0.230	1.042 0.098	50.96 2.50	18.88 1.70	7.68 0.58	17.86 0.60	4.62 1.15	82.2 27.1	26.0 3.2	206.6 69.7	0.82 0.13	0.040 0.000		
1000 mg/kg	5	Mean S.D.	5.94 0.26	3.074 0.288	1.074 0.122	51.68 3.02	18.80 2.78	7.34 0.50	17.20 0.75	4.98 1.27	107.6 37.2	29.4 5.3	248.0 108.8	0.76 0.18	0.040 0.007		

(to be continued)

Table 27 Biochemical findings of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207) (continued)

Group	Number of animals	Glucose mg/dL	T-Cho mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
0 mg/kg	5 S.D.	144.0 10.8	55.6 11.1	35.0 14.8	21.32 2.31	0.584 0.033	142.2 1.1	4.302 0.145	105.0 0.7	10.82 0.22	9.18 0.83
100 mg/kg	5 S.D.	136.6 7.1	57.2 14.5	38.6 13.5	21.00 2.01	0.592 0.024	142.6 1.1	4.378 0.191	103.6 0.9	11.14 0.23	9.28 0.82
300 mg/kg	5 S.D.	138.8 13.6	59.4 7.3	38.6 5.4	25.54* 2.00	0.624 0.028	142.6 0.5	4.202 0.138	103.6 2.1	11.00 0.35	9.82 1.28
1000 mg/kg	5 S.D.	138.6 11.5	70.2 2.8	59.6* 13.6	22.10 2.85	0.646** 0.022	142.8 1.3	4.434 0.172	104.0 3.1	10.88 0.20	8.76 0.72

\* : Significantly different from the 0 mg/kg group at  $p \leq 0.05$  (Dunnett's test).

\*\* : Significantly different from the 0 mg/kg group at  $p \leq 0.01$  (Dunnett's test).

Table 28 Biochemical findings of female rats in 14-day recovery test following 42-day repeated oral dose with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%)			AST IU/L	ALT IU/L	ALP IU/L	$\gamma$ -GTP IU/L	T-Bil mg/dL					
					Globulin												
					$\alpha_1$	$\alpha_2$	$\beta$										
0 mg/kg	5	Mean S.D.	6.36 0.19	3.552 0.069	1.268 0.079	55.86 1.51	18.28 1.98	6.04 0.78	13.64 0.97	6.18 0.58	69.4 25.9	25.4 12.0	127.0 12.0	0.42 13.2	0.092 0.019		
1000 mg/kg	5	Mean S.D.	6.24 0.33	3.374 0.292	1.180 0.150	53.98 3.09	17.66 2.32	6.38 0.54	15.12* 6.86	6.86 0.83	69.2 1.01	34.8 13.8	145.8 15.7	0.70 29.9	0.094 0.66	0.027	
Group	Number of animals	Glucose mg/dL	T-Chol mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL						
0 mg/kg	5	Mean S.D.	129.4 15.0	81.6 4.8	14.4 4.8	17.44 1.67	0.602 0.041	144.4 1.3	4.178 0.163	108.8 1.9	10.14 0.32	6.36 0.52					
1000 mg/kg	5	Mean S.D.	139.4 22.2	61.8 15.3	19.6 10.2	14.56* 2.07	0.634 0.128	143.8 1.3	4.220 0.375	107.2 0.8	10.00 0.32	6.72 0.92					

\* : Significantly different from the 0 mg/kg group at  $p \leq 0.05$  (Dunnett's test).

Table 29      Serum hormone levels of male rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals		T3 ng/mL	T4 ng/mL	TSH ng/mL
0 mg/kg	5	Mean S.D.	1.1026 0.2192	54.4980 10.6385	6.790 2.637
100 mg/kg	5	Mean S.D.	1.2278 0.0700	73.8348 * 11.9758	7.144 1.598
300 mg/kg	5	Mean S.D.	1.0874 0.2092	61.4330 8.1784	7.680 2.119
1000 mg/kg	5	Mean S.D.	1.1374 0.2814	49.5626 11.9631	5.876 1.763

\*. Significantly different from the 0 mg/kg group at p≤0.05 (Dunnett's test).

Table 30 Serum hormone levels of male rats in 14-day recovery test following 42-day repeated oral dose with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals		T3 ng/mL	T4 ng/mL	TSH ng/mL
0 mg/kg	5	Mean S.D.	1.1130 0.1342	77.3444 9.9352	7.728 3.542
1000 mg/kg	5	Mean S.D.	1.1680 0.1448	87.1546 9.3698	5.848 1.367

Table 31      Serum hormone levels of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
 (SR09207)

Group	Number of animals		T3 ng/mL	T4 ng/mL	TSH ng/mL
0 mg/kg	5	Mean S.D.	1.2506 0.0975	47.9508 10.9313	4.156 4.079
100 mg/kg	5	Mean S.D.	1.3824 0.2386	56.2316 14.7929	4.408 2.569
300 mg/kg	5	Mean S.D.	1.2348 0.1654	49.1774 13.0805	6.900 2.931
1000 mg/kg	5	Mean S.D.	1.0676 0.0986	49.4392 8.5969	4.688 1.645

Table 32 Serum hormone levels of female rats in 14-day recovery test following 42-day repeated oral dose with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals		T3 ng/mL	T4 ng/mL	TSH ng/mL
0 mg/kg	5	Mean S.D.	1.1912 0.1235	45.1766 16.7616	5.390 1.380
1000 mg/kg	5	Mean S.D.	1.2434 0.2755	48.7404 8.0069	4.882 1.466

Table 33 Gross findings of male rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

	Group	End of administration			End of recovery		
		0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg	0 mg/kg	1000 mg/kg
Number of animals examined		7	12	7	5	5	5
No abnormal findings		7	9	11	7	5	5
Organ : Findings							
Testis : Small size	0	2	1	0	0	0	0
Epididymis : Small size	0	2	1	0	0	0	0
Epididymis : Yellowish white mass, cauda	0	1	0	0	0	0	0
Harderian gland : Hemorrhage	0	0	1	0	0	0	0

Values are number of animals with findings.

Table 34 Gross findings of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

	Group	Day 6 of lactation			1000 mg/kg
		0 mg/kg	100 mg/kg	300 mg/kg	
Number of animals examined	12	12	12	12	12
Number of not copulated animals	1	0	0	0	0
No abnormal findings	0	#	#	#	#
Number of pregnant animals	11	12	12	12	11
No abnormal findings	11	12	11	11	11
Organ : Findings					
Lung : Yellowish green patch, anterior lobe	0	0	0	1	1
Glandular stomach : Black patch, mucosa	0	0	1	0	0
Number of non-pregnant animals	0	0	0	1	1
No abnormal findings	#	#	#	0	0

Values are number of animals with findings.

# : Not applicable.

Table 35 Gross findings of female rats in 14-day recovery test following 42-day repeated oral dose with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

	Group	End of recovery	
		0 mg/kg	1000 mg/kg
Number of animals examined		5	5
No abnormal findings		5	4
Organ : Findings			
Stomach : White mass, limiting ridge		0	1

Values are number of animals with findings.

Table 36 Absolute and relative organ weights of male rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR99207)

Group	Number of animals	Body weight		Liver		Kidney		Spleen		Heart		Brain		Pituitary gland		Thymus	
		g	%	g	%	g	%	g	%	g	%	g	%	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %
0 mg/kg	5	Mean	434.6	11.302	2.584	2.850	0.656	0.772	0.174	1.272	0.292	2.186	0.504	12.84	2.966	282.6	65.440
		S.D.	35.1	2.094	0.260	0.154	0.047	0.141	0.019	0.111	0.022	0.062	0.032	0.49	0.240	81.7	20.231
100 mg/kg	5	Mean	475.2	12.938	2.724	3.166	0.668	0.780	0.166	1.472*	0.312	2.204	0.464	12.10	2.550	283.0	59.646
		S.D.	16.9	0.397	0.072	0.267	0.052	0.044	0.009	0.084	0.023	0.071	0.021	1.36	0.297	46.2	10.433
300 mg/kg	5	Mean	454.0	12.336	2.708	3.236	0.714	0.772	0.168	1.382	0.304	2.152	0.476	11.32	2.506	283.8	62.488
		S.D.	35.3	1.942	0.253	0.291	0.034	0.163	0.026	0.169	0.023	0.100	0.038	1.76	0.463	47.8	8.605
1000 mg/kg	5	Mean	465.8	12.650	2.718	3.290*	0.706	0.722	0.154	1.380	0.296	2.094	0.452	11.50	2.464	284.8	61.032
		S.D.	22.5	1.175	0.246	0.292	0.064	0.114	0.023	0.065	0.021	0.086	0.034	1.47	0.207	62.1	11.868

Group	Number of animals	Thyroid		Adrenal		
		mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	
0 mg/kg	5	Mean	16.02	3.690	51.4	11.864
		S.D.	2.12	0.470	4.6	1.192
100 mg/kg	5	Mean	22.36*	4.726	59.4	12.488
		S.D.	3.91	0.958	7.0	1.262
300 mg/kg	5	Mean	19.14	4.230	59.4	13.098
		S.D.	2.68	0.594	6.1	1.111
1000 mg/kg	5	Mean	20.42	4.388	57.2	12.228
		S.D.	5.21	1.087	11.2	1.972

(to be continued)

\* : Significantly different from the 0 mg/kg group at p≤0.05 (Dunnett's test).

Table 36    Absolute and relative organ weights of male rats dosed orally with Isotriidecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
 (SR09207) (continued)

Group	Number of animals	Body weight g	Testis		Epididymis	
			%	g	%	g
0 mg/kg	7	Mean S.D.	460.3 54.9	3.240 0.354	0.714 0.119	1.230 0.153
100 mg/kg	12	Mean S.D.	471.5 22.8	3.216 0.440	0.684 0.105	1.333 0.216
300 mg/kg	12	Mean S.D.	467.9 29.2	3.233 0.513	0.695 0.125	1.310 0.173
1000 mg/kg	7	Mean S.D.	484.7 37.5	3.300 0.283	0.683 0.054	1.294 0.081

Table 37

Absolute and relative organ weights of male rats in 14-day recovery test following 42-day repeated oral dose with Isotriidecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals	Body weight		Liver		Kidney		Spleen		Heart		Brain		Pituitary gland		Thymus	
		g	%	g	%	g	%	g	%	g	%	g	%	mg	$10^{-3}\%$	mg	$10^{-3}\%$
0 mg/kg	5	Mean	474.6	11.918	2.502	3.074	0.648	0.814	0.172	1.554	0.328	2.232	0.470	11.66	2.468	244.8	51.664
		S.D.	32.3	1.755	0.234	0.175	0.024	0.088	0.022	0.147	0.036	0.072	0.027	1.29	0.356	60.5	11.915
1000 mg/kg	5	Mean	487.6	12.518	2.568	3.344*	0.684	0.810	0.166	1.522	0.310	2.202	0.452	12.72	2.614	306.6	62.694
		S.D.	15.1	0.214	0.053	0.193	0.029	0.113	0.023	0.150	0.024	0.095	0.015	1.08	0.303	58.6	10.629

Group	Number of animals	Thyroid		Adrenal		Testis		Epididymis		
		mg	$10^{-3}\%$	mg	$10^{-3}\%$	g	%	g	%	
0 mg/kg	5	Mean	21.22	4.476	62.0	13.122	3.242	0.684	1.438	0.302
		S.D.	2.92	0.588	4.7	1.424	0.334	0.084	0.132	0.033
1000 mg/kg	5	Mean	21.66	4.424	59.4	12.184	3.266	0.670	1.314	0.268
		S.D.	4.76	0.856	9.0	1.806	0.181	0.047	0.107	0.026

\* : Significantly different from the 0 mg/kg group at  $p \leq 0.05$  (Dunnett's test).

Table 38 Absolute and relative organ weights of female rats dosed orally with Isotriacyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals	Body weight		Liver		Kidney		Spleen		Heart		Brain		Pituitary gland	
		g	%	g	%	g	%	g	%	g	%	g	%	mg	10 <sup>-3</sup> %
0 mg/kg	5	Mean	310.8	10.796	3.476	2.166	0.696	0.784	0.256	0.984	0.320	2.060	0.664	17.50	5.644
		S.D.	22.6	1.039	0.235	0.139	0.047	0.102	0.035	0.056	0.040	0.100	0.030	1.43	0.481
100 mg/kg	5	Mean	317.8	11.278	3.550	2.152	0.680	0.892	0.282	1.116*	0.352	2.074	0.656	17.04	5.368
		S.D.	13.8	0.767	0.232	0.091	0.034	0.086	0.035	0.072	0.033	0.091	0.052	0.82	0.346
300 mg/kg	5	Mean	305.4	11.116	3.648	2.216	0.726	0.764	0.250	1.016	0.332	2.046	0.670	16.54	5.428
		S.D.	14.5	0.516	0.222	0.194	0.055	0.075	0.027	0.082	0.028	0.057	0.026	1.53	0.564
1000 mg/kg	5	Mean	311.6	12.396*	3.986**	2.170	0.696	0.770	0.248	1.012	0.326	2.060	0.662	16.22	5.214
		S.D.	18.3	0.582	0.222	0.087	0.048	0.122	0.049	0.051	0.026	0.060	0.036	1.63	0.567

Group	Number of animals	Thymus		Thyroid		Adrenal		Ovary		
		mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	
0 mg/kg	5	Mean	300.0	95.976	14.70	4.732	72.8	23.400	116.0	37.256
		S.D.	90.3	25.237	2.35	0.672	9.6	2.214	22.4	6.012
100 mg/kg	5	Mean	307.8	96.656	19.18	6.050	74.6	23.570	142.6	44.890
		S.D.	50.8	13.877	1.49	0.616	7.5	3.141	18.6	5.794
300 mg/kg	5	Mean	227.6	74.726	17.84	5.830	88.8*	29.110*	118.2	38.884
		S.D.	53.5	17.769	3.13	0.873	10.1	3.398	15.9	6.584
1000 mg/kg	5	Mean	340.2	108.496	19.02	6.084	73.2	23.668	111.2	35.778
		S.D.	168.9	50.304	3.85	1.073	8.2	4.040	6.6	2.777

\* : Significantly different from the 0 mg/kg group at p≤0.05 (Dunnett's test),  
 \*\* : Significantly different from the 0 mg/kg group at p≤0.01 (Dunnett's test).

Table 39      Absolute and relative organ weights of female rats in 14-day recovery test following 42-day repeated oral dose with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of animals	Body weight g	Liver		Kidney		Spleen		Heart		Brain		Pituitary gland		
			%	g	%	g	%	g	%	g	%	g	%	mg	10 <sup>-3</sup> %
0 mg/kg	5	Mean	292.4	7.610	2.604	1.924	0.658	0.628	0.212	0.990	0.338	2.046	0.704	17.04	5.828
		S.D.	24.3	0.695	0.123	0.170	0.019	0.152	0.037	0.072	0.024	0.135	0.080	2.57	0.731
1000 mg/kg	5	Mean	302.2	7.908	2.622	1.936	0.646	0.550	0.182	0.992	0.328	2.064	0.688	15.24	5.074
		S.D.	22.8	0.680	0.160	0.153	0.076	0.068	0.026	0.097	0.023	0.059	0.033	2.71	1.040

Group	Number of animals	Thymus		Thyroid		Adrenal		Ovary		
		mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	
0 mg/kg	5	Mean	318.0	109.032	15.84	5.500	80.2	27.742	113.8	38.792
		S.D.	53.1	18.270	3.18	1.521	10.4	5.657	28.6	9.079
1000 mg/kg	5	Mean	257.0	84.562*	15.32	5.060	69.0	22.970	113.8	37.640
		S.D.	54.2	12.542	2.73	0.747	7.6	3.449	20.9	6.181

\* : Significantly different from the 0 mg/kg group at p≤0.05 (Dunnett's test).

Table 40 Histopathological findings of male rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

	Group	Control	100 mg/kg	300 mg/kg	1000 mg/kg	
Number of animals examined		7	12	12	7	
Organ: Findings	Grade					
Liver: Microgranuloma	+	2 (5)	-	-	-	2 (5)
Heart: Myocardial degeneration, focal	+	0 (5)	-	-	-	1 (5)
Kidney: Eosinophilic body, proximal tubular epithelium	+	2	1	8	-	7 *
Cast, hyaline	+	0	0	1	1	1
Regeneration, tubular epithelium	+	0	1	1	0	0
Testis: Atrophy, seminiferous tubule	+	0 (5)	1 (2)	0 (1)	0 (5)	
	++	0 (5)	0 (2)	1 (1)	1 (1)	0 (5)
	+++	0 (5)	1 (2)	0 (1)	0 (5)	
Epididymis: Decrease, spermatozoa	+	0 (5)	0 (2)	1 (1)	1 (1)	0 (5)
	++	0 (5)	1 (3)	0 (1)	0 (1)	0 (5)
	+++	0 (5)	1 (3)	1 (1)	1 (1)	0 (5)
Edema, interstitium	+	0 (5)	1 (2)	0 (1)	0 (1)	0 (5)
Cell debris, lumen	+	0 (5)	2 (3)	1 (1)	1 (1)	0 (5)
Granuloma, spermatoc	++	0 (5)	1 (3)	0 (1)	0 (1)	0 (5)
Prostate: Cellular infiltration, inflammatory cell	+	2 (5)	-	-	-	1 (5)
Pituitary gland: Cyst, pars distalis	+	0 (5)	-	-	-	1 (5)
Cyst, pars intermedia	+	1 (5)	-	-	-	0 (5)
Eyeball: Atrophy, retina	+	1 (5)	-	-	-	1 (5)
Harderian gland: Cellular infiltration, inflammatory cell	+	0 (5)	-	1 (1)	0 (5)	

Values are the number of animals with findings.

Values in parentheses are the number of animals examined.

-: Blank value.

Grade; +: slight change, ++: moderate change, +++: severe change.

\* : Significantly different from the 0 mg/kg group at  $p \leq 0.05$  (Fisher's exact test).

Table 41 Histopathological findings of male rats in 14-day recovery test following 42-day repeated oral dose with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

	Group	Control	1000 mg/kg
Number of animals examined	Grade	5	5
Organ: Findings			
Lung: Aggregation, macrophage, alveolar Mineralization, artery	+	1	0
Liver: Microgranuloma	+	1	2
Kidney: Eosinophilic body, proximal tubular epithelium Regeneration, tubular epithelium	+	3	2
Cast, hyaline	+	1	0
Prostate: Cellular infiltration, inflammatory cell	+	0	1
Pituitary gland: Cyst, pars intermedia	+	2	3
		1	0

Values are the number of animals with findings.

Grade; +: slight change.

Table 42-1 Histopathological findings of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

	Group	Control	100 mg/kg	300 mg/kg	1000 mg/kg
Number of pregnant animals examined	Grade	11	12	12	11
Organ: Findings					
Lung: Aggregation, macrophage, alveolar	+	0 (5)	-	-	1 (5)
Inflammation, granulomatous with foreign body	+	0 (5)	-	-	1 (5)
Glandular stomach: Erosion	+	0 (5)	-	1 (1)	0 (5)
Liver: Microgranuloma	+	2 (5)	-	-	4 (5)
Kidney: Regeneration, tubular epithelium	+	1	0	0	2
Cast, hyaline	+	0	0	0	1
Cellular infiltration, inflammatory cell, renal pelvic mucosa	+	0	1	0	1
Mineralization, cortex	+	0	1	0	0

Values are the number of animals with findings.

Values in parentheses are the number of animals examined.

-: Blank value.

Grade; +: slight change.

Table 42-2 Histopathological findings of female rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

	Group	Control	100 mg/kg	300 mg/kg	1000 mg/kg
Number of not copulated animals examined		1	0	0	0
No abnormal findings		1	-	-	-
Number of non-pregnant animals examined		0	0	0	1
No abnormal findings		-	-	-	1

Values are the number of animals with findings.

-: Blank value.

Table 43 Histopathological findings of female rats in 14-day recovery test following 42-day repeated oral dose with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

	Group	Control	1000 mg/kg
Number of animals examined		5	5
Organ: Findings	Grade		
Lung: Metaplasia, osseous, alveoli	+	1	0
Stomach, limiting ridge: Cyst, squamous cell	+	0	1
Liver: Microgranuloma	+	2	2

Values are the number of animals with findings.

Grade; +: slight change.

Table 44 Reproduction performance in parental rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Estrous cycle		Copulation index		Fertility index		Gestation index		Gestation length (days)		Nursing index
	Length (days)		Incidence (%)		Male		Female		Incidence (%)		Incidence (%)
	Mean	S.D.	Incidence	(%)	Incidence	(%)	Incidence	(%)	Mean	S.D.	Incidence (%)
0 mg/kg	4.03	0.09	1/12	(8.3)	11/12	(91.7)	11/12	(100.0)	11/11	(100.0)	22.3 (100.0)
100 mg/kg	4.03	0.09	0/12	(0.0)	12/12	(100.0)	12/12	(100.0)	12/12	(100.0)	22.5 (100.0)
300 mg/kg	4.00	0.00	0/12	(0.0)	12/12	(100.0)	12/12	(100.0)	12/12	(100.0)	22.3 (100.0)
1000 mg/kg	4.20	0.48	1/12	(8.3)	12/12	(100.0)	12/12	(91.7)	11/11	(100.0)	22.1 (100.0)

Abnormal estrous cycle = (number of female with abnormal estrous cycle / number of females examined) x 100.

Copulation index = (number of copulated animals / number of animals mated) x 100.

Fertility index = (number of pregnant females / number of copulated females) x 100.

Gestation index = (number of females with live pups / number of pregnant females) x 100.

Nursing index = (number of females nursing live pups on lactation day 4 / number of females with live pups delivery) x 100.

Table 45

Estrous cycle of female rats in 14-day recovery test following 42-day repeated oral dose with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Estrous cycle						Recovery day							
	Administration day			Estrous cycle			Length (days)	Mean	S.D.	Incidence (%)	Length (days)	Mean	S.D.	Incidence (%)
	Length (days)	S.D.	Incidence (%)	Abnormal estrous cycle	(%)	Abnormal estrous cycle								
0 mg/kg	4.00	0.00	0/5	(0.0)			4.00	4.00	0.00	0/5	(0.0)			
1000 mg/kg	4.00	0.00	1/5	(20.0)			[4]	[4]	0.00	1/5	(20.0)			

Abnormal estrous cycle = (number of female with abnormal estrous cycle / number of females examined) x 100.

Values in brackets are animal number.

Table 46 Pregnancy and litter data of rats dosed orally with Isotridecyl stearate in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR09207)

Group	Number of Dams	Number of corpora lutea	Number of implantation sites	Delivery index (%)	Number of total pups born	Lactation day 0		Lactation day 4		Number of total live pups	Number of sex ratio	Viability index (%)
						total dead pups	Number of pups	total live pups	Sex ratio			
0 mg/kg	11	Mean	16.1	15.5	96.777	94.968	14.7	0.0	14.7	0.478	100.000	14.7
0 mg/kg		S.D.	2.3	2.1	4.066	5.656	1.8	0.0	1.8	0.184	0.000	1.8
100 mg/kg	12	Mean	16.7	16.0	96.016	94.330	15.1	0.1	15.0	0.516	99.306	14.8
100 mg/kg		S.D.	1.6	1.7	5.227	6.484	1.8	0.3	2.0	0.115	0.113	2.405
300 mg/kg	12	Mean	16.3	15.8	97.635	95.257	15.1	0.3	14.8	0.534	98.347	14.6
300 mg/kg		S.D.	1.7	1.3	3.638	3.929	1.4	0.5	1.5	0.085	0.094	3.016
1000 mg/kg	11	Mean	16.3	15.9	97.752	97.977	15.5	0.2	15.4	0.473	0.470	98.926
1000 mg/kg		S.D.	1.6	1.7	4.196	3.751	1.3	0.4	1.1	0.174	0.177	2.394

Implantation index = (Number of implantation sites / number of corpora lutea) x 100.

Delivery index = (Number of pups born / number of implantation sites) x 100.

Sex ratio on Lactation day 0 = (number of male pups born / number of pups born) and (number of live male pups / number of live pups).

Sex ratio on Lactation day 4 = number of live male pups / number of live pups.

Live birth index = (Number of live pups on lactation day 0 / number of pups born) x 100.

Viability index = (Number of live pups on lactation day 4 / number of live pups on lactation day 0) x 100.

Table 47 General appearance of pups in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test of Isotridecyl stearate in rats (SR09207)

Group	Findings	Male				Female					
		Lactation day		Lactation day		0	1	0	1	2	3
		0	1	2	3	4		0	1	2	3
0 mg/kg	Number of pups examined	75	75	75	75	75	75	87	87	87	87
	No abnormal findings	75	75	75	75	75	87	87	87	87	87
100 mg/kg	Number of pups examined	94	94	94	94	94	87	86	85	85	85
	No abnormal findings	94	94	94	94	94	86	85	85	85	84
	Death	0	0	0	0	0	1	1	0	0	1
	Lost	0	0	0	0	0	0	1	0	0	0
300 mg/kg	Number of pups examined	96	95	95	94	94	85	83	83	82	81
	No abnormal findings	95	95	94	94	94	83	82	81	81	81
	Milk-band negative	0	0	0	0	0	0	1	1	0	0
	Death	1	0	1	0	0	2	0	1	1	0
	Lost	0	0	1	0	0	0	0	0	1	0
1000 mg/kg	Number of pups examined	79	78	78	78	78	92	91	89	89	89
	No abnormal findings	78	78	78	78	78	91	89	89	89	89
	Death	1	0	0	0	0	1	2	0	0	0
	Lost	0	0	0	0	0	0	1	0	0	0

Values are number of animals with findings.

Table 48 Body weight of pups in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test of Isotridecyl stearate in rats (SR09207)

Group	Number of litters	Body weight (g)							
		Male				Female			
		Lactation day		Lactation day		Lactation day		Lactation day	
		0	1	4	0	1	4	1	4
0 mg/kg	11	Mean	6.59	7.28	10.57	6.36	7.02	10.06	
		S.D.	0.50	0.57	0.88	0.44	0.56	0.71	
100 mg/kg	12	Mean	6.95	7.68	11.06	6.53	7.26	10.52	
		S.D.	0.47	0.58	0.95	0.57	0.75	1.38	
300 mg/kg	12	Mean	6.63	7.24	10.43	6.25	6.85	10.33	
		S.D.	0.37	0.48	0.88	0.43	0.53	1.31	
1000 mg/kg	11	Mean	6.36	7.02	10.20	6.01	6.64	9.72	
		S.D.	0.39	0.59	0.95	0.28	0.37	0.60	

Table 49 Gross findings of pups in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test of Isotridecyl stearate in rats (SR09207)

Item		Group	Male			Female		
			0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg	0 mg/kg	100 mg/kg
<b>Findings of dead pups during days 0-4 of lactation</b>								
Number of pups examined		0	0	2	1	0	3	4
No abnormal findings		0	0	1	0	0	2	2
Intrapерitoneum : Autolysis		0	0	0	1	0	1	0
Lost		0	0	1	0	0	1	1
<b>Findings of pups euthanized on day 4 of lactation</b>								
Number of pups examined		75	94	94	78	87	84	81
No abnormal findings		74	94	94	77	87	84	81
Liver : Yellowish green patch, multifocal, middle lobe,		1	0	0	0	0	0	0
medial left lobe and lateral left lobe								
Liver : Yellowish white patch, middle lobe		0	0	0	1	0	0	0

Values are number of pups with findings.

## Symbols and process for statistical analysis in INDIVIDUAL DATA

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M/C: Values for Bartlett's test for homogeneity of variance,

$p \leq 0.05$  -----> Kruskal-Wallis test

$p > 0.05$  -----> One way analysis of variance

F : Values for one way analysis of variance,

$p \leq 0.10$  -----> Dunnett's test

H : Values for Kruskal-Wallis test,

$p \leq 0.10$  -----> Mann-Whitney's U-test

† : Significant difference,  $p \leq 0.10$

\* : Significant difference,  $p \leq 0.05$

\*\* : Significant difference,  $p \leq 0.01$

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t' : Values for Dunnett's test

U : Values for Mann-Whitney's U-test

\* : Significant difference,  $p \leq 0.05$

\*\* : Significant difference,  $p \leq 0.01$

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$\chi^2$  : Values for chi-square test

p : Values for Fisher's exact probability test

\* : Significant difference,  $p \leq 0.05$

\*\* : Significant difference,  $p \leq 0.01$

INDIVIDUAL DATA 1-1-1  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 0 mg/kg

Animal No.	Administration day																					Autopsy day								
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21									
101	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
102	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
103	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
104	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
105	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
106	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
107	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
108	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
109	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
110	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
111	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
112	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
Animal No.	Administration day																					Autopsy day								
	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42									
101	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
102	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
103	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
104	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
105	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
106	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
107	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
108	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
109	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
110	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
111	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
112	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	

N : No abnormal findings.  
 # : Not applicable.

(to be continued)

INDIVIDUAL DATA 1-1-1 (continued)  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 0 mg/kg

Animal No.	Recovery day												Autopsy		
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	day
101	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#
102	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#
103	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
104	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#
105	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#
106	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#
107	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
108	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#
109	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
110	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
111	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
112	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#

N : No abnormal findings.  
 # : Not applicable.

INDIVIDUAL DATA 1-1-2  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 100 mg/kg

Animal No.	Administration day																					Autopsy day	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21		
201	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
202	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
203	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
204	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
205	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
206	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
207	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
208	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
209	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
210	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
211	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
212	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
Animal No.	Administration day																						
	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	Autopsy day	
201	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
202	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
203	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
204	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
205	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
206	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
207	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
208	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
209	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
210	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
211	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
212	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	

N : No abnormal findings.

INDIVIDUAL DATA 1-1-3  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 300 mg/kg

Animal No.	Administration day																					Autopsy day	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21		
301	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
302	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
303	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
304	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
305	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
306	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
307	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
308	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
309	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
310	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
311	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
312	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
Animal No.	Administration day																						
	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	Autopsy day	
301	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
302	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
303	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
304	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
305	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
306	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
307	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
308	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
309	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
310	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
311	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
312	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	

N : No abnormal findings.

INDIVIDUAL DATA 1-1-4  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 1000 mg/kg

Animal No.	Administration day																					Autopsy day								
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21									
401	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
402	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
403	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
404	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
405	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
406	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
407	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
408	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
409	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
410	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
411	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
412	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
Animal No.	Administration day																					Autopsy day								
	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42									
401	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
402	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
403	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
404	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
405	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
406	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
407	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
408	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
409	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
410	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
411	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
412	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	

N : No abnormal findings.  
 # : Not applicable.

(to be continued)

INDIVIDUAL DATA 1-1-4 (continued)  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 1000 mg/kg

Animal No.	Recovery day													Autopsy		
	1	2	3	4	5	6	7	8	9	10	11	12	13	14		
401	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
402	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#
403	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
404	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#
405	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#
406	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#
407	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
408	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#
409	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
410	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
411	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#
412	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#

N : No abnormal findings.

# : Not applicable.

INDIVIDUAL DATA 1-2-1  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance ANIMAL : Rat, Crf:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Pre-mating day													Matting day													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
151	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
152	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
153	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
154	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
155	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
156	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
157	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
158	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
159	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
160	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
161	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
162	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

N : No abnormal findings.  
 # : Not applicable (Copulated).

(to be continued)

## INDIVIDUAL DATA 1-2-1 (continued)

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Administration day												Autopsy day	
	29	30	31	32	33	34	35	36	37	38	39	40	41	42
151	#	#	#	#	#	#	#	#	#	#	#	#	#	#
152	#	#	#	#	#	#	#	#	#	#	#	#	#	#
153	#	#	#	#	#	#	#	#	#	#	#	#	#	#
154	#	#	#	#	#	#	#	#	#	#	#	#	#	#
155	#	#	#	#	#	#	#	#	#	#	#	#	#	#
156	#	#	#	#	#	#	#	#	#	#	#	#	#	#
157	#	#	#	#	#	#	#	#	#	#	#	#	#	#
158	#	#	#	#	#	#	#	#	#	#	#	#	#	#
159	#	#	#	#	#	#	#	#	#	#	#	#	#	#
160	#	#	#	#	#	#	#	#	#	#	#	#	#	#
161	#	#	#	#	#	#	#	#	#	#	#	#	#	#
162	N	N	N	N	N	N	N	N	N	N	N	N	N	N

Animal No.	Administration day												Autopsy day	
	43	44	45	46	47	48	49	50	51					
151	#	#	#	#	#	#	#	#	#	#	#	#	#	#
152	#	#	#	#	#	#	#	#	#	#	#	#	#	#
153	#	#	#	#	#	#	#	#	#	#	#	#	#	#
154	#	#	#	#	#	#	#	#	#	#	#	#	#	#
155	#	#	#	#	#	#	#	#	#	#	#	#	#	#
156	#	#	#	#	#	#	#	#	#	#	#	#	#	#
157	#	#	#	#	#	#	#	#	#	#	#	#	#	#
158	#	#	#	#	#	#	#	#	#	#	#	#	#	#
159	#	#	#	#	#	#	#	#	#	#	#	#	#	#
160	#	#	#	#	#	#	#	#	#	#	#	#	#	#
161	#	#	#	#	#	#	#	#	#	#	#	#	#	#
162	N	N	N	N	N	N	N	N	N	N	N	N	N	N

N : No abnormal findings.

# : Not applicable (Copulated).

INDIVIDUAL DATA 1-2-2  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 100 mg/kg

Animal No.	Pre-mating day													Matting day																					
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	
251	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
252	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
253	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
254	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
255	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
256	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
257	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
258	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
259	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
260	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
261	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
262	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

N : No abnormal findings.

# : Not applicable (Copulated).

INDIVIDUAL DATA 1-2-3  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance ANIMAL : Rat, Crf:CD(SD) SEX : Female GROUP : 300 mg/kg

Animal No.	Pre-mating day													Matting day												
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24		
351	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
352	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
353	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
354	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
355	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
356	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
357	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
358	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
359	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
360	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
361	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
362	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	

N : No abnormal findings.  
 #: Not applicable (Copulated).

INDIVIDUAL DATA 1-2-4  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 1000 mg/kg

Animal No.	Pre-mating day													Matting day												
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
451	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
452	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
453	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
454	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
455	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
456	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
457	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
458	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
459	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
460	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
461	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
462	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

N : No abnormal findings.  
 # : Not applicable (Copulated).

INDIVIDUAL DATA 1-3-1  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance ANIMAL : Rat, Crf:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Gestation day																				
	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
151	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
152	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
153	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
154	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
155	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
156	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
157	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
158	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
159	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
160	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
161	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

Animal No.      Gestation day  
 151            21      22

151	N	#
152	N	#
153	N	#
154	N	#
155	N	#
156	N	#
157	N	#
158	N	#
159	N	#
160	N	#
161	N	#

N : No abnormal findings.  
 # : Not applicable (Delivered).

INDIVIDUAL DATA 1-3-2  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 100 mg/kg

Animal No.	Gestation day																				
	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
251	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
252	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
253	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
254	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
255	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
256	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
257	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
258	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
259	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
260	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
261	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
262	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

Animal No.      Gestation day  
 21                22

251	N	N
252	N	N
253	N	#
254	N	#
255	N	N
256	N	#
257	N	#
258	N	N
259	N	N
260	N	N
261	N	#
262	N	#

N : No abnormal findings.

# : Not applicable (Delivered).

INDIVIDUAL DATA 1-3-3  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance ANIMAL : Rat, Crf:CD(SD) SEX : Female GROUP : 300 mg/kg

Animal No.	Gestation day																				
	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
351	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
352	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
353	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
354	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
355	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	B	B	B
356	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
357	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
358	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
359	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
360	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
361	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
362	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

Animal No.	Gestation day																				
	21	22																			
351	N	#																			
352	N	#																			
353	N																				
354	N	#																			
355	B	#																			
356	N	#																			
357	N	#																			
358	N	#																			
359	N	#																			
360	N	#																			
361	N	N																			
362	N	N																			

N : No abnormal findings.  
 A : Swelling of left forelimb.  
 B : Loss of 3rd digit in left forelimb.  
 # : Not applicable (Delivered).

INDIVIDUAL DATA 1-3-4  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 1000 mg/kg

Animal No.	Gestation day																			
	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
451	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
452	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
453	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
454 <sup>a</sup>	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
455	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
456	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
457	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
458	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
459	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
460	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
461	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
462	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

Animal No.	Gestation day				
	21	22	23	24	25
451	N	#	#	#	#
452	N	#	#	#	#
453	N	#	#	#	#
454 <sup>a</sup>	N	N	N	N	N
455	N	#	#	#	#
456	N	#	#	#	#
457	N	#	#	#	#
458	N	#	#	#	#
459	N	N	#	#	#
460	N	#	#	#	#
461	N	#	#	#	#
462	N	#	#	#	#

N : No abnormal findings.

a : Non-pregnant.

# : Not applicable (Delivered).

Day 26 of gestation : Autopsy day.

INDIVIDUAL DATA 1-4-1  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Lactation day					Autopsy day
	0	1	2	3	4	
151	N	N	N	N	N	N
152	N	N	N	N	N	N
153	N	N	N	N	N	N
154	N	N	N	N	N	N
155	N	N	N	N	N	N
156	N	N	N	N	N	N
157	N	N	N	N	N	N
158	N	N	N	N	N	N
159	N	N	N	N	N	N
160	N	N	N	N	N	N
161	N	N	N	N	N	N

N : No abnormal findings.

## INDIVIDUAL DATA 1-4-2

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 100 mg/kg

Animal No.	Lactation day					Autopsy day
	0	1	2	3	4	
251	N	N	N	N	N	N
252	N	N	N	N	N	N
253	N	N	N	N	N	N
254	N	N	N	N	N	N
255	N	N	N	N	N	N
256	N	N	N	N	N	N
257	N	N	N	N	N	N
258	N	N	N	N	N	N
259	N	N	N	N	N	N
260	N	N	N	N	N	N
261	N	N	N	N	N	N
262	N	N	N	N	N	N

N : No abnormal findings.

INDIVIDUAL DATA 1-4-3  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 300 mg/kg

Animal No.	Lactation day					Autopsy day
	0	1	2	3	4	
351	N	N	N	N	N	N
352	N	N	N	N	N	N
353	N	N	N	N	N	N
354	N	N	N	N	N	N
355	B	B	B	B	B	B
356	N	N	N	N	N	N
357	N	N	N	N	N	N
358	N	N	N	N	N	N
359	N	N	N	N	N	N
360	N	N	N	N	N	N
361	N	N	N	N	N	N
362	N	N	N	N	N	N

N : No abnormal findings.

B : Loss of 3rd digit in left forelimb.

INDIVIDUAL DATA 1-4-4  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 1000 mg/kg

Animal No.	Lactation day					Autopsy day
	0	1	2	3	4	
451	N	N	N	N	N	N
452	N	N	N	N	N	N
453	N	N	N	N	N	N
455	N	N	N	N	N	N
456	N	N	N	N	N	N
457	N	N	N	N	N	N
458	N	N	N	N	N	N
459	N	N	N	N	N	N
460	N	N	N	N	N	N
461	N	N	N	N	N	N
462	N	N	N	N	N	N

N : No abnormal findings.

INDIVIDUAL DATA 1-5-1  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Administration day																				
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
163	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
164	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
165	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
166	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
167	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Animal No.	Administration day																				
	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42
163	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
164	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
165	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
166	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
167	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Animal No.	Recovery day																				
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Autopsy day						
163	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
164	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
165	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
166	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
167	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

N : No abnormal findings.

INDIVIDUAL DATA 1-5-2  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 1000 mg/kg

Animal No.	Administration day																				
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
463	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
464	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
465	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
466	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
467	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Animal No.	Administration day																				
	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42
463	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
464	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
465	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
466	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
467	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Animal No.	Recovery day																				
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Autopsy day						
463	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
464	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
465	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
466	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
467	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

N : No abnormal findings.

Definitions for detailed clinical observations

Item	Category No.	
In the cage:		
Body position/Posture	1; Normal (sitting, etc.)	2; Sleeping
Respiratory pattern	1; Normal	2; Slightly abnormal, rapid or slow
Tremor / Convulsion	1; Not present	2; Irregularly, only the legs
Stereotype	0; Not present	1; Sometimes
Rolling	0; Not present	1; Sometimes
Repetitive circling	0; Not present	1; Sometimes
Bizarre behavior		
Bitting/Selfmutilation	1; Not present	2; Present
On the hand: while removing the animal from its cage		
Handling : Removal from cage	1; Very easy	2; Easy
Treating : Reactivity to handling	1; Very easy	2; Easy
Muscle tone	1; Low	2; Normal
Piloerection	1; Not present	2; Slightly present, around head and back
Fur	1; Normal	2; Slightly stained
Eyes	1; Not present, normal	2; Slight ptosis, half closed
Mucous membranes	-1; Dark purplish appearance, cyanosis	0; Normal
		1; Red appearance

(to be continued)

(Continued 1)

Item	Category No.	
Skin	0; Pale appearance, cyanosis	1; Normal 2; Red appearance
Pupil size	1; Normal	2; Slightly mydriatic 3; Mydriatic
Lacrimation	1; Not present	2; Wet around the eye 3; Wet
Salivation	1; Not present	2; Wet around the mouth 3; Wet
Secretions/Excretions		
In the open-field: when placed the animal in an open-field	0; Not present	1; Present
Gait	0; Not moved	1; Normal 2; Difficult to walk 3; Unable to walk, paralytic
Co-ordination of movement		
Reactivity to environmental stimuli	0; staggering (ataxic)	1; Normal
Searching	0; Not present	1; present (to noise, etc.)
Urination	0; Not present	1; present (sniffing, standing, etc.)
Defecation	0; Not present	1; Present
Stereotype		
Excessive grooming	0; Not present	1; Sometimes 2; Frequently
Unusual head movement	0; Not present	1; Sometimes 2; Frequently
Bizarre behavior		
Walking backward	1; Not present	2; Present
Vocalization	1; Not present, sometimes	2; Present, frequently
Aggression	1; Not present	2; Present

(to be continued)

(Continued 2)

Item	Category No.	
On the desk: stimulus reactivity		
Visual reactivity: approach response		
1; Jumping	2; Turning away	3; No reaction
Touch reactivity: touch response	2; Turning away	4; Approach
1; Hypersensitive		5; Attack
Auditory reactivity: response to Galton's whistle		
0; No reaction	1; Normal, moving the auricle	2; Sensitive, moving the body
Pain reactivity: tail pinch response		
0; No reaction	1; Dull, vocalizing	2; Normal, vocalizing and turning back
Proprioceptive reactivity: returning from enforced posture		
0; No returning	1; Returning	
Righting reflex: landing performance from 30 cm above		
1; Normal, landing by foot	2; Abnormal, landing by body	
Others		
Grip strength: measuring by CPU gage®		
		expressed by mean values (g) from 3 trials; forelimb and hindlimb
Locomotor activity measurements : measuring by SUPERMEX and CompACT AMS		
		expressed by total counts for 60 minutes at 10 minutes' intervals

## INDIVIDUAL DATA 2-1-1

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Pre-administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
101	1	1	1	0	0
102	1	1	1	0	0
103	1	1	1	0	0
104	1	1	1	0	0
105	1	1	1	0	0
106	1	1	1	0	0
107	1	1	1	0	0
108	1	1	1	0	0
109	1	1	1	0	0
110	1	1	1	0	0
111	1	1	1	0	0
112	1	1	1	0	0
N	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-1-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : Pre-administration

Animal No.	Body position/ Posture pattern	In the cage				Bizarre behavior	
		Stereotype		Repetitive circling	Rolling		
		Tremor/ Convulsion	Repetitive circling				
201	1	1	1	0	0	1	
202	1	1	1	0	0	1	
203	1	1	1	0	0	1	
204	1	1	1	0	0	1	
205	1	1	1	0	0	1	
206	1	1	1	0	0	1	
207	1	1	1	0	0	1	
208	1	1	1	0	0	1	
209	1	1	1	0	0	1	
210	1	1	1	0	0	1	
211	1	1	1	0	0	1	
212	1	1	1	0	0	1	
N	12	12	12	12	12	12	

## INDIVIDUAL DATA 2-1-3

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : Pre-administration

Animal No.	Body position/ Posture pattern	In the cage				
		Stereotype	Tremor/ Convulsion	Rolling	Repetitive circling	Biting/ Selfmutilation
301	1	1	1	0	0	1
302	1	1	1	0	0	1
303	1	1	1	0	0	1
304	1	1	1	0	0	1
305	1	1	1	0	0	1
306	1	1	1	0	0	1
307	1	1	1	0	0	1
308	1	1	1	0	0	1
309	1	1	1	0	0	1
310	1	1	1	0	0	1
311	1	1	1	0	0	1
312	1	1	1	0	0	1
N	12	12	12	12	12	12

## INDIVIDUAL DATA 2-1-4

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Pre-administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling Repetitive circling	Biting/ Selfmutilation	
401	1	1	1	0	0
402	1	1	1	0	0
403	1	1	1	0	0
404	1	1	1	0	0
405	1	1	1	0	0
406	1	1	1	0	0
407	1	1	1	0	0
408	1	1	1	0	0
409	1	1	1	0	0
410	1	1	1	0	0
411	1	1	1	0	0
412	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-1-5

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Pre-administration

Animal No.	On the hand											
	Ease of Removal		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/Excretions
101	1	1	2	1	1	0	1	1	1	1	1	0
102	1	1	2	1	1	1	0	1	1	1	1	0
103	1	1	2	1	1	1	0	1	1	1	1	0
104	1	1	2	1	1	1	0	1	1	1	1	0
105	1	1	2	1	1	1	0	1	1	1	1	0
106	1	1	2	1	1	1	0	1	1	1	1	0
107	1	1	2	1	1	1	0	1	1	1	1	0
108	1	1	2	1	1	1	0	1	1	1	1	0
109	1	1	2	1	1	1	0	1	1	1	1	0
110	1	1	2	1	1	1	0	1	1	1	1	0
111	1	1	2	1	1	1	0	1	1	1	1	0
112	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-1-6

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : Pre-administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/Excretions
201	1	1	2	1	1	0	1	1	1	1	1	1	1	0
202	1	1	2	1	1	1	0	0	1	1	1	1	1	0
203	1	1	2	1	1	1	0	0	1	1	1	1	1	0
204	1	1	2	1	1	1	0	1	1	1	1	1	1	0
205	1	1	2	1	1	1	0	0	1	1	1	1	1	0
206	1	1	2	1	1	1	0	0	1	1	1	1	1	0
207	1	1	2	1	1	1	0	0	1	1	1	1	1	0
208	1	1	2	1	1	1	0	1	1	1	1	1	1	0
209	1	1	2	1	1	1	0	0	1	1	1	1	1	0
210	1	1	2	1	1	1	0	0	1	1	1	1	1	0
211	1	1	2	1	1	1	0	1	1	1	1	1	1	0
212	1	1	2	1	1	1	0	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-1-7

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : Pre-administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/Excretions
301	1	1	2	1	1	0	1	1	1	1	1	1	1	0
302	1	1	2	1	1	0	1	1	1	1	1	1	1	0
303	1	1	2	1	1	0	1	1	1	1	1	1	1	0
304	1	1	2	1	1	0	1	1	1	1	1	1	1	0
305	1	1	2	1	1	0	1	1	1	1	1	1	1	0
306	1	1	2	1	1	0	1	1	1	1	1	1	1	0
307	1	1	2	1	1	0	1	1	1	1	1	1	1	0
308	1	1	2	1	1	0	1	1	1	1	1	1	1	0
309	1	1	2	1	1	0	1	1	1	1	1	1	1	0
310	1	1	2	1	1	0	1	1	1	1	1	1	1	0
311	1	1	2	1	1	0	1	1	1	1	1	1	1	0
312	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-1-8

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD)

SEX : Male GROUP : 1000 mg/kg

PERIOD : Pre-administration

Animal No.	On the hand											
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur					
								Eyes	Mucous membranes	Skin	Pupil size	Lacrimation
401	1	1	2	1	1	0	1	1	1	1	1	0
402	1	1	2	1	1	0	1	1	1	1	1	0
403	1	1	2	1	1	0	1	1	1	1	1	0
404	1	1	2	1	1	0	1	1	1	1	1	0
405	1	1	2	1	1	0	1	1	1	1	1	0
406	1	1	2	1	1	0	1	1	1	1	1	0
407	1	1	2	1	1	0	1	1	1	1	1	0
408	1	1	2	1	1	0	1	1	1	1	1	0
409	1	1	2	1	1	0	1	1	1	1	1	0
410	1	1	2	1	1	0	1	1	1	1	1	0
411	1	1	2	1	1	0	1	1	1	1	1	0
412	1	1	2	1	1	0	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-1-9

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Pre-administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Searching Urination Defecation			Stereotype	Walking backward	Vocalization
			Excessive grooming	Unusual head movement	Unusual head movement	Defecation	Walking backward	Vocalization	Aggression		
101	1	1	1	0	0	0	0	0	1	1	1
102	1	1	1	1	0	0	0	0	1	1	1
103	1	1	1	0	0	0	0	0	1	1	1
104	1	1	1	1	1	0	0	0	1	1	1
105	1	1	1	0	0	0	0	0	1	1	1
106	1	1	1	0	0	0	0	0	1	1	1
107	1	1	1	0	0	0	0	0	1	1	1
108	1	1	1	0	0	0	0	0	1	1	1
109	1	1	1	0	0	0	0	0	1	1	1
110	1	1	1	0	0	0	0	0	1	1	1
111	1	1	1	0	0	0	0	0	1	1	1
112	1	1	1	0	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	1.8014	1.4729	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-1-10

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : Pre-administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Searching Urination Defecation			Stereotype	Walking backward	Vocalization
			Excessive grooming	Unusual head movement	Unusual head movement	Walking backward	Vocalization	Aggression			
201	1	1	1	1	1	0	0	0	1	1	1
202	1	1	1	1	0	0	0	0	1	1	1
203	1	1	1	1	0	0	0	0	1	1	1
204	1	1	1	1	1	0	0	0	1	1	1
205	1	1	1	0	1	0	0	0	1	1	1
206	1	1	1	1	0	0	0	0	1	1	1
207	1	1	1	0	0	0	0	0	1	1	1
208	1	1	1	0	0	0	0	0	1	1	1
209	1	1	1	0	0	0	0	0	1	1	1
210	1	1	1	0	0	0	0	0	1	1	1
211	1	1	1	0	0	0	0	0	1	1	1
212	1	1	1	0	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-1-11

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : Pre-administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Searching Urination Defecation			Stereotype	Walking backward	Vocalization
			Excessive grooming	Unusual head movement	Unusual head movement	Walking backward	Vocalization	Aggression			
301	1	1	1	0	0	0	0	0	1	1	1
302	1	1	1	0	0	0	0	0	1	1	1
303	1	1	1	0	0	0	0	0	1	1	1
304	1	1	1	0	1	0	0	0	1	1	1
305	1	1	1	0	0	0	0	0	1	1	1
306	1	1	1	0	1	0	0	0	1	1	1
307	1	1	1	0	0	0	0	0	1	1	1
308	1	1	1	0	0	0	0	0	1	1	1
309	1	1	1	1	0	0	0	0	1	1	1
310	1	1	1	1	0	0	0	0	1	1	1
311	1	1	1	1	0	0	0	0	1	1	1
312	1	1	1	0	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-1-12

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Pre-administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Searching			Urination	Defecation	Stereotype
			Excessive grooming	Unusual head movement	Aggression						
401	1	1	1	0	1	0	1	0	0	0	1
402	1	1	1	1	1	1	1	0	0	0	1
403	1	1	1	1	0	0	0	0	0	0	1
404	1	1	1	1	0	0	0	0	0	0	1
405	1	1	1	0	0	0	0	0	0	0	1
406	1	1	1	0	0	0	0	0	0	0	1
407	1	1	1	0	0	0	0	0	0	0	1
408	1	1	1	0	1	0	0	0	0	0	1
409	1	1	1	0	0	0	0	0	0	0	1
410	1	1	1	0	0	0	0	0	0	0	1
411	1	1	1	0	0	0	0	0	0	0	1
412	1	1	1	0	0	0	0	0	0	0	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-2-1

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 7 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
101	1	1	1	0	0
102	1	1	1	0	0
103	1	1	1	0	0
104	1	1	1	0	0
105	1	1	1	0	0
106	1	1	1	0	0
107	1	1	1	0	0
108	1	1	1	0	0
109	1	1	1	0	0
110	1	1	1	0	0
111	1	1	1	0	0
112	1	1	1	0	0
N	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-2-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : Day 7 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling Repetitive circling	Biting/ Selfmutilation	
201	1	1	1	0	0
202	1	1	1	0	0
203	1	1	1	0	0
204	1	1	1	0	0
205	1	1	1	0	0
206	1	1	1	0	0
207	1	1	1	0	0
208	1	1	1	0	0
209	1	1	1	0	0
210	1	1	1	0	0
211	1	1	1	0	0
212	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-2-3

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : Day 7 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
301	1	1	1	0	0
302	1	1	1	0	0
303	1	1	1	0	0
304	1	1	1	0	0
305	1	1	1	0	0
306	1	1	1	0	0
307	1	1	1	0	0
308	1	1	1	0	0
309	1	1	1	0	0
310	1	1	1	0	0
311	1	1	1	0	0
312	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-2-4

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Day 7 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
401	1	1	1	0	0
402	1	1	1	0	0
403	1	1	1	0	0
404	1	1	1	0	0
405	1	1	1	0	0
406	1	1	1	0	0
407	1	1	1	0	0
408	1	1	1	0	0
409	1	1	1	0	0
410	1	1	1	0	0
411	1	1	1	0	0
412	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-2-5

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 7 of administration

Animal No.	On the hand												
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation
101	1	1	2	1	1	0	1	1	1	1	1	1	0
102	1	1	2	1	1	0	1	1	1	1	1	1	0
103	1	1	2	1	1	0	1	1	1	1	1	1	0
104	1	1	2	1	1	0	1	1	1	1	1	1	0
105	1	1	2	1	1	0	1	1	1	1	1	1	0
106	1	1	2	1	1	0	1	1	1	1	1	1	0
107	1	1	2	1	1	0	1	1	1	1	1	1	0
108	1	1	2	1	1	0	1	1	1	1	1	1	0
109	1	1	2	1	1	0	1	1	1	1	1	1	0
110	1	1	2	1	1	0	1	1	1	1	1	1	0
111	1	1	2	1	1	0	1	1	1	1	1	1	0
112	1	1	2	1	1	0	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-2-6

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : Day 7 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
201	1	1	2	1	1	1	0	1	1	1	1	1	1	0
202	1	1	2	1	1	1	0	0	1	1	1	1	1	0
203	1	1	2	1	1	1	0	0	1	1	1	1	1	0
204	1	1	2	1	1	1	0	1	1	1	1	1	1	0
205	1	1	2	1	1	1	0	0	1	1	1	1	1	0
206	1	1	2	1	1	1	0	0	1	1	1	1	1	0
207	1	1	2	1	1	1	0	1	1	1	1	1	1	0
208	1	1	2	1	1	1	0	1	1	1	1	1	1	0
209	1	1	2	1	1	1	0	0	1	1	1	1	1	0
210	1	1	2	1	1	1	0	0	1	1	1	1	1	0
211	1	1	2	1	1	1	0	1	1	1	1	1	1	0
212	1	1	2	1	1	1	0	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-2-7

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : Day 7 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
301	1	1	2	1	1	0	1	1	1	1	1	1	1	0
302	1	1	2	1	1	0	1	1	1	1	1	1	1	0
303	1	1	2	1	1	0	1	1	1	1	1	1	1	0
304	1	1	2	1	1	0	1	1	1	1	1	1	1	0
305	1	1	2	1	1	0	1	1	1	1	1	1	1	0
306	1	1	2	1	1	0	1	1	1	1	1	1	1	0
307	1	1	2	1	1	0	1	1	1	1	1	1	1	0
308	1	1	2	1	1	0	1	1	1	1	1	1	1	0
309	1	1	2	1	1	0	1	1	1	1	1	1	1	0
310	1	1	2	1	1	0	1	1	1	1	1	1	1	0
311	1	1	2	1	1	0	1	1	1	1	1	1	1	0
312	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-2-8

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Day 7 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
401	1	1	2	1	1	0	1	1	1	1	1	1	1	0
402	1	1	2	1	1	0	1	1	1	1	1	1	1	0
403	1	1	2	1	1	0	1	1	1	1	1	1	1	0
404	1	1	2	1	1	0	1	1	1	1	1	1	1	0
405	1	1	2	1	1	0	1	1	1	1	1	1	1	0
406	1	1	2	1	1	0	1	1	1	1	1	1	1	0
407	1	1	2	1	1	0	1	1	1	1	1	1	1	0
408	1	1	2	1	1	0	1	1	1	1	1	1	1	0
409	1	1	2	1	1	0	1	1	1	1	1	1	1	0
410	1	1	2	1	1	0	1	1	1	1	1	1	1	0
411	1	1	2	1	1	0	1	1	1	1	1	1	1	0
412	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-2-9

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 7 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
101	1	1	1	0	1	0	0	0	1	1	1
102	1	1	1	1	0	0	0	0	1	1	1
103	1	1	1	1	0	0	0	0	1	1	1
104	1	1	1	1	1	0	0	0	1	1	1
105	1	1	1	1	0	0	0	0	1	1	1
106	1	1	1	1	0	0	0	0	1	1	1
107	1	1	1	1	0	0	0	0	1	1	1
108	1	1	1	1	0	1	0	0	1	1	1
109	1	1	1	1	0	0	0	0	1	1	1
110	1	1	1	1	0	0	0	0	1	1	1
111	1	1	1	1	0	0	0	0	1	1	1
112	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	4.1535	2.3500	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-2-10

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : Day 7 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
201	1	1	1	1	0	0	0	0	1	1	1
202	1	1	1	1	0	0	0	0	1	1	1
203	1	1	1	1	0	0	0	0	1	1	1
204	1	1	1	1	1	0	0	0	1	1	1
205	1	1	1	1	0	0	0	0	1	1	1
206	1	1	1	1	0	0	0	0	1	1	1
207	1	1	1	1	0	0	0	0	1	1	1
208	1	1	1	1	0	0	0	0	1	1	1
209	1	1	1	0	0	0	0	0	1	1	1
210	1	1	1	1	0	0	0	0	1	1	1
211	1	1	1	1	0	0	0	0	1	1	1
212	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-2-11

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : Day 7 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
301	1	1	1	0	1	0	0	0	1	1	1
302	1	1	1	1	0	0	0	0	1	1	1
303	1	1	1	1	0	0	0	0	1	1	1
304	1	1	1	1	0	0	0	0	1	1	1
305	1	1	1	1	0	0	0	0	1	1	1
306	1	1	1	1	0	0	0	0	1	1	1
307	1	1	1	1	0	0	0	0	1	1	1
308	1	1	1	1	0	0	0	0	1	1	1
309	1	1	1	0	0	0	0	0	1	1	1
310	1	1	1	1	0	0	0	0	1	1	1
311	1	1	1	1	0	0	0	0	1	1	1
312	1	1	1	0	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-2-12

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Day 7 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
401	1	1	1	1	1	0	0	1	1	1	1
402	1	1	1	1	1	0	0	0	1	1	1
403	1	1	1	1	1	1	0	0	1	1	1
404	1	1	1	1	0	1	0	0	1	1	1
405	1	1	1	0	0	0	0	0	1	1	1
406	1	1	1	0	0	0	0	0	1	1	1
407	1	1	1	0	0	0	0	0	1	1	1
408	1	1	1	0	0	0	0	0	1	1	1
409	1	1	1	0	0	0	0	0	1	1	1
410	1	1	1	0	0	0	0	0	1	1	1
411	1	1	1	0	0	0	0	0	1	1	1
412	1	1	1	0	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-3-1

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 14 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
101	1	1	1	0	0
102	1	1	1	0	0
103	1	1	1	0	0
104	1	1	1	0	0
105	1	1	1	0	0
106	1	1	1	0	0
107	1	1	1	0	0
108	1	1	1	0	0
109	1	1	1	0	0
110	1	1	1	0	0
111	1	1	1	0	0
112	1	1	1	0	0
N	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-3-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : Day 14 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
201	1	1	1	0	0
202	1	1	1	0	0
203	1	1	1	0	0
204	1	1	1	0	0
205	1	1	1	0	0
206	1	1	1	0	0
207	1	1	1	0	0
208	1	1	1	0	0
209	1	1	1	0	0
210	1	1	1	0	0
211	1	1	1	0	0
212	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-3-3

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : Day 14 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
301	1	1	1	0	0
302	1	1	1	0	0
303	1	1	1	0	0
304	1	1	1	0	0
305	1	1	1	0	0
306	1	1	1	0	0
307	1	1	1	0	0
308	1	1	1	0	0
309	1	1	1	0	0
310	1	1	1	0	0
311	1	1	1	0	0
312	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-3-4

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Day 14 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
401	1	1	1	0	0
402	1	1	1	0	0
403	1	1	1	0	0
404	1	1	1	0	0
405	1	1	1	0	0
406	1	1	1	0	0
407	1	1	1	0	0
408	1	1	1	0	0
409	1	1	1	0	0
410	1	1	1	0	0
411	1	1	1	0	0
412	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-3-5

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 14 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
101	1	1	2	1	1	0	1	1	1	1	1	1	1	0
102	1	1	2	1	1	0	1	1	1	1	1	1	1	0
103	1	1	2	1	1	0	1	1	1	1	1	1	1	0
104	1	1	2	1	1	0	1	1	1	1	1	1	1	0
105	1	1	2	1	1	0	1	1	1	1	1	1	1	0
106	1	1	2	1	1	0	1	1	1	1	1	1	1	0
107	1	1	2	1	1	0	1	1	1	1	1	1	1	0
108	1	1	2	1	1	0	1	1	1	1	1	1	1	0
109	1	1	2	1	1	0	1	1	1	1	1	1	1	0
110	1	1	2	1	1	0	1	1	1	1	1	1	1	0
111	1	1	2	1	1	0	1	1	1	1	1	1	1	0
112	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-3-6

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : Day 14 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
201	1	1	2	1	1	1	0	1	1	1	1	1	1	0
202	1	1	2	1	1	1	0	0	1	1	1	1	1	0
203	1	1	2	1	1	1	0	0	1	1	1	1	1	0
204	1	1	2	1	1	1	0	1	1	1	1	1	1	0
205	1	1	2	1	1	1	0	0	1	1	1	1	1	0
206	1	1	2	1	1	1	0	0	1	1	1	1	1	0
207	1	1	2	1	1	1	0	0	1	1	1	1	1	0
208	1	1	2	1	1	1	0	1	1	1	1	1	1	0
209	1	1	2	1	1	1	0	0	1	1	1	1	1	0
210	1	1	2	1	1	1	0	0	1	1	1	1	1	0
211	1	1	2	1	1	1	0	1	1	1	1	1	1	0
212	1	1	2	1	1	1	0	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-3-7

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : Day 14 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
301	1	1	2	1	1	0	1	1	1	1	1	1	1	0
302	1	1	2	1	1	0	1	1	1	1	1	1	1	0
303	1	1	2	1	1	0	1	1	1	1	1	1	1	0
304	1	1	2	1	1	0	1	1	1	1	1	1	1	0
305	1	1	2	1	1	0	1	1	1	1	1	1	1	0
306	1	1	2	1	1	0	1	1	1	1	1	1	1	0
307	1	1	2	1	1	0	1	1	1	1	1	1	1	0
308	1	1	2	1	1	0	1	1	1	1	1	1	1	0
309	1	1	2	1	1	0	1	1	1	1	1	1	1	0
310	1	1	2	1	1	0	1	1	1	1	1	1	1	0
311	1	1	2	1	1	0	1	1	1	1	1	1	1	0
312	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-3-8

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Day 14 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
401	1	1	2	1	1	0	1	1	1	1	1	1	1	0
402	1	1	2	1	1	0	1	1	1	1	1	1	1	0
403	1	1	2	1	1	0	1	1	1	1	1	1	1	0
404	1	1	2	1	1	0	1	1	1	1	1	1	1	0
405	1	1	2	1	1	0	1	1	1	1	1	1	1	0
406	1	1	2	1	1	0	1	1	1	1	1	1	1	0
407	1	1	2	1	1	0	1	1	1	1	1	1	1	0
408	1	1	2	1	1	0	1	1	1	1	1	1	1	0
409	1	1	2	1	1	0	1	1	1	1	1	1	1	0
410	1	1	2	1	1	0	1	1	1	1	1	1	1	0
411	1	1	2	1	1	0	1	1	1	1	1	1	1	0
412	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-3-9

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 14 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Searching Urination Defecation			Stereotype	Walking backward	Vocalization
			Excessive grooming	Unusual head movement							
101	1	1	1	0	1	0	0	0	1	1	1
102	1	1	1	1	0	0	0	0	1	1	1
103	1	1	1	0	0	0	0	0	1	1	1
104	1	1	1	0	0	0	0	0	1	1	1
105	1	1	1	0	0	0	0	0	1	1	1
106	1	1	1	0	0	0	0	0	1	1	1
107	1	1	1	0	0	0	0	0	1	1	1
108	1	1	1	0	0	0	0	0	1	1	1
109	1	1	1	0	0	0	0	0	1	1	1
110	1	1	1	0	0	0	0	0	1	1	1
111	1	1	1	0	0	0	0	0	1	1	1
112	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	6.1304	2.0435	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-3-10

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : Day 14 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
201	1	1	1	0	0	0	0	0	1	1	1
202	1	1	1	0	0	0	0	0	1	1	1
203	1	1	1	0	0	0	0	0	1	1	1
204	1	1	1	0	0	0	0	0	1	1	1
205	1	1	1	0	0	0	0	0	1	1	1
206	1	1	1	0	0	0	0	0	1	1	1
207	1	1	1	0	0	0	0	0	1	1	1
208	1	1	1	0	0	0	0	0	1	1	1
209	1	1	1	0	0	0	0	0	1	1	1
210	1	1	1	0	0	0	0	0	1	1	1
211	1	1	1	0	0	0	0	0	1	1	1
212	1	1	1	0	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-3-11

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : Day 14 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
301	1	1	1	0	1	0	0	0	1	1	1
302	1	1	1	1	0	0	0	0	1	1	1
303	1	1	1	1	0	0	0	0	1	1	1
304	1	1	1	1	0	0	0	0	1	1	1
305	1	1	1	1	0	0	0	0	1	1	1
306	1	1	1	1	0	0	0	0	1	1	1
307	1	1	1	1	0	0	0	0	1	1	1
308	1	1	1	1	0	0	0	0	1	1	1
309	1	1	1	0	0	0	0	0	1	1	1
310	1	1	1	1	0	0	0	0	1	1	1
311	1	1	1	1	0	0	0	0	1	1	1
312	1	1	1	0	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-3-12

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Day 14 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Searching Urination Defecation			Stereotype	Walking backward	Vocalization
			Excessive grooming	Unusual head movement	Unusual head movement	Walking backward	Vocalization	Aggression			
401	1	1	1	0	0	0	0	0	1	1	1
402	1	1	1	0	0	0	0	0	1	1	1
403	1	1	1	0	0	0	0	0	1	1	1
404	1	1	1	0	0	0	0	0	1	1	1
405	1	1	1	0	0	0	0	0	1	1	1
406	1	1	1	0	0	0	0	0	1	1	1
407	1	1	1	0	0	0	0	0	1	1	1
408	1	1	1	0	0	0	0	0	1	1	1
409	1	1	1	0	0	0	0	0	1	1	1
410	1	1	1	0	0	0	0	0	1	1	1
411	1	1	1	0	0	0	0	0	1	1	1
412	1	1	1	0	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-4-1

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 21 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
101	1	1	1	0	0
102	1	1	1	0	0
103	1	1	1	0	0
104	1	1	1	0	0
105	1	1	1	0	0
106	1	1	1	0	0
107	1	1	1	0	0
108	1	1	1	0	0
109	1	1	1	0	0
110	1	1	1	0	0
111	1	1	1	0	0
112	1	1	1	0	0
N	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-4-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : Day 21 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
201	1	1	1	0	0
202	1	1	1	0	0
203	1	1	1	0	0
204	1	1	1	0	0
205	1	1	1	0	0
206	1	1	1	0	0
207	1	1	1	0	0
208	1	1	1	0	0
209	1	1	1	0	0
210	1	1	1	0	0
211	1	1	1	0	0
212	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-4-3

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : Day 21 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
301	1	1	1	0	0
302	1	1	1	0	0
303	1	1	1	0	0
304	1	1	1	0	0
305	1	1	1	0	0
306	1	1	1	0	0
307	1	1	1	0	0
308	1	1	1	0	0
309	1	1	1	0	0
310	1	1	1	0	0
311	1	1	1	0	0
312	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-4-4

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Day 21 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
401	1	1	1	0	0
402	1	1	1	0	0
403	1	1	1	0	0
404	1	1	1	0	0
405	1	1	1	0	0
406	1	1	1	0	0
407	1	1	1	0	0
408	1	1	1	0	0
409	1	1	1	0	0
410	1	1	1	0	0
411	1	1	1	0	0
412	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-4-5

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 21 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
101	1	1	2	1	1	0	1	1	1	1	1	1	1	0
102	1	1	2	1	1	0	1	1	1	1	1	1	1	0
103	1	1	2	1	1	0	1	1	1	1	1	1	1	0
104	1	1	2	1	1	0	1	1	1	1	1	1	1	0
105	1	1	2	1	1	0	1	1	1	1	1	1	1	0
106	1	1	2	1	1	0	1	1	1	1	1	1	1	0
107	1	1	2	1	1	0	1	1	1	1	1	1	1	0
108	1	1	2	1	1	0	1	1	1	1	1	1	1	0
109	1	1	2	1	1	0	1	1	1	1	1	1	1	0
110	1	1	2	1	1	0	1	1	1	1	1	1	1	0
111	1	1	2	1	1	0	1	1	1	1	1	1	1	0
112	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 24-6

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : Day 21 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
201	1	1	2	1	1	1	0	1	1	1	1	1	1	0
202	1	1	2	1	1	1	0	0	1	1	1	1	1	0
203	1	1	2	1	1	1	0	0	1	1	1	1	1	0
204	1	1	2	1	1	1	0	1	1	1	1	1	1	0
205	1	1	2	1	1	1	0	0	1	1	1	1	1	0
206	1	1	2	1	1	1	0	0	1	1	1	1	1	0
207	1	1	2	1	1	1	0	1	1	1	1	1	1	0
208	1	1	2	1	1	1	0	1	1	1	1	1	1	0
209	1	1	2	1	1	1	0	1	1	1	1	1	1	0
210	1	1	2	1	1	1	0	1	1	1	1	1	1	0
211	1	1	2	1	1	1	0	1	1	1	1	1	1	0
212	1	1	2	1	1	1	0	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-4-7

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : Day 21 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
301	1	1	2	1	1	0	1	1	1	1	1	1	1	0
302	1	1	2	1	1	0	1	1	1	1	1	1	1	0
303	1	1	2	1	1	0	1	1	1	1	1	1	1	0
304	1	1	2	1	1	0	1	1	1	1	1	1	1	0
305	1	1	2	1	1	0	1	1	1	1	1	1	1	0
306	1	1	2	1	1	0	1	1	1	1	1	1	1	0
307	1	1	2	1	1	0	1	1	1	1	1	1	1	0
308	1	1	2	1	1	0	1	1	1	1	1	1	1	0
309	1	1	2	1	1	0	1	1	1	1	1	1	1	0
310	1	1	2	1	1	0	1	1	1	1	1	1	1	0
311	1	1	2	1	1	0	1	1	1	1	1	1	1	0
312	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-4-8

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Day 21 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
401	1	1	2	1	1	0	1	1	1	1	1	1	1	0
402	1	1	2	1	1	0	1	1	1	1	1	1	1	0
403	1	1	2	1	1	0	1	1	1	1	1	1	1	0
404	1	1	2	1	1	0	1	1	1	1	1	1	1	0
405	1	1	2	1	1	0	1	1	1	1	1	1	1	0
406	1	1	2	1	1	0	1	1	1	1	1	1	1	0
407	1	1	2	1	1	0	1	1	1	1	1	1	1	0
408	1	1	2	1	1	0	1	1	1	1	1	1	1	0
409	1	1	2	1	1	0	1	1	1	1	1	1	1	0
410	1	1	2	1	1	0	1	1	1	1	1	1	1	0
411	1	1	2	1	1	0	1	1	1	1	1	1	1	0
412	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-4-9

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 21 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
101	1	1	1	1	1	0	0	1	1	1	1
102	1	1	1	1	0	0	0	1	1	1	1
103	1	1	1	1	1	0	0	1	1	1	1
104	1	1	1	1	0	1	0	1	1	1	1
105	1	1	1	1	0	0	0	0	1	1	1
106	1	1	1	1	0	0	0	0	1	1	1
107	1	1	1	1	0	0	0	0	1	1	1
108	1	1	1	1	0	0	0	0	1	1	1
109	1	1	1	1	0	0	0	0	1	1	1
110	1	1	1	1	0	0	0	0	1	1	1
111	1	1	1	1	0	0	0	0	1	1	1
112	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	2.1364	2.1364	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 24-10

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : Day 21 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
201	1	1	1	0	0	0	0	1	1	1	1
202	1	1	1	0	0	0	0	1	1	1	1
203	1	1	1	0	0	0	0	1	1	1	1
204	1	1	1	1	1	0	0	1	1	1	1
205	1	1	1	0	0	0	0	1	1	1	1
206	1	1	1	0	0	0	0	1	1	1	1
207	1	1	1	0	0	0	0	1	1	1	1
208	1	1	1	0	0	0	0	1	1	1	1
209	1	1	1	0	0	0	0	1	1	1	1
210	1	1	1	0	0	0	0	1	1	1	1
211	1	1	1	0	0	0	0	1	1	1	1
212	1	1	1	0	0	0	0	1	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 24-11

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : Day 21 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
301	1	1	1	0	0	0	0	1	1	1	1
302	1	1	1	0	0	0	0	1	1	1	1
303	1	1	1	0	0	0	0	1	1	1	1
304	1	1	1	0	0	0	0	1	1	1	1
305	1	1	1	0	0	0	0	1	1	1	1
306	1	1	1	0	0	0	0	1	1	1	1
307	1	1	1	0	0	0	0	1	1	1	1
308	1	1	1	0	0	0	0	1	1	1	1
309	1	1	1	0	0	0	0	1	1	1	1
310	1	1	1	0	0	0	0	1	1	1	1
311	1	1	1	0	0	0	0	1	1	1	1
312	1	1	1	0	0	0	0	1	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 24-12

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Day 21 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
401	1	1	1	1	0	0	0	1	1	1	1
402	1	1	1	1	0	0	0	1	1	1	1
403	1	1	1	1	0	0	0	1	1	1	1
404	1	1	1	1	0	1	0	1	1	1	1
405	1	1	1	1	0	0	0	1	1	1	1
406	1	1	1	1	0	0	0	1	1	1	1
407	1	1	1	1	0	0	0	1	1	1	1
408	1	1	1	1	0	0	0	1	1	1	1
409	1	1	1	1	0	0	0	1	1	1	1
410	1	1	1	1	0	0	0	1	1	1	1
411	1	1	1	1	0	0	0	1	1	1	1
412	1	1	1	1	0	0	0	1	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-5-1

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 28 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
101	1	1	1	0	0
102	1	1	1	0	0
103	1	1	1	0	0
104	1	1	1	0	0
105	1	1	1	0	0
106	1	1	1	0	0
107	1	1	1	0	0
108	1	1	1	0	0
109	1	1	1	0	0
110	1	1	1	0	0
111	1	1	1	0	0
112	1	1	1	0	0
N	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-5-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : Day 28 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
201	1	1	1	0	0
202	1	1	1	0	0
203	1	1	1	0	0
204	1	1	1	0	0
205	1	1	1	0	0
206	1	1	1	0	0
207	1	1	1	0	0
208	1	1	1	0	0
209	1	1	1	0	0
210	1	1	1	0	0
211	1	1	1	0	0
212	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-5-3

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : Day 28 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling Repetitive circling	Biting/ Selfmutilation	
301	1	1	1	0	0
302	1	1	1	0	0
303	1	1	1	0	0
304	1	1	1	0	0
305	1	1	1	0	0
306	1	1	1	0	0
307	1	1	1	0	0
308	1	1	1	0	0
309	1	1	1	0	0
310	1	1	1	0	0
311	1	1	1	0	0
312	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-5-4

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Day 28 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
401	1	1	1	0	0
402	1	1	1	0	0
403	1	1	1	0	0
404	1	1	1	0	0
405	1	1	1	0	0
406	1	1	1	0	0
407	1	1	1	0	0
408	1	1	1	0	0
409	1	1	1	0	0
410	1	1	1	0	0
411	1	1	1	0	0
412	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-5-5

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 28 of administration

Animal No.	On the hand												
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation
101	1	1	2	1	1	0	0	1	1	1	1	1	0
102	1	1	2	1	1	0	0	1	1	1	1	1	0
103	1	1	2	1	1	0	0	1	1	1	1	1	0
104	1	1	2	1	1	0	0	1	1	1	1	1	0
105	1	1	2	1	1	0	0	1	1	1	1	1	0
106	1	1	2	1	1	0	0	1	1	1	1	1	0
107	1	1	2	1	1	0	0	1	1	1	1	1	0
108	1	1	2	1	1	0	0	1	1	1	1	1	0
109	1	1	2	1	1	0	0	1	1	1	1	1	0
110	1	1	2	1	1	0	0	1	1	1	1	1	0
111	1	1	2	1	1	0	0	1	1	1	1	1	0
112	1	1	2	1	1	0	0	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-5-6

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : Day 28 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
201	1	1	2	1	1	1	0	1	1	1	1	1	1	0
202	1	1	2	1	1	1	0	0	1	1	1	1	1	0
203	1	1	2	1	1	1	0	0	1	1	1	1	1	0
204	1	1	2	1	1	1	0	1	1	1	1	1	1	0
205	1	1	2	1	1	1	0	0	1	1	1	1	1	0
206	1	1	2	1	1	1	0	0	1	1	1	1	1	0
207	1	1	2	1	1	1	0	1	1	1	1	1	1	0
208	1	1	2	1	1	1	0	1	1	1	1	1	1	0
209	1	1	2	1	1	1	0	1	1	1	1	1	1	0
210	1	1	2	1	1	1	0	1	1	1	1	1	1	0
211	1	1	2	1	1	1	0	1	1	1	1	1	1	0
212	1	1	2	1	1	1	0	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-5-7

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : Day 28 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
301	1	1	2	1	1	0	1	1	1	1	1	1	1	0
302	1	1	2	1	1	0	1	1	1	1	1	1	1	0
303	1	1	2	1	1	0	1	1	1	1	1	1	1	0
304	1	1	2	1	1	0	1	1	1	1	1	1	1	0
305	1	1	2	1	1	0	1	1	1	1	1	1	1	0
306	1	1	2	1	1	0	1	1	1	1	1	1	1	0
307	1	1	2	1	1	0	1	1	1	1	1	1	1	0
308	1	1	2	1	1	0	1	1	1	1	1	1	1	0
309	1	1	2	1	1	0	1	1	1	1	1	1	1	0
310	1	1	2	1	1	0	1	1	1	1	1	1	1	0
311	1	1	2	1	1	0	1	1	1	1	1	1	1	0
312	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-5-8

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Day 28 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
401	1	1	2	1	1	0	1	1	1	1	1	1	1	0
402	1	1	2	1	1	0	1	1	1	1	1	1	1	0
403	1	1	2	1	1	0	1	1	1	1	1	1	1	0
404	1	1	2	1	1	0	1	1	1	1	1	1	1	0
405	1	1	2	1	1	0	1	1	1	1	1	1	1	0
406	1	1	2	1	1	0	1	1	1	1	1	1	1	0
407	1	1	2	1	1	0	1	1	1	1	1	1	1	0
408	1	1	2	1	1	0	1	1	1	1	1	1	1	0
409	1	1	2	1	1	0	1	1	1	1	1	1	1	0
410	1	1	2	1	1	0	1	1	1	1	1	1	1	0
411	1	1	2	1	1	0	1	1	1	1	1	1	1	0
412	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-5-9

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 28 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Searching Urination Defecation			Stereotype	Walking backward	Vocalization
			Excessive grooming	Unusual head movement	Unusual head movement	Defecation	Walking backward	Vocalization	Aggression		
101	1	1	1	0	0	0	0	0	1	1	1
102	1	1	1	0	0	0	0	0	1	1	1
103	1	1	1	0	0	0	0	0	1	1	1
104	1	1	1	0	0	0	0	0	1	1	1
105	1	1	1	0	0	0	0	0	1	1	1
106	1	1	1	0	0	0	0	0	1	1	1
107	1	1	1	0	0	0	0	0	1	1	1
108	1	1	1	0	0	0	0	0	1	1	1
109	1	1	1	0	0	0	0	0	1	1	1
110	1	1	1	0	0	0	0	0	1	1	1
111	1	1	1	0	0	0	0	0	1	1	1
112	1	1	1	0	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	2.0435	3.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-5-10

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : Day 28 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Searching Urination Defecation			Stereotype	Walking backward	Vocalization
			Excessive grooming	Unusual head movement	Unusual head movement	Walking backward	Vocalization	Aggression			
201	1	1	1	0	0	0	0	0	1	1	1
202	1	1	1	1	0	0	0	0	1	1	1
203	1	1	1	0	0	0	0	0	1	1	1
204	1	1	1	0	1	0	0	0	1	1	1
205	1	1	1	0	0	0	0	0	1	1	1
206	1	1	1	0	0	0	0	0	1	1	1
207	1	1	1	0	0	0	0	0	1	1	1
208	1	1	1	0	0	0	0	0	1	1	1
209	1	1	1	0	0	0	0	0	1	1	1
210	1	1	1	0	0	0	0	0	1	1	1
211	1	1	1	0	0	0	0	0	1	1	1
212	1	1	1	0	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-5-11

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : Day 28 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Searching Urination Defecation			Stereotype	Walking backward	Vocalization
			Excessive grooming	Unusual head movement	Unusual head movement	Walking backward	Vocalization	Aggression			
301	1	1	1	0	0	0	0	0	1	1	1
302	1	1	1	0	0	0	0	0	1	1	1
303	1	1	1	0	0	0	0	0	1	1	1
304	1	1	1	0	0	0	0	0	1	1	1
305	1	1	1	0	0	0	0	0	1	1	1
306	1	1	1	0	0	0	0	0	1	1	1
307	1	1	1	0	0	0	0	0	1	1	1
308	1	1	1	0	0	0	0	0	1	1	1
309	1	1	1	0	0	0	0	0	1	1	1
310	1	1	1	0	0	0	0	0	1	1	1
311	1	1	1	0	0	0	0	0	1	1	1
312	1	1	1	0	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-5-12

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Day 28 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Searching Urination Defecation			Stereotype	Walking backward	Vocalization
			Excessive grooming	Unusual head movement	Unusual head movement	Walking backward	Vocalization	Aggression			
401	1	1	1	0	0	0	0	0	1	1	1
402	1	1	1	1	0	0	0	0	1	1	1
403	1	1	1	0	0	0	0	0	1	1	1
404	1	1	1	0	0	0	0	0	1	1	1
405	1	1	1	0	0	0	0	0	1	1	1
406	1	1	1	0	0	0	0	0	1	1	1
407	1	1	1	0	0	0	0	0	1	1	1
408	1	1	1	0	0	0	0	0	1	1	1
409	1	1	1	0	0	0	0	0	1	1	1
410	1	1	1	0	0	0	0	0	1	1	1
411	1	1	1	0	0	0	0	0	1	1	1
412	1	1	1	0	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-6-1

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 35 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
101	1	1	1	0	0
102	1	1	1	0	0
103	1	1	1	0	0
104	1	1	1	0	0
105	1	1	1	0	0
106	1	1	1	0	0
107	1	1	1	0	0
108	1	1	1	0	0
109	1	1	1	0	0
110	1	1	1	0	0
111	1	1	1	0	0
112	1	1	1	0	0
N	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-6-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : Day 35 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
201	1	1	1	0	0
202	1	1	1	0	0
203	1	1	1	0	0
204	1	1	1	0	0
205	1	1	1	0	0
206	1	1	1	0	0
207	1	1	1	0	0
208	1	1	1	0	0
209	1	1	1	0	0
210	1	1	1	0	0
211	1	1	1	0	0
212	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-6-3

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : Day 35 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
301	1	1	1	0	0
302	1	1	1	0	0
303	1	1	1	0	0
304	1	1	1	0	0
305	1	1	1	0	0
306	1	1	1	0	0
307	1	1	1	0	0
308	1	1	1	0	0
309	1	1	1	0	0
310	1	1	1	0	0
311	1	1	1	0	0
312	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-6-4

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Day 35 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
401	1	1	1	0	0
402	1	1	1	0	0
403	1	1	1	0	0
404	1	1	1	0	0
405	1	1	1	0	0
406	1	1	1	0	0
407	1	1	1	0	0
408	1	1	1	0	0
409	1	1	1	0	0
410	1	1	1	0	0
411	1	1	1	0	0
412	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-6-5

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 35 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
101	1	1	2	1	1	0	1	1	1	1	1	1	1	0
102	1	1	2	1	1	0	1	1	1	1	1	1	1	0
103	1	1	2	1	1	0	1	1	1	1	1	1	1	0
104	1	1	2	1	1	0	1	1	1	1	1	1	1	0
105	1	1	2	1	1	0	1	1	1	1	1	1	1	0
106	1	1	2	1	1	0	1	1	1	1	1	1	1	0
107	1	1	2	1	1	0	1	1	1	1	1	1	1	0
108	1	1	2	1	1	0	1	1	1	1	1	1	1	0
109	1	1	2	1	1	0	1	1	1	1	1	1	1	0
110	1	1	2	1	1	0	1	1	1	1	1	1	1	0
111	1	1	2	1	1	0	1	1	1	1	1	1	1	0
112	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-6-6

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : Day 35 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
201	1	1	2	1	1	0	1	1	1	1	1	1	1	0
202	1	1	2	1	1	0	1	1	1	1	1	1	1	0
203	1	1	2	1	1	0	1	1	1	1	1	1	1	0
204	1	1	2	1	1	0	1	1	1	1	1	1	1	0
205	1	1	2	1	1	0	1	1	1	1	1	1	1	0
206	1	1	2	1	1	0	1	1	1	1	1	1	1	0
207	1	1	2	1	1	0	1	1	1	1	1	1	1	0
208	1	1	2	1	1	0	1	1	1	1	1	1	1	0
209	1	1	2	1	1	0	1	1	1	1	1	1	1	0
210	1	1	2	1	1	0	1	1	1	1	1	1	1	0
211	1	1	2	1	1	0	1	1	1	1	1	1	1	0
212	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-6-7

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : Day 35 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
301	1	1	2	1	1	0	1	1	1	1	1	1	1	0
302	1	1	2	1	1	0	1	1	1	1	1	1	1	0
303	1	1	2	1	1	0	1	1	1	1	1	1	1	0
304	1	1	2	1	1	0	1	1	1	1	1	1	1	0
305	1	1	2	1	1	0	1	1	1	1	1	1	1	0
306	1	1	2	1	1	0	1	1	1	1	1	1	1	0
307	1	1	2	1	1	0	1	1	1	1	1	1	1	0
308	1	1	2	1	1	0	1	1	1	1	1	1	1	0
309	1	1	2	1	1	0	1	1	1	1	1	1	1	0
310	1	1	2	1	1	0	1	1	1	1	1	1	1	0
311	1	1	2	1	1	0	1	1	1	1	1	1	1	0
312	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-6-8

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Day 35 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
401	1	1	2	1	1	0	1	1	1	1	1	1	1	0
402	1	1	2	1	1	0	1	1	1	1	1	1	1	0
403	1	1	2	1	1	0	1	1	1	1	1	1	1	0
404	1	1	2	1	1	0	1	1	1	1	1	1	1	0
405	1	1	2	1	1	0	1	1	1	1	1	1	1	0
406	1	1	2	1	1	0	1	1	1	1	1	1	1	0
407	1	1	2	1	1	0	1	1	1	1	1	1	1	0
408	1	1	2	1	1	0	1	1	1	1	1	1	1	0
409	1	1	2	1	1	0	1	1	1	1	1	1	1	0
410	1	1	2	1	1	0	1	1	1	1	1	1	1	0
411	1	1	2	1	1	0	1	1	1	1	1	1	1	0
412	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-6-9

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 35 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior						
			Reactivity to environmental stimuli			Searching			Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocalization	Aggression
			Stereotype												
101	1	1	1	1	1	0	0	0	0	0	1	1	1	1	
102	1	1	1	1	1	0	0	0	0	0	1	1	1	1	
103	1	1	1	1	0	0	0	0	0	0	1	1	1	1	
104	1	1	1	1	0	0	0	0	0	0	1	1	1	1	
105	1	1	1	0	0	0	0	0	0	0	1	1	1	1	
106	1	1	1	0	0	0	0	0	0	0	1	1	1	1	
107	1	1	1	0	0	0	0	0	0	0	1	1	1	1	
108	1	1	1	0	0	0	0	0	0	0	1	1	1	1	
109	1	1	1	0	0	0	0	0	0	0	1	1	1	1	
110	1	1	1	0	0	0	0	0	0	0	1	1	1	1	
111	1	1	1	0	0	0	0	0	0	0	1	1	1	1	
112	1	1	1	1	0	0	0	0	0	0	1	1	1	1	
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12	
H	0.0000	0.0000	0.0000	0.0000	6.4091†	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	

## INDIVIDUAL DATA 2-6-10

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : Day 35 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
201	1	1	1	0	0	0	0	0	1	1	1
202	1	1	1	0	0	0	0	0	1	1	1
203	1	1	1	0	0	0	0	0	1	1	1
204	1	1	1	0	0	0	0	0	1	1	1
205	1	1	1	0	0	0	0	0	1	1	1
206	1	1	1	0	0	0	0	0	1	1	1
207	1	1	1	0	0	0	0	0	1	1	1
208	1	1	1	0	0	0	0	0	1	1	1
209	1	1	1	0	0	0	0	0	1	1	1
210	1	1	1	0	0	0	0	0	1	1	1
211	1	1	1	0	0	0	0	0	1	1	1
212	1	1	1	0	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12
U											
									54.0000		

## INDIVIDUAL DATA 2-6-11

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : Day 35 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Bizarre behavior		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocalization	Aggression	
301	1	1	1	0	0	0	0	1	1	1	1
302	1	1	1	0	0	0	0	1	1	1	1
303	1	1	1	0	0	0	0	1	1	1	1
304	1	1	1	0	0	0	0	1	1	1	1
305	1	1	1	0	0	0	0	1	1	1	1
306	1	1	1	0	0	0	0	1	1	1	1
307	1	1	1	0	0	0	0	1	1	1	1
308	1	1	1	0	0	0	0	1	1	1	1
309	1	1	1	0	0	0	0	1	1	1	1
310	1	1	1	0	0	0	0	1	1	1	1
311	1	1	1	0	0	0	0	1	1	1	1
312	1	1	1	0	0	0	0	1	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12
U											

54.0000

## INDIVIDUAL DATA 2-6-12

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD)

SEX : Male GROUP : 1000 mg/kg

PERIOD : Day 35 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
401	1	1	1	1	0	0	0	0	1	1	1
402	1	1	1	1	0	0	0	0	1	1	1
403	1	1	1	1	0	0	0	0	1	1	1
404	1	1	1	1	0	0	0	0	1	1	1
405	1	1	1	1	0	0	0	0	1	1	1
406	1	1	1	1	0	0	0	0	1	1	1
407	1	1	1	1	0	0	0	0	1	1	1
408	1	1	1	1	0	0	0	0	1	1	1
409	1	1	1	1	0	0	0	0	1	1	1
410	1	1	1	1	0	0	0	0	1	1	1
411	1	1	1	1	0	0	0	0	1	1	1
412	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

60.0000

U

## INDIVIDUAL DATA 2-7-1

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 42 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
101	1	1	1	0	0
102	1	1	1	0	0
103	1	1	1	0	0
104	1	1	1	0	0
105	1	1	1	0	0
106	1	1	1	0	0
107	1	1	1	0	0
108	1	1	1	0	0
109	1	1	1	0	0
110	1	1	1	0	0
111	1	1	1	0	0
112	1	1	1	0	0
N	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-7-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : Day 42 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
201	1	1	1	0	0
202	1	1	1	0	0
203	1	1	1	0	0
204	1	1	1	0	0
205	1	1	1	0	0
206	1	1	1	0	0
207	1	1	1	0	0
208	1	1	1	0	0
209	1	1	1	0	0
210	1	1	1	0	0
211	1	1	1	0	0
212	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-7-3

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : Day 42 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
301	1	1	1	0	0
302	1	1	1	0	0
303	1	1	1	0	0
304	1	1	1	0	0
305	1	1	1	0	0
306	1	1	1	0	0
307	1	1	1	0	0
308	1	1	1	0	0
309	1	1	1	0	0
310	1	1	1	0	0
311	1	1	1	0	0
312	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-7-4

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Day 42 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
401	1	1	1	0	0
402	1	1	1	0	0
403	1	1	1	0	0
404	1	1	1	0	0
405	1	1	1	0	0
406	1	1	1	0	0
407	1	1	1	0	0
408	1	1	1	0	0
409	1	1	1	0	0
410	1	1	1	0	0
411	1	1	1	0	0
412	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-7-5

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 42 of administration

Animal No.	On the hand												
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation
101	1	1	2	1	1	0	0	1	1	1	1	1	0
102	1	1	2	1	1	0	0	1	1	1	1	1	0
103	1	1	2	1	1	0	0	1	1	1	1	1	0
104	1	1	2	1	1	0	0	1	1	1	1	1	0
105	1	1	2	1	1	0	0	1	1	1	1	1	0
106	1	1	2	1	1	0	0	1	1	1	1	1	0
107	1	1	2	1	1	0	0	1	1	1	1	1	0
108	1	1	2	1	1	0	0	1	1	1	1	1	0
109	1	1	2	1	1	0	0	1	1	1	1	1	0
110	1	1	2	1	1	0	0	1	1	1	1	1	0
111	1	1	2	1	1	0	0	1	1	1	1	1	0
112	1	1	2	1	1	0	0	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-7-6

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : Day 42 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
201	1	1	2	1	1	0	0	1	1	1	1	1	1	0
202	1	1	2	1	1	0	0	1	1	1	1	1	1	0
203	1	1	2	1	1	0	0	1	1	1	1	1	1	0
204	1	1	2	1	1	0	0	1	1	1	1	1	1	0
205	1	1	2	1	1	0	0	1	1	1	1	1	1	0
206	1	1	2	1	1	0	0	1	1	1	1	1	1	0
207	1	1	2	1	1	0	0	1	1	1	1	1	1	0
208	1	1	2	1	1	0	0	1	1	1	1	1	1	0
209	1	1	2	1	1	0	0	1	1	1	1	1	1	0
210	1	1	2	1	1	0	0	1	1	1	1	1	1	0
211	1	1	2	1	1	0	1	1	1	1	1	1	1	0
212	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-7-7

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : Day 42 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
301	1	1	2	1	1	0	1	1	1	1	1	1	1	0
302	1	1	2	1	1	0	1	1	1	1	1	1	1	0
303	1	1	2	1	1	0	1	1	1	1	1	1	1	0
304	1	1	2	1	1	0	1	1	1	1	1	1	1	0
305	1	1	2	1	1	0	1	1	1	1	1	1	1	0
306	1	1	2	1	1	0	1	1	1	1	1	1	1	0
307	1	1	2	1	1	0	1	1	1	1	1	1	1	0
308	1	1	2	1	1	0	1	1	1	1	1	1	1	0
309	1	1	2	1	1	0	1	1	1	1	1	1	1	0
310	1	1	2	1	1	0	1	1	1	1	1	1	1	0
311	1	1	2	1	1	0	1	1	1	1	1	1	1	0
312	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-7-8

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Day 42 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
401	1	1	2	1	1	0	1	1	1	1	1	1	1	0
402	1	1	2	1	1	0	1	1	1	1	1	1	1	0
403	1	1	2	1	1	0	1	1	1	1	1	1	1	0
404	1	1	2	1	1	0	1	1	1	1	1	1	1	0
405	1	1	2	1	1	0	1	1	1	1	1	1	1	0
406	1	1	2	1	1	0	1	1	1	1	1	1	1	0
407	1	1	2	1	1	0	1	1	1	1	1	1	1	0
408	1	1	2	1	1	0	1	1	1	1	1	1	1	0
409	1	1	2	1	1	0	1	1	1	1	1	1	1	0
410	1	1	2	1	1	0	1	1	1	1	1	1	1	0
411	1	1	2	1	1	0	1	1	1	1	1	1	1	0
412	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-7-9

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 42 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
101	1	1	1	1	0	0	0	0	1	1	1
102	1	1	1	1	0	0	0	0	1	1	1
103	1	1	1	1	0	0	0	0	1	1	1
104	1	1	1	1	0	0	0	0	1	1	1
105	1	1	1	1	0	0	0	0	1	1	1
106	1	1	1	1	0	0	0	0	1	1	1
107	1	1	1	1	0	0	0	0	1	1	1
108	1	1	1	1	0	0	0	0	1	1	1
109	1	1	1	1	0	0	0	0	1	1	1
110	1	1	1	1	0	0	0	0	1	1	1
111	1	1	1	1	0	0	0	0	1	1	1
112	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	2.0435	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-7-10

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : Day 42 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Bizarre behavior		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocalization	Aggression	
201	1	1	1	1	0	0	0	1	1	1	1
202	1	1	1	1	0	0	0	0	1	1	1
203	1	1	1	1	0	0	0	0	1	1	1
204	1	1	1	1	0	0	0	0	1	1	1
205	1	1	1	1	0	0	0	0	1	1	1
206	1	1	1	1	0	0	0	0	1	1	1
207	1	1	1	1	0	0	0	0	1	1	1
208	1	1	1	1	0	0	0	0	1	1	1
209	1	1	1	1	0	0	0	0	1	1	1
210	1	1	1	1	0	0	0	0	1	1	1
211	1	1	1	1	0	0	0	0	1	1	1
212	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-7-11

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : Day 42 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
301	1	1	1	0	0	0	0	1	1	1	1
302	1	1	1	0	0	0	0	1	1	1	1
303	1	1	1	0	0	0	0	1	1	1	1
304	1	1	1	0	0	0	0	1	1	1	1
305	1	1	1	0	0	0	0	1	1	1	1
306	1	1	1	0	0	0	0	1	1	1	1
307	1	1	1	0	0	0	0	1	1	1	1
308	1	1	1	0	0	0	0	1	1	1	1
309	1	1	1	0	0	0	0	1	1	1	1
310	1	1	1	0	0	0	0	1	1	1	1
311	1	1	1	0	0	0	0	1	1	1	1
312	1	1	1	0	0	0	0	1	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-7-12

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD)

SEX : Male GROUP : 1000 mg/kg

PERIOD : Day 42 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Bizarre behavior		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocalization	Aggression	
401	1	1	1	0	0	0	0	1	1	1	1
402	1	1	1	0	0	0	0	1	1	1	1
403	1	1	1	0	0	0	0	1	1	1	1
404	1	1	1	0	0	0	0	1	1	1	1
405	1	1	1	0	0	0	0	1	1	1	1
406	1	1	1	0	0	0	0	1	1	1	1
407	1	1	1	0	0	0	0	1	1	1	1
408	1	1	1	0	0	0	0	1	1	1	1
409	1	1	1	0	0	0	0	1	1	1	1
410	1	1	1	0	0	0	0	1	1	1	1
411	1	1	1	0	0	0	0	1	1	1	1
412	1	1	1	0	0	0	0	1	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-8-1

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 7 of recovery

Animal No.	Body position/ Posture pattern	In the cage			Bizarre behavior
		Stereotype	Tremor/ Convulsion	Rolling Repetitive circling	
103	1	1	1	0	0
107	1	1	1	0	0
109	1	1	1	0	0
110	1	1	1	0	0
111	1	1	1	0	0

N	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-8-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Day 7 of recovery

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
401	1	1	1	0	0
403	1	1	1	0	0
407	1	1	1	0	0
409	1	1	1	0	0
410	1	1	1	0	0
N	5	5	5	5	5

## INDIVIDUAL DATA 2-8-3

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 7 of recovery

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
103	1	1	2	1	1	1	0	0	1	1	1	1	1	0
107	1	1	2	1	1	1	0	0	1	1	1	1	1	0
109	1	1	2	1	1	1	0	0	1	1	1	1	1	0
110	1	1	2	1	1	1	0	0	1	1	1	1	1	0
111	1	1	2	1	1	1	0	0	1	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-8-4

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Day 7 of recovery

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
401	1	1	2	1	1	1	0	0	1	1	1	1	1	0
403	1	1	2	1	1	1	0	0	1	1	1	1	1	0
407	1	1	2	1	1	1	0	0	1	1	1	1	1	0
409	1	1	2	1	1	1	0	0	1	1	1	1	1	0
410	1	1	2	1	1	1	0	0	1	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5

## INDIVIDUAL DATA 2-8-5

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD)

SEX : Male GROUP : 0 mg/kg

PERIOD : Day 7 of recovery

Animal No.	Gait	Co-ordination of movement	In the open-field					
			Reactivity to environmental stimuli			Stereotype		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward
103	1	1	1	1	0	0	0	1
107	1	1	1	1	0	0	0	1
109	1	1	1	1	0	0	0	1
110	1	1	1	1	0	0	0	1
111	1	1	1	1	0	0	0	1
N	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	1.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-8-6

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Day 7 of recovery

Animal No.	Gait	Co-ordination of movement	In the open-field					
			Reactivity to environmental stimuli			Stereotype		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward
401	1	1	1	1	0	0	0	1
403	1	1	1	0	0	0	0	1
407	1	1	1	0	0	0	0	1
409	1	1	1	0	0	0	0	1
410	1	1	1	0	0	0	0	1
N	5	5	5	5	5	5	5	5

## INDIVIDUAL DATA 2-9-1

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 14 of recovery

Animal No.	Body position/ Posture pattern	In the cage				
		Stereotype	Tremor/ Convulsion	Rolling	Repetitive circling	Biting/ Selfmutilation
103	1	1	1	0	0	1
107	1	1	1	0	0	1
109	1	1	1	0	0	1
110	1	1	1	0	0	1
111	1	1	1	0	0	1

N	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-9-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Day 14 of recovery

Animal No.	Body position/ Posture	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
401	1	1	1	0	0
403	1	1	1	0	0
407	1	1	1	0	0
409	1	1	1	0	0
410	1	1	1	0	0
N	5	5	5	5	5

## INDIVIDUAL DATA 2-9-3

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD)

SEX : Male GROUP : 0 mg/kg

PERIOD : Day 14 of recovery

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
103	1	1	2	1	1	1	0	0	1	1	1	1	1	0
107	1	1	2	1	1	1	0	0	1	1	1	1	1	0
109	1	1	2	1	1	1	0	0	1	1	1	1	1	0
110	1	1	2	1	1	1	0	0	1	1	1	1	1	0
111	1	1	2	1	1	1	0	0	1	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-9-4

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Day 14 of recovery

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
401	1	1	2	1	1	1	0	0	1	1	1	1	1	0
403	1	1	2	1	1	1	0	0	1	1	1	1	1	0
407	1	1	2	1	1	1	0	0	1	1	1	1	1	0
409	1	1	2	1	1	1	0	0	1	1	1	1	1	0
410	1	1	2	1	1	1	0	0	1	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5

## INDIVIDUAL DATA 2-9-5

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 14 of recovery

Animal No.	Gait	Co-ordination of movement	In the open-field						Stereotype	Bizarre behavior		
			Reactivity to environmental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement				
103	1	1	1	1	0	0	0	0	1	1		
107	1	1	1	1	0	0	0	0	1	1		
109	1	1	1	1	0	0	0	0	1	1		
110	1	1	1	1	0	0	0	0	1	1		
111	1	1	1	1	0	0	0	0	1	1		
N	5	5	5	5	5	5	5	5	5	5		
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000		

## INDIVIDUAL DATA 2-9-6

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Day 14 of recovery

Animal No.	Gait	Co-ordination of movement	In the open-field						Stereotype			Bizarre behavior		
			Reactivity to environmental stimuli			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocalization	Aggression	
401	1	1	1	1	0	0	0	0	0	0	1	1	1	1
403	1	1	1	1	0	0	0	0	0	0	1	1	1	1
407	1	1	1	1	0	0	0	0	0	0	1	1	1	1
409	1	1	1	1	0	0	0	0	0	0	1	1	1	1
410	1	1	1	1	0	0	0	0	0	0	1	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5

## INDIVIDUAL DATA 2-10-1

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Pre-administration

Animal No.	Body position/ Posture pattern	In the cage				Bizarre behavior	
		Stereotype		Tremor/ Convulsion	Rolling Repetitive circling		
151	1	1	1	0	0	1	
152	1	1	1	0	0	1	
153	1	1	1	0	0	1	
154	1	1	1	0	0	1	
155	1	1	1	0	0	1	
156	1	1	1	0	0	1	
157	1	1	1	0	0	1	
158	1	1	1	0	0	1	
159	1	1	1	0	0	1	
160	1	1	1	0	0	1	
161	1	1	1	0	0	1	
162	1	1	1	0	0	1	
N	12	12	12	12	12	12	
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	

## INDIVIDUAL DATA 2-10-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 100 mg/kg PERIOD : Pre-administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
251	1	1	1	0	0
252	1	1	1	0	0
253	1	1	1	0	0
254	1	1	1	0	0
255	1	1	1	0	0
256	1	1	1	0	0
257	1	1	1	0	0
258	1	1	1	0	0
259	1	1	1	0	0
260	1	1	1	0	0
261	1	1	1	0	0
262	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-10-3

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 300 mg/kg PERIOD : Pre-administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling Repetitive circling	Biting/ Selfmutilation	
351	1	1	1	0	0
352	1	1	1	0	0
353	1	1	1	0	0
354	1	1	1	0	0
355	1	1	1	0	0
356	1	1	1	0	0
357	1	1	1	0	0
358	1	1	1	0	0
359	1	1	1	0	0
360	1	1	1	0	0
361	1	1	1	0	0
362	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-10-4

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Pre-administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
451	1	1	1	0	0
452	1	1	1	0	0
453	1	1	1	0	0
454	1	1	1	0	0
455	1	1	1	0	0
456	1	1	1	0	0
457	1	1	1	0	0
458	1	1	1	0	0
459	1	1	1	0	0
460	1	1	1	0	0
461	1	1	1	0	0
462	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-10-5

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Pre-administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
151	1	1	2	1	1	0	0	1	1	1	1	1	1	0
152	1	1	2	1	1	0	0	1	1	1	1	1	1	0
153	1	1	2	1	1	0	0	1	1	1	1	1	1	0
154	1	1	2	1	1	0	0	1	1	1	1	1	1	0
155	1	1	2	1	1	0	0	1	1	1	1	1	1	0
156	1	1	2	1	1	0	0	1	1	1	1	1	1	0
157	1	1	2	1	1	0	0	1	1	1	1	1	1	0
158	1	1	2	1	1	0	0	1	1	1	1	1	1	0
159	1	1	2	1	1	0	0	1	1	1	1	1	1	0
160	1	1	2	1	1	0	0	1	1	1	1	1	1	0
161	1	1	2	1	1	0	0	1	1	1	1	1	1	0
162	1	1	2	1	1	0	0	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-10-6

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Female 100 mg/kg PERIOD : Pre-administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
251	1	1	2	1	1	1	0	0	1	1	1	1	1	0
252	1	1	2	1	1	1	0	0	1	1	1	1	1	0
253	1	1	2	1	1	1	0	0	1	1	1	1	1	0
254	1	1	2	1	1	1	0	1	0	1	1	1	1	0
255	1	1	2	1	1	1	0	0	1	1	1	1	1	0
256	1	1	2	1	1	1	0	0	1	1	1	1	1	0
257	1	1	2	1	1	1	0	1	0	1	1	1	1	0
258	1	1	2	1	1	1	0	0	1	1	1	1	1	0
259	1	1	2	1	1	1	0	0	1	1	1	1	1	0
260	1	1	2	1	1	1	0	0	1	1	1	1	1	0
261	1	1	2	1	1	1	0	1	0	1	1	1	1	0
262	1	1	2	1	1	1	0	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-10-7

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 300 mg/kg PERIOD : Pre-administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
351	1	1	2	1	1	0	0	1	1	1	1	1	1	0
352	1	1	2	1	1	0	0	1	1	1	1	1	1	0
353	1	1	2	1	1	0	0	1	1	1	1	1	1	0
354	1	1	2	1	1	0	0	1	1	1	1	1	1	0
355	1	1	2	1	1	0	0	1	1	1	1	1	1	0
356	1	1	2	1	1	0	0	1	1	1	1	1	1	0
357	1	1	2	1	1	0	0	1	1	1	1	1	1	0
358	1	1	2	1	1	0	0	1	1	1	1	1	1	0
359	1	1	2	1	1	0	0	1	1	1	1	1	1	0
360	1	1	2	1	1	0	0	1	1	1	1	1	1	0
361	1	1	2	1	1	0	0	1	1	1	1	1	1	0
362	1	1	2	1	1	0	0	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-10-8

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Female PERIOD : Pre-administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
451	1	1	2	1	1	0	0	1	1	1	1	1	1	0
452	1	1	2	1	1	0	0	1	1	1	1	1	1	0
453	1	1	2	1	1	0	0	1	1	1	1	1	1	0
454	1	1	2	1	1	0	0	1	1	1	1	1	1	0
455	1	1	2	1	1	0	0	1	1	1	1	1	1	0
456	1	1	2	1	1	0	0	1	1	1	1	1	1	0
457	1	1	2	1	1	0	0	1	1	1	1	1	1	0
458	1	1	2	1	1	0	0	1	1	1	1	1	1	0
459	1	1	2	1	1	0	0	1	1	1	1	1	1	0
460	1	1	2	1	1	0	0	1	1	1	1	1	1	0
461	1	1	2	1	1	0	0	1	1	1	1	1	1	0
462	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-10-9

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD)

SEX : Female GROUP : 0 mg/kg

PERIOD : Pre-administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior			
			Reactivity to environmental stimuli			Searching			Urination	Defecation	Excessive grooming	Stereotype
151	1	1	1	1	1	0	0	0	0	0	1	1
152	1	1	1	1	0	0	0	0	0	0	1	1
153	1	1	1	1	0	0	0	0	0	0	1	1
154	1	1	1	1	0	0	0	0	0	0	1	1
155	1	1	1	1	0	0	0	0	0	0	1	1
156	1	1	1	1	0	0	0	0	0	0	1	1
157	1	1	1	1	0	0	0	0	0	0	1	1
158	1	1	1	1	0	0	0	0	0	0	1	1
159	1	1	1	1	0	0	0	0	0	0	1	1
160	1	1	1	1	1	0	0	0	0	0	1	1
161	1	1	1	1	0	0	0	0	0	0	1	1
162	1	1	1	1	0	0	0	0	0	0	1	1
N	12	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	5.8750	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-10-10

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 100 mg/kg PERIOD : Pre-administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
251	1	1	1	0	0	0	0	1	1	1	1
252	1	1	1	1	0	0	0	0	1	1	1
253	1	1	1	0	0	0	0	1	1	1	1
254	1	1	1	0	0	0	0	1	1	1	1
255	1	1	1	0	0	0	0	1	1	1	1
256	1	1	1	0	0	0	0	1	1	1	1
257	1	1	1	0	0	0	0	1	1	1	1
258	1	1	1	0	0	0	0	1	1	1	1
259	1	1	1	0	0	0	0	1	1	1	1
260	1	1	1	0	0	0	0	1	1	1	1
261	1	1	1	0	0	0	0	1	1	1	1
262	1	1	1	0	0	0	0	1	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-10-11

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 300 mg/kg PERIOD : Pre-administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
351	1	1	1	1	0	0	0	0	1	1	1
352	1	1	1	1	0	0	0	0	1	1	1
353	1	1	1	1	0	0	0	0	1	1	1
354	1	1	1	1	0	0	0	0	1	1	1
355	1	1	1	1	0	0	0	0	1	1	1
356	1	1	1	1	0	0	0	0	1	1	1
357	1	1	1	1	1	0	0	0	1	1	1
358	1	1	1	1	0	0	0	0	1	1	1
359	1	1	1	1	0	0	0	0	1	1	1
360	1	1	1	1	0	0	0	0	1	1	1
361	1	1	1	1	0	0	0	0	1	1	1
362	1	1	1	1	1	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-10-12

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Pre-administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
451	1	1	1	0	0	0	0	0	1	1	1
452	1	1	1	0	0	0	0	0	1	1	1
453	1	1	1	0	0	0	0	0	1	1	1
454	1	1	1	0	0	0	0	0	1	1	1
455	1	1	1	0	0	0	0	0	1	1	1
456	1	1	1	0	0	0	0	0	1	1	1
457	1	1	1	0	0	0	0	0	1	1	1
458	1	1	1	0	0	0	0	0	1	1	1
459	1	1	1	0	0	0	0	0	1	1	1
460	1	1	1	0	0	0	0	0	1	1	1
461	1	1	1	0	0	0	0	0	1	1	1
462	1	1	1	0	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-10-13

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Pre-administration

Animal No.	Body position/ Posture pattern	In the cage			Bizarre behavior
		Stereotype	Tremor/ Convulsion	Rolling Repetitive circling	
163	1	1	1	0	0
164	1	1	1	0	0
165	1	1	1	0	0
166	1	1	1	0	0
167	1	1	1	0	0
N	5	5	5	5	5

H	0.0000	0.0000	0.0000	0.0000	0.0000
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INDIVIDUAL DATA 2-10-14

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Pre-administration

Animal No.	Body position/ Posture	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
463	1	1	1	0	0
464	1	1	1	0	0
465	1	1	1	0	0
466	1	1	1	0	0
467	1	1	1	0	0
N	5	5	5	5	5

## INDIVIDUAL DATA 2-10-15

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Pre-administration

Animal No.	On the hand												
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation
163	1	1	2	1	1	1	0	1	1	1	1	1	0
164	1	1	2	1	1	1	0	1	1	1	1	1	0
165	1	1	2	1	1	1	0	1	1	1	1	1	0
166	1	1	2	1	1	1	0	1	1	1	1	1	0
167	1	1	2	1	1	1	0	1	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-10-16

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Female PERIOD : Pre-administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
463	1	1	2	1	1	0	0	1	1	1	1	1	1	0
464	1	1	2	1	1	1	0	0	1	1	1	1	1	0
465	1	1	2	1	1	1	0	0	1	1	1	1	1	0
466	1	1	2	1	1	1	0	0	1	1	1	1	1	0
467	1	1	2	1	1	1	0	0	1	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5

## INDIVIDUAL DATA 2-10-17

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Pre-administration

Animal No.	Gait	Co-ordination of movement	In the open-field							
			Reactivity to environmental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Stereotype	Bizarre behavior
163	1	1	1	1	0	0	0	0	1	1
164	1	1	1	1	0	0	0	0	1	1
165	1	1	1	1	0	0	0	0	1	1
166	1	1	1	1	0	0	0	0	1	1
167	1	1	1	1	0	0	0	0	1	1
N	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

	Walking backward	Vocalization	Aggression

INDIVIDUAL DATA 2-10-18

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Pre-administration

Animal No.	Gait of movement	Co-ordination stimuli	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype	Unusual head movement	Walking backward			Vocalization
			Searching	Urination	Defecation	Excessive grooming	0	0	1	1	Aggression
463	1	1	1	0	0	0	0	0	1	1	1
464	1	1	1	0	0	0	0	0	1	1	1
465	1	1	1	0	0	0	0	0	1	1	1
466	1	1	1	0	0	0	0	0	1	1	1
467	1	1	1	0	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5

## INDIVIDUAL DATA 2-11-1

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 7 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling Repetitive circling	Biting/ Selfmutilation	
151	1	1	1	0	0
152	1	1	1	0	0
153	1	1	1	0	0
154	1	1	1	0	0
155	1	1	1	0	0
156	1	1	1	0	0
157	1	1	1	0	0
158	1	1	1	0	0
159	1	1	1	0	0
160	1	1	1	0	0
161	1	1	1	0	0
162	1	1	1	0	0
N	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-11-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 100 mg/kg PERIOD : Day 7 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
251	1	1	1	0	0
252	1	1	1	0	0
253	1	1	1	0	0
254	1	1	1	0	0
255	1	1	1	0	0
256	1	1	1	0	0
257	1	1	1	0	0
258	1	1	1	0	0
259	1	1	1	0	0
260	1	1	1	0	0
261	1	1	1	0	0
262	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-11-3

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 300 mg/kg PERIOD : Day 7 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
351	1	1	1	0	0
352	1	1	1	0	0
353	1	1	1	0	0
354	1	1	1	0	0
355	1	1	1	0	0
356	1	1	1	0	0
357	1	1	1	0	0
358	1	1	1	0	0
359	1	1	1	0	0
360	1	1	1	0	0
361	1	1	1	0	0
362	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-11-4

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation

ANIMAL : Rat, Cri:CD(SD)

SEX : Female

GROUP : Day 7 of administration

PERIOD : 1000 mg/kg

Day 7 of administration

Animal No.	Body position/ Posture pattern	In the cage			Bizarre behavior
		Stereotype	Tremor/ Convulsion	Rolling Repetitive circling	
451	1	1	1	0	0
452	1	1	1	0	0
453	1	1	1	0	0
454	1	1	1	0	0
455	1	1	1	0	0
456	1	1	1	0	0
457	1	1	1	0	0
458	1	1	1	0	0
459	1	1	1	0	0
460	1	1	1	0	0
461	1	1	1	0	0
462	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-11-5

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 7 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
151	1	1	2	1	1	0	1	1	1	1	1	1	1	0
152	1	1	2	1	1	0	1	1	1	1	1	1	1	0
153	1	1	2	1	1	0	1	1	1	1	1	1	1	0
154	1	1	2	1	1	0	1	1	1	1	1	1	1	0
155	1	1	2	1	1	0	1	1	1	1	1	1	1	0
156	1	1	2	1	1	0	1	1	1	1	1	1	1	0
157	1	1	2	1	1	0	1	1	1	1	1	1	1	0
158	1	1	2	1	1	0	1	1	1	1	1	1	1	0
159	1	1	2	1	1	0	1	1	1	1	1	1	1	0
160	1	1	2	1	1	0	1	1	1	1	1	1	1	0
161	1	1	2	1	1	0	1	1	1	1	1	1	1	0
162	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-11-6

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 100 mg/kg PERIOD : Day 7 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
251	1	1	2	1	1	0	1	1	1	1	1	1	1	0
252	1	1	2	1	1	0	1	1	1	1	1	1	1	0
253	1	1	2	1	1	0	1	1	1	1	1	1	1	0
254	1	1	2	1	1	0	1	1	1	1	1	1	1	0
255	1	1	2	1	1	0	1	1	1	1	1	1	1	0
256	1	1	2	1	1	0	1	1	1	1	1	1	1	0
257	1	1	2	1	1	0	1	1	1	1	1	1	1	0
258	1	1	2	1	1	0	1	1	1	1	1	1	1	0
259	1	1	2	1	1	0	1	1	1	1	1	1	1	0
260	1	1	2	1	1	0	1	1	1	1	1	1	1	0
261	1	1	2	1	1	0	1	1	1	1	1	1	1	0
262	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-11-7

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 300 mg/kg PERIOD : Day 7 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
351	1	1	2	1	1	0	1	1	1	1	1	1	1	0
352	1	1	2	1	1	0	1	1	1	1	1	1	1	0
353	1	1	2	1	1	0	1	1	1	1	1	1	1	0
354	1	1	2	1	1	0	1	1	1	1	1	1	1	0
355	1	1	2	1	1	0	1	1	1	1	1	1	1	0
356	1	1	2	1	1	0	1	1	1	1	1	1	1	0
357	1	1	2	1	1	0	1	1	1	1	1	1	1	0
358	1	1	2	1	1	0	1	1	1	1	1	1	1	0
359	1	1	2	1	1	0	1	1	1	1	1	1	1	0
360	1	1	2	1	1	0	1	1	1	1	1	1	1	0
361	1	1	2	1	1	0	1	1	1	1	1	1	1	0
362	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-11-8

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Female PERIOD : Day 7 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
451	1	1	2	1	1	0	1	1	1	1	1	1	1	0
452	1	1	2	1	1	0	1	1	1	1	1	1	1	0
453	1	1	2	1	1	0	1	1	1	1	1	1	1	0
454	1	1	2	1	1	0	1	1	1	1	1	1	1	0
455	1	1	2	1	1	0	1	1	1	1	1	1	1	0
456	1	1	2	1	1	0	1	1	1	1	1	1	1	0
457	1	1	2	1	1	0	1	1	1	1	1	1	1	0
458	1	1	2	1	1	0	1	1	1	1	1	1	1	0
459	1	1	2	1	1	0	1	1	1	1	1	1	1	0
460	1	1	2	1	1	0	1	1	1	1	1	1	1	0
461	1	1	2	1	1	0	1	1	1	1	1	1	1	0
462	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-11-9

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 7 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward Vocalization Aggression		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement				
151	1	1	1	1	0	0	0	0	1	1	1
152	1	1	1	1	0	0	0	0	1	1	1
153	1	1	1	1	0	0	0	0	1	1	1
154	1	1	1	1	0	0	0	0	1	1	1
155	1	1	1	1	0	0	0	0	1	1	1
156	1	1	1	1	0	0	0	0	1	1	1
157	1	1	1	1	0	0	0	0	1	1	1
158	1	1	1	1	0	0	0	0	1	1	1
159	1	1	1	1	0	0	0	0	1	1	1
160	1	1	1	1	0	0	0	0	1	1	1
161	1	1	1	1	0	0	0	0	1	1	1
162	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	3.0000	3.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-11-10

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Female PERIOD : Day 7 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
251	1	1	1	1	0	0	0	0	1	1	1
252	1	1	1	1	1	0	0	0	1	1	1
253	1	1	1	1	0	0	0	0	1	1	1
254	1	1	1	1	0	0	0	0	1	1	1
255	1	1	1	1	0	0	0	0	1	1	1
256	1	1	1	1	0	0	0	0	1	1	1
257	1	1	1	1	0	0	0	0	1	1	1
258	1	1	1	1	0	0	0	0	1	1	1
259	1	1	1	1	0	0	0	0	1	1	1
260	1	1	1	1	0	0	0	0	1	1	1
261	1	1	1	1	0	0	0	0	1	1	1
262	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-11-11

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 300 mg/kg PERIOD : Day 7 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward Vocalization Aggression		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement				
351	1	1	1	1	0	0	0	0	1	1	1
352	1	1	1	1	0	0	0	0	1	1	1
353	1	1	1	1	0	0	0	0	1	1	1
354	1	1	1	1	0	0	0	0	1	1	1
355	1	1	1	1	0	0	0	0	1	1	1
356	1	1	1	1	0	0	0	0	1	1	1
357	1	1	1	1	0	0	0	0	1	1	1
358	1	1	1	1	0	0	0	0	1	1	1
359	1	1	1	1	0	0	0	0	1	1	1
360	1	1	1	1	0	0	0	0	1	1	1
361	1	1	1	1	0	0	0	0	1	1	1
362	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-11-12

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 7 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward Vocalization Aggression		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement				
451	1	1	1	1	0	0	0	0	1	1	1
452	1	1	1	1	0	0	0	0	1	1	1
453	1	1	1	1	0	0	0	0	1	1	1
454	1	1	1	1	0	0	0	0	1	1	1
455	1	1	1	1	0	0	0	0	1	1	1
456	1	1	1	1	0	0	0	0	1	1	1
457	1	1	1	1	0	0	0	0	1	1	1
458	1	1	1	1	0	0	0	0	1	1	1
459	1	1	1	1	0	0	0	0	1	1	1
460	1	1	1	1	0	0	0	0	1	1	1
461	1	1	1	1	0	0	0	0	1	1	1
462	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-11-13

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 7 of administration

Animal No.	Body position/ Posture pattern	In the cage			Bizarre behavior
		Stereotype	Tremor/ Convulsion	Rolling Repetitive circling	
163	1	1	1	0	0
164	1	1	1	0	0
165	1	1	1	0	0
166	1	1	1	0	0
167	1	1	1	0	0
N	5	5	5	5	5

H	0.0000	0.0000	0.0000	0.0000	0.0000
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## INDIVIDUAL DATA 2-11-14

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Day 7 of administration PERIOD : Day 7 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
463	1	1	1	0	0
464	1	1	1	0	0
465	1	1	1	0	0
466	1	1	1	0	0
467	1	1	1	0	0
N	5	5	5	5	5

## INDIVIDUAL DATA 2-11-15

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 7 of administration

Animal No.	On the hand										
	Ease of		Muscle tone	Piloerection	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
Removal	Handling										
163	1	1	2	1	1	0	1	1	1	1	0
164	1	1	2	1	1	0	1	1	1	1	0
165	1	1	2	1	1	0	1	1	1	1	0
166	1	1	2	1	1	0	1	1	1	1	0
167	1	1	2	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-11-16

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Female PERIOD : Day 7 of administration

Animal No.	On the hand									
	Ease of Removal		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation
	Handling									Secretions/Excretions
463	1	1	2	1	1	0	0	1	1	1
464	1	1	2	1	1	0	0	1	1	1
465	1	1	2	1	1	0	0	1	1	0
466	1	1	2	1	1	0	0	1	1	1
467	1	1	2	1	1	0	0	1	1	0
N	5	5	5	5	5	5	5	5	5	5

## INDIVIDUAL DATA 2-11-17

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 7 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field							
			Reactivity to environmental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Stereotype	Bizarre behavior
163	1	1	1	1	1	0	0	0	1	1
164	1	1	1	0	0	0	0	0	1	1
165	1	1	1	0	0	0	0	0	1	1
166	1	1	1	0	0	0	0	0	1	1
167	1	1	1	0	0	0	0	0	1	1
N	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	1.0000	1.0000	0.0000	0.0000	0.0000	0.0000

Animal No.	Gait	Co-ordination of movement	In the open-field							
			Reactivity to environmental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Stereotype	Bizarre behavior
163	1	1	1	1	1	0	0	0	1	1
164	1	1	1	0	0	0	0	0	1	1
165	1	1	1	0	0	0	0	0	1	1
166	1	1	1	0	0	0	0	0	1	1
167	1	1	1	0	0	0	0	0	1	1
N	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	1.0000	1.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-11-18

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Day 7 of administration PERIOD : Day 7 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
463	1	1	1	0	0	0	0	1	1	1	1
464	1	1	1	0	0	0	0	1	1	1	1
465	1	1	1	0	0	0	0	1	1	1	1
466	1	1	1	0	0	0	0	1	1	1	1
467	1	1	1	0	0	0	0	1	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5

## INDIVIDUAL DATA 2-12-1

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 14 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling Repetitive circling	Biting/ Selfmutilation	
151	1	1	1	0	0
152	1	1	1	0	0
153	1	1	1	0	0
154	1	1	1	0	0
155	1	1	1	0	0
156	1	1	1	0	0
157	1	1	1	0	0
158	1	1	1	0	0
159	1	1	1	0	0
160	1	1	1	0	0
161	1	1	1	0	0
162	1	1	1	0	0
N	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-12-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 100 mg/kg PERIOD : Day 14 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
251	1	1	1	0	0
252	1	1	1	0	0
253	1	1	1	0	0
254	1	1	1	0	0
255	1	1	1	0	0
256	1	1	1	0	0
257	1	1	1	0	0
258	1	1	1	0	0
259	1	1	1	0	0
260	1	1	1	0	0
261	1	1	1	0	0
262	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-12-3

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation

ANIMAL : Rat, Cri:CD(SD)

SEX : Female

GROUP : Day 14 of administration

PERIOD : Day 14 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype	Tremor/ Convulsion	Rolling	Bizarre behavior
		Repetitive circling	Repetitive circling	Biting/ Selfmutilation	
351	1	1	1	0	0
352	1	1	1	0	0
353	1	1	1	0	0
354	1	1	1	0	0
355	1	1	1	0	0
356	1	1	1	0	0
357	1	1	1	0	0
358	1	1	1	0	0
359	1	1	1	0	0
360	1	1	1	0	0
361	1	1	1	0	0
362	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-12-4

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 14 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
451	1	1	1	0	0
452	1	1	1	0	0
453	1	1	1	0	0
454	1	1	1	0	0
455	1	1	1	0	0
456	1	1	1	0	0
457	1	1	1	0	0
458	1	1	1	0	0
459	1	1	1	0	0
460	1	1	1	0	0
461	1	1	1	0	0
462	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-12-5

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 14 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
151	1	1	2	1	1	0	0	1	1	1	1	1	1	0
152	1	1	2	1	1	0	0	1	1	1	1	1	1	0
153	1	1	2	1	1	0	0	1	1	1	1	1	1	0
154	1	1	2	1	1	0	0	1	1	1	1	1	1	0
155	1	1	2	1	1	0	0	1	1	1	1	1	1	0
156	1	1	2	1	1	0	0	1	1	1	1	1	1	0
157	1	1	2	1	1	0	0	1	1	1	1	1	1	0
158	1	1	2	1	1	0	0	1	1	1	1	1	1	0
159	1	1	2	1	1	0	0	1	1	1	1	1	1	0
160	1	1	2	1	1	0	0	1	1	1	1	1	1	0
161	1	1	2	1	1	0	0	1	1	1	1	1	1	0
162	1	1	2	1	1	0	0	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-12-6

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 100 mg/kg PERIOD : Day 14 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
251	1	1	2	1	1	1	0	0	1	1	1	1	1	0
252	1	1	2	1	1	1	0	0	1	1	1	1	1	0
253	1	1	2	1	1	1	0	0	1	1	1	1	1	0
254	1	1	2	1	1	1	0	1	0	1	1	1	1	0
255	1	1	2	1	1	1	0	0	1	1	1	1	1	0
256	1	1	2	1	1	1	0	0	1	1	1	1	1	0
257	1	1	2	1	1	1	0	0	1	1	1	1	1	0
258	1	1	2	1	1	1	0	0	1	1	1	1	1	0
259	1	1	2	1	1	1	0	0	1	1	1	1	1	0
260	1	1	2	1	1	1	0	0	1	1	1	1	1	0
261	1	1	2	1	1	1	0	1	1	1	1	1	1	0
262	1	1	2	1	1	1	0	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-12-7

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 300 mg/kg PERIOD : Day 14 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
351	1	1	2	1	1	1	0	0	1	1	1	1	1	0
352	1	1	2	1	1	1	0	0	1	1	1	1	1	0
353	1	1	2	1	1	1	0	0	1	1	1	1	1	0
354	1	1	2	1	1	1	0	1	0	1	1	1	1	0
355	1	1	2	1	1	1	0	0	1	1	1	1	1	0
356	1	1	2	1	1	1	0	0	1	1	1	1	1	0
357	1	1	2	1	1	1	0	1	0	1	1	1	1	0
358	1	1	2	1	1	1	0	1	0	1	1	1	1	0
359	1	1	2	1	1	1	0	0	1	1	1	1	1	0
360	1	1	2	1	1	1	0	0	1	1	1	1	1	0
361	1	1	2	1	1	1	0	1	0	1	1	1	1	0
362	1	1	2	1	1	1	0	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-12-8

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Female PERIOD : Day 14 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
451	1	1	2	1	1	0	0	1	1	1	1	1	1	0
452	1	1	2	1	1	0	0	1	1	1	1	1	1	0
453	1	1	2	1	1	0	0	1	1	1	1	1	1	0
454	1	1	2	1	1	0	0	1	1	1	1	1	1	0
455	1	1	2	1	1	0	0	1	1	1	1	1	1	0
456	1	1	2	1	1	0	0	1	1	1	1	1	1	0
457	1	1	2	1	1	0	0	1	1	1	1	1	1	0
458	1	1	2	1	1	0	0	1	1	1	1	1	1	0
459	1	1	2	1	1	0	0	1	1	1	1	1	1	0
460	1	1	2	1	1	0	0	1	1	1	1	1	1	0
461	1	1	2	1	1	0	0	1	1	1	1	1	1	0
462	1	1	2	1	1	0	0	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-12-9

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 14 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
151	1	1	1	1	0	0	0	0	1	1	1
152	1	1	1	1	0	0	0	0	1	1	1
153	1	1	1	1	0	0	0	0	1	1	1
154	1	1	1	1	0	0	0	0	1	1	1
155	1	1	1	1	0	0	0	0	1	1	1
156	1	1	1	1	0	0	0	0	1	1	1
157	1	1	1	1	0	0	0	0	1	1	1
158	1	1	1	1	0	0	0	0	1	1	1
159	1	1	1	1	0	0	0	0	1	1	1
160	1	1	1	1	0	0	0	0	1	1	1
161	1	1	1	1	0	0	0	0	1	1	1
162	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	3.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-12-10

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD)

SEX : Female GROUP : Day 14 of administration

PERIOD : Day 14 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward Vocalization Aggression		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement				
251	1	1	1	1	0	0	0	0	1	1	1
252	1	1	1	1	1	0	0	0	1	1	1
253	1	1	1	1	0	0	0	0	1	1	1
254	1	1	1	1	0	0	0	0	1	1	1
255	1	1	1	1	0	0	0	0	1	1	1
256	1	1	1	1	0	0	0	0	1	1	1
257	1	1	1	1	0	0	0	0	1	1	1
258	1	1	1	1	0	0	0	0	1	1	1
259	1	1	1	1	0	0	0	0	1	1	1
260	1	1	1	1	0	0	0	0	1	1	1
261	1	1	1	1	0	0	0	0	1	1	1
262	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

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## INDIVIDUAL DATA 2-12-11

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD)

SEX : Female GROUP : 300 mg/kg

PERIOD : Day 14 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward Vocalization Aggression		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement				
351	1	1	1	1	0	0	0	0	1	1	1
352	1	1	1	1	0	0	0	0	1	1	1
353	1	1	1	1	0	0	0	0	1	1	1
354	1	1	1	1	0	0	0	0	1	1	1
355	1	1	1	1	0	0	0	0	1	1	1
356	1	1	1	1	0	0	0	0	1	1	1
357	1	1	1	1	0	0	0	0	1	1	1
358	1	1	1	1	0	0	0	0	1	1	1
359	1	1	1	1	0	0	0	0	1	1	1
360	1	1	1	1	0	0	0	0	1	1	1
361	1	1	1	1	0	0	0	0	1	1	1
362	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-12-12

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 14 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward Vocalization Aggression		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement				
451	1	1	1	1	0	0	0	0	1	1	1
452	1	1	1	1	0	0	0	0	1	1	1
453	1	1	1	1	0	0	0	0	1	1	1
454	1	1	1	1	0	0	0	0	1	1	1
455	1	1	1	1	0	0	0	0	1	1	1
456	1	1	1	1	0	0	0	0	1	1	1
457	1	1	1	1	0	0	0	0	1	1	1
458	1	1	1	1	0	0	0	0	1	1	1
459	1	1	1	1	0	0	0	0	1	1	1
460	1	1	1	1	0	0	0	0	1	1	1
461	1	1	1	1	0	0	0	0	1	1	1
462	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-12-13

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 14 of administration

Animal No.	Body position/ Posture pattern	In the cage			Bizarre behavior
		Stereotype	Tremor/ Convulsion	Rolling Repetitive circling	
163	1	1	1	0	0
164	1	1	1	0	0
165	1	1	1	0	0
166	1	1	1	0	0
167	1	1	1	0	0
N	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-12-14

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 14 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
463	1	1	1	0	0
464	1	1	1	0	0
465	1	1	1	0	0
466	1	1	1	0	0
467	1	1	1	0	0
N	5	5	5	5	5

## INDIVIDUAL DATA 2-12-15

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 14 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
163	1	1	2	1	1	1	0	0	1	1	1	1	1	0
164	1	1	2	1	1	1	0	0	1	1	1	1	1	0
165	1	1	2	1	1	1	0	0	1	1	1	1	1	0
166	1	1	2	1	1	1	0	0	1	1	1	1	1	0
167	1	1	2	1	1	1	0	0	1	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-12-16

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Female PERIOD : Day 14 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
463	1	1	2	1	1	0	0	1	1	1	1	1	1	0
464	1	1	2	1	1	1	0	0	1	1	1	1	1	0
465	1	1	2	1	1	1	0	0	1	1	1	1	1	0
466	1	1	2	1	1	1	0	0	1	1	1	1	1	0
467	1	1	2	1	1	1	0	0	1	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5

## INDIVIDUAL DATA 2-12-17

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 14 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						
			Reactivity to environmental stimuli			Stereotype			
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	
163	1	1	1	1	0	0	0	1	1
164	1	1	1	1	0	0	0	1	1
165	1	1	1	1	0	0	0	1	1
166	1	1	1	1	0	0	0	1	1
167	1	1	1	1	0	0	0	1	1
N	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

	Stereotype	Unusual head movement	Walking backward	Vocalization	Aggression

INDIVIDUAL DATA 2-12-18

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Female PERIOD : Day 14 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
463	1	1	1	1	0	0	0	0	1	1	1
464	1	1	1	1	0	0	0	0	1	1	1
465	1	1	1	1	0	0	0	0	1	1	1
466	1	1	1	1	0	0	0	0	1	1	1
467	1	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5

## INDIVIDUAL DATA 2-13-1

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 21 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling Repetitive circling	Biting/ Selfmutilation	
151	1	1	1	0	0
152	1	1	1	0	0
153	1	1	1	0	0
154	1	1	1	0	0
155	1	1	1	0	0
156	1	1	1	0	0
157	1	1	1	0	0
158	1	1	1	0	0
159	1	1	1	0	0
160	1	1	1	0	0
161	1	1	1	0	0
162	1	1	1	0	0
N	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-13-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation

ANIMAL : Rat, Cri:CD(SD)

SEX : Female

GROUP : Day 21 of administration

PERIOD : Day 21 of administration

Animal No.	Body position/ Posture pattern	In the cage			Bizarre behavior
		Stereotype	Tremor/ Convulsion	Rolling Repetitive circling	
251	1	1	1	0	0
252	1	1	1	0	0
253	1	1	1	0	0
254	1	1	1	0	0
255	1	1	1	0	0
256	1	1	1	0	0
257	1	1	1	0	0
258	1	1	1	0	0
259	1	1	1	0	0
260	1	1	1	0	0
261	1	1	1	0	0
262	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-13-3

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation

ANIMAL : Rat, Cri:CD(SD)

SEX : Female

GROUP : Day 21 of administration

PERIOD : Day 21 of administration

Animal No.	Body position/ Posture pattern	In the cage			Bizarre behavior
		Stereotype	Tremor/ Convulsion	Rolling Repetitive circling	
351	1	1	1	0	0
352	1	1	1	0	0
353	1	1	1	0	0
354	1	1	1	0	0
355	1	1	1	0	0
356	1	1	1	0	0
357	1	1	1	0	0
358	1	1	1	0	0
359	1	1	1	0	0
360	1	1	1	0	0
361	1	1	1	0	0
362	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-13-4

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 21 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
451	1	1	1	0	0
452	1	1	1	0	0
453	1	1	1	0	0
454	1	1	1	0	0
455	1	1	1	0	0
456	1	1	1	0	0
457	1	1	1	0	0
458	1	1	1	0	0
459	1	1	1	0	0
460	1	1	1	0	0
461	1	1	1	0	0
462	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-13-5

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 21 of administration

Animal No.	On the hand													
	Ease of Removal		Handling tone		Muscle	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
151	1	1	2	1	1	1	0	0	1	1	1	1	1	0
152	1	1	2	1	1	1	0	0	1	1	1	1	1	0
153	1	1	2	1	1	1	0	0	1	1	1	1	1	0
154	1	1	2	1	1	1	0	0	1	1	1	1	1	0
155	1	1	2	1	1	1	0	0	1	1	1	1	1	0
156	1	1	2	1	1	1	0	0	1	1	1	1	1	0
157	1	1	2	1	1	1	0	0	1	1	1	1	1	0
158	1	1	2	1	1	1	0	0	1	1	1	1	1	0
159	1	1	2	1	1	1	0	0	1	1	1	1	1	0
160	1	1	2	1	1	1	0	0	1	1	1	1	1	0
161	1	1	2	1	1	1	0	0	1	1	1	1	1	0
162	1	1	2	1	1	1	0	0	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-13-6

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 100 mg/kg PERIOD : Day 21 of administration

Animal No.	On the hand											
	Ease of Removal		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
251	1	1	2	1	1	1	0	1	1	1	1	0
252	1	1	2	1	1	1	0	1	1	1	1	0
253	1	1	2	1	1	1	0	1	1	1	1	0
254	1	1	2	1	1	1	0	1	1	1	1	0
255	1	1	2	1	1	1	0	1	1	1	1	0
256	1	1	2	1	1	1	0	1	1	1	1	0
257	1	1	2	1	1	1	0	1	1	1	1	0
258	1	1	2	1	1	1	0	1	1	1	1	0
259	1	1	2	1	1	1	0	1	1	1	1	0
260	1	1	2	1	1	1	0	1	1	1	1	0
261	1	1	2	1	1	1	0	1	1	1	1	0
262	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-13-7

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 300 mg/kg PERIOD : Day 21 of administration

Animal No.	On the hand							On the hand						
	Ease of Removal		Handling tone		Muscle	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
351	1	1	2	1	1	1	0	1	1	1	1	1	1	0
352	1	1	2	1	1	1	0	1	1	1	1	1	1	0
353	1	1	2	1	1	1	0	1	1	1	1	1	1	0
354	1	1	2	1	1	1	0	1	1	1	1	1	1	0
355	1	1	2	1	1	1	0	1	1	1	1	1	1	0
356	1	1	2	1	1	1	0	1	1	1	1	1	1	0
357	1	1	2	1	1	1	0	1	1	1	1	1	1	0
358	1	1	2	1	1	1	0	1	1	1	1	1	1	0
359	1	1	2	1	1	1	0	1	1	1	1	1	1	0
360	1	1	2	1	1	1	0	1	1	1	1	1	1	0
361	1	1	2	1	1	1	0	1	1	1	1	1	1	0
362	1	1	2	1	1	1	0	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-13-8

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 21 of administration

Animal No.	On the hand													
	Ease of Removal		Handling tone		Muscle	Piloerection	Fur	Eyes						
									Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
451	1	1	2	1	1	1	0	0	1	1	1	1	1	0
452	1	1	2	1	1	1	0	0	1	1	1	1	1	0
453	1	1	2	1	1	1	0	0	1	1	1	1	1	0
454	1	1	2	1	1	1	0	0	1	1	1	1	1	0
455	1	1	2	1	1	1	0	0	1	1	1	1	1	0
456	1	1	2	1	1	1	0	0	1	1	1	1	1	0
457	1	1	2	1	1	1	0	0	1	1	1	1	1	0
458	1	1	2	1	1	1	0	0	1	1	1	1	1	0
459	1	1	2	1	1	1	0	0	1	1	1	1	1	0
460	1	1	2	1	1	1	0	0	1	1	1	1	1	0
461	1	1	2	1	1	1	0	0	1	1	1	1	1	0
462	1	1	2	1	1	1	0	0	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-13-9

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 21 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Stereotype	Bizarre behavior
			Reactivity to environmental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement		
151	1	1	1	1	0	0	0	0	1	1
152	1	1	1	1	0	0	0	0	1	1
153	1	1	1	1	0	0	0	0	1	1
154	1	1	1	1	0	0	0	0	1	1
155	1	1	1	1	0	0	0	0	1	1
156	1	1	1	1	0	0	0	0	1	1
157	1	1	1	1	0	0	0	0	1	1
158	1	1	1	1	0	0	0	0	1	1
159	1	1	1	1	0	0	0	0	1	1
160	1	1	1	1	0	0	0	0	1	1
161	1	1	1	1	0	0	0	0	1	1
162	1	1	1	1	0	0	0	0	1	1
N	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-13-10

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD)

SEX : Female GROUP : 100 mg/kg PERIOD : Day 21 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Stereotype	Bizarre behavior
			Reactivity to environmental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement		
251	1	1	1	1	0	0	0	0	1	1
252	1	1	1	1	0	0	0	0	1	1
253	1	1	1	1	0	0	0	0	1	1
254	1	1	1	1	0	0	0	0	1	1
255	1	1	1	1	0	0	0	0	1	1
256	1	1	1	1	0	0	0	0	1	1
257	1	1	1	1	0	0	0	0	1	1
258	1	1	1	1	0	0	0	0	1	1
259	1	1	1	1	0	0	0	0	1	1
260	1	1	1	1	0	0	0	0	1	1
261	1	1	1	1	0	0	0	0	1	1
262	1	1	1	1	0	0	0	0	1	1
N	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-13-11

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 300 mg/kg PERIOD : Day 21 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Stereotype	Bizarre behavior
			Reactivity to environmental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement		
351	1	1	1	1	0	0	0	0	1	1
352	1	1	1	1	0	0	0	0	1	1
353	1	1	1	1	0	0	0	0	1	1
354	1	1	1	1	0	0	0	0	1	1
355	1	1	1	1	0	0	0	0	1	1
356	1	1	1	1	0	0	0	0	1	1
357	1	1	1	1	0	0	0	0	1	1
358	1	1	1	1	0	0	0	0	1	1
359	1	1	1	1	0	0	0	0	1	1
360	1	1	1	1	0	0	0	0	1	1
361	1	1	1	1	0	0	0	0	1	1
362	1	1	1	1	0	0	0	0	1	1
N	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-13-12

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 21 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Stereotype	Bizarre behavior
			Reactivity to environmental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement		
451	1	1	1	1	0	0	0	0	1	1
452	1	1	1	1	0	0	0	0	1	1
453	1	1	1	1	0	0	0	0	1	1
454	1	1	1	1	0	0	0	0	1	1
455	1	1	1	1	0	0	0	0	1	1
456	1	1	1	1	0	0	0	0	1	1
457	1	1	1	1	0	0	0	0	1	1
458	1	1	1	1	0	0	0	0	1	1
459	1	1	1	1	0	0	0	0	1	1
460	1	1	1	1	0	0	0	0	1	1
461	1	1	1	1	0	0	0	0	1	1
462	1	1	1	1	0	0	0	0	1	1
N	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-13-13

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 21 of administration

Animal No.	Body position/ Posture pattern	In the cage			Bizarre behavior
		Stereotype	Tremor/ Convulsion	Rolling Repetitive circling	
163	1	1	1	0	0
164	1	1	1	0	0
165	1	1	1	0	0
166	1	1	1	0	0
167	1	1	1	0	0
N	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-13-14

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 21 of administration

Animal No.	Body position/ Posture	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
463	1	1	1	0	0
464	1	1	1	0	0
465	1	1	1	0	0
466	1	1	1	0	0
467	1	1	1	0	0
N	5	5	5	5	5

## INDIVIDUAL DATA 2-13-15

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 21 of administration

Animal No.	On the hand											
	Ease of		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
Removal	Handling											
163	1	1	2	1	1	0	1	1	1	1	1	0
164	1	1	2	1	1	0	1	1	1	1	1	0
165	1	1	2	1	1	0	1	1	1	1	1	0
166	1	1	2	1	1	0	1	1	1	1	1	0
167	1	1	2	1	1	0	1	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-13-16

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Female PERIOD : Day 21 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
463	1	1	2	1	1	0	0	1	1	1	1	1	1	0
464	1	1	2	1	1	1	0	0	1	1	1	1	1	0
465	1	1	2	1	1	1	0	0	1	1	1	1	1	0
466	1	1	2	1	1	1	0	0	1	1	1	1	1	0
467	1	1	2	1	1	1	0	0	1	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5

## INDIVIDUAL DATA 2-13-17

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 21 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						
			Reactivity to environmental stimuli			Stereotype	Bizarre behavior		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocalization
163	1	1	1	1	0	0	0	1	1
164	1	1	1	0	0	0	0	1	1
165	1	1	1	0	0	0	0	1	1
166	1	1	1	0	0	0	0	1	1
167	1	1	1	0	0	0	0	1	1
N	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	1.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-13-18

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Day 21 of administration PERIOD : Day 21 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
463	1	1	1	0	0	0	0	1	1	1	1
464	1	1	1	0	0	0	0	1	1	1	1
465	1	1	1	0	0	0	0	1	1	1	1
466	1	1	1	0	0	0	0	1	1	1	1
467	1	1	1	0	0	0	0	1	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5

## INDIVIDUAL DATA 2-14-1

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 28 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling Repetitive circling	Biting/ Selfmutilation	
151	1	1	1	0	0
152	1	1	1	0	0
153	1	1	1	0	0
154	1	1	1	0	0
155	1	1	1	0	0
156	1	1	1	0	0
157	1	1	1	0	0
158	1	1	1	0	0
159	1	1	1	0	0
160	1	1	1	0	0
161	1	1	1	0	0
162	1	1	1	0	0
N	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-14-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation

ANIMAL : Rat, Cri:CD(SD)

SEX : Female

GROUP : Day 28 of administration

PERIOD : Day 28 of administration

Animal No.	Body position/ Posture pattern	In the cage			Bizarre behavior
		Stereotype	Tremor/ Convulsion	Rolling Repetitive circling	
251	1	1	1	0	0
252	1	1	1	0	0
253	1	1	1	0	0
254	1	1	1	0	0
255	1	1	1	0	0
256	1	1	1	0	0
257	1	1	1	0	0
258	1	1	1	0	0
259	1	1	1	0	0
260	1	1	1	0	0
261	1	1	1	0	0
262	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-14-3

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation

ANIMAL : Rat, Cri:CD(SD)

SEX : Female

GROUP : Day 28 of administration

PERIOD : Day 28 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype	Tremor/ Convulsion	Rolling	Bizarre behavior
		Repetitive circling	Repetitive circling	Biting/ Selfmutilation	
351	1	1	1	0	0
352	1	1	1	0	0
353	1	1	1	0	0
354	1	1	1	0	0
355	1	1	1	0	0
356	1	1	1	0	0
357	1	1	1	0	0
358	1	1	1	0	0
359	1	1	1	0	0
360	1	1	1	0	0
361	1	1	1	0	0
362	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-14-4

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 28 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
451	1	1	1	0	0
452	1	1	1	0	0
453	1	1	1	0	0
454	1	1	1	0	0
455	1	1	1	0	0
456	1	1	1	0	0
457	1	1	1	0	0
458	1	1	1	0	0
459	1	1	1	0	0
460	1	1	1	0	0
461	1	1	1	0	0
462	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-14-5

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 28 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
151	1	1	2	1	1	0	1	1	1	1	1	1	1	0
152	1	1	2	1	1	0	1	1	1	1	1	1	1	0
153	1	1	2	1	1	0	1	1	1	1	1	1	1	0
154	1	1	2	1	1	0	1	1	1	1	1	1	1	0
155	1	1	2	1	1	0	1	1	1	1	1	1	1	0
156	1	1	2	1	1	0	1	1	1	1	1	1	1	0
157	1	1	2	1	1	0	1	1	1	1	1	1	1	0
158	1	1	2	1	1	0	1	1	1	1	1	1	1	0
159	1	1	2	1	1	0	1	1	1	1	1	1	1	0
160	1	1	2	1	1	0	1	1	1	1	1	1	1	0
161	1	1	2	1	1	0	1	1	1	1	1	1	1	0
162	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-14-6

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Female PERIOD : Day 28 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
251	1	1	2	1	1	0	1	1	1	1	1	1	1	0
252	1	1	2	1	1	0	1	1	1	1	1	1	1	0
253	1	1	2	1	1	0	1	1	1	1	1	1	1	0
254	1	1	2	1	1	0	1	1	1	1	1	1	1	0
255	1	1	2	1	1	0	1	1	1	1	1	1	1	0
256	1	1	2	1	1	0	1	1	1	1	1	1	1	0
257	1	1	2	1	1	0	1	1	1	1	1	1	1	0
258	1	1	2	1	1	0	1	1	1	1	1	1	1	0
259	1	1	2	1	1	0	1	1	1	1	1	1	1	0
260	1	1	2	1	1	0	1	1	1	1	1	1	1	0
261	1	1	2	1	1	0	1	1	1	1	1	1	1	0
262	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-14-7

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation

ANIMAL : Rat, Cri:CD(SD)

SEX : Female

GROUP : 300 mg/kg

PERIOD : Day 28 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
351	1	1	2	1	1	0	1	1	1	1	1	1	1	0
352	1	1	2	1	1	0	1	1	1	1	1	1	1	0
353	1	1	2	1	1	0	1	1	1	1	1	1	1	0
354	1	1	2	1	1	0	1	1	1	1	1	1	1	0
355	1	1	2	1	1	0	1	1	1	1	1	1	1	0
356	1	1	2	1	1	0	1	1	1	1	1	1	1	0
357	1	1	2	1	1	0	1	1	1	1	1	1	1	0
358	1	1	2	1	1	0	1	1	1	1	1	1	1	0
359	1	1	2	1	1	0	1	1	1	1	1	1	1	0
360	1	1	2	1	1	0	1	1	1	1	1	1	1	0
361	1	1	2	1	1	0	1	1	1	1	1	1	1	0
362	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-14-8

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Female PERIOD : Day 28 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
451	1	1	2	1	1	0	1	1	1	1	1	1	1	0
452	1	1	2	1	1	0	1	1	1	1	1	1	1	0
453	1	1	2	1	1	0	1	1	1	1	1	1	1	0
454	1	1	2	1	1	0	1	1	1	1	1	1	1	0
455	1	1	2	1	1	0	1	1	1	1	1	1	1	0
456	1	1	2	1	1	0	1	1	1	1	1	1	1	0
457	1	1	2	1	1	0	1	1	1	1	1	1	1	0
458	1	1	2	1	1	0	1	1	1	1	1	1	1	0
459	1	1	2	1	1	0	1	1	1	1	1	1	1	0
460	1	1	2	1	1	0	1	1	1	1	1	1	1	0
461	1	1	2	1	1	0	1	1	1	1	1	1	1	0
462	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-14-9

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 28 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward
											Vocalization Aggression
151	1	1	1	1	0	0	0	0	0	1	1
152	1	1	1	1	0	0	0	0	0	1	1
153	1	1	1	1	0	0	0	0	0	1	1
154	1	1	1	1	0	0	0	0	0	1	1
155	1	1	1	1	0	0	0	0	0	1	1
156	1	1	1	1	0	0	0	0	0	1	1
157	1	1	1	1	0	0	0	0	0	1	1
158	1	1	1	1	0	0	0	0	0	1	1
159	1	1	1	1	0	0	0	0	0	1	1
160	1	1	1	1	0	0	0	0	0	1	1
161	1	1	1	1	0	0	0	0	0	1	1
162	1	1	1	1	0	0	0	0	0	1	1
N	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	3.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-14-10

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD)

SEX : Female GROUP : Female

100 mg/kg

PERIOD : Day 28 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward
											Vocalization Aggression
251	1	1	1	1	0	0	0	0	0	1	1
252	1	1	1	1	1	0	0	0	0	1	1
253	1	1	1	1	0	0	0	0	0	1	1
254	1	1	1	1	0	0	0	0	0	1	1
255	1	1	1	1	0	0	0	0	0	1	1
256	1	1	1	1	0	0	0	0	0	1	1
257	1	1	1	1	0	0	0	0	0	1	1
258	1	1	1	1	0	0	0	0	0	1	1
259	1	1	1	1	0	0	0	0	0	1	1
260	1	1	1	1	0	0	0	0	0	1	1
261	1	1	1	1	0	0	0	0	0	1	1
262	1	1	1	1	0	0	0	0	0	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-14-11

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD)

SEX : Female GROUP : 300 mg/kg

PERIOD : Day 28 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward
											Vocalization Aggression
351	1	1	1	1	0	0	0	0	0	1	1
352	1	1	1	1	0	0	0	0	0	1	1
353	1	1	1	1	0	0	0	0	0	1	1
354	1	1	1	1	0	0	0	0	0	1	1
355	1	1	1	1	0	0	0	0	0	1	1
356	1	1	1	1	0	0	0	0	0	1	1
357	1	1	1	1	0	0	0	0	0	1	1
358	1	1	1	1	0	0	0	0	0	1	1
359	1	1	1	1	0	0	0	0	0	1	1
360	1	1	1	1	0	0	0	0	0	1	1
361	1	1	1	1	0	0	0	0	0	1	1
362	1	1	1	1	0	0	0	0	0	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-14-12

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 28 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward
											Vocalization Aggression
451	1	1	1	1	0	0	0	0	0	1	1
452	1	1	1	1	0	0	0	0	0	1	1
453	1	1	1	1	0	0	0	0	0	1	1
454	1	1	1	1	0	0	0	0	0	1	1
455	1	1	1	1	0	0	0	0	0	1	1
456	1	1	1	1	0	0	0	0	0	1	1
457	1	1	1	1	0	0	0	0	0	1	1
458	1	1	1	1	0	0	0	0	0	1	1
459	1	1	1	1	0	0	0	0	0	1	1
460	1	1	1	1	0	0	0	0	0	1	1
461	1	1	1	1	0	0	0	0	0	1	1
462	1	1	1	1	0	0	0	0	0	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-14-13

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 28 of administration

Animal No.	Body position/ Posture pattern	In the cage			Bizarre behavior
		Stereotype	Tremor/ Convulsion	Repetitive circling	
163	1	1	1	0	0
164	1	1	1	0	0
165	1	1	1	0	0
166	1	1	1	0	0
167	1	1	1	0	0
N	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-14-14

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 28 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
463	1	1	1	0	0
464	1	1	1	0	0
465	1	1	1	0	0
466	1	1	1	0	0
467	1	1	1	0	0
N	5	5	5	5	5

## INDIVIDUAL DATA 2-14-15

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 28 of administration

Animal No.	On the hand										
	Ease of		Muscle tone	Piloerection	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
Removal	Handling										
163	1	1	2	1	1	0	1	1	1	1	0
164	1	1	2	1	1	0	1	1	1	1	0
165	1	1	2	1	1	0	1	1	1	1	0
166	1	1	2	1	1	0	1	1	1	1	0
167	1	1	2	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-14-16

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Female PERIOD : Day 28 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/Excretions
463	1	1	2	1	1	0	0	1	1	1	1	1	1	0
464	1	1	2	1	1	1	0	0	1	1	1	1	1	0
465	1	1	2	1	1	1	0	0	1	1	1	1	1	0
466	1	1	2	1	1	1	0	0	1	1	1	1	1	0
467	1	1	2	1	1	1	0	0	1	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5

## INDIVIDUAL DATA 2-14-17

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 28 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field							
			Reactivity to environmental stimuli			Stereotype	Bizarre behavior			
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocalization	Aggression
163	1	1	1	1	0	0	0	1	1	1
164	1	1	1	0	0	0	0	1	1	1
165	1	1	1	0	0	0	0	1	1	1
166	1	1	1	0	0	0	0	1	1	1
167	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	1.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-14-18

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Female PERIOD : Day 28 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field					
			Reactivity to environmental stimuli			Stereotype		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward
463	1	1	1	0	0	0	0	1
464	1	1	1	0	0	0	0	1
465	1	1	1	0	0	0	0	1
466	1	1	1	0	0	0	0	1
467	1	1	1	0	0	0	0	1
N	5	5	5	5	5	5	5	5

## INDIVIDUAL DATA 2-15-1

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 35 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling Repetitive circling	Biting/ Selfmutilation	
151	1	1	1	0	0
152	1	1	1	0	0
153	1	1	1	0	0
154	1	1	1	0	0
155	1	1	1	0	0
156	1	1	1	0	0
157	1	1	1	0	0
158	1	1	1	0	0
159	1	1	1	0	0
160	1	1	1	0	0
161	1	1	1	0	0
162	1	1	1	0	0
N	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-15-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 100 mg/kg PERIOD : Day 35 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling Repetitive circling	Biting/ Selfmutilation	
251	1	1	1	0	0
252	1	1	1	0	0
253	1	1	1	0	0
254	1	1	1	0	0
255	1	1	1	0	0
256	1	1	1	0	0
257	1	1	1	0	0
258	1	1	1	0	0
259	1	1	1	0	0
260	1	1	1	0	0
261	1	1	1	0	0
262	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-15-3

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation

ANIMAL : Rat, Cri:CD(SD)

SEX : Female

GROUP : Day 35 of administration

PERIOD : Day 35 of administration

Animal No.	Body position/ Posture pattern	In the cage				Bizarre behavior	
		Stereotype		Tremor/ Convulsion	Rolling Repetitive circling		
351	1	1	1	0	0	1	
352	1	1	1	0	0	1	
353	1	1	1	0	0	1	
354	1	1	1	0	0	1	
355	1	1	1	0	0	1	
356	1	1	1	0	0	1	
357	1	1	1	0	0	1	
358	1	1	1	0	0	1	
359	1	1	1	0	0	1	
360	1	1	1	0	0	1	
361	1	1	1	0	0	1	
362	1	1	1	0	0	1	
N	12	12	12	12	12	12	

## INDIVIDUAL DATA 2-15-4

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 35 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
451	1	1	1	0	0
452	1	1	1	0	0
453	1	1	1	0	0
454	1	1	1	0	0
455	1	1	1	0	0
456	1	1	1	0	0
457	1	1	1	0	0
458	1	1	1	0	0
459	1	1	1	0	0
460	1	1	1	0	0
461	1	1	1	0	0
462	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-15-5

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 35 of administration

Animal No.	On the hand												
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation
151	1	1	2	1	1	0	0	1	1	1	1	1	0
152	1	1	2	1	1	0	0	1	1	1	1	1	0
153	1	1	2	1	1	0	0	1	1	1	1	1	0
154	1	1	2	1	1	0	0	1	1	1	1	1	0
155	1	1	2	1	1	0	0	1	1	1	1	1	0
156	1	1	2	1	1	0	0	1	1	1	1	1	0
157	1	1	2	1	1	0	0	1	1	1	1	1	0
158	1	1	2	1	1	0	0	1	1	1	1	1	0
159	1	1	2	1	1	0	0	1	1	1	1	1	0
160	1	1	2	1	1	0	0	1	1	1	1	1	0
161	1	1	2	1	1	0	0	1	1	1	1	1	0
162	1	1	2	1	1	0	0	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-15-6

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Female 100 mg/kg PERIOD : Day 35 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
251	1	1	2	1	1	1	0	0	1	1	1	1	1	0
252	1	1	2	1	1	1	0	0	1	1	1	1	1	0
253	1	1	2	1	1	1	0	0	1	1	1	1	1	0
254	1	1	2	1	1	1	0	1	1	1	1	1	1	0
255	1	1	2	1	1	1	0	0	1	1	1	1	1	0
256	1	1	2	1	1	1	0	0	1	1	1	1	1	0
257	1	1	2	1	1	1	0	0	1	1	1	1	1	0
258	1	1	2	1	1	1	0	0	1	1	1	1	1	0
259	1	1	2	1	1	1	0	0	1	1	1	1	1	0
260	1	1	2	1	1	1	0	0	1	1	1	1	1	0
261	1	1	2	1	1	1	0	1	1	1	1	1	1	0
262	1	1	2	1	1	1	0	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-15-7

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 300 mg/kg PERIOD : Day 35 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
351	1	1	2	1	1	0	1	1	1	1	1	1	1	0
352	1	1	2	1	1	0	1	1	1	1	1	1	1	0
353	1	1	2	1	1	0	1	1	1	1	1	1	1	0
354	1	1	2	1	1	0	1	1	1	1	1	1	1	0
355	1	1	2	1	1	0	1	1	1	1	1	1	1	0
356	1	1	2	1	1	0	1	1	1	1	1	1	1	0
357	1	1	2	1	1	0	1	1	1	1	1	1	1	0
358	1	1	2	1	1	0	1	1	1	1	1	1	1	0
359	1	1	2	1	1	0	1	1	1	1	1	1	1	0
360	1	1	2	1	1	0	1	1	1	1	1	1	1	0
361	1	1	2	1	1	0	1	1	1	1	1	1	1	0
362	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-15-8

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Female PERIOD : Day 35 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
451	1	1	2	1	1	0	1	1	1	1	1	1	1	0
452	1	1	2	1	1	0	1	1	1	1	1	1	1	0
453	1	1	2	1	1	0	1	1	1	1	1	1	1	0
454	1	1	2	1	1	0	1	1	1	1	1	1	1	0
455	1	1	2	1	1	0	1	1	1	1	1	1	1	0
456	1	1	2	1	1	0	1	1	1	1	1	1	1	0
457	1	1	2	1	1	0	1	1	1	1	1	1	1	0
458	1	1	2	1	1	0	1	1	1	1	1	1	1	0
459	1	1	2	1	1	0	1	1	1	1	1	1	1	0
460	1	1	2	1	1	0	1	1	1	1	1	1	1	0
461	1	1	2	1	1	0	1	1	1	1	1	1	1	0
462	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-15-9

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 35 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward Vocalization Aggression		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement				
151	1	1	1	1	0	0	0	0	1	1	1
152	1	1	1	1	0	0	0	0	1	1	1
153	1	1	1	1	0	0	0	0	1	1	1
154	1	1	1	1	0	0	0	0	1	1	1
155	1	1	1	1	0	0	0	0	1	1	1
156	1	1	1	1	0	0	0	0	1	1	1
157	1	1	1	1	0	0	0	0	1	1	1
158	1	1	1	1	0	0	0	0	1	1	1
159	1	1	1	1	0	0	0	0	1	1	1
160	1	1	1	1	0	0	0	0	1	1	1
161	1	1	1	1	0	0	0	0	1	1	1
162	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-15-10

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Female 100 mg/kg PERIOD : Day 35 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward Vocalization Aggression		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement				
251	1	1	1	1	0	0	0	0	1	1	1
252	1	1	1	1	0	0	0	0	1	1	1
253	1	1	1	1	0	0	0	0	1	1	1
254	1	1	1	1	0	0	0	0	1	1	1
255	1	1	1	1	0	0	0	0	1	1	1
256	1	1	1	1	0	0	0	0	1	1	1
257	1	1	1	1	0	0	0	0	1	1	1
258	1	1	1	1	0	0	0	0	1	1	1
259	1	1	1	1	0	0	0	0	1	1	1
260	1	1	1	1	0	0	0	0	1	1	1
261	1	1	1	1	0	0	0	0	1	1	1
262	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-15-11

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 300 mg/kg PERIOD : Day 35 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward Vocalization Aggression		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement				
351	1	1	1	1	0	0	0	0	1	1	1
352	1	1	1	1	0	0	0	0	1	1	1
353	1	1	1	1	0	0	0	0	1	1	1
354	1	1	1	1	0	0	0	0	1	1	1
355	1	1	1	1	0	0	0	0	1	1	1
356	1	1	1	1	0	0	0	0	1	1	1
357	1	1	1	1	0	0	0	0	1	1	1
358	1	1	1	1	0	0	0	0	1	1	1
359	1	1	1	1	0	0	0	0	1	1	1
360	1	1	1	1	0	0	0	0	1	1	1
361	1	1	1	1	0	0	0	0	1	1	1
362	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-15-12

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Day 35 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward Vocalization Aggression		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement				
451	1	1	1	1	0	0	0	0	1	1	1
452	1	1	1	1	0	0	0	0	1	1	1
453	1	1	1	1	0	0	0	0	1	1	1
454	1	1	1	1	0	0	0	0	1	1	1
455	1	1	1	1	0	0	0	0	1	1	1
456	1	1	1	1	0	0	0	0	1	1	1
457	1	1	1	1	0	0	0	0	1	1	1
458	1	1	1	1	0	0	0	0	1	1	1
459	1	1	1	1	0	0	0	0	1	1	1
460	1	1	1	1	0	0	0	0	1	1	1
461	1	1	1	1	0	0	0	0	1	1	1
462	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-15-13

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 35 of administration

Animal No.	Body position/ Posture pattern	In the cage			Bizarre behavior
		Stereotype	Tremor/ Convulsion	Repetitive circling	
163	1	1	1	0	0
164	1	1	1	0	0
165	1	1	1	0	0
166	1	1	1	0	0
167	1	1	1	0	0
N	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-15-14

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Female PERIOD : Day 35 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
463	1	1	1	0	0
464	1	1	1	0	0
465	1	1	1	0	0
466	1	1	1	0	0
467	1	1	1	0	0
N	5	5	5	5	5

## INDIVIDUAL DATA 2-15-15

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 35 of administration

Animal No.	On the hand									
	Ease of		Muscle tone	Piloerection	Eyes	Mucous membranes	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
Removal	Handling									
163	1	1	2	1	1	0	1	1	1	0
164	1	1	2	1	1	0	1	1	1	0
165	1	1	2	1	1	0	1	1	1	0
166	1	1	2	1	1	0	1	1	1	0
167	1	1	2	1	1	0	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000


## INDIVIDUAL DATA 2-15-16

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Female PERIOD : Day 35 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/Excretions
463	1	1	2	1	1	0	0	1	1	1	1	1	1	0
464	1	1	2	1	1	1	0	0	1	1	1	1	1	0
465	1	1	2	1	1	1	0	0	1	1	1	1	1	0
466	1	1	2	1	1	1	0	0	1	1	1	1	1	0
467	1	1	2	1	1	1	0	0	1	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5

## INDIVIDUAL DATA 2-15-17

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 35 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
163	1	1	1	0	0	0	0	1	1	1	1
164	1	1	1	0	0	0	0	1	1	1	1
165	1	1	1	0	0	0	0	1	1	1	1
166	1	1	1	0	0	0	0	1	1	1	1
167	1	1	1	0	0	0	0	1	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-15-18

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Day 35 of administration PERIOD : Day 35 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
463	1	1	1	0	0	0	0	1	1	1	1
464	1	1	1	0	0	0	0	1	1	1	1
465	1	1	1	0	0	0	0	1	1	1	1
466	1	1	1	0	0	0	0	1	1	1	1
467	1	1	1	0	0	0	0	1	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5

## INDIVIDUAL DATA 2-16-1

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 42 of administration

Animal No.	Body position/ Posture pattern	In the cage				Bizarre behavior	
		Stereotype		Tremor/ Convulsion	Rolling Repetitive circling		
151	1	1	1	0	0	1	
152	1	1	1	0	0	1	
153	1	1	1	0	0	1	
154	1	1	1	0	0	1	
155	1	1	1	0	0	1	
156	1	1	1	0	0	1	
157	1	1	1	0	0	1	
158	1	1	1	0	0	1	
159	1	1	1	0	0	1	
160	1	1	1	0	0	1	
161	1	1	1	0	0	1	
162	1	1	1	0	0	1	
N	12	12	12	12	12	12	
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	

## INDIVIDUAL DATA 2-16-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 100 mg/kg PERIOD : Day 42 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
251	1	1	1	0	0
252	1	1	1	0	0
253	1	1	1	0	0
254	1	1	1	0	0
255	1	1	1	0	0
256	1	1	1	0	0
257	1	1	1	0	0
258	1	1	1	0	0
259	1	1	1	0	0
260	1	1	1	0	0
261	1	1	1	0	0
262	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-16-3

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 300 mg/kg PERIOD : Day 42 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
351	1	1	1	0	0
352	1	1	1	0	0
353	1	1	1	0	0
354	1	1	1	0	0
355	1	1	1	0	0
356	1	1	1	0	0
357	1	1	1	0	0
358	1	1	1	0	0
359	1	1	1	0	0
360	1	1	1	0	0
361	1	1	1	0	0
362	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-16-4

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 42 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
451	1	1	1	0	0
452	1	1	1	0	0
453	1	1	1	0	0
454	1	1	1	0	0
455	1	1	1	0	0
456	1	1	1	0	0
457	1	1	1	0	0
458	1	1	1	0	0
459	1	1	1	0	0
460	1	1	1	0	0
461	1	1	1	0	0
462	1	1	1	0	0
N	12	12	12	12	12

## INDIVIDUAL DATA 2-16-5

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 42 of administration

Animal No.	On the hand												
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation
151	1	1	2	1	1	0	0	1	1	1	1	1	0
152	1	1	2	1	1	0	0	1	1	1	1	1	0
153	1	1	2	1	1	0	0	1	1	1	1	1	0
154	1	1	2	1	1	0	0	1	1	1	1	1	0
155	1	1	2	1	1	0	0	1	1	1	1	1	0
156	1	1	2	1	1	0	0	1	1	1	1	1	0
157	1	1	2	1	1	0	0	1	1	1	1	1	0
158	1	1	2	1	1	0	0	1	1	1	1	1	0
159	1	1	2	1	1	0	0	1	1	1	1	1	0
160	1	1	2	1	1	0	0	1	1	1	1	1	0
161	1	1	2	1	1	0	0	1	1	1	1	1	0
162	1	1	2	1	1	0	0	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-16-6

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 100 mg/kg PERIOD : Day 42 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
251	1	1	2	1	1	0	1	1	1	1	1	1	1	0
252	1	1	2	1	1	0	1	1	1	1	1	1	1	0
253	1	1	2	1	1	0	1	1	1	1	1	1	1	0
254	1	1	2	1	1	0	1	1	1	1	1	1	1	0
255	1	1	2	1	1	0	1	1	1	1	1	1	1	0
256	1	1	2	1	1	0	1	1	1	1	1	1	1	0
257	1	1	2	1	1	0	1	1	1	1	1	1	1	0
258	1	1	2	1	1	0	1	1	1	1	1	1	1	0
259	1	1	2	1	1	0	1	1	1	1	1	1	1	0
260	1	1	2	1	1	0	1	1	1	1	1	1	1	0
261	1	1	2	1	1	0	1	1	1	1	1	1	1	0
262	1	1	2	1	1	0	1	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-16-7

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation

ANIMAL : Rat, Cri:CD(SD)

SEX : Female

GROUP : 300 mg/kg

PERIOD : Day 42 of administration

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
351	1	1	2	1	1	1	0	1	1	1	1	1	1	0
352	1	1	2	1	1	1	0	0	1	1	1	1	1	0
353	1	1	2	1	1	1	0	0	1	1	1	1	1	0
354	1	1	2	1	1	1	0	1	1	1	1	1	1	0
355	1	1	2	1	1	1	0	0	1	1	1	1	1	0
356	1	1	2	1	1	1	0	0	1	1	1	1	1	0
357	1	1	2	1	1	1	0	1	1	1	1	1	1	0
358	1	1	2	1	1	1	0	1	1	1	1	1	1	0
359	1	1	2	1	1	1	0	0	1	1	1	1	1	0
360	1	1	2	1	1	1	0	0	1	1	1	1	1	0
361	1	1	2	1	1	1	0	1	1	1	1	1	1	0
362	1	1	2	1	1	1	0	1	1	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12	12	

## INDIVIDUAL DATA 2-16-8

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 42 of administration

Animal No.	On the hand									
	Ease of Removal		Handling	Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size
										Secretions/ Excretions
451	1	1	2	1	1	1	0	1	1	1
452	1	1	2	1	1	1	0	1	1	1
453	1	1	2	1	1	1	0	1	1	1
454	1	1	2	1	1	1	0	1	1	1
455	1	1	2	1	1	1	0	1	1	1
456	1	1	2	1	1	1	0	1	1	1
457	1	1	2	1	1	1	0	1	1	1
458	1	1	2	1	1	1	0	1	1	1
459	1	1	2	1	1	1	0	1	1	1
460	1	1	2	1	1	1	0	1	1	1
461	1	1	2	1	1	1	0	1	1	1
462	1	1	2	1	1	1	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-16-9

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 42 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward Vocalization Aggression		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement				
151	1	1	1	1	0	0	0	0	1	1	1
152	1	1	1	1	0	0	0	0	1	1	1
153	1	1	1	1	0	0	0	0	1	1	1
154	1	1	1	1	0	0	0	0	1	1	1
155	1	1	1	1	0	0	0	0	1	1	1
156	1	1	1	1	0	0	0	0	1	1	1
157	1	1	1	1	0	0	0	0	1	1	1
158	1	1	1	1	0	0	0	0	1	1	1
159	1	1	1	1	0	0	0	0	1	1	1
160	1	1	1	1	0	0	0	0	1	1	1
161	1	1	1	1	0	0	0	0	1	1	1
162	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	3.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-16-10

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD)

SEX : Female GROUP : Female

PERIOD : Day 42 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
251	1	1	1	1	0	0	0	0	1	1	1
252	1	1	1	1	0	0	0	0	1	1	1
253	1	1	1	1	0	0	0	0	1	1	1
254	1	1	1	1	0	0	0	0	1	1	1
255	1	1	1	1	0	0	0	0	1	1	1
256	1	1	1	1	0	0	0	0	1	1	1
257	1	1	1	1	0	0	0	0	1	1	1
258	1	1	1	1	0	0	0	0	1	1	1
259	1	1	1	1	0	0	0	0	1	1	1
260	1	1	1	1	0	0	0	0	1	1	1
261	1	1	1	1	0	0	0	0	1	1	1
262	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-16-11

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 300 mg/kg PERIOD : Day 42 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Vocalization	Aggression		
351	1	1	1	1	0	0	0	0	1	1	1
352	1	1	1	1	0	0	0	0	1	1	1
353	1	1	1	1	0	0	0	0	1	1	1
354	1	1	1	1	0	0	0	0	1	1	1
355	1	1	1	1	0	0	0	0	1	1	1
356	1	1	1	1	0	0	1	0	1	1	1
357	1	1	1	1	0	0	0	0	1	1	1
358	1	1	1	1	0	0	0	0	1	1	1
359	1	1	1	1	0	0	0	0	1	1	1
360	1	1	1	1	0	0	0	0	1	1	1
361	1	1	1	1	0	0	0	0	1	1	1
362	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-16-12

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 42 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward Vocalization Aggression		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement				
451	1	1	1	1	0	0	0	0	1	1	1
452	1	1	1	1	0	0	0	0	1	1	1
453	1	1	1	1	0	0	0	0	1	1	1
454	1	1	1	1	0	0	0	0	1	1	1
455	1	1	1	1	0	0	0	0	1	1	1
456	1	1	1	1	0	0	0	0	1	1	1
457	1	1	1	1	0	0	0	0	1	1	1
458	1	1	1	1	0	0	0	0	1	1	1
459	1	1	1	1	0	0	0	0	1	1	1
460	1	1	1	1	0	0	0	0	1	1	1
461	1	1	1	1	0	0	0	0	1	1	1
462	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

## INDIVIDUAL DATA 2-16-13

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 42 of administration

Animal No.	Body position/ Posture pattern	In the cage			Bizarre behavior
		Stereotype	Tremor/ Convulsion	Repetitive circling	
163	1	1	1	0	0
164	1	1	1	0	0
165	1	1	1	0	0
166	1	1	1	0	0
167	1	1	1	0	0
N	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-16-14

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 42 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
463	1	1	1	0	0
464	1	1	1	0	0
465	1	1	1	0	0
466	1	1	1	0	0
467	1	1	1	0	0
N	5	5	5	5	5

## INDIVIDUAL DATA 2-16-15

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 42 of administration

Animal No.	On the hand										
	Ease of		Muscle tone	Piloerection	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
Removal	Handling										
163	1	1	2	1	1	0	1	1	1	1	0
164	1	1	2	1	1	0	1	1	1	1	0
165	1	1	2	1	1	0	1	1	1	1	0
166	1	1	2	1	1	0	1	1	1	1	0
167	1	1	2	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-16-16

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Female PERIOD : Day 42 of administration

Animal No.	On the hand											
	Ease of		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/Excretions
Removal	Handling											
463	1	1	2	1	1	0	1	1	1	1	1	0
464	1	1	2	1	1	0	1	1	1	1	1	0
465	1	1	2	1	1	0	1	1	1	1	1	0
466	1	1	2	1	1	0	1	1	1	1	1	0
467	1	1	2	1	1	0	1	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5

## INDIVIDUAL DATA 2-16-17

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 42 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field				Stereotype			Bizarre behavior		
			Reactivity to environmental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocalization	Aggression	
163	1	1	1	1	0	0	0	0	1	1	1	1
164	1	1	1	1	0	0	0	0	1	1	1	1
165	1	1	1	1	0	0	0	0	1	1	1	1
166	1	1	1	1	0	0	0	0	1	1	1	1
167	1	1	1	1	0	0	0	0	1	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-16-18

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Female PERIOD : Day 42 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field					
			Reactivity to environmental stimuli			Stereotype		
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward
463	1	1	1	0	0	0	0	1
464	1	1	1	0	0	0	0	1
465	1	1	1	0	0	0	0	1
466	1	1	1	0	0	0	0	1
467	1	1	1	0	0	0	0	1
N	5	5	5	5	5	5	5	5

## INDIVIDUAL DATA 2-16-19

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 49 of administration

Animal No.	Body position/ Posture pattern	In the cage				
		Stereotype	Tremor/ Convulsion	Rolling	Repetitive circling	Biting/ Selfmutilation
151	#	#	#	#	#	#
152	#	#	#	#	#	#
153	#	#	#	#	#	#
154	#	#	#	#	#	#
155	#	#	#	#	#	#
156	#	#	#	#	#	#
157	#	#	#	#	#	#
158	#	#	#	#	#	#
159	#	#	#	#	#	#
160	#	#	#	#	#	#
161	#	#	#	#	#	#
162	1	1	1	0	0	1
N	1	1	1	1	1	1

# : Not applicable.

## INDIVIDUAL DATA 2-16-20

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 49 of administration

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling Repetitive circling	Biting/ Selfmutilation	
451	#	#	#	#	#
452	#	#	#	#	#
453	#	#	#	#	#
454	1	1	0	0	1
455	#	#	#	#	#
456	#	#	#	#	#
457	#	#	#	#	#
458	#	#	#	#	#
459	#	#	#	#	#
460	#	#	#	#	#
461	#	#	#	#	#
462	#	#	#	#	#
N	1	1	1	1	1

# : Not applicable.

## INDIVIDUAL DATA 2-16-21

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Day 49 of administration

Animal No.	On the hand											
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur					
	#	#	#	#	#	#	#	#	#	#	#	#
151	#	#	#	#	#	#	#	#	#	#	#	#
152	#	#	#	#	#	#	#	#	#	#	#	#
153	#	#	#	#	#	#	#	#	#	#	#	#
154	#	#	#	#	#	#	#	#	#	#	#	#
155	#	#	#	#	#	#	#	#	#	#	#	#
156	#	#	#	#	#	#	#	#	#	#	#	#
157	#	#	#	#	#	#	#	#	#	#	#	#
158	#	#	#	#	#	#	#	#	#	#	#	#
159	#	#	#	#	#	#	#	#	#	#	#	#
160	#	#	#	#	#	#	#	#	#	#	#	#
161	#	#	#	#	#	#	#	#	#	#	#	#
162	1	1	2	1	1	1	0	1	1	1	1	0
N	1	1	1	1	1	1	1	1	1	1	1	1

# : Not applicable.

## INDIVIDUAL DATA 2-16-22

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Female PERIOD : Day 49 of administration

Animal No.	On the hand									
	Ease of Removal		Handling	Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size
	#	#	#	#	#	#	#	#	#	#
451	#	#	#	#	#	#	#	#	#	#
452	#	#	#	#	#	#	#	#	#	#
453	#	#	#	#	#	#	#	#	#	#
454	1	1	2	1	1	1	0	1	1	1
455	#	#	#	#	#	#	#	#	#	#
456	#	#	#	#	#	#	#	#	#	#
457	#	#	#	#	#	#	#	#	#	#
458	#	#	#	#	#	#	#	#	#	#
459	#	#	#	#	#	#	#	#	#	#
460	#	#	#	#	#	#	#	#	#	#
461	#	#	#	#	#	#	#	#	#	#
462	#	#	#	#	#	#	#	#	#	#
N	1	1	1	1	1	1	1	1	1	1

# : Not applicable.

Animal No.	Gait	Co-ordination of movement	In the open-field				Stereotype			Bizarre behavior		
			Reactivity to environmental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocalization	Aggression	
151	#	#	#	#	#	#	#	#	#	#	#	#
152	#	#	#	#	#	#	#	#	#	#	#	#
153	#	#	#	#	#	#	#	#	#	#	#	#
154	#	#	#	#	#	#	#	#	#	#	#	#
155	#	#	#	#	#	#	#	#	#	#	#	#
156	#	#	#	#	#	#	#	#	#	#	#	#
157	#	#	#	#	#	#	#	#	#	#	#	#
158	#	#	#	#	#	#	#	#	#	#	#	#
159	#	#	#	#	#	#	#	#	#	#	#	#
160	#	#	#	#	#	#	#	#	#	#	#	#
161	#	#	#	#	#	#	#	#	#	#	#	#
162	1	1	1	0	0	0	0	0	1	1	1	1
N	1	1	1	1	1	1	1	1	1	1	1	1

# : Not applicable.

## INDIVIDUAL DATA 2-16-24

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Female PERIOD : Day 49 of administration

Animal No.	Gait	Co-ordination of movement	In the open-field						Bizarre behavior		
			Reactivity to environmental stimuli			Stereotype			Walking backward		
			Unusual head movement	Excessive grooming	Defecation	Unusual head	grooming movement	Urination	Searching	Defecation	Vocalization Aggression
451	#	#	#	#	#	#	#	#	#	#	#
452	#	#	#	#	#	#	#	#	#	#	#
453	#	#	#	#	#	#	#	#	#	#	#
454	1	1	1	0	0	0	0	0	1	1	1
455	#	#	#	#	#	#	#	#	#	#	#
456	#	#	#	#	#	#	#	#	#	#	#
457	#	#	#	#	#	#	#	#	#	#	#
458	#	#	#	#	#	#	#	#	#	#	#
459	#	#	#	#	#	#	#	#	#	#	#
460	#	#	#	#	#	#	#	#	#	#	#
461	#	#	#	#	#	#	#	#	#	#	#
462	#	#	#	#	#	#	#	#	#	#	#
N	1	1	1	1	1	1	1	1	1	1	1

# : Not applicable.

## INDIVIDUAL DATA 2-17-1

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD)

SEX : Female GROUP : 0 mg/kg PERIOD : Day 7 of recovery

Animal No.	Body position/ Posture pattern	In the cage			Bizarre behavior
		Stereotype	Tremor/ Convulsion	Rolling Repetitive circling	
163	1	1	1	0	0
164	1	1	1	0	0
165	1	1	1	0	0
166	1	1	1	0	0
167	1	1	1	0	0

N	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-17-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Day 7 of recovery PERIOD : Day 7 of recovery

Animal No.	Body position/ Posture pattern	In the cage			Bizarre behavior
		Stereotype	Tremor/ Convulsion	Rolling circling	
463	1	1	1	0	0
464	1	1	1	0	0
465	1	1	1	0	0
466	1	1	1	0	0
467	1	1	1	0	0
N	5	5	5	5	5

## INDIVIDUAL DATA 2-17-3

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 7 of recovery

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
163	1	1	2	1	1	1	0	0	1	1	1	1	1	0
164	1	1	2	1	1	1	0	0	1	1	1	1	1	0
165	1	1	2	1	1	1	0	0	1	1	1	1	1	0
166	1	1	2	1	1	1	0	0	1	1	1	1	1	0
167	1	1	2	1	1	1	0	0	1	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-17-4

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD)

SEX : Female GROUP : Day 7 of recovery

PERIOD : Day 7 of recovery

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
463	1	1	2	1	1	1	0	0	1	1	1	1	1	0
464	1	1	2	1	1	1	0	0	1	1	1	1	1	0
465	1	1	2	1	1	1	0	0	1	1	1	1	1	0
466	1	1	2	1	1	1	0	0	1	1	1	1	1	0
467	1	1	2	1	1	1	0	0	1	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5

## INDIVIDUAL DATA 2-17-5

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 7 of recovery

Animal No.	Gait	Co-ordination of movement	In the open-field					
			Reactivity to environmental stimuli			Stereotype	Bizarre behavior	
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward
163	1	1	1	0	0	0	0	1
164	1	1	1	0	0	0	0	1
165	1	1	1	0	0	0	0	1
166	1	1	1	0	0	0	0	1
167	1	1	1	0	0	0	0	1
N	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-17-6

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 7 of recovery

Animal No.	Gait	Co-ordination of movement	In the open-field							
			Reactivity to environmental stimuli			Stereotype	Bizarre behavior			
			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocalization	Aggression
463	1	1	1	0	0	0	0	1	1	1
464	1	1	1	0	0	0	0	1	1	1
465	1	1	1	0	0	0	0	1	1	1
466	1	1	1	0	0	0	0	1	1	1
467	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5

## INDIVIDUAL DATA 2-18-1

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD)

SEX : Female GROUP : 0 mg/kg PERIOD : Day 14 of recovery

Animal No.	Body position/ Posture pattern	In the cage			Bizarre behavior
		Stereotype	Tremor/ Convulsion	Rolling Repetitive circling	
163	1	1	1	0	0
164	1	1	1	0	0
165	1	1	1	0	0
166	1	1	1	0	0
167	1	1	1	0	0

N	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-18-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Day 14 of recovery PERIOD : Day 14 of recovery

Animal No.	Body position/ Posture pattern	In the cage			
		Stereotype		Bizarre behavior	
		Tremor/ Convulsion	Rolling circling	Repetitive circling	Biting/ Selfmutilation
463	1	1	1	0	0
464	1	1	1	0	0
465	1	1	1	0	0
466	1	1	1	0	0
467	1	1	1	0	0
N	5	5	5	5	5

## INDIVIDUAL DATA 2-18-3

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 14 of recovery

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
163	1	1	2	1	1	1	0	0	1	1	1	1	1	0
164	1	1	2	1	1	1	0	0	1	1	1	1	1	0
165	1	1	2	1	1	1	0	0	1	1	1	1	1	0
166	1	1	2	1	1	1	0	0	1	1	1	1	1	0
167	1	1	2	1	1	1	0	0	1	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-18-4

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : Female PERIOD : Day 14 of recovery

Animal No.	On the hand													
	Ease of Removal		Handling		Muscle tone	Piloerection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrimation	Salivation	Secretions/ Excretions
463	1	1	2	1	1	1	0	0	1	1	1	1	1	0
464	1	1	2	1	1	1	0	0	1	1	1	1	1	0
465	1	1	2	1	1	1	0	0	1	1	1	1	1	0
466	1	1	2	1	1	1	0	0	1	1	1	1	1	0
467	1	1	2	1	1	1	0	0	1	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5

## INDIVIDUAL DATA 2-18-5

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 14 of recovery

Animal No.	Gait	Co-ordination of movement	In the open-field						Stereotype			Bizarre behavior		
			Reactivity to environmental stimuli			Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocalization	Aggression	
163	1	1	1	1	0	0	0	0	0	0	1	1	1	1
164	1	1	1	1	0	0	0	0	0	0	1	1	1	1
165	1	1	1	1	0	0	0	0	0	0	1	1	1	1
166	1	1	1	1	0	0	0	0	0	0	1	1	1	1
167	1	1	1	1	0	0	0	0	0	0	1	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 2-18-6

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Detailed clinical observation ANIMAL : Rat, Cri:CD(SD)

SEX : Female GROUP : Female

PERIOD : Day 14 of recovery

Animal No.	Gait	Co-ordination of movement	In the open-field						Stereotype	Bizarre behavior		
			Reactivity to environmental stimuli			Urination	Defecation	Excessive grooming				
			Searching	Aggression	Walking backward							
463	1	1	1	1	0	0	0	0	1	1		
464	1	1	1	1	0	0	0	0	1	1		
465	1	1	1	1	0	0	0	0	1	1		
466	1	1	1	1	0	0	0	0	1	1		
467	1	1	1	1	0	0	0	0	1	1		
N	5	5	5	5	5	5	5	5	5	5		

INDIVIDUAL DATA 3-1-1  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Week 6 of administration

Animal No.	Reactivity			Righting reflex	
	Visual	Touch	Auditory	Pain	Proprioceptive
103	4	2	1	2	1
107	4	2	1	2	1
109	4	2	1	2	1
110	4	2	1	2	1
111	4	2	1	2	1
N	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 3-1-2  
STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : Week 6 of administration

Animal No.	Reactivity			Pain	Proprioceptive	Righting reflex
	Visual	Touch	Auditory			
202	4	2	1	2	1	1
203	4	2	1	2	1	1
205	4	2	1	2	1	1
208	4	2	1	2	1	1
211	4	2	1	2	1	1
N	5	5	5	5	5	5

INDIVIDUAL DATA 3-1-3  
STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : Week 6 of administration

Animal No.	Reactivity			Righting reflex	
	Visual	Touch	Auditory	Pain	Proprioceptive
302	4	2	1	2	1
303	4	2	1	2	1
305	4	2	1	2	1
307	4	2	1	2	1
310	4	2	1	2	1
N	5	5	5	5	5

## INDIVIDUAL DATA 3-1-4

STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Functional test ANIMAL : Rat, Cri:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Week 6 of administration

Animal No.	Reactivity			Righting reflex	
	Visual	Touch	Auditory	Pain	Proprioceptive
401	4	2	1	2	1
403	4	2	1	2	1
407	4	2	1	2	1
409	4	2	1	2	1
410	4	2	1	2	1
N	5	5	5	5	5

INDIVIDUAL DATA 3-2-1  
STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Week 6 of administration

Animal No.	Grip strength (g)		Motor activity measurements (count)						
	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	Total
103	1173.7	449.7	528	330	199	60	69	126	1312
107	958.0	437.0	879	459	420	255	247	234	2494
109	1055.0	468.0	711	550	414	324	355	365	2719
110	1173.7	446.7	582	254	115	2	0	16	969
111	1001.0	473.7	806	595	395	224	86	147	2253
N	5	5	5	5	5	5	5	5	5
MEAN	1072.28	455.02	701.2	437.6	308.6	173.0	151.4	177.6	1949.4
S.D.	98.76	15.33	147.4	144.2	141.8	136.1	145.4	130.4	766.2
S.E.	44.17	6.85	65.9	64.5	63.4	60.9	65.0	58.3	342.7
M/C	2.6449	11.5998**	1.8119	1.4791	10.6517*	6.2146	3.2686	9.981*	5.4593
F	0.5853	0.8062	0.8604	0.2023	0.2174				0.7203
H	3.2514			2.1771				2.4400	

INDIVIDUAL DATA 3-2-2  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : Week 6 of administration

Animal No.	Grip strength (g)		Motor activity measurements (count)						Total
	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	
202	1496.3	471.0	477	173	175	120	55	81	1081
203	1116.0	446.3	398	293	116	8	49	111	975
205	1096.0	452.0	388	316	156	134	137	102	1233
208	1025.7	505.3	692	457	163	124	203	52	1691
211	992.0	472.3	630	353	167	122	163	76	1511
N	5	5	5	5	5	5	5	5	5
MEAN	1145.20	469.38	517.0	318.4	155.4	101.6	121.4	84.4	1298.2
S.D.	202.67	23.11	137.7	102.7	23.1	52.6	67.6	23.2	298.1
S.E.	90.64	10.33	61.6	45.9	10.3	23.5	30.2	10.4	133.3

INDIVIDUAL DATA 3-2-3  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : Week 6 of administration

Animal No.	Grip strength (g)		Motor activity measurements (count)						
	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	Total
302	991.3	437.3	650	468	410	263	169	124	2084
303	1153.3	465.3	515	418	305	272	161	194	1865
305	1048.0	450.3	380	149	95	49	59	64	796
307	1144.0	513.7	888	405	218	8	0	99	1618
310	840.3	526.0	565	352	131	42	115	38	1243
N	5	5	5	5	5	5	5	5	5
MEAN	1035.38	478.52	599.6	358.4	231.8	126.8	100.8	103.8	1521.2
S.D.	128.32	39.25	188.6	124.1	128.6	129.4	71.4	60.2	511.8
S.E.	57.39	17.55	84.3	55.5	57.5	57.9	31.9	26.9	228.9

INDIVIDUAL DATA 3-2-4  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Week 6 of administration

Animal No.	Grip strength (g)		Motor activity measurements (count)						Total
	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	
401	973.7	430.3	613	197	72	28	81	50	1041
403	1086.7	450.0	639	252	130	1	6	28	1056
407	1213.7	305.7	615	262	224	84	163	105	1453
409	1212.0	365.3	904	638	567	542	357	364	3372
410	1073.7	533.0	189	176	150	62	112	90	779
N	5	5	5	5	5	5	5	5	5
MEAN	1111.96	416.86	592.0	305.0	228.6	143.4	143.8	127.4	1540.2
S.D.	101.95	86.29	256.4	189.6	196.8	225.1	132.1	135.8	1051.9
S.E.	45.59	38.59	114.7	84.8	88.0	100.7	59.1	60.7	470.4

INDIVIDUAL DATA 3-3-1  
STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Week 2 of recovery

Animal No.	Reactivity			Pain	Proprioceptive	Righting reflex
	Visual	Touch	Auditory			
103	4	2	1	2	1	1
107	4	2	1	2	1	1
109	4	2	1	2	1	1
110	4	2	1	2	1	1
111	4	2	1	2	1	1
N	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 3-3-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Week 2 of recovery

Animal No.	Reactivity			Pain	Proprioceptive	Righting reflex
	Visual	Touch	Auditory			
401	4	2	1	2	1	1
403	4	2	1	2	1	1
407	4	2	1	2	1	1
409	4	2	1	2	1	1
410	4	2	1	2	1	1
N	5	5	5	5	5	5

INDIVIDUAL DATA 3-4-1  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Week 2 of recovery

Animal No.	Grip strength (g)		Motor activity measurements (count)						
	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	Total
103	1394.3	633.7	256	307	448	282	335	205	1833
107	1443.0	598.7	344	300	246	238	136	193	1457
109	1257.0	550.7	724	608	1046	803	657	451	4289
110	1130.7	521.7	526	405	198	178	125	120	1552
111	1543.0	546.0	572	321	417	316	205	78	1909
N	5	5	5	5	5	5	5	5	5
MEAN	1353.60	570.16	484.4	388.2	471.0	363.4	291.6	209.4	2208.0
S.D.	161.66	45.17	186.2	129.9	338.8	251.1	220.7	144.8	1178.4
S.E.	72.30	20.20	83.3	58.1	151.5	112.3	98.7	64.8	527.0
M/C	0.4393	0.7049	0.0028	0.1073	5.8019*	3.6517	7.9135**	4.2240*	3.5115
F	0.3622	0.1401	0.9431	1.0897	1.3326	2.4545	0.0109	1.8436	1.8753
H									

## INDIVIDUAL DATA 3-4-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Week 2 of recovery

Animal No.	Grip strength (g)		Motor activity measurements (count)						Total
	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	
401	1330.3	549.7	278	245	150	292	173	110	1248
403	1240.0	553.3	198	250	232	100	209	157	1146
407	1254.0	592.3	442	333	297	198	148	59	1477
409	1541.7	581.3	670	490	336	308	246	79	2129
410	1781.0	619.0	254	227	174	236	184	153	1228
N	5	5	5	5	5	5	5	5	5
MEAN	1429.40	579.12	368.4	309.0	237.8	226.8	192.0	111.6	1445.6
S.D.	230.59	28.73	191.5	109.1	79.0	83.4	37.3	43.6	401.3
S.E.	103.12	12.85	85.6	48.8	35.3	37.3	16.7	19.5	179.5

## INDIVIDUAL DATA 3-5-1

STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 4 of lactation

Animal No.	Reactivity			Pain	Proprioceptive	Righting reflex
	Visual	Touch	Auditory			
151	4	2	1	2	1	1
152	4	2	1	2	1	1
153	4	2	1	2	1	1
154	4	2	1	2	1	1
158	4	2	1	2	1	1
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N	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 3-5-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 100 mg/kg PERIOD : Day 4 of lactation

Animal No.	Reactivity			Pain	Proprioceptive	Righting reflex
	Visual	Touch	Auditory			
253	4	2	1	2	1	1
255	4	2	1	2	1	1
257	4	2	1	2	1	1
260	4	2	1	2	1	1
262	4	2	1	2	1	1
N	5	5	5	5	5	5

INDIVIDUAL DATA 3-5-3  
STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 300 mg/kg PERIOD : Day 4 of lactation

Animal No.	Reactivity			Righting reflex	
	Visual	Touch	Auditory	Pain	Proprioceptive
351	4	2	1	2	1
353	4	2	1	2	1
354	4	2	1	2	1
357	4	2	1	2	1
358	4	2	1	2	1
N	5	5	5	5	5

## INDIVIDUAL DATA 3-5-4

STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 4 of lactation

Animal No.	Reactivity			Pain	Proprioceptive	Righting reflex
	Visual	Touch	Auditory			
451	4	2	1	2	1	1
452	4	2	1	2	1	1
453	4	2	1	2	1	1
456	4	2	1	2	1	1
458	4	2	1	2	1	1
N	5	5	5	5	5	5

INDIVIDUAL DATA 3-6-1  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 4 of lactation

Animal No.	Grip strength (g)		Motor activity measurements (count)						
	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	Total
151	1150.7	634.0	295	30	1	31	0	0	357
152	1048.7	378.7	267	161	109	75	180	0	792
153	1206.0	633.3	1093	552	488	88	364	113	2698
154	1103.3	594.7	586	164	41	0	0	58	849
158	1105.7	403.0	586	463	222	187	85	1	1544
N	5	5	5	5	5	5	5	5	5
MEAN	1122.88	528.74	565.4	274.0	172.2	76.2	125.8	34.4	1248.0
S.D.	58.87	127.17	332.2	222.2	195.4	71.2	152.5	50.5	915.3
S.E.	26.33	56.87	148.6	99.4	87.4	31.8	68.2	22.6	409.3
M/C	1.1730	8.1641*	2.8914	4.5835	3.2929	2.7274	5.9013	5.3296	0.7197
F	2.4414	0.6355	0.2182	0.0520	0.3166	0.9546	1.2662	0.1333	
H		1.9029							

INDIVIDUAL DATA 3-6-2  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 100 mg/kg PERIOD : Day 4 of lactation

Animal No.	Grip strength (g)		Motor activity measurements (count)						Total
	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	
253	1214.0	445.7	621	138	32	98	80	241	1210
255	1210.3	780.7	597	247	93	142	77	99	1255
257	1069.3	464.7	977	538	219	326	149	329	2538
260	1233.7	528.7	460	146	15	2	38	0	661
262	1118.3	392.7	775	728	334	42	0	103	1982
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N	5	5	5	5	5	5	5	5	5
MEAN	1169.12	522.50	686.0	359.4	138.6	122.0	68.8	154.4	1529.2
S.D.	71.46	152.31	197.4	262.2	135.4	125.9	55.5	129.9	733.7
S.E.	31.96	68.11	88.3	117.3	60.6	56.3	24.8	58.1	328.1

INDIVIDUAL DATA 3-6-3  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 300 mg/kg PERIOD : Day 4 of lactation

Animal No.	Grip strength (g)		Motor activity measurements (count)						Total
	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	
351	1137.7	468.3	510	68	31	0	6	0	615
353	1043.0	423.7	403	221	78	52	333	118	1205
354	1168.3	502.0	325	33	51	28	118	0	555
357	985.0	506.3	519	382	45	0	0	65	1011
358	955.3	462.7	772	734	639	414	390	180	3129
N	5	5	5	5	5	5	5	5	5
MEAN	1057.86	472.60	505.8	287.6	168.8	98.8	169.4	72.6	1303.0
S.D.	93.03	33.57	169.0	285.3	263.4	177.5	182.7	77.8	1056.2
S.E.	41.60	15.01	75.6	127.6	117.8	79.4	81.7	34.8	472.3

INDIVIDUAL DATA 3-6-4  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 4 of lactation

Animal No.	Grip strength (g)		Motor activity measurements (count)						Total
	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	
451	938.0	344.3	290	292	240	112	0	0	934
452	1091.0	510.0	476	142	0	22	0	0	640
453	1191.0	414.0	569	331	272	333	322	330	2157
456	1032.7	433.3	655	172	178	36	382	80	1503
458	983.3	458.7	659	306	223	274	515	321	2298
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N	5	5	5	5	5	5	5	5	5
MEAN	1047.20	432.06	529.8	248.6	182.6	155.4	243.8	146.2	1506.4
S.D.	98.51	60.86	153.5	85.4	107.6	141.0	233.3	166.9	729.4
S.E.	44.05	27.22	68.7	38.2	48.1	63.1	104.3	74.7	326.2

INDIVIDUAL DATA 3-7-1  
STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Week 6 of administration

Animal No.	Reactivity			Pain	Proprioceptive	Righting reflex
	Visual	Touch	Auditory			
163	4	2	1	2	1	1
164	4	2	1	2	1	1
165	4	2	1	2	1	1
166	4	2	1	2	1	1
167	4	2	1	2	1	1
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N	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## INDIVIDUAL DATA 3-7-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Week 6 of administration

Animal No.	Reactivity			Righting reflex	
	Visual	Touch	Auditory	Pain	Proprioceptive
463	4	2	1	2	1
464	4	2	1	2	1
465	4	2	1	2	1
466	4	2	1	2	1
467	4	2	1	2	1
N	5	5	5	5	5

INDIVIDUAL DATA 3-8-1  
STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Week 6 of administration

Animal No.	Grip strength (g)		Motor activity measurements (count)						
	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	Total
163	896.3	316.0	481	249	172	4	91	165	1162
164	721.7	350.7	1212	690	725	491	53	447	3618
165	892.3	400.0	1425	1053	811	620	480	365	4754
166	734.7	404.3	1052	798	1072	908	458	66	4354
167	809.0	363.3	553	373	167	454	82	3	1632
N	5	5	5	5	5	5	5	5	5
MEAN	810.80	366.86	944.6	632.6	589.4	495.4	232.8	209.2	3104.0
S.D.	83.20	36.61	412.9	324.8	404.1	327.5	216.2	190.9	1619.2
S.E.	37.21	16.37	184.7	145.2	180.7	146.5	96.7	85.4	724.1
M/C	1.3697	1.8415	1.9604	2.9933	4.8173*	3.7670	9.1977**	0.9369	4.0929*
F	3.5600†	0.9749	4.1406†	2.7634	3.1279	0.2727	1.0976	1.6959	1.8436
H									

INDIVIDUAL DATA 3-8-2  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Week 6 of administration

Animal No.	Grip strength (g)		Motor activity measurements (count)						Total
	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	
463	1195.3	322.3	445	341	179	97	62	57	1181
464	1055.7	516.3	403	398	293	255	101	5	1455
465	856.0	447.7	363	194	195	126	112	60	1050
466	840.0	382.7	820	414	258	297	53	2	1844
467	860.0	354.7	624	527	455	340	44	276	2266
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N	5	5	5	5	5	5	5	5	5
MEAN	961.40	404.74	531.0	374.8	276.0	223.0	74.4	80.0	1559.2
S.D.	157.90	77.58	189.9	121.5	110.3	106.6	30.2	113.0	498.5
S.E.	70.62	34.70	84.9	54.3	49.3	47.7	13.5	50.5	222.9
t'	1.8868		2.0349						

## INDIVIDUAL DATA 3-9-1

STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Week 2 of recovery

Animal No.	Reactivity			Pain	Proprioceptive	Righting reflex
	Visual	Touch	Auditory			
163	4	2	1	2	1	1
164	4	2	1	2	1	1
165	4	2	1	2	1	1
166	4	2	1	2	1	1
167	4	2	1	2	1	1
<hr/>						
N	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 3-9-2  
STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Week 2 of recovery

Animal No.	Reactivity			Righting reflex	
	Visual	Touch	Auditory	Pain	Proprioceptive
463	4	2	1	2	1
464	4	2	1	2	1
465	4	2	1	2	1
466	4	2	1	2	1
467	4	2	1	2	1
N	5	5	5	5	5

INDIVIDUAL DATA 3-10-1  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Week 2 of recovery

Animal No.	Grip strength (g)		Motor activity measurements (count)						Total
	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	
163	1151.3	425.3	494	239	64	59	86	86	1028
164	1056.7	466.3	689	432	299	258	218	172	2068
165	1072.7	451.7	1026	683	794	646	744	604	4497
166	992.3	423.7	1272	1017	947	838	828	255	5157
167	1114.3	470.3	234	143	177	25	191	49	819
N	5	5	5	5	5	5	5	5	5
MEAN	1077.46	447.46	743.0	502.8	456.2	365.2	413.4	233.2	2713.8
S.D.	60.24	22.08	413.5	353.9	391.0	361.7	345.0	222.1	1999.9
S.E.	26.94	9.87	184.9	158.3	174.9	161.8	154.3	99.3	894.4
M/C	2.3815	0.0032	3.7582	3.4936	3.4935	1.5214	2.5833	1.1954	2.7824
F	5.9889*	1.0574	1.2264	0.5114	1.0685	0.4116	1.1646	0.2707	0.8426

## INDIVIDUAL DATA 3-10-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Week 2 of recovery

Animal No.	Grip strength (g)		Motor activity measurements (count)						
	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	Total
463	1477.3	443.7	408	246	137	87	90	68	1036
464	1264.0	443.0	660	422	352	353	353	303	2443
465	1236.3	397.7	688	564	431	489	325	254	2751
466	1109.7	456.0	450	310	281	266	328	224	1859
467	1149.3	424.0	432	374	125	49	73	22	1075
N	5	5	5	5	5	5	5	5	5
MEAN	1247.32	432.88	527.6	383.2	265.2	248.8	233.8	174.2	1832.8
S.D.	143.04	22.75	134.8	120.9	133.6	183.7	139.6	122.4	778.7
S.E.	63.97	10.17	60.3	54.1	59.7	82.1	62.4	54.7	348.2
t'	2.4472*								

## INDIVIDUAL DATA 4-1-1

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Body weight ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 0 mg/kg

Animal No.	Administration day	Body weight (g)						Body weight gain (g)			Body weight (g)			Body weight gain (g)		
		1	3	5	7	10	14	21	28	35	42	1-42	%	7	14	42-42R14
101	346	354	359	362	362	375	388	402	415	420	74	21.39	#	#	#	#
102	353	364	366	373	388	409	424	438	449	96	27.20	#	#	#	#	#
103	361	367	381	382	385	405	429	439	455	450	89	24.65	466	455	5	1.11
104	365	370	379	380	389	401	409	418	431	440	75	20.55	#	#	#	#
105	360	357	372	375	380	390	408	421	443	452	92	25.56	#	#	#	#
106	373	383	397	407	417	438	462	475	499	514	141	37.80	#	#	#	#
107	362	369	380	390	394	407	428	444	456	466	104	28.73	481	488	22	4.72
108	372	379	387	391	401	422	454	476	506	526	154	41.40	#	#	#	#
109	376	380	389	395	403	418	440	446	471	476	100	26.60	491	496	20	4.20
110	383	394	401	410	420	435	453	471	503	512	129	33.68	532	543	31	6.05
111	386	394	399	409	421	438	453	467	492	516	130	33.68	536	544	28	5.43
112	408	418	426	436	451	472	488	517	553	579	171	41.91	#	#	#	#
N	12	12	12	12	12	12	12	12	12	12	12	5	5	5	5	5
MEAN	370.4	376.7	386.2	391.9	399.7	415.8	435.1	450.0	471.8	483.3	112.9	30.263	501.2	505.2	21.2	4.302
S.D.	16.7	18.9	18.2	21.1	24.7	27.1	28.5	32.4	39.6	46.0	31.5	7.334	31.3	38.2	10.1	1.917
S.E.	4.8	5.5	5.3	6.1	7.1	7.8	8.2	9.3	11.4	13.3	9.1	2.117	14.0	17.1	4.5	0.857
M/C	0.2588	1.0425	0.9973	1.8911	2.9720	3.6280	5.2160	6.4498	7.4075	6.3788	3.3264	2.2749	2.1247	3.1111	0.2801	0.1431
F	0.0747	0.1404	0.0996	0.1973	0.2628	0.2008	0.9190	1.1971	1.0387	0.8039	1.1619	1.3236	0.2468	0.4209	0.5530	0.6171

R14 : Recovery day 14.

# : Not applicable.

## INDIVIDUAL DATA 4-1-2

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Body weight ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 100 mg/kg

Animal No.	Administration day						Body weight (g)				Body weight gain (g)		
	1	3	5	7	10	14	21	28	35	42	1-42	%	
201	350	356	366	371	383	400	421	436	463	485	135	38.57	
202	358	370	384	395	404	416	437	460	479	491	133	37.15	
203	354	363	375	381	386	409	432	456	480	490	136	38.42	
204	361	366	375	378	384	398	425	440	460	481	120	33.24	
205	369	376	385	391	400	414	441	456	480	488	119	32.25	
206	366	370	380	385	397	407	434	460	490	515	149	40.71	
207	373	383	395	404	411	423	450	468	490	506	133	35.66	
208	380	387	403	408	420	427	440	445	469	482	102	26.84	
209	379	389	402	408	419	439	451	466	498	511	132	34.83	
210	379	384	389	395	397	413	435	443	448	451	72	19.00	
211	391	393	398	401	410	425	444	459	479	496	105	26.85	
212	396	403	412	417	426	448	474	490	510	541	145	36.62	
N	12	12	12	12	12	12	12	12	12	12	12	12	
MEAN	371.3	378.3	388.7	394.5	403.1	418.3	440.3	456.6	478.8	494.8	123.4	33.345	
S.D.	14.3	13.8	13.7	13.9	14.5	15.0	13.9	14.7	17.2	22.1	21.6	6.264	
S.E.	4.1	4.0	3.9	4.0	4.2	4.3	4.0	4.2	5.0	6.4	6.2	1.808	

## INDIVIDUAL DATA 4-1-3

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Body weight ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 300 mg/kg

Animal No.	Administration day						Body weight (g)				Body weight gain (g)		
	1	3	5	7	10	14	21	28	35	42	1-42	%	
301	341	341	350	352	352	363	389	404	417	434	93	27.27	
302	359	363	373	379	386	408	433	458	480	491	132	36.77	
303	352	363	372	381	388	403	428	454	476	479	127	36.08	
304	366	373	386	391	397	413	432	444	466	485	119	32.51	
305	368	377	388	396	403	424	444	464	490	501	133	36.14	
306	369	376	389	395	405	418	439	445	467	484	115	31.17	
307	368	374	388	395	406	420	438	452	469	479	111	30.16	
308	376	383	396	410	417	438	462	486	511	529	153	40.69	
309	382	390	398	410	414	424	421	430	448	465	83	21.73	
310	379	387	401	406	420	426	440	461	485	491	112	29.55	
311	387	390	409	414	429	447	474	500	520	533	146	37.73	
312	395	403	415	421	428	443	464	479	505	520	125	31.65	
N	12	12	12	12	12	12	12	12	12	12	12	12	
MEAN	370.2	376.7	388.8	395.8	403.8	418.9	438.7	456.4	477.8	490.9	120.8	32.621	
S.D.	15.0	16.1	17.6	18.9	21.5	22.1	22.2	25.4	28.2	27.7	20.0	5.210	
S.E.	4.3	4.7	5.1	5.4	6.2	6.4	7.3	8.1	8.0	5.8	1.504		

## INDIVIDUAL DATA 4-1-4

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Body weight ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 1000 mg/kg

Animal No.	Administration day						Body weight (g)						Body weight gain (g)						Body weight (g)					
	1	3	5	7	10	14	21	28	35	42	-142	%	Recovery day	7	14	-42-R14	%	Recovery day	7	14	-42-R14	%	Recovery day	7
401	356	367	374	381	396	416	441	462	490	492	134	37.64	514	528	38	7.76	#	#	#	#	#	#	#	#
402	360	365	376	385	394	414	438	458	485	494	134	37.22	#	#	#	#	#	#	#	#	#	#	#	#
403	357	366	375	383	389	404	434	459	480	479	122	34.17	494	505	26	5.43	#	#	#	#	#	#	#	#
404	362	369	382	386	392	403	429	446	455	473	111	30.66	#	#	#	#	#	#	#	#	#	#	#	#
405	361	372	383	393	403	416	437	456	482	502	141	39.06	#	#	#	#	#	#	#	#	#	#	#	#
406	369	370	373	375	388	399	423	438	463	476	107	29.00	#	#	#	#	#	#	#	#	#	#	#	#
407	376	380	390	394	406	422	449	466	488	481	105	27.93	494	499	18	3.74	#	#	#	#	#	#	#	#
408	374	380	393	398	404	420	459	476	500	525	151	40.37	#	#	#	#	#	#	#	#	#	#	#	#
409	379	380	385	399	404	420	451	474	499	506	127	33.51	523	529	23	4.55	#	#	#	#	#	#	#	#
410	382	393	405	411	422	436	459	474	491	502	120	31.41	519	524	22	4.38	#	#	#	#	#	#	#	#
411	397	411	424	435	447	466	491	516	548	571	174	43.83	#	#	#	#	#	#	#	#	#	#	#	#
412	401	412	417	430	439	454	481	496	518	545	144	35.91	#	#	#	#	#	#	#	#	#	#	#	#
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12	5	5	5	5	5	5	5	5	5	5
MEAN	372.8	380.4	389.8	397.5	407.0	422.5	449.3	468.4	491.8	503.7	130.8	35.059	508.8	517.0	25.4	5.172	#	#	#	#	#	#	#	#
S.D.	15.0	16.6	17.1	19.0	20.3	20.5	21.3	24.2	29.9	20.0	4.830	13.9	14.0	7.6	1.568	#	#	#	#	#	#	#	#	#
S.E.	4.3	4.8	4.9	5.5	5.6	5.8	5.9	6.1	7.0	8.6	5.8	1.394	6.2	6.3	3.4	0.701	#	#	#	#	#	#	#	#

R14 : Recovery day 14.

# : Not applicable.

## INDIVIDUAL DATA 4-2-1

STUDY NO. SR09207 TITLE : Isotriidecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Body weight ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Body weight(g) on pre-mating period						Body weight gain(g)		
	Administration day 1	3	5	7	10	14	1-14 %		
151	236	233	237	237	241	245	9	3.81	
152	228	227	237	234	247	253	25	10.96	
153	243	240	250	249	265	272	29	11.93	
154	235	240	248	251	261	268	33	14.04	
155	245	250	250	257	263	270	25	10.20	
156	240	248	251	257	261	264	24	10.00	
157	257	252	265	259	271	279	22	8.56	
158	263	252	274	263	281	290	27	10.27	
159	251	254	257	261	260	271	20	7.97	
160	259	260	268	267	278	283	24	9.27	
161	255	257	264	265	262	270	15	5.88	
162	267	273	285	289	288	294	27	10.11	

N	12	12	12	12	12	12	12	12
MEAN	248.3	248.8	257.2	257.4	264.8	271.6	23.3	9.417
S.D.	12.3	12.5	14.5	14.4	13.3	14.0	6.4	2.680
S.E.	3.5	3.6	4.2	4.1	3.9	4.0	1.8	0.774
M/C	0.3798	0.1741	0.1087	0.0979	0.2831	0.7815	0.6525	0.4722
F	0.3387	0.0272	0.2779	0.0956	0.4208	0.2445	1.4782	1.6275

(to be continued)

## INDIVIDUAL DATA 4-2-1 (continued)

STUDY NO. SR09207 TITLE : Isotriidecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Body weight ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Administration day					Body weight(g)
	21	28	35	42	49	
151	#	#	#	#	#	#
152	#	#	#	#	#	#
153	#	#	#	#	#	#
154	#	#	#	#	#	#
155	#	#	#	#	#	#
156	#	#	#	#	#	#
157	#	#	#	#	#	#
158	#	#	#	#	#	#
159	#	#	#	#	#	#
160	#	#	#	#	#	#
161	#	#	#	#	#	#
162	339	362	354	359	360	

N 1 1 1 1 1

# : Not applicable.

## INDIVIDUAL DATA 4-2-2

STUDY NO. SR09207 TITLE : Isotriidecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Body weight ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 100 mg/kg

Animal No.	Body weight(g) on pre-mating period						Body weight gain(g)
	1	3	5	7	10	14	
251	229	227	233	231	236	7	3.06
252	235	235	237	242	241	248	5.53
253	227	241	235	245	245	248	9.25
254	242	247	254	254	249	257	6.20
255	250	246	257	257	266	273	9.20
256	245	243	250	255	254	262	6.94
257	236	247	247	255	262	272	15.25
258	254	255	263	266	263	272	18
259	245	255	255	264	269	274	7.09
260	265	260	271	272	276	285	29
261	257	258	265	268	268	278	11.84
262	269	277	279	284	283	292	20
							7.55
							21
							8.17
							23
							8.55

N	12	12	12	12	12	12	12
MEAN	246.2	249.3	253.8	257.9	258.9	266.4	20.3
S.D.	13.4	13.0	14.4	14.0	15.2	16.5	8.219
S.E.	3.9	3.7	4.2	4.0	4.4	4.8	3.104

## INDIVIDUAL DATA 4-2-3

STUDY NO. SR09207 TITLE : Isotriidecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Body weight ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 300 mg/kg

Animal No.	Body weight(g) on pre-mating period						Body weight gain(g)		
	Administration day 1	3	5	7	10	14	1-14	%	
351	221	230	233	237	241	250	29	13.12	
352	231	233	240	244	242	247	16	6.93	
353	231	236	236	245	245	252	21	9.09	
354	232	238	241	247	253	258	26	11.21	
355	240	245	249	255	265	275	35	14.58	
356	230	241	237	248	248	256	26	11.30	
357	254	257	263	264	269	280	26	10.24	
358	253	247	264	260	270	280	27	10.67	
359	242	257	253	269	264	272	30	12.40	
360	260	259	267	267	264	269	9	3.46	
361	262	264	268	274	274	287	25	9.54	
362	261	276	276	289	292	301	40	15.33	
N	12	12	12	12	12	12	12	12	
MEAN	243.1	248.6	252.3	258.3	260.6	268.9	25.8	10.656	
S.D.	14.4	14.0	14.9	15.1	15.2	16.7	8.1	3.256	
S.E.	4.1	4.1	4.3	4.3	4.4	4.8	2.3	0.940	

## INDIVIDUAL DATA 4-2-4

STUDY NO. SR09207 TITLE : Isotriidecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Body weight ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg

Animal No.	Body weight(g) on pre-mating period						Body weight gain(g)		
	Administration day 1	3	5	7	10	14	1-14	%	
451	236	230	246	238	251	262	26	11.02	
452	230	233	237	235	234	245	15	6.52	
453	242	236	247	241	249	258	16	6.61	
454	243	236	249	250	250	257	14	5.76	
455	235	243	244	251	256	259	24	10.21	
456	249	244	255	249	258	267	18	7.23	
457	235	249	248	254	254	266	31	13.19	
458	260	251	266	257	268	277	17	6.54	
459	252	253	260	266	270	278	26	10.32	
460	251	257	263	264	267	277	26	10.36	
461	268	274	284	289	289	297	29	10.82	
462	263	267	272	270	266	272	9	3.42	
N	12	12	12	12	12	12	12	12	
MEAN	247.0	247.8	255.9	255.3	259.3	267.9	20.9	8.500	
S.D.	12.2	13.6	13.5	15.2	13.9	13.5	6.9	2.855	
S.E.	3.5	3.9	3.9	4.4	4.0	3.9	2.0	0.824	

(to be continued)

## INDIVIDUAL DATA 4-2-4 (continued)

STUDY NO. SR09207 TITLE : Isotriidecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Body weight ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg

Animal No.	Body weight(g)	Administration day
451	#	
452	#	
453	#	
454	300	
455	#	
456	#	
457	#	
458	#	
459	#	
460	#	
461	#	
462	#	

N 1

# : Not applicable.

## INDIVIDUAL DATA 4-3-1

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Body weight ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Gestation day							Body weight (g)				Body weight gain (g)		
	0	1	3	5	7	10	14	17	20	0-20	%			
151	253	258	268	277	281	300	318	347	394	141	55.73			
152	253	258	276	286	295	319	348	380	428	175	69.17			
153	276	280	301	310	320	342	366	400	453	177	64.13			
154	267	270	279	284	291	303	334	367	413	146	54.68			
155	276	283	301	309	321	340	375	408	471	195	70.65			
156	276	272	280	285	294	309	327	361	413	137	49.64			
157	281	289	303	319	327	345	374	407	463	182	64.77			
158	290	304	318	328	336	360	378	416	465	175	60.34			
159	281	286	294	297	310	324	342	372	420	139	49.47			
160	283	286	298	308	315	329	348	372	410	127	44.88			
161	287	289	298	305	312	331	351	384	438	151	52.61			
N	11	11	11	11	11	11	11	11	11	11	11			
MEAN	274.8	279.5	292.4	300.7	309.3	327.5	351.0	383.1	433.5	158.6	57.825			
S.D.	12.4	14.0	14.8	16.2	17.0	18.8	20.3	22.1	26.1	22.6	8.564			
S.E.	3.7	4.2	4.5	4.9	5.1	5.7	6.1	6.7	7.9	6.8	2.582			
M/C	2.2850	0.4730	0.5458	0.4654	1.1228	1.7177	1.1841	1.5216	2.1559	6.7639	3.9111			
F	0.0035	0.0449	0.0853	0.0796	0.1150	0.1459	0.1972	0.3904	0.4771	1.0335	0.8728			

## INDIVIDUAL DATA 4-3-2

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Body weight ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 100 mg/kg

Animal No.	Gestation day							Body weight (g)				Body weight gain (g)		
	0	1	3	5	7	10	14	17	20	0-20	%			
251	250	251	270	276	289	306	324	357	400	150	60.00			
252	260	266	279	288	301	311	334	364	411	151	58.08			
253	258	265	273	280	291	317	335	370	424	166	64.34			
254	274	281	290	300	310	316	343	372	420	146	53.28			
255	273	282	291	300	310	327	346	386	448	175	64.10			
256	267	268	289	302	307	328	357	390	444	177	66.29			
257	283	288	300	307	318	334	361	394	447	164	57.95			
258	280	282	296	302	309	324	342	376	427	147	52.50			
259	276	283	296	309	314	334	358	390	443	167	60.51			
260	291	296	308	312	318	339	360	391	448	157	53.95			
261	288	299	318	323	336	354	385	419	469	181	62.85			
262	290	297	313	324	329	351	376	414	471	181	62.41			
N	12	12	12	12	12	12	12	12	12	12	12			
MEAN	274.2	279.8	293.6	301.9	311.0	328.4	351.8	385.3	437.7	163.5	59.688			
S.D.	13.3	14.8	15.0	15.0	13.7	14.9	17.8	18.7	21.8	13.2	4.614			
S.E.	3.8	4.3	4.3	4.3	4.0	4.3	5.1	5.4	6.3	3.8	1.332			

## INDIVIDUAL DATA 4-3-3

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Body weight ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 300 mg/kg

Animal No.	Gestation day							Body weight (g)				Body weight gain (g)		
	0	1	3	5	7	10	14	17	20	0-20	%			
351	251	262	271	280	290	310	321	360	403	152	60.56			
352	266	274	283	289	303	322	349	382	438	172	64.66			
353	255	264	274	283	290	300	326	357	416	161	63.14			
354	259	266	276	292	300	319	341	376	435	176	67.95			
355	263	272	285	290	289	310	333	379	431	168	63.88			
356	260	264	270	285	291	309	332	369	423	163	62.69			
357	283	289	299	306	316	329	347	382	421	138	48.76			
358	281	290	300	312	318	333	353	384	434	153	54.45			
359	279	284	294	303	312	329	351	385	448	169	60.57			
360	293	296	309	313	324	340	372	413	457	164	55.97			
361	301	302	307	322	326	340	371	398	455	154	51.16			
362	302	305	323	324	337	355	384	420	462	160	52.98			
N	12	12	12	12	12	12	12	12	12	12	12			
MEAN	274.4	280.7	290.9	299.9	308.0	324.7	348.3	383.8	435.3	160.8	58.898			
S.D.	17.9	15.6	17.1	15.4	16.5	16.0	19.5	19.0	17.9	10.4	6.060			
S.E.	5.2	4.5	4.9	4.5	4.8	4.6	5.6	5.5	5.2	3.0	1.749			

## INDIVIDUAL DATA 4-3-4

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Body weight ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg

Animal No.	Gestation day							Body weight (g)				Body weight gain (g)		
	0	1	3	5	7	10	14	17	20	0-20	%			
451	264	273	286	299	306	320	346	387	432	168	63.64			
452	243	248	261	268	276	290	313	348	406	163	67.08			
453	259	268	279	288	297	311	339	369	416	157	60.62			
454 <sup>a</sup>	(316)	(309)	(320)	(323)	(334)	(340)	(345)	(340)	(340)	(330)	(14)	(4.43)		
455	265	271	280	283	291	306	326	359	414	149	56.23			
456	266	276	284	294	305	321	346	383	429	163	61.28			
457	270	284	297	312	316	346	377	414	481	211	78.15			
458	278	283	304	311	317	339	361	404	458	180	64.75			
459	281	290	304	320	326	344	372	403	455	174	61.92			
460	294	296	304	314	321	336	354	394	444	150	51.02			
461	307	310	325	329	343	365	400	436	483	176	57.33			
462	291	300	310	315	330	344	370	414	472	181	62.20			
N	11	11	11	11	11	11	11	11	11	11	11			
MEAN	274.4	281.7	294.0	303.0	311.6	329.3	354.9	391.9	444.5	170.2	62.202			
S.D.	18.1	17.2	17.9	18.2	19.1	21.7	24.7	26.1	27.4	17.5	6.889			
S.E.	5.5	5.2	5.4	5.5	5.8	6.5	7.4	7.9	8.2	5.3	2.077			

a : Non-pregnant (Values in parentheses are excluded from calculation).

## INDIVIDUAL DATA 4-4-1

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Body weight ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Body weight (g)			Body weight gain (g)		
	Lactation day 0	1	4	0-4	%	
151	284	288	314	30	10.56	
152	336	329	350	14	4.17	
153	334	341	338	4	1.20	
154	322	323	324	2	0.62	
155	351	356	357	6	1.71	
156	317	314	331	14	4.42	
157	360	350	358	-2	-0.56	
158	354	354	373	19	5.37	
159	327	337	347	20	6.12	
160	340	338	343	3	0.88	
161	331	328	336	5	1.51	
N	11	11	11	11	11	
MEAN	332.4	332.5	342.8	10.5	3.273	
S.D.	20.9	19.7	16.8	9.7	3.241	
S.E.	6.3	5.9	5.1	2.9	0.977	
M/C	1.9509	1.6269	2.8917	1.4410	1.1103	
F	0.5597	1.0363	1.3590	0.3393	0.2861	

## INDIVIDUAL DATA 4-4-2

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Body weight ANIMAL : Rat, Crl:CD(SD)

SEX : Female GROUP : 100 mg/kg

Animal No.	Lactation day			Body weight gain (g)		
	0	1	4	0-4	%	
251	303	307	324	21	6.93	
252	320	323	340	20	6.25	
253	330	322	334	4	1.21	
254	320	321	325	5	1.56	
255	323	322	340	17	5.26	
256	331	338	346	15	4.53	
257	342	347	354	12	3.51	
258	313	318	324	11	3.51	
259	310	319	342	32	10.32	
260	339	336	337	-2	-0.59	
261	396	388	379	-17	-4.29	
262	367	360	373	6	1.63	
N	12	12	12	12	12	
MEAN	332.8	333.4	343.2	10.3	3.319	
S.D.	26.1	22.5	17.9	12.6	3.808	
S.E.	7.5	6.5	5.2	3.6	1.099	

## INDIVIDUAL DATA 4-4-3

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Body weight ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 300 mg/kg

Animal No.	Lactation day			Body weight gain (g)		
	0	1	4	0-4	%	
351	310	309	338	28	9.03	
352	324	319	332	8	2.47	
353	299	304	305	6	2.01	
354	326	322	343	17	5.21	
355	331	321	326	-5	-1.51	
356	317	306	309	-8	-2.52	
357	341	340	335	-6	-1.76	
358	341	343	338	-3	-0.88	
359	317	319	328	11	3.47	
360	346	332	345	-1	-0.29	
361	325	327	361	36	11.08	
362	368	369	375	7	1.90	
N	12	12	12	12	12	
MEAN	328.8	325.9	336.3	7.5	2.351	
S.D.	18.3	18.3	19.4	13.8	4.301	
S.E.	5.3	5.3	5.6	4.0	1.242	

## INDIVIDUAL DATA 4-4-4

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Body weight ANIMAL : Rat, CrI:CD(SD)

SEX : Female GROUP : 1000 mg/kg

Animal No.	Lactation day			Body weight gain (g)		
	0	1	4	0-4	%	
451	327	327	346	19	5.81	
452	289	294	312	23	7.96	
453	323	334	348	25	7.74	
455	321	308	320	-1	-0.31	
456	325	333	338	13	4.00	
457	366	367	388	22	6.01	
458	366	355	364	-2	-0.55	
459	344	349	352	8	2.33	
460	346	343	343	-3	-0.87	
461	377	381	400	23	6.10	
462	367	371	377	10	2.72	
N	11	11	11	11	11	
MEAN	341.0	342.0	353.5	12.5	3.722	
S.D.	26.7	26.5	27.0	10.8	3.286	
S.E.	8.1	8.0	8.1	3.3	0.991	

## INDIVIDUAL DATA 4-5-1

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Body weight ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Administration day						Body weight (g)						Body weight gain (g)						Body weight (g)		Body weight gain (g)	
	1	3	5	7	10	14	21	28	35	42	1-42	%	7	14	42-R14	%	Recovery day	7	14	42-R14	%	
163	240	243	248	251	248	252	267	272	280	277	37	15.42	294	304	27	9.75						
164	250	243	255	245	258	259	266	264	264	272	22	8.80	274	271	-1	-0.37						
165	257	252	263	261	271	281	293	302	309	321	64	24.90	331	337	16	4.98						
166	254	257	261	264	259	269	289	291	296	294	40	15.75	304	321	27	9.18						
167	254	262	267	274	273	285	306	312	325	323	69	27.17	335	343	20	6.19						
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5						
MEAN	251.0	251.4	258.8	259.0	261.8	269.2	284.2	288.2	294.8	297.4	46.4	18.408	307.6	315.2	17.8	5.946						
S.D.	6.6	8.4	7.4	11.3	10.3	14.0	17.3	20.1	23.9	23.9	19.7	7.537	25.6	29.0	11.5	4.056						
S.E.	3.0	3.8	3.3	5.1	4.6	6.3	7.8	9.0	10.7	10.7	8.8	3.371	11.5	13.0	5.2	1.814						
M/C	0.3351	0.0012	0.2132	0.0423	1.6466	0.6726	0.2381	0.3680	0.2555	0.0067	0.0227	0.0602	0.0201	0.1212	2.6340	2.9790						
F	0.0255	0.0129	0.0055	0.0078	0.6088	0.8296	0.1352	0.1056	0.2559	1.3561	2.4699	2.8308	0.6906	0.1104	4.9922†	4.7126†						

R14 : Recovery day 14.

## INDIVIDUAL DATA 4-5-2

STUDY NO. SR09207 TITLE : Isotriacyl stearate combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Body weight ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg

Animal No.	Administration day						Body weight (g)						Body weight gain (g)						Body weight (g)					
	1	3	5	7	10	14	21	28	35	42	1-42	%	7	14	42-R14	%	7	14	42-R14	%	7	14	42-R14	%
463	245	243	253	247	264	268	272	273	279	290	45	18.37	297	299	9	3.10								
464	249	242	260	254	271	286	297	305	307	328	79	31.73	339	335	7	2.13								
465	239	251	245	254	258	265	276	280	290	295	56	23.43	293	295	0	0.00								
466	256	258	266	264	269	281	291	297	305	313	57	22.27	321	323	10	3.19								
467	262	260	268	273	267	280	303	304	327	351	89	33.97	358	352	1	0.28								
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	250.2	250.8	258.4	258.4	265.8	276.0	287.8	291.8	301.6	315.4	65.2	25.954	321.6	320.8	5.4	1.740								
S.D.	9.0	8.3	9.5	10.2	5.1	9.0	13.4	14.5	18.2	25.0	18.1	6.616	27.6	24.1	4.6	1.522								
S.E.	4.0	3.7	4.2	4.5	2.3	4.0	6.0	6.5	8.2	11.2	8.1	2.959	12.4	10.8	2.1	0.681								
t'																	2.2343	2.1709						

R14 : Recovery day 14.

## INDIVIDUAL DATA 5-1-1

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Food consumption ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 0 mg/kg

Animal No.	Administration day			Food consumption (g/rat/day)						Recovery day	
	-1~1	1~3	3~5	5~7	7~10	10~14	21~28	28~35	35~42	42~R7	R7~R14
101	20.0	18.5	17.5	17.5	17.0	16.8	17.1	17.1	15.6	#	#
102	25.0	19.5	20.0	18.5	20.0	18.8	20.4	20.4	19.3	#	#
103	24.0	21.0	23.0	18.0	20.3	19.6	20.3	18.2	24.1	23.5	
104	25.0	20.0	21.5	19.5	21.0	19.3	20.0	20.1	19.7	#	#
105	26.0	19.0	22.0	20.0	20.0	18.5	18.7	19.6	19.0	#	#
106	26.0	22.0	23.5	22.5	23.7	23.3	20.9	21.6	21.4	#	#
107	25.0	20.0	21.0	21.0	18.7	18.8	19.0	18.3	19.2	23.6	25.7
108	27.0	23.5	21.5	21.0	21.3	20.3	22.0	22.0	23.7	#	#
109	24.0	18.5	17.5	19.0	19.0	19.0	17.3	19.7	18.3	23.6	25.5
110	27.0	23.5	22.0	21.5	22.0	20.3	21.6	22.3	22.7	27.3	29.8
111	28.0	22.5	22.0	22.5	23.0	21.5	21.9	23.4	25.0	29.7	31.5
112	28.0	23.5	23.0	23.0	23.3	23.3	a	25.9	25.0	#	#
	N	12	12	12	12	12	11	12	12	5	5
MEAN	25.42	20.96	21.21	20.33	20.78	20.02	19.86	21.03	20.59	25.66	27.20
S.D.	2.19	1.97	1.97	1.86	2.02	1.93	1.72	2.47	2.96	2.74	3.32
S.E.	0.63	0.57	0.57	0.54	0.58	0.56	0.52	0.71	0.85	1.22	1.48
M/C	1.5450	1.5175	2.5387	1.4234	3.2033	3.4596	1.2388	5.1479	4.9179	0.6425	1.9877
F	2.1673	1.9782	0.5189	1.3310	1.3746	2.0389	6.3670**	3.2854*	2.0386	1.2333	0.8221

R7 : Recovery day 7, R14 : Recovery day 14.

a : No data because of the course of mating.

# : Not applicable.

## INDIVIDUAL DATA 5-1-2

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Food consumption ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 100 mg/kg

Animal No.	Food consumption (g/rat/day)								
	-1~1	1~3	3~5	5~7	7~10	10~14	21~28	28~35	35~42
Administration day									
201	21.0	18.0	20.0	18.5	19.3	19.3	19.6	20.3	21.7
202	25.0	21.0	21.5	23.0	21.7	21.0	21.3	21.1	21.5
203	25.0	21.0	21.5	20.5	20.3	22.3	22.9	23.3	22.3
204	26.0	21.0	22.0	18.5	20.3	19.5	22.4	22.7	24.0
205	24.0	20.5	20.5	20.0	20.3	20.5	21.4	21.3	20.7
206	25.0	20.0	22.0	19.5	20.3	19.3	21.6	22.4	23.0
207	25.0	22.0	22.0	21.5	21.0	18.8	19.7	20.1	20.9
208	27.0	20.5	24.5	21.0	23.0	20.8	20.9	21.1	22.3
209	28.0	23.5	23.5	22.5	23.3	22.0	20.3	22.6	21.7
210	26.0	22.0	20.5	21.5	21.7	20.0	19.6	18.6	17.6
211	27.0	21.0	22.0	22.0	22.0	21.3	22.9	22.4	24.0
212	27.0	23.0	21.5	20.5	21.3	21.3	22.6	23.6	24.6
N	12	12	12	12	12	12	12	12	12
MEAN	25.50	21.13	21.79	20.75	21.21	20.51	21.27	21.63	22.03
S.D.	1.83	1.43	1.25	1.45	1.19	1.13	1.27	1.47	1.87
S.E.	0.53	0.41	0.36	0.42	0.34	0.33	0.37	0.43	0.54
t'							2.3070	0.8095	

## INDIVIDUAL DATA 5-1-3

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Food consumption ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 300 mg/kg

Animal No.	Food consumption (g/rat/day)								
	-1~1	1~3	3~5	5~7	7~10	10~14	21~28	28~35	35~42
Administration day									
301	23.0	17.5	18.0	17.0	17.0	17.3	17.7	16.9	18.3
302	26.0	21.0	21.0	22.0	22.0	22.3	22.7	23.3	23.5
303	32.0	21.5	20.0	21.0	20.3	21.0	23.0	22.6	23.0
304	30.0	22.5	23.0	22.5	23.3	21.0	20.9	22.0	22.7
305	25.0	21.5	21.5	20.0	20.3	20.5	20.6	21.3	19.7
306	30.0	22.5	23.0	21.5	24.0	21.8	21.0	21.7	21.9
307	26.0	20.5	21.5	21.0	22.7	21.0	20.4	20.3	20.2
308	30.0	24.5	24.0	25.0	22.7	21.8	22.0	23.1	23.3
309	28.0	25.0	23.5	24.0	22.3	20.5	19.7	20.9	20.6
310	27.0	22.0	22.5	20.5	21.3	19.0	21.1	21.0	22.0
311	26.0	20.5	22.5	21.5	22.0	20.8	22.6	22.3	22.1
312	27.0	22.0	23.5	22.5	20.0	20.5	19.7	21.6	20.6
N	12	12	12	12	12	12	12	12	12
MEAN	27.50	21.75	22.00	21.54	21.49	20.63	20.95	21.42	21.49
S.D.	2.58	1.94	1.72	2.02	1.88	1.34	1.51	1.68	1.61
S.E.	0.74	0.56	0.50	0.58	0.54	0.39	0.44	0.49	0.46
t'							1.7863	0.5245	

## INDIVIDUAL DATA 5-1-4

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Food consumption ANIMAL : Rat, CrI:CD(SD) SEX : Male GROUP : 1000 mg/kg

Animal No.	Administration day			Food consumption (g/rat/day)						Recovery day	
	-1~1	1~3	3~5	5~7	7~10	10~14	21~28	28~35	35~42	42~R7	R7~R14
401	22.0	23.0	22.0	22.5	23.7	22.3	22.7	23.3	20.3	27.0	30.3
402	24.0	21.0	20.5	20.0	21.3	20.3	22.3	22.9	20.9	#	#
403	24.0	22.5	22.0	22.0	22.3	24.0	23.4	22.0	26.9	29.5	
404	24.0	22.5	22.0	21.5	22.3	21.3	a	22.9	22.4	#	#
405	25.0	22.0	21.5	22.5	22.7	20.5	20.7	21.6	21.6	#	#
406	26.0	22.0	20.5	18.5	22.3	20.3	22.9	22.9	22.1	#	#
407	25.0	20.0	20.0	20.0	19.7	21.0	20.4	21.3	20.7	24.7	26.3
408	25.0	20.0	21.0	19.7	20.8	23.0	23.6	25.3	#	#	
409	26.0	23.0	20.0	20.0	20.7	19.5	22.7	22.9	22.3	29.4	29.0
410	30.0	24.5	24.5	22.5	23.3	22.8	21.4	22.3	23.8	28.4	28.3
411	27.0	23.5	23.5	23.5	23.3	24.3	24.6	26.3	24.7	#	
412	31.0	27.5	23.0	23.5	24.7	22.3	23.4	24.6	26.1	#	#
										4.3316**	2.9188*
										t'	
N	12	12	12	12	12	11	12	12	5	5	
MEAN	25.75	22.63	21.71	21.46	22.14	21.48	22.55	23.17	22.68	27.28	28.68
S.D.	2.56	2.04	1.42	1.57	1.56	1.35	1.30	1.32	1.88	1.78	1.52
S.E.	0.74	0.59	0.41	0.45	0.45	0.39	0.39	0.38	0.54	0.79	0.68

R7 : Recovery day 7, R14 : Recovery day 14.

a : No data because of the course of mating.  
# : Not applicable.

## INDIVIDUAL DATA 5-2-1

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Food consumption ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Food consumption (g/rat/day) on pre-mating period					
	-1~1	1~3	3~5	5~7	7~10	10~14
151	19.0	11.5	13.0	16.0	15.3	14.8
152	16.0	16.5	15.5	13.5	16.7	15.8
153	20.0	13.0	16.0	14.0	17.7	15.3
154	18.0	16.5	16.5	18.0	17.3	17.5
155	16.0	16.0	14.5	17.5	15.3	16.0
156	15.0	16.5	16.5	16.0	15.7	15.8
157	22.0	13.5	18.0	14.5	17.0	16.0
158	22.0	12.5	19.0	14.0	19.0	17.3
159	17.0	14.0	16.5	15.5	16.3	16.8
160	20.0	17.0	16.0	17.0	16.7	16.3
161	17.0	13.0	18.0	14.5	16.3	17.3
162	20.0	16.5	20.5	18.0	18.7	18.8
N	12	12	12	12	12	12
MEAN	18.50	14.71	16.67	15.71	16.83	16.48
S.D.	2.35	1.97	2.00	1.63	1.20	1.11
S.E.	0.68	0.57	0.58	0.47	0.35	0.32
M/C	0.0068	0.1512	3.9383	8.9608*	5.6337	3.8035
F	0.3026	1.2484	0.3516	6.2664†	0.1790	0.4987
H						

(to be continued)

## INDIVIDUAL DATA 5-2-1 (continued)

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Food consumption ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Food consumption (g/rat/day) on pre-mating period		
	Administration day 28~35	35~42	42~49
151	#	#	#
152	#	#	#
153	#	#	#
154	#	#	#
155	#	#	#
156	#	#	#
157	#	#	#
158	#	#	#
159	#	#	#
160	#	#	#
161	#	#	#
162	19.0	16.4	17.6
N	1	1	1

# : Not applicable.

## INDIVIDUAL DATA 5-2-2

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Food consumption ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 100 mg/kg

Animal No.	Food consumption (g/rat/day) on pre-mating period					
	-1~1	1~3	3~5	5~7	7~10	10~14
Administration day						
251	19.0	13.0	17.0	14.5	15.0	14.5
252	18.0	12.0	14.0	13.5	14.7	15.5
253	15.0	15.5	14.5	14.5	13.3	13.5
254	21.0	16.0	19.5	16.0	17.7	17.5
255	18.0	14.0	17.0	15.5	17.3	16.3
256	20.0	13.0	18.0	15.0	16.7	16.5
257	14.0	17.5	15.5	15.5	16.3	17.0
258	19.0	15.5	18.5	16.5	16.7	17.3
259	20.0	18.0	15.0	18.5	16.7	16.5
260	22.0	14.5	18.0	16.0	17.0	16.0
261	20.0	13.0	16.0	13.5	15.7	16.0
262	20.0	16.0	18.5	16.5	20.0	18.5
N	12	12	12	12	12	12
MEAN	18.83	14.83	16.79	15.46	16.43	16.26
S.D.	2.33	1.90	1.78	1.41	1.68	1.34
S.E.	0.67	0.55	0.51	0.41	0.48	0.39
U				67.0000		

## INDIVIDUAL DATA 5-2-3

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Food consumption ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 300 mg/kg

Animal No.	Food consumption (g/rat/day) on pre-mating period					
	-1~1	1~3	3~5	5~7	7~10	10~14
Administration day						
351	16.0	15.0	12.5	15.5	14.0	14.8
352	20.0	14.0	18.5	16.0	16.7	16.5
353	16.0	14.0	11.5	14.5	13.0	13.5
354	18.0	16.5	14.5	17.5	15.3	16.5
355	19.0	17.0	15.0	19.0	17.3	17.5
356	15.0	17.5	13.5	17.0	14.7	15.3
357	21.0	17.0	18.5	18.5	18.7	18.5
358	20.0	14.5	18.0	10.5	17.7	17.0
359	14.0	16.5	14.0	18.0	14.7	16.3
360	20.0	14.0	19.0	14.5	16.7	16.8
361	20.0	15.5	17.5	17.5	17.7	19.0
362	19.0	21.0	19.5	23.5	21.0	20.5
N	12	12	12	12	12	12
MEAN	18.17	16.04	16.00	16.83	16.46	16.85
S.D.	2.33	2.03	2.80	3.13	2.24	1.89
S.E.	0.67	0.59	0.81	0.90	0.65	0.55
U				49.0000		

## INDIVIDUAL DATA 5-2-4

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Food consumption ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 1000 mg/kg

Animal No.	Food consumption (g/rat/day) on pre-mating period					
	-1~1	1~3	3~5	5~7	7~10	10~14
Administration day						
451	18.0	13.0	17.5	14.0	18.0	16.0
452	16.0	13.5	15.0	13.0	14.0	11.0
453	20.0	13.0	15.5	12.5	16.0	15.8
454	20.0	13.0	17.0	14.5	16.0	16.0
455	16.0	17.0	15.5	17.0	16.3	16.8
456	20.0	14.5	18.0	14.5	17.3	17.0
457	13.0	17.0	14.0	14.0	16.3	15.5
458	20.0	14.0	18.5	14.5	17.3	16.0
459	18.0	17.5	15.0	17.5	14.7	17.0
460	16.0	15.5	17.0	15.5	17.7	17.8
461	20.0	17.0	19.0	17.5	17.7	18.0
462	19.0	13.5	18.0	13.0	15.7	16.5
N	12	12	12	12	12	12
MEAN	18.00	14.88	16.67	14.79	16.42	16.12
S.D.	2.30	1.81	1.61	1.74	1.24	1.79
S.E.	0.66	0.52	0.47	0.50	0.36	0.52
U				49.0000		

## INDIVIDUAL DATA 5-3-1

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Food consumption ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Gestation day							Food consumption (g/rat/day)
	0~1	1~3	3~5	5~7	7~10	10~14	14~17	
151	17.0	19.0	19.5	20.0	21.7	19.8	21.0	19.7
152	15.0	21.5	22.0	22.5	23.7	26.0	25.0	22.3
153	15.0	23.5	23.0	25.5	26.7	26.0	23.3	21.7
154	15.0	21.0	19.0	22.0	23.3	24.0	24.7	22.0
155	16.0	21.5	20.0	22.5	23.7	24.8	27.0	23.7
156	11.0	17.5	19.5	19.5	20.3	21.0	21.0	21.0
157	18.0	22.0	24.0	23.5	24.3	26.0	26.3	24.3
158	21.0	24.0	23.5	23.0	24.3	23.0	23.0	19.3
159	14.0	18.5	17.5	21.5	20.0	21.5	22.7	21.0
160	14.0	20.5	21.5	21.0	21.3	22.8	23.3	21.3
161	16.0	20.5	20.5	20.5	23.0	22.0	22.7	21.0
N	11	11	11	11	11	11	11	11
MEAN	15.64	20.86	20.91	21.95	22.94	23.35	23.64	21.57
S.D.	2.54	1.99	2.06	1.72	1.97	2.18	1.94	1.50
S.E.	0.77	0.60	0.62	0.52	0.60	0.66	0.59	0.45
M/C	3.8479	0.5333	2.1551	2.7360	6.4516	1.9690	3.0397	0.0419
F	0.3453	0.3466	0.0635	0.2613	0.2458	0.0649	0.3353	0.3247

## INDIVIDUAL DATA 5-3-2

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Food consumption ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 100 mg/kg

Animal No.	Gestation day						
	0~1	1~3	3~5	5~7	7~10	10~14	14~17
251	16.0	20.5	21.0	22.5	23.0	22.0	22.7
252	16.0	19.5	20.5	22.5	22.0	21.8	22.3
253	17.0	17.5	18.5	20.5	21.7	21.5	21.0
254	20.0	24.0	24.5	25.5	24.3	26.3	24.7
255	17.0	19.0	19.0	21.5	21.0	20.8	23.7
256	10.0	22.0	24.0	23.0	26.0	25.8	25.0
257	20.0	21.5	21.0	22.5	22.0	24.8	24.3
258	15.0	21.5	20.5	22.5	23.3	22.0	23.0
259	18.0	20.0	19.5	21.0	23.3	21.8	23.7
260	19.0	22.0	20.5	19.5	23.0	23.5	25.7
261	19.0	22.0	22.0	24.5	26.7	26.5	25.3
262	12.0	21.5	22.5	23.0	24.0	23.3	24.0

	N	12	12	12	12	12	12
MEAN	16.58	20.92	21.13	22.38	23.36	23.34	23.78
S.D.	3.09	1.72	1.85	1.64	1.70	2.03	22.03
S.E.	0.89	0.50	0.53	0.47	0.49	0.58	1.53

## INDIVIDUAL DATA 5-3-3

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Food consumption ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 300 mg/kg

Animal No.	Gestation day							Food consumption (g/rat/day)
	0~1	1~3	3~5	5~7	7~10	10~14	14~17	
351	18.0	19.5	18.0	21.0	22.3	19.3	23.0	22.7
352	17.0	20.5	22.5	24.0	26.7	25.8	22.7	21.7
353	18.0	17.0	19.0	20.0	19.3	20.0	23.0	20.3
354	15.0	20.0	20.0	22.5	23.7	22.8	25.3	22.3
355	9.0	19.0	19.5	16.0	15.3	21.8	25.7	20.7
356	15.0	18.0	20.5	21.5	21.3	22.8	22.7	22.3
357	18.0	21.0	18.5	21.5	21.0	21.8	21.3	19.0
358	19.0	22.5	23.5	23.0	24.7	23.5	23.7	20.7
359	18.0	19.5	20.5	22.0	21.7	23.3	21.0	23.7
360	15.0	21.0	22.0	22.0	24.7	25.8	27.7	23.0
361	16.0	19.5	23.0	22.0	24.0	24.8	21.3	21.0
362	21.0	25.0	23.5	26.5	27.0	29.5	27.7	24.3
N	12	12	12	12	12	12	12	12
MEAN	16.58	20.21	20.88	21.83	22.64	23.43	23.76	21.81
S.D.	3.00	2.08	1.97	2.46	3.27	2.78	2.34	1.53
S.E.	0.87	0.60	0.57	0.71	0.94	0.80	0.68	0.44

## INDIVIDUAL DATA 5-3-4

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Food consumption ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 1000 mg/kg

Animal No.	Gestation day						
	0~1	1~3	3~5	5~7	7~10	10~14	14~17
451	16.0	22.0	23.0	21.5	24.0	24.8	24.0
452	13.0	18.5	19.5	20.0	19.7	20.3	21.7
453	16.0	20.5	20.0	20.0	21.0	22.8	23.7
454 <sup>a</sup>	(14.0)	(21.0)	(22.0)	(22.0)	(20.7)	(19.8)	(16.0)
455	16.0	18.0	19.5	20.5	19.7	20.5	21.3
456	16.0	19.5	19.5	22.0	22.3	24.5	27.0
457	19.0	21.5	22.0	21.0	24.0	24.8	24.7
458	16.0	23.0	21.0	24.5	23.7	24.3	26.0
459	18.0	23.0	22.5	22.5	23.7	25.0	23.3
460	16.0	19.0	19.5	20.0	23.0	23.0	24.7
461	17.0	22.0	21.0	23.0	23.7	25.0	25.7
462	19.0	21.0	21.5	24.0	24.7	25.8	26.0

N	11	11	11	11	11	11	11
MEAN	16.55	20.73	20.82	21.73	22.68	23.71	24.37
S.D.	1.69	1.77	1.31	1.62	1.78	1.85	1.80
S.E.	0.51	0.53	0.39	0.49	0.54	0.56	0.54

a : Non-pregnant (Values in parentheses are excluded from calculation).

## INDIVIDUAL DATA 5-4-1

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Food consumption ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Food consumption (g/rat/day)	
	0~1	1~4
151	15.0	33.3
152	15.0	30.7
153	14.0	24.0
154	17.0	27.3
155	20.0	37.0
156	21.0	34.3
157	15.0	30.7
158	17.0	32.0
159	27.0	36.0
160	11.0	22.7
161	19.0	31.7
N	11	11
MEAN	17.36	30.88
S.D.	4.30	4.59
S.E.	1.30	1.38
M/C	1.5781	8.0775*
F	3.2960*	
H		8.0168*

## INDIVIDUAL DATA 5-4-2

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Food consumption ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 100 mg/kg

Animal No.	Food consumption (g/rat/day)	
	0~1	1~4
251	21.0	38.7
252	22.0	38.3
253	16.0	34.0
254	18.0	39.7
255	21.0	39.3
256	20.0	34.7
257	17.0	39.7
258	26.0	35.3
259	18.0	40.0
260	17.0	32.7
261	10.0	23.0
262	17.0	30.7
N	12	12
MEAN	18.58	35.51
S.D.	3.92	5.03
S.E.	1.13	1.45
t'	0.7265	28.0000*
U		

## INDIVIDUAL DATA 5-4-3

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Food consumption ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 300 mg/kg

Animal No.	Food consumption (g/rat/day)	
	0~1	1~4
351	19.0	38.0
352	17.0	32.0
353	14.0	27.7
354	17.0	38.7
355	13.0	28.3
356	6.0	25.0
357	17.0	27.3
358	22.0	28.3
359	16.0	36.0
360	10.0	31.3
361	11.0	36.3
362	20.0	32.3
N	12	12
MEAN	15.17	31.77
S.D.	4.57	4.60
S.E.	1.32	1.33
t'	1.3087	58.5000
U		

## INDIVIDUAL DATA 5-4-4

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Food consumption ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 1000 mg/kg

Animal No.	Food consumption (g/rat/day)	
	0~1	1~4
451	19.0	32.7
452	16.0	31.7
453	23.0	33.3
455	20.0	31.7
456	17.0	31.0
457	20.0	36.3
458	18.0	28.7
459	25.0	33.3
460	22.0	32.3
461	18.0	34.7
462	25.0	31.7
N	11	11
MEAN	20.27	32.49
S.D.	3.10	1.98
S.E.	0.94	0.60
t'	1.6964	
U		48.5000

## INDIVIDUAL DATA 5-5-1

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Food consumption ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Administration day			Food consumption (g/rat/day)						Recovery day		
	-1~1	1~3	3~5	5~7	7~10	10~14	14~21	21~28	28~35	35~42	42~R7	R7~R14
163	13.0	13.5	15.5	13.5	13.3	14.8	15.0	13.9	14.0	14.7	18.9	19.3
164	22.0	15.0	17.5	14.5	16.7	16.0	15.3	14.3	14.7	14.2	16.1	17.8
165	23.0	16.0	18.5	17.5	18.3	17.0	18.0	17.7	20.1	19.5	23.4	24.7
166	21.0	13.0	18.5	13.0	15.7	16.3	16.4	14.7	14.3	15.7	19.4	20.5
167	21.0	16.5	18.0	17.0	17.3	18.0	19.7	18.6	18.9	17.8	21.6	23.2
N	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	20.00	14.80	17.60	15.10	16.26	16.42	16.88	15.84	16.40	16.38	19.88	21.10
S.D.	4.00	1.52	1.24	2.04	1.90	1.19	1.97	2.15	2.87	2.22	2.78	2.82
S.E.	1.79	0.68	0.56	0.91	0.85	0.53	0.88	0.96	1.28	0.99	1.24	1.26
M/C	1.0340	0.0004	0.4284	0.2056	0.3884	0.1002	0.6159	1.1840	3.5403	0.4229	0.5269	4.6817*
F	0.0845	0.5213	0.0107	0.8963	1.8364	4.5701†	0.4952	1.0015	0.3308	1.3602	0.1203	0.0982
H												

R7 : Recovery day 7 , R14 : Recovery day 14.

## INDIVIDUAL DATA 5-5-2

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Food consumption ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 1000 mg/kg

Animal No.	Administration day			Food consumption (g/rat/day)						Recovery day		
	-1~1	1~3	3~5	5~7	7~10	10~14	14~21	21~28	28~35	35~42	42~R7	R7~R14
463	17.0	14.5	16.5	13.5	16.7	16.0	15.4	14.9	15.9	16.8	19.1	20.0
464	20.0	14.5	19.5	16.0	20.0	19.5	17.7	17.3	17.1	17.2	19.4	19.7
465	17.0	18.0	15.0	17.5	17.3	17.8	18.4	18.0	16.9	16.7	19.0	19.5
466	22.0	16.0	18.0	17.0	17.7	19.3	18.0	17.1	17.4	17.8	21.1	21.5
467	21.0	14.5	18.5	17.0	16.7	18.3	18.6	17.4	18.6	20.5	23.4	20.3

N	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	19.40	15.50	17.50	16.20	17.68	18.18	17.62	16.94	17.18	17.80	20.40	20.20
S.D.	2.30	1.54	1.77	1.60	1.36	1.41	1.29	1.19	0.97	1.57	1.88	0.79
S.E.	1.03	0.69	0.79	0.72	0.61	0.63	0.58	0.53	0.44	0.70	0.84	0.35
t'											2.1378	

R7 : Recovery day 7, R14 : Recovery day 14.

INDIVIDUAL DATA 6-1-1  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Urinary findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Week 6 of administration

Animal No.	pH	Protein	Glucose	Ketone body	Urobilinogen EU/dL	Bili-rubin	Occult blood	Color	Urine volume mL/21hr		
									Specific gravity	Color	Specific gravity
103	8.0	2+	-	-	0.1	-	-	A	1.050<	5.5	
107	8.0	1+	-	-	0.1	-	±	A	1.050<	7.5	
109	8.0	1+	-	-	0.1	-	-	A	1.048	10.0	
110	8.5	2+	-	-	0.1	-	-	A	1.050<	5.5	
111	8.5	1+	-	-	0.1	-	-	A	1.050<	8.5	
N	5	5	5	5	5	5	5	5	5	5	
MEAN									7.40		
S.D.										1.95	
S.E.										0.87	
M/C									3.6980		
F									0.4081		
H	1.7518	1.5796	0.0000	0.0000	0.0000	0.0000	3.0000	0.0000	1.9498		

, Normal ; ±, Slight ; 1+, Moderate ; 2+, Severe.  
 Color : A = Pale yellow or yellow.

INDIVIDUAL DATA 6-1-2  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Urinary findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : Week 6 of administration

Animal No.	pH	Protein	Glucose	Ketone body	Urobilinogen EU/dL	Bili-rubin	Occult blood	Color	Urine volume mL/24hr		
									Specific gravity	Color	Specific gravity
202	8.5	1+	-	-	0.1	-	-	A	1.050<	5.5	
203	8.5	±	-	-	0.1	-	-	A	1.050<	9.0	
205	8.0	1+	-	-	0.1	-	-	A	1.050<	9.5	
208	8.5	2+	-	-	0.1	-	-	A	1.050	10.0	
211	8.0	1+	-	-	0.1	-	-	A	1.050	10.0	
N	5	5	5	5	5	5	5	5	8.80		
MEAN											
S.D.											
S.E.											

- Normal ; ±, Slight ; 1+, Moderate ; 2+, Severe.  
 Color : A = Pale yellow or yellow.

INDIVIDUAL DATA 6-1-3  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Urinary findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : Week 6 of administration

Animal No.	pH	Protein	Glucose	Ketone body	Urobilinogen EU/dL	Bili-rubin	Occult blood	Color	Urine volume mL/24hr		
									Specific gravity	Color	Specific gravity
302	8.5	1+	-	-	0.1	-	-	A	1.050<	11.5	
303	8.5	1+	-	-	0.1	-	-	A	1.050<	7.5	
305	7.0	1+	-	-	0.1	-	-	A	1.050<	8.0	
307	8.0	2+	-	-	0.1	-	-	A	1.050<	5.0	
310	8.5	1+	-	-	0.1	-	-	A	1.050<	6.0	
N	5	5	5	5	5	5	5	5	7.60		
MEAN											
S.D.									2.48		
S.E.									1.11		

- Normal ; 1+, Moderate ; 2+, Severe.  
 Color : A = Pale yellow or yellow.

INDIVIDUAL DATA 6-1-4  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Urinary findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Week 6 of administration

Animal No.	pH	Protein	Glucose	Ketone body	Urobilinogen EU/dL	Bili-rubin	Occult blood	Color	Urine volume mL/24hr		
									Specific gravity	Color	Specific gravity
401	8.5	2+	-	-	0.1	-	-	A	1.050<	10.0	
403	8.5	2+	-	-	0.1	-	-	A	1.050<	7.5	
407	7.0	1+	-	-	0.1	-	-	A	1.050<	7.0	
409	7.5	1+	-	-	0.1	-	-	A	1.050<	4.5	
410	7.5	1+	-	-	0.1	-	-	A	1.036	16.0	
N	5	5	5	5	5	5	5	5	9.00		
MEAN											
S.D.											
S.E.											

- Normal ; 1+, Moderate ; 2+, Severe.  
 Color : A = Pale yellow or yellow.

INDIVIDUAL DATA 6-2-1  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Urinary findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Week 2 of recovery

Animal No.	pH	Protein	Glucose	Ketone body	Urobilinogen EU/dL	Bili-rubin	Occult blood	Color	Urine volume mL/21hr		
									Specific gravity	Color	Specific gravity
103	8.5	2+	-	-	0.1	-	-	A	1.050<	9.0	
107	8.0	1+	-	-	0.1	-	-	A	1.050<	8.5	
109	8.5	2+	-	-	0.1	-	-	A	1.050	12.0	
110	7.5	1+	-	-	0.1	-	-	A	1.050<	8.0	
111	8.5	2+	-	-	0.1	-	-	A	1.050<	10.5	
N	5	5	5	5	5	5	5	5	5	5	5
MEAN									9.60		
S.D.									1.64		
S.E.									0.73		
M/C									5.7008*		
H	0.2667	0.3600	0.0000	0.0000	0.0000	0.0000	1.0000	0.0000	0.6000	1.0976	

- Normal ; 1+, Moderate ; 2+, Severe.  
 Color : A = Pale yellow or yellow.

INDIVIDUAL DATA 6-2-2  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Urinary findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : Week 2 of recovery

Animal No.	pH	Protein	Glucose	Ketone body	Urobilinogen EU/dL	Bili-rubin	Occult blood	Color	Urine volume mL/24hr		
									Specific gravity	Color	Specific gravity
401	8.5	2+	-	-	0.1	-	-	A	1.050<	11.5	
403	8.5	1+	-	-	0.1	-	-	A	1.050	13.0	
407	8.5	1+	-	-	0.1	-	2+	A	1.050<	10.0	
409	8.5	2+	-	-	0.1	-	-	A	1.050<	8.0	
410	7.5	1+	-	-	0.1	-	-	A	1.030	25.5	
N	5	5	5	5	5	5	5	5	13.60		
MEAN											
S.D.									6.90		
S.E.									3.09		

- Normal ; 1+, Moderate ; 2+, Severe.  
 Color : A = Pale yellow or yellow.

INDIVIDUAL DATA 6-3-1  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Urinary findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Week 6 of administration

Animal No.	pH	Protein	Glucose	Ketone body	Urobilinogen EU/dL	Bili-rubin	Occult blood	Color	Urine volume mL/21hr		
									Specific gravity	Color	Specific gravity
163	8.0	-	-	-	0.1	-	-	A	1.035	10.0	
164	8.5	±	-	-	0.1	-	-	A	1.040	12.0	
165	8.5	-	-	-	0.1	-	-	A	1.041	13.0	
166	8.5	-	-	-	0.1	-	-	A	1.050<	6.0	
167	8.5	-	-	-	0.1	-	-	A	1.040	15.0	
N	5	5	5	5	5	5	5	5	5	5	5
MEAN									11.20		
S.D.									3.42		
S.E.									1.53		
M/C									4.7143*		
H	1.7286	0.6000	0.0000	0.0000	0.0000	0.0000	1.0000	0.0000	0.7111	0.5411	

- Normal ; ±, Slight.

Color : A = Pale yellow or yellow.

INDIVIDUAL DATA 6-3-2  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Urinary findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Week 6 of administration

Animal No.	pH	Protein	Glucose	Ketone body	Urobilinogen EU/dL	Bili-rubin	Occult blood	Color	Urine volume mL/21hr		
									Specific gravity	Color	Specific gravity
463	8.5	±	-	-	0.1	-	-	A	1.045	10.0	
464	7.5	-	-	-	0.1	-	-	A	1.050<	6.0	
465	8.0	-	-	-	0.1	-	-	A	1.045	8.5	
466	8.5	1+	-	-	0.1	-	-	A	1.050	8.0	
467	8.0	-	-	-	0.1	-	-	A	1.025	35.5	
N	5	5	5	5	5	5	5	5	5	5	5
MEAN									13.60		
S.D.									12.33		
S.E.									5.51		

, Normal ; ±, Slight ; 1+, Moderate.  
 Color : A = Pale yellow or yellow.

INDIVIDUAL DATA 6-4-1  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Urinary findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Week 2 of recovery

Animal No.	pH	Protein	Glucose	Ketone body	Urobilinogen EU/dL	Bili-rubin	Occult blood	Color	Urine volume mL/21hr		
									Specific gravity	Color	Specific gravity
163	6.0	-	-	-	0.1	-	-	A	1.050<	6.0	
164	8.5	1+	-	-	0.1	-	-	A	1.043	11.5	
165	8.0	-	-	-	0.1	-	-	A	1.050<	8.0	
166	6.5	1+	-	-	0.1	-	-	A	1.050<	5.5	
167	7.5	1+	-	-	0.1	-	-	A	1.050	10.0	
N	5	5	5	5	5	5	5	5	5	5	
MEAN									8.20		
S.D.									2.56		
S.E.									1.15		
M/C									0.6648		
F									0.2232		
H	1.1538	0.0129	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.2215		

, Normal ; 1+, Moderate.  
 Color : A = Pale yellow or yellow.

INDIVIDUAL DATA 64-2  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Urinary findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Week 2 of recovery

Animal No.	pH	Protein	Glucose	Ketone body	Urobilinogen EU/dL	Bili-rubin	Occult blood	Color	Urine volume mL/21hr		
									Specific gravity	Color	Specific gravity
463	6.5	±	-	-	0.1	-	-	A	1.050<	5.5	
464	8.0	1+	-	-	0.1	-	-	A	1.050<	7.0	
465	8.5	±	-	-	0.1	-	-	A	1.036	13.0	
466	8.5	1+	-	-	0.1	-	-	A	1.050<	6.5	
467	8.0	±	-	-	0.1	-	-	A	1.040	14.0	
N	5	5	5	5	5	5	5	5	9.20		
MEAN											
S.D.									3.98		
S.E.									1.78		

, Normal ; ±, Slight ; 1+, Moderate.  
 Color : A = Pale yellow or yellow.

INDIVIDUAL DATA 7-1-1  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of administration

Animal No.	WBC 10 <sup>2</sup> /µL	RBC 10 <sup>4</sup> /µL	HGB g/dL	HCT %	MCV fl	MCH pg	MCHC g/dL	Platelet 10 <sup>4</sup> /µL
101	85.3	948	16.5	45.3	47.8	17.4	36.4	115.4
102	58.5	912	16.4	48.4	53.1	18.0	33.9	98.3
104	79.5	886	15.7	44.9	50.7	17.7	35.0	126.4
105	47.1	903	15.8	45.9	50.8	17.5	34.4	108.9
106	107.0	871	15.6	44.7	51.3	17.9	34.9	111.4
N	5	5	5	5	5	5	5	5
MEAN	75.48	904.0	16.00	45.84	50.74	17.70	34.92	112.08
S.D.	23.45	29.2	0.42	1.50	1.91	0.25	0.94	10.20
S.E.	10.49	13.1	0.19	0.67	0.85	0.11	0.42	4.56
M/C	1.8322	1.6548	1.6117	0.6526	3.1035	5.3761	8.5860*	1.6797
F	1.3981	0.4608	1.6233	1.7310	0.1130	0.2522		0.8047
H							0.4018	

## INDIVIDUAL DATA 7-1-2

STUDY NO. SR09207

TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : End of administration

Animal No.	WBC 10 <sup>2</sup> /µL	RBC 10 <sup>4</sup> /µL	HGB g/dL	HCT %	MCV fl	MCH pg	MCHC g/dL	Platelet 10 <sup>4</sup> /µL
201	80.7	933	16.0	44.8	48.0	17.1	35.7	106.3
204	67.1	909	15.4	44.8	49.3	16.9	34.4	113.3
206	80.7	894	14.9	42.3	47.3	16.7	35.2	132.2
207	33.2	833	15.3	44.9	53.9	18.4	34.1	83.5
209	75.5	855	15.1	43.9	51.3	17.7	34.4	118.5
N	5	5	5	5	5	5	5	5
MEAN	67.44	884.8	15.34	44.14	49.96	17.36	34.76	110.76
S.D.	19.93	40.5	0.42	1.11	2.68	0.69	0.67	17.95
S.E.	8.91	18.1	0.19	0.49	1.20	0.31	0.30	8.03

INDIVIDUAL DATA 7-1-3  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : End of administration

Animal No.	WBC 10 <sup>2</sup> /µL	RBC 10 <sup>4</sup> /µL	HGB g/dL	HCT %	MCV fl	MCH pg	MCHC g/dL	Platelet 10 <sup>4</sup> /µL
301	77.0	919	16.4	45.8	49.8	17.8	35.8	132.3
304	80.0	901	16.1	46.2	51.3	17.9	34.8	114.4
306	60.8	883	15.7	44.9	50.8	17.8	35.0	114.6
308	90.3	915	15.4	44.5	48.6	16.8	34.6	140.4
309	62.5	836	14.6	42.4	50.7	17.5	34.4	107.0
N	5	5	5	5	5	5	5	5
MEAN	74.12	890.8	15.64	44.76	50.24	17.56	34.92	121.74
S.D.	12.42	33.7	0.69	1.48	1.06	0.45	0.54	13.98
S.E.	5.55	15.1	0.31	0.66	0.48	0.20	0.24	6.25

## INDIVIDUAL DATA 7-1-4

STUDY NO. SR09207

TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : End of administration

Animal No.	WBC 10 <sup>2</sup> /µL	RBC 10 <sup>4</sup> /µL	HGB g/dL	HCT %	MCV fl	MCH pg	MCHC g/dL	Platelet 10 <sup>4</sup> /µL
402	36.4	804	14.3	41.3	51.4	17.8	34.6	105.2
404	47.7	954	15.3	43.8	45.9	16.0	34.9	126.9
405	71.3	874	15.4	44.1	50.5	17.6	34.9	107.2
406	66.3	852	15.5	44.4	52.1	18.2	34.9	111.9
408	51.3	888	16.1	46.0	51.8	18.1	35.0	100.2
N	5	5	5	5	5	5	5	5
MEAN	54.60	874.4	15.32	43.92	50.34	17.54	34.86	110.28
S.D.	14.19	54.7	0.65	1.69	2.55	0.89	0.15	10.19
S.E.	6.35	24.5	0.29	0.76	1.14	0.40	0.07	4.56

INDIVIDUAL DATA 7-1-5  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of administration

Animal No.	Reticulo- cyte %	PT sec	APTT sec	Differential count of WBC ( $10^2/\mu\text{L}$ )				
				Neutrophil	Lympho- cyte	Monocyte	Eosinophil	Basophil
101	2.26	22.3	26.1	8.5	73.8	1.8	1.2	0.0
102	2.83	19.5	24.5	10.1	46.1	1.6	0.7	0.0
104	2.66	22.8	24.9	8.1	68.9	1.7	0.8	0.0
105	3.23	18.4	26.5	10.7	34.2	1.5	0.7	0.0
106	3.41	17.0	21.7	19.9	84.4	1.9	0.8	0.0
N	5	5	5	5	5	5	5	5
MEAN	2.878	20.00	24.74	11.46	61.48	1.70	0.84	0.00
S.D.	0.458	2.50	1.89	4.84	20.69	0.16	0.21	0.00
S.E.	0.205	1.12	0.84	2.16	9.25	0.07	0.09	0.00
M/C	7.8568*	11.3230*	2.7064	1.1170	1.3016	7.0314	3.4563	0.0000
F			1.9836	0.3934	1.5988	0.9506	0.5255	0.0000
H	2.5782	8.4378*						

INDIVIDUAL DATA 7-1-6  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : End of administration

Animal No.	Reticulo- cyte %	PT sec	APTT sec	Differential count of WBC ( $10^3/\mu\text{L}$ )				
				Neutrophil	Lympho- cyte	Monocyte	Eosinophil	Basophil
201	3.68	19.3	23.3	13.6	63.9	2.1	1.1	0.0
204	3.40	18.5	25.8	19.1	44.7	2.0	1.3	0.0
206	3.31	18.9	24.2	14.7	63.4	2.1	0.5	0.0
207	3.07	17.7	25.1	6.6	25.5	0.6	0.5	0.0
209	3.18	19.1	26.1	12.3	60.9	1.6	0.7	0.0
N	5	5	5	5	5	5	5	5
MEAN	3.328	18.70	24.90	13.26	51.68	1.68	0.82	0.00
S.D.	0.233	0.63	1.16	4.52	16.63	0.64	0.36	0.00
S.E.	0.104	0.28	0.52	2.02	7.44	0.29	0.16	0.00
U				9.0000				

INDIVIDUAL DATA 7-1-7  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : End of administration

Animal No.	Reticulo- cyte %	PT sec	APTT sec	Differential count of WBC ( $10^3/\mu\text{L}$ )				
				Neutrophil	Lympho- cyte	Monocyte	Eosinophil	Basophil
301	3.35	19.6	26.8	8.9	65.4	1.4	1.3	0.0
304	3.31	17.7	22.2	6.4	72.1	0.9	0.6	0.0
306	3.12	19.2	26.7	11.5	47.3	1.5	0.5	0.0
308	3.13	22.9	29.2	13.3	74.0	1.9	1.1	0.0
309	3.06	23.0	27.5	16.4	43.0	1.2	1.9	0.0
N	5	5	5	5	5	5	5	5
MEAN	3.194	20.48	26.48	11.30	60.36	1.38	1.08	0.00
S.D.	0.128	2.36	2.59	3.87	14.33	0.37	0.57	0.00
S.E.	0.057	1.06	1.16	1.73	6.41	0.17	0.25	0.00
U				9.0000				

INDIVIDUAL DATA 7-1-8  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : End of administration

Animal No.	Reticulo- cyte %	PT sec	APTT sec	Differential count of WBC ( $10^3/\mu\text{L}$ )				
				Neutrophil	Lympho- cyte	Monocyte	Eosinophil	Basophil
402	2.67	20.3	25.2	7.9	26.7	1.4	0.4	0.0
404	3.06	32.6	30.9	7.6	37.9	1.2	1.0	0.0
405	3.78	22.2	25.2	12.2	56.7	1.7	0.7	0.0
406	4.07	27.1	26.8	14.2	49.2	1.6	1.3	0.0
408	3.10	29.5	29.9	10.9	38.6	1.1	0.7	0.0
N	5	5	5	5	5	5	5	5
MEAN	3.336	26.34	27.60	10.56	41.82	1.40	0.82	0.00
S.D.	0.573	5.08	2.66	2.82	11.51	0.25	0.34	0.00
S.E.	0.256	2.27	1.19	1.26	5.15	0.11	0.15	0.00
U				4.0000				

INDIVIDUAL DATA 7-2-1  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of recovery

Animal No.	WBC 10 <sup>3</sup> /μL	RBC 10 <sup>3</sup> /μL	HGB g/dL	HCT %	MCV fl	MCH pg	MCHC g/dL	Platelet 10 <sup>3</sup> /μL
103	58.4	934	15.5	42.9	45.9	16.6	36.1	117.1
107	60.5	930	16.2	45.2	48.6	17.4	35.8	129.3
109	43.0	906	15.6	44.3	48.9	17.2	35.2	92.7
110	75.1	865	16.2	46.6	53.9	18.7	34.8	105.9
111	83.4	985	15.9	44.4	45.1	16.1	35.8	146.7
N	5	5	5	5	5	5	5	5
MEAN	64.08	924.0	15.88	44.68	48.48	17.20	35.54	118.34
S.D.	15.69	43.8	0.33	1.36	3.45	0.98	0.53	20.85
S.E.	7.01	19.6	0.15	0.61	1.54	0.44	0.24	9.32
M/C	0.0706	0.8320	0.3857	0.0190	1.4004	3.2708	0.4530	1.9781
F	3.2273	0.0554	0.1016	0.0374	0.1034	0.0018	0.6800	0.1359

## INDIVIDUAL DATA 7-2-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : End of recovery

Animal No.	WBC 10 <sup>2</sup> /µL	RBC 10 <sup>4</sup> /µL	HGB g/dL	HCT %	MCV fl	MCH pg	MCHC g/dL	Platelet 10 <sup>4</sup> /µL
401	103.5	959	16.5	45.6	47.5	17.2	36.2	113.9
403	76.8	947	16.3	45.3	47.8	17.2	36.0	105.3
407	73.6	893	15.5	44.8	50.2	17.4	34.6	129.4
409	61.9	912	16.0	44.5	48.8	17.5	36.0	107.3
410	100.7	936	15.5	42.4	45.3	16.6	36.6	116.9
<hr/>								
N	5	5	5	5	5	5	5	5
MEAN	83.30	929.4	15.96	44.52	47.92	17.18	35.88	114.56
S.D.	18.06	26.7	0.46	1.26	1.80	0.35	0.76	9.55
S.E.	8.08	12.0	0.20	0.56	0.81	0.16	0.34	4.27

INDIVIDUAL DATA 7-2-3  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of recovery

Animal No.	Reticulo- cyte %	PT sec	APTT sec	Differential count of WBC ( $10^2/\mu\text{L}$ )				
				Neutrophil	Lympho- cyte	Monocyte	Eosinophil	Basophil
103	1.99	26.2	29.5	8.5	48.1	0.8	1.0	0.0
107	2.96	21.6	28.1	12.3	45.9	1.6	0.7	0.0
109	1.98	23.1	25.8	8.8	32.4	1.5	0.3	0.0
110	2.56	17.5	22.8	6.7	66.2	1.3	0.9	0.0
111	3.72	21.2	25.8	27.6	51.4	3.2	1.2	0.0
N	5	5	5	5	5	5	5	5
MEAN	2.642	21.92	26.40	12.78	48.80	1.68	0.82	0.00
S.D.	0.730	3.16	2.56	8.53	12.12	0.90	0.34	0.00
S.E.	0.327	1.41	1.14	3.81	5.42	0.40	0.15	0.00
M/C	1.5569	0.7346	3.2557	1.8330	0.4869	0.0715	4.5307*	0.0000
F	1.7665	0.4506	0.5249	0.0038	3.3717	0.3575	5.3448*	0.0000
H								

INDIVIDUAL DATA 7-2-4  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : End of recovery

Animal No.	Reticulo- cyte %	PT sec	APTT sec	Differential count of WBC ( $10^3/\mu\text{L}$ )				
				Neutrophil	Lympho- cyte	Monocyte	Eosinophil	Basophil
401	3.39	23.0	25.5	15.7	83.0	3.2	1.6	0.0
403	3.51	23.1	25.3	11.7	61.7	2.2	1.2	0.0
407	2.56	24.9	26.7	7.9	63.0	1.1	1.6	0.0
409	3.07	24.4	24.2	18.3	40.9	1.6	1.1	0.0
410	3.11	19.8	25.9	11.6	83.2	1.9	4.0	0.0
N	5	5	5	5	5	5	5	5
MEAN	3.128	23.04	25.52	13.04	66.36	2.00	1.90	0.00
S.D.	0.368	1.99	0.91	4.03	17.62	0.78	1.20	0.00
S.E.	0.164	0.89	0.41	1.80	7.88	0.35	0.53	0.00
U					1.5000*			

INDIVIDUAL DATA 7-3-1  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 6 of lactation

Animal No.	WBC 10 <sup>3</sup> /μL	RBC 10 <sup>3</sup> /μL	HGB g/dL	HCT %	MCV fl	MCH pg	MCHC g/dL	Platelet 10 <sup>3</sup> /μL
151	57.5	655	13.4	40.3	61.5	20.5	33.3	142.4
152	88.1	776	14.0	41.0	52.8	18.0	34.1	117.6
153	59.0	724	13.9	41.0	56.6	19.2	33.9	111.9
154	57.4	782	15.3	44.3	56.6	19.6	34.5	140.8
158	75.7	761	14.0	41.6	54.7	18.4	33.7	140.6
MEAN	67.54	739.6	14.12	41.64	56.44	19.14	33.90	130.66
S.D.	13.84	52.4	0.70	1.56	3.24	0.99	0.45	14.68
S.E.	6.19	23.4	0.32	0.70	1.45	0.44	0.20	6.56
M/C	3.7399	0.58888	2.3887	4.0934	2.5466	1.0128	4.8255	4.4509
F	3.3138*	0.6542	1.6684	2.4326	0.1415	0.0797	0.1815	0.9541

## INDIVIDUAL DATA 7-3-2

STUDY NO. SR09207

TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Hematological findings

ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 100 mg/kg PERIOD : Day 6 of lactation

Animal No.	WBC 10 <sup>2</sup> /μL	RBC 10 <sup>4</sup> /μL	HGB g/dL	HCT %	MCV fl	MCH pg	MCHC g/dL	Platelet 10 <sup>4</sup> /μL
253	58.6	798	15.0	43.4	54.4	18.8	34.6	105.3
255	55.2	817	14.7	42.4	51.9	18.0	34.7	94.4
257	54.4	800	15.6	46.5	58.1	19.5	33.5	126.6
260	44.6	675	13.9	43.8	64.9	20.6	31.7	137.7
262	50.8	763	14.4	42.5	55.7	18.9	33.9	137.9
<hr/>								
N	5	5	5	5	5	5	5	5
MEAN	52.72	770.6	14.72	43.72	57.00	19.16	33.68	120.38
S.D.	5.32	56.9	0.64	1.66	4.95	0.97	1.21	19.67
S.E.	2.38	25.5	0.29	0.74	2.21	0.43	0.54	8.80
t'	2.3942							

INDIVIDUAL DATA 7-3-3  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 300 mg/kg PERIOD : Day 6 of lactation

Animal No.	WBC 10 <sup>3</sup> /µL	RBC 10 <sup>3</sup> /µL	HGB g/dL	HCT %	MCV fl	MCH pg	MCHC g/dL	Platelet 10 <sup>3</sup> /µL
351	58.4	747	14.6	43.3	58.0	19.5	33.7	126.8
353	44.6	795	14.7	42.7	53.7	18.5	34.4	109.2
354	64.4	711	14.2	42.6	59.9	20.0	33.3	119.6
357	53.6	821	15.2	44.0	53.6	18.5	34.5	140.7
358	37.5	815	14.8	43.3	53.1	18.2	34.2	139.9
N	5	5	5	5	5	5	5	5
MEAN	51.70	777.8	14.70	43.18	55.66	18.94	34.02	127.24
S.D.	10.75	47.3	0.36	0.56	3.09	0.77	0.51	13.47
S.E.	4.81	21.2	0.16	0.25	1.38	0.34	0.23	6.02
t'	2.5590							

## INDIVIDUAL DATA 7-3-4

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 6 of lactation

Animal No.	WBC 10 <sup>2</sup> /µL	RBC 10 <sup>4</sup> /µL	HGB g/dL	HCT %	MCV fl	MCH pg	MCHC g/dL	Platelet 10 <sup>4</sup> /µL
451	60.2	752	14.6	44.1	58.6	19.4	33.1	132.8
452	65.7	756	14.2	41.3	54.6	18.8	34.4	131.0
453	75.4	748	14.2	40.9	54.7	19.0	34.7	138.9
456	59.7	692	13.6	40.1	57.9	19.7	33.9	129.8
458	58.9	800	14.5	43.1	53.9	18.1	33.6	143.5
N	5	5	5	5	5	5	5	5
MEAN	63.98	749.6	14.22	41.90	55.94	19.00	33.94	135.20
S.D.	6.92	38.4	0.39	1.65	2.15	0.61	0.63	5.81
S.E.	3.10	17.2	0.17	0.74	0.96	0.27	0.28	2.60
t'	0.5751							

INDIVIDUAL DATA 7-3-5  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 6 of lactation

Animal No.	Reticulo- cyte %	PT sec	APTT sec	Differential count of WBC ( $10^3/\mu\text{L}$ )				
				Neutrophil	Lympho- cyte	Monocyte	Eosinophil	Basophil
151	14.59	18.8	21.3	14.3	40.9	2.0	0.3	0.0
152	9.67	18.5	19.8	24.8	59.4	3.2	0.7	0.0
153	8.95	17.5	20.1	23.9	29.2	4.4	1.5	0.0
154	8.49	18.3	19.1	25.3	27.3	3.7	1.1	0.0
158	8.80	18.6	16.6	16.0	55.8	2.7	1.2	0.0
N	5	5	5	5	5	5	5	5
MEAN	10.100	18.34	19.38	20.86	42.52	3.20	0.96	0.00
S.D.	2.547	0.50	1.75	5.27	14.77	0.92	0.47	0.00
S.E.	1.139	0.22	0.78	2.36	6.61	0.41	0.21	0.00
M/C	1.0443	3.8437	1.0639	1.2805	10.6493*	3.2412	2.8589	0.0000
F	0.5686	2.0754	2.9424†	2.4376		1.0045	0.7669	0.0000
H					4.0003			

## INDIVIDUAL DATA 7-3-6

STUDY NO. SR09207

TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Hematological findings

ANIMAL : Rat, Crl:CD(SD)

SEX : Female

GROUP : 100 mg/kg

PERIOD : Day 6 of lactation

Animal No.	Reticulo- cyte %	PT sec	APTT sec	Differential count of WBC ( $10^3/\mu\text{L}$ )				
				Neutrophil	Lympho- cyte	Monocyte	Eosinophil	Basophil
253	9.05	17.8	20.0	21.3	33.1	3.4	0.8	0.0
255	8.41	18.1	21.6	15.4	34.9	4.2	0.7	0.0
257	11.12	16.9	19.1	16.5	32.1	4.8	1.0	0.0
260	17.42	18.7	19.0	12.4	29.7	2.1	0.4	0.0
262	10.41	18.4	18.6	15.5	32.0	2.6	0.7	0.0
N	5	5	5	5	5	5	5	5
MEAN	11.282	17.98	19.66	16.22	32.36	3.42	0.72	0.00
S.D.	3.595	0.69	1.20	3.23	1.89	1.11	0.22	0.00
S.E.	1.608	0.31	0.54	1.44	0.84	0.50	0.10	0.00
t'				0.3311				

INDIVIDUAL DATA 7-3-7  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 300 mg/kg PERIOD : Day 6 of lactation

Animal No.	Reticulo- cyte %	PT sec	APTT sec	Differential count of WBC ( $10^2/\mu\text{L}$ )				
				Neutrophil	Lympho- cyte	Monocyte	Eosinophil	Basophil
351	10.69	17.5	20.3	14.7	39.7	3.1	0.9	0.0
353	7.18	15.8	18.7	7.3	34.9	2.0	0.4	0.0
354	12.12	19.1	19.6	18.9	41.7	2.7	1.1	0.0
357	6.89	16.8	18.3	17.1	33.1	2.5	0.9	0.0
358	8.82	17.6	17.6	11.6	23.0	2.3	0.6	0.0
N	5	5	5	5	5	5	5	5
MEAN	9.140	17.36	18.90	13.92	34.48	2.52	0.78	0.00
S.D.	2.252	1.21	1.07	4.60	7.30	0.41	0.28	0.00
S.E.	1.007	0.54	0.48	2.06	3.27	0.19	0.12	0.00
t'		0.5675						

INDIVIDUAL DATA 7-3-8  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 6 of lactation

Animal No.	Reticulo- cyte %	PT sec	APTT sec	Differential count of WBC ( $10^2/\mu\text{L}$ )				
				Neutrophil	Lympho- cyte	Monocyte	Eosinophil	Basophil
451	11.70	17.7	17.8	20.8	34.2	4.5	0.7	0.0
452	12.33	17.8	18.7	15.5	47.5	2.2	0.5	0.0
453	7.40	17.5	18.2	17.9	54.3	2.2	1.0	0.0
456	9.30	16.7	16.1	21.7	34.7	2.9	0.4	0.0
458	7.10	16.7	16.0	14.0	42.0	2.1	0.8	0.0
N	5	5	5	5	5	5	5	5
MEAN	9.566	17.28	17.36	17.98	42.54	2.78	0.68	0.00
S.D.	2.400	0.54	1.24	3.31	8.58	1.01	0.24	0.00
S.E.	1.073	0.24	0.55	1.48	3.84	0.45	0.11	0.00
t'				2.3884				

## INDIVIDUAL DATA 7-4-1

STUDY NO. SR09207    TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Hematological findings    ANIMAL : Rat, Crl:CD(SD)    SEX : Female    GROUP : 0 mg/kg    PERIOD : End of recovery

Animal No.	WBC 10 <sup>3</sup> /µL	RBC 10 <sup>3</sup> /µL	HGB g/dL	HCT %	MCV fl	MCH pg	MCHC g/dL	Platelet 10 <sup>3</sup> /µL
163	27.7	864	16.4	46.9	54.3	19.0	35.0	100.1
164	36.4	878	15.2	43.1	49.1	17.3	35.3	138.3
165	55.8	864	15.4	43.1	49.9	17.8	35.7	100.9
166	41.9	822	15.7	46.0	56.0	19.1	34.1	106.0
167	48.9	857	16.3	47.1	55.0	19.0	34.6	107.0
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N	5	5	5	5	5	5	5	5
MEAN	42.14	857.0	15.80	45.24	52.86	18.44	34.94	110.46
S.D.	10.88	21.0	0.53	2.00	3.14	0.83	0.62	15.86
S.E.	4.87	9.4	0.24	0.89	1.40	0.37	0.28	7.09
M/C	0.8118	0.6842	0.0007	0.2062	1.2135	0.8866	1.4952	0.2767
F	4.1855†	1.4540	2.4057	4.1033†	0.8546	0.1039	4.5093†	0.5292

## INDIVIDUAL DATA 7-4-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : End of recovery

Animal No.	WBC 10 <sup>2</sup> /µL	RBC 10 <sup>4</sup> /µL	HGB g/dL	HCT %	MCV fl	MCH pg	MCHC g/dL	Platelet 10 <sup>4</sup> /µL
463	68.0	830	15.2	43.2	52.0	18.3	35.2	112.6
464	37.7	882	16.2	45.5	51.6	18.4	35.6	134.5
465	58.9	846	14.9	41.4	48.9	17.6	36.0	121.5
466	55.2	831	15.1	42.2	50.8	18.2	35.8	139.8
467	86.0	791	15.0	42.4	53.6	19.0	35.4	86.7
<hr/>								
N	5	5	5	5	5	5	5	5
MEAN	61.16	836.0	15.28	42.94	51.38	18.30	35.60	119.02
S.D.	17.71	32.8	0.53	1.57	1.72	0.50	0.32	21.00
S.E.	7.92	14.7	0.24	0.70	0.77	0.22	0.14	9.39
t'	2.0459			2.0257			2.1235	

INDIVIDUAL DATA 7-4-3  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : End of recovery

Animal No.	Reticulo- cyte %	PT sec	APTT sec	Differential count of WBC ( $10^3/\mu\text{L}$ )				
				Neutrophil	Lympho- cyte	Monocyte	Eosinophil	Basophil
163	3.43	17.0	16.1	7.2	19.2	0.9	0.4	0.0
164	2.35	18.3	18.0	2.9	31.8	0.9	0.8	0.0
165	2.57	18.2	17.0	5.4	48.4	1.0	1.0	0.0
166	3.39	16.3	19.2	7.5	33.2	0.7	0.5	0.0
167	3.37	17.9	17.9	5.4	42.2	0.9	0.4	0.0
N	5	5	5	5	5	5	5	5
MEAN	3.022	17.54	17.64	5.68	34.96	0.88	0.62	0.00
S.D.	0.519	0.86	1.16	1.84	11.12	0.11	0.27	0.00
S.E.	0.232	0.39	0.52	0.82	4.97	0.05	0.12	0.00
M/C	0.0678	0.8772	1.1975	0.4431	0.9177	5.6125*	0.0046	0.0000
F	1.2622	0.0007	0.3305	1.9476	2.7417	7.6115*	0.0000	
H						6.0650*		

INDIVIDUAL DATA 7-4-4  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : End of recovery

Animal No.	Reticulo- cyte %	PT sec	APTT sec	Differential count of WBC ( $10^3/\mu\text{L}$ )				
				Neutrophil	Lympho- cyte	Monocyte	Eosinophil	Basophil
463	2.78	19.6	21.2	11.4	53.8	1.4	1.4	0.0
464	2.32	17.2	16.1	7.4	28.5	1.0	0.8	0.0
465	2.84	18.4	17.2	6.4	50.4	1.2	0.9	0.0
466	2.15	16.4	19.7	8.8	43.0	2.1	1.3	0.0
467	3.29	16.2	17.1	4.4	79.6	1.0	1.0	0.0
N	5	5	5	5	5	5	5	5
MEAN	2.676	17.56	18.26	7.68	51.06	1.34	1.08	0.00
S.D.	0.452	1.43	2.11	2.63	18.68	0.46	0.26	0.00
S.E.	0.202	0.64	0.94	1.17	8.36	0.20	0.12	0.00
t' U					2.7589*		1.0000*	

INDIVIDUAL DATA 8-1-1  
STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of administration

Animal No.	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%)				AST IU/L	ALT IU/L	ALP IU/L	$\gamma$ -GTP IU/L	T-Bil mg/dL					
				Globulin													
				$\alpha_1$	$\alpha_2$	$\beta$											
101	5.3	2.67	1.02	50.5	22.1	7.2	15.0	5.2	72	35	522	0.3					
102	4.9	2.61	1.13	53.2	16.6	8.6	16.5	5.1	64	35	541	0.3					
104	5.4	2.84	1.11	52.5	22.2	6.7	14.9	3.7	61	27	301	0.2					
105	5.1	2.48	0.95	48.6	23.6	8.3	15.8	3.7	56	26	335	0.3					
106	5.4	2.76	1.04	51.0	19.3	7.4	17.1	5.2	60	31	302	0.2					
												0.07					
N	5	5	5	5	5	5	5	5	5	5	5	5					
MEAN	5.22	2.672	1.050	51.16	20.76	7.64	15.86	4.58	62.6	30.8	400.2	0.26					
S.D.	0.22	0.138	0.072	1.80	2.80	0.79	0.95	0.80	6.0	4.3	120.8	0.05					
S.E.	0.10	0.062	0.032	0.81	1.25	0.35	0.42	0.36	2.7	1.9	54.0	0.02					
M/C	2.0547	6.1034	2.1419	1.5987	2.3174	4.3871	1.8574	1.3329	18.5863**	11.9294**	2.7098	4.3334					
F	2.9964†	1.5722	1.9618	2.0046	1.3079	0.7901	0.5107	0.5223	0.0449	3.1739	1.4206	1.1596					
H									0.9296			1.8689					

INDIVIDUAL DATA 8-1-2  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : End of administration

Animal No.	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%)				AST IU/L	ALT IU/L	ALP IU/L	$\gamma$ -GTP IU/L	T-Bil mg/dL					
				Globulin													
				$\alpha_1$	$\alpha_2$	$\beta$											
201	5.4	2.63	0.95	48.7	25.2	6.9	15.0	4.2	57	31	399	0.5					
204	5.2	2.62	1.01	50.2	22.4	7.0	15.8	4.6	57	31	444	0.1					
206	5.1	2.55	1.00	50.0	22.9	7.9	15.3	3.9	63	28	450	0.5					
207	5.1	2.57	1.02	50.5	21.9	7.4	15.6	4.6	56	26	264	0.3					
209	5.4	2.60	0.92	48.0	22.6	7.4	16.2	5.8	70	36	357	0.4					
	N	5	5	5	5	5	5	5	5	5	5	5					
MEAN	5.24	2.594	0.980	49.48	23.00	7.32	15.58	4.62	60.6	30.4	382.8	0.36					
S.D.	0.15	0.034	0.043	1.08	1.28	0.40	0.46	0.72	5.9	3.8	76.3	0.17					
S.E.	0.07	0.015	0.019	0.48	0.57	0.18	0.21	0.32	2.7	1.7	34.1	0.07					
t'	0.1474																

INDIVIDUAL DATA 8-1-3  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : End of administration

Animal No.	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%)				AST IU/L	ALT IU/L	ALP IU/L	$\gamma$ -GTP IU/L	T-Bil mg/dL					
				Globulin													
				$\alpha_1$	$\alpha_2$	$\beta$											
301	5.5	2.69	0.97	49.1	23.6	7.2	15.2	4.9	150	59	453	0.6					
304	5.0	2.54	1.03	50.9	22.2	7.6	15.4	3.9	56	24	301	0.2					
306	5.2	2.68	1.06	51.4	21.6	7.9	14.7	4.4	51	26	360	0.4					
308	5.0	2.51	1.01	50.2	22.1	7.4	16.1	4.2	51	21	458	0.3					
309	4.7	2.46	1.10	52.4	19.0	8.3	16.5	3.8	68	26	308	0.5					
	N	5	5	5	5	5	5	5	5	5	5	5					
MEAN	5.08	2.576	1.034	50.80	21.70	7.68	15.58	4.24	75.2	31.2	376.0	0.40					
S.D.	0.29	0.104	0.049	1.24	1.68	0.43	0.72	0.44	42.4	15.7	76.1	0.16					
S.E.	0.13	0.046	0.022	0.56	0.75	0.19	0.32	0.20	19.0	7.0	34.0	0.007					
t'	1.0321																

INDIVIDUAL DATA 8-1-4  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : End of administration

Animal No.	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%)				AST IU/L	ALT IU/L	ALP IU/L	$\gamma$ -GTP IU/L	T-Bil mg/dL					
				Globulin													
				$\alpha_1$	$\alpha_2$	$\beta$	$\gamma$										
402	4.6	2.35	1.05	51.1	21.6	7.0	14.9	5.4	56	23	286	0.5					
404	5.0	2.47	0.98	49.7	23.5	7.4	14.9	4.5	87	34	428	0.1					
405	4.9	2.62	1.16	53.6	20.5	7.3	14.8	3.8	56	26	648	0.1					
406	5.0	2.69	1.17	54.0	17.9	7.7	15.6	4.8	57	29	272	0.2					
408	4.9	2.48	1.02	50.6	20.8	7.1	16.3	5.2	61	30	328	0.3					
N	5	5	5	5	5	5	5	5	5	5	5	5					
MEAN	4.88	2.522	1.076	51.80	20.86	7.30	15.30	4.74	63.4	28.4	392.4	0.24					
S.D.	0.16	0.134	0.085	1.90	2.03	0.27	0.64	0.63	13.4	4.2	155.4	0.17					
S.E.	0.07	0.060	0.038	0.85	0.91	0.12	0.29	0.28	6.0	1.9	69.5	0.07					
t'	2.5065																

INDIVIDUAL DATA 8-1-5  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of administration

Animal No.	Glucose mg/dL	T-Chol mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
101	160	50	9	13.0	0.58	145	4.58	107	9.3	6.7
102	169	38	30	11.1	0.50	145	4.17	107	9.5	8.8
104	158	61	25	12.6	0.54	146	4.21	106	9.5	6.2
105	159	59	16	16.6	0.52	146	4.30	107	9.7	8.3
106	156	67	30	13.7	0.52	145	4.05	104	10.1	7.3
N	5	5	5	5	5	5	5	5	5	5
MEAN	160.4	55.0	22.0	13.40	0.532	145.4	4.262	106.2	9.62	7.46
S.D.	5.0	11.3	9.2	2.03	0.030	0.5	0.199	1.3	0.30	1.08
S.E.	2.2	5.0	4.1	0.91	0.014	0.2	0.089	0.6	0.14	0.48
M/C	6.3203	4.7814	3.0189	2.3958	5.5466	4.5047	2.2391	1.5650	3.2674	3.3232
F	0.5667	0.4053	0.6939	0.7532	0.6883	0.4096	1.1763	0.5891	2.1461	0.5728

INDIVIDUAL DATA 8-1-6  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : End of administration

Animal No.	Glucose mg/dL	T-Cho mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
201	145	53	26	13.3	0.55	145	4.34	105	9.7	7.3
204	136	44	51	13.8	0.52	145	4.48	105	9.8	7.8
206	176	51	51	14.1	0.55	145	4.35	106	9.7	6.9
207	145	46	16	11.9	0.52	147	4.31	105	10.0	7.3
209	132	50	16	13.7	0.56	148	4.18	108	9.8	8.3
N	5	5	5	5	5	5	5	5	5	5
MEAN	146.8	48.8	32.0	13.36	0.540	146.0	4.332	105.8	9.80	7.52
S.D.	17.3	3.7	17.8	0.86	0.019	1.4	0.107	1.3	0.12	0.54
S.E.	7.7	1.7	8.0	0.39	0.008	0.6	0.048	0.6	0.05	0.24

INDIVIDUAL DATA 8-1-7  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : End of administration

Animal No.	Glucose mg/dL	T-Chol mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
301	178	64	11	13.1	0.63	143	4.85	105	9.8	7.7
304	153	51	33	13.9	0.49	145	4.47	106	9.7	8.6
306	158	52	30	11.4	0.47	146	4.22	106	9.7	7.1
308	148	48	26	11.2	0.48	145	4.43	106	10.0	8.2
309	115	29	28	14.5	0.53	148	4.31	108	9.4	8.3
N	5	5	5	5	5	5	5	5	5	5
MEAN	150.4	48.8	25.6	12.82	0.520	145.4	4.456	106.2	9.72	7.98
S.D.	22.8	12.6	8.6	1.48	0.066	1.8	0.241	1.1	0.22	0.59
S.E.	10.2	5.7	3.8	0.66	0.029	0.8	0.108	0.5	0.10	0.26

INDIVIDUAL DATA 8-1-8  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : End of administration

Animal No.	Glucose mg/dL	T-Chol mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
402	146	60	16	12.4	0.56	145	4.12	106	8.9	7.1
404	172	49	15	15.3	0.63	144	4.46	104	9.4	7.1
405	167	63	54	12.6	0.52	147	4.34	108	9.7	7.8
406	127	37	40	15.7	0.54	147	4.05	109	9.5	7.4
408	148	40	38	15.4	0.54	148	4.36	108	9.6	8.2
N	5	5	5	5	5	5	5	5	5	5
MEAN	152.0	49.8	32.6	14.28	0.558	146.2	4.266	107.0	9.42	7.52
S.D.	18.0	11.6	16.8	1.63	0.043	1.6	0.173	2.0	0.31	0.48
S.E.	8.1	5.2	7.5	0.73	0.019	0.7	0.077	0.9	0.14	0.21

INDIVIDUAL DATA 8-2-1  
STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of recovery

Animal No.	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%)				AST IU/L	ALT IU/L	ALP IU/L	$\gamma$ -GTP IU/L	T-Bil mg/dL					
				Globulin													
				$\alpha_1$	$\alpha_2$	$\beta$	$\gamma$										
103	5.3	2.67	1.02	50.4	19.0	8.2	17.1	5.3	59	29	246	0.5					
107	5.5	2.46	0.81	44.7	24.9	8.2	16.5	5.7	53	24	306	0.5					
109	5.0	2.42	0.94	48.5	23.1	7.9	14.9	5.6	61	24	387	0.1					
110	5.2	2.43	0.88	46.9	24.0	7.5	15.9	5.7	56	26	196	0.4					
111	5.7	2.73	0.91	47.7	20.6	8.1	17.8	5.8	62	24	314	0.3					
												0.09					
N	5	5	5	5	5	5	5	5	5	5	5	5					
MEAN	5.34	2.542	0.912	47.64	22.32	7.98	16.44	5.62	58.2	25.4	289.8	0.36					
S.D.	0.27	0.147	0.077	2.09	2.45	0.29	1.11	0.19	3.7	2.2	72.5	0.17					
S.E.	0.12	0.066	0.035	0.94	1.10	0.13	0.50	0.09	1.7	1.0	32.4	0.07					
M/C	0.0193	0.3747	0.0009	0.0125	0.0146	0.0380	1.9312	6.9611**	0.2209	2.5554	0.1914	3.7364					
F	0.0000	0.5354	1.1506	1.1827	0.0214	6.4433*	0.3846	0.4455	0.3787	1.6000	0.1019	1.8815					
H												2.5128					

INDIVIDUAL DATA 8-2-2  
STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : End of recovery

Animal No.	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%)				AST IU/L	ALT IU/L	ALP IU/L	$\gamma$ -GTP IU/L	T-Bil mg/dL					
				Globulin													
				$\alpha_1$	$\alpha_2$	$\beta$											
401	5.5	2.79	1.03	50.7	21.8	7.5	16.5	3.5	59	28	336	0.3					
403	5.4	2.74	1.03	50.7	20.0	8.0	15.9	5.4	64	34	250	0.3					
407	5.5	2.61	0.91	47.5	25.9	7.1	15.4	4.1	60	28	324	0.2					
409	4.9	2.28	0.86	46.4	23.7	7.4	16.7	5.8	59	19	236	0.2					
410	5.4	2.70	0.99	49.9	21.3	7.4	16.0	5.4	56	26	369	0.3					
	N	5	5	5	5	5	5	5	5	5	5	0.06					
MEAN	5.34	2.624	0.964	49.04	22.54	7.48	16.10	4.84	59.6	27.0	303.0	0.26					
S.D.	0.25	0.203	0.076	1.97	2.30	0.33	0.51	0.99	2.9	5.4	57.4	0.05					
S.E.	0.11	0.091	0.034	0.88	1.03	0.15	0.23	0.44	1.3	2.4	25.7	0.02					
	t'								2.5384*								

INDIVIDUAL DATA 8-2-3  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of recovery

Animal No.	Glucose mg/dL	T-Chol mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
	N	5	5	5	5	5	5	5	5	5
103	135	44	15	17.3	0.53	147	4.18	108	9.1	7.0
107	135	49	16	16.8	0.49	146	4.32	106	9.5	7.3
109	128	49	16	14.0	0.51	147	4.18	106	9.5	8.0
110	148	63	42	16.7	0.52	146	4.25	107	9.5	7.6
111	204	83	40	16.6	0.48	144	4.50	107	10.0	7.2
MEAN	150.0	57.6	25.8	16.28	0.506	146.0	4.286	106.8	9.52	7.42
S.D.	31.0	15.9	13.9	1.30	0.021	1.2	0.133	0.8	0.32	0.39
S.E.	13.9	7.1	6.2	0.58	0.009	0.5	0.059	0.4	0.14	0.17
M/C	5.1073*	0.0513	0.3481	0.3627	0.0793	0.0182	6.9481**	1.5868	0.1451	3.7431
F		0.0423	1.6223	1.1398	2.3960	3.5000†		0.0571	1.1294	0.9962
H	1.8549						3.1720†			

INDIVIDUAL DATA 8-2-4  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : End of recovery

Animal No.	Glucose mg/dL	T-Chol mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
401	156	50	36	17.7	0.51	144	4.27	107	9.8	7.2
403	166	57	50	16.1	0.49	143	4.59	108	9.8	7.2
407	145	85	26	15.3	0.50	146	5.92	104	10.3	9.8
409	151	47	26	13.7	0.45	145	4.43	106	9.2	8.6
410	149	38	40	13.3	0.47	145	4.39	108	9.7	7.1
N	5	5	5	5	5	5	5	5	5	5
MEAN	153.4	55.4	35.6	15.22	0.484	144.6	4.720	106.6	9.76	7.98
S.D.	8.1	17.9	10.1	1.80	0.024	1.1	0.681	1.7	0.39	1.19
S.E.	3.6	8.0	4.5	0.80	0.011	0.5	0.304	0.7	0.17	0.53
t'						1.8708				
U								4.0000		

INDIVIDUAL DATA 8-3-1  
STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 6 of lactation

Animal No.	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%)				AST IU/L	ALT IU/L	ALP IU/L	$\gamma$ -GTP IU/L	T-Bil mg/dL					
				Globulin													
				$\alpha_1$	$\alpha_2$	$\beta$											
151	5.9	3.08	1.09	52.2	18.5	8.0	16.6	4.7	70	31	278	0.6					
152	6.1	3.21	1.11	52.5	19.0	6.8	16.8	4.9	67	26	178	0.8					
153	4.8	2.30	0.92	47.9	17.3	9.6	20.6	4.6	85	22	191	0.9					
154	6.4	3.29	1.07	51.6	20.0	6.5	17.9	4.0	82	27	157	0.6					
158	6.2	3.17	1.05	51.3	18.8	6.7	18.9	4.3	74	39	373	0.6					
	N	5	5	5	5	5	5	5	5	5	5	0.06					
MEAN	5.88	3.010	1.048	51.10	18.72	7.52	18.16	4.50	75.6	29.0	235.4	0.70					
S.D.	0.63	0.404	0.075	1.85	0.97	1.30	1.65	0.35	7.7	6.4	89.7	0.14					
S.E.	0.28	0.181	0.034	0.83	0.44	0.58	0.74	0.16	3.4	2.9	40.1	0.06					
M/C	2.9350	1.4287	2.5449	2.8481	3.6468	4.6857	6.0586	7.4415	8.4465*	2.0445	2.8905	0.7599					
F	0.1416	0.2837	0.3680	0.3347	0.2429	1.1397	0.8724	1.2353	0.8173	0.7804	0.4673	$\infty^{**}$					
H									2.7065			4.4287					

INDIVIDUAL DATA 8-3-2  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 100 mg/kg PERIOD : Day 6 of lactation

Animal No.	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%)				AST IU/L	ALT IU/L	ALP IU/L	$\gamma$ -GTP IU/L	T-Bil mg/dL					
				Globulin													
				$\alpha_1$	$\alpha_2$	$\beta$											
253	6.0	2.98	0.99	49.7	18.6	8.9	18.7	4.1	86	31	177	0.5					
255	5.4	2.62	0.94	48.5	22.8	8.3	17.3	3.1	92	28	170	1.0					
257	5.8	2.91	1.01	50.2	19.2	7.9	18.4	4.3	63	23	135	0.7					
260	5.4	2.77	1.06	51.4	18.3	8.7	17.6	4.0	74	25	148	0.8					
262	6.4	3.29	1.07	51.5	19.3	7.4	17.8	4.0	59	21	248	0.9					
N				5	5	5	5	5	5	5	5	5					
MEAN	5.80	2.914	1.014	50.26	19.64	8.24	17.96	3.90	74.8	25.6	175.6	0.78					
S.D.	0.42	0.251	0.053	1.25	1.81	0.61	0.58	0.46	14.2	4.0	43.8	0.19					
S.E.	0.19	0.112	0.024	0.56	0.81	0.27	0.26	0.21	6.4	1.8	19.6	0.09					
												0.002					

INDIVIDUAL DATA 8-3-3  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 300 mg/kg PERIOD : Day 6 of lactation

Animal No.	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%)				AST IU/L	ALT IU/L	ALP IU/L	$\gamma$ -GTP IU/L	T-Bil mg/dL					
				Globulin													
				$\alpha_1$	$\alpha_2$	$\beta$											
351	5.7	2.90	1.04	51.0	19.3	8.4	17.7	3.6	97	28	169	1.0	0.04				
353	5.2	2.66	1.05	51.2	19.9	7.3	17.6	4.0	61	22	145	0.8	0.04				
354	6.0	2.80	0.88	46.8	20.6	8.2	18.8	5.6	123	30	324	0.7	0.04				
357	6.1	3.21	1.11	52.6	16.2	7.1	18.0	6.1	67	24	186	0.7	0.04				
358	5.9	3.14	1.13	53.2	18.4	7.4	17.2	3.8	63	26	209	0.9	0.04				
N	5	5	5	5	5	5	5	5	5	5	5	5	5				
MEAN	5.78	2.942	1.042	50.96	18.88	7.68	17.86	4.62	82.2	26.0	206.6	0.82	0.040				
S.D.	0.36	0.230	0.098	2.50	1.70	0.58	0.60	1.15	27.1	3.2	69.7	0.13	0.000				
S.E.	0.16	0.103	0.044	1.12	0.76	0.26	0.27	0.51	12.1	1.4	31.2	0.06	0.000				

INDIVIDUAL DATA 8-3-4  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 6 of lactation

Animal No.	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%)				AST IU/L	ALT IU/L	ALP IU/L	$\gamma$ -GTP IU/L	T-Bil mg/dL					
				Globulin													
				$\alpha_1$	$\alpha_2$	$\beta$	$\gamma$										
451	6.1	3.14	1.07	51.6	20.6	7.8	16.7	3.3	76	25	189	1.0	0.04				
452	5.5	2.57	0.87	46.6	21.5	7.9	18.1	5.9	136	34	347	0.9	0.05				
453	6.1	3.20	1.10	52.4	18.5	7.1	17.1	4.9	114	30	212	0.7	0.04				
456	5.9	3.16	1.15	53.6	19.1	6.7	16.3	4.3	149	35	118	0.6	0.04				
458	6.1	3.30	1.18	54.2	14.3	7.2	17.8	6.5	63	23	374	0.6	0.03				
N	5	5	5	5	5	5	5	5	5	5	5	5	5				
MEAN	5.94	3.074	1.074	51.68	18.80	7.34	17.20	4.98	107.6	29.4	248.0	0.76	0.040				
S.D.	0.26	0.288	0.122	3.02	2.78	0.50	0.75	1.27	37.2	5.3	108.8	0.18	0.007				
S.E.	0.12	0.129	0.054	1.35	1.24	0.22	0.33	0.57	16.7	2.4	48.7	0.08	0.003				

INDIVIDUAL DATA 8-3-5  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 6 of lactation

Animal No.	Glucose mg/dL	T-Chol mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
151	133	49	25	20.2	0.55	141	4.33	104	10.5	9.1
152	148	46	45	25.0	0.62	141	4.27	105	10.7	8.4
153	132	48	19	19.2	0.59	143	4.14	105	11.0	10.6
154	152	70	31	20.1	0.55	143	4.53	106	11.0	8.9
158	155	65	55	22.1	0.61	143	4.24	105	10.9	8.9
N	5	5	5	5	5	5	5	5	5	5
MEAN	144.0	55.6	35.0	21.32	0.584	142.2	4.302	105.0	10.82	9.18
S.D.	10.8	11.1	14.8	2.31	0.033	1.1	0.145	0.7	0.22	0.83
S.E.	4.8	4.9	6.6	1.03	0.015	0.5	0.065	0.3	0.10	0.37
M/C	1.4245	7.9059*	3.4449	0.6319	0.7065	2.5351	0.5034	9.1290*	1.5121	1.4760
F	0.4133		4.1012*	4.0398*	5.6884**	0.2815	1.9021		1.4981	1.0806
H		6.7361†						3.5749		

## INDIVIDUAL DATA 8-3-6

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 100 mg/kg PERIOD : Day 6 of lactation

Animal No.	Glucose mg/dL	T-Cho mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
253	144	55	33	24.2	0.60	142	4.31	103	11.4	8.5
255	126	39	23	20.3	0.55	141	4.25	103	10.8	9.0
257	133	68	32	20.1	0.61	143	4.18	103	11.3	9.7
260	140	75	56	21.5	0.60	144	4.51	104	11.1	10.5
262	140	49	49	18.9	0.60	143	4.64	105	11.1	8.7
N	5	5	5	5	5	5	5	5	5	5
MEAN	136.6	57.2	38.6	21.00	0.592	142.6	4.378	103.6	11.14	9.28
S.D.	7.1	14.5	13.5	2.01	0.024	1.1	0.191	0.9	0.23	0.82
S.E.	3.2	6.5	6.0	0.90	0.011	0.5	0.086	0.4	0.10	0.37
t'		0.4591	0.2181	0.4690						
U		10.5000								

INDIVIDUAL DATA 8-3-7  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 300 mg/kg PERIOD : Day 6 of lactation

Animal No.	Glucose mg/dL	T-Chol mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
351	145	60	43	25.7	0.60	142	4.01	101	11.2	10.1
353	126	52	30	26.0	0.63	143	4.28	106	10.4	8.7
354	123	52	40	23.2	0.59	142	4.12	102	11.3	11.5
357	146	67	43	24.3	0.65	143	4.36	105	11.0	8.4
358	154	66	37	28.5	0.65	143	4.24	104	11.1	10.4
N	5	5	5	5	5	5	5	5	5	5
MEAN	138.8	59.4	38.6	25.54	0.624	142.6	4.202	103.6	11.00	9.82
S.D.	13.6	7.3	5.4	2.00	0.028	0.5	0.138	2.1	0.35	1.28
S.E.	6.1	3.2	2.4	0.89	0.012	0.2	0.062	0.9	0.16	0.57
t'			0.4591	2.8763*	2.3448					
U			8.0000							

## INDIVIDUAL DATA 8-3-8

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 6 of lactation

Animal No.	Glucose mg/dL	T-Cho mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
451	157	69	67	21.6	0.64	142	4.58	102	11.1	8.6
452	126	68	48	27.1	0.62	143	4.26	101	10.7	9.4
453	133	75	60	21.1	0.65	142	4.28	104	11.1	7.9
456	138	70	78	20.1	0.68	142	4.41	104	10.7	8.3
458	139	69	45	20.6	0.64	145	4.64	109	10.8	9.6
N	5	5	5	5	5	5	5	5	5	5
MEAN	138.6	70.2	59.6	22.10	0.646	142.8	4.434	104.0	10.88	8.76
S.D.	11.5	2.8	13.6	2.85	0.022	1.3	0.172	3.1	0.20	0.72
S.E.	5.1	1.2	6.1	1.27	0.010	0.6	0.077	1.4	0.09	0.32
t'		3.1371*	0.5316	3.6345**						
U		3.5000								

## INDIVIDUAL DATA 8-4-1

STUDY NO. SR09207

TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Biochemical findings

ANIMAL

: Rat, Crl:CD(SD)

SEX

: Female

GROUP

: 0 mg/kg

PERIOD

: End of recovery

Animal No.	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%)				AST IU/L	ALT IU/L	ALP IU/L	$\gamma$ -GTP IU/L	T-Bil mg/dL					
				Globulin													
				$\alpha_1$	$\alpha_2$	$\beta$											
163	6.1	3.45	1.30	56.5	15.4	6.9	14.9	6.3	62	18	117	0.3					
164	6.6	3.60	1.20	54.5	18.8	6.6	14.3	5.8	48	20	115	0.4					
165	6.3	3.61	1.35	57.4	17.6	5.5	12.7	6.8	67	26	125	0.5					
166	6.3	3.59	1.32	56.9	18.8	6.2	12.7	5.4	114	46	130	0.4					
167	6.5	3.51	1.17	54.0	20.8	5.0	13.6	6.6	56	17	148	0.5					
N	5	5	5	5	5	5	5	5	5	5	5	5	5				
MEAN	6.36	3.552	1.268	55.86	18.28	6.04	13.64	6.18	69.4	25.4	127.0	0.42	0.092				
S.D.	0.19	0.069	0.079	1.51	1.98	0.78	0.97	0.58	25.9	12.0	13.2	0.08	0.019				
S.E.	0.09	0.031	0.035	0.68	0.88	0.35	0.44	0.26	11.6	5.4	5.9	0.04	0.009				
M/C	0.9287	5.6683*	1.4035	1.6686	0.0918	0.4781	0.0960	1.0798	1.3252	0.2438	2.1404	9.8669**	0.4028				
F	0.4932	1.3458	1.4951	0.2064	0.6387	6.7190*	1.7000	0.0002	1.1328	1.6583	0.0182						
H		1.8436										0.1019					

INDIVIDUAL DATA 84-2  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : End of recovery

Animal No.	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%)				AST IU/L	ALT IU/L	ALP IU/L	$\gamma$ -GTP IU/L	T-Bil mg/dL					
				Globulin													
				$\alpha_1$	$\alpha_2$	$\beta$											
463	6.4	3.34	1.08	52.0	18.6	5.7	15.7	8.0	62	31	161	0.3					
464	6.0	3.47	1.37	57.7	14.0	6.4	15.5	6.4	74	57	103	1.6					
465	6.4	3.37	1.11	52.7	18.4	6.0	15.1	7.8	56	23	175	0.3					
466	6.6	3.75	1.31	56.8	17.1	6.8	13.7	5.6	91	44	163	0.1					
467	5.8	2.94	1.03	50.7	20.2	7.0	15.6	6.5	63	19	127	0.09					
												0.07					
N	5	5	5	5	5	5	5	5	5	5	5	5					
MEAN	6.24	3.374	1.180	53.98	17.66	6.38	15.12	6.86	69.2	34.8	145.8	0.70					
S.D.	0.33	0.292	0.150	3.09	2.32	0.54	0.83	1.01	13.8	15.7	29.9	0.66					
S.E.	0.15	0.130	0.067	1.38	1.04	0.24	0.37	0.45	6.2	7.0	13.4	0.29					
t'								2.5921*				0.012					

INDIVIDUAL DATA 84-3  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : End of recovery

	Glucose mg/dL	T-Chol mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
Animal No.										
163	125	89	12	17.6	0.63	146	4.31	108	9.9	6.7
164	122	82	18	18.0	0.55	143	4.33	108	10.4	6.0
165	120	82	17	19.6	0.57	143	3.93	107	10.3	6.4
166	124	76	7	17.0	0.65	145	4.20	112	9.7	5.7
167	156	79	18	15.0	0.61	145	4.12	109	10.4	7.0
N	5	5	5	5	5	5	5	5	5	5
MEAN	129.4	81.6	14.4	17.44	0.602	144.4	4.178	108.8	10.14	6.36
S.D.	15.0	4.8	4.8	1.67	0.041	1.3	0.163	1.9	0.32	0.52
S.E.	6.7	2.2	2.2	0.75	0.019	0.6	0.073	0.9	0.14	0.23
M/C	0.5301	3.9444*	1.8231	0.1617	3.7855	0.0029	2.2393	2.2231	0.0008	1.0834
F	0.6982		1.0637	5.8692*	0.2837	0.5143	0.0527	2.9091	0.4828	0.5786
H		3.1720†								

INDIVIDUAL DATA 84-4  
 STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : End of recovery

Animal No.	Glucose mg/dL	T-Cho mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
463	118	57	15	18.1	0.57	145	4.38	108	10.1	7.6
464	135	59	31	14.4	0.56	143	4.58	107	10.3	7.1
465	132	63	30	13.3	0.54	145	3.89	107	9.9	6.6
466	135	86	13	14.1	0.65	142	4.50	106	10.2	5.2
467	177	44	9	12.9	0.85	144	3.75	108	9.5	7.1
N	5	5	5	5	5	5	5	5	5	5
MEAN	139.4	61.8	19.6	14.56	0.634	143.8	4.220	107.2	10.00	6.72
S.D.	22.2	15.3	10.2	2.07	0.128	1.3	0.375	0.8	0.32	0.92
S.E.	9.9	6.8	4.6	0.92	0.057	0.6	0.168	0.4	0.14	0.41
t'					2.4226*					
U					4.0000					

INDIVIDUAL DATA 9-1-1

**STUDY NO.** SR09207      **TITLE :** Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
**ANIMAL :** Rat, Crl:CD(SD)      **SEX :** Male      **GROUP :** 0 mg/kg  
**PERIOD :** End of administration  
Serum hormone levels

Animal No.	T3 ng/mL	T4 ng/mL	TSH ng/mL
101	0.803	37.753	9.98
102	0.969	55.866	4.79
104	1.126	52.546	9.21
105	1.299	60.291	5.78
106	1.316	66.034	4.19
N	5	5	5
MEAN	1.1026	54.4980	6.790
S.D.	0.2192	10.6385	2.637
S.E.	0.0980	4.7577	1.179
M/C	5.5193	0.6351	1.0865
F	0.4500	4.7514*	0.6726

## INDIVIDUAL DATA 9-1-2

STUDY NO. SR09207      TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Serum hormone levels      ANIMAL : Rat, Crl:CD(SD)      SEX : Male      GROUP : 100 mg/kg      PERIOD : End of administration

Animal No.	T3 ng/mL	T4 ng/mL	TSH ng/mL
201	1.179	79.529	6.23
204	1.152	89.078	5.93
206	1.326	76.703	9.58
207	1.214	58.989	7.97
209	1.268	64.875	6.01

N	5	5	5
MEAN	1.2278	73.8348	7.144
S.D.	0.0700	11.9758	1.598
S.E.	0.0313	5.3558	0.715
t'	2.8308 *		

## INDIVIDUAL DATA 9-1-3

STUDY NO. SR09207      TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Serum hormone levels      ANIMAL : Rat, Crl:CD(SD)      SEX : Male      GROUP : 300 mg/kg      PERIOD : End of administration

Animal No.	T3 ng/mL	T4 ng/mL	TSH ng/mL
301	0.869	62.242	10.12
304	0.965	69.019	5.23
306	1.169	69.713	9.63
308	1.027	52.158	6.31
309	1.407	54.033	7.11
N	5	5	5
MEAN	1.0874	61.4330	7.680
S.D.	0.2092	8.1784	2.119
S.E.	0.0936	3.6575	0.948
t'		1.0153	

## INDIVIDUAL DATA 9-1-4

STUDY NO. SR09207      TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Serum hormone levels      ANIMAL : Rat, Crl:CD(SD)      SEX : Male      GROUP : 1000 mg/kg      PERIOD : End of administration

Animal No.	T3 ng/mL	T4 ng/mL	TSH ng/mL
402	1.073	37.263	4.57
404	0.803	59.302	6.35
405	1.090	38.460	7.68
406	1.583	63.801	3.55
408	1.138	48.987	7.23
N	5	5	5
MEAN	1.1374	49.5626	5.876
S.D.	0.2814	11.9631	1.763
S.E.	0.1259	5.3501	0.788
t'	0.7225		

INDIVIDUAL DATA 9-2-1

**STUDY NO.** SRD9207      **TITLE :** Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
**ANIMAL :** Rat, Chl:CD(SD)      **SEX :** Male      **GROUP :** 0 mg/kg  
**PERIOD :** End of recovery

Animal No.	T3 ng/ml	T4 ng/ml	TSH ng/ml
103	1.060	68.718	4.65
107	1.039	93.438	8.49
109	1.277	79.500	13.12
110	0.960	74.821	4.41
111	1.229	70.245	7.97
N		5	5
MEAN	1.1130	77.3444	7.728
S.D.	0.1342	9.9352	3.542
S.E.	0.0600	4.4432	1.584
M/C	0.0206	0.0122	2.8305
F	0.3879	2.5801	1.2258

## INDIVIDUAL DATA 9-2-2

STUDY NO. SR09207      TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Serum hormone levels      ANIMAL : Rat, Crl:CD(SD)      SEX : Male      GROUP : 1000 mg/kg      PERIOD : End of recovery

Animal No.	T3 ng/mL	T4 ng/mL	TSH ng/mL
401	1.143	93.224	7.41
403	1.349	92.004	5.52
407	1.194	72.635	7.13
409	0.948	95.018	4.35
410	1.206	82.892	4.83
N	5	5	5
MEAN	1.1680	87.1546	5.848
S.D.	0.1448	9.3698	1.367
S.E.	0.0648	4.1903	0.611

## INDIVIDUAL DATA 9-3-1

STUDY NO. SR09207      TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Serum hormone levels, Main group      ANIMAL : Rat, CrI:CD(SD)      GROUP : 0 mg/kg  
 SEX : Female      PERIOD : Day 6 of lactation

Animal No.	T3 ng/mL	T4 ng/mL	TSH ng/mL
151	1.206	55.752	4.68
152	1.135	34.263	0.00
153	1.239	54.783	7.21
154	1.274	57.034	8.89
158	1.399	37.922	0.00
N	5	5	5
MEAN	1.2506	47.9508	4.156
S.D.	0.0975	10.9313	4.079
S.E.	0.0436	4.8886	1.824
M/C	4.1151	1.1347	2.8166
F	3.2182 †	0.4807	0.9197

## INDIVIDUAL DATA 9-3-2

STUDY NO. SR09207      TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Serum hormone levels, Main group      ANIMAL : Rat, CrI:CD(SD)      SEX : Female      GROUP : 100 mg/kg      PERIOD : Day 6 of lactation

Animal No.	T3 ng/mL	T4 ng/mL	TSH ng/mL
253	1.338	81.655	3.55
255	1.213	48.559	3.90
257	1.777	56.889	3.26
260	1.180	47.373	2.43
262	1.404	46.682	8.90
N	5	5	5
MEAN	1.3824	56.2316	4.408
S.D.	0.2386	14.7929	2.569
S.E.	0.1067	6.6156	1.149
t'	1.2952		

## INDIVIDUAL DATA 9-3-3

STUDY NO. SR09207      TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Serum hormone levels, Main group      ANIMAL : Rat, Crl:CD(SD)      GROUP : Female      SEX : Female      PERIOD : Day 6 of lactation

Animal No.	T3 ng/mL	T4 ng/mL	TSH ng/mL
351	1.352	68.796	12.06
353	1.152	55.348	6.27
354	1.409	43.937	4.96
357	0.995	42.283	5.28
358	1.266	35.523	5.93
N	5	5	5
MEAN	1.2348	49.1774	6.900
S.D.	0.1654	13.0805	2.931
S.E.	0.0740	5.8498	1.311
t'	0.1553		

## INDIVIDUAL DATA 9-3-4

STUDY NO. SR09207      TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Serum hormone levels, Main group      ANIMAL : Rat, CrI:CD(SD)      SEX : Female      GROUP : 1000 mg/kg      PERIOD : Day 6 of lactation

Animal No.	T3 ng/mL	T4 ng/mL	TSH ng/mL
451	1.217	57.778	6.87
452	1.049	37.522	4.43
453	1.107	57.354	2.36
456	0.993	44.819	4.39
458	0.972	49.723	5.39
N	5	5	5
MEAN	1.0676	49.4392	4.688
S.D.	0.0986	8.5969	1.645
S.E.	0.0441	3.8446	0.736
t'	1.7983		

## INDIVIDUAL DATA 9-4-1

STUDY NO. SR09207      TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Serum hormone levels, Recovery group      ANIMAL : Rat, CrI:CD(SD)      SEX : Female      GROUP : 0 mg/kg      PERIOD : End of recovery

Animal No.	T3 ng/mL	T4 ng/mL	TSH ng/mL
163	1.152	63.195	5.31
164	1.204	26.812	4.90
165	1.112	27.923	3.92
166	1.398	51.818	5.16
167	1.090	56.135	7.66
N	5	5	5
MEAN	1.1912	45.1766	5.390
S.D.	0.1235	16.7616	1.380
S.E.	0.0552	7.4960	0.617
M/C	2.0793	1.7862	0.0131
F	0.1495	0.1840	0.3184

## INDIVIDUAL DATA 9-4-2

STUDY NO. SR09207      TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Serum hormone levels, Recovery group      ANIMAL : Rat, Crl:CD(SD)      SEX : Female      GROUP : 1000 mg/kg      PERIOD : End of recovery

Animal No.	T3 ng/mL	T4 ng/mL	TSH ng/mL
463	1.051	42.535	5.68
464	1.711	56.969	2.62
465	1.274	54.306	6.56
466	1.100	38.221	4.82
467	1.081	51.671	4.73
N	5	5	5
MEAN	1.2434	48.7404	4.882
S.D.	0.2755	8.0069	1.466
S.E.	0.1232	3.5808	0.656

## INDIVIDUAL DATA 10-1-1

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Gross findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of administration

Animal No.	Findings	Other description
101	No abnormal findings	Euthanasia on next day of Day 42 of administration
102	No abnormal findings	Euthanasia on next day of Day 42 of administration
104	No abnormal findings	Euthanasia on next day of Day 42 of administration
105	No abnormal findings	Euthanasia on next day of Day 42 of administration
106	No abnormal findings	Euthanasia on next day of Day 42 of administration
108	No abnormal findings	Euthanasia on next day of Day 42 of administration
112	No abnormal findings	Euthanasia on next day of Day 42 of administration

## INDIVIDUAL DATA 10-1-2

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Gross findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : End of administration

Animal No.	Findings	Other description
201	No abnormal findings	Euthanasia on next day of Day 42 of administration
202	Testis (right and left) : Small size Epididymis (right and left) : Small size	Euthanasia on next day of Day 42 of administration
203	No abnormal findings	Euthanasia on next day of Day 42 of administration
204	No abnormal findings	Euthanasia on next day of Day 42 of administration
205	No abnormal findings	Euthanasia on next day of Day 42 of administration
206	Testis (left) : Small size Epididymis (left) : Small size	Euthanasia on next day of Day 42 of administration
207	No abnormal findings	Euthanasia on next day of Day 42 of administration
208	No abnormal findings	Euthanasia on next day of Day 42 of administration
209	No abnormal findings	Euthanasia on next day of Day 42 of administration
210	Epididymis (right) : Yellowish white mass, cauda (10 x 5 x 5, mm) Epididymis (left) : Yellowish white mass, cauda (10 x 4 x 3, mm)	Euthanasia on next day of Day 42 of administration
211	No abnormal findings	Euthanasia on next day of Day 42 of administration
212	No abnormal findings	Euthanasia on next day of Day 42 of administration

## INDIVIDUAL DATA 10-1-3

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Gross findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : End of administration

Animal No.	Findings	Other description
301	No abnormal findings	Euthanasia on next day of Day 42 of administration
302	No abnormal findings	Euthanasia on next day of Day 42 of administration
303	No abnormal findings	Euthanasia on next day of Day 42 of administration
304	No abnormal findings	Euthanasia on next day of Day 42 of administration
305	No abnormal findings	Euthanasia on next day of Day 42 of administration
306	No abnormal findings	Euthanasia on next day of Day 42 of administration
307	No abnormal findings	Euthanasia on next day of Day 42 of administration
308	No abnormal findings	Euthanasia on next day of Day 42 of administration
309	No abnormal findings	Euthanasia on next day of Day 42 of administration
310	No abnormal findings	Euthanasia on next day of Day 42 of administration
311	Testis (right and left) : Small size Epididymis (right and left) : Small size Harderian gland (left) : Hemorrhage	Euthanasia on next day of Day 42 of administration
312	No abnormal findings	Euthanasia on next day of Day 42 of administration

## INDIVIDUAL DATA 10-1-4

STUDY NO. SR09207 TITLE : Isotriidecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Gross findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : End of administration

Animal No.	Findings	Other description
402	No abnormal findings	Euthanasia on next day of Day 42 of administration
404	No abnormal findings	Euthanasia on next day of Day 42 of administration
405	No abnormal findings	Euthanasia on next day of Day 42 of administration
406	No abnormal findings	Euthanasia on next day of Day 42 of administration
408	No abnormal findings	Euthanasia on next day of Day 42 of administration
411	No abnormal findings	Euthanasia on next day of Day 42 of administration
412	No abnormal findings	Euthanasia on next day of Day 42 of administration

## INDIVIDUAL DATA 10-2-1

STUDY NO. SR09207 TITLE : Isotriidecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Gross findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of recovery

Animal No.	Findings	Other description
103	No abnormal findings	Euthanasia on next day of Day 14 of recovery
107	No abnormal findings	Euthanasia on next day of Day 14 of recovery
109	No abnormal findings	Euthanasia on next day of Day 14 of recovery
110	No abnormal findings	Euthanasia on next day of Day 14 of recovery
111	No abnormal findings	Euthanasia on next day of Day 14 of recovery

## INDIVIDUAL DATA 10-2-2

STUDY NO. SR09207 TITLE : Isotriidecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Gross findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : End of recovery

Animal No.	Findings	Other description
401	No abnormal findings	Euthanasia on next day of Day 14 of recovery
403	No abnormal findings	Euthanasia on next day of Day 14 of recovery
407	No abnormal findings	Euthanasia on next day of Day 14 of recovery
409	No abnormal findings	Euthanasia on next day of Day 14 of recovery
410	No abnormal findings	Euthanasia on next day of Day 14 of recovery

## INDIVIDUAL DATA 10-3-1

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Gross findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 6 of lactation

Animal No.	Findings	Other description
151	No abnormal findings	Euthanasia on Day 6 of lactation
152	No abnormal findings	Euthanasia on Day 6 of lactation
153	No abnormal findings	Euthanasia on Day 6 of lactation
154	No abnormal findings	Euthanasia on Day 6 of lactation
155	No abnormal findings	Euthanasia on Day 6 of lactation
156	No abnormal findings	Euthanasia on Day 6 of lactation
157	No abnormal findings	Euthanasia on Day 6 of lactation
158	No abnormal findings	Euthanasia on Day 6 of lactation
159	No abnormal findings	Euthanasia on Day 6 of lactation
160	No abnormal findings	Euthanasia on Day 6 of lactation
161	No abnormal findings	Euthanasia on Day 6 of lactation
162 <sup>a</sup>	No abnormal findings	Euthanasia on next day of Day 51 of administration

<sup>a</sup>: Not copulated.

## INDIVIDUAL DATA 10-3-2

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Gross findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 100 mg/kg PERIOD : Day 6 of lactation

Animal No.	Findings	Other description
251	No abnormal findings	Euthanasia on Day 6 of lactation
252	No abnormal findings	Euthanasia on Day 6 of lactation
253	No abnormal findings	Euthanasia on Day 6 of lactation
254	No abnormal findings	Euthanasia on Day 6 of lactation
255	No abnormal findings	Euthanasia on Day 6 of lactation
256	No abnormal findings	Euthanasia on Day 6 of lactation
257	No abnormal findings	Euthanasia on Day 6 of lactation
258	No abnormal findings	Euthanasia on Day 6 of lactation
259	No abnormal findings	Euthanasia on Day 6 of lactation
260	No abnormal findings	Euthanasia on Day 6 of lactation
261	No abnormal findings	Euthanasia on Day 6 of lactation
262	No abnormal findings	Euthanasia on Day 6 of lactation

## INDIVIDUAL DATA 10-3-3

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Gross findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 300 mg/kg PERIOD : Day 6 of lactation

Animal No.	Findings	Other description
351	No abnormal findings	Euthanasia on Day 6 of lactation
352	No abnormal findings	Euthanasia on Day 6 of lactation
353	No abnormal findings	Euthanasia on Day 6 of lactation
354	No abnormal findings	Euthanasia on Day 6 of lactation
355 <sup>a</sup>	No abnormal findings	Euthanasia on Day 6 of lactation
356	Glandular stomach : Black patch, mucosa (3 x 1, mm)	Euthanasia on Day 6 of lactation
357	No abnormal findings	Euthanasia on Day 6 of lactation
358	No abnormal findings	Euthanasia on Day 6 of lactation
359	No abnormal findings	Euthanasia on Day 6 of lactation
360	No abnormal findings	Euthanasia on Day 6 of lactation
361	No abnormal findings	Euthanasia on Day 6 of lactation
362	No abnormal findings	Euthanasia on Day 6 of lactation

<sup>a</sup> : This animal was lost of the 3rd digit in left forelimb in an accident (catch ones digit in the cage) on Day 6 of gestation.

## INDIVIDUAL DATA 10-3-4

STUDY NO. SR09207 TITLE : Isotrioleyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Gross findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 6 of lactation

Animal No.	Findings	Other description
451	No abnormal findings	Euthanasia on Day 6 of lactation
452	Lung (right) : Yellowish green patch , anterior lobe (7 x 5, mm)	Euthanasia on Day 6 of lactation
453	No abnormal findings	Euthanasia on Day 6 of lactation
454 <sup>a</sup>	No abnormal findings	Euthanasia on Day 26 of gestation
455	No abnormal findings	Euthanasia on Day 6 of lactation
456	No abnormal findings	Euthanasia on Day 6 of lactation
457	No abnormal findings	Euthanasia on Day 6 of lactation
458	No abnormal findings	Euthanasia on Day 6 of lactation
459	No abnormal findings	Euthanasia on Day 6 of lactation
460	No abnormal findings	Euthanasia on Day 6 of lactation
461	No abnormal findings	Euthanasia on Day 6 of lactation
462	No abnormal findings	Euthanasia on Day 6 of lactation

<sup>a</sup> : Non-pregnant.

## INDIVIDUAL DATA 10-4-1

STUDY NO. SR09207 TITLE : Isotriidecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Gross findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : End of recovery

Animal No.	Findings	Other description
163	No abnormal findings	Euthanasia on next day of Day 14 of recovery
164	No abnormal findings	Euthanasia on next day of Day 14 of recovery
165	No abnormal findings	Euthanasia on next day of Day 14 of recovery
166	No abnormal findings	Euthanasia on next day of Day 14 of recovery
167	No abnormal findings	Euthanasia on next day of Day 14 of recovery

## INDIVIDUAL DATA 10-4-2

STUDY NO. SR09207 TITLE : Isotriidecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Gross findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : End of recovery

Animal No.	Findings	Other description
463	No abnormal findings	Euthanasia on next day of Day 14 of recovery
464	Stomach : White mass , limiting ridge (1 x 1 x 1, mm)	Euthanasia on next day of Day 14 of recovery
465	No abnormal findings	Euthanasia on next day of Day 14 of recovery
466	No abnormal findings	Euthanasia on next day of Day 14 of recovery
467	No abnormal findings	Euthanasia on next day of Day 14 of recovery

## INDIVIDUAL DATA 11-1-1

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of administration

Animal No.	Body weight g	Liver		Kidney		Spleen		Heart		Brain		Pituitary gland		Thymus		Thyroid		Adrenal	
		g	%	g	%	g	%	g	%	g	%	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %
101	401	9.22	2.30	2.73	0.68	0.16	0.10	0.27	2.22	0.55	13.3	3.32	204	50.87	12.6	3.14	45	11.22	
102	429	11.08	2.58	2.89	0.67	0.77	0.18	1.35	0.31	2.15	0.50	12.2	2.84	229	53.38	15.5	3.61	58	13.52
104	420	10.21	2.43	2.66	0.63	0.65	0.15	1.33	0.32	2.10	0.50	12.9	3.07	394	93.81	17.7	4.21	51	12.14
105	429	11.24	2.62	3.04	0.71	0.78	0.18	1.22	0.28	2.20	0.51	12.5	2.91	343	79.95	17.7	4.13	52	12.12
106	494	14.76	2.99	2.93	0.59	1.00	0.20	1.36	0.28	2.26	0.46	13.3	2.69	243	49.19	16.6	3.36	51	10.32
N		5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	434.6	11.302	2.584	2.850	0.656	0.772	0.174	1.272	0.292	2.186	0.504	12.84	2.966	282.6	65.440	16.02	3.690	51.4	11.864
S.D.	35.1	2.094	0.260	0.154	0.047	0.141	0.019	0.111	0.022	0.062	0.032	0.49	0.240	81.7	20.231	2.12	0.470	4.6	1.192
S.E.	15.7	0.936	0.116	0.069	0.021	0.063	0.009	0.050	0.010	0.028	0.014	0.22	0.108	36.5	9.048	0.95	0.210	2.1	0.533
M/C	2.5330	8.1872*	5.3086	1.6606	1.4788	5.2209	3.6616	3.6715	0.0505	0.9485	1.3016	4.8981	2.8645	1.5934	3.2126	3.3207	3.1178	3.0979	1.6495
F	1.8702	0.4500	2.9257†	1.5801	0.2308	0.8474	2.5570†	0.8068	1.7808	2.4433	1.2330	2.6786†	0.0013	0.1679	2.6231†	1.3954	1.2249	0.6642	
H		3.1767																	

## INDIVIDUAL DATA 11-1-2

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : End of administration

Animal No.	Body weight g	Liver		Kidney		Spleen		Heart		Brain		Pituitary gland		Thymus		Thyroid		Adrenal	
		g	%	g	%	g	%	g	%	g	%	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %
201	457	12.41	2.72	2.89	0.63	0.82	0.18	1.40	0.31	2.11	0.46	11.8	2.58	344	75.27	24.3	5.32	52	11.38
204	457	12.84	2.81	3.15	0.69	0.73	0.16	1.61	0.35	2.30	0.50	12.1	2.65	227	49.67	27.3	5.97	58	12.69
206	492	13.26	2.70	3.08	0.63	0.77	0.16	1.46	0.30	2.24	0.46	11.2	2.28	248	50.41	22.0	4.47	59	11.99
207	483	13.40	2.77	3.61	0.75	0.75	0.16	1.48	0.31	2.18	0.45	14.4	2.98	296	61.28	16.7	3.46	57	11.80
209	487	12.78	2.62	3.10	0.64	0.83	0.17	1.41	0.29	2.19	0.45	11.0	2.26	300	61.60	21.5	4.41	71	14.58
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	475.2	12.938	2.724	3.166	0.668	0.780	0.166	1.472	0.312	2.204	0.464	12.10	2.550	283.0	59.646	22.36	4.726	59.4	12.488
S.D.	16.9	0.397	0.072	0.267	0.052	0.044	0.009	0.084	0.023	0.071	0.021	1.36	0.297	46.2	10.433	3.91	0.958	7.0	1.262
S.E.	7.6	0.178	0.032	0.119	0.023	0.019	0.004	0.038	0.010	0.032	0.009	0.61	0.133	20.7	4.666	1.75	0.428	3.1	0.564
t															2.7639*		2.0721		2.7272*

## INDIVIDUAL DATA 11-1-3

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : End of administration

Animal No.	Body weight g	Liver		Kidney		Spleen		Heart		Brain		Pituitary gland		Thymus		Thyroid		Adrenal	
		g	%	g	%	g	%	g	%	g	%	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %
301	407	10.90	2.68	2.83	0.70	0.58	0.14	1.23	0.30	2.02	0.50	13.2	3.24	268	65.85	17.4	4.28	59	14.50
304	465	13.40	2.88	3.51	0.75	0.90	0.19	1.34	0.29	2.27	0.49	11.0	2.37	230	49.46	23.7	5.10	60	12.90
306	457	12.23	2.68	3.41	0.75	0.80	0.18	1.55	0.34	2.19	0.48	11.3	2.47	268	58.64	17.2	3.76	61	13.35
308	503	15.00	2.98	3.40	0.68	0.95	0.19	1.57	0.31	2.08	0.41	12.5	2.49	359	71.37	18.1	3.60	67	13.32
309	438	10.15	2.32	3.03	0.69	0.63	0.14	1.22	0.28	2.20	0.50	8.6	1.96	294	67.12	19.3	4.41	50	11.42
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	454.0	12.336	2.708	3.236	0.714	0.772	0.168	1.382	0.304	2.152	0.476	11.32	2.506	283.8	62.488	19.14	4.230	59.4	13.098
S.D.	35.3	1.942	0.253	0.291	0.034	0.163	0.026	0.169	0.023	0.100	0.038	1.76	0.463	47.8	8.605	2.68	0.594	6.1	1.111
S.E.	15.8	0.868	0.113	0.130	0.015	0.073	0.012	0.076	0.010	0.045	0.017	0.79	0.207	21.4	3.848	1.20	0.265	2.7	0.497
t'										1.5202				2.2913				1.3421	

## INDIVIDUAL DATA 11-1-4

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : End of administration

Animal No.	Body weight g	Liver		Kidney		Spleen		Heart		Brain		Pituitary gland		Thymus		Thyroid		Adrenal	
		g	%	g	%	g	%	g	%	g	%	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %
402	474	11.13	2.35	2.99	0.63	0.59	0.12	1.30	0.27	1.97	0.42	11.2	2.36	202	42.62	16.7	3.52	57	12.03
404	443	12.28	2.77	3.53	0.80	0.62	0.14	1.34	0.30	2.09	0.47	10.3	2.33	263	59.37	19.7	4.45	40	9.03
405	474	12.38	2.61	3.33	0.70	0.79	0.17	1.46	0.31	2.14	0.45	11.4	2.41	302	63.71	14.6	3.08	61	12.87
406	443	13.15	2.97	2.99	0.67	0.75	0.17	1.43	0.32	2.20	0.50	10.6	2.39	284	64.11	23.6	5.33	57	12.87
408	495	14.31	2.89	3.61	0.73	0.86	0.17	1.37	0.28	2.07	0.42	14.0	2.83	373	75.35	27.5	5.56	71	14.34
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	465.8	12.650	2.718	3.290	0.706	0.722	0.154	1.380	0.296	2.094	0.452	11.50	2.464	284.8	61.032	20.42	4.388	57.2	12.228
S.D.	22.5	1.175	0.246	0.292	0.064	0.114	0.023	0.065	0.021	0.086	0.034	1.47	0.207	62.1	11.868	5.21	1.087	11.2	1.972
S.E.	10.1	0.526	0.110	0.131	0.029	0.051	0.010	0.029	0.009	0.038	0.015	0.66	0.092	27.8	5.308	2.33	0.486	5.0	0.882
t				2.7016*				1.4925				2.5005			1.8927				

## INDIVIDUAL DATA 111-1-5

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of administration

Animal No.	Body weight g	Testis		Epididymis	
		g	%	g	%
101	401	3.27	0.82	1.16	0.29
102	429	3.16	0.74	1.31	0.31
104	420	3.39	0.81	1.18	0.28
105	429	3.26	0.76	1.25	0.29
106	494	2.69	0.54	1.00	0.20
108	496	3.86	0.78	1.50	0.30
112	553	3.05	0.55	1.21	0.22
<hr/>					
N	7	7	7	7	7
MEAN	460.3	3.240	0.714	1.230	0.270
S.D.	54.9	0.354	0.119	0.153	0.042
S.E.	20.8	0.134	0.045	0.058	0.016
M/C	6.7981	2.6475	4.2445	5.5121	8.9549*
F	0.6080	0.0592	0.1395	0.5358	
H				2.6256	

## INDIVIDUAL DATA 111-1-6

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 100 mg/kg PERIOD : End of administration

Animal No.	Body weight g	Testis		Epididymis	
		g	%	g	%
201	457	3.16	0.69	1.26	0.28
202	474	2.23	0.47	0.89	0.19
203	470	3.25	0.69	1.31	0.28
204	457	3.62	0.79	1.56	0.34
205	462	3.27	0.71	1.28	0.28
206	492	2.48	0.50	1.08	0.22
207	483	3.54	0.73	1.57	0.33
208	463	3.32	0.72	1.35	0.29
209	487	3.11	0.64	1.19	0.24
210	426	3.48	0.82	1.64	0.38
211	468	3.54	0.76	1.39	0.30
212	519	3.59	0.69	1.47	0.28
N	12	12	12	12	12
MEAN	471.5	3.216	0.684	1.333	0.284
S.D.	22.8	0.440	0.105	0.216	0.052
S.E.	6.6	0.127	0.030	0.062	0.015

## INDIVIDUAL DATA 11-1-7

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 300 mg/kg PERIOD : End of administration

Animal No.	Body weight g	Testis		Epididymis	
		g	%	g	%
301	407	3.08	0.76	1.23	0.30
302	469	3.42	0.73	1.40	0.30
303	456	3.47	0.76	1.39	0.30
304	465	3.07	0.66	1.40	0.30
305	481	3.40	0.71	1.41	0.29
306	457	3.47	0.76	1.35	0.30
307	458	3.87	0.84	1.62	0.35
308	503	3.34	0.66	1.34	0.27
309	438	3.38	0.77	1.25	0.29
310	471	3.02	0.64	1.18	0.25
311	516	1.78	0.34	0.90	0.17
312	494	3.50	0.71	1.25	0.25
N	12	12	12	12	12
MEAN	467.9	3.233	0.695	1.310	0.281
S.D.	29.2	0.513	0.125	0.173	0.044
S.E.	8.4	0.148	0.036	0.050	0.013

## INDIVIDUAL DATA 111-1-8

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1000 mg/kg PERIOD : End of administration

Animal No.	Body weight g	Testis		Epididymis	
		g	%	g	%
402	474	3.14	0.66	1.19	0.25
404	443	2.96	0.67	1.20	0.27
405	474	3.73	0.79	1.31	0.28
406	443	3.09	0.70	1.27	0.29
408	495	3.20	0.65	1.33	0.27
411	541	3.37	0.62	1.42	0.26
412	523	3.61	0.69	1.34	0.26
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N	7	7	7	7	7
MEAN	484.7	3.300	0.683	1.294	0.269
S.D.	37.5	0.283	0.054	0.081	0.013
S.E.	14.2	0.107	0.020	0.031	0.005

## INDIVIDUAL DATA 11-2-1

STUDY NO. SR09207    TITLE : isofridecy stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Absolute and relative organ weights    ANIMAL : Rat, Crl:CD(SD)    SEX : Male    GROUP : 0 mg/kg    PERIOD : End of recovery

Animal No.	Body weight g	Liver		Kidney		Spleen		Heart		Brain		Pituitary gland		Thymus		Thyroid		Adrenal	
		g	%	g	%	g	%	g	%	g	%	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %
103	431	10.53	2.44	2.94	0.68	0.85	0.20	1.65	0.38	2.17	0.50	12.8	2.97	240	55.68	20.5	4.76	60	13.92
107	461	10.79	2.34	2.86	0.62	0.70	0.15	1.43	0.31	2.25	0.49	12.0	2.60	230	49.89	16.7	3.62	62	13.45
109	468	11.05	2.36	3.10	0.66	0.83	0.18	1.40	0.30	2.20	0.47	9.7	2.07	237	50.64	24.3	5.19	69	14.74
110	506	12.46	2.46	3.29	0.65	0.93	0.18	1.54	0.30	2.35	0.46	12.7	2.51	342	67.59	21.5	4.25	63	12.45
111	507	14.76	2.91	3.18	0.63	0.76	0.15	1.75	0.35	2.19	0.43	11.1	2.19	175	34.52	23.1	4.56	56	11.05
N		5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	474.6	11.918	2.502	3.074	0.648	0.814	0.172	1.554	0.328	2.232	0.470	11.66	2.468	244.8	51.664	21.22	4.476	62.0	13.122
S.D.	32.3	1.755	0.234	0.175	0.024	0.088	0.022	0.147	0.036	0.072	0.027	1.29	0.356	60.5	11.915	2.92	0.588	4.7	1.424
S.E.	14.4	0.785	0.105	0.078	0.011	0.039	0.010	0.066	0.016	0.032	0.012	0.58	0.159	27.0	5.329	1.30	0.263	2.1	0.637
M/C	1.8764	10.1498**	6.0238*	0.0353	0.1248	0.2272	0.0128	0.0011	0.4885	0.2679	1.2608	0.1083	0.0937	0.0036	0.0463	0.8179	0.4920	1.3635	0.1996
F	0.6656	5.3674*	4.6286†	0.0039	0.1800	0.1157	0.8663	0.3149	1.6701	1.9817	0.4883	2.6947	2.3861	0.0311	0.0125	0.3272	0.8317		
H		1.8436	2.4695																

## INDIVIDUAL DATA 11-2-2

STUDY NO. SR09207    TITLE : isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Absolute and relative organ weights    ANIMAL : Rat, Crl:CD(SD)    SEX : Male    GROUP : 1000 mg/kg    PERIOD : End of recovery

Animal No.	Body weight g	Liver		Kidney		Spleen		Heart		Brain		Pituitary gland		Thymus		Thyroid		Adrenal	
		g	%	g	%	g	%	g	%	g	%	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %
401	493	12.53	2.54	3.26	0.66	0.71	0.14	1.45	0.29	2.12	0.43	11.9	2.41	312	63.29	18.8	3.81	74	15.01
403	470	12.16	2.59	3.10	0.66	0.70	0.15	1.33	0.28	2.17	0.46	14.3	3.04	291	61.91	18.2	3.87	55	11.70
407	473	12.55	2.65	3.37	0.71	0.89	0.19	1.51	0.32	2.13	0.45	13.4	2.83	222	46.93	17.6	3.72	58	12.26
409	502	12.63	2.52	3.63	0.72	0.79	0.16	1.73	0.34	2.24	0.45	12.1	2.41	324	64.54	26.9	5.36	60	11.95
410	500	12.72	2.54	3.36	0.67	0.96	0.19	1.59	0.32	2.35	0.47	11.9	2.38	384	76.80	26.8	5.36	50	10.00
N		5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	487.6	12.518	2.568	3.344	0.684	0.810	0.166	1.522	0.310	2.202	0.452	12.72	2.614	306.6	62.694	21.66	4.424	59.4	12.184
S.D.	15.1	0.214	0.053	0.193	0.029	0.113	0.023	0.150	0.024	0.095	0.015	1.08	0.303	58.6	10.629	4.76	0.856	9.0	1.806
S.E.	6.8	0.096	0.024	0.086	0.013	0.051	0.010	0.067	0.011	0.043	0.007	0.48	0.135	26.2	4.753	2.13	0.383	4.0	0.808
t'				2.3168*	2.1514														

## INDIVIDUAL DATA 11-2-3

STUDY NO. SR09207    TITLE : isofridecy stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Absolute and relative organ weights    ANIMAL : Rat, Crl:CD(SD)    SEX : Male    GROUP : 0 mg/kg    PERIOD : End of recovery

Animal No.	Body weight g	Testis		Epididymis	
		%	g	%	g
103	431	2.99	0.69	1.34	0.31
107	461	3.14	0.68	1.44	0.31
109	468	3.82	0.82	1.60	0.34
110	506	3.05	0.60	1.28	0.25
111	507	3.21	0.63	1.53	0.30
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N      5      5      5      5      5					
MEAN	474.6	3.242	0.684	1.438	0.302
S.D.	32.3	0.334	0.084	0.132	0.033
S.E.	14.4	0.149	0.038	0.059	0.015
M/C	1.8764	1.2471	1.1222	0.1557	0.1930
F	0.6656	0.0199	0.1045	2.6787	3.3218

## INDIVIDUAL DATA 11-2-4

STUDY NO. SR09207    TITLE : isofridecy stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Absolute and relative organ weights    ANIMAL : Rat, Crl:CD(SD)    SEX : Male    GROUP : 1000 mg/kg    PERIOD : End of recovery

Animal No.	Body weight g	Testis		Epididymis	
		%	g	%	g
401	493	3.45	0.70	1.33	0.27
403	470	3.17	0.67	1.22	0.26
407	473	3.46	0.73	1.48	0.31
409	502	3.05	0.61	1.32	0.26
410	500	3.20	0.64	1.22	0.24

	N	5	5	5	5	5
MEAN	487.6	3.266	0.670	1.314	0.268	
S.D.	15.1	0.181	0.047	0.107	0.026	
S.E.	6.8	0.081	0.021	0.048	0.012	

INDIVIDUAL DATA 11-3-1

STUDY NO. SR9207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 6 of lactation

Animal No.	Body weight g	Liver		Kidney		Spleen		Heart		Brain		Pituitary gland		Thymus		Thyroid		Adrenal	
		g	%	g	%	g	%	g	%	g	%	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %
151	277	9.56	3.45	2.11	0.76	0.82	0.30	1.07	0.39	1.91	0.69	17.6	6.35	247	89.17	14.8	5.34	65	23.47
152	310	10.29	3.32	2.12	0.68	0.76	0.25	0.92	0.30	2.16	0.70	17.3	5.58	374	120.65	11.9	3.84	65	20.97
153	326	10.43	3.20	2.39	0.73	0.91	0.28	1.00	0.31	2.10	0.64	17.2	5.28	266	81.60	17.1	5.25	88	26.99
154	305	11.55	3.79	2.02	0.66	0.63	0.21	0.96	0.31	2.01	0.66	15.7	5.15	199	65.25	12.8	4.20	70	22.95
158	336	12.15	3.62	2.19	0.65	0.80	0.24	0.97	0.29	2.12	0.63	19.7	5.86	414	123.21	16.9	5.03	76	22.62
N		5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	310.8	10.796	3.476	2.166	0.696	0.784	0.256	0.984	0.320	2.060	0.664	17.50	5.644	300.0	95.976	14.70	4.732	72.8	23.400
S.D.	22.6	1.039	0.235	0.139	0.047	0.102	0.035	0.056	0.040	0.100	0.030	1.43	0.481	90.3	25.237	2.35	0.672	9.6	2.214
S.E.	10.1	0.465	0.105	0.062	0.021	0.046	0.016	0.025	0.018	0.045	0.014	0.64	0.215	40.4	11.286	1.05	0.300	4.3	0.990
M/C	1.1511	2.1698	0.0186	3.1913	0.8342	0.9793	1.2438	1.0450	0.8339	1.7425	1.9417	1.7404	1.0280	7.1196	7.1897	3.1878	1.4056	0.4008	1.2611
F	0.4131	4.2583*	4.8941*	0.2118	0.8444	1.8943	0.8857	3.8026*	0.9257	0.1039	0.1195	0.8198	0.6402	1.0712	1.0748	2.6668†	2.9663†	3.7091*	3.6361*
H																			

## INDIVIDUAL DATA 11-3-2

STUDY NO. SR9207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 100 mg/kg PERIOD : Day 6 of lactation

Animal No.	Body weight g	Liver		Kidney		Spleen		Heart		Brain		Pituitary gland		Thymus		Thyroid		Adrenal		
		g	%	g	%	g	%	g	%	g	%	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	
253	31.3	11.42	3.65	2.18	0.70	0.95	0.30	1.09	0.35	2.03	0.65	18.2	5.81	366	116.93	17.8	5.69	75	23.96	
255	309	10.75	3.48	2.21	0.72	0.81	0.26	1.09	0.35	2.06	0.67	17.3	5.60	263	85.11	21.6	6.99	86	27.83	
257	316	10.25	3.24	2.01	0.64	0.87	0.28	1.22	0.39	2.20	0.70	16.0	5.06	281	88.92	19.5	6.17	73	23.10	
260	309	11.97	3.87	2.12	0.69	1.01	0.33	1.15	0.37	2.12	0.69	16.6	5.37	269	87.06	18.7	6.05	74	23.95	
262	342	12.00	3.51	2.24	0.65	0.82	0.24	1.03	0.30	1.96	0.57	17.1	5.00	360	105.26	18.3	5.35	65	19.01	
N		5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	
MEAN	317.8	11.278	3.550	2.152	0.680	0.892	0.282	1.116	0.352	2.074	0.656	17.04	5.368	307.8	96.656	19.18	6.050	74.6	23.570	
S.D.	13.8	0.767	0.232	0.091	0.034	0.086	0.035	0.072	0.033	0.091	0.052	0.82	0.346	50.8	13.877	1.49	0.616	7.5	3.141	
S.E.	6.2	0.343	0.104	0.041	0.015	0.039	0.016	0.032	0.015	0.041	0.023	0.37	0.155	22.7	6.206	0.67	0.275	3.4	1.405	
t'		1.0108	0.5138					3.1500*							2.4898	2.5158	0.3195	0.0823		

## INDIVIDUAL DATA 11-3-3

STUDY NO. SR9207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 300 mg/kg PERIOD : Day 6 of lactation

Animal No.	Body weight g	Liver		Kidney		Spleen		Heart		Brain		Pituitary gland		Thymus		Thyroid		Adrenal	
		g	%	g	%	g	%	g	%	g	%	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %
351	302	11.95	3.96	2.36	0.78	0.77	0.25	1.09	0.36	1.99	0.66	5.60	255	84.44	14.6	4.83	106	35.10	
353	282	10.62	3.77	1.99	0.71	0.73	0.26	0.97	0.34	1.99	0.71	5.71	225	79.79	16.4	5.82	80	28.37	
354	310	11.07	3.57	2.43	0.78	0.89	0.29	1.09	0.35	2.12	0.68	19.0	6.13	177	57.10	15.8	5.10	86	27.74
357	314	11.17	3.56	2.04	0.65	0.73	0.23	0.90	0.29	2.08	0.66	15.1	4.81	303	96.50	21.2	6.75	84	26.75
358	319	10.77	3.38	2.26	0.71	0.70	0.22	1.03	0.32	2.05	0.64	15.6	4.89	178	55.80	21.2	6.65	88	27.59
N		5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	305.4	11.116	3.648	2.216	0.726	0.764	0.250	1.016	0.332	2.046	0.670	16.54	5.428	227.6	74.726	17.84	5.830	88.8	29.110
S.D.	14.5	0.516	0.222	0.194	0.055	0.075	0.027	0.082	0.028	0.057	0.026	1.53	0.564	53.5	17.769	3.13	0.873	10.1	3.398
S.E.	6.5	0.231	0.099	0.087	0.025	0.033	0.012	0.037	0.012	0.025	0.012	0.68	0.252	23.9	7.947	1.40	0.391	4.5	1.520
t'		0.6711	1.1942					0.7636								1.7451	2.0959	2.8400*	2.7653*

## INDIVIDUAL DATA 11-34

STUDY NO. SR9207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 6 of lactation

Animal No.	Body weight g	Liver		Kidney		Spleen		Heart		Brain		Pituitary gland		Thymus		Thyroid		Adrenal		
		g	%	g	%	g	%	g	%	g	%	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	
451	319	13.00	4.08	2.11	0.66	0.76	0.24	0.96	0.30	2.15	0.67	14.3	4.48	165	51.72	21.3	6.68	73	22.88	
452	284	12.24	4.31	2.22	0.78	0.92	0.32	1.03	0.36	2.05	0.72	15.8	5.56	345	121.48	13.8	4.86	85	29.93	
453	319	11.86	3.72	2.21	0.69	0.86	0.27	1.09	0.34	2.03	0.64	15.2	4.76	412	129.15	23.9	7.49	63	19.75	
456	304	11.86	3.90	2.05	0.67	0.62	0.20	1.00	0.33	1.99	0.65	17.7	5.82	198	65.13	18.8	6.18	76	25.00	
458	332	13.02	3.92	2.26	0.68	0.69	0.21	0.98	0.30	2.08	0.63	18.1	5.45	581	175.00	17.3	5.21	69	20.78	
N		5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	
MEAN	311.6	12.396	3.986	2.170	0.696	0.770	0.248	1.012	0.326	2.060	0.662	16.22	5.214	340.2	108.496	19.02	6.084	73.2	23.668	
S.D.	18.3	0.582	0.222	0.087	0.048	0.122	0.049	0.051	0.026	0.060	0.036	1.63	0.567	168.9	50.304	3.85	1.073	8.2	4.040	
S.E.	8.2	0.260	0.099	0.039	0.022	0.055	0.022	0.023	0.012	0.027	0.016	0.73	0.254	75.5	22.497	1.72	0.480	3.7	1.807	
t'		3.3555*	3.5411**					0.6682							2.4009	2.5807	0.0710	0.1298		

## INDIVIDUAL DATA 11-3-5

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 6 of lactation

Animal No.	Body weight g	Ovary		$10^{-3}\%$
		mg	10 <sup>-3</sup> %	
151	277	107	38.63	
152	310	107	34.52	
153	326	152	46.63	
154	305	93	30.49	
158	336	121	36.01	
	N	5	5	5
MEAN	310.8	116.0	37.256	
S.D.	22.6	22.4	6.012	
S.E.	10.1	10.0	2.689	
M/C	1.1511	4.499	2.5986	
F	0.4131	3.4460*	2.6477†	

## INDIVIDUAL DATA 11-3-6

STUDY NO. SR99207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 100 mg/kg PERIOD : Day 6 of lactation

Animal No.	Body weight g	Ovary	
		mg	$10^{-3}\%$
253	313	147	46.96
255	309	163	52.75
257	316	117	37.03
260	309	131	42.39
262	342	155	45.32
	N	5	5
MEAN	317.8	142.6	44.890
S.D.	13.8	18.6	5.794
S.E.	6.2	8.3	2.591
t'	2.4867	2.1967	

## INDIVIDUAL DATA 11-3-7

STUDY NO. SR9207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 300 mg/kg PERIOD : Day 6 of lactation

Animal No.	Body weight g	Ovary	
		mg	$10^{-3}\%$
351	302	102	33.77
353	282	138	48.94
354	310	112	36.13
357	314	132	42.04
358	319	107	33.54
	N	5	5
MEAN	305.4	118.2	38.884
S.D.	14.5	15.9	6.584
S.E.	6.5	7.1	2.944
t'		0.2057	0.4685

## INDIVIDUAL DATA 11-3-8

STUDY NO. SR99207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : Day 6 of lactation

Animal No.	Body weight g	Ovary	
		mg	$10^{-3}\%$
451	319	119	37.30
452	284	108	38.03
453	319	117	36.68
456	304	109	35.86
458	332	103	31.02
N		5	5
MEAN	311.6	111.2	35.778
S.D.	18.3	6.6	2.777
S.E.	8.2	3.0	1.242
t'	0.4487	0.4253	

## INDIVIDUAL DATA 11-4-1

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : End of recovery

Animal No.	Body weight g	Liver		Kidney		Spleen		Heart		Brain		Pituitary gland		Thymus		Thyroid		Adrenal	
		g	%	g	%	g	%	g	%	g	%	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %
163	280	6.87	2.45	1.78	0.64	0.48	0.17	0.98	0.35	1.94	0.69	16.4	5.86	386	137.86	14.0	5.00	72	25.71
164	257	7.01	2.73	1.70	0.66	0.47	0.18	0.92	0.36	2.07	0.81	13.9	5.41	265	103.11	20.5	7.98	96	37.35
165	313	7.88	2.52	2.05	0.65	0.82	0.26	0.95	0.30	2.00	0.64	17.4	5.56	290	92.65	12.0	3.83	70	22.36
166	297	7.71	2.60	2.04	0.69	0.65	0.22	0.99	0.33	2.27	0.76	21.0	7.07	286	96.30	16.2	5.45	80	26.94
167	315	8.58	2.72	2.05	0.65	0.72	0.23	1.11	0.35	1.95	0.62	16.5	5.24	363	115.24	16.5	5.24	83	26.35
N		5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	292.4	7.610	2.604	1.924	0.658	0.628	0.212	0.990	0.338	2.046	0.704	17.04	5.828	318.0	109.032	15.84	5.500	80.2	27.742
S.D.	24.3	0.695	0.123	0.170	0.019	0.152	0.037	0.072	0.024	0.135	0.080	2.57	0.731	53.1	18.270	3.18	1.521	10.4	5.657
S.E.	10.9	0.311	0.055	0.076	0.009	0.068	0.017	0.032	0.011	0.061	0.036	1.15	0.327	23.7	8.170	1.42	0.680	4.6	2.530
M/C	0.0137	0.0016	0.2463	0.0424	5.2580*	2.0817	0.4454	0.2942	0.0075	2.2147	2.4267	0.0110	0.4337	0.0016	0.4916	0.0806	1.6637	0.3395	0.8367
F	0.4316	0.4696	0.0400	0.0138	1.0935	2.2059	0.0014	0.4587	0.0743	0.1695	1.1604	1.7598	3.2323	6.0964*	0.0769	0.3369	3.8081†	2.5939	
H				0.2778															

## INDIVIDUAL DATA 11-4-2

STUDY NO. SR092077 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg PERIOD : End of recovery

Animal No.	Body weight g	Liver		Kidney		Spleen		Heart		Brain		Pituitary gland		Thymus		Thyroid		Adrenal	
		g	%	g	%	g	%	g	%	g	%	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %	mg	10 <sup>-3</sup> %
463	280	7.30	2.61	2.09	0.75	0.61	0.22	0.93	0.33	2.03	0.73	15.7	5.61	215	76.79	16.0	5.71	80	28.57
464	319	7.50	2.35	1.84	0.58	0.49	0.15	0.94	0.29	2.09	0.66	12.9	4.04	273	85.58	17.2	5.39	61	19.12
465	278	7.58	2.73	1.78	0.64	0.48	0.17	0.91	0.33	1.98	0.71	17.5	6.29	232	83.45	13.0	4.68	63	22.66
466	305	8.19	2.69	2.11	0.69	0.54	0.18	1.04	0.34	2.09	0.69	12.0	3.93	220	72.13	12.0	3.93	69	22.62
467	329	8.97	2.73	1.86	0.57	0.63	0.19	1.14	0.35	2.13	0.65	18.1	5.50	345	104.86	18.4	5.59	72	21.88
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	302.2	7.908	2.622	1.936	0.646	0.550	0.182	0.992	0.328	2.064	0.688	15.24	5.074	257.0	84.562	15.32	5.060	69.0	22.970
S.D.	22.8	0.680	0.160	0.153	0.076	0.068	0.026	0.097	0.023	0.059	0.033	2.71	1.040	54.2	12.542	2.73	0.747	7.6	3.449
S.E.	10.2	0.304	0.071	0.068	0.034	0.030	0.012	0.043	0.010	0.026	0.015	1.21	0.465	24.2	5.609	1.22	0.334	3.4	1.543
t'															2.4691*				1.9514

## INDIVIDUAL DATA 11-4-3

STUDY NO. SR09207    TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Absolute and relative organ weights    ANIMAL : Rat, Crl:CD(SD)    SEX : Female    GROUP : 0 mg/kg    PERIOD : End of recovery

Animal No.	Body weight g	Ovary	
		mg	$10^{-3}\%$
163	280	142	50.71
164	257	72	28.02
165	313	99	31.63
166	297	121	40.74
167	315	135	42.86

	N	5	5	5
MEAN	292.4	113.8	38.792	
S.D.	24.3	28.6	9.079	
S.E.	10.9	12.8	4.060	
M/C	0.0137	0.3403	0.5132	
F	0.4316	0.0000	0.0550	

## INDIVIDUAL DATA 11-4

STUDY NO. SR09207    TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Absolute and relative organ weights    ANIMAL : Rat, Crl:CD(SD)    SEX : Female    GROUP : 1000 mg/kg    PERIOD : End of recovery

Animal No.	Body weight g	Ovary	
		mg	$10^{-3}\%$
463	280	124	44.29
464	319	128	40.13
465	278	96	34.53
466	305	87	28.52
467	329	134	40.73

	N	5	5	5
MEAN	302.2	113.8	37.640	
S.D.	22.8	20.9	6.181	
S.E.	10.2	9.4	2.764	

## INDIVIDUAL DATA I2-1-1

STUDY NO. SR09207                   TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Histopathological findings           ANIMAL: Rat, CrI: CD (SD)           SEX: Male           GROUP: 0 mg/kg  
 PERIOD: End of administration

Animal No.	101	102	104	105	106	108	112
Organ: Findings							
Lung:	*	*	*	*	*	*	*
Trachea:	N	N	N	N	N	N	N
Esophagus:	N	N	N	N	N	N	N
Forestomach:	N	N	N	N	N	N	N
Stomach, limiting ridge:	N	N	N	N	N	N	N
Glandular stomach:	N	N	N	N	N	N	N
Duodenum:	N	N	N	N	N	N	N
Jejunum:	N	N	N	N	N	N	N
Ileum (including Peyer's patch):	N	N	N	N	N	N	N
Cecum:	N	N	N	N	N	N	N
Colon:	N	N	N	N	N	N	N
Rectum:	-	N	-	-	N	-	-
Pancreas:	N	+ N	-	-	N	N	N
Liver: Microgranuloma	-	N	-	-	N	N	N
Heart:							
Right kidney: Eosinophilic body, proximal tubular epithelium							
Left kidney: Eosinophilic body, proximal tubular epithelium							
Urinary bladder:							
Right testis:							
Left testis:							
Right epididymis:							
Left epididymis:							
Prostate: Cellular infiltration, inflammatory cell							
Right seminal vesicle:							
Left seminal vesicle:							
Right coagulating gland:							
Left coagulating gland:							

N: No abnormal findings, -: normal, +: slight change.

a: Alpha-2u-globulin antibody positive.

\*: Not examined.

(to be continued)

## INDIVIDUAL DATA I2-I-1 (continued)

STUDY NO. SR09207                   TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Histopathological findings           ANIMAL: Rat, CrI: CD (SD)           SEX: Male           GROUP: 0 mg/kg  
 PERIOD: End of administration

Animal No.	101	102	104	105	106	108	112
Organ: Findings							
Cerebrum:	*	*	*	*	*	*	*
Cerebellum:	N	N	N	N	N	N	N
Pons:	N	N	N	N	N	N	N
Spinal cord:	N	N	N	N	N	N	N
Sciatic nerve:	N	N	N	N	N	N	N
Spleen:	N	N	N	N	N	N	N
Thymus:	N	N	N	N	N	N	N
Bone marrow of right femur:	-	-	-	-	-	-	-
Right submandibular lymph node:	N	N	N	N	N	N	N
Left submandibular lymph node:	N	N	N	N	N	N	N
Mesenteric lymph node:	-	-	-	-	-	-	-
Pituitary gland: Cyst, pars intermedia	N	N	N	N	N	N	N
Right thyroid:	N	N	N	N	N	N	N
Left thyroid:	N	N	N	N	N	N	N
Right parathyroid:	N	N	N	N	N	N	N
Left parathyroid:	N	N	N	N	N	N	N
Right adrenal:	N	N	N	N	N	N	N
Left adrenal:	N	N	N	N	N	N	N
Right eyeball: Atrophy, retina	+	+	+	+	+	+	+
Left eyeball: Atrophy, retina	N	N	N	N	N	N	N
Right Harderian gland:	N	N	N	N	N	N	N
Left Harderian gland:	N	N	N	N	N	N	N
Right femur:	N	N	N	N	N	N	N

N: No abnormal findings, -: normal, +: slight change.  
 \*: Not examined.

## INDIVIDUAL DATA I2-1-2

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Histopathological findings ANIMAL: Rat, Crl: CD (SD) SEX: Male GROUP: 100 mg/kg PERIOD: End of administration

Animal No.	201	202	203	204	205	206	207	208	209	210	211	212
Organ: Findings												
Right kidney: Eosinophilic body, proximal tubular epithelium	-	-	-	-	-	-	+a	-	-	-	-	-
Regeneration, tubular epithelium	+	-	-	-	-	-	-	-	-	-	-	-
Left kidney: Eosinophilic body, proximal tubular epithelium	-	-	-	-	-	-	+a	-	-	-	-	-
Right testis: Atrophy, seminiferous tubule	*	+	*	*	*	*	*	*	*	*	*	*
Left testis: Atrophy, seminiferous tubule	*	+	*	*	*	*	+++	*	*	*	*	*
Right epididymis: Decrease, spermatozoa	*	+	*	*	*	*	*	*	*	*	*	*
Cell debris, lumen	*	+	*	*	*	*	*	*	*	*	*	*
Granuloma, spermatic	*	-	*	*	*	*	*	*	*	*	*	*
Left epididymis: Decrease, spermatozoa	*	+	*	*	*	*	++	*	*	*	*	*
Cell debris, lumen	*	+	*	*	*	*	+	*	*	*	*	*
Granuloma, spermatic	*	-	*	*	*	*	-	++	*	*	*	*

-: Normal, +: slight change, ++: moderate change, +++: severe change.

a: Alpha-2u-globulin antibody positive.

\*: Not examined.

## INDIVIDUAL DATA I2-1-3

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Histopathological findings ANIMAL: Rat, Crl: CD (SD) SEX: Male GROUP: 300 mg/kg PERIOD: End of administration

Animal No.	301	302	303	304	305	306	307	308	309	310	311	312
Organ: Findings												
Right kidney: Eosinophilic body, proximal tubular epithelium	-	+a	-							-	-	+
Left kidney: Eosinophilic body, proximal tubular epithelium	-	+a	-							-	-	+
Cast, hyaline	-	-	-							-	-	-
Regeneration, tubular epithelium	-	-	-							-	-	-
Right testis: Atrophy, seminiferous tubule	*	*	*	*	*	*	*	*	*	*	*	*
Left testis: Atrophy, seminiferous tubule	*	*	*	*	*	*	*	*	*	*	*	*
Edema, interstitium	*	*	*	*	*	*	*	*	*	*	*	*
Right epididymis: Decrease, spermatozoa	*	*	*	*	*	*	*	*	*	*	*	*
Cell debris, lumen	*	*	*	*	*	*	*	*	*	*	*	*
Left epididymis: Decrease, spermatozoa	*	*	*	*	*	*	*	*	*	*	*	*
Cell debris, lumen	*	*	*	*	*	*	*	*	*	*	*	*
Left Harderian gland: Cellular infiltration, inflammatory cell	*	*	*	*	*	*	*	*	*	*	*	*

-: Normal, +: slight change, ++: moderate change.

a: Alpha-2u-globulin antibody positive.

\*: Not examined.

## INDIVIDUAL DATA I2-1-4

STUDY NO. SR09207 Histopathological findings	TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)		SEX: Male	GROUP: 1000 mg/kg	PERIOD: End of administration
	ANIMAL: Rat, Crl: CD (SD)	Animal No.			
Organ: Findings		402	404	405	406
Lung:					
Trachea:					
Esophagus:					
Forestomach:					
Stomach, limiting ridge:					
Glandular stomach:					
Duodenum:					
Jejunum:					
Ileum (including Peyer's patch):					
Cecum:					
Colon:					
Rectum:					
Pancreas:					
Liver: Microgranuloma					
Heart: Myocardial degeneration, focal					
Right kidney: Eosinophilic body, proximal tubular epithelium					
Left kidney: Eosinophilic body, proximal tubular epithelium					
Cast, hyaline					
Urinary bladder:					
Right testis:					
Left testis:					
Right epididymis:					
Left epididymis:					
Prostate: Cellular infiltration, inflammatory cell					
Right seminal vesicle:					
Left seminal vesicle:					
Right coagulating gland:					
Left coagulating gland:					

(to be continued)

N: No abnormal findings, -: normal, +: slight change.

a: Alpha-2u-globulin antibody positive.

\*: Not examined.

## INDIVIDUAL DATA I2-1-4 (continued)

STUDY NO. SR09207                   TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Histopathological findings           ANIMAL: Rat, Crl: CD (SD)           SEX: Male           GROUP: 1000 mg/kg  
 PERIOD: End of administration

Animal No.	402	404	405	406	408	411	412
Organ: Findings							
Cerebrum:	*	*	*	*	*	*	*
Cerebellum:	N	N	N	N	N	N	N
Pons:	N	N	N	N	N	N	N
Spinal cord:	N	N	N	N	N	N	N
Sciatic nerve:	N	N	N	N	N	N	N
Spleen:	N	N	N	N	N	N	N
Thymus:	N	N	N	N	N	N	N
Bone marrow of right femur:	N	N	N	N	N	N	N
Right submandibular lymph node:	-	-	-	-	-	-	-
Left submandibular lymph node:	N	N	N	N	N	N	N
Mesenteric lymph node:	N	N	N	N	N	N	N
Pituitary gland: Cyst, pars distalis	-	-	#	N	N	N	N
Right thyroid:	N	N	N	N	N	N	N
Left thyroid:	N	N	N	N	N	N	N
Right parathyroid:	N	N	N	N	N	N	N
Left parathyroid:	N	N	N	N	N	N	N
Right adrenal:	N	N	N	N	N	N	N
Left adrenal:	N	N	N	N	N	N	N
Right eyeball: Atrophy, retina	-	-	-	-	-	-	-
Left eyeball: Atrophy, retina	N	N	N	N	N	N	N
Right Harderian gland:	N	N	N	N	N	N	N
Left Harderian gland:	N	N	N	N	N	N	N
Right femur:	N	N	N	N	N	N	N

N: No abnormal findings, -: normal, +: slight change.

\*: Not examined.

#: Not examined because of missing.

INDIVIDUAL DATA 12-2-1

**STUDY NO.** SR09207      **TITLE:** Isotridecy1 stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
**ANIMAL:** Rat, Ch: CD (SD)      **SEX:** Male      **GROUP:** 0 mg/kg  
**Histopathological findings**      **PERIOD:** End of recovery

Animal No.	Organ: Findings	103	107	109	110	111
Lung:	Aggregation, macrophage, alveolar	-	-	N	N	N
Mineralization, artery		-	-	N	N	N
Trachea:		-	-	N	N	N
Esophagus:		-	-	N	N	N
Forestomach:		-	-	N	N	N
Stomach, limiting ridge:		-	-	N	N	N
Glandular stomach:		-	-	N	N	N
Duodenum:		-	-	N	N	N
Jejunum:		-	-	N	N	N
Ileum (including Peyer's patch):		-	-	N	N	N
Cecum:		-	-	N	N	N
Colon:		-	-	N	N	N
Rectum:		-	-	N	N	N
Pancreas:		-	-	N	N	N
Liver: Microgranuloma		-	-	N	N	N
Heart:		-	-	N	N	N
Right kidney: Eosinophilic body, proximal tubular epithelium		-	-	N	N	N
Left kidney: Eosinophilic body, proximal tubular epithelium		-	-	N	N	N
Regeneration, tubular epithelium		-	-	N	N	N
Urinary bladder:		-	-	N	N	N
Right testis:		-	-	N	N	N
Left testis:		-	-	N	N	N
Right epididymis:		-	-	N	N	N
Left epididymis:		-	-	N	N	N
Prostate: Cellular infiltration, inflammatory cell		-	-	N	N	N
Right seminal vesicle:		-	-	N	N	N
Left seminal vesicle:		-	-	N	N	N
Right coagulating gland:		-	-	N	N	N
Left coagulating gland:		-	-	N	N	N

N: No abnormal findings, -: normal, +: slight change.

a: Alpha-2u-globulin antibody positive.

(to be continued)

INDIVIDUAL DATA 12-2-1 (continued)

**STUDY NO.** SR09207      **TITLE:** Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
**ANIMAL:** Rat, Crl:CD (SD)      **SEX:** Male      **GROUP:** 0 mg/kg  
**Histopathological findings**      **PERIOD:** End of recovery

N: No abnormal findings, -: normal, +: slight change.

#: Not examined because of missing.

## INDIVIDUAL DATA 12-2-2

STUDY NO. SR09207 Histopathological findings	TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)			GROUP: 1000 mg/kg	PERIOD: End of recovery
	ANIMAL: Rat, CrI: CD (SD)	SEX: Male	Animal No.		
Organ: Findings					
Lung: Mineralization, artery	-	-	401	-	
Trachea:	N	N	403	-	
Esophagus:	N	N	407	-	
Forestomach:	N	N	409	-	
Stomach, limiting ridge:	N	N	410	-	
Glandular stomach:	N	N		-	
Duodenum:	N	N		-	
Jejunum:	N	N		-	
Ileum (including Peyer's patch):	N	N		-	
Cecum:	N	N		-	
Colon:	N	N		-	
Rectum:	N	N		-	
Pancreas:	N	N		-	
Liver: Microgranuloma	N	N		-	
Heart:	N	N		-	
Right kidney: Cast, hyaline	N	N		-	
Left kidney:	N	N		-	
Urinary bladder:	N	N		-	
Right testis:	N	N		-	
Left testis:	N	N		-	
Right epididymis:	N	N		-	
Left epididymis:	N	N		-	
Prostate: Cellular infiltration, inflammatory cell	N	N		-	
Right seminal vesicle:	N	N		-	
Left seminal vesicle:	N	N		-	
Right coagulating gland:	N	N		-	
Left coagulating gland:	N	N		-	

(to be continued)

N: No abnormal findings, -: normal, +: slight change.

INDIVIDUAL DATA 12-2-2 (continued)

**STUDY NO.** SR09207      **TITLE:** Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
**Histopathological findings**      **ANIMAL:** Rat, Cr, CD (SD)      **SEX:** Male      **GROUP:** 1000 mg/kg      **PERIOD:** End of recovery

N: No abnormal findings, -: normal, +: slight change.

## INDIVIDUAL DATA I2-3-1

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Histopathological findings ANIMAL: Rat, Crl: CD (SD) SEX: Female GROUP: 0 mg/kg

Animal No.	151	152	153	154	155	156	157	158	159	160	161	162 <sup>a</sup>
Organ: Findings												
Lung:	N	N	N	N	N	N	N	N	N	N	N	*
Trachea:	N	N	N	N	N	N	N	N	N	N	N	*
Esophagus:	N	N	N	N	N	N	N	N	N	N	N	*
Forestomach:	N	N	N	N	N	N	N	N	N	N	N	*
Stomach, limiting ridge:	N	N	N	N	N	N	N	N	N	N	N	*
Glandular stomach:	N	N	N	N	N	N	N	N	N	N	N	*
Duodenum:	N	N	N	N	N	N	N	N	N	N	N	*
Jejunum:	N	N	N	N	N	N	N	N	N	N	N	*
Ileum (including Peyer's patch):	N	N	N	N	N	N	N	N	N	N	N	*
Cecum:	N	N	N	N	N	N	N	N	N	N	N	*
Colon:	N	N	N	N	N	N	N	N	N	N	N	*
Rectum:	N	N	N	N	N	N	N	N	N	N	N	*
Pancreas:	-	-	-	-	-	-	-	-	-	-	-	*
Liver: Microgranuloma	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	*
Heart:	N	N	N	N	N	N	N	N	N	N	N	*
Right kidney:	N	N	N	N	N	N	N	N	N	N	N	*
Left kidney: Regeneration, tubular epithelium	-	-	-	-	-	-	-	-	-	-	-	*
Urinary bladder:	N	N	N	N	N	N	N	N	N	N	N	*
Right ovary:	N	N	N	N	N	N	N	N	N	N	N	*
Left ovary:	N	N	N	N	N	N	N	N	N	N	N	*
Right uterine horn:	N	N	N	N	N	N	N	N	N	N	N	*
Left uterine horn:	N	N	N	N	N	N	N	N	N	N	N	*
Uterine cervix:	N	N	N	N	N	N	N	N	N	N	N	*

(to be continued)

N: No abnormal findings, -: normal, +: slight change.

\*: Not examined.

a : Not copulated.

## INDIVIDUAL DATA I2-3-1 (continued)

STUDY NO. SR09207                    TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Histopathological findings            ANIMAL: Rat, CrL: CD (SD)            SEX: Female            GROUP: 0 mg/kg  
 PERIOD: End of administration

Animal No.	151	152	153	154	155	156	157	158	159	160	161	162 <sup>a</sup>
Organ: Findings												
Cerebrum:	N	N	N	N	N	N	N	N	N	N	N	*
Cerebellum:	N	N	N	N	N	N	N	N	N	N	N	*
Pons:	N	N	N	N	N	N	N	N	N	N	N	*
Spinal cord:	N	N	N	N	N	N	N	N	N	N	N	*
Sciatic nerve:	N	N	N	N	N	N	N	N	N	N	N	*
Spleen:	N	N	N	N	N	N	N	N	N	N	N	*
Thymus:	N	N	N	N	N	N	N	N	N	N	N	*
Bone marrow of right femur:	N	N	N	N	N	N	N	N	N	N	N	*
Right submandibular lymph node:	N	N	N	N	N	N	N	N	N	N	N	*
Left submandibular lymph node:	N	N	N	N	N	N	N	N	N	N	N	*
Mesenteric lymph node:	N	N	N	N	N	N	N	N	N	N	N	*
Pituitary gland:	N	N	N	N	N	N	N	N	N	N	N	*
Right thyroid:	N	N	N	N	N	N	N	N	N	N	N	*
Left thyroid:	N	N	N	N	N	N	N	N	N	N	N	*
Right parathyroid:	N	N	N	N	N	N	N	N	N	N	N	*
Left parathyroid:	N	N	N	N	N	N	N	N	N	N	N	*
Right adrenal:	N	N	N	N	N	N	N	N	N	N	N	*
Left adrenal:	N	N	N	N	N	N	N	N	N	N	N	*
Right eyeball:	N	N	N	N	N	N	N	N	N	N	N	*
Left eyeball:	N	N	N	N	N	N	N	N	N	N	N	*
Right Harderian gland:	N	N	N	N	N	N	N	N	N	N	N	*
Left Harderian gland:	N	N	N	N	N	N	N	N	N	N	N	*
Right femur:	N	N	N	N	N	N	N	N	N	N	N	*
Mammary gland:	N	N	N	N	N	N	N	N	N	N	N	*

N: No abnormal findings.

\*: Not examined.

a : Not copulated.

## INDIVIDUAL DATA I2-3-2

STUDY NO. SR09207 Histopathological findings	ANIMAL: Rat, Crl: CD (SD)	SEX: Female	GROUP: 100 mg/kg	PERIOD: End of administration								
Animal No.	251	252	253	254	255	256	257	258	259	260	261	262
<b>Organ: Findings</b>												
Right kidney: Cellular infiltration, inflammatory cell, renal pelvic mucosa	-	-	-	-	-	-	-	+	-	-	-	-
Mineralization, cortex	-	-	-	-	+	-	-	-	-	-	-	-
Left kidney:	N	N	N	N	N	N	N	N	N	N	N	N

N: No abnormal findings, -: normal, +: slight change.

## INDIVIDUAL DATA I2-3-3

STUDY NO. SR09207 Histopathological findings	ANIMAL: Rat, Crl: CD (SD)	SEX: Female	GROUP: 300 mg/kg	PERIOD: End of administration								
Animal No.	351	352	353	354	355	356	357	358	359	360	361	362
<b>Organ: Findings</b>												
Glandular stomach: Erosion	*	*	*	*	*	*	*	*	*	*	*	*
Right kidney:	N	N	N	N	N	N	N	N	N	N	N	N
Left kidney:	N	N	N	N	N	N	N	N	N	N	N	N
Left forelimb: Fibrosis, periosteal, 3rd digit	*	*	*	*	*	*	*	*	*	*	*	*

N: No abnormal findings, +: slight change.

\*: Not examined.

## INDIVIDUAL DATA I2-3-4

STUDY NO. SR09207 TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Histopathological findings ANIMAL: Rat, Crl: CD (SD) GROUP: 1000 mg/kg

SEX: Female PERIOD: End of administration

Animal No.	451	452	453	454 <sup>a</sup>	455	456	457	458	459	460	461	462
Organ: Findings												
Lung: Aggregation, macrophage, alveolar	-	-	-	*	*	*	*	*	*	*	*	*
Inflammation, granulomatous, with foreign body	-	-	-	*	*	*	*	*	*	*	*	*
Trachea:	-	-	-	N	N	N	N	N	N	N	N	N
Esophagus:	-	-	-	N	N	N	N	N	N	N	N	N
Forestomach:	-	-	-	N	N	N	N	N	N	N	N	N
Stomach, limiting ridge:	-	-	-	N	N	N	N	N	N	N	N	N
Glandular stomach:	-	-	-	N	N	N	N	N	N	N	N	N
Duodenum:	-	-	-	N	N	N	N	N	N	N	N	N
Jejunum:	-	-	-	N	N	N	N	N	N	N	N	N
Ileum (including Peyer's patch):	-	-	-	N	N	N	N	N	N	N	N	N
Cecum:	-	-	-	N	N	N	N	N	N	N	N	N
Colon:	-	-	-	N	N	N	N	N	N	N	N	N
Rectum:	-	-	-	N	N	N	N	N	N	N	N	N
Pancreas:	-	-	-	N	N	N	N	N	N	N	N	N
Liver: Microgranuloma	-	-	-	N	N	N	N	N	N	N	N	N
Heart:	-	-	-	-	-	-	-	-	-	-	-	-
Right kidney: Regeneration, tubular epithelium	-	-	-	-	-	-	-	-	-	-	-	-
Cast, hyaline	-	-	-	-	-	-	-	-	-	-	-	-
Cellular infiltration, inflammatory cell, renal pelvic mucosa	-	-	-	-	-	-	-	-	-	-	-	-
Left kidney: Regeneration, tubular epithelium	-	-	-	-	-	-	-	-	-	-	-	-
Urinary bladder:	-	-	-	-	-	-	-	-	-	-	-	-
Right ovary:	-	-	-	-	-	-	-	-	-	-	-	-
Left ovary:	-	-	-	-	-	-	-	-	-	-	-	-
Right uterine horn:	-	-	-	-	-	-	-	-	-	-	-	-
Left uterine horn:	-	-	-	-	-	-	-	-	-	-	-	-
Uterine cervix:	-	-	-	-	-	-	-	-	-	-	-	-

(to be continued)

N: No abnormal findings, -: normal, +: slight change.

\*: Not examined.

a : Non-pregnant.

## INDIVIDUAL DATA 12-3-4 (continued)

STUDY NO. SR09207                   TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Histopathological findings           ANIMAL: Rat, Crl: CD (SD)           SEX: Female           GROUP: 1000 mg/kg           PERIOD: End of administration

Animal No.	451	452	453	454 <sup>a</sup>	455	456	457	458	459	460	461	462
Organ: Findings												
Cerebrum:	N	N	N	N	N	N	N	N	N	N	N	N
Cerebellum:	*	*	*	*	*	*	*	*	*	*	*	*
Pons:	*	*	*	*	*	*	*	*	*	*	*	*
Spinal cord:	*	*	*	*	*	*	*	*	*	*	*	*
Sciatic nerve:	*	*	*	*	*	*	*	*	*	*	*	*
Spleen:	*	*	*	*	*	*	*	*	*	*	*	*
Thymus:	*	*	*	*	*	*	*	*	*	*	*	*
Bone marrow of right femur:	*	*	*	*	*	*	*	*	*	*	*	*
Right submandibular lymph node:	*	*	*	*	*	*	*	*	*	*	*	*
Left submandibular lymph node:	*	*	*	*	*	*	*	*	*	*	*	*
Mesenteric lymph node:	*	*	*	*	*	*	*	*	*	*	*	*
Pituitary gland:	*	*	*	*	*	*	*	*	*	*	*	*
Right thyroid:	*	*	*	*	*	*	*	*	*	*	*	*
Left thyroid:	*	*	*	*	*	*	*	*	*	*	*	*
Right parathyroid:	*	*	*	*	*	*	*	*	*	*	*	*
Left parathyroid:	*	*	*	*	*	*	*	*	*	*	*	*
Right adrenal:	*	*	*	*	*	*	*	*	*	*	*	*
Left adrenal:	*	*	*	*	*	*	*	*	*	*	*	*
Right eyeball:	*	*	*	*	*	*	*	*	*	*	*	*
Left eyeball:	*	*	*	*	*	*	*	*	*	*	*	*
Right Harderian gland:	*	*	*	*	*	*	*	*	*	*	*	*
Left Harderian gland:	*	*	*	*	*	*	*	*	*	*	*	*
Right femur:	*	*	*	*	*	*	*	*	*	*	*	*
Mammary gland:	*	*	*	*	*	*	*	*	*	*	*	*

N: No abnormal findings.

\*: Not examined.

a : Non-pregnant.

## INDIVIDUAL DATA I2-4-1

STUDY NO. SR09207                    TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Histopathological findings            ANIMAL: Rat, CrI: CD (SD)                    SEX: Female                    GROUP: 0 mg/kg  
 PERIOD: End of recovery

Animal No.	163	164	165	166	167
Organ: Findings					
Lung: Metaplasia, osseous, alveoli	-	-	-	-	-
Trachea:	N	N	N	N	N
Esophagus:	N	N	N	N	N
Forestomach:	N	N	N	N	N
Stomach, limiting ridge:	N	N	N	N	N
Glandular stomach:	N	N	N	N	N
Duodenum:	N	N	N	N	N
Jejunum:	N	N	N	N	N
Ileum (including Peyer's patch):	N	N	N	N	N
Cecum:	N	N	N	N	N
Colon:	N	N	N	N	N
Rectum:	N	N	N	N	N
Pancreas:	N	N	N	N	N
Liver: Microgranuloma	N	N	N	N	N
Heart:	-	-	-	-	-
Right kidney:	N	N	N	N	N
Left kidney:	N	N	N	N	N
Urinary bladder:	N	N	N	N	N
Right ovary:	N	N	N	N	N
Left ovary:	N	N	N	N	N
Right uterine horn:	N	N	N	N	N
Left uterine horn:	N	N	N	N	N
Uterine cervix:	N	N	N	N	N

(to be continued)

N: No abnormal findings, -: normal, +: slight change.

## INDIVIDUAL DATA I2-4-1 (continued)

STUDY NO. SR09207 Histopathological findings	ANIMAL: Rat, Crl: CD (SD)	SEX: Female	TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)					
			GROUP: 0 mg/kg	163	164	165	166	167
Animal No.								
Organ: Findings								
Cerebrum:				N	N	N	N	N
Cerebellum:				N	N	N	N	N
Pons:				N	N	N	N	N
Spinal cord:				N	N	N	N	N
Sciatic nerve:				N	N	N	N	N
Spleen:				N	N	N	N	N
Thymus:				N	N	N	N	N
Bone marrow of right femur:				N	N	N	N	N
Right submandibular lymph node:				N	N	N	N	N
Left submandibular lymph node:				N	N	N	N	N
Mesenteric lymph node:				N	N	N	N	N
Pituitary gland:				N	N	N	N	N
Right thyroid:				N	N	N	N	N
Left thyroid:				N	N	N	N	N
Right parathyroid:				#	N	N	N	N
Left parathyroid:				N	N	N	N	N
Right adrenal:				N	N	N	N	N
Left adrenal:				N	N	N	N	N
Right eyeball:				N	N	N	N	N
Left eyeball:				N	N	N	N	N
Right Harderian gland:				N	N	N	N	N
Left Harderian gland:				N	N	N	N	N
Right femur:				N	N	N	N	N
Mammary gland:				N	N	N	N	N

N: No abnormal findings.

#: Not examined because of missing.

## INDIVIDUAL DATA 12-4-2

STUDY NO. SR09207                   TITLE: Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Histopathological findings           ANIMAL: Rat, CrI: CD (SD)           SEX: Female           GROUP: 1000 mg/kg  
 PERIOD: End of recovery

Animal No.	463	464	465	466	467
Organ: Findings					
Lung:	N	N	N	N	N
Trachea:	N	N	N	N	N
Esophagus:	N	N	N	N	N
Forestomach:	-	-	-	-	-
Stomach, limiting ridge: Cyst, squamous cell	N	N	N	N	N
Glandular stomach:	-	-	-	-	-
Duodenum:	N	N	N	N	N
Jejunum:	-	-	-	-	-
Ileum (including Peyer's patch):	N	N	N	N	N
Cecum:	N	N	N	N	N
Colon:	N	N	N	N	N
Rectum:	N	N	N	N	N
Pancreas:	N	N	N	N	N
Liver: Microgranuloma	-	-	-	-	-
Heart:	N	N	N	N	N
Right kidney:	N	N	N	N	N
Left kidney:	N	N	N	N	N
Urinary bladder:	N	N	N	N	N
Right ovary:	N	N	N	N	N
Left ovary:	N	N	N	N	N
Right uterine horn:	N	N	N	N	N
Left uterine horn:	N	N	N	N	N
Uterine cervix:	N	N	N	N	N

(to be continued)

N: No abnormal findings, -: normal, +: slight change.

INDIVIDUAL DATA 12-4-2 (continued)

**STUDY NO.** SR09207      **TITLE:** Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
**Histopathological findings**  
**ANIMAL:** Rat, Cri: CD (SD)      **SEX:** Female      **GROUP:** 1000 mg/kg      **PERIOD:** End of recovery

Animal No.	Organ: Findings				
	Cerebrum:	N	N	N	467
	Cerebellum:	N	N	N	
	Pons:	N	N	N	
	Spinal cord:	N	N	N	
	Sciatic nerve:	N	N	N	
	Spleen:	N	N	N	
	Thymus:	Bone marrow of right femur: Right submandibular lymph node: Left submandibular lymph node: Mesenteric lymph node: Pituitary gland: Right thyroid: Left thyroid: Right parathyroid: Left parathyroid: Right adrenal: Left adrenal: Right eyeball: Left eyeball: Right Harderian gland: Left Harderian gland: Right femur: Mammary gland:	N	N	
463		N	N	# N	
464		N	N	N	
465		N	N	N	
466		N	N	N	

N: No abnormal findings, -: normal, +: slight change.

#: Not examined because of missing.

## INDIVIDUAL DATA 13-1-1

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Estrous cycle ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg

No.	Administration day							Pre-mating period							Mating period														
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
151	V	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	#	#	#	#	#	#	#	#	#	#	#		
152	V	V	III	IV	V	V	III	IV	V	II	III	IV	V	II	III	#	#	#	#	#	#	#	#	#	#	#	#		
153	V	V	III	IV	V	V	III	IV	V	II	III	IV	V	II	III	#	#	#	#	#	#	#	#	#	#	#	#		
154	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	#	#	#	#	#	#	#	#	#	#	#		
155	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	#	#	#	#	#	#	#	#	#	#	#		
156	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V		
157	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	
158	V	II	III	IV	V	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV
159	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	
160	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV
161	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	
162	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	

II : Proestrus. III : Estrus. IV : Metestrus. V : Diestrus. C : Copulated.

# : Not applicable.

(to be continued)

## INDIVIDUAL DATA 13-1-1 (continued)

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Estrous cycle ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Administration day										Autopsy day											
	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50
151	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#
152	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#
153	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#
154	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#
155	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#
156	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#
157	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#
158	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#
159	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#
160	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#
161	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#	#
162	V	V	II	III	IV	V	V	III	IV	V	II	III	IV	V	II	III	IV	V	III	IV	V	II

II : Proestrus. III : Estrus. IV : Metestrus. V : Diestrus. C : Copulated.

# : Not applicable.

## INDIVIDUAL DATA 13-1-2

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Estrous cycle ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 100 mg/kg

Animal No.	Administration day										Pre-mating period							Mating period						
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18						
251	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	C	
252	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III		
253	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	#		
254	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III		
255	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	#
256	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III		
257	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	#		
258	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III		
259	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	#	#		
260	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	#
261	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III		
262	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	#	

II : Proestrus. III : Estrus. IV : Metestrus. V : Diestrus. C : Copulated.

# : Not applicable.

## INDIVIDUAL DATA 13-1-3

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Estrous cycle ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 300 mg/kg

Animal No.	Administration day										Pre-mating period							Mating period					
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18					
351	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	C	#					
352	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III					
353	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	C	#					
354	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	C	#					
355	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	C	#					
356	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	C	#				
357	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	C	#	#					
358	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	C	#	#					
359	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	C	#				
360	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	C	#			
361	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	C	#			
362	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	C	#				

II : Proestrus. III : Estrus. IV : Metestrus. V : Diestrus. C : Copulated.

# : Not applicable.

## INDIVIDUAL DATA 13-1-4

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Estrous cycle ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg

Animal No.	Administration day							Pre-mating period							Mating period											
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
451	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	#	#	#	#	#	#	#	#	#	#	#
452	II	III	IV	V	II	III	IV	V	V	II	III	IV	V	II	III	#	#	#	#	#	#	#	#	#	#	#
453	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	#	#	#	#	#	#	#	#	#	#	#
454	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	V	V	V	V	V	V	V	V	V	V
455	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	C	#	#	#	#	#	#	#	#
456	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	#	#	#	#	#	#	#	#	#	#	#
457	IV	V	V	II	III	IV	V	V	V	II	III	IV	V	V	V	II	III	C	#	#	#	#	#	#	#	#
458	V	V	III	IV	V	II	III	IV	V	II	III	IV	V	V	V	III	#	#	#	#	#	#	#	#	#	#
459	V	V	II	III	IV	V	V	III	IV	V	V	III	IV	V	V	V	III	C	#	#	#	#	#	#	#	#
460	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	V	II	III	C	#	#	#	#	#	#
461	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	V	II	III	C	#	#	#	#	#	#
462	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	V	II	III	C	#	#	#	#	#	#

II : Proestrus. III : Estrus. IV : Metestrus. V : Diestrus. C : Copulated.

# : Not applicable.

## INDIVIDUAL DATA 13-2-1

STUDY NO. SR09207    TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Estrous cycle    ANIMAL : Rat, CrI:CD(SD)    SEX : Female    GROUP : 0 mg/kg

Animal No.	Administration day																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
163	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV
164	V	V	III	IV	V	V	III	IV	V	II	III	V	II	III	V												
165	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	V	II	III	V
166	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	V
167	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV

II : Proestrus.    III : Estrus.    IV : Metestrus.    V : Diestrus.

(to be continued)

## INDIVIDUAL DATA 13-2-1 (continued)

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Estrous cycle ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Administration day	Estrous cycle												Autopsy day	Normal or Abnormal	Length (days)	Estrous cycle
		1	2	3	4	5	6	7	8	9	10	11	12	13	14		
163	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V
164	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV
165	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV
166	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V
167	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V

II : Proestrus. III : Estrus. IV : Metestrus. V : Diestrus.

N

5

MEAN  
S.D.

4.00  
0.00

Abnormal estrous  
cycle (%)  
0/5 (0.0)

Abnormal estrous  
cycle (%)  
0/5 (0.0)

Estrous cycle : Female rats cycling normally ; Defined as having a cycle length between 4 and 6 days.

Female rats cycling abnormally ; Defined as having a cycle length more than 7 days.

Abnormal estrous cycle = (number of female with abnormal estrous cycle / number of females examined) x 100.

## INDIVIDUAL DATA 13-2-2

STUDY NO. SR09207    TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Estrous cycle    ANIMAL : Rat, Crl:CD(SD)    SEX : Female    GROUP : 1000 mg/kg

Animal No.	Administration day																											
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	
463	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	
464	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	
465	III	IV	V	II	IV	V	II	III																				
466	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	
467	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III		

II : Proestrus.    III : Estrus.    IV : Metestrus.    V : Diestrus.

(to be continued)

## INDIVIDUAL DATA 13-2-2 (continued)

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Estrous cycle ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg

Animal No.	Administration day	Estrous cycle												Autopsy day	Normal or Abnormal	Length (days)	Estrous cycle	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14			
463	IV	V	II	III	IV	V	III	IV	V	II	Normal	4.0	III	IV	V	III	IV	V
464	IV	V	V	III	IV	V	II	III	IV	V	II	Normal	4.0	III	IV	V	III	IV
465	V	III	IV	V	II	III	IV	V	II	III	IV	Normal	4.0	V	II	III	IV	V
466	IV	V	II	III	IV	V	II	III	IV	V	II	Normal	4.0	II	IV	V	II	III
467	III	IV	V	V	II	III	IV	V	V	V	V	Abnormal	a	V	V	V	II	IV

II : Proestrus. III : Estrus. IV : Metestrus. V : Diestrus.

N      N      N      N      N      N      N      N      N      N      N      N      N      N      N      N      N      N

	MEAN	S.D.
Recovery day	4.00	0.00
Length (days)	4.00	0.00

Abnormal estrous  
cycle (%)  
1/5 (20.0)

Abnormal estrous  
cycle (%)  
1/5 (20.0)

Estrous cycle : Female rats cycling normally ; Defined as having a cycle length between 4 and 6 days.

Female rats cycling abnormally ; Defined as having a cycle length more than 7 days.

Abnormal estrous cycle = (number of female with abnormal estrous cycle / number of females examined) x 100.

a : Not calculated due to continuing observed to diestros until 35~42 days of administration and 1~7 days of recovery.

## INDIVIDUAL DATA 14-1

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Reproduction performance ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 0 mg/kg

Female No.	Estrous cycle		Paired male No.	Copulation	Pregnancy	Parturition	Gestation length (days)	Nursing
	Normal or Abnormal	Mean cycle Length (days)						
151	Normal	4.0	101	+	+	+	22	+
152	Normal	4.0	102	+	+	+	22	+
153	Normal	4.0	103	+	+	+	23	+
154	Normal	4.0	104	+	+	+	22	+
155	Normal	4.0	105	+	+	+	23	+
156	Normal	4.3	106	+	+	+	22	+
157	Normal	4.0	107	+	+	+	23	+
158	Normal	4.0	108	+	+	+	22	+
159	Normal	4.0	109	+	+	+	22	+
160	Normal	4.0	110	+	+	+	22	+
161	Normal	4.0	111	+	+	+	22	+
162	Abnormal	a	112	-	#	#	#	#
N		11					11	
MEAN		4.03					22.3	
S.D.	Abnormal estrous cycle (%)		0.09	Copulation index (%) Male	Fertility index (%) Female	Gestation index (%)	0.5	Nursing index (%)
	1/12 (8.3)			11/12 (91.7)	11/12 (91.7)	11/11 (100.0)	11/11 (100.0)	11/11 (100.0)

Estrous cycle : Female rats cycling normally ; Defined as having a cycle length between 4 and 6 days.

Female rats cycling abnormally ; Defined as having cycle length more than 7 days.

Copulation, pregnancy, parturition and nursing : + ; Positive, - ; Negative.

Abnormal estrous cycle = (number of female with abnormal estrous cycle / number of females examined) x 100.

Copulation index = (number of copulated animals / number of animals mated) x 100.

Fertility index = (number of pregnant females / number of copulated females) x 100.

Gestation index = (number of females with live pups / number of pregnant females) x 100.

Nursing index = (number of females nursing live pups on lactation day 4 / number of females with live pups delivery) x 100.

# : Not applicable.

a : Not calculated due to continuing observed to diestrous until 16~30 days of administration.

## INDIVIDUAL DATA 14-2

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Reproduction performance ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 100 mg/kg

Female No.	Estrous cycle		Paired male No.	Copulation	Pregnancy	Parturition	Gestation length (days)	Nursing
	Normal or Abnormal	Mean cycle Length (days)						
251	Normal	4.0	201	+	+	+	23	+
252	Normal	4.0	202	+	+	+	23	+
253	Normal	4.0	203	+	+	+	22	+
254	Normal	4.0	204	+	+	+	22	+
255	Normal	4.0	205	+	+	+	23	+
256	Normal	4.0	206	+	+	+	22	+
257	Normal	4.0	207	+	+	+	22	+
258	Normal	4.0	208	+	+	+	23	+
259	Normal	4.0	209	+	+	+	23	+
260	Normal	4.0	210	+	+	+	23	+
261	Normal	4.0	211	+	+	+	22	+
262	Normal	4.3	212	+	+	+	22	+
N		12					12	
MEAN		4.03					22.5	
S.D.		0.09					0.5	
Abnormal estrous cycle (%)			Copulation index (%)		Fertility index (%)		Nursing index (%)	
0/12 (0.0)			Male	Female				
			12/12 (100.0)	12/12 (100.0)	12/12 (100.0)	12/12 (100.0)	12/12 (100.0)	

Estrous cycle : Female rats cycling normally ; Defined as having a cycle length between 4 and 6 days.

Copulation, pregnancy, parturition and nursing : + ; Positive.

Abnormal estrous cycle = (number of female with abnormal estrous cycle / number of females examined) x 100.

Copulation index = (number of copulated animals / number of animals mated) x 100.

Fertility index = (number of pregnant females / number of copulated females) x 100.

Gestation index = (number of females with live pups / number of pregnant females) x 100.

Nursing index = (number of females nursing live pups on lactation day 4 / number of females with live pups delivery) x 100.

## INDIVIDUAL DATA 14-3

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Reproduction performance ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 300 mg/kg

Female No.	Estrous cycle		Paired male No.	Copulation	Pregnancy	Parturition	Gestation length (days)	Nursing
	Normal or Abnormal	Mean cycle Length (days)						
351	Normal	4.0	301	+	+	+	22	+
352	Normal	4.0	302	+	+	+	22	+
353	Normal	4.0	303	+	+	+	23	+
354	Normal	4.0	304	+	+	+	22	+
355	Normal	4.0	305	+	+	+	22	+
356	Normal	4.0	306	+	+	+	22	+
357	Normal	4.0	307	+	+	+	22	+
358	Normal	4.0	308	+	+	+	22	+
359	Normal	4.0	309	+	+	+	22	+
360	Normal	4.0	310	+	+	+	22	+
361	Normal	4.0	311	+	+	+	23	+
362	Normal	4.0	312	+	+	+	23	+
N		12	12		22.3		22.3	
MEAN		4.00	0.00		0.5		0.5	
S.D.	Abnormal estrous cycle (%)		Copulation index (%)		Fertility index (%)		Nursing index (%)	
	0/12 (0.0)		Male		Female		12/12 (100.0)	
	12/12 (100.0)		12/12 (100.0)		12/12 (100.0)		12/12 (100.0)	

Estrous cycle : Female rats cycling normally ; Defined as having a cycle length between 4 and 6 days.

Copulation, pregnancy, parturition and nursing : + ; Positive.

Abnormal estrous cycle = (number of female with abnormal estrous cycle / number of females examined) x 100.

Copulation index = (number of copulated animals / number of animals mated) x 100.

Fertility index = (number of pregnant females / number of copulated females) x 100.

Gestation index = (number of females with live pups / number of pregnant females) x 100.

Nursing index = (number of females nursing live pups on lactation day 4 / number of females with live pups delivery) x 100.

## INDIVIDUAL DATA 14-4

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Reproduction performance ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1000 mg/kg

Female No.	Estrous cycle		Paired male No.	Copulation	Pregnancy	Parturition	Gestation length (days)	Nursing
	Normal or Abnormal	Mean cycle Length (days)						
451	Normal	4.0	401	+	+	+	22	+
452	Normal	4.7	402	+	+	+	22	+
453	Normal	4.0	403	+	+	+	22	+
454	Abnormal	a	404	+	-	#	#	#
455	Normal	4.0	405	+	+	+	22	+
456	Normal	4.0	406	+	+	+	22	+
457	Normal	5.5	407	+	+	+	22	+
458	Normal	4.0	408	+	+	+	22	+
459	Normal	4.0	409	+	+	+	23	+
460	Normal	4.0	410	+	+	+	22	+
461	Normal	4.0	411	+	+	+	22	+
462	Normal	4.0	412	+	+	+	22	+
N		11					11	
MEAN		4.20					22.1	
S.D.	Abnormal estrous cycle (%)		0.48	Copulation index (%) Male	Fertility index (%) Female	Gestation index (%)	0.3	Nursing index (%)
	1/12 (8.3)			12/12 (100.0)	12/12 (100.0)	11/12 (91.7)	11/11 (100.0)	11/11 (100.0)

Estrous cycle : Female rats cycling normally ; Defined as having a cycle length between 4 and 6 days.

Female rats cycling abnormally ; Defined as having cycle length more than 7 days.

Copulation, pregnancy, parturition and nursing : + ; Positive, - ; Negative.

Abnormal estrous cycle = (number of female with abnormal estrous cycle / number of females examined) x 100.

Copulation index = (number of copulated animals / number of animals mated) x 100.

Fertility index = (number of pregnant females / number of copulated females) x 100.

Gestation index = (number of females with live pups / number of pregnant females) x 100.

Nursing index = (number of females nursing live pups on lactation day 4 / number of females with live pups delivery) x 100.  
 #: Not applicable.

a : Not calculated due to continuing observed to diestros until 16~25 days of administration.

INDIVIDUAL DATA 15-1  
STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
Pregnancy and litter data ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 0 mg/kg

Dam No.	Number of corpora lutea	Number of implantation sites	Implantation index (%)	Delivery index (%)	Lactation Day 0			Lactation Day 4		
					Number of pups born			Number of live pups		
					Total	Male	Female	Total	Male	Female
151	17	15	88.24	100.00	15	5	10	15	5	10
152	16	16	100.00	93.75	15	6	9	15	6	9
153	18	18	100.00	88.89	16	6	10	16	6	10
154	15	14	93.33	100.00	14	6	8	14	6	8
155	19	18	94.74	83.33	15	8	7	15	8	7
156	17	16	94.12	100.00	16	11	5	16	11	5
157	14	14	100.00	100.00	14	7	7	14	7	7
158	17	16	94.12	100.00	16	8	8	16	8	8
159	15	15	100.00	93.33	14	5	9	14	5	9
160	11	11	100.00	90.91	10	9	1	10	9	1
161	18	18	100.00	94.44	17	4	13	0	17	4
N	11	11	11	11	11	11	11	11	11	11
MEAN	16.1	15.5	96.777	94.968	14.7	6.8	7.9	7.9	4.478	14.7
S.D.	2.3	2.1	4.066	5.656	1.8	2.0	3.1	0.0	0.184	1.8
M/C	2.0436	2.0923	1.5178	4.3748	1.8204	<sup>∞*</sup> ** 3.7000		7.3029	6.2474	<sup>∞**</sup> 4.8734
F	0.2228	0.1459	0.4119	1.1187	0.4695	0.3163		0.4901	0.5853	0.2610
H						3.5739		3.3867		

Implantation index = (number of implantation sites / number of corpora lutea) × 100.

Delivery index = (number of pups born / number of implantation sites) × 100.

Sex ratio on Lactation day 0 = (number of male pups born / number of pups born) and (number of live male pups / number of live pups).

Sex ratio on Lactation day 4 = number of live male pups / number of live pups.

Live birth index = (number of live pups on lactation day 0 / number of pups born) × 100.

Viability index = (number of live pups on lactation day 4 / number of live pups on lactation day 0) × 100.

0.433  
0.400  
0.380  
0.433  
0.530  
0.690  
0.500  
0.500  
0.360  
0.900  
0.244

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0.53  
0.69  
0.50  
0.50  
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100.00

INDIVIDUAL DATA 15-2  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Pregnancy and litter data ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 100 mg/kg

Dam No.	Number of corpora lutea	Number of implantation sites	Implantation index (%)	Delivery index (%)	Lactation Day 0			Lactation Day 4		
					Number of pups born		Total	Number of live pups		Live birth index (%)
					Male	Female		Male	Female	
251	16	14	87.50	100.00	14	7	0	14	7	0.50
252	17	17	100.00	88.24	15	7	0	15	7	0.47
253	17	17	100.00	100.00	17	10	0	17	10	0.59
254	14	13	92.86	100.00	13	10	3	13	10	0.77
255	18	18	100.00	94.44	17	9	8	17	9	0.53
256	16	16	100.00	100.00	16	9	7	16	9	0.56
257	15	15	100.00	100.00	15	5	10	15	10	0.33
258	17	16	94.12	93.75	15	8	7	15	8	0.53
259	19	19	100.00	94.74	18	11	7	18	11	0.61
260	15	15	100.00	80.00	12	5	7	11	5	0.42
261	17	15	88.24	86.67	13	5	8	13	5	0.38
262	19	17	89.47	94.12	16	8	0	16	8	0.50
N	12	12	12	12	12	12	12	12	12	12
MEAN	16.7	16.0	96.016	94.330	15.1	7.8	0.1	15.0	7.8	7.0
S.D.	1.6	1.7	5.227	6.484	1.8	2.1	1.6	0.3	2.0	1.6

Implantation index = (number of implantation sites / number of corpora lutea) x 100.

Delivery index = (number of pups born / number of implantation sites) x 100.

Sex ratio on Lactation day 0 = (number of male pups born / number of pups born) and (number of live male pups / number of live pups).

Sex ratio on Lactation day 4 = number of live male pups / number of live pups.

Live birth index = (number of live pups on lactation day 0 / number of pups born) x 100.

Viability index = (number of live pups on lactation day 4 / number of live pups on lactation day 0) x 100.

INDIVIDUAL DATA 15-3  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Pregnancy and litter data ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 300 mg/kg

Dam No.	Number of corpora lutea	Number of implantation sites	Implantation index (%)	Delivery index (%)	Lactation Day 0			Lactation Day 4											
					Number of pups born		Number of live pups	Number of live pups		Number of live pups									
					Total	Male		Female	Dead	Total	Male	Female	Pups born	Live birth index (%)	Total	Male	Female	Sex Ratio	Number of live pups
351	16	15	93.75	93.33	14	10	4	1	13	10	3	0.71	0.77	92.86	13	10	3	0.77	100.00
352	16	16	100.00	93.75	15	7	8	0	15	7	8	0.47	0.47	100.00	15	7	8	0.47	100.00
353	16	16	100.00	93.75	15	9	6	0	15	9	6	0.60	0.60	100.00	15	9	6	0.60	100.00
354	16	16	100.00	100.00	16	8	8	0	16	8	8	0.50	0.50	100.00	16	8	8	0.50	100.00
355	17	17	100.00	94.12	16	8	8	0	16	8	8	0.50	0.50	100.00	16	8	8	0.50	100.00
356	16	15	93.75	93.33	14	8	6	1	13	7	6	0.57	0.54	92.86	13	7	6	0.54	100.00
357	14	14	100.00	92.86	13	7	6	0	13	7	6	0.54	0.54	100.00	12	7	5	0.58	92.31
358	14	14	100.00	100.00	14	7	7	0	14	7	7	0.50	0.50	100.00	14	7	7	0.50	100.00
359	18	18	100.00	94.44	17	7	10	0	17	7	10	0.41	0.41	100.00	17	7	10	0.41	100.00
360	20	18	90.00	100.00	18	8	10	1	17	8	9	0.44	0.47	94.44	15	7	8	0.47	88.24
361	15	15	100.00	100.00	15	8	7	0	15	8	7	0.53	0.53	100.00	15	8	7	0.53	100.00
362	17	16	94.12	87.50	14	9	5	0	14	9	5	0.64	0.64	100.00	14	9	5	0.64	100.00
N	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12
MEAN	16.3	15.8	97.635	95.257	15.1	8.0	7.1	0.3	14.8	7.9	6.9	0.534	0.539	98.347	14.6	7.8	6.8	0.543	98.379
S.D.	1.7	1.3	3.638	3.929	1.4	1.0	1.8	0.5	1.5	1.0	1.9	0.085	0.094	3.016	1.4	1.0	1.9	0.095	3.884

Implantation index = (number of implantation sites / number of corpora lutea) x 100.

Delivery index = (number of pups born / number of implantation sites) x 100.

Sex ratio on Lactation day 0 = (number of male pups born / number of pups born) and (number of live male pups / number of live pups).

Sex ratio on Lactation day 4 = number of live male pups / number of live pups.

Live birth index = (number of live pups on lactation day 0 / number of pups born) x 100.

Viability index = (number of live pups on lactation day 4 / number of live pups on lactation day 0) x 100.

INDIVIDUAL DATA 15-4  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Pregnancy and litter data ANIMAL : Rat, Cri:CD(SD) SEX : Female GROUP : 1000 mg/kg

Dam No.	Number of corpora lutea	Number of implantation sites	Implantation index (%)	Delivery index (%)	Lactation Day 0			Lactation Day 4		
					Number of pups born			Number of live pups		
					Total	Male	Female	Total	Male	Female
451	16	16	100.00	100.00	16	8	8	16	8	8
452	15	15	100.00	100.00	15	6	9	15	6	9
453	15	14	93.33	100.00	14	9	5	14	9	5
454 <sup>a</sup>	(0)	(0)	#	#	#	#	#	#	#	#
455	18	17	94.44	100.00	17	3	14	17	3	14
456	16	14	87.50	100.00	14	9	5	14	9	5
457	19	19	100.00	94.74	18	5	13	1	17	5
458	14	14	100.00	100.00	14	10	4	10	4	10
459	18	18	100.00	88.89	16	6	10	16	6	10
460	15	15	100.00	100.00	15	8	7	15	8	7
461	17	17	100.00	94.12	16	5	11	1	15	4
462	16	16	100.00	100.00	16	10	6	16	10	6
N	11	11	11	11	11	11	11	11	11	11
MEAN	16.3	15.9	97.752	97.977	15.5	7.2	8.4	0.2	15.4	7.1
S.D.	1.6	1.7	4.196	3.751	1.3	2.3	3.4	0.4	1.1	2.4

Implantation index = (number of implantation sites / number of corpora lutea) × 100.

Delivery index = (number of pups born / number of implantation sites) × 100.

Sex ratio on Lactation day 0 = (number of male pups born / number of pups born) and (number of live male pups / number of live pups).

Sex ratio on Lactation day 4 = number of live male pups / number of live pups.

Live birth index = (number of live pups on lactation day 0 / number of pups born) × 100.

Viability index = (number of live pups on lactation day 4 / number of live pups on lactation day 0) × 100.

# : Not applicable.

a : Non-pregnant (Values in parentheses are excluded from calculation).

INDIVIDUAL DATA 16-1  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance of pups ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 0 mg/kg

Dam No.	Day of lactation period	Number of pups	Male		Female	
			Finding and number of animals with findings	Number of pups	Finding and number of animals with findings	Number of pups
151	0-4	5	No abnormal findings ; 5	10	No abnormal findings ; 10	
152	0-4	6	No abnormal findings ; 6	9	No abnormal findings ; 9	
153	0-4	6	No abnormal findings ; 6	10	No abnormal findings ; 10	
154	0-4	6	No abnormal findings ; 6	8	No abnormal findings ; 8	
155	0-4	8	No abnormal findings ; 8	7	No abnormal findings ; 7	
156	0-4	11	No abnormal findings ; 11	5	No abnormal findings ; 5	
157	0-4	7	No abnormal findings ; 7	7	No abnormal findings ; 7	
158	0-4	8	No abnormal findings ; 8	8	No abnormal findings ; 8	
159	0-4	5	No abnormal findings ; 5	9	No abnormal findings ; 9	
160	0-4	9	No abnormal findings ; 9	1	No abnormal findings ; 1	
161	0-4	4	No abnormal findings ; 4	13	No abnormal findings ; 13	

INDIVIDUAL DATA 16-2  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance of pups ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 100 mg/kg

Dam No.	Day of lactation period	Number of pups	Male		Female	
			Finding and number of animals with findings	Number of pups	Finding and number of animals with findings	Number of pups
251	0-4	7	No abnormal findings ; 7	7	No abnormal findings ; 7	7
252	0-3	7	No abnormal findings ; 7	8	No abnormal findings ; 8	8
	4	7	No abnormal findings ; 7	8	Death ; 1, No abnormal findings ; 7	7
253	0-4	10	No abnormal findings ; 10	7	No abnormal findings ; 7	7
254	0-4	10	No abnormal findings ; 10	3	No abnormal findings ; 3	3
255	0-4	9	No abnormal findings ; 9	8	No abnormal findings ; 8	8
256	0-4	9	No abnormal findings ; 9	7	No abnormal findings ; 7	7
257	0-4	5	No abnormal findings ; 5	10	No abnormal findings ; 10	10
258	0-4	8	No abnormal findings ; 8	7	No abnormal findings ; 7	7
259	0-4	11	No abnormal findings ; 11	7	No abnormal findings ; 7	7
260	0	5	No abnormal findings ; 5	7	Death ; 1, No abnormal findings ; 6	7
	1-4	5	No abnormal findings ; 5	6	No abnormal findings ; 6	6
261	0	5	No abnormal findings ; 5	8	No abnormal findings ; 8	8
	1	5	No abnormal findings ; 5	8	Death (lost) ; 1, No abnormal findings ; 7	8
	2-4	5	No abnormal findings ; 5	7	No abnormal findings ; 7	7
262	0-4	8	No abnormal findings ; 8	8	No abnormal findings ; 8	8

INDIVIDUAL DATA 16-3  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance of pups ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 300 mg/kg

Dam No.	Day of lactation period	Number of pups	Male		Female	
			Finding and number of animals with findings	Number of pups	Finding and number of animals with findings	Number of pups
351	0	10	No abnormal findings ; 10	4	Death ; 1, No abnormal findings ; 3	
	1-4	10	No abnormal findings ; 10	3	No abnormal findings ; 3	
352	0-4	7	No abnormal findings ; 7	8	No abnormal findings ; 8	
353	0-4	9	No abnormal findings ; 9	6	No abnormal findings ; 6	
354	0-4	8	No abnormal findings ; 8	8	No abnormal findings ; 8	
355	0-4	8	No abnormal findings ; 8	8	No abnormal findings ; 8	
356	0	8	Death ; 1, No abnormal findings ; 7	6	No abnormal findings ; 6	
	1-4	7	No abnormal findings ; 7	6	No abnormal findings ; 6	
357	0,1	7	No abnormal findings ; 7	6	No abnormal findings ; 6	
	2	7	No abnormal findings ; 7	6	Death ; 1, No abnormal findings ; 5	
	3,4	7	No abnormal findings ; 7	5	No abnormal findings ; 5	
358	0-4	7	No abnormal findings ; 7	7	No abnormal findings ; 7	
359	0-4	7	No abnormal findings ; 7	10	No abnormal findings ; 10	
360	0	8	No abnormal findings ; 8	10	Death ; 1, No abnormal findings ; 9	
	1	8	No abnormal findings ; 8	9	Milk-band negative ; 1, No abnormal findings ; 8	
	2	8	Death (lost) ; 1, No abnormal findings ; 7	9	Milk-band negative ; 1, No abnormal findings ; 8	
	3	7	No abnormal findings ; 7	9	Death (lost) ; 1, No abnormal findings ; 8	
	4	7	No abnormal findings ; 7	8	No abnormal findings ; 8	
361	0-4	8	No abnormal findings ; 8	7	No abnormal findings ; 7	
362	0-4	9	No abnormal findings ; 9	5	No abnormal findings ; 5	

INDIVIDUAL DATA 164  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 General appearance of pups ANIMAL : Rat, CrI:CD(SD) SEX : Female GROUP : 1000 mg/kg

Dam No.	Day of lactation period	Number of pups	Male		Female	
			Finding and number of animals with findings	Number of pups	Finding and number of animals with findings	Number of pups
451	0-4	8	No abnormal findings ; 8	8	No abnormal findings ; 8	8
452	0-4	6	No abnormal findings ; 6	9	No abnormal findings ; 9	9
453	0-4	9	No abnormal findings ; 9	5	No abnormal findings ; 5	5
455	0	3	No abnormal findings ; 3	14	No abnormal findings ; 14	14
	1	3	No abnormal findings ; 3	14	Death ; 1, No abnormal findings ; 13	14
	2-4	3	No abnormal findings ; 3	13	No abnormal findings ; 13	13
456	0-4	9	No abnormal findings ; 9	5	No abnormal findings ; 5	5
457	0	5	No abnormal findings ; 5	13	Death ; 1, No abnormal findings ; 12	13
	1-4	5	No abnormal findings ; 5	12	No abnormal findings ; 12	12
458	0-4	10	No abnormal findings ; 10	4	No abnormal findings ; 4	4
459	0-4	6	No abnormal findings ; 6	10	No abnormal findings ; 10	10
460	0	8	No abnormal findings ; 8	7	No abnormal findings ; 7	7
	1	8	No abnormal findings ; 8	7	Death (lost) ; 1, No abnormal findings ; 6	7
	2-4	8	No abnormal findings ; 8	6	No abnormal findings ; 6	6
461	0	5	Death ; 1, No abnormal findings ; 4	11	No abnormal findings ; 11	11
	1-4	4	No abnormal findings ; 4	11	No abnormal findings ; 11	11
462	0-4	10	No abnormal findings ; 10	6	No abnormal findings ; 6	6

INDIVIDUAL DATA 17-1  
STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
Body weight, pups ANIMAL : Rat, Crl:CD(SD) SEX : Male,Female GROUP : 0 mg/kg

Dam No.	n	Male						Female					
		Lactation day			Body weight (g)			Lactation day			Body weight (g)		
		0	Mean	n	1	Mean	n	4	Mean	n	0	Mean	n
151	5	6.3	5	7.0	5	10.2	10	6.0	10	6.6	10	9.6	
152	6	6.2	6	6.8	6	10.4	9	6.1	9	6.7	9	9.8	
153	6	6.8	6	7.4	6	10.2	10	6.6	10	7.3	10	9.8	
154	6	6.2	6	7.0	6	10.0	8	6.0	8	6.7	8	9.7	
155	8	7.0	8	7.8	8	11.2	7	7.0	7	7.8	7	11.0	
156	11	6.3	11	6.9	11	10.0	5	6.2	5	6.8	5	9.9	
157	7	7.8	7	8.5	7	11.8	7	7.2	7	8.2	7	11.2	
158	8	6.4	8	7.1	8	10.7	8	6.2	8	6.7	8	9.8	
159	5	6.5	5	7.1	5	10.5	9	6.1	9	6.7	9	10.0	
160	9	6.9	9	7.9	9	12.2	1	6.7	1	7.3	1	11.0	
161	4	6.1	4	6.6	4	9.1	13	5.9	13	6.4	13	8.9	
N		11		11		11		11		11		11	
MEAN		6.59		7.28		10.57		6.36		7.02		10.06	
S.D.		0.50		0.57		0.88		0.44		0.56		0.71	
S.E.		0.15		0.17		0.26		0.13		0.17		0.21	
M/C		1.3312		0.5743		0.1195		4.5876		4.7226		9.7051*	
F		3.5810*		2.8929*		1.8261		2.7256†		2.4454†		2.4283	
H													

n : Number of pups.

## INDIVIDUAL DATA 17-2

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Body weight, pups ANIMAL : Rat, CrI:CD(SD) SEX : Male,Female GROUP : 100 mg/kg

Dam No.	Male						Female					
	Lactation day			Body weight (g)			Lactation day			Body weight (g)		
	0	n	Mean	1	n	Mean	4	n	Mean	0	n	Mean
251	7	7.3	7	8.0	7	11.4	7	6.9	7	7.5	7	11.0
252	7	7.5	7	8.2	7	11.5	8	6.8	8	7.6	7	11.8
253	10	6.2	10	6.6	10	9.0	7	6.0	7	6.4	7	8.8
254	10	6.8	10	7.6	10	11.0	3	5.8	3	6.6	3	9.6
255	9	7.1	9	7.9	9	11.4	8	7.0	8	7.8	8	10.1
256	9	6.4	9	7.1	9	10.3	7	5.8	7	6.4	7	8.9
257	5	6.5	5	7.2	5	10.9	10	6.2	10	6.6	10	10.1
258	8	7.6	8	8.3	8	11.4	7	7.3	7	8.0	7	10.8
259	11	7.0	11	7.6	11	11.0	7	6.5	7	7.0	7	10.2
260	5	7.4	5	8.6	5	13.0	6	7.3	6	8.7	6	13.8
261	5	7.1	5	7.9	5	11.5	8	6.8	7	7.8	7	11.4
262	8	6.5	8	7.2	8	10.3	8	5.9	8	6.7	8	9.7

N	12	12	12	12	12	12	12	12	12	12	12	12
MEAN	6.95	7.68	11.06	6.53	7.26	10.52						
S.D.	0.47	0.58	0.95	0.57	0.75	1.38						
S.E.	0.13	0.17	0.27	0.16	0.22	0.40						
t'	1.9826	1.7330	0.8713	1.0073								

n : Number of pups.

## INDIVIDUAL DATA 17-3

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Body weight, pups ANIMAL : Rat, CrI:CD(SD) SEX : Male,Female GROUP : 300 mg/kg

Dam No.	n	Male						Female					
		Lactation day			Body weight (g)			Lactation day			Body weight (g)		
		0	Mean	n	1	Mean	n	4	Mean	n	0	Mean	n
351	10	6.8	10	7.7	10	12.0	3	6.4	3	7.3	3	11.5	
352	7	6.3	7	7.0	7	10.4	8	6.2	8	6.9	8	10.0	
353	9	6.9	9	7.2	9	9.7	6	6.4	6	6.8	6	9.1	
354	8	6.5	8	7.0	8	10.3	8	6.3	8	6.7	8	9.9	
355	8	6.5	8	6.8	8	9.3	8	6.1	8	6.8	8	10.0	
356	7	6.7	7	7.3	7	10.5	6	6.6	6	7.1	6	10.7	
357	7	6.7	7	7.4	7	11.1	6	6.4	6	7.2	5	10.8	
358	7	6.7	7	7.7	7	11.1	7	5.9	7	6.7	7	10.0	
359	7	6.1	7	6.5	7	9.3	10	5.7	10	6.1	10	9.0	
360	8	6.0	8	6.6	7	9.6	9	5.4	9	5.7	8	8.9	
361	8	7.1	8	7.7	8	10.3	7	6.9	7	7.4	7	10.3	
362	9	7.2	9	8.0	9	11.6	5	6.7	5	7.5	4	13.7	
	N	12		12		12		12		12		12	
MEAN		6.63		7.24		10.43		6.25		6.85		10.33	
S.D.		0.37		0.48		0.88		0.43		0.53		1.31	
S.E.		0.11		0.14		0.25		0.12		0.15		0.38	
t'		0.1882		0.1733				0.6136		0.7054			

n : Number of pups.

## INDIVIDUAL DATA 17-4

STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Body weight, pups ANIMAL : Rat, Crl:CD(SD) SEX : Male,Female GROUP : 1000 mg/kg

Dam No.	n	Male						Female					
		Lactation day			Body weight (g)			Lactation day			Body weight (g)		
		0	Mean	n	1	Mean	n	4	Mean	n	0	Mean	n
451	8	6.1	8	6.6	8	9.5	8	5.7	8	6.1	8	9.0	
452	6	6.5	6	7.1	6	9.9	9	6.5	9	7.2	9	10.0	
453	9	6.3	9	6.9	9	9.9	5	5.9	5	6.6	5	9.7	
455	3	5.9	3	6.1	3	8.9	14	6.1	13	6.3	13	9.0	
456	9	6.4	9	7.3	9	10.3	5	5.9	5	6.7	5	10.1	
457	5	5.7	5	6.1	5	8.7	12	5.8	12	6.3	12	9.2	
458	10	6.5	10	7.3	10	10.8	4	6.2	4	6.9	4	10.6	
459	6	6.9	6	8.0	6	11.4	10	6.1	10	7.0	10	9.6	
460	8	6.8	8	7.6	8	11.6	7	6.2	6	7.0	6	10.3	
461	4	6.8	4	7.4	4	11.0	11	6.2	11	6.7	11	10.4	
462	10	6.1	10	6.8	10	10.2	6	5.5	6	6.2	6	9.0	
N		11	11	11	11	11	11	11	11	11	11	11	
MEAN	6.36	7.02		10.20		6.01		6.64		9.72			
S.D.	0.39	0.59		0.95		0.28		0.37		0.60			
S.E.	0.12	0.18		0.29		0.08		0.11		0.18			
t'	1.2284	1.1140		1.8741		1.5678							

n : Number of pups.

## INDIVIDUAL DATA 18

STUDY NO. SR09207    TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Gross findings of dead pups on days 0-4 of lactation    ANIMAL : Rat, CrI:CD(SD)

Group	Dam No.	Day of death	Number of pups		
			Male	Female	Findings
100 mg/kg	252	4	#	1	No abnormal findings
	260	0	#	1	No abnormal findings
	261	1	#	1	Lost
300 mg/kg	351	0	#	1	Intrapertitoneum : Autolysis
	356	0	1	#	No abnormal findings
	357	2	#	1	No abnormal findings
	360	0	#	1	No abnormal findings
		2	1	#	Lost
		3	#	1	Lost
1000 mg/kg	455	1	#	1	No abnormal findings
	457	0	#	1	No abnormal findings
	460	1	#	1	Lost
	461	0	1	#	Intrapertitoneum : Autolysis

# : Not applicable.

INDIVIDUAL DATA 19-1  
 STUDY NO. SR09207 TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Gross findings of pups euthanized on day 4 of lactation ANIMAL : Rat, CrI:CD(SD) GROUP : 0 mg/kg

Dam No.	Number of pups		Findings
	Male	Female	
151	5	10	No abnormal findings
152	6	9	No abnormal findings
153	6	10	No abnormal findings
154	6	8	No abnormal findings
155	8	7	No abnormal findings
156	11	5	No abnormal findings
157	7	7	No abnormal findings
158	8	8	No abnormal findings
159	5	9	Liver : Yellowish green patch, multifocal, middle lobe, medial left lobe and lateral left lobe (less than 6 x 6 x 6, mm) ; 1(Male), No abnormal findings ; 13
160	9	1	No abnormal findings ; 13
161	4	13	No abnormal findings

## INDIVIDUAL DATA 19-2

STUDY NO. SR09207    TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Gross findings of pups euthanized on day 4 of lactation    ANIMAL : Rat, CrI:CD(SD)    GROUP : 100 mg/kg

Dam No.	Number of pups		Findings
	Male	Female	
251	7	7	No abnormal findings
252	7	7	No abnormal findings
253	10	7	No abnormal findings
254	10	3	No abnormal findings
255	9	8	No abnormal findings
256	9	7	No abnormal findings
257	5	10	No abnormal findings
258	8	7	No abnormal findings
259	11	7	No abnormal findings
260	5	6	No abnormal findings
261	5	7	No abnormal findings
262	8	8	No abnormal findings

## INDIVIDUAL DATA 19-3

STUDY NO. SRO9207    TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Gross findings of pups euthanized on day 4 of lactation    ANIMAL : Rat, CrI:CD(SD)    GROUP : 300 mg/kg

Dam No.	Number of pups		Findings
	Male	Female	
351	10	3	No abnormal findings
352	7	8	No abnormal findings
353	9	6	No abnormal findings
354	8	8	No abnormal findings
355	8	8	No abnormal findings
356	7	6	No abnormal findings
357	7	5	No abnormal findings
358	7	7	No abnormal findings
359	7	10	No abnormal findings
360	7	8	No abnormal findings
361	8	7	No abnormal findings
362	9	5	No abnormal findings

## INDIVIDUAL DATA 19-4

STUDY NO. SR09207    TITLE : Isotridecyl stearate Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)  
 Gross findings of pups euthanized on day 4 of lactation    ANIMAL : Rat, CrI:CD(SD)    GROUP : 1000 mg/kg

Dam No.	Number of pups		Findings
	Male	Female	
451	8	8	No abnormal findings
452	6	9	No abnormal findings
453	9	5	No abnormal findings
455	3	13	No abnormal findings
456	9	5	No abnormal findings
457	5	12	No abnormal findings
458	10	4	No abnormal findings
459	6	10	No abnormal findings
460	8	6	No abnormal findings
461	4	11	Liver : Yellowish white patch, middle lobe (5 x 2, mm) ; 1(Male), No abnormal findings ; 14
462	10	6	No abnormal findings

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2010年9月29日

竹本油脂株式会社

第二事業本部

**被験物質(CAS No. 31565-37-4)の件**

拝啓、時下ますますご清栄のこととお喜び申し上げます。

ご要望賜りました被験物質(CAS No. 31565-37-4)の成分比率につきまして、ご報告申し上げます。御査収、ご試験の程宜しくお願ひ申し上げます。

敬具

記

## 1. 被験物質(CAS No. 31565-37-4) (LOT 00119) の成分比率

成分	AREA%
パルチミン酸とイソトリデカノールのエステル化物	29
ステアリン酸とイソトリデカノールのエステル化物	71

※2-3頁GCチャート参照ください。

## 2. 分析方法: GC/MS分析

## 測定機器

- GC : Agilent 6890, Column : DB-1 (100% Dimethylpolysiloxane)

## 検出器

- MS : Automass II (JEOL)

## 測定条件

- 100°C → 10°C/min → 300°C (10min hold)

## 参考データ (使用原料の成分比率)

## 1) 脂肪酸原料成分

成分	成分%*
パルチミン酸	30
ステアリン酸	69
その他脂肪酸	1

\*代表値

## 2) アルコール原料成分

成分	成分%*	*代表値
イソトリデカノール(異性体混合物)	99以上	

以上

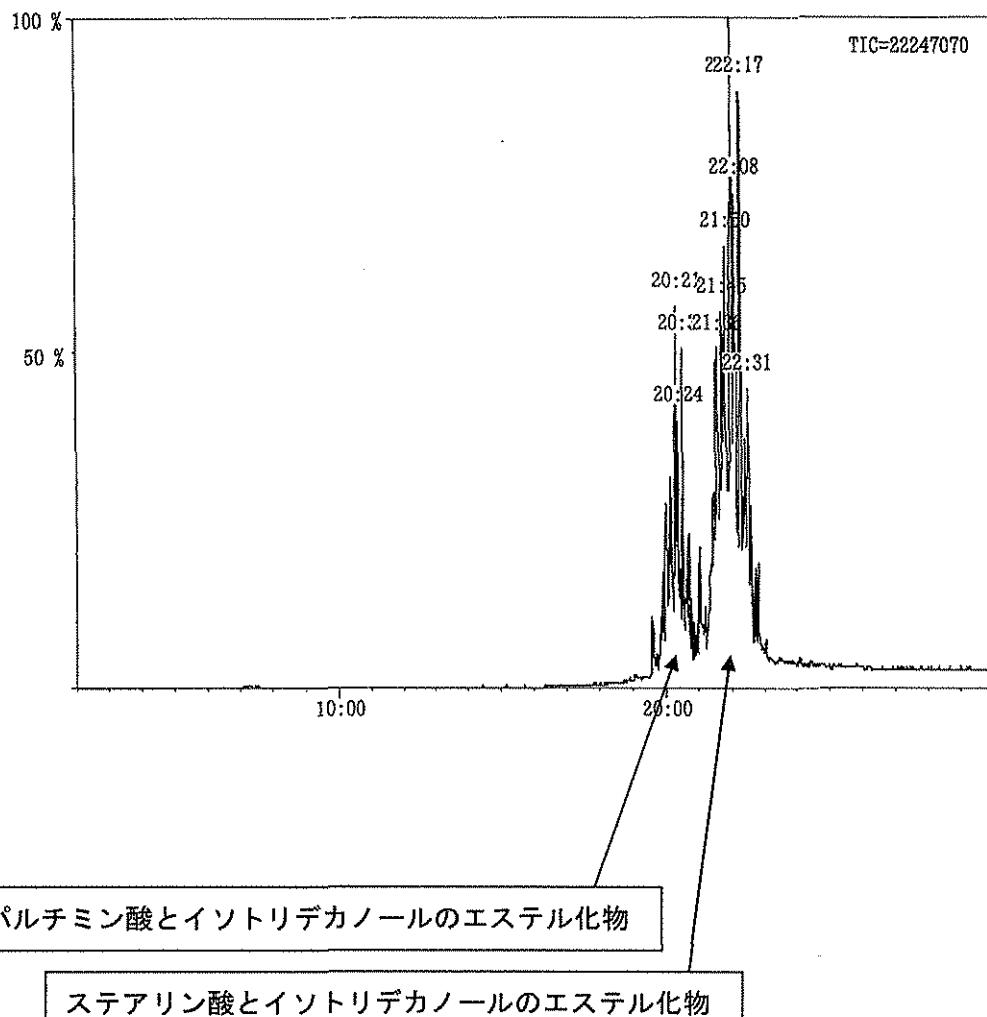
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## ■添付資料 1

GCチャート:

Display V4.02 C:\LUCY\00927SI2.SPA 09/28/10 17:21:59  
Station : JMS-AMSUN200/300 User : 日本電子(株)  
100927 sitde



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## ■添付資料 2

## GC : 各ピークの AREA % データ

#	Scan	RT	Area	Area %	Intensity	Int %
1	2717	00:19:36	14676116	0.62	2029638	0.87
2	2728	00:19:41	3649793	0.15	670652	0.29
3	2738	00:19:45	6657321	0.28	804492	0.34
4	2760	00:19:53	19792210	0.83	2026952	0.86
5	2768	00:19:56	24464822	1.03	3641349	1.51
6	2778	00:20:00	59404480	2.50	5801770	2.48
7	2792	00:20:06	24254840	1.02	3442537	1.47
8	2800	00:20:09	36528892	1.54	6663693	2.84
9	2807	00:20:11	54724700	2.30	5945403	2.54
10	2832	00:20:21	117316440	4.94	12238032	5.22
11	2840	00:20:24	45693652	1.92	8497488	3.83
12	2847	00:20:27	26190348	1.10	3550241	1.51
13	2861	00:20:32	76277416	3.21	10855885	4.63
14	2877	00:20:39	39769760	1.87	3185842	1.36
15	2888	00:20:43	37896138	1.60	4685391	2.00
16	2901	00:20:48	15901702	0.67	2530489	1.08
17	2915	00:20:53	12588776	0.53	1746326	0.75
18	2929	00:20:59	10948579	0.46	1608693	0.69
19	2941	00:21:04	32547518	1.37	4161721	1.78
20	2951	00:21:07	16537333	0.70	1642529	0.70
21	2965	00:21:13	20634260	0.87	2174779	0.93
22	2992	00:21:23	49691040	2.09	3663463	1.52
23	3008	00:21:29	89930776	2.94	6001121	2.56
24	3024	00:21:36	172318144	7.25	10795340	4.61
25	3037	00:21:41	54366432	2.29	6714134	2.86
26	3048	00:21:45	124267536	5.23	11942928	5.10
27	3061	00:21:50	157050384	6.61	14085626	6.01
28	3091	00:22:02	315465664	13.28	21586344	9.21
29	3106	00:22:08	188241888	7.92	15794237	6.74
30	3131	00:22:17	211843232	8.92	19127004	8.16
31	3141	00:22:21	29924598	1.26	5684374	2.43
32	3150	00:22:26	79039168	3.33	7615342	3.25
33	3166	00:22:31	94966176	4.00	9279175	3.96
34	3180	00:22:36	50537120	2.13	5374761	2.29
35	3199	00:22:44	28046678	1.18	3290498	1.40
36	3214	00:22:50	31112104	1.31	3394041	1.45
37	3227	00:22:55	5600699	0.24	675951	0.29
38	3236	00:22:58	4488432	0.19	581357	0.26
39	3251	00:23:04	9566874	0.40	862942	0.36
40	3274	00:23:13	2778683	0.12	225113	0.10

パルミチン酸と  
イソリノラーレ  
9.8%

29.3%

ステアリン酸と  
イソリノラーレ  
9.8%

70.7%

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2011年9月26日

竹本油脂株式会社

第二事業本部

**被験物質(CAS No. 31565-37-4)の事後分析の件**

拝啓、時下ますますご清栄のこととお喜び申し上げます。

ご要望賜りました被験物質(CAS No. 31565-37-4)の事後分析結果につきまして、ご報告申し上げます。御査収、ご試験の程宜しくお願ひ申し上げます。

敬具

記

1. 被験物質(CAS No. 31565-37-4) (LOT 00119) の成分比率

成分	AREA%
パルチミン酸とイソトリデカノールのエステル化物	26
ステアリン酸とイソトリデカノールのエステル化物	74

※2-3頁GCチャート参照ください。

2. 分析方法: GC/MS分析

測定機器

・GC: Agilent 6890, Column: DB-1 (100% Dimethylpolysiloxane)

検出器

・MS: Automass II (JEOL)

測定条件

・ 100°C → 10°C/min → 300°C (10min hold)

※尚、前回(2010.9)測定時からカラムを更新しています。

参考データ (使用原料の成分比率)

1) 脂肪酸原料成分

成分	成分%*
パルチミン酸	30
ステアリン酸	69
その他脂肪酸	1

\*代表値

2) アルコール原料成分

成分	成分%*	*代表値
イソトリデカノール(異性体混合物)	99以上	

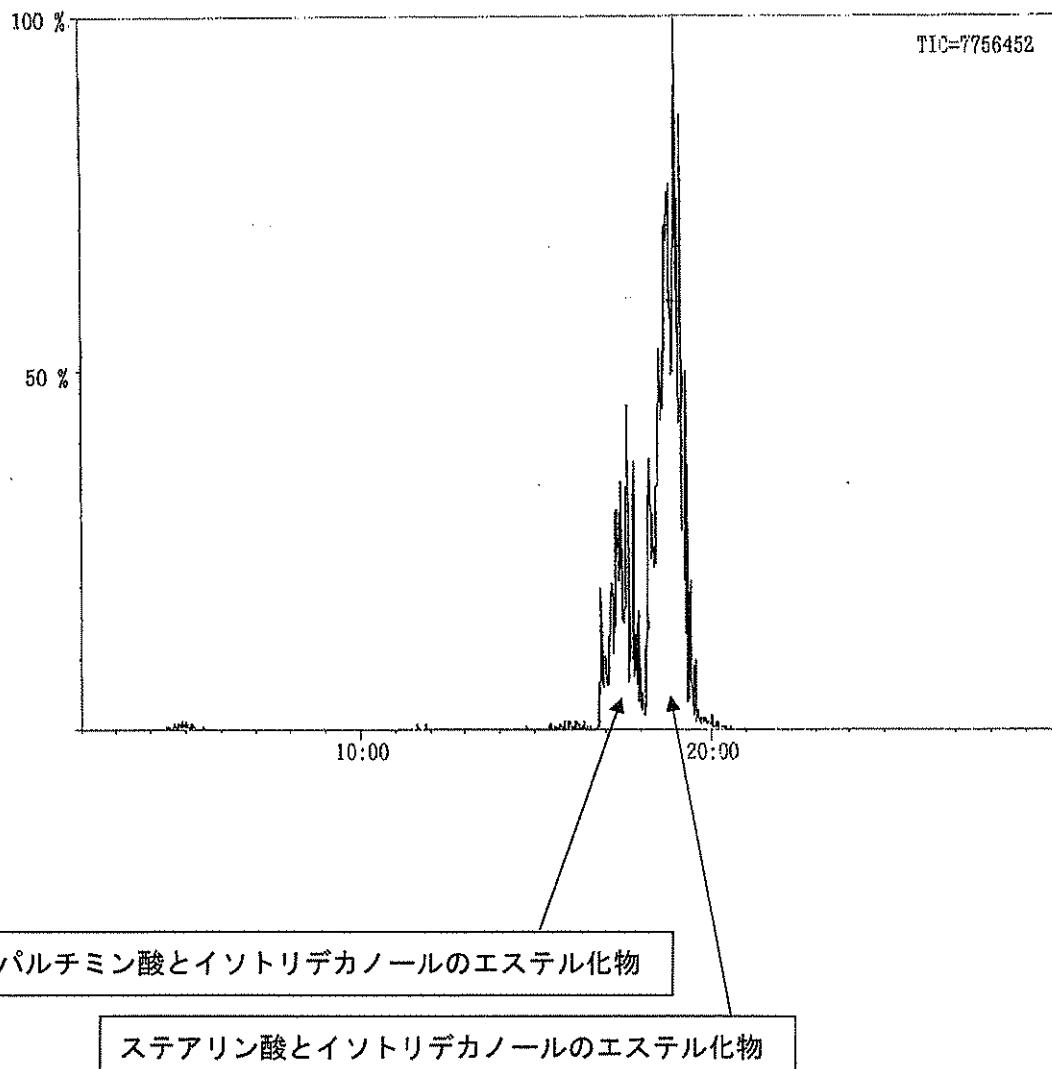
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以上

## ■添付資料 1

GCチャート：

Display V4.02 C:\LUCY\10920-7.SPA 09/20/11 17:04:31  
 Station : JMS-AMSUN200/300 User : 日本電子(株)  
 SITDE



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**■添付資料2****G C : 各ピークの AREA % データ**

#	Scan	RT	Area	Area %	Intensity	Int %
1	2314	00:16:52	14842766	1.61	1504344	1.61
2	2330	00:16:59	6141005	0.66	775971	0.83
3	2336	00:17:01	3679489	0.40	670540	0.72
4	2343	00:17:04	2681080	0.29	553667	0.59
5	2360	00:17:10	16998870	1.84	1475900	1.58
6	2366	00:17:12	13634807	1.48	1551430	1.67
7	2383	00:17:19	24217334	2.62	2330836	2.50
8	2393	00:17:23	20226312	2.19	2308039	2.48
9	2403	00:17:27	27540678	2.98	2650058	2.84
10	2415	00:17:31	5790758	0.63	1190143	1.28
11	2433	00:17:38	41776848	4.52	3450898	3.70
12	2438	00:17:40	10251428	1.11	2420915	2.60
13	2447	00:17:44	8283021	0.90	1225311	1.32
14	2458	00:17:48	20740858	2.25	2836874	3.05
15	2467	00:17:51	8547101	0.93	949869	1.02
16	2481	00:17:57	7528532	0.81	1211869	1.30
17	2490	00:18:00	3473741	0.38	628851	0.68
18	2500	00:18:04	2084115	0.23	301426	0.32
19	2526	00:18:14	46796836	5.07	2831470	3.04
20	2544	00:18:21	21888400	2.37	2253612	2.42
21	2551	00:18:24	10590145	1.15	1867006	2.00
22	2573	00:18:32	77092496	8.34	4003405	4.30
23	2602	00:18:43	108426464	11.74	5466291	5.87
24	2611	00:18:47	43436596	4.70	5698670	6.12
25	2617	00:18:49	71986672	7.79	5775436	6.20
26	2647	00:19:01	127954144	13.85	7555464	8.11
27	2653	00:19:03	23817756	2.58	5614399	6.03
28	2659	00:19:05	21508710	2.33	3651156	3.92
29	2670	00:19:10	55736756	6.03	6480046	6.96
30	2680	00:19:14	27801442	3.01	3849911	4.13
31	2690	00:19:17	22382300	2.42	3703338	3.98
32	2697	00:19:20	10169948	1.10	2715199	2.91
33	2706	00:19:24	5203307	0.56	1332508	1.43
34	2714	00:19:27	7464219	0.81	1434825	1.54
35	2723	00:19:30	1009894	0.11	235602	0.25
36	2733	00:19:34	2158326	0.23	646877	0.69

ヘキサメチル  
アリテルカルボン酸  
1/トライカルボン酸  
25.8%

スチアリル酸と  
ヘキサメチルカルボン酸  
74.2%

## 最終報告書

### 試験名

投与液中のイソトリデシル=ステアラートの安定性試験

### 著者

津嶋 信平

### 試験終了日

2010年12月16日

### 試験施設

株式会社日曹分析センター（略称 NCAS）小田原事業所

〒250-0216 神奈川県小田原市高田 345

### 試験委託者

株式会社化合物安全性研究所

〒004-0839 北海道札幌市清田区真栄 363 番 24

### 試験番号

NCAS 10-197

## GLP 適合陳述書

試験番号 : NCAS 10-197

試験名 : 投与液中のイソトリデシル=ステアラートの安定性試験

この試験は、以下の GLP 規則に従って実施した。

「新規化学物質等に係る試験を実施する試験施設に関する基準について」(平成 15 年 11 月 21 日  
薬食発第 1121003 号、平成 15・11・17 製局第 3 号、環保企発第 031121004 号)、最終改正 平成  
20 年 7 月 4 日

この試験はここに述べられた方法により行われ、この最終報告書は試験実施により得られた生データ  
を正確に反映したものである。

試験責任者 :



12/16/2010

株式会社日曹分析センター 小田原事業所

## 信頼性保証書

試験番号： NCAS 10-197

試験名： 投与液中のイソトリデシル=ステアラートの安定性試験

上記試験の信頼性保証の監査又は査察を適用 GLP および信頼性保証部門 (QAU) の SOP に基づいて実施した。監査又は査察の結果は、以下の日付で試験責任者および運営管理者に報告した。

監査又は査察項目	日付 (月/日/年)		
	監査又は査察日	試験責任者	運営管理者
試験計画書	11/11/2010	11/11/2010	11/11/2010
実験操作			
・IR スペクトルの測定	11/18/2010	11/18/2010	11/18/2010
・安定性確認用模擬投与液 (保存安定性確認試料) の調製	11/19/2010	11/19/2010	11/19/2010
・試料前処理	11/29,30/2010	11/30/2010	11/30/2010
・標準溶液の調製	11/29,30/2010	11/30/2010	11/30/2010
・LC/MS/MS 測定	11/29,30/2010	11/30/2010	11/30/2010
・ブランク溶液の調製	11/29,30/2010	11/30/2010	11/30/2010
生データ	12/3~6/2010	12/6/2010	12/6/2010
報告書草案	12/3~6/2010	12/6/2010	12/6/2010
最終報告書	12/16/2010	12/16/2010	12/16/2010

QAU は、この試験が試験計画書および SOP に従って行われ、報告された方法や手段が実際に使われたものであり、結果は記録されたデータを正確に反映していることを確認した。

QAU 責任者



2010年12月16日

(株) 日曹分析センター

## 試験情報

試験番号 : NCAS 10-197

試験名 : 投与液中のイソトリデシル=ステアラートの安定性試験

報告書番号 : NCAS 10-197

試験委託者 : 株式会社化合物安全性研究所

〒004-0839 北海道札幌市清田区真栄 363 番地 24

TEL 011-885-5031、 FAX 011-885-5313

試験施設 : 株式会社日曹分析センター 小田原事業所

〒250-0216 神奈川県小田原市高田 345

TEL 0465-42-8201、 FAX 0465-42-3586

試験責任者 :



試験従事者 :



試験開始日 : 2010 年 11 月 11 日

実験開始日 : 2010 年 11 月 18 日

実験終了日 : 2010 年 11 月 29 日

試験終了日 : 2010 年 12 月 16 日

適用ガイドライン : なし

関連する試験 : NCAS 10-196NG 「投与液中のイソトリデシル=ステアラート分析法検討および分析法バリデーション」

NCAS 10-198 「投与液中のイソトリデシル=ステアラートの濃度確認試験」

試資料保管 : 本試験に関する全ての文書は、当試験施設の資料室に試験終了後 10 年間保管する。その後の保管場所については、試験委託者と協議して決定する。標準物質は、イソトリデシル=ステアラートに関する一連の試験が終了した後、試験施設で廃棄する。

SOP および試験計画書からの逸脱 :

SOP および試験計画書からの逸脱はなかった。

試験成績の信頼性に影響を及ぼしたと思われる環境要因 :

試験成績の信頼性に影響を及ぼしたと思われる環境要因はなかった。

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## 概要

株式会社化合物安全性研究所の委託により、投与液中のイソトリデシル=ステアラートの安定性試験を行った。

安定性確認用模擬投与液調製前に測定した標準物質の赤外線吸収スペクトルは、試験委託者より提供されたイソトリデシル=ステアラートの赤外線吸収スペクトルと一致し、同一性が確認された。

安定性試験として試験施設で 0.1 mg/mL および 200 mg/mL の模擬投与液を調製し、室温で 10 日間保存した後、模擬投与液中のイソトリデシル=ステアラート濃度を確認した。調製直後の模擬投与液中のイソトリデシル=ステアラート濃度と比較し残存率を算出したところ、0.1 mg/mL 模擬投与液で 99.8%、200 mg/mL 模擬投与液で 98.9% となり、安定性の基準値である残存率 100.0±10.0% を満たした。従って、投与液中のイソトリデシル=ステアラートは調製後室温で 10 日間安定であることが確認された。なお、保存期間中の温度は 17.6~25.1°C であった。

## 緒言

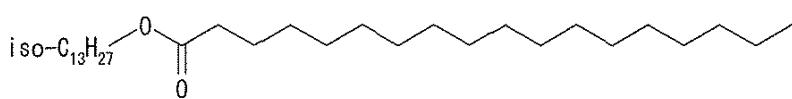
株式会社化合物安全性研究所の委託により、測定対象物質であるイソトリデシル=ステアラートの同一性試験、投与液中のイソトリデシル=ステアラートの安定性試験を実施した。その内容について以下に報告する。

## 実験材料および方法

### 1. 測定対象物質

化合物名 :	イソトリデシル=ステアラート
化学名 :	Isotridecyl stearate
CAS No. :	31565-37-4
分子式 :	C <sub>31</sub> H <sub>62</sub> O <sub>2</sub>
分子量 :	466.82

構造式 :



### 2. 標準物質

化合物名 :	イソトリデシル=ステアラート
化学名 :	isotridecyl stearate
ロット番号 :	00119
NCAS 検索番号 :	STD-1179
入手先 :	[REDACTED]
入手日 :	2010 年 6 月 30 日

入手量 : 19.24 g  
 純度 : 100%として取り扱った。  
 保存条件 : 褐色瓶に入れ、室温保存  
 外観 : 淡黄色透明液体  
 その他情報は、1項参照。

### 3. 試薬および機器

トウモロコシ油 : 投与液媒体、ナカライテスク(株)  
 酢酸エチル : 試薬特級、和光純薬工業(株)  
 アセトニトリル : HPLC 用、和光純薬工業(株)  
 ぎ酸 : 試薬特級、和光純薬工業(株)  
 0.1%ぎ酸アセトニトリル溶液 : アセトニトリル 1 Lあたり、ぎ酸 1 mLを溶解した。  
 混合溶媒 A : 酢酸エチル + アセトニトリル = 30 + 70 (v/v)  
 混合溶媒 B : トウモロコシ油 1 mLに混合溶媒 A を加え 1Lとした。  
                           酢酸エチル + アセトニトリル = 30 + 70 (v/v) (0.1%トウモロコシ油含有)  
 天秤 : XP205、メトラー・トレド(株)  
 スターラー : MAGNETIC STIRRER IS-34N、(株)池田理化  
 フーリエ変換赤外分光光度計(FT-IR) : Spectrum One、PerkinElmer  
 液体クロマトグラフ質量分析計(LC/MS/MS) : API4000、Applied Biosystems  
 マイクロピペット : 100-1000  $\mu$ L、eppendorf

### 4. 実験方法

#### 4.1. イソトリデシル=ステアラートの同一性および安定性の確認

##### 4.1.1 同一性

安定性確認用模擬投与液調製前に FT-IR を用いて、標準物質の赤外線吸収スペクトル(IR スペクトル)を測定し、試験委託者より提供された IR スペクトルとの比較により同一性を確認した。

##### <IR スペクトル測定条件>

測定法 : 液膜法  
 測定波数 : 4000~400  $\text{cm}^{-1}$   
 積算回数 : 20  
 分解能 : 4  $\text{cm}^{-1}$

##### 4.1.2 安定性

標準物質の安定性は、別途実施する濃度確認試験(試験番号 NCAS 10-198)内で確認する。

#### 4.2. 投与液中イソトリデシル=ステアラートの安定性確認

##### 4.2.1 安定性確認用模擬投与液の調製方法

標準物質を以下のように秤取し、トウモロコシ油で溶解させた後、定容した。安定性確認用模擬投与液の調製は、初日と10日間経過後の2時点で実施した。初日に調製した安定性確認用模擬投与液(保存安定性確認試料)は、室温で10日間保存した後、前処理を実施した。保存安定性確認試料調製日から10日間経過後に調製した安定性確認用模擬投与液(調製直後試料)は、調製直後に前処理を実施した。

調製区分	標準物質 秤取量 (mg)	トウモロコシ油 定容量 (mL)	安定性確認用 模擬投与液調製濃度 (mg/mL)
保存安定性 確認試料	10.01	100	0.1001
	2000.03	10	200.0
調製直後 試料	10.00	100	0.1000
	2000.01	10	200.0

##### 4.2.2 LC/MS/MS 条件

###### <LC 条件>

カラム : CAPCELL PAK NH2 UG80、4.6 mm i.d.×250 mm、(株)資生堂  
 移動相 : 0.1%ぎ酸アセトニトリル溶液  
 流速 : 1 mL/min  
 カラム温度 : 40°C  
 注入量 : 10 µL

###### <MS 条件>

Ion Source : Heated Nebulizer (atmospheric pressure chemical ionization;APCI)  
 Scan Type : MRM (Multiple Reaction Monitoring)  
 Polarity : Positive  
 Monitoring *m/z* :

Q1 Mass (amu)	Q3 Mass (amu)
467.4	183.3

#### 4.2.3 標準溶液の調製

標準物質 100.00 mg を 100 mL のメスフラスコに秤量し、混合溶媒 B に溶解させた後、定容して 1000 µg/mL 標準溶液を調製した(標準溶液 No. SS-0)。この溶液を混合溶媒 B で以下に示したように希釀することにより、各標準溶液を調製した。標準溶液中には、0.1%のトウモロコシ油が含有する。標準溶液は用時に調製した。

標準溶液 No.	使用標準溶液 No.	採取量 (mL)	調製量 (mL)	調製濃度 (µg/mL)
SS-1	SS-0	1	100	10.00
SS-2	SS-1	10	50	2.000
SS-3	SS-1	5	50	1.000
SS-4	SS-1	2.5	50	0.5000
SS-5	SS-3	5	50	0.1000
SS-6	SS-4	5	50	0.05000

#### 4.2.4 検量線用標準溶液の分析と回帰式の算出

4.2.3項で調製した標準溶液 No. SS-2～SS-6 を4.2.2項記載の条件の LC/MS/MS で測定した。得られたクロマトグラムより、イソトリデシル=ステアラートのピーク面積を縦軸に、濃度(µg/mL)を横軸にとり、LC/MS/MS のデータ処理ソフト Analyst 1.4 を用いて最小 2 乗法により回帰式および相関係数を求めた。さらに、検量線の各点について逆回帰値を算出し、設定値に対する真度(%)を算出した。なお、検量線は、重み付け( $1/x$ )を行った。

検量線の判定基準は、相関係数が 0.990 以上、真度が最低濃度の標準溶液で±20%以内、それ以外の標準溶液で±15%以内とした。

#### 4.2.5 機器使用前点検

模擬投与液濃度測定の前に、4.2.3項で調製した最高濃度の検量線用標準溶液(SS-2)を4.2.2項記載の条件の LC/MS/MS で3回測定し、イソトリデシル=ステアラートのピーク面積を求めた。ピーク面積値の変動係数が 10%以内の場合、異常なしと判断して測定を開始した。

#### 4.2.6 ブランク溶液の調製および定量妨害の確認

トウモロコシ油を 1 mL 採り、混合溶媒 A で 100 mL に定容した。この溶液を 1 mL 採り、混合溶媒 A で 10 mL に定容してブランク溶液とした(希釀倍率:1000 倍、試料 ID:1129Blank)。このブランク溶液を4.2.2項記載の条件の LC/MS/MS で測定し、クロマトグラムのイソトリデシル=ステアラートの検出時間付近に、定量を妨害するようなピークがないことを確認した(n=1)。

#### 4.2.7 試料前処理および濃度測定

4.2.1項で調製した安定性確認用模擬投与液を以下に従って前処理を行い、試料溶液とした。試料溶液の調製は、2連で実施した。また、投与液を分取する際には、スターラーを用いて適度な速度で攪拌しながら投与液を分取した。試料溶液中には、最終濃度として0.1%のトウモロコシ油が含有する。各試料溶液IDは、表3参照。

##### 0.1 mg/mL 模擬投与液

0.1 mg/mL 模擬投与液を1mL採り、混合溶媒Aで100mLに定容した。この溶液を1mL採り、混合溶媒Aで10mLに定容して試料溶液とした(希釈倍率：1000倍)。

##### 200 mg/mL 模擬投与液

200 mg/mL 模擬投与液を1mL採り、混合溶媒Aで100mLに定容した。この溶液を1mL採り、混合溶媒Aで10mLに定容した。さらに、この溶液を1mL採り、混合溶媒Bで200mLに定容して試料溶液とした(希釈倍率：200000倍)。

上記で調製した試料溶液を4.2.2項記載の条件のLC/MS/MSで測定した。得られたクロマトグラムよりイソトリデシル=ステアラートのピーク面積を求め、予め作成した検量線の回帰式に代入して検出濃度(μg/mL)を算出した。この検出濃度より、下式を用いて模擬投与液中イソトリデシル=ステアラート濃度を算出した。

$$\text{模擬投与液中イソトリデシル=ステアラート濃度(mg/mL)} = \frac{\text{検出濃度}(\mu\text{g/mL}) \times \text{希釈倍率}}{1000}$$

#### 4.2.8 解析および評価方法

各模擬投与液の濃度(n=2)の変動係数が15%以内であれば試料前処理および濃度測定に問題はなく、かつ調製直後試料の濃度の真度が設定濃度に対して±15%以内であれば設定濃度に調製されたと判断し、得られた結果は有効とした。

測定で得られた濃度から下式より、測定対象物質の残存率(%)を算出し、100±10%以内であれば安定であると判断した。

$$\text{残存率(%)} = \frac{\text{保存安定性確認試料の平均濃度}}{\text{調製直後試料の平均濃度}} \times \frac{\text{調製直後試料調製時の標準物質秤量値}}{\text{保存安定性確認試料調製時の標準物質秤量値}} \times 100$$

#### 4.3. 計算および数値の取り扱い

検量線の作成および試料溶液の検出濃度までの計算は、LC/MS/MSのデータ処理ソフト Analyst 1.4で行い、それ以降の計算はMicrosoft Office Excel 2003(SP3)で行った。

個々の定量値は有効数字4桁とし、平均値は有効数字3桁とした。標準偏差は平均値の最小桁数とし、変動係数および真度は小数第1位まで求めた。検量線の傾きおよび切片は、有効数字4桁とし、相関係数は小数第5位までとした。

## 結果、考察および結論

### 1. イソトリデシル=ステアラートの同一性試験

試験委託者より提供されたイソトリデシル=ステアラートの IR スペクトルを図 1に、安定性用模擬投与液調製前に測定した標準物質の IR スペクトルを図 2に示す。両者の吸収波数はほぼ一致しており、同一性が確認された。

### 2. 投与液中のイソトリデシル=ステアラートの安定性試験

機器使用前点検結果を表 1に示す。最高濃度の検量線用標準溶液(SS-2)を 3 回測定して求めたピーク面積の変動係数は 1.1% であったことより、異常なしと判断し濃度測定を実施した。

検量線用標準溶液の測定結果を表 2に、検量線を図 3に示す。また、標準溶液の代表的な LC/MS/MS クロマトグラムを図 4および図 5に示す。

検量線の相関係数は 0.99996 となり、真度は -1.1~1.9% の範囲内であった。従って、検量線の判定基準を満たした。

ブランク溶液の LC/MS/MS クロマトグラムを図 6に示す。イソトリデシル=ステアラートの検出時間付近に定量を妨害するピークがないことを確認した。

安定性確認用模擬投与液の濃度測定結果を表 3に、代表的な LC/MS/MS クロマトグラムを図 7~図 10に示す。各模擬投与液の 2 連測定において、変動係数は 0~1.1% の範囲内であったことより、試料前処理および濃度測定に問題ないと判断した。また、調製直後試料の濃度の設定濃度に対する真度は、0.1 mg/mL 模擬投与液で 0.8% および -0.9%、200 mg/mL 模擬投与液で -8.5% および -7.3% であったことより、設定濃度に調製されたと判断した。以上より、濃度測定結果は有効と判断した。

0.1 mg/mL 模擬投与液における 2 連測定の平均濃度は、調製直後試料で 0.0997 mg/mL(秤量値 10.00 mg)、保存安定性確認試料で 0.0996 mg/mL(秤量値 10.01 mg) であった。残存率は 99.8% となり、安定性の判定基準(残存率が  $100.0 \pm 10.0\%$ )を満たした。従って、0.1 mg/mL 模擬投与液中のイソトリデシル=ステアラートは、室温で 10 日間安定であることが確認された。同様に、200 mg/mL 模擬投与液における 2 連測定の平均濃度は、調製直後試料で 184 mg/mL(秤量値 2000.01 mg)、保存安定性確認試料で 182 mg/mL(秤量値 2000.03 mg) であった。残存率は 98.9% となり、安定性の判定基準(残存率が  $100.0 \pm 10.0\%$ )を満たした。従って、200 mg/mL 模擬投与液中のイソトリデシル=ステアラートは、室温で 10 日間安定であることが確認された。

なお、保存期間中の温度は 17.6~25.1°C であった。

表 1 機器使用前点検結果

測定日：2010年11月29日測定

試料 ID	イソトリデシル=ステアラートピーク面積値			
	個別	平均	標準偏差	変動係数 (%)
1129precheck-1	282391	286077	3289	1.1
1129precheck-2	287130			
1129precheck-3	288711			

表 2 検量線用標準溶液の測定結果

測定日：2010年11月29日測定

標準溶液 No.	標準溶液濃度 ( $\mu\text{g/mL}$ )	イソトリデシル=ステアラート ピーク面積	逆回帰値 ( $\mu\text{g/mL}$ )	真度 (%)
SS-6	0.05000	7312	0.04992	-0.2
SS-5	0.1000	14724	0.09890	-1.1
SS-4	0.5000	76884	0.5097	1.9
SS-3	1.000	150277	0.9948	-0.5
SS-2	2.000	301879	1.997	-0.2
標準物質秤量値： 100.00 mg				
検量線回帰式： $y = 1.513 \times 10^5 x - 241.2$ (重み付け : $1/x$ )				
相関係数： 0.99996				

表 3 安定性確認用模擬投与液の濃度測定

測定日：2010年11月29日測定

試料ID	調製区分	模擬投与液 調製濃度 (mg/mL)	希釈倍率	イソトリペチル=ステアラート ピーク面積	検出濃度 ( $\mu\text{g/mL}$ )	定量値				真度 個別 (%)	秤量値 (mg)	残存率 (%)	
						個別 (mg/mL)	平均値 (mg/mL)	標準偏差 (mg/mL)	変動係数 (%)				
1129-0.1mg/mL-1	調製直後試料	0.1000	1000	14930	0.1003	0.1003	0.0997	0.0008	0.8	0.3	10.00	\diagup\diagdown	
1129-0.1mg/mL-2				14754	0.09910	0.09910				-0.9			
1129-200mg/mL-1		200.0	200000	138311	0.9157	183.1	184	2	1.1	-8.5	2000.01		
1129-200mg/mL-2				139974	0.9267	185.3				-7.3			
1119-0.1mg/mL-1	保存安定性 確認試料 (室温 10日間保存)	0.1001	1000	14713	0.09883	0.09883	0.0996	0.0010	1.0	\diagup\diagdown	10.01	99.8	
1119-0.1mg/mL-2				14931	0.1003	0.1003				\diagup\diagdown			
1119-200mg/mL-1		200.0	200000	137088	0.9076	181.5	182	0	0.0	\diagup\diagdown	2000.03		
1119-200mg/mL-2				137459	0.9101	182.0				\diagup\diagdown			

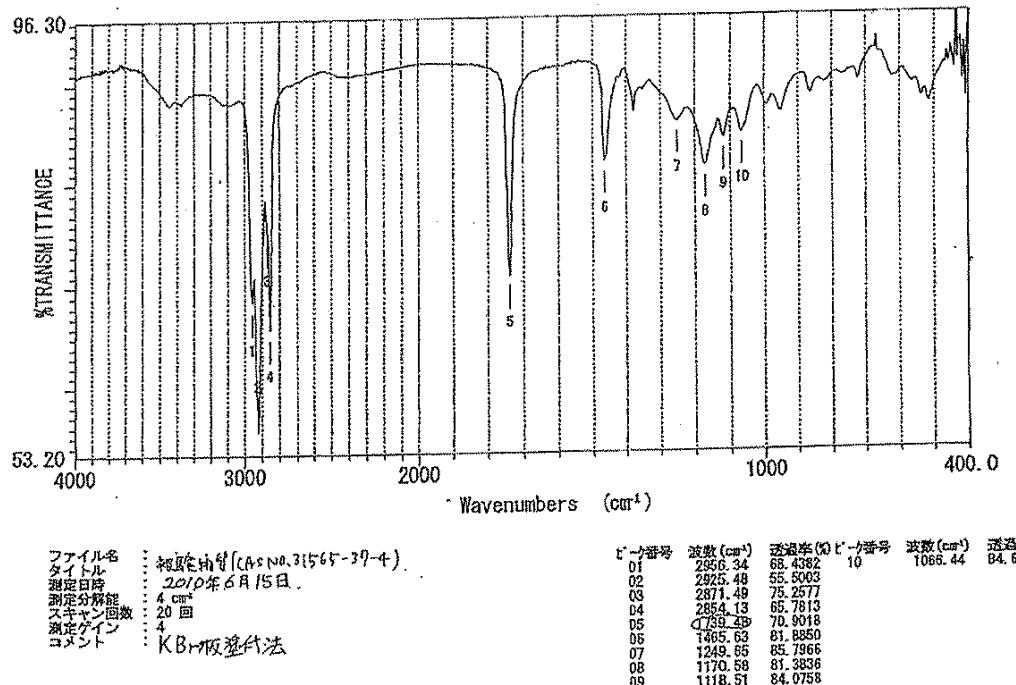
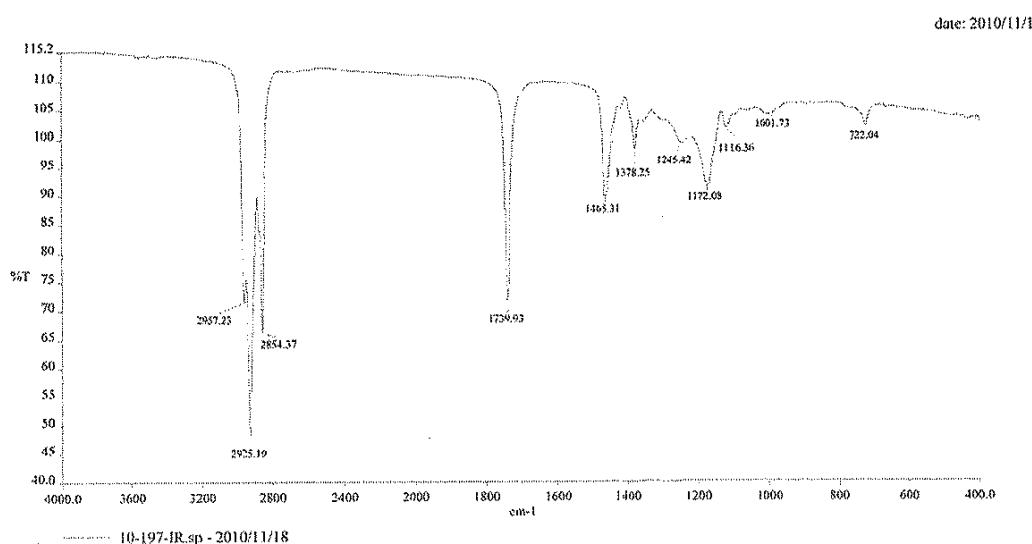


図 1 試験委託者より提供されたイソトリデシル=ステアラートの赤外線吸収スペクトル



instrument model: Spectrum One (G-641)  
 spectrum pathname: C:\pel\_data\spectra\10-197\10-197-JR.sp  
 date created: thu nov 18 13:07:23 2010  
 description:  
 resolution: 4.00 cm<sup>-1</sup>    accumulations: 20

Protocol No. 10-197  
 Ref. No. 10-197-IR  
 11/18/10 S.T.  
 Sign: \_\_\_\_\_  
 Date: 11/18/10

図 2 実験開始時の標準物質の赤外線吸収スペクトル

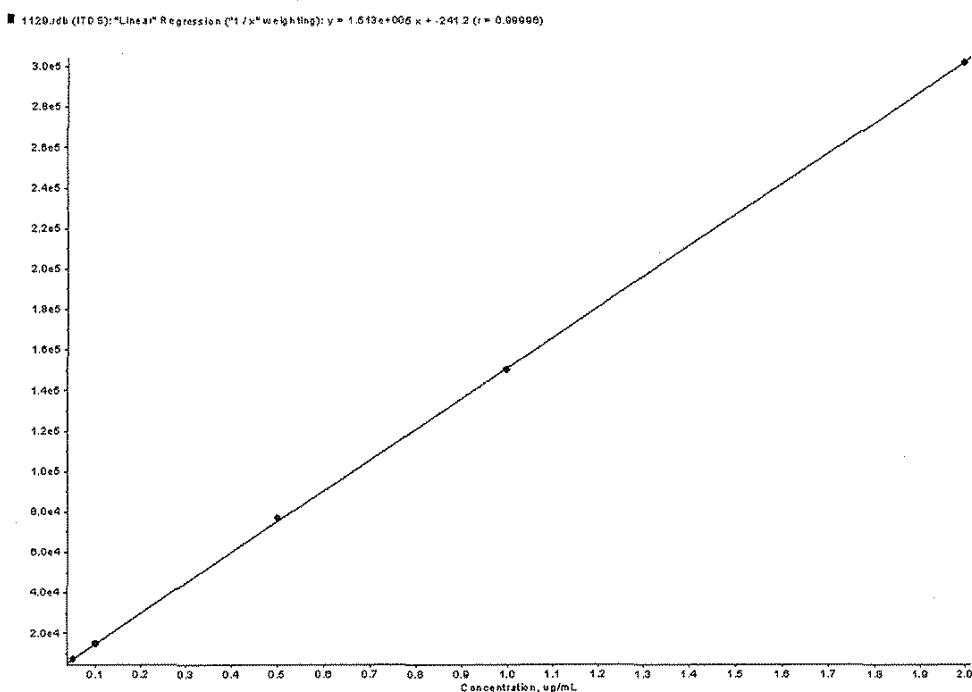


図 3 検量線

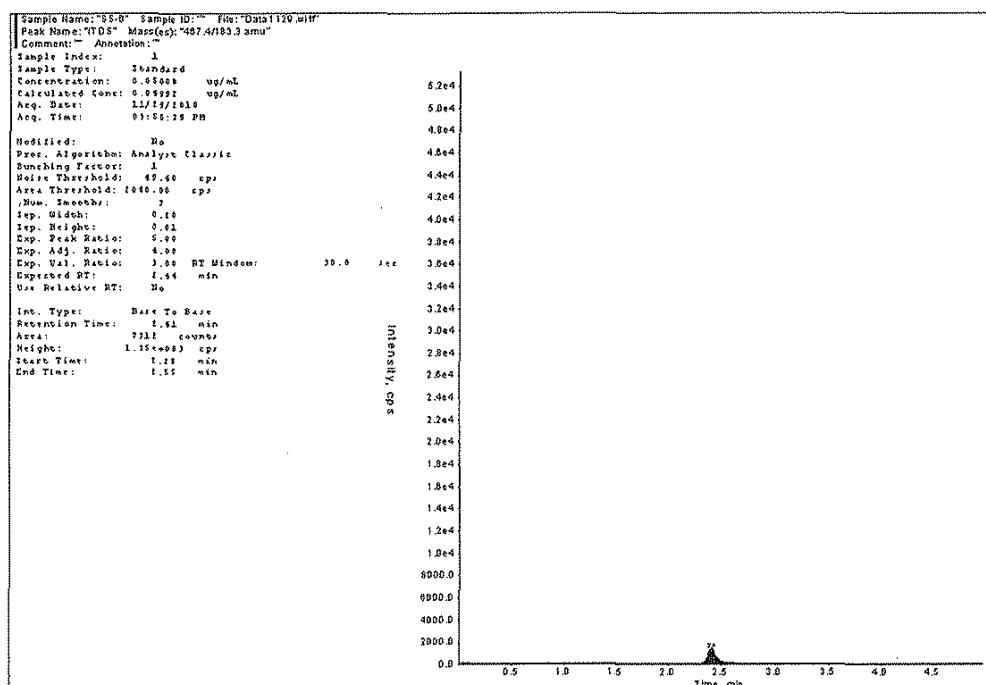


図 4 標準溶液の代表的な LC/MS/MS クロマトグラム(標準溶液 No. : SS-6、0.5000 µg/mL)

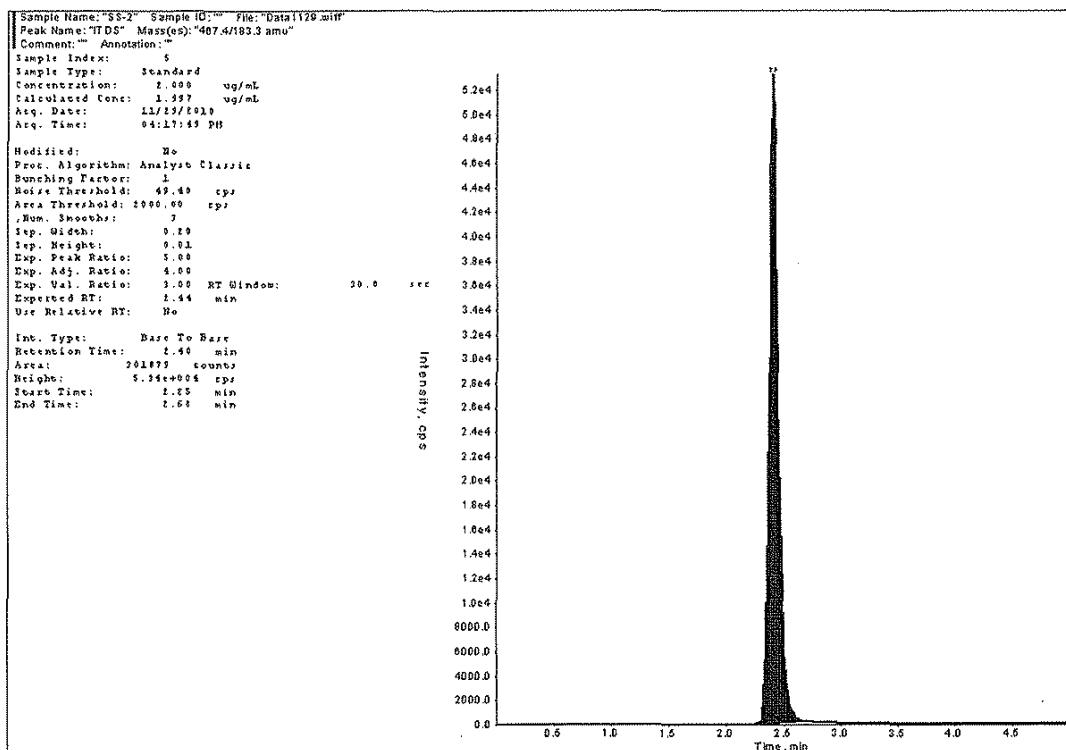


図 5 標準溶液の代表的なLC/MS/MSクロマトグラム(標準溶液No. : SS-2、2.000 μg/mL)

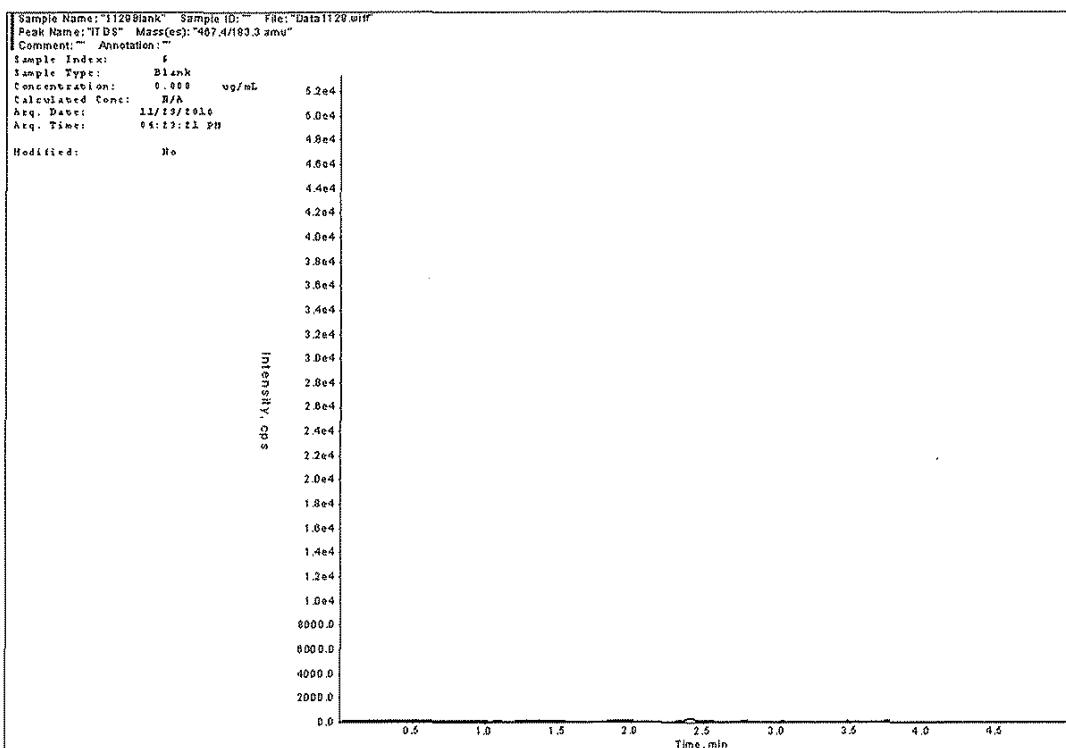


図 6 ブランク溶液のLC/MS/MSクロマトグラム(試料ID : 1129Blank)

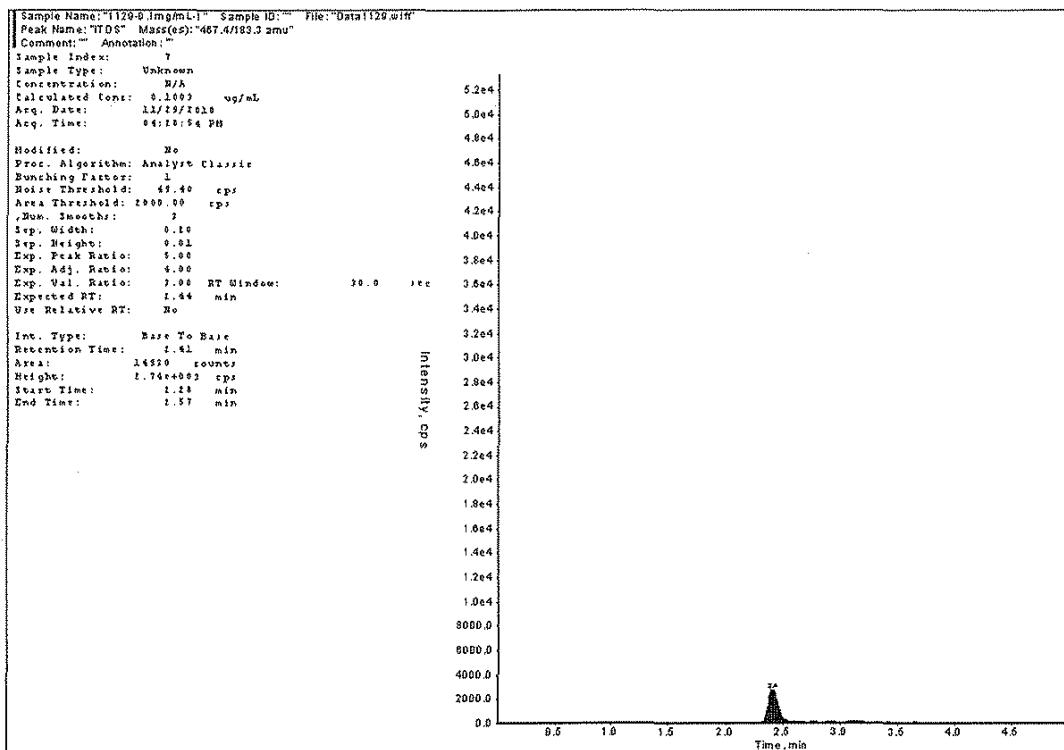


図 7 安定性確認用模擬投与液(調製直後試料、試料 ID : 1129-0.1mg/mL-1)  
の代表的な LC/MS/MS クロマトグラム

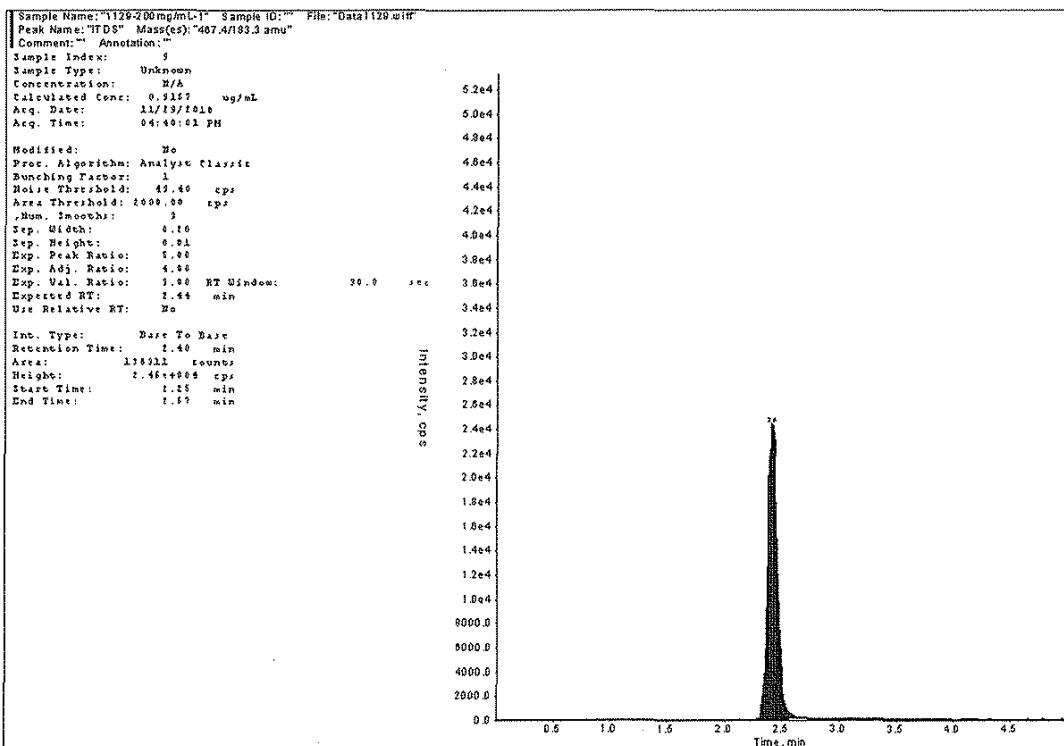


図 8 安定性確認用模擬投与液(調製直後試料、試料 ID : 1129-200mg/mL-1)  
の代表的な LC/MS/MS クロマトグラム

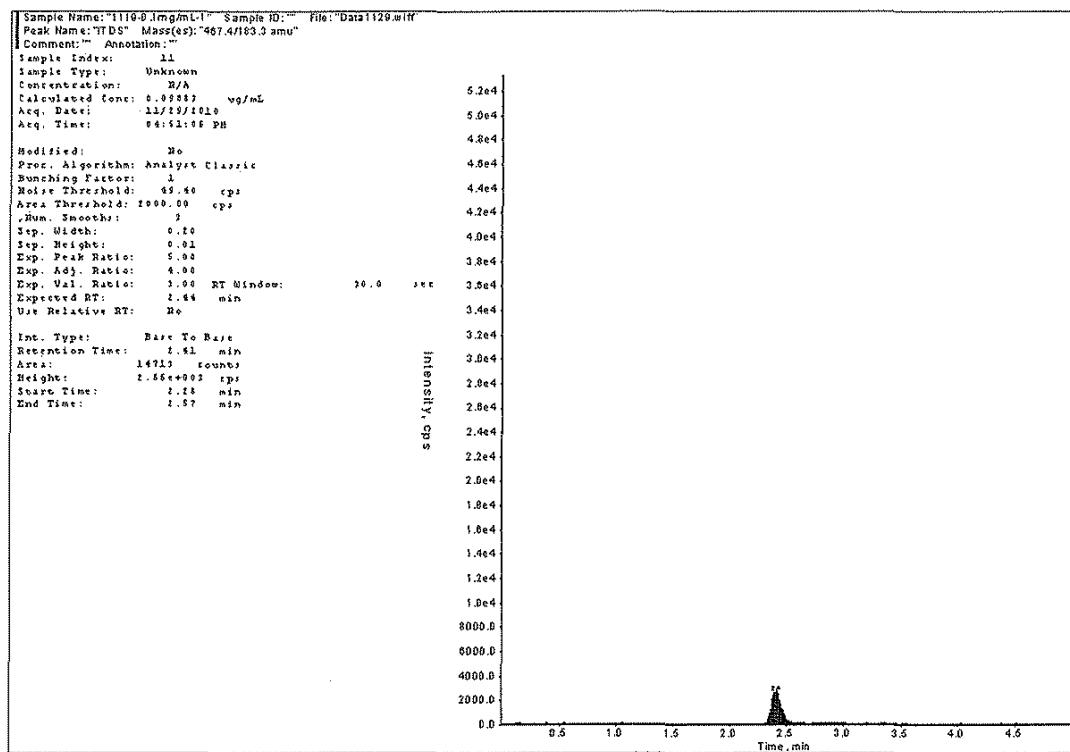


図 9 安定性確認用模擬投与液(保存安定性確認試料、試料 ID : 1119-0.1mg/mL·1)  
の代表的な LC/MS/MS クロマトグラム

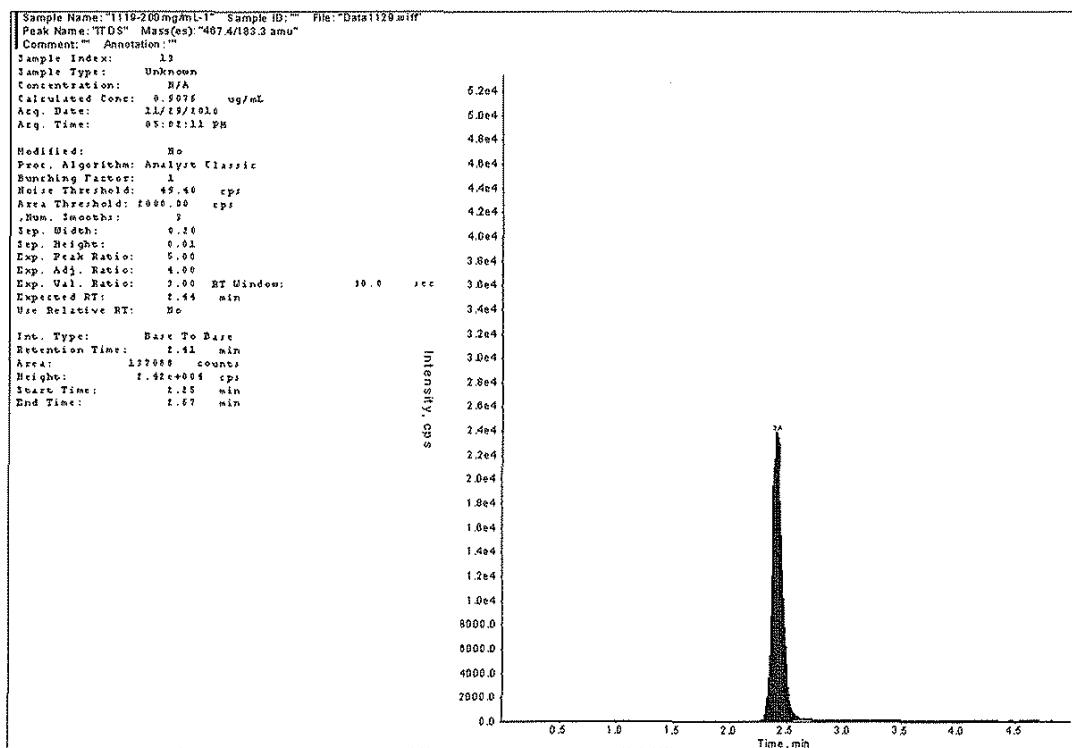


図 10 安定性確認用模擬投与液(保存安定性確認試料、試料 ID : 1119-200mg/mL·1)  
の代表的な LC/MS/MS クロマトグラム

## 最終報告書

### 試験名

投与液中のイソトリデシル=ステアラートの濃度確認試験

### 著者

### 試験終了日

2011年5月26日

### 試験施設

株式会社日曹分析センター(略称 NCAS) 小田原事業所  
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### 試験委託者

株式会社化合物安全性研究所  
〒004-0839 北海道札幌市清田区真栄 363 番 24

### 試験番号

NCAS 10-198

## GLP 適合陳述書

試験番号 : NCAS 10-198

試験名 : 投与液中のイソトリデシル=ステアラートの濃度確認試験

この試験は、以下の GLP 規則に従って実施した。

「新規化学物質等に係る試験を実施する試験施設に関する基準について」(平成 15 年 11 月 21 日 薬食発第 1121003 号、平成 15・11・17 製局第 3 号、環保企発第 031121004 号)、最終改正 平成 20 年 7 月 4 日

この試験はここに述べられた方法により行われ、この最終報告書は試験実施により得られた生データを正確に反映したものである。

試験責任者 :



2011 年 5 月 26 日

株式会社日曹分析センター 小田原事業所

報告書番号 NCAS 10-198

Page 3 of 23

## 信頼性保証書

試験番号： NCAS 10-198

試験名： 投与液中のイソトリデシル=ステアラートの濃度確認試験

上記試験の信頼性保証の監査又は査察を適用 GLP および信頼性保証部門（QAU）の SOP に基づいて実施した。監査又は査察の結果は、以下の日付で試験責任者および運営管理者に報告した。

監査又は査察項目	日付（月/日/年）		
	監査又は査察日	報告日	
		試験責任者	運営管理者
試験計画書	1/12/2011	1/12/2011	1/12/2011
試験計画書変更届 1	5/26/2011	5/26/2011	5/26/2011
実験操作			
・投与液の受領	2/4, 7/2011	2/7/2011	2/7/2011
・標準溶液の調製	2/4, 7/2011	2/7/2011	2/7/2011
・試料溶液の調製	2/4, 7/2011	2/7/2011	2/7/2011
・LC/MS/MS 測定	2/4, 7/2011	2/7/2011	2/7/2011
・IR スペクトル測定	4/18/2011	4/18/2011	4/18/2011
生データおよび関連試験資料	5/9/2011	5/9/2011	5/9/2011
報告書草案	5/7-9/2011	5/9/2011	5/9/2011
最終報告書	5/26/2011	5/26/2011	5/26/2011

QAU は、この試験が試験計画書および SOP に従って行われ、報告された方法や手段が実際に使われたものであり、結果は記録されたデータを正確に反映していることを確認した。

QAU 責任者


2011年5月26日

(株) 日曹分析センター

## 試験情報

試験番号 : NCAS 10-198

試験名 : 投与液中のイソトリデシル=ステアラートの濃度確認試験

報告書番号 : NCAS 10-198

試験委託者 : 株式会社化合物安全性研究所

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試験施設 : 株式会社日曹分析センター 小田原事業所

〒250-0216 神奈川県小田原市高田 345

TEL 0465-42-8201、 FAX 0465-42-3586

試験責任者 :

試験従事者 :

試験開始日 : 2011 年 1 月 11 日

実験開始日 : 2011 年 2 月 4 日

実験終了日 : 2011 年 4 月 18 日

試験終了日 : 2011 年 5 月 26 日

適用ガイドライン : なし

関連する試験 : NCAS 10-196NG 「投与液中のイソトリデシル=ステアラート分析法検討および分析法  
バリデーション」

NCAS 10-197 「投与液中のイソトリデシル=ステアラートの安定性試験」

試資料保管 : 本試験に関する全ての文書は、当試験施設の資料室に試験終了後 10 年間保管する。その後の保  
管場所については、試験委託者と協議して決定する。標準物質は、イソトリデシル=ステアラートに関する一連の試験が終了した後、試験委託者に返却する。

SOP および試験計画書からの逸脱 :

SOP および試験計画書からの逸脱はなかった。

試験成績の信頼性に影響を及ぼしたと思われる環境要因 :

試験成績の信頼性に影響を及ぼしたと思われる環境要因はなかった。

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## 概要

株式会社化合物安全性研究所の委託により、投与液中のイソトリデシル=ステアラートの濃度確認試験を実施した。濃度測定は液体クロマトグラフ質量分析計を用いて行い、結果は以下の通りとなった。

投与液調製日	投与液受領日 (濃度測定日)	投与液名	設定濃度 (mg/mL)	測定濃度 (mg/mL)	変動係数 (%)	真度 (%)
2011年2月3日	2011年2月4日	イソトリデシル=ステアラート 20 mg/mL 調製液	20	20.9	1.9	4.5
		イソトリデシル=ステアラート 60 mg/mL 調製液	60	63.6	1.3	6.0
		イソトリデシル=ステアラート 200 mg/mL 調製液	200	208	1.0	4.0
2011年3月23日	2011年3月24日	イソトリデシル=ステアラート 20 mg/mL 調製液	20	21.5	0.5	7.5
		イソトリデシル=ステアラート 60 mg/mL 調製液	60	63.8	1.1	6.3
		イソトリデシル=ステアラート 200 mg/mL 調製液	200	210	0.5	5.0

規定した判定基準「各投与液について、2連測定の変動係数が15%以内であり、かつ測定濃度の設定濃度に対する真度が±15%以内」を満たしたことより、投与液は設定濃度に調製されたと判断した。

また、試験委託者が実施した毒性試験(委託者試験番号 SR09207)における投与終了日以降に、実験に用いた標準物質の赤外線吸収スペクトルを測定し、同一性確認時の標準物質の赤外線吸収スペクトル(試験番号 NCAS 10-197「投与液中のイソトリデシル=ステアラートの安定性試験」)と比較した。その結果、両者の主な吸収波数は整数値で一致したことより、試験委託者が実施した毒性試験(委託者試験番号 SR09207)期間中の標準物質は安定であったと判断した。

## 緒言

株式会社化合物安全性研究所の委託により、測定対象物質であるイソトリデシル=ステアラートの投与液中の濃度確認試験および標準物質の安定性試験を実施した。その内容について以下に報告する。

## 実験材料および方法

### 1. 測定対象物質

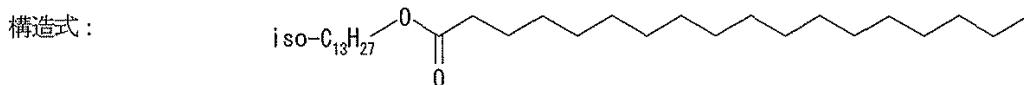
化合物名 : イソトリデシル=ステアラート

化学名 : Isotridecyl stearate

CAS No. : 31565-37-4

分子式 : C<sub>31</sub>H<sub>62</sub>O<sub>2</sub>

分子量 : 466.82



### 2. 標準物質

化合物名 : イソトリデシル=ステアラート

化学名 : isotridecyl stearate

ロット番号 : 00119

NCAS 検索番号 : STD-1179

入手先 :

[REDACTED]

入手日 : 2010年6月30日

入手量 : 19.24 g

純度 : 100%として取り扱った。

保存条件 : 褐色瓶に入れ、室温保存

外観 : 淡黄色透明液体

その他情報は、1項参照。

### 3. 投与液

投与液は、イソトリデシル=ステアラートをトウモロコシ油で溶解した溶液である。2011年2月3日および2011年3月23日に試験委託者が実施した毒性試験(委託者試験番号 SR09207)で調製した20、60および200 mg/mLの投与液をそれぞれ翌日に受領した。受領した投与液は即日分析した。

#### 4. 試薬および機器

トウモロコシ油 : 投与液媒体、ナカライトスク(株)  
酢酸エチル : 試薬特級、和光純薬工業(株)  
アセトニトリル : HPLC 用、和光純薬工業(株)  
ぎ酸 : 試薬特級、和光純薬工業(株)  
0.1%ぎ酸アセトニトリル溶液 : アセトニトリル 1Lあたり、ぎ酸 1 mL を溶解した。  
混合溶媒 A : 酢酸エチル + アセトニトリル = 30 + 70 (v/v)  
混合溶媒 B : トウモロコシ油 1 mL に混合溶媒 A を加え 1 L とした。  
                  酢酸エチル + アセトニトリル = 30 + 70 (v/v) (0.1%トウモロコシ油含有)  
天秤 : XP205、メトラー・トレド(株)  
スターラー : MAGNETIC STIRRER IS-34N、(株)池田理化  
フーリエ変換赤外分光光度計(FT-IR) : Spectrum One、PerkinElmer  
液体クロマトグラフ質量分析計(LC/MS/MS) : API4000、Applied Biosystems  
マイクロピペット : 100-1000 μL、eppendorf

#### 5. 実験方法

##### 5.1. イソトリデシル=ステアラートの同一性・安定性試験

###### 5.1.1 同一性

試験番号 NCAS 10-197 「投与液中のイソトリデシル=ステアラートの安定性試験」において、標準物質がイソトリデシル=ステアラートであることを確認した。

###### 5.1.2 安定性

試験委託者が実施した毒性試験(委託者試験番号 SR09207)の投与終了日である 2011 年 3 月 26 日以降の 2011 年 4 月 18 日に、FT-IR を用いて標準物質の赤外線吸収スペクトル(IR スペクトル)を測定し、同一性確認時の標準物質の IR スペクトル(試験番号 NCAS 10-197 で得られた IR スペクトル)と比較した。スペクトルが一致した場合、試験委託者が実施した毒性試験(委託者試験番号 SR09207)期間中の標準物質は安定であったと判断した。

###### <IR スペクトル測定条件>

測定法 : 液膜法  
測定波数 : 4000~400 cm<sup>-1</sup>  
積算回数 : 20  
分解能 : 4 cm<sup>-1</sup>

## 5.2. 投与液中イソトリデシル=ステアラートの濃度確認試験

### 5.2.1 LC/MS/MS 条件

#### <LC 条件>

カラム :	CAPCELL PAK NH2 UG80、4.6 mm i.d.×250 mm、(株)資生堂
移動相 :	0.1%ぎ酸アセトニトリル溶液
流速 :	1 mL/min
カラム温度 :	40°C
注入量 :	10 µL

#### <MS 条件>

Ion Source :	Heated Nebulizer (atmospheric pressure chemical ionization ; APCI)				
Scan Type :	MRM (Multiple Reaction Monitoring)				
Polarity :	Positive				
Monitoring <i>m/z</i> :					
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;">Q1 Mass (amu)</td> <td style="padding: 2px;">Q3 Mass (amu)</td> </tr> <tr> <td style="padding: 2px;">467.4</td> <td style="padding: 2px;">183.3</td> </tr> </table>	Q1 Mass (amu)	Q3 Mass (amu)	467.4	183.3
Q1 Mass (amu)	Q3 Mass (amu)				
467.4	183.3				

### 5.2.2 標準溶液の調製

標準物質 100.00 mg を 100 mL のメスフラスコに秤量し、混合溶媒 B に溶解させた後、定容して 1000 µg/mL 標準溶液を調製した(標準溶液 No. SS-0)。この溶液を混合溶媒 B で以下に示したように希釈することにより、各標準溶液を調製した。標準溶液中には、0.1%のトウモロコシ油が含まれる。これらは用時調製とし、標準溶液 No. の頭に「調製した月日」を付して区別した。標準溶液 No. は、表 2および表 5 参照。

標準溶液 No.	使用標準溶液 No.	採取量 (mL)	調製量 (mL)	調製濃度 (µg/mL)
SS-1	SS-0	1	100	10.00
SS-2	SS-1	10	50	2.000
SS-3	SS-1	5	50	1.000
SS-4	SS-1	2.5	50	0.5000
SS-5	SS-3	5	50	0.1000
SS-6	SS-4	5	50	0.05000

### 5.2.3 検量線用標準溶液の分析と回帰式の算出

5.2.2項で調製した標準溶液 No. SS-2～SS-6 を5.2.1項記載の条件の LC/MS/MS で測定した。得られたクロマトグラムより、イソトリデシル=ステアラートのピーク面積を縦軸に、濃度(μg/mL)を横軸にとり、LC/MS/MS のデータ処理ソフト Analyst 1.4 を用いて最小2乗法により回帰式および相関係数を求めた。さらに、検量線の各点について逆回帰値を算出し、設定値に対する真度(%)を算出した。なお、検量線は、重み付け(1/x)を行った。

検量線の判定基準は、相関係数が 0.990 以上、真度が最低濃度の標準溶液で±20%以内、それ以外の標準溶液で±15%以内とした。

### 5.2.4 機器使用前点検

投与液の濃度測定の前に、5.2.2項で調製した最高濃度の検量線用標準溶液(SS-2)を5.2.1項記載の条件の LC/MS/MS で 3 回測定し、イソトリデシル=ステアラートのピーク面積を求めた。ピーク面積値の変動係数が 10%以内の場合、異常なしと判断して測定を開始した。

### 5.2.5 ブランク溶液の調製および定量妨害の確認

トウモロコシ油を 1 mL 採り、混合溶媒 A で 100 mL に定容した。この溶液を 1 mL 採り、混合溶媒 A で 10 mL に定容してブランク溶液とした(希釈倍率：1000 倍)。このブランク溶液を5.2.1項記載の条件の LC/MS/MS で測定し、クロマトグラムのイソトリデシル=ステアラートの検出時間付近に、定量を妨害するようなピークがないことを確認した(n=1)。

以上の操作は、分析日(調製日)ごとに行った。試料 ID は Blank とし、「調製した月日・」を付して区別した。

### 5.2.6 濃度測定

3 項で受領した投与液を以下に従って希釈し、試料溶液とした。試料溶液の調製は、2 連で実施した。また、投与液を分取する際には、スターラーを用いて適度な速度で攪拌しながら投与液を分取した。試料溶液中には、最終濃度として 0.1% のトウモロコシ油が含まれる。各試料溶液 ID は、表 3 および表 6 参照。

#### 20 mg/mL 投与液

20 mg/mL 投与液を 1 mL 採り、混合溶媒 A で 100 mL に定容した。この溶液を 1 mL 採り、混合溶媒 A で 10 mL に定容した。さらに、この溶液を 1 mL 採り、混合溶媒 B で 20 mL に定容して試料溶液とした(希釈倍率：20000 倍)。

#### 60 mg/mL 投与液

60 mg/mL 投与液を 1 mL 採り、混合溶媒 A で 100 mL に定容した。この溶液を 1 mL 採り、混合溶媒 A で 10 mL に定容した。さらに、この溶液を 1 mL 採り、混合溶媒 B で 100 mL に定容して試料溶液とした(希釈倍率：100000 倍)。

### 200 mg/mL 投与液

200 mg/mL 投与液を 1 mL 採り、混合溶媒 A で 100 mL に定容した。この溶液を 1 mL 採り、混合溶媒 A で 10 mL に定容した。さらに、この溶液を 1 mL 採り、混合溶媒 B で 200 mL に定容して試料溶液とした(希釈倍率 : 200000 倍)。

上記で調製した試料溶液を 5.2.1 項記載の条件の LC/MS/MS で測定した。得られたクロマトグラムよりイソトリデシル=ステアラートのピーク面積を求め、予め作成した検量線の回帰式に代入して検出濃度(μg/mL)を算出した。この検出濃度より、下式を用いて投与液中イソトリデシル=ステアラート濃度を算出し、その平均値、変動係数(%)および平均値の設定値に対する真度(%)を求めた。2 連測定の変動係数が 15%以内であり、かつ真度が ±15%以内であれば設定濃度に調製されたと判断し、得られた結果は有効とした。各投与液の平均濃度を最終的な投与液濃度とした。

$$\text{各投与液中イソトリデシル=ステアラート濃度(mg/mL)} = \frac{\text{検出濃度}(\mu\text{g/mL}) \times \text{希釈倍率}}{1000}$$

### 5.3. 計算および数値の取り扱い

検量線の作成および試料溶液の検出濃度までの計算は、LC/MS/MS のデータ処理ソフト Analyst 1.4 で行い、それ以降の計算は Microsoft Office Excel 2003 (SP3) で行った。

個々の定量値は有効数字 4 術とし、平均値は有効数字 3 術とした。標準偏差は平均値の最小桁数とし、変動係数および真度は小数第 1 位まで求めた。検量線の傾きおよび切片は、有効数字 4 術とし、相関係数は小数第 5 位までとした。

## 結果、考察および結論

### 1. イソトリデシル=ステアラートの安定性試験

安定性確認時の標準物質の IR スペクトルを図 1に、同一性確認時の標準物質の IR スペクトル(試験番号 NCAS 10-197 で得られた IR スペクトル)を図 2に示す。両者の主な吸収波数は整数値で一致した。従って、実験期間中の標準物質は安定であったと判断した。

### 2. 投与液中のイソトリデシル=ステアラートの濃度確認試験

#### 2.1. 2011年2月4日受領投与液の濃度測定結果

機器使用前点検結果を表 1に示す。最高濃度の検量線用標準溶液(0204SS-2)を 3 回測定して求めたピーク面積の変動係数は 1.8% であったことより、異常なしと判断し、濃度測定を実施した。

検量線用標準溶液の測定結果を表 2に、検量線を図 3に示す。また、標準溶液の代表的な LC/MS/MS クロマトグラムを図 5および図 6に示す。検量線の相関係数は 0.99989 となり、真度は -2.0~2.0% の範囲内であった。従って、検量線の判定基準を満たした。

ブランク溶液の LC/MS/MS クロマトグラムを図 9に示す。イソトリデシル=ステアラートの検出時間付近に定量を妨害するピークがないことを確認した。

投与液の濃度測定結果を表 3に、代表的な LC/MS/MS クロマトグラムを図 11~図 13に示す。各投与液の 2 連測定において、変動係数は 1.0~1.9% の範囲内であったことより、試料前処理および濃度測定に問題はないと判断した。また、定量値平均値の設定濃度に対する真度は、20 mg/mL 投与液で 4.5%、60 mg/mL 投与液で 6.0%、200 mg/mL 投与液で 4.0% であった。従って、いずれの投与液も設定濃度に調製されたと判断した。

以上より、2011年2月4日受領投与液の濃度測定結果は有効と判断した。

#### 2.2. 2011年3月24日受領投与液の濃度測定結果

機器使用前点検結果を表 4に示す。最高濃度の検量線用標準溶液(0324SS-2)を 3 回測定して求めたピーク面積の変動係数は 1.6% であったことより、異常なしと判断し、濃度測定を実施した。

検量線用標準溶液の測定結果を表 5に、検量線を図 4に示す。また、標準溶液の代表的な LC/MS/MS クロマトグラムを図 7および図 8に示す。検量線の相関係数は 0.99988 となり、真度は -2.5~3.0% の範囲内であった。従って、検量線の判定基準を満たした。

ブランク溶液の LC/MS/MS クロマトグラムを図 10に示す。イソトリデシル=ステアラートの検出時間付近に定量を妨害するピークがないことを確認した。

投与液の濃度測定結果を表 6に、代表的な LC/MS/MS クロマトグラムを図 14~図 16に示す。各投与液の 2 連測定において、変動係数は 0.5~1.1% の範囲内であったことより、試料前処理および濃度測定に問題はないと判断した。また、定量値平均値の設定濃度に対する真度は、20 mg/mL 投与液で 7.5%、60 mg/mL 投与液で 6.8%、200 mg/mL 投与液で 5.0% であった。従って、いずれの投与液も設定濃度に調製されたと判断した。

以上より、2011年3月24日受領投与液の濃度測定結果は有効と判断した。

表 1 機器使用前点検結果(2011年2月4日受領投与液)

測定日：2011年2月4日

試料ID	イソトリデシル=ステアラートピーク面積値			
	個別	平均	標準偏差	変動係数 (%)
0204precheck-1	110807			
0204precheck-2	113618	111363	2035	1.8
0204precheck-3	109664			

表 2 検量線用標準溶液の測定結果(2011年2月4日受領投与液)

測定日：2011年2月4日

標準溶液No.	標準溶液濃度 ( $\mu\text{g/mL}$ )	イソトリデシル=ステアラート ピーク面積	逆回帰値 ( $\mu\text{g/mL}$ )	真度 (%)
0204SS-6	0.05000	3227	0.04899	-2.0
0204SS-5	0.1000	6912	0.1020	2.0
0204SS-4	0.5000	34115	0.4936	-1.3
0204SS-3	1.000	70671	1.020	2.0
0204SS-2	2.000	137752	1.985	-0.7

標準物質秤量値： 100.00 mg

検量線回帰式：  $y = 6.947 \times 10^4 x - 176.2$  (重み付け : 1/x)

相関係数： 0.99989

表 3 投与液の濃度測定結果(2011年2月4日受領投与液)

測定日：2011年2月4日

試料ID	投与液 設定濃度 ( $\text{mg/mL}$ )	希釈倍率	イソトリデシル=ステアラート ピーク面積	検出濃度 ( $\mu\text{g/mL}$ )	定量値				真度 (%)
					個別 ( $\text{mg/mL}$ )	平均値 ( $\text{mg/mL}$ )	標準偏差 ( $\text{mg/mL}$ )	変動係数 (%)	
0204-20 mg/mL-1	20	20000	73472	1.060	21.20	20.9	0.4	1.9	4.5
0204-20 mg/mL-2			71480	1.032	20.64				
0204-60 mg/mL-1	60	100000	43618	0.6304	63.04	63.6	0.8	1.3	6.0
0204-60 mg/mL-2			44437	0.6422	64.22				
0204-200 mg/mL-1	200	200000	71606	1.033	206.6	208	2	1.0	4.0
0204-200 mg/mL-2			72778	1.050	210.0				

表 4 機器使用前点検結果(2011年3月24日受領投与液)

測定日：2011年3月24日

試料ID	イソトリデシル=ステアラートピーク面積値			
	個別	平均	標準偏差	変動係数 (%)
0324precheck-1	173013			
0324precheck-2	169518	172447	2691	1.6
0324precheck-3	174809			

表 5 検量線用標準溶液の測定結果(2011年3月24日受領投与液)

測定日：2011年3月24日

標準溶液No.	標準溶液濃度 ( $\mu\text{g/mL}$ )	イソトリデシル=ステアラート ピーク面積	逆回帰値 ( $\mu\text{g/mL}$ )	真度 (%)
0324SS-6	0.05000	4084	0.05149	3.0
0324SS-5	0.1000	8246	0.09801	-2.0
0324SS-4	0.5000	43091	0.4874	-2.5
0324SS-3	1.000	90512	1.017	1.7
0324SS-2	2.000	178040	1.996	-0.2

標準物質秤量値： 100.00 mg

検量線回帰式：  $y = 8.948 \times 10^4 x - 523.3$  (重み付け : 1/x)

相関係数： 0.99988

表 6 投与液の濃度測定結果(2011年3月24日受領投与液)

測定日：2011年3月24日

試料ID	投与液 設定濃度 ( $\text{mg/mL}$ )	希釈倍率	イソトリデシル=ステアラート ピーク面積	検出濃度 ( $\mu\text{g/mL}$ )	定量値				真度 (%)
					個別 ( $\text{mg/mL}$ )	平均値 ( $\text{mg/mL}$ )	標準偏差 ( $\text{mg/mL}$ )	変動係数 (%)	
0324-20 mg/mL-1	20	20000	95482	1.073	21.46	21.5	0.1	0.5	7.5
0324-20 mg/mL-2			95806	1.077	21.54				
0324-60 mg/mL-1	60	100000	56093	0.6328	63.28	63.8	0.7	1.1	6.3
0324-60 mg/mL-2			56968	0.6425	64.25				
0324-200 mg/mL-1	200	200000	93064	1.046	209.2	210	1	0.5	5.0
0324-200 mg/mL-2			93563	1.052	210.4				

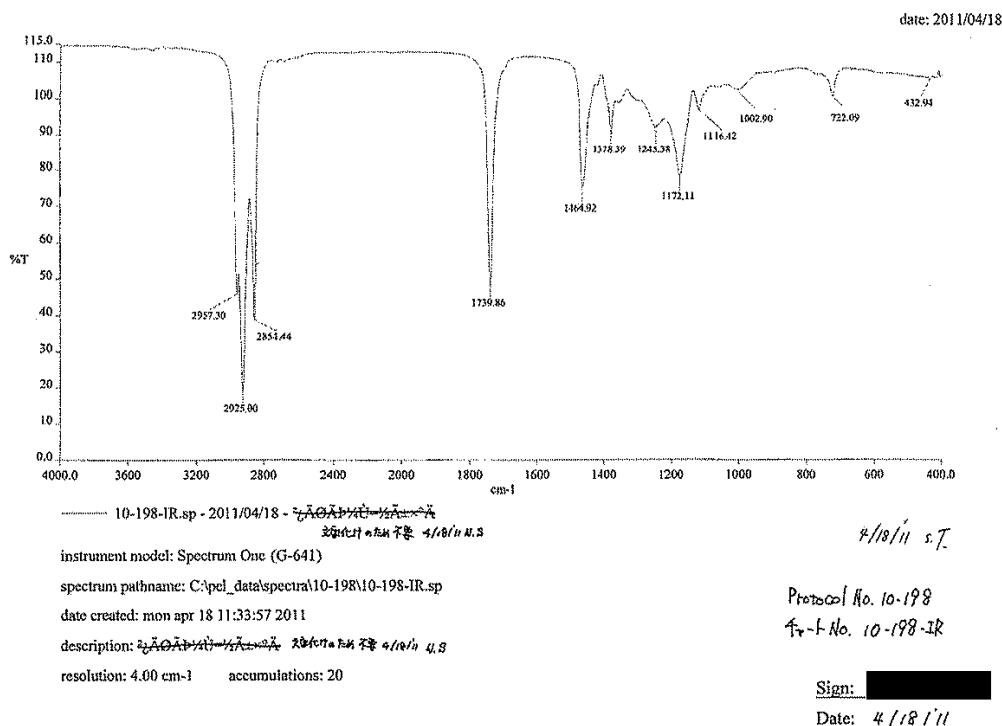


図 1 安定性確認時の標準物質のIRスペクトル

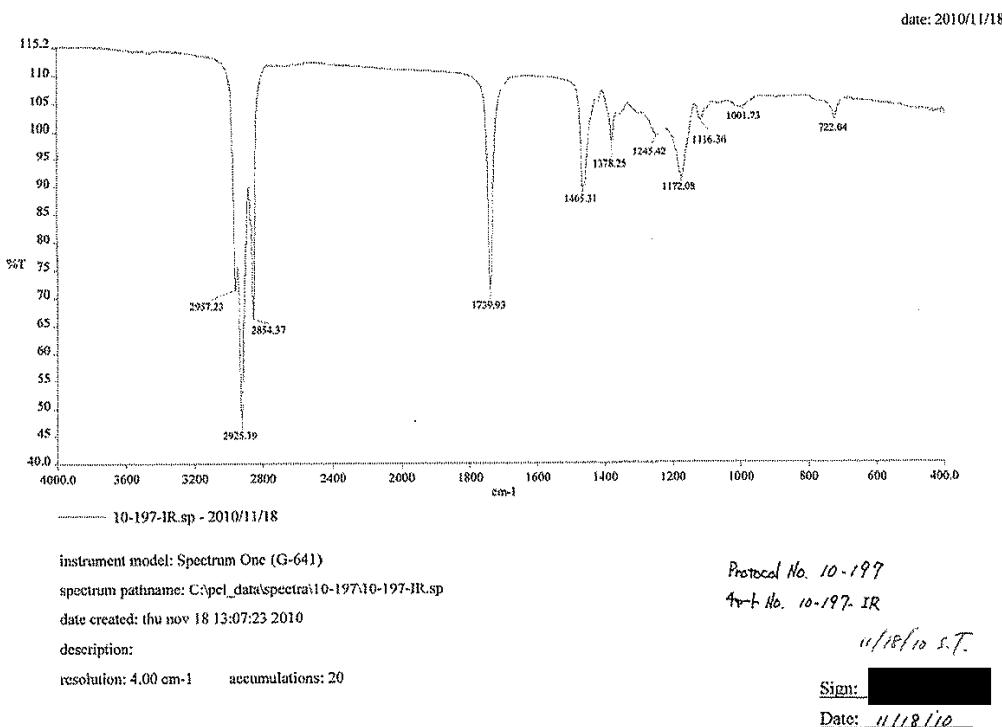


図 2 同一性確認時の標準物質のIRスペクトル

(試験番号 NCAS 10-197 の IR スペクトル)

■ 110204.rdb (ITDS): "Linear" Regression ("1 / x" weighting):  $y = 6.947e+004 x + -176.2$  ( $r = 0.99989$ )

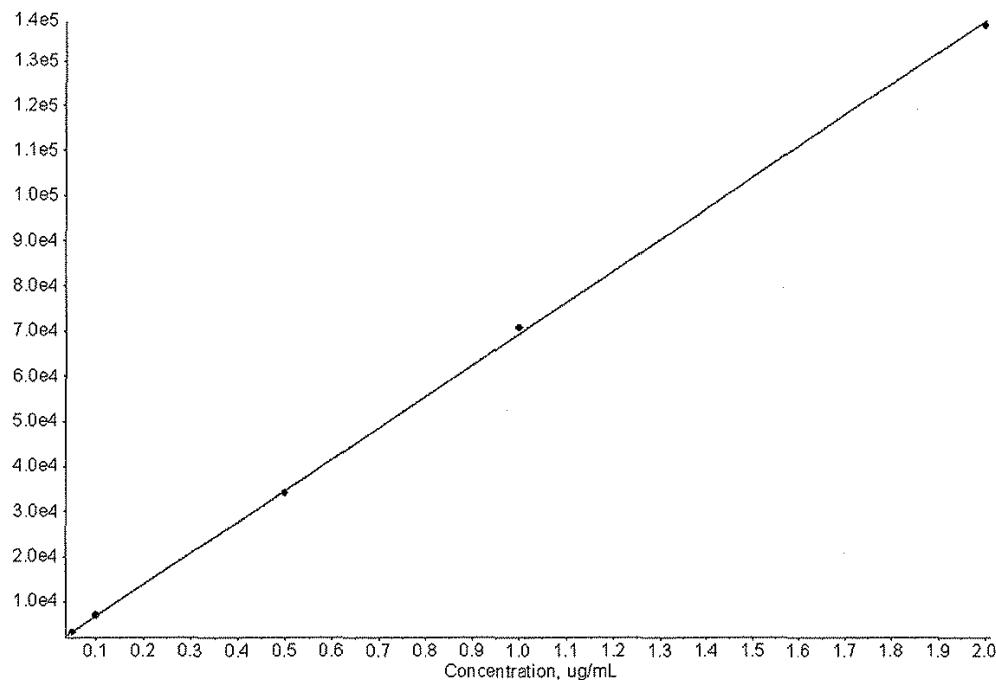


図 3 検量線(2011年2月4日測定)

■ 110324.rdb (ITDS): "Linear" Regression ("1 / x" weighting):  $y = 8.948e+004 x + -523.3$  ( $r = 0.99988$ )

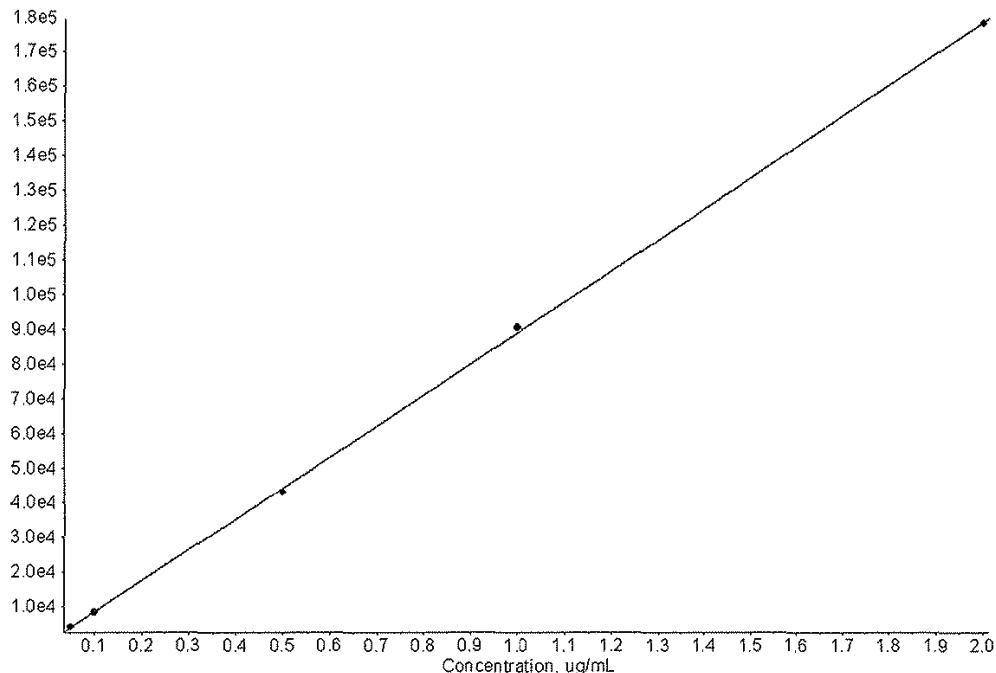


図 4 検量線(2011年3月24日測定)

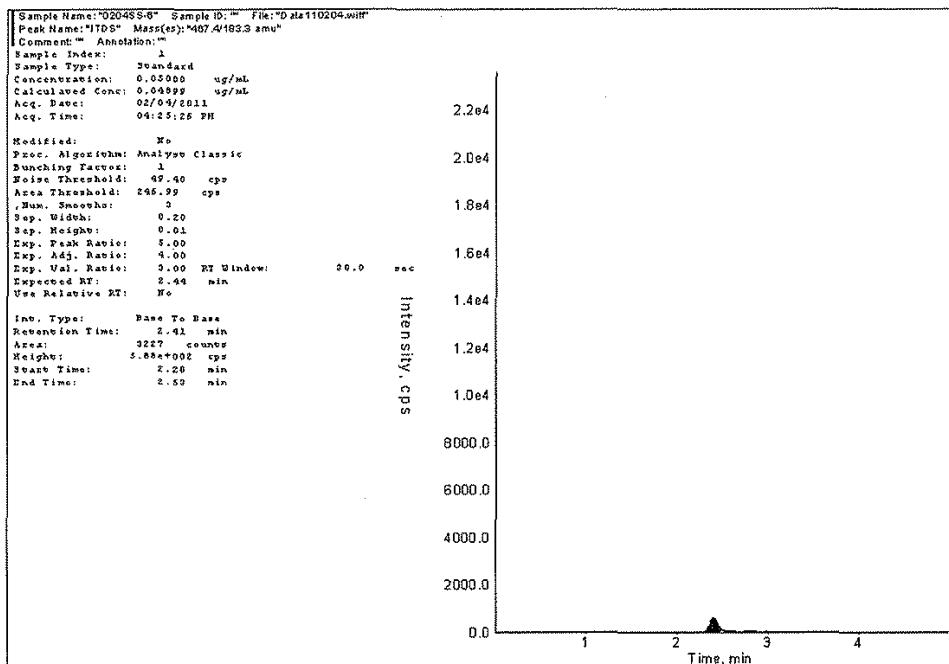


図 5 標準溶液の代表的な LC/MS/MS クロマトグラム(標準溶液 No. : 0204SS-6、0.05000 µg/mL)

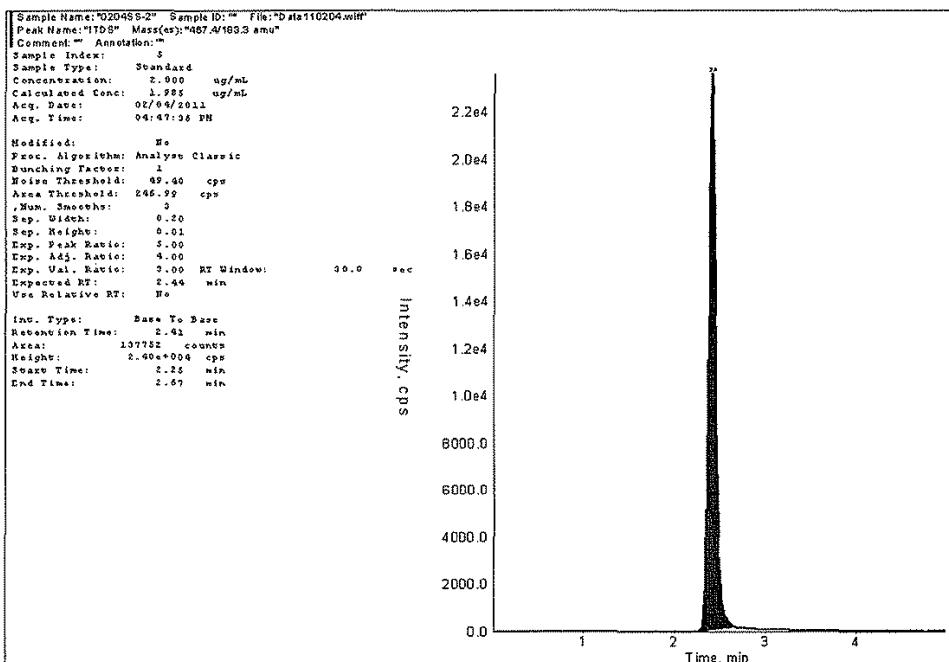


図 6 標準溶液の代表的な LC/MS/MS クロマトグラム(標準溶液 No. : 0204SS-2、2.000 µg/mL)

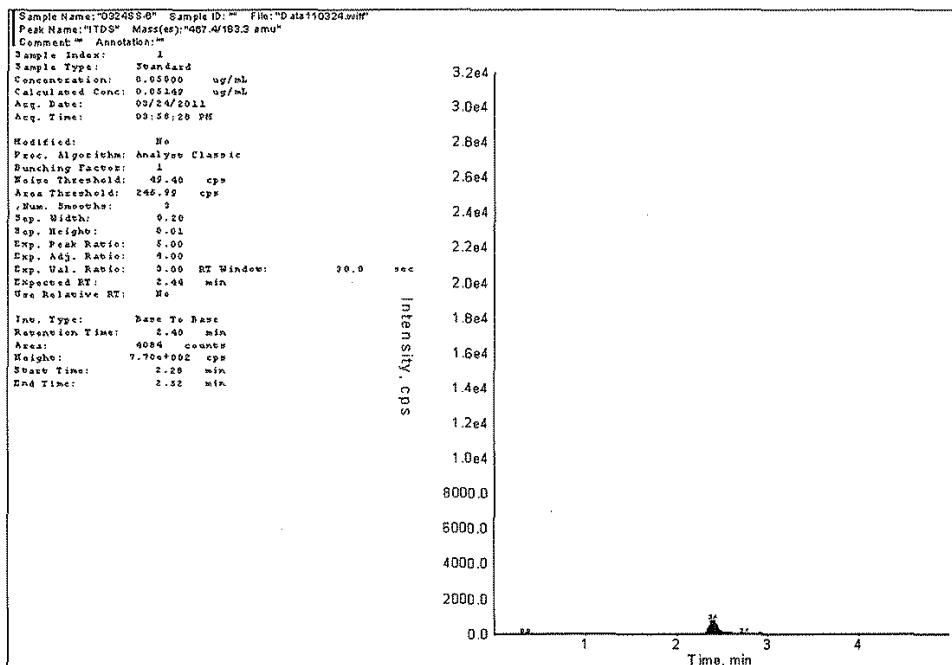


図 7 標準溶液の代表的な LC/MS/MS クロマトグラム(標準溶液 No. : 0324SS-6、0.05000 µg/mL)

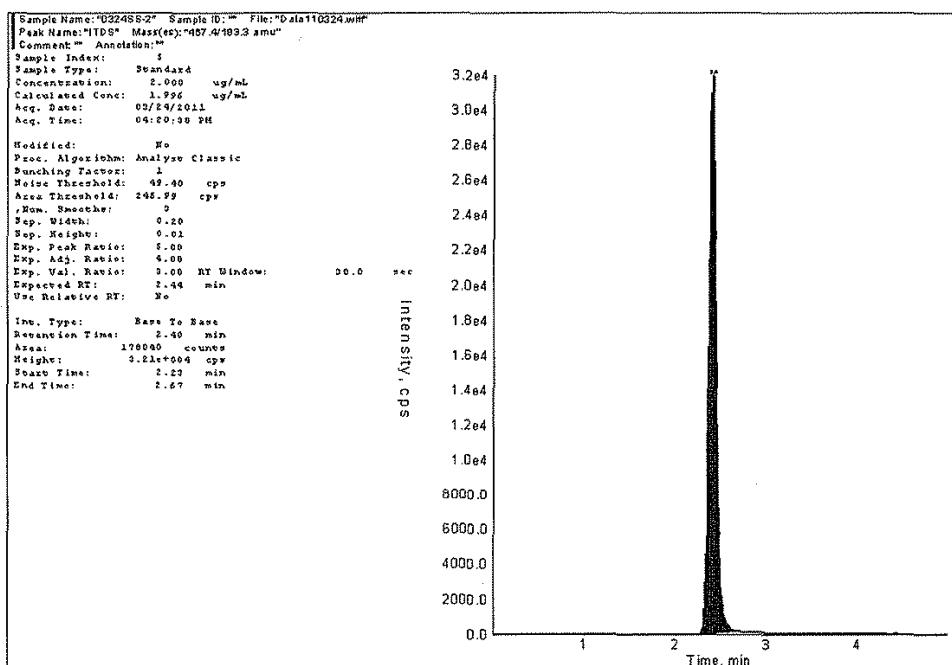


図 8 標準溶液の代表的な LC/MS/MS クロマトグラム(標準溶液 No. : 0324SS-2、2.000 µg/mL)

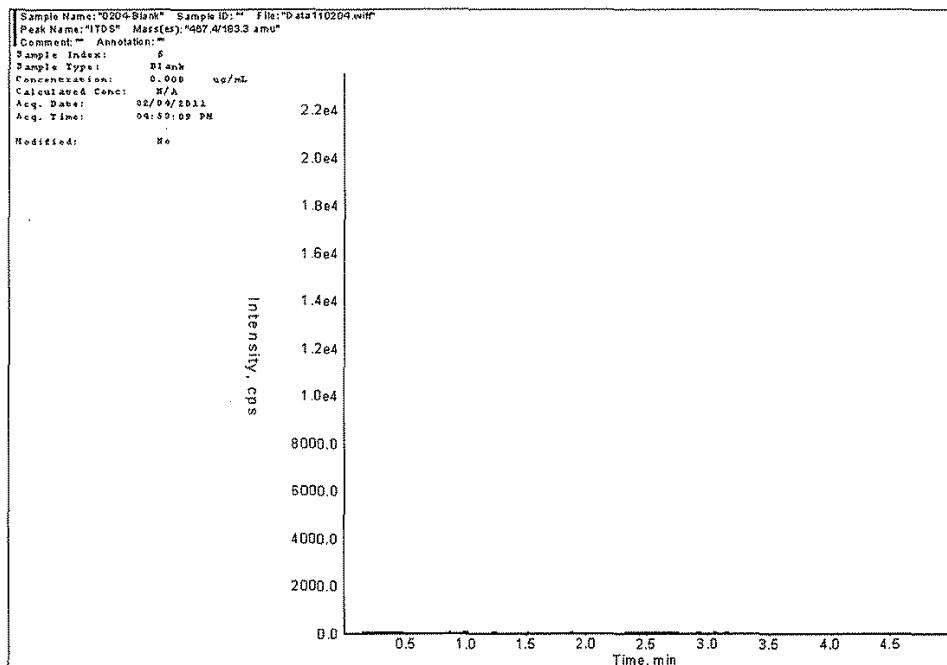


図 9 ブランク溶液の LC/MS/MS クロマトグラム(試料 ID : 0204-Blank)

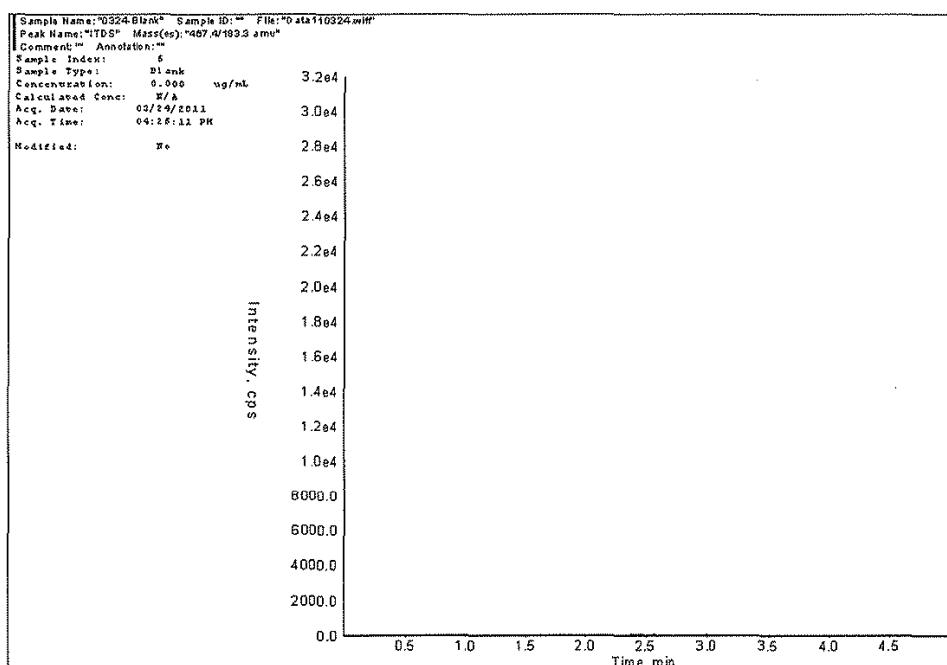


図 10 ブランク溶液の LC/MS/MS クロマトグラム(試料 ID : 0324-Blank)

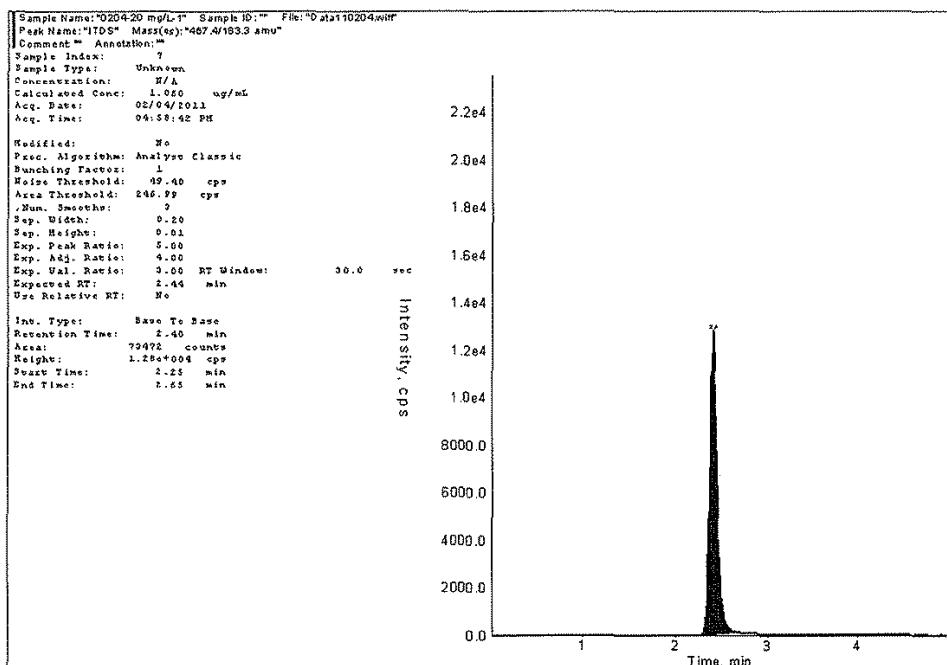


図 11 試料溶液の代表的なクロマトグラム(試料 ID:0204-20 mg/mL)

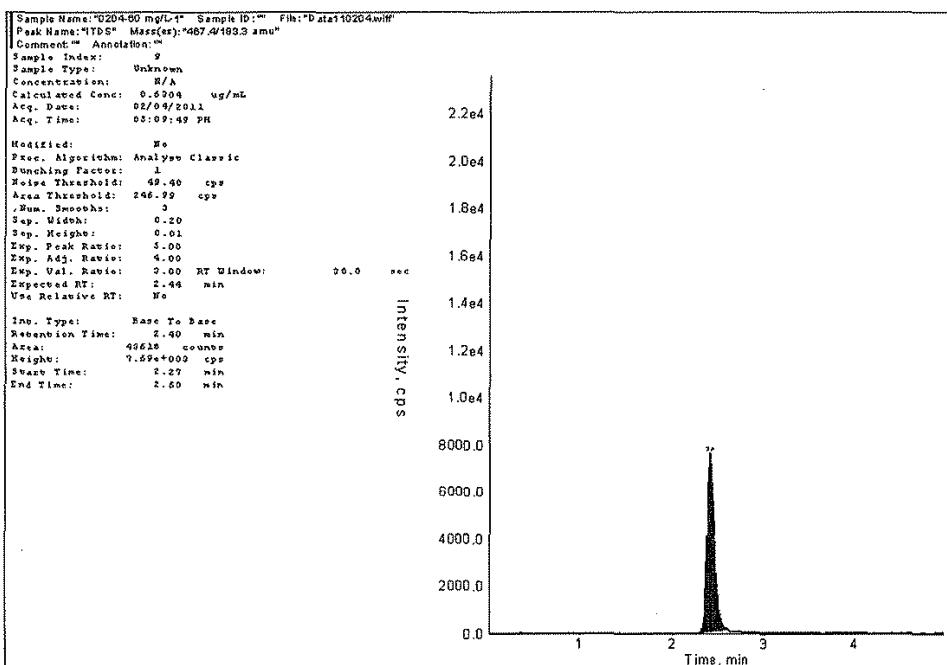


図 12 試料溶液の代表的なクロマトグラム(試料 ID:0204-60 mg/mL)

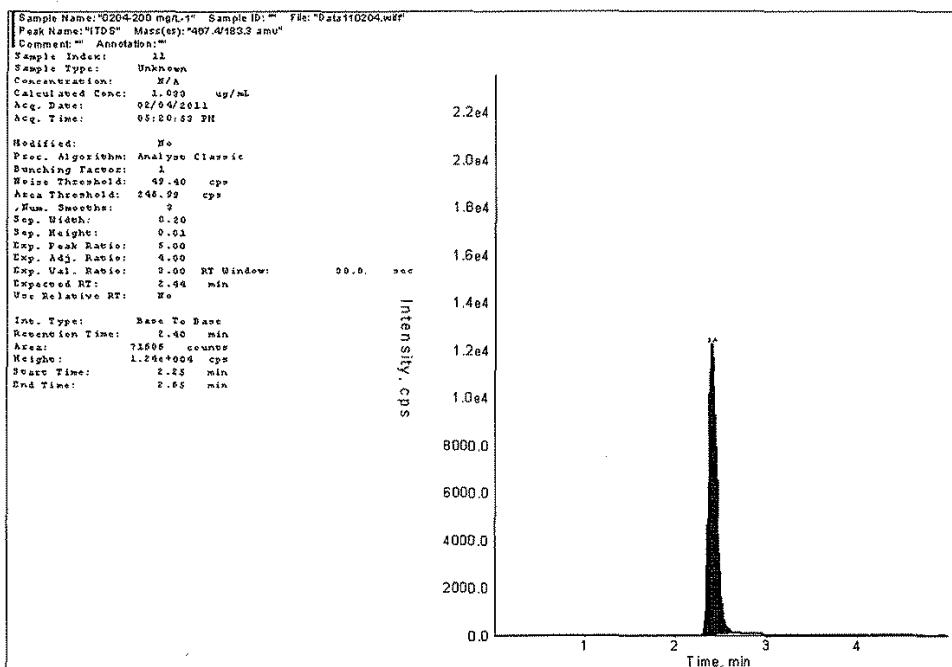


図 13 試料溶液の代表的なクロマトグラム(試料 ID:0204-200 mg/mL-1)

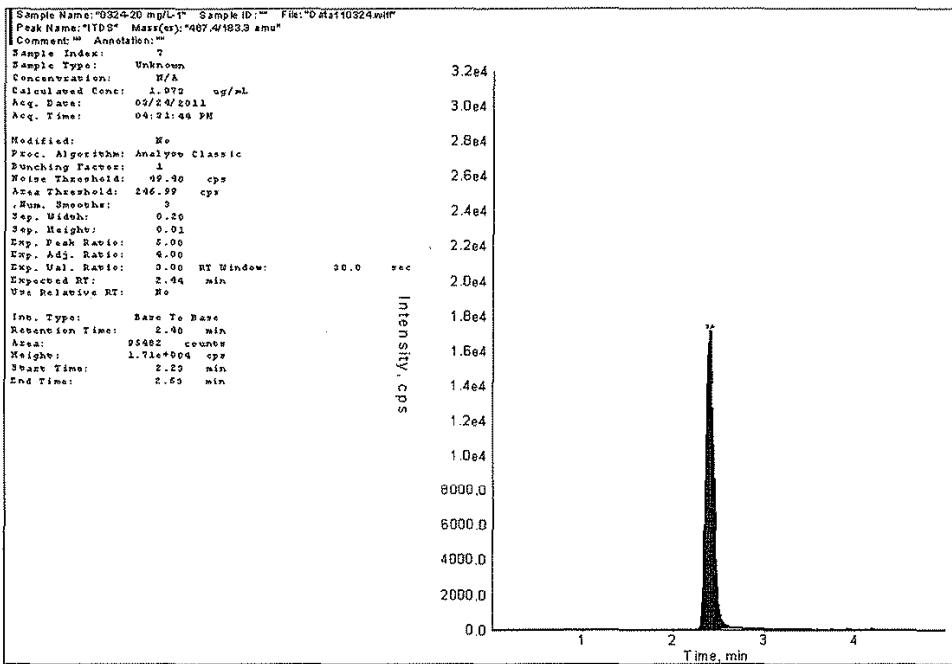


図 14 試料溶液の代表的なクロマトグラム(試料 ID:0324-20 mg/mL-1)

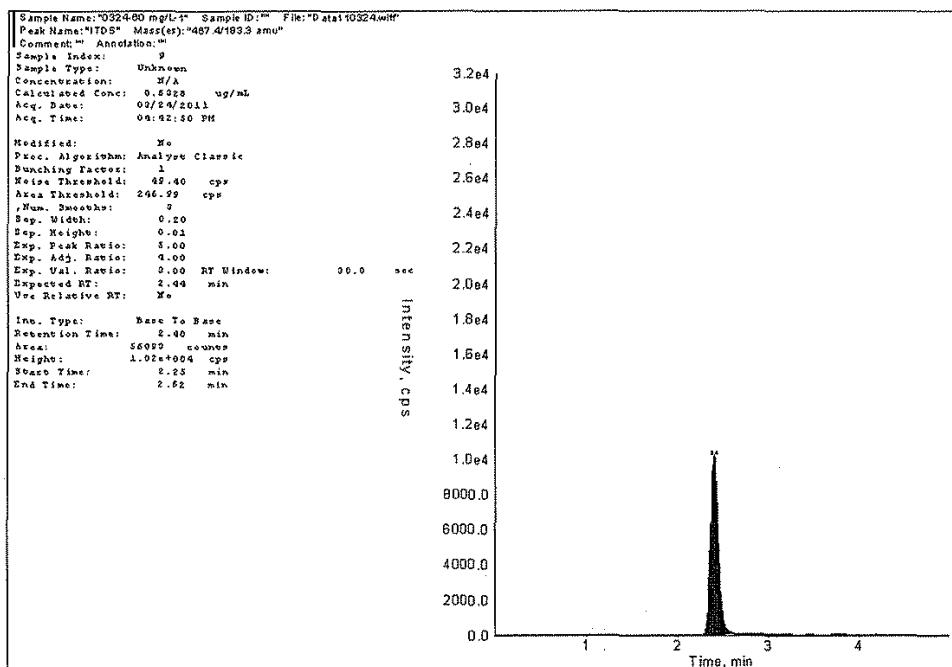


図 15 試料溶液の代表的なクロマトグラム(試料 ID:0324-60 mg/mL-1)

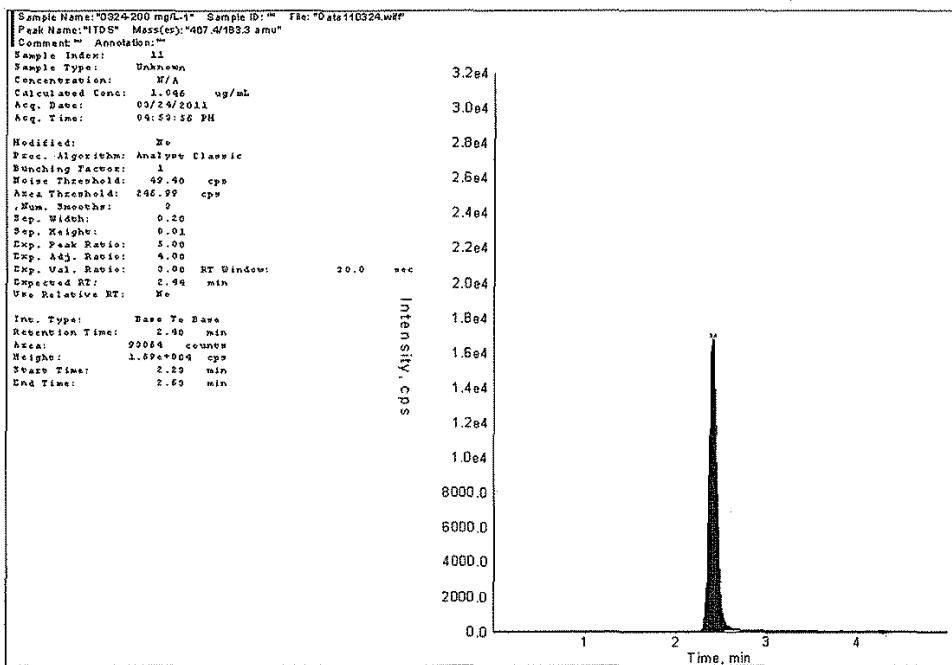


図 16 試料溶液の代表的なクロマトグラム(試料 ID:0324-200 mg/mL-1)