

最終報告書

2-Decyltetradecanolのラットを用いる
反復投与毒性・生殖発生毒性併合試験

厚生労働省医薬食品局審査管理課 化学物質安全対策室 委託

試験施設

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試験番号 R-12-016

被験物質 2-Decyltetradecanol

試験項目 反復投与毒性ならびに生殖発生毒性試験

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試資料保管場所 秦野研究所資料保存室

被験物質保管場所 秦野研究所被験物質保存庫

保管期間 試験終了後 10 年間
その後の保管については試験委託者と協議する。

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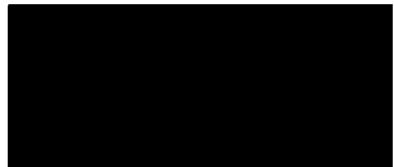
本試験は、「新規化学物質等に係る試験の方法について」(平成 23 年 3 月 31 日付け、薬食発 0331 第 7 号厚生労働省医薬食品局長、平成 23・03・29 製局第 5 号経済産業省製造産業局長、環保企発第 110331009 号環境省総合環境政策局長通知)に準拠し、「新規化学物質等に係る試験を実施する試験施設に関する基準」(平成 23 年 3 月 31 日付け、薬食発 0331 第 8 号厚生労働省医薬食品局長、平成 23・03・29 製局第 6 号経済産業省製造産業局長、環保企発第 110331010 号環境省総合環境政策局長通知)を遵守して実施した。

2013 年 9 月 25 日

試験責任者 [REDACTED]

試験従事者

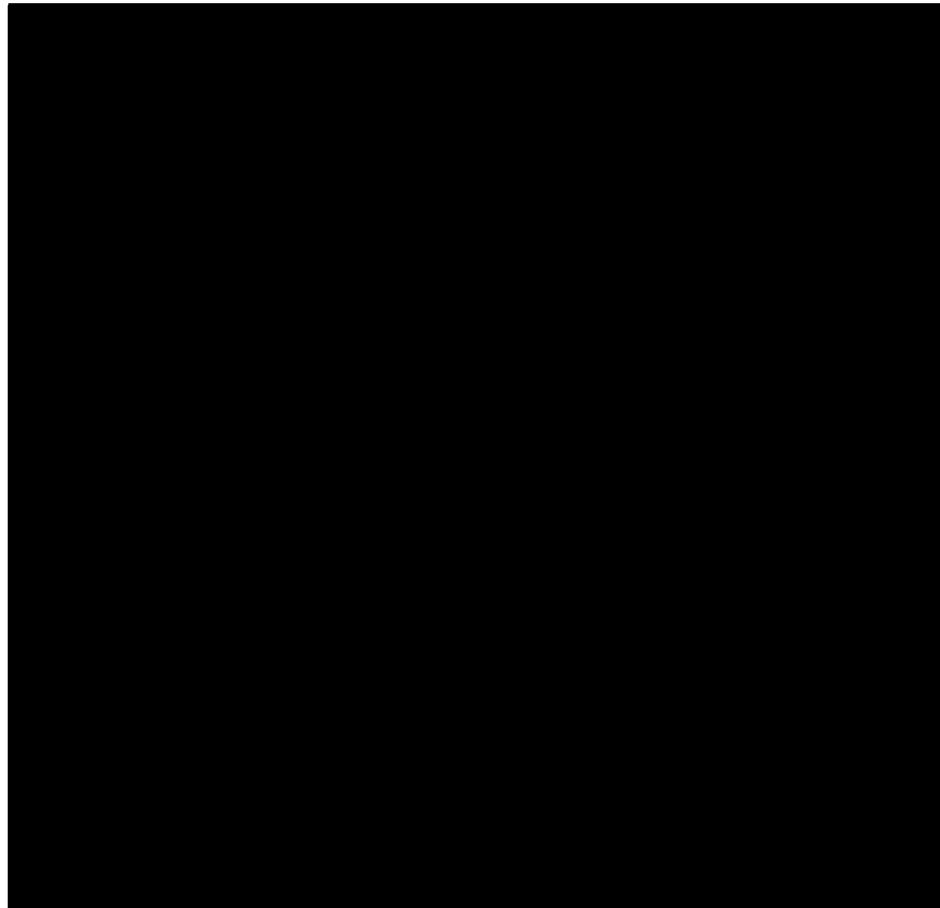
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投与観察



動物飼育管理

(検疫を含む)

血液学検査

(採血を含む)

血液生化学検査

尿 検 査

病理学検査

被験物質管理

検体調製

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信頼性保証書

要約

今回、2-decyltetradecanol の雌雄動物の反復投与毒性および回復性、ならびに生殖能力に対する影響および新生児の発育に及ぼす影響を検討することを目的として、反復投与毒性ならびに生殖発生毒性試験を化審法ガイドラインに従って実施した。被験物質をトウモロコシ油に溶解して、0、62.5、250 ならびに 1000 mg/kg の用量で、各群とも雌雄各 12 匹の Crl:CD (SD) ラットに強制経口投与した。

雄は 42 日間投与した後に剖検し、雌は交配前 2 週間および交配期間、妊娠期間を通して哺育 4 日まで 41～55 日間投与し、出生児は哺育 4 日、母動物は哺育 5 日に剖検した。また、雌の非交配群として 0 および 1000 mg/kg の用量にサテライト群(10 匹/群)を設け、42 日間投与した後に半数の 5 例を剖検した。回復性を確認するために、0 および 1000 mg/kg 群の各雄 5 匹と非交配群(サテライト群)の各雌 5 匹は、42 日間投与した後、14 日間飼育して剖検した。

1. 親動物所見

投与終了時の尿検査では、1000 mg/kg 投与群の雄で潜血陽性尿が、同群の非交配雌では尿量の減少および尿中ナトリウム、カリウム、塩素排泄量の減少が認められたが、回復期間終了時にはこれらの変化は観察されなかった。

投与終了時の血液学検査では、雄の 250 mg/kg 以上の投与群で PT が延長し、APTT は延長傾向を示した。回復期間終了時の検査では、雄の 1000 mg/kg 投与群で PT が延長傾向を示し、APTT は延長した。

投与期間終了時の血液生化学検査では、雄の 250 mg/kg 以上の投与群で LDH 活性が上昇した。回復期間終了時の検査では、雄の 1000 mg/kg 投与群で LDH 活性の上昇傾向が観察された。

2. 生殖発生毒性学的所見および出生児所見

生殖発生毒性は認められず、出生児にも被験物質投与による影響は認められなかった。

3. 無毒性量

以上の結果から、本試験条件下における 2-decyltetradecanol の親動物に対する反復投与毒性の無毒性量は、雄では腎臓および血液凝固系への影響が 250 mg/kg 以上の投与群で認められたことから 62.5 mg/kg/day、雌では腎臓への影響が 1000 mg/kg 投与群でみられたことから 250 mg/kg/day と判断した。生殖発生毒性の無毒性量および次世代児に対する無毒性量は、いずれの投与群にも被験物質投与による影響はみられなかつたことから 1000 mg/kg/day と考えられた。

また、一般毒性学的变化は 14 日間の回復期間後でも消失しなかつたが、投与終了時と比較して变化の程度が軽度になっていることから、回復性を示す変化であると考えられた。

試験目的

雌雄ラットの交配前(2週間)および交配期間中(最長2週間)、ならびに雄では交配期間終了後2週間(投与日数:42日間)、生殖能を評価した交配雌では妊娠期間を通して周産期(哺育4日まで、投与日数:41~55日間)に、非交配群(サテライト群)では雄と同様の期間に、2-decyltetradecanolを強制経口投与し、雌雄ラットに対する反復投与毒性および回復性、ならびに生殖発生毒性および新生児の発育に及ぼす影響について検討した。

試験ガイドラインと GLP

本試験は、「新規化学物質等に係る試験の方法について:以下、化審法ガイドライン」(平成23年3月31日付け、薬食発0331第7号厚生労働省医薬食品局長、平成23・03・29製局第5号経済産業省製造産業局長、環保企発第110331009号環境省総合環境政策局長通知)に準拠し、「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」(平成23年3月31日付け、薬食発0331第8号厚生労働省医薬食品局長、平成23・03・29製局第6号経済産業省製造産業局長、環保企発第110331010号環境省総合環境政策局長通知)を遵守して実施した。

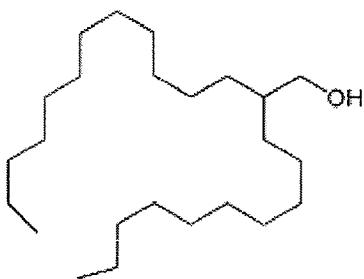
動物愛護

全ての実験操作は、「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、平成24年9月5日一部改正)、「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)および「厚生労働省の所管する実施機関における動物実験等の実施に関する基本指針」(平成18年6月1日、科発第0601001号)を遵守し、「財団法人食品药品安全センター秦野研究所動物実験に関する指針」(平成2年10月1日、平成22年10月1日改正)に基づいて実施した。本試験における動物実験計画は、秦野研究所動物実験委員会の審査を受け、承認されている(動物実験承認番号:1120249A)。なお、承認された動物実験計画からの変更はなかった。

材料と方法

1. 被験物質

被験物質である2-decyltetradecanol(別名:2-デシル-1-テトラデカノール、デシルテトラデカノール、CAS No. 58670-89-6、分子式:C₂₄H₅₀O、分子量:354.65、性状:粘性のある無色液体、融点:17~20°C、沸点:271~275°C/33 mmHg、密度:0.842 g/mL(25°C)、ロット番号:08403DOV、純度:98.4%(GC)、Annex A、以下、2-DT)は、[REDACTED]より購入し(被験物質入手:2012年7月6日)、使用時まで冷蔵、密閉(実測値3~8°C)で保管した。2-DTの構造式を次に示す。



被験物質の安定性については、実験開始前および実験終了後に秦野研究所にて赤外吸収スペクトルを測定し、スペクトルに変化がないことを他試験(試験番号:M-12-023)で確認した。

2. 動物および飼育方法

日本チャールス・リバー厚木飼育センターより 8 週齢の Sprague-Dawley (SD) 系 [Crl:CD(SD)、SPF] ラット雄 55 匹、雌 83 匹を購入し、飼育室(17 号室)に収容した。入荷日も含めて 15 日間、検疫と飼育環境への馴化のため飼育した。その間毎日、動物の一般状態を観察し、入荷日(検疫 1 日)および検疫終了日に体重を測定した。検疫・馴化期間中は動物の尾に赤のフェルトペンで馴化番号を記し、飼育ケージに試験番号および馴化番号を記入した動物カードを掛けて識別した。また、雌動物については、検疫 3 日から毎日、性周期を観察した。入荷動物の入荷時および検疫終了時の体重は下記の通りであった。なお、検疫期間終了日に全ての動物を 12 号室へ移動した。

動物入荷日 : 2012 年 11 月 19 日

入荷時体重 : 雄 268.4～295.2 g、雌 182.9～211.1 g

検疫終了日 : 2012 年 12 月 3 日

検疫終了時体重 : 雄 342.9～448.9 g、雌 206.9～281.0 g

検疫・馴化期間中、雄の 1 例(馴化番号 M00053)で痩せが観察され、検疫期間中の体重増加量も他の動物に比較して少なかった。また、雌 2 例(馴化番号 F00009 および F00050)でそれぞれ紅涙および眼球白濁が観察された。これ以外の動物に一般状態、詳細な症状観察および体重推移に試験実施に影響を及ぼすと判断される異常は認められなかった。異常が認められた雄 1 例雌 2 例および規則的な性周期の回帰が認められない 7 匹を除外し、検疫終了時の体重を基に体重別層化無作為抽出法により群分けを行った。群分けした動物には一連の動物番号を割り当て、フェルトペンで尾に動物番号を標識し、色彩の異なる動物カードに試験番号および動物番号を記入して飼育ケージに掛けた。初回投与時(2012 年 12 月 4 日)に高用量群(サテライト群)の 1 例(動物番号 F06068)において、ゾンデを飲み込まれ摘出不能となつたために(誤投与)、余剰動物から一般状態、性周期に異常がなく、当該例に体重が近似した動物を 1 例(馴化番号 F00024)選出し試験に供した。その他の群分けから棄却した雄動物 7 匹、雌動物 14 匹(性周期の結果により除外した例を含む)は全て余剰動物とし、他目的に転用した。

動物は許容温度 21.0～25.0°C、許容湿度 40.0～75.0 %、換気設定約 15 回/時間、明暗サイクル 12 時間(7 時～19 時)点灯、12 時間(19 時～7 時)消灯に設定された飼育室内で、金属製金網床ケージ

(220w×270d×190h mm)に1匹ずつ(交配時は2匹)収容し、固型飼料(CE-2、日本クレア)と水道水(秦野市水道局給水)を自由に摂取させて飼育した(ただし、雄動物、分娩した雌動物ならびにサテライト群の動物は、解剖前に絶食させた)。雌動物は分娩例全例について、妊娠18日から哺育4日までラット用プラスチック製繁殖ケージ(350w×400d×180h mm)に1匹ずつ収容し、床敷として紙パルプ製チップ(ペパークリーン、日本エスエルシー)を適宜供給した。飼育期間中の動物室の温度は22.0~25.5°C、湿度は46.0~66.0%であった。また、供給した飼料、飲料水および床敷の分析結果は、いずれも標準操作手順書に記載の許容範囲内であることを確認した。

3. 投与検体

1) 調製

被験物質を秤量し、媒体(トウモロコシ油、製造元:ナカライトスク、製造番号:V2K9025)を加え搅拌混和させ、25 w/v%液を調製した。さらに25 w/v%液を媒体によって希釈し、6.25ならびに1.5625 w/v%液を段階的に調製した。調製した検体は冷蔵・遮光下(実測値2~12°C)で保管し、安定性の保証期間内に使用した。

2) 安定性試験

トウモロコシ油を媒体とした1.5625および25 w/v%濃度の調製検体について、冷蔵、遮光条件下(実測値3~5°C)における8日間の安定性を確認した(安定性試験開始日:2012年11月21日、調製後8日:2012年11月29日)。その結果、各試料採取時点(調製直後および調製後8日)の平均含量がそれぞれ調製濃度の93.5~102.9%であり、各測定値のばらつきがそれぞれ平均値の95.5~105.9%であり、かつ、調製直後の測定平均値に対する調製後8日の残存率の平均値が95.1および96.8%であり、いずれも規定範囲内にあった(Annex B)。

3) 含量試験

初回調製検体(調製日:2012年12月3日)について、1.5625、6.25および25 w/v%濃度の被験物質含量を測定した。その結果、平均含量は調製濃度の98.9~101.3%であり、各測定値のばらつきはそれぞれ平均値の93.8~104.8%で規定範囲内にあった(Annex C)。

調製検体中の被験物質濃度は以下の方法で測定した。投与検体の1mLを正確にとり、アセトンで適宜希釈し、検量線の範囲内となるように試料溶液を調製した。これらの試料溶液と内部標準溶液(IS溶液)を1:1(v/v)の割合で混合し、測定用試料溶液とした。測定用試料溶液は、投与検体の採取からn=3で調製した。

試料溶液および標準溶液を以下に示すガスクロマトグラフィーにより測定し、標準溶液から作成した検量線を用いて調製検体中の2-DT濃度を算出した。

ガスクロマトグラフ測定条件

検出器	水素炎イオン化検出器(FID)
分析カラム	DB-5(長さ30m、内径0.32mm、膜厚0.25μm、J&W Scientific)

キャリヤガス	ヘリウム
カラム温度	測定用標準溶液:200°C(0 分)→30°C/分→320°C(1.5 分) 測定用試料溶液:200°C(0 分)→30°C/分→320°C(10 分)
注入口設定温度	300°C
検出器設定温度	320°C
試料注入量	3.0 μL
試料注入方式	スプリット
オートインジェクタ洗浄液	アセトン
モニター時間	5.5 分
システムの適合性	分析開始前に測定用標準溶液(約 100 μg/mL)を 3 回測定し、2-DT のピーク保持時間および IS に対するピーク面積比の相対標準偏差(%)を確認した。相対標準偏差の許容基準は、ピーク保持時間が±3.0%以内、ピーク面積比が±5.0%以内とした。

4. 投与量の設定および投与方法

本試験の投与量は、「2-Decyltetradecanol のラットを用いる反復投与毒性・生殖発生毒性併合試験（予備試験）」（試験番号：R-12-015）¹⁾の結果をもとに設定した。すなわち、0（媒体：トウモロコシ油）、100、300 および 1000 mg/kg の 2-DT を 8 週齢の雌雄各 3 匹の SD 系ラットに 14 日間、反復強制経口投与した。なお、予備試験で使用した被験物質および媒体は本試験と同じロットを用いた。

その結果、雌雄ともに 1000 mg/kg 投与群においても、一般状態、体重、血液学検査、血液生化学検査、病理学検査に被験物質投与による影響は認められなかった。したがって、最高投与限度用量である 1000 mg/kg を本試験における高用量群の投与量に設定し、以下、公比 4 で減じて、250 mg/kg を中用量、62.5 mg/kg を低用量に設定した。

本試験では、雄動物は交配前 2 週間、交配期間を通して剖検前日まで（総投与回数 42 回）、雌動物は交配前 2 週間、交配期間、妊娠期間を通して分娩後の哺育 4 日まで（総投与回数 41～55 回）、交尾が確認されなかった雌は剖検前日まで（総投与回数 52 回）、非交配雌の反復毒性を評価するために設定したサテライト群は投与 42 日まで、1 日 1 回、1 週 7 回、毎日 9 時～13 時の間（9 時 13 分～11 時 45 分）に投与した。投与容量は 4 mL/kg とし、雌雄とも最新の測定日の体重をもとに投与液量を算出した。なお、対照群には媒体であるトウモロコシ油を同様に投与した。投与経路は化審法ガイドラインに拠り、ラット用胃管による強制経口投与とした。

本試験の群構成および動物番号を次頁に示した。

群	投与物質	投与量 (mg/kg)	濃度 (w/v%)	投与容量 (mL/kg)	動物番号	
					雄	雌
対照群	トウモロコシ油 (媒体)	0	0	4	M01001～M01012 ^a	F01001～F01012
低用量群	2-DT	62.5	1.5625	4	M02013～M02024	F02013～F02024
中用量群	2-DT	250	6.25	4	M03025～M03036	F03025～F03036
高用量群	2-DT	1000	25	4	M04037～M04048 ^a	F04037～F04048
対照群 (サテライト群)	トウモロコシ油 (媒体)	0	0	4	-	F05049～F05058 ^a
高用量群 (サテライト群)	2-DT	1000	25	4	-	F06059～F06069 ^{a, b}

a:雄の対照群および高用量群、雌のサテライト群の動物番号の大きい各 5 例は回復観察に供した。

b:動物番号 F06068 は投与初日の誤投与により評価対象から除外し、動物番号 F06069 を追加した。

5. 検査法

1) 親動物(F₀)

①一般状態の観察

全例について、飼育期間中は毎日 1 回、投与期間中は投与前後の毎日 2 回以上観察した。

②回復および遅発毒性の観察

雄動物は対照群および高用量群のうち動物番号の大きい各 5 例を、雌動物はサテライト群の動物番号の大きい各 5 例を最終投与翌日(回復 1 日)から 14 日間、毎日 1 回以上、一般状態を観察した。

③詳細な症状観察

全例について、検疫終了日、投与 8、15、24、30、36 および 42 日(分娩例は哺育 0 日から 4 日の間)、投与 49 日までに分娩しなかった例(未交尾例を含む)は投与 49 日にも、回復期間中は回復 7 および 14 日にスコアリング法による詳細な症状観察を行った。観察は、いずれも 13 時～17 時の間(13 時 07 分～15 時 06 分)に行った。

まず、ケージ越しでの観察を行い、ケージから取り出す際に外表を観察し、作業台上での観察を行った。作業台上では、体位、姿勢、探索行動、立毛、眼裂、振戦、痙攣、呼吸数、歩行、常同行動、奇妙な行動、挙尾反応、身づくろい、発声、排尿、排便、接触に対する反応、撤去反射、耳介反射を観察した。

④機能検査

雄の各群の動物番号の若い 5 例では、投与 39 日に自発運動測定と握力測定を実施し、投与 42 日に詳細な症状観察に引き続いて刺激に対する感覚運動反応を検査した。分娩例については投与期間が近接し、分娩から日数が経過した各群の 5 例を選び、投与最終週に自発運動測定、握力測定および刺激に対する感覚運動反応を検査した。サテライト群の動物番号の若い 5 例では、投与 41 日に自発運動測定と握力測定を実施し、投与 42 日に詳細な症状観察に引き続いて刺激に対する感覚運動反応を検査した。

なお、投与最終週に実施した握力測定では、2-DT 投与群の雄で前肢握力に統計学的な有意差

が認められたため、回復 14 日の詳細な症状観察後に雄の握力を測定した。また、投与最終週に実施した自発運動量測定では、2-DT 投与群の雄で自発運動量(区画移動数)に統計学的な有意差が認められたが、用量依存的な変化ではなく、被験物質投与の影響ではないと判断したため、回復期間中の検査は実施しなかった。

(1) 刺激に対する感覚運動反応

プライエル反応、瞳孔反射、視覚定位、驚愕反応、後肢引込み反射、眼瞼(瞬目)反射、正向反射の有無を検査した。

(2) 握力測定

小動物握力測定システムを用いて握力を測定した。各動物の前肢および後肢の握力をそれぞれ 5 回測定し、最高値および最低値を除外した 3 回の握力値の平均値を求めた。

(3) 自発運動測定

自発運動量測定装置(SUPER-MEX、室町機器)を用いて、20 分間の自発運動量(区画移動数および立ち上がり回数)を計測し、計測値は 5 分毎に集計した。試験対象動物は、検査直前に別室の装置設置場所に運搬し、速やかに自発運動測定を開始した。

⑤体重測定

雄および雌動物のサテライト群は、投与 1(投与開始日)、4、7、14、21、28、35、42 日、回復 1、7、14 日および剖検日に測定した。雌動物は投与 1、4、7、14 日、妊娠 0、7、14、20 日、哺育 0、4 日および剖検日に測定し、未交尾例は投与 21、28、35、42、49 日および剖検日に測定した。

⑥摂餌量測定

雄および雌動物のサテライト群は、投与 1~2、7~8、14~15、29~30、35~36、41~42 日、回復 6~7、12~13 日に測定し、サテライト群は投与 21~22 日にも測定した。雌動物は投与 1~2、7~8、14~15 日および妊娠 0~1、7~8、14~15、20~21 日ならびに哺育 3~4 日に測定し、未交尾例は投与 29~30、35~36、41~42、48~49 日にも測定した。

⑦尿検査

雄動物および雌動物のサテライト群を検査対象とし、投与 37 日の検査では各群の動物番号が若い 5 例、また、回復 13 日における検査では回復例全例を検査した。

投与 37 日の検査では当日の投与後に、回復 13 日の検査では一般状態の観察終了後に動物を代謝ケージに収容し、以下の項目について検査した。ただし、色調・濁度、試験紙による検査および尿沈渣は、採尿開始後約 4~8 時間の時点で採取した蓄尿で、その他の項目は約 24 時間の蓄尿を行った。

項目	測定法	使用機器
色調・濁度	視診	
pH・潜血・蛋白・糖・ケトン体	試験紙法	オーションイレブン AE-4020(アークレイ)
ウロビリノーゲン・ビリルビン	同上	同上
沈渣	鏡検	光学顕微鏡
尿量	計量	メスシリンドー等
比重	屈折法	デジタル臨床屈折計 SU-202(エルマ販売)
ナトリウムイオン濃度	イオン電極法	全自动電解質分析装置 EA05(エイアンドティー)
カリウムイオン濃度	同上	同上
塩素イオン濃度	同上	同上

⑧性周期観察

全例の雌について、検疫 3 日から性周期を観察し、群分け後、投与開始以降も引き続きサテライト群を除く全例の膣スメア標本を作製し、各動物の同居後、交尾が確認されるまで性周期を観察した。また、群ごとの平均発情回帰日数(個体ごとの発情期から発情期までの日数の平均)および投与開始後に 4 あるいは 5 日間隔の性周期がそれ以外の性周期に変化した動物の頻度を群毎に算出した。なお、規則的に 4~5 日の間で性周期が回帰している動物は正常と判断した。

⑨交配

投与 15 日の 16 時 05 分より同群内の雌雄を 1 対 1 で同居させた。翌朝より毎朝、膣栓を確認し、同居中の雌の膣スメア標本を作製して鏡検した。膣内に膣栓あるいは膣スメア標本中に精子が確認された動物を交尾成立動物とし、この日を妊娠 0 日と起算して同居を解消し、個別に飼育した。交配結果および妊娠の成否により、同居開始日から交尾確認日までの日数およびその間に回帰した発情期の回数、交尾率[(交尾動物数/交配に用いた動物数) × 100, %]、妊娠率[(妊娠動物数/交尾した雌動物数) × 100, %]を算出した。

⑩妊娠・分娩・哺育状態の観察

交尾が確認された全例を自然分娩させた。分娩の確認は、妊娠 21 日相当日から分娩が確認されるまで毎日、午前と午後に観察し、15 時までに分娩が完了した例について、その日を哺育 0 日(分娩日)とした。分娩状態の直接観察は観察可能な動物について行い、直接観察できなかった動物についても、分娩後の一般状態および産児の状態から異常の有無を判断した。分娩後は、哺育状態を哺育 1~4 日の間、毎日観察した。分娩した全例の妊娠期間(妊娠 0 日から分娩日までの日数)を求めた。哺育 5 日の剖検時に卵巣については実体顕微鏡下で妊娠黄体数を、子宮については着床数を数え、着床率[(着床数/妊娠黄体数) × 100, %]を算出した。

⑪採血

雄の投与終了時剖検では各群の動物番号が若い 5 例、回復 15 日における剖検では回復観察に供した全例について採血を行った。また、分娩雌の投与終了時剖検では、哺育 5 日に投与期間が近接した各群の 5 例について採血を行った。サテライト群の投与終了時剖検では各群の動物番号が若い 5 例、回復 15 日における剖検では回復観察に供した全例について採血を行った。いずれも解剖前 18~22 時間絶食させた後、腹部後大静脈から以下の(1)、(2)、(3)の順に注射筒を換えて採血した。

- (1) 血液学検査用:抗凝固剤 EDTA-2K
- (2) 血液学検査用:抗凝固剤 クエン酸ナトリウム
- (3) 血液生化学検査用:抗凝固剤 ヘパリン

⑫血液学検査

採血対象動物について以下の項目を検査した。抗凝固剤としてクエン酸ナトリウムを用いて採取した血液から血漿を分離して、プロトロンビン時間および活性化部分トロンボプラスチン時間を測定し、その他の項目は抗凝固剤として EDTA-2K を用いて採取した血液で測定した。

項目	測定法	使用機器
赤血球数(RBC)	電気抵抗検出法	血液自動分析装置 XT-2000iV(シスメックス)
白血球数(WBC)	半導体レーザを用いたフローサイトメトリー法	同上
白血球分類	同上	同上
網状赤血球比率(RET%)	同上	同上
血色素量(HGB)	SLSヘモグロビン法	同上
平均赤血球容積(MCV)	計算(HCT×1000/RBC)	同上
血小板数(PLT)	電気抵抗検出法	同上
ヘマトクリット値(HCT)	同上	同上
平均赤血球血色素量(MCH)	計算(HGB×1000/RBC)	同上
平均赤血球血色素濃度(MCHC)	計算(HGB×100/HCT)	同上
活性化部分トロンボプラスチン時間(APTT)	光散乱検出法	全自動血液凝固測定装置 CA-1000(シスメックス)
プロトロンビン時間(PT)	同上	同上

⑬血液生化学検査

採血対象動物について以下の項目を検査した。抗凝固剤としてヘパリンを用いて採取した血液から血漿を分離して測定した。なお、得られた血漿の一部は甲状腺機能に関するホルモン(T3、T4 およびTSH)測定用として凍結保存(-70°C以下)したが、甲状腺の病理学検査およびその他全ての検査項目の結果から、本被験物質は甲状腺機能に影響を及ぼさないと判断されたため、甲状腺ホルモン測定は実施しなかった。

項目	測定法	使用機器
総蛋白濃度(TP)	ピュレット法	自動分析装置 JCA-BM6010(日本電子)
アルブミン濃度(rALB)	BCG法	同上
グルコース濃度(Glc)	ヘキソキナーゼ・G-6-PDH法	同上
総コレステロール濃度(TC)	コレステロールオキシダーゼ・HMMPS法	同上
トリグリセライド濃度(TG)	GPO・HMMPS法、グリセリン消去法	同上
リン脂質濃度(PL)	コリンオキシダーゼ・DAOS法	同上
尿素窒素濃度(BUN)	ウレアーゼ・GOD法,ウレアーゼ律速系	同上
クレアチニン濃度(cre)	Jaffé法	同上
γ-グルタミルトランスペプチダーゼ活性(γ-GTP)	IFCC法	同上
アルカリ fosfatas活性(ALP)	GSCC法	同上
アスパラギン酸アミノトランスフェラーゼ活性(AST)	IFCC法	同上
アラニンアミトランスフェラーゼ活性(ALT)	IFCC法	同上
乳酸脱水素酵素活性(LDH)	JSCC標準化対応法	同上
カルシウム濃度(Ca)	OCPC法	同上
総ヒルビン濃度(tbil)	酵素法	同上
無機リン濃度(IP)	モリブデン酸直接法	同上
胆汁酸濃度(TBA)	酵素サイクリング法	同上
A/G比	計算(rALB/(TP-rALB))	同上
ナトリウムイオン濃度(Na)	イオン電極法	全自动電解質分析装置 EA05(エイアンドティー)
カリウムイオン濃度(K)	同上	同上
塩素イオン濃度(Cl)	同上	同上

⑭剖検および器官重量

雄動物およびサテライト群の投与終了時剖検例は投与 42 日の翌日に、雌動物の分娩例は哺育 4 日の翌日に、交尾が確認されなかった雌(対照群の 1 例:動物番号 F01005)は投与 52 日の翌日に、雄動物およびサテライト群の回復観察例は回復 15 日に、それぞれ剖検した。

血液学、血液生化学検査を実施する動物はペントバルビタールナトリウム麻酔下で採血し、これ以外の動物はペントバルビタールナトリウム麻酔下で放血致死させた。

全例について、脳、甲状腺および上皮小体、胸腺、心臓、肝臓、腎臓、脾臓、副腎、精巣、精巣上体、前立腺(腹側葉)および精嚢(凝固腺を含む)、卵巣、子宮の重量を測定した。また、全例の脳、脊髄、下垂体、眼球(ハーダー腺)、顎下腺および舌下腺、気管、甲状腺および上皮小体、胸腺、心臓、肺および気管支、肝臓、腎臓、脾臓、副腎、胃、十二指腸、空腸、回腸、盲腸、結腸、直腸、下顎リンパ節、腸間膜リンパ節、精巣、精巣上体、前立腺、精嚢および凝固腺、卵巣、子宮、腎、膀胱、大腿骨および大腿骨骨髓、骨格筋、坐骨神経、乳腺、および病変部を採取し、保存した。肺および気管支は 15 cm 水柱以下の圧力で、気管内に 10% 中性緩衝ホルマリン溶液 5 mL 以下を注入し固定してから摘出して同固定液に保存した。精巣および精巣上体はブアン液に固定(長期保存は 10% 中性緩衝ホルマリン溶液)し、その他の器官・組織は 10% 中性緩衝ホルマリン溶液に固定した。なお、未交尾例の器官重量値は評価対象から除外した。

⑮病理組織学検査

剖検した動物のうち、雄およびサテライト群の投与終了時剖検では対照群ならびに高用量群の動物番号が若い各 5 例、雌の投与終了時剖検では分娩例について哺育 5 日に投与期間が近接し可能な限り分娩から日数が経過している対照群ならびに高用量群の各 5 例について、組織学検査対象器官のヘマトキシリン・エオジン(HE)標本を作製し、病理組織学検査を実施した。

剖検時に異常がみられ、検査対象外であった動物の器官・組織(胃)に関しても同様に HE 標本を作製し、病理組織学検査を実施した。

なお、投与期間終了時屠殺例の病理組織学検査において、被験物質投与の影響が示唆された器官・組織はなかつたために回復期間終了時屠殺例の病理組織学検査を実施しなかつた。

2) 出生児(F₁)

①出生児の観察

哺育 0 日に生存児数および死亡児数を雌雄別に数えて、性別および外表奇形の有無を観察し、分娩率[(産児数/着床痕数) × 100, %]、生児出産率[(出産生児数/着床痕数) × 100, %]、出産率[(生児出産雌数/妊娠動物数) × 100, %]および出生率[(出産生児数/産児数) × 100, %]を算出した。また、哺育 0~4 日まで、毎日、一般状態を観察し、生存児数と死亡児数を雌雄別に数え、新生児生存率[(哺育 4 日の生児数/哺育 0 日の生児数) × 100, %]を算出した。生存児については、哺育 0 および 4 日に個別の体重を測定し、腹ごとに雌雄別の平均体重を算出するとともに、哺育 0 日および 4 日における性比[(雄生児数/総生児数) × 100, %]を算出した。

②剖検

死亡児は外表奇形の有無を観察して剖検し、10%中性緩衝ホルマリン溶液に固定して保存した。生存児は哺育 4 日に外表奇形の有無を観察してセボフルラン吸入麻酔下に放血致死させて剖検し、内部器官の異常の有無を観察した。

6. データの解析法

性周期の変化した動物の頻度、交尾率、受胎率については Fisher の直接確率検定を行った(有意水準:5%)。

被験物質投与群の病理組織学検査所見のうち、グレード分けしたデータは Mann-Whitney の U 検定により、また陽性グレードの合計値は Fisher の直接確率の片側検定により対照群との間の有意差検定を行った(有意水準:5%)。

その他のデータは、個体ごとに得られた値あるいは litter ごとの平均値を 1 標本とし、サテライト群内あるいはその他の群内で比較した。その際、解析の対象が 2 群の場合には、まず F 検定を行い、有意差が認められなければ Student's-t 検定を行った。F 検定において有意差が認められた場合は、Aspin-Welch 検定を行った。解析の対象が 3 群以上の場合は、先ず、Bartlett の方法により各群の分散の一様性について検定(有意水準:5%)を行った。分散が一様であった場合には、一元配置型の分散分析(有意水準:5%)を行い、群間に有意性が認められた場合は、Dunnett 法により多重比較を行った(有意水準:5%)。一方、いずれかの群で分散が 0 となった場合および分散が一様でなかった場合には、Kruskal-Wallis の順位検定(有意水準:5%)を行い、群間に有意性が認められた場合には、Dunnett 型の検定法により多重比較を行った(有意水準:5%)。

予見することができなかつた試験の信頼性に影響を及ぼす疑いのある事態及び試験計画書に従わなかつたこと

初回投与時(2012 年 12 月 4 日)に高用量群(サテライト群)の 1 例(動物番号 F06068)において、ゾンデを飲み込まれ摘出不能となつたために(誤投与)、余剰動物から一般状態、性周期に異常がなく、当該例に体重が近似した動物を 1 例(馴化番号 F00024)選出した。この動物を動物番号 F06069 として高用量群(サテライト群)に振り分け、新たに試験に供した。なお、誤投与した動物は安楽殺させ、評価対象から除外した。動物入れ換え後の体重範囲は平均体重の 20%以内に入つておらず、一般状態、体重、投与、摂餌量は全て試験計画書どおりに実施したことから、試験への影響はないと判断した。

2013 年 01 月 14 日 18:07～18:13 に暴風雪の影響と考えられる停電が発生し、この間、動物飼育室内の照明が明期に消灯した。同停電に伴い同日の 18:07～18:16 に空調が停止したために、空調起動後の温度オーバーシュートによる温度上昇がみられ(最高温度 25.5°C、逸脱時間 18:45～19:00)し、許容範囲を逸脱した。しかし、停電による照明の消灯時間は短く、温度上昇は許容範囲から僅かであった。また、その後の動物の一般状態等にも上述事象に起因したと考えられる異常は認められなかつたことか

ら、試験への影響はないと判断した。

その他、「予見することができなかつた試験の信頼性に影響を及ぼす疑いのある事態及び試験計画書に従わなかつたこと」はなかつた。

試験成績

1. 親動物

1) 一般状態 (Table 1～Table 4, Appendix 1～Appendix 4)

雌雄ともに死亡動物はみられず、一般状態の異常も観察されなかつた。

2) 詳細な症状観察 (Table 5～Table 6, Appendix 5～Appendix 6)

投与期間の観察では、常同行動としての後肢立ちが 62.5 mg/kg 投与群の雄 1 例で投与 15 日に、接触に対する反応がやや過敏な動物が 62.5 mg/kg 投与群の雄 1 例および 250 mg/kg 投与群の雌 1 例でいずれも投与 8 日に観察された。なお、後肢立ちは投与前の観察でも 1000 mg/kg 投与群の雌 1 例で認められた。その他の観察項目にはいずれの観察日にも異常は認められず、排尿および排便数にも対照群と比較して差はなかつた。

回復期間の観察では、雌雄ともにいずれの観察項目に異常は認められず、排尿および排便数にも対照群と比較して差はなかつた。

3) 体重 (Table 7～Table 10, Appendix 7～Appendix 10)

雌雄ともに対照群と 2-DT 各投与群との間で体重推移に有意差は認められなかつた。

4) 摂餌量 (Table 11～Table 14, Appendix 11～Appendix 14)

投与期間中、雄では、1000 mg/kg 投与群の投与 29 日の摂餌量に有意な増加 ($p<0.05$) が認められた。雌では、1000 mg/kg 投与群の非交配雌(サテライト群)で投与 35 日の摂餌量に有意な増加 ($p<0.01$) が認められた。分娩雌では対照群と 2-DT 各投与群との間で摂餌量に有意差は認められなかつた。

回復期間では、雌雄ともに対照群と 2-DT 投与群との間で摂餌量に有意差は認められなかつた。

5) 機能検査

① 刺激に対する感覚運動反応 (Table 15～Table 16, Appendix 15～Appendix 16)

投与最終週に実施した観察では、雌雄ともに異常は認められなかつた。

② 握力測定 (Table 17～Table 19, Appendix 17～Appendix 19)

投与最終週に実施した検査では、1000 mg/kg 投与群の雄で前肢握力に有意な減少 ($p<0.05$) が認められた。分娩雌および非交配雌(サテライト群)では、対照群と 2-DT 各投与群との間で握力(前肢および後肢)に有意差は認められなかつた。雄のみ回復 14 日に検査を実施した結果、握力(前肢および後肢)に有意差は認められなかつた。

③ 自発運動量測定 (Table 20～Table 22, Appendix 20～Appendix 22)

投与最終週に実施した検査では、250 mg/kg 投与群の雄で 0-5 分、10-15 分、0-20 分の自発運

動量(区画移動数)に有意な増加(いずれも $p<0.05$)が認められた。分娩雌および非交配雌(サテライト群)では、対照群と 2-DT 各投与群との間で自発運動量(区画移動数および立ち上がり回数)に有意差は認められなかった。なお、雄でみられた自発運動の増加は用量依存的な変化ではなく、被験物質投与の影響ではないと判断し、回復期間中の検査は実施しなかった。

6) 尿検査 (Table 23～Table 24, Appendix 23～Appendix 24)

投与最終週の検査では、1000 mg/kg 投与群の雄 1 例で潜血反応(2+)が観察された。また、非交配雌(サテライト群)の 1000 mg/kg 投与群では尿量、ナトリウム、カリウムおよび塩素イオン排泄量にそれぞれ有意な減少(いずれも $p<0.05$)が認められた。

回復期間終了時の検査では、1000 mg/kg 投与群の雄 1 例で混濁尿(+)が観察された以外に、対照群と 2-DT 投与群との間に有意差は認められず、雌雄ともに被験物質の影響を示唆する変化は認められなかった。

7) 血液学検査 (Table 25～Table 26, Appendix 25～Appendix 26)

投与期間終了時の検査では、雄の 250 および 1000 mg/kg 投与群でプロトロンビン時間(PT)が有意に延長し(それぞれ $p<0.05$ および $p<0.01$)、活性化部分トロンボプラスチン時間(ATPP)が延長傾向を示した。分娩雌では、62.5 mg/kg 投与群で好中球比率の有意な増加($p<0.01$)、単球およびリンパ球比率の有意な減少(いずれも $p<0.05$)が、250 mg/kg 投与群でもリンパ球比率の有意な減少($p<0.05$)が認められた。非交配雌(サテライト群)では、1000 mg/kg 投与群で平均赤血球容積(MCV)および平均赤血球血色素量(MCH)の有意な減少(それぞれ $p<0.05$ および $p<0.01$)が認められた。

回復期間終了時の検査では、雄の 1000 mg/kg 投与群でプロトロンビン時間(PT)が延長傾向を示し、活性化部分トロンボプラスチン時間(APTT)に有意な延長($p<0.05$)が認められた。非交配雌(サテライト群)では血液学検査結果に対照群と 2-DT 投与群との間に有意差は認められなかった。

8) 血液生化学検査 (Table 27～Table 28, Appendix 27～Appendix 28)

投与期間終了時の検査では、雄の 250 および 1000 mg/kg 投与群で乳酸脱水素酵素(LDH)活性に有意な上昇(それぞれ $p<0.05$ および $p<0.01$)が観察された。分娩雌および非交配雌(サテライト群)では血液生化学検査結果に対照群と 2-DT 各投与群との間に有意差は認められなかった。

回復期間終了時の検査では、雄の 1000 mg/kg 投与群で対照群に比較して LDH 活性の上昇傾向が認められた。非交配雌(サテライト群)では、1000 mg/kg 投与群で A/G 比に有意な上昇($p<0.05$)が観察された。

9) 器官重量 (Table 29～Table 30, Appendix 29～Appendix 30)

投与期間終了時の検査では、雄の 1000 mg/kg 投与群で前立腺の実重量および相対重量に有意な増加(いずれも $p<0.05$)が観察された。分娩雌では対照群と 2-DT 各投与群との間でいずれの器官重量に有意差は認められなかった。非交配雌(サテライト群)では解剖時体重および子宮の実重量および相対重量に有意な減少(いずれも $p<0.05$)が、脳の実重量($p<0.05$)および相対重量($p<0.01$)、腎臓($p<0.01$)および卵巣(右側のみ、 $p<0.05$)の相対重量に有意な増加が認められた。

回復期間終了時の検査では、雄の 1000 mg/kg 投与群で脳および副腎(左側のみ)の相対重量に有

意な減少(いずれも $p<0.05$)が認められた。非交配雌(サテライト群)では、心臓($p<0.01$)、肝臓($p<0.05$)および腎臓($p<0.05$)の実重量に有意な増加が認められた。

10) 剖検所見 (Table 31～Table 32, Appendix 31～Appendix 32)

①雄の投与期間終了時屠殺例

前胃粘膜の水腫様が 1000 mg/kg 投与群の 2 例に認められた。また、対照群の 1 例では前立腺および精嚢の小型化が観察された。

②雄の回復期間終了時屠殺例

対照群および 1000 mg/kg 投与群に異常は認められなかった。

③分娩雌の投与期間終了時屠殺例 (哺育 5 日剖検)

前胃粘膜の水腫様が 1000 mg/kg 投与群の 3 例に認められた。

腺胃粘膜の黒色点が 1000 mg/kg 投与群の 1 例に、腺胃粘膜に陥凹部が対照群に 2 例、62.5 mg/kg 投与群に 1 例、250 mg/kg に 1 例で観察された。

④非交配雌(サテライト群)の投与期間終了時屠殺例

前胃粘膜の水腫様が 1000 mg/kg 投与群の 1 例に認められた。

⑤非交配雌(サテライト群)の回復期間終了時屠殺例

対照群および 1000 mg/kg 投与群に異常は認められなかった。

11) 病理組織学検査 (Table 33～Table 34, Appendix 33～Appendix 34)

①雄の投与期間終了時屠殺例

剖検時に、1000 mg/kg 投与群の 2 例に胃に肉眼的所見が認められたが、このうち 1 例には病理組織学的变化は認められなかった。

胃では、前胃粘膜固有層および粘膜下織にごく軽度の水腫が 1000 mg/kg 投与群の 1 例(剖検時の病変例)に観察された。対照群の 2 例の腺胃粘膜下織に単核細胞浸潤が観察された。

肝臓では、小肉芽腫が対照群に 3 例および 1000 mg/kg 投与群に 4 例、門脈周囲性に肝細胞の脂肪化が両群に各 1 例、それぞれ観察されたが程度に差はなかった。また、1000 mg/kg 投与群では限局性の壊死、髄外造血像が各 1 例に観察されたが、いずれもごく軽度から軽度の変化であった。その他、対照群の 1 例では門脈周囲性にリンパ球浸潤が観察された。

脾臓では、髄外造血像および褐色色素沈着が対照群および 1000 mg/kg 投与群の全例に観察されたが、両群間の程度には差はなかった。

腎臓では、皮質に好塩基性尿細管が対照群に 4 例および 1000 mg/kg 投与群に 3 例、皮髓境界部あるいは乳頭部に硝子円柱が両群に各 1 例観察されたが、両群間の程度に差はなかった。その他、1000 mg/kg 投与群の 1 例に好酸性小体が、対照群の 1 例の皮質に鉱質沈着が、それぞれ観察されたがごく軽度な変化であった。

心臓では、右室に心筋の変性/線維化が対照群および 1000 mg/kg 投与群に各 1 例観察されたが、両群間の程度に差はなかった。

前立腺では、剖検時に小型化を示した対照群の 1 例を含め、間質にリンパ球浸潤が対照群に 1 例

および 1000 mg/kg に 2 例観察されたが、両群間の程度に差はなかった。

また、対照群では下顎腺間質にリンパ球浸潤が、甲状腺に異所性胸腺組織が、肺胞に泡沫細胞の集簇が、骨格筋線維の変性が観察された。

その他の組織学検査対象器官・組織には、病理組織学的変化は観察されなかった。

②分娩雌の投与期間終了時屠殺例 (哺育 5 日剖検)

剖検時に、対照群の 2 例、62.5 mg/kg 投与群の 1 例、300 mg/kg 投与群の 1 例、1000 mg/kg 投与群の 4 例の胃に肉眼的所見が認められたが、1000 mg/kg 投与群の 3 例には病理組織学的変化は観察されなかった。

胃では、腺胃に限局性的びらんが対照群、62.5 mg/kg 投与群および 1000 mg/kg 投与群に、それぞれ 1 例、胃底腺の拡張が対照群および 250 mg/kg 投与群の各 1 例に観察されたが、いずれもごく軽度の変化であった。また、対照群の 1 例では前胃粘膜固有層および粘膜下織に水腫が観察された。

肝臓では、髄外造血像、限局性的壞死が対照群および 1000 mg/kg 投与群のそれぞれ各 1 例、小肉芽腫が対照群に 1 例および 1000 mg/kg 投与群に 2 例観察されたが、いずれもごく軽度な変化であった。対照群では、門脈周囲性の肝細胞の脂肪化が 1 例に観察された。

脾臓では、髄外造血像および褐色色素沈着が対照群および 1000 mg/kg 投与群の全例に観察されたが、両群間の程度には差はなかった。

腎臓では、皮質に好塩基性尿細管が対照群に 2 例および 1000 mg/kg 投与群に 1 例、間質にリンパ球浸潤が両群の各 1 例に、皮髓境界部に鉱質沈着が対照群に 1 例、乳頭部に鉱質沈着が 1000 mg/kg 投与群に 1 例、それぞれ観察されたが、程度には差はなかった。また、対照群では片側に腎孟の拡張が観察された。

膀胱では、粘膜固有層に炎症細胞浸潤が 1000 mg/kg 投与群の 1 例に観察されたが、ごく軽度な変化であった。

心臓では、心筋の変性/線維化が対照群では心室中隔に、1000 mg/kg 投与群では左心室に各 1 例観察されたが程度には差はなかった。

肺では、肺胞に泡沫細胞の集簇が対照群および 1000 mg/kg 投与群に各 2 例観察されたが、程度に差はなかった。

骨格筋線維の変性が対照群および 1000 mg/kg 投与群の各 1 例に、大腿骨骨髓の造血亢進が両群の各 2 例に、それぞれ観察されたが程度には差はなかった。

対照群では、下垂体にラトケ囊遺残が、甲状腺に鰓後体遺残が、卵巣に卵胞囊胞が観察された。

上記以外の組織学検査対象器官・組織には、病理組織学的変化は観察されなかった。

③非交配雌(サテライト群)の投与期間終了時屠殺例

剖検時に、1000 mg/kg 投与群の 1 例に胃に肉眼的所見が認められたが、病理組織学的変化は認められなかった。

肝臓では、小肉芽腫が対照群に 4 例および 1000 mg/kg 投与群に 5 例観察されたが、両群間の程度には差はなかった。

腎臓では、皮質に好塩基性尿細管が対照群および 1000 mg/kg 投与群に各 1 例観察されたが、程度に差はなかった。対照群の 1 例の乳頭部に鉛質沈着が観察された。

脾臓では、髓外造血像および褐色色素沈着が対照群および 1000 mg/kg 投与群の全例に観察されたが、両群間の程度には差はなかった。

肺では、肺胞に泡沫細胞の集簇が対照群に 1 例、1000 mg/kg 投与群に 3 例観察されたが、頻度および程度に差はなかった。また、1000 mg/kg 投与群の 2 例にごく軽度の小肉芽腫が観察された。

下垂体では、ラトケ囊遺残が対照群に 1 例および 1000 mg/kg 投与群に 3 例、甲状腺では鰓後体遺残が対照群に 2 例および 1000 mg/kg 投与群に 1 例、それぞれ観察されたが、頻度および程度に差はなかった。

対照群では、心臓の左心室心筋に変性/線維化が、子宮では発情前期像である子宮内腔の拡張が観察された。

上記以外の組織学検査対象器官・組織には、病理組織学的変化は観察されなかった。

2. 生殖能力

1) 性周期および交配成績 (Table 35～Table 36, Appendix 35～Appendix 36)

対照群の 1 例、62.5 mg/kg 投与群の 1 例および 250 mg/kg 投与群の 2 例では、投与開始後に性周期が 4～5 日の間に回帰しなくなり、投与開始後の平均発情回帰日数が対照群に比較して 250 mg/kg 群で有意に延長 ($p<0.01$) した。しかし、1000 mg/kg 投与群では投与開始後に性周期が変化した動物はみられなかった。

交配の結果、対照群 1 例(動物番号 F01005)を除く全ての動物において交尾が確認され、交尾までの日数およびその間の発情回数に対照群と 2-DT 各投与群との間に有意差は認められなかった。

また、交尾した全ての動物で妊娠が確認され、交尾率および妊娠率に対照群と 2-DT 各投与群との間に有意差は認められなかった。

2) 出産率および妊娠期間 (Table 37, Appendix 37)

出産率および妊娠期間に対照群と 2-DT 各投与群との間に有意差は認められなかった。

3) 分娩および哺育状態 (Table 37, Appendix 37)

全ての妊娠動物は妊娠 21～23 日に出産し、分娩状態および哺育状態に異常は認められなかった。

4) 黄体数、着床数および着床率 (Table 37, Appendix 37)

黄体数、着床数および着床率に対照群と 2-DT 各投与群との間に有意差は認められなかった。

3. 出生児

1) 生存 (Table 37, Appendix 37)

分娩率、生児出産率、出生率、新生児生存率および性比には対照群と 2-DT 各投与群との間に有意差は認められなかった。

2) 体重 (Table 38, Appendix 38)

哺育 0 および 4 日における出生児の体重に対照群と 2-DT 各投与群との間に有意差は認められなかつた。

3) 出生児観察 (Table 39～Table 40, Appendix 39)

死亡児が対照群を含む各投与群に認められた。250 mg/kg 投与群の 1 例(動物番号 F03032)では哺育 1 日に 16 例の死亡児が観察されたが、母動物の一般状態に異常は認められなかつた。また、死亡児には、母動物の喰殺により所在が不明になったと推察される児(不明児)、あるいは死後経過が進み自己融解により内部器官観察ができなかつた児を含むが、剖検が可能であった死亡児には外表奇形は観察されず、内部器官観察が可能であった死亡児についても内部器官に異常は認められなかつた。

哺育 4 日の出生児剖検の結果、対照群を含む各投与群の生存児に外表奇形および内部器官異常は観察されなかつた。

考察

雌雄ラットの交配前(2 週間)および交配期間中、ならびに雄では交配期間終了後を通して計 42 日間、交配雌では妊娠期間を通して周産期(哺育 4 日まで)に 41～55 日間、非交配群(サテライト群)では雄と同様の期間に 2-decyltetradecanol(2-DT)を経口投与し、雌雄ラットに対する反復投与毒性および回復性、ならびに生殖発生毒性および新生児の発育に及ぼす影響について検討した。

1. 親動物

握力検査において、1000 mg/kg 投与群の雄で前肢握力が減少した。しかし、その程度は僅かであり、一般状態、詳細な症状観察や自発運動量測定には 2-DT 投与によると考えられる変化は観察されず、病理組織学検査においても脳および坐骨神経に異常は認められていないことから、2-DT が神経系等に影響を及ぼしている可能性はないと判断した。

1000 mg/kg 投与群の非交配雌では、解剖前日の絶食により解剖時体重が対照群と比較して顕著に減少した。解剖時の脳、腎臓、子宮重量に変化がみられたが、脳および腎臓重量の変化は僅かであり、これらの器官の病理組織学検査では異常は観察されず、子宮重量の変化も性周期に起因した変化と考えられた。また、1000 mg/kg 投与群の雄では前立腺重量の増加がみられた。過去 2 年間に実施した同種試験でトウモロコシ油を溶媒对照群とした試験(6 試験、動物数=44 囗)の背景値(実重量の平均値±2SD: 580.5 ± 265.4 mg、最小値～最大値: 303.9～880.5 mg; 相対重量の平均値±2SD: 1.172 ± 0.584 mg、最小値～最大値: 0.632～1.800 mg/g)と比較すると、1000 mg/kg 投与群の雄 7 例中 2 例の前立腺実重量(913.1、956.4 mg)は背景値より僅かに高値を示し、このうち 1 例の相対重量(1.819 mg/g)は背景値を僅かに上回った。しかし、その程度はごくわずかであり、残りの 5 例は実測値および相対重量ともに背景データ範囲内であった。また、病理組織学検査では異常は観察されなかつたことから、前立腺重量の増加は偶発的な変化であり被験物質投与の影響ではないと判断した。

血液生化学検査では、雄の 250mg/kg 以上の投与群で LDH 活性が上昇した。LDH は肝臓、腎臓および心臓に比較的多く存在するが、肝障害を示唆する γ -GTP、AST および ALT 活性に変化はなく、肝臓および心臓の病理組織学検査においても 2-DT 投与によると考えられる変化は認められなかった。

尿検査において、1000 mg/kg 投与群の雄 1 例で潜血陽性尿が、同群の非交配雌では尿量および尿中電解質排泄量の減少が認められた。一般的に飲水量が減少した場合、尿量の減少とともに尿中電解質濃度が増加するが、本試験では電解質濃度の増加はみられていない。また、本試験では尿中電解質排泄量の減少が生じていることから、飲水量の影響ではなく 2-DT が腎臓の排泄機能に影響を及ぼすと考えられた。LDH 活性の上昇は腎障害に起因した変化と考えられたが、腎臓の病理組織学検査では 2-DT 投与によると考えられる変化は認められなかった。

血液学検査では、雄の 250 mg/kg 以上の投与群で PT が延長し、APTT も延長傾向を示したことから、2-DT が血液凝固系に影響を及ぼすと考えられた。その他、分娩雌で白血球分類比の変動が認められたが、白血球数に変化がみられないこと、用量依存的な変化ではないことから、被験物質投与の影響ではないと判断した。また、非交配雌では MCV および MCH の有意な減少が認められたが、赤血球数、血色素量およびヘマトクリット値に変化がみられないことから、被験物質投与の影響ではないと判断した。

投与期間中に 1000 mg/kg 投与群の雄および非交配雌で摂餌量の増加が各 1 日みられたが、一時的な変化であるため、被験物質投与による影響ではないと判断した。

その他、雌雄ともに一般状態、詳細な症状観察、体重推移、自発運動量、剖検および病理組織学検査に 2-DT 投与によると考えられる変化は認められなかった。

2. 毒性の回復性

14 日間の回復期間後、腎臓障害に起因すると考えられる LDH 活性の上昇傾向が 1000 mg/kg 投与群の雄で認められた。また、同群雄では PT は延長傾向を示し ATPP の延長が観察された。一方、尿検査では、投与期間にみられた変化は雌雄ともに認められなかった。よって、被験物質投与によると考えられる変化は回復期間後も完全に消失しなかったが、投与終了時と比較して変化の程度が軽度になっていることから、回復性を示す変化であると考えられた。

その他、1000 mg/kg 投与群の雄で脳重量の減少が、非交配雌では A/G 比の上昇、心臓、肝臓および腎臓重量の増加が観察されたが、脳、心臓、肝臓および腎臓に病理組織学的な異常が観察されなかつたこと、あるいは投与期間中に同様の変化はみられなかつたことから偶発的な変化と考えられた。

3. 生殖発生毒性および出生児

対照群、62.5 および 250 mg/kg 投与群で、投与開始後の性周期が 4~5 日の間に回帰しなくなる動物がみられ、また、投与開始後の平均発情回帰日数が 250 mg/kg 投与群で有意に延長した。しかし、1000 mg/kg 投与群では投与開始後に性周期が変化した動物はみられず、対照群でも性周期が回帰しない動物がみられたことから、2-DT は性周期に影響は及ぼさないと判断した。交配成績、出産率、妊娠期間、哺育状態、黄体数、着床数および着床率には被験物質投与による影響は認められなかった。

出生児の生存性および体重に被験物質投与の影響はみられず、死亡児には外表奇形および内部器官異常は観察されなかった。また、哺育 4 日の出生児剖検の結果、外表奇形および内部器官異常は観察されなかった。

4. 無毒性量

以上の結果から、本試験条件下における 2-decyltetradecanol の親動物に対する反復投与毒性の無毒性量は、雄では腎臓および血液凝固系への影響が 250 mg/kg 以上の投与群で認められたことから 62.5 mg/kg/day、雌では腎臓への影響が 1000 mg/kg 投与群でみられたことから 250 mg/kg/day と判断した。生殖発生毒性の無毒性量および次世代児に対する無毒性量は、いずれの投与群にも被験物質投与による影響はみられなかったことから 1000 mg/kg/day と考えられた。

参考文献

- 1) 2-Decyltetradecanol のラットを用いる反復投与毒性・生殖発生毒性併合試験（予備試験）

Annex A

Certificate of Analysis

SIGMA-ALDRICH®

Product Name	2-Decyl-1-tetradecanol, 97%
Product Number	464503
Product Brand	ALDRICH
CAS Number	<u>58670-89-6</u>
Molecular Formula	CH ₃ (CH ₂) ₁₁ CH[(CH ₂) ₈ CH ₃]CH ₂ OH
Molecular Weight	354.65

TEST	LOT 08403DOV RESULTS
APPEARANCE	VISCOS COLORLESS LIQUID
INFRARED SPECTRUM	CONFORMS TO STRUCTURE.
PROTON NMR SPECTRUM	CONFORMS TO STRUCTURE.
GAS LIQUID	98.4 %
CHROMATOGRAPHY	
QUALITY CONTROL	APRIL 2001
ACCEPTANCE DATE	


[Redacted] Supervisor

Quality Control
Milwaukee, Wisconsin USA

Annex B

安定性試験結果

試験番号	R - 12 - 016
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被 験 物 質 : 2-Decyltetradecanol

調製年月日 2012年11月21日

ロット番号 : 08403DOV

測定年月日 A 2012年11月21日(調製直後)

媒 体 : トウモロコシ油

B 2012年11月29日(調製後8日)

保管条件 冷蔵、遮光

調製濃度 (mg/mL)	A				B				
	試料 番号	測定濃度 (mg/mL)	含量 ^{a)} (%)	ばらつき ^{b)} (%)	試料 番号	測定濃度 (mg/mL)	含量 ^{a)} (%)	ばらつき ^{b)} (%)	残存率 ^{c)} (%)
15.625	1	16.54	105.9	102.9	7	15.57	99.6	102.0	96.9
	2	16.25	104.0	101.1	8	15.61	99.9	102.2	97.1
	3	15.43	98.8	96.0	9	14.65	93.8	95.9	91.2
	平均	16.07	102.9		平均	15.27	97.8		95.1
250	4	248.3	99.3	102.8	10	247.5	99.0	105.9	102.5
	5	239.9	96.0	99.3	11	223.1	89.2	95.5	92.4
	6	236.5	94.6	97.9	12	230.5	92.2	98.6	95.4
	平均	241.5	96.6		平均	233.7	93.5		96.8

a) : 各測定時の測定濃度 / 調製濃度 × 100

b) : 各測定時の測定濃度 / 各測定時の平均測定濃度 × 100

c) : 各測定時の測定濃度 / 初回の平均測定濃度 × 100

安定性の判断基準(溶液検体)

各試料採取時点(調製直後および各保管期間後)の平均含量がそれぞれ調製濃度の90.0~110.0%、また、各測定値のばらつきがそれぞれ平均値の90.0~110.0%以内であり、かつ、初回(調製直後)の測定平均値に対する各保管期間後の測定値の比(残存率)の平均値が90.0%以上を示す期間を投与検体の有効期間とする。

Annex C

試験番号	R - 12 - 016
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含 量 試 験 結 果

被 験 物 質 : 2-Decyltetradecanol

調製年月日 : 2012年12月3日

ロット番号 : 08403DOV

測定年月日 : 2012年12月3日

媒 体 : トウモロコシ油

試料番号	調製濃度 (A) (mg/mL)	測定濃度 (B) (mg/mL)	平均測定濃度 (C) (mg/mL)	含量 B/A×100 (%)	平均含量 (%)	ばらつき B/C×100 (%)
1	15.625	15.86	15.82	101.5	101.3	100.3
2		15.98		102.3		101.0
3		15.62		100.0		98.7
4	62.5	63.82	62.82	102.1	100.5	101.6
5		63.28		101.2		100.7
6		61.36		98.2		97.7
7	250	250.6	247.1	100.2	98.9	101.4
8		258.9		103.6		104.8
9		231.9		92.8		93.8

含量の判断基準(溶液検体)

平均含量が調製濃度の90.0～110.0%、また、各測定値のばらつきがそれぞれ平均値の90.0～110.0%以内とする。

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 1-1. General conditions of male rats

Pre: Before administration, Post: after administration

Pre: Before administration, Post: after administration

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 1-2. General conditions of male rats at the recovery period

Group	Number of males and general conditions	Days of recovery period													
		1	2	3	4	5	6	7	8	9	10	11	12	13	14
Control (vehicle: corn oil)	Number of males	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	General appearance, No abnormality	5	5	5	5	5	5	5	5	5	5	5	5	5	5
2-DT 1000 mg/kg	Number of males	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	General appearance, No abnormality	5	5	5	5	5	5	5	5	5	5	5	5	5	5

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 2-1. General conditions of female rats

Group	Number of females and general conditions	Days of administration																											
		1 Pre	2 Post	3 Pre	4 Post	5 Pre	6 Post	7 Pre	8 Post	9 Pre	10 Post	11 Pre	12 Post	13 Pre	14 Post	15 Pre	16 Post	17 Pre	18 Post	19 Pre	20 Post	21 Pre	22 Post	23 Pre	24 Post	25 Pre	Post		
Control (vehicle: corn oil)	Number of females	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	8	8	6	6	4	4	1	1	1	1	
	General appearance, No abnormality	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	8	8	6	6	4	4	1	1	1	1
2-DT 62.5 mg/kg	Number of females	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	9	9	4	4	1	1	0	0	0	0
	General appearance, No abnormality	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	9	9	4	4	1	1	0	0	0	0
2-DT 250 mg/kg	Number of females	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	9	9	7	7	2	2	1	1	1	1
	General appearance, No abnormality	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	9	9	7	7	2	2	1	1	1	1
2-DT 1000 mg/kg	Number of females	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	7	7	3	3	2	2	0	0	0	0
	General appearance, No abnormality	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	7	7	3	3	2	2	0	0	0	0

Pre: Before administration, Post: after administration.

Group	Number of females and general conditions	Days of administration																												
		26 Pre	27 Post	28 Pre	29 Post	30 Pre	31 Post	32 Pre	33 Post	34 Pre	35 Post	36 Pre	37 Post	38 Pre	39 Post	40 Pre	41 Post	42 Pre	43 Post	44 Pre	45 Post	46 Pre	47 Post	48 Pre	49 Post	50 Pre	Post			
Control (vehicle: corn oil)	Number of females	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
	General appearance, No abnormality	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
2-DT 250 mg/kg	Number of females	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	General appearance, No abnormality	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Pre: Before administration, Post: after administration.

Group	Number of females and general conditions	Days of administration		
		51 Pre	52 Post	53 Pre
Control (vehicle: corn oil)	Number of females	1	1	1
	General appearance, No abnormality	1	1	1

Pre: Before administration, Post: after administration.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 2-2. General conditions of female rats, satellite group

Pre: Before administration, Post: after administration.

Pre: Before administration, Post: after administration.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 2-3. General conditions of female rats at the recovery period

Group	Number of females and general conditions	Days of recovery period													
		1	2	3	4	5	6	7	8	9	10	11	12	13	14
Control (vehicle: corn oil)	Number of females	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	General appearance, No abnormality	5	5	5	5	5	5	5	5	5	5	5	5	5	5
2-DT 1000 mg/kg	Number of females	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	General appearance, No abnormality	5	5	5	5	5	5	5	5	5	5	5	5	5	5

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 3. General conditions in dams during pregnancy

Group	Number of females and general conditions	Days of pregnancy																									
		0		1		2		3		4		5		6		7		8		9		10		11		12	
		Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Control (vehicle: corn oil)	Number of females	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11
	General appearance, No abnormality	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11
2-DT 62.5 mg/kg	Number of females	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12
	General appearance, No abnormality	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12
2-DT 250 mg/kg	Number of females	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12
	General appearance, No abnormality	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12
2-DT 1000 mg/kg	Number of females	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12
	General appearance, No abnormality	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12

Pre: Before administration, Post: after administration.

Group	Number of females and general conditions	Days of pregnancy																		
		14		15		16		17		18		19		20		21		22		
		Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	
Control (vehicle: corn oil)	Number of females	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	4	4
	General appearance, No abnormality	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	4	4
2-DT 62.5 mg/kg	Number of females	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	5	5
	General appearance, No abnormality	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	5	5
2-DT 250 mg/kg	Number of females	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	4	4
	General appearance, No abnormality	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	4	4
2-DT 1000 mg/kg	Number of females	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	3	3
	General appearance, No abnormality	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	3	3

Pre: Before administration, Post: after administration.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 4. General conditions in dams during lactation

Group	Number of females and general conditions	Days of lactation									
		0		1		2		3		4	
		Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Control (vehicle: corn oil)	Number of females	8	8	11	11	11	11	11	11	11	11
	General appearance, No abnormality	8	8	11	11	11	11	11	11	11	11
2-DT 62.5 mg/kg	Number of females	9	9	12	12	12	12	12	12	12	12
	General appearance, No abnormality	9	9	12	12	12	12	12	12	12	12
2-DT 250 mg/kg	Number of females	9	9	12	12	12	12	12	12	12	12
	General appearance, No abnormality	9	9	12	12	12	12	12	12	12	12
2-DT 1000 mg/kg	Number of females	8	8	12	12	12	12	12	12	12	12
	General appearance, No abnormality	8	8	12	12	12	12	12	12	12	12

Pre: Before administration, Post: after administration.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 5. Detailed clinical observations of male rats

Findings	Group	Initial number of animals	Pre-treatment	Days of treatment						<u>Days of recovery</u> ^a	
				8	15	24	30	36	42	7	14
[Stereotypy] Rearing	Control (vehicle: corn oil)	12	0 ^b	0	0	0	0	0	0	0	0
	2-DT 62.5 mg/kg	12	0	0	1	0	0	0	0	0	0
	2-DT 250 mg/kg	12	0	0	0	0	0	0	0	0	0
	2-DT 1000 mg/kg	12	0	0	0	0	0	0	0	0	0
[Touch response] Hypersensitivity (slight)	Control (vehicle: corn oil)	12	0 ^b	0	0	0	0	0	0	0	0
	2-DT 62.5 mg/kg	12	0	1	0	0	0	0	0	0	0
	2-DT 250 mg/kg	12	0	0	0	0	0	0	0	0	0
	2-DT 1000 mg/kg	12	0	0	0	0	0	0	0	0	0
[Urination] (frequency/30sec)	Control (vehicle: corn oil)	12	2 ^c	0	0	1	1	2	0	0	0
	2-DT 62.5 mg/kg	12	2	1	3	1	3	4	0	0	0
	2-DT 250 mg/kg	12	1	2	0	0	1	2	1	0	0
	2-DT 1000 mg/kg	12	2	0	1	1	0	5	0	0	0
[Defecation] (frequency/30sec)	Control (vehicle: corn oil)	12	2 ^c	0	0	0	0	0	0	0	0
	2-DT 62.5 mg/kg	12	1	0	0	0	0	0	0	0	0
	2-DT 250 mg/kg	12	1	0	0	0	0	0	0	0	0
	2-DT 1000 mg/kg	12	2	0	0	0	0	0	0	0	0

^aThe recovery test was performed in 5 animals for each of the 0 and 1000 mg/kg groups.^bValues represent number of animals with the findings.^cValues represent total score of each group.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 6-1. Detailed clinical observations of female rats

Findings	Group	Initial number of animals	Pre-treatment	Days of treatment							The lactation period
				8	15	24	30	36	42	49	
[Stereotypy] Rearing	Control (vehicle: corn oil)	12	0 ^a	0	0	0	0	0	0 (1)	0 (1)	0 (11)
	2-DT 62.5 mg/kg	12	0	0	0	0	0	0			0
	2-DT 250 mg/kg	12	0	0	0	0	0	0	0 (1)	0 (1)	0
	2-DT 1000 mg/kg	12	1	0	0	0	0	0			0
[Touch response] Hypersensitivity, slight	Control (vehicle: corn oil)	12	0 ^a	0	0	0	0	0	0 (1)	0 (1)	0 (11)
	2-DT 62.5 mg/kg	12	0	0	0	0	0	0			0
	2-DT 250 mg/kg	12	0	1	0	0	0	0	0 (1)	0 (1)	0
	2-DT 1000 mg/kg	12	0	0	0	0	0	0			0
[Urination] (frequency/30sec)	Control (vehicle: corn oil)	12	1 ^b	0	0	0	0	0	0 (1)	0 (1)	0 (11)
	2-DT 62.5 mg/kg	12	0	0	0	0	0	0			0
	2-DT 250 mg/kg	12	0	0	0	1	0	0	0 (1)	0 (1)	0
	2-DT 1000 mg/kg	12	1	1	0	0	0	0			1
[Defecation] (frequency/30sec)	Control (vehicle: corn oil)	12	0 ^b	0	0	0	0	0	0 (1)	0 (1)	0 (11)
	2-DT 62.5 mg/kg	12	0	0	0	0	0	0			0
	2-DT 250 mg/kg	12	0	0	0	0	0	0	0 (1)	0 (1)	0
	2-DT 1000 mg/kg	12	0	0	0	0	0	0			0

^a Values represent number of animals with the findings.^b Values represent total score of each group.

Figures in parenthesis indicate number of animals.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 6-2. Detailed clinical observations of female rats, satellite group

Findings	Group	Initial number of animals	Pre-treatment	Days of treatment						Days of recovery ^a	
				8	15	24	30	36	42	7	14
[Urination] (frequency/30sec)	Control (vehicle: corn oil)	10	0 ^b	1	0	0	1	2	3	0	0
	2-DT 1000 mg/kg	10	0	0	0	0	0	0	0	0	0
[Defecation] (frequency/30sec)	Control (vehicle: corn oil)	10	0 ^b	0	0	0	1	0	1	0	0
	2-DT 1000 mg/kg	10	0	0	0	0	0	0	0	0	0

^a The recovery test was performed in 5 animals for each of the 0 and 1000 mg/kg groups.^b Values represent total score of each group.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 7-1. Body weights of male rats

Group	Control (vehicle: corn oil)	2-DT 62.5 mg/kg	2-DT 250 mg/kg	2-DT 1000 mg/kg
Number of males	12	12	12	12
Days of administration				
1	409.5 ± 16.0	406.6 ± 17.2	408.9 ± 15.3	408.1 ± 12.5
4	421.0 ± 17.1	422.5 ± 19.7	421.0 ± 16.2	423.6 ± 15.3
7	433.4 ± 18.4	431.0 ± 22.5	435.2 ± 17.6	432.0 ± 23.1
14	452.9 ± 29.9	454.0 ± 27.0	452.3 ± 20.7	456.7 ± 20.5
21	475.9 ± 28.6	478.0 ± 27.3	479.5 ± 18.0	479.8 ± 19.9
28	496.6 ± 33.9	502.2 ± 30.7	503.3 ± 18.0	505.4 ± 23.0
35	523.8 ± 35.6	520.9 ± 32.2	524.0 ± 22.5	528.6 ± 24.9
42	534.4 ± 34.1	529.8 ± 34.0	537.4 ± 29.3	536.3 ± 28.2

Each value shows mean (g) ± S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 7-2. Body weights of male rats at the recovery period

Group	Control (vehicle: corn oil)	2-DT 1000 mg/kg
Number of males	5	5
Days of recovery period		
1	521.8 ± 20.1	547.2 ± 27.0
7	528.3 ± 24.4	556.5 ± 28.2
14	529.5 ± 26.9	561.1 ± 30.9

Each value shows mean (g) ± S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 8-1. Body weights of female rats

Group	Control (vehicle: corn oil)	2-DT 62.5 mg/kg	2-DT 250 mg/kg	2-DT 1000 mg/kg
Number of females	12	12	12	12
Days of administration				
1	245.5 ± 11.9	245.6 ± 10.6	248.0 ± 9.2	245.9 ± 9.1
4	251.0 ± 15.4	246.6 ± 10.0	252.3 ± 11.6	253.2 ± 11.7
7	256.6 ± 14.7	251.1 ± 11.0	257.5 ± 9.2	258.6 ± 13.2
14	266.6 ± 23.4	260.0 ± 14.1	270.3 ± 12.1	271.0 ± 13.6

Each value shows mean (g) ± S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 8-2. Body weights of female rats, satellite group

Group Number of females	Control (vehicle: corn oil)		2-DT 1000 mg/kg
	10	10	10
Days of administration			
1	246.1 ± 13.2		241.9 ± 12.5
4	252.0 ± 14.4		251.5 ± 13.5
7	259.7 ± 16.2		254.8 ± 14.5
14	271.0 ± 20.7		265.3 ± 16.5
21	284.8 ± 24.0		278.0 ± 19.9
28	293.0 ± 26.2		289.4 ± 22.3
35	302.0 ± 27.5		295.9 ± 22.6
42	308.6 ± 26.8		297.2 ± 24.8

Each value shows mean (g) ± S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 8-3. Body weights of female rats at the recovery period

Group	Control (vehicle: corn oil)	2-DT 1000 mg/kg
Number of females	5	5
Days of recovery period		
1	292.3 ± 21.7	311.9 ± 23.3
7	300.7 ± 21.8	318.9 ± 23.1
14	305.6 ± 23.4	318.2 ± 31.5

Each value shows mean (g) ± S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 9. Body weights of dams during pregnancy

Group	Control (vehicle: corn oil)	2-DT 62.5 mg/kg	2-DT 250 mg/kg	2-DT 1000 mg/kg
Number of dams	11	12	12	12
Days of pregnancy				
0	275.1 ± 21.6	268.8 ± 18.6	280.0 ± 13.7	275.6 ± 13.7
7	310.8 ± 18.5	308.9 ± 19.1	315.2 ± 11.6	311.8 ± 16.8
14	348.0 ± 17.7	349.6 ± 23.5	354.4 ± 14.6	347.5 ± 18.8
20	428.5 ± 20.9	433.9 ± 31.0	438.5 ± 22.2	431.7 ± 33.1

Each value shows mean ± S.D. (g).

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 10. Body weights of dams during lactation

Group	Control (vehicle: corn oil)	2-DT 62.5 mg/kg	2-DT 250 mg/kg	2-DT 1000 mg/kg
Number of dams	11	12	12	12
Days of lactation				
0	323.1 ± 27.8	333.5 ± 22.3	336.8 ± 16.7	329.9 ± 26.5
4	339.4 ± 21.6	344.0 ± 20.2	348.5 ± 12.1	341.6 ± 11.2

Each value shows mean ± S.D. (g).

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 11-1. Food consumption of male rats

Group	Control (vehicle: corn oil)	2-DT 62.5 mg/kg	2-DT 250 mg/kg	2-DT 1000 mg/kg
Number of males	12	12	12	12
Days of administration				
1	27.1 ± 2.0	27.8 ± 3.1	29.0 ± 3.1	28.6 ± 4.4
7	26.5 ± 2.1	24.4 ± 2.6	27.4 ± 2.7	27.3 ± 2.7
14	24.2 ± 2.2	23.8 ± 2.5	25.0 ± 3.0	26.6 ± 2.0
29	26.1 ± 2.3	23.9 ± 2.3	26.6 ± 2.4	29.1 ± 3.3 *
35	24.5 ± 2.4	23.7 ± 2.6	24.3 ± 2.3	26.0 ± 2.6
41	25.6 ± 3.4	22.7 ± 5.4	24.8 ± 4.7	25.2 ± 5.6

Each value shows mean (g) ± S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 11-2. Food consumption of male rats at the recovery period

Group	Control (vehicle: corn oil)	2-DT 1000 mg/kg
Number of males	5	5
Days of recovery period		
6	28.5 ± 2.4	29.4 ± 1.8
12	27.6 ± 3.3	28.7 ± 2.2

Each value shows mean (g) ± S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 12-1. Food consumption of female rats

Group	Control (vehicle: corn oil)	2-DT 62.5 mg/kg	2-DT 250 mg/kg	2-DT 1000 mg/kg
Number of females	12	12	12	12
Days of administration				
1	18.1 ± 1.9	16.5 ± 3.2	16.5 ± 3.5	19.6 ± 2.7
7	18.0 ± 3.5	16.8 ± 3.5	17.4 ± 3.3	19.0 ± 3.2
14	17.2 ± 2.9	17.6 ± 2.2	18.1 ± 2.2	19.3 ± 3.1

Each value shows mean (g) ± S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 12-2. Food consumption of female rats, satellite group

Group	Control (vehicle: corn oil)		2-DT 1000 mg/kg	
	Number of females	10		10
Days of administration				
1	19.0	±	2.3	16.4 ± 4.9
7	19.0	±	2.5	20.9 ± 1.8
14	18.9	±	2.5	18.4 ± 3.0
21	19.8	±	3.0	19.9 ± 2.9
29	19.1	±	2.6	18.1 ± 2.5
35	16.4	±	2.6	19.8 ± 2.4 **
41	18.4	±	2.1	17.7 ± 2.2

Each value shows mean (g) ± S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 12-3. Food consumption of female rats at the recovery period

Group	Control (vehicle: corn oil)	2-DT 1000 mg/kg
Number of females	5	5
Days of recovery period		
6	19.7 ± 0.7	20.3 ± 4.1
12	19.4 ± 3.0	21.9 ± 2.6

Each value shows mean (g) ± S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 13. Food consumption in dams during pregnancy

Group	Control (vehicle: corn oil)	2-DT 62.5 mg/kg	2-DT 250 mg/kg	2-DT 1000 mg/kg
Number of dams	11	12	12	12
Days of pregnancy				
0	18.5 ± 1.6	20.2 ± 2.4	18.8 ± 3.6	20.7 ± 3.9
7	24.3 ± 1.9	24.9 ± 2.1	24.5 ± 3.6	24.3 ± 2.3
14	23.4 ± 2.2	24.7 ± 3.1	24.6 ± 2.8	25.0 ± 2.2
20	20.8 ± 3.9	21.6 ± 1.9	21.1 ± 3.5	21.5 ± 6.7

Each value shows mean ± S.D. (g).

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 14. Food consumption in dams during lactation

Group	Control (vehicle: corn oil)	2-DT 62.5 mg/kg	2-DT 250 mg/kg	2-DT 1000 mg/kg
Number of dams	11	12	12	12
Days of lactation				
3	38.5 ± 7.2	42.5 ± 6.0	40.3 ± 8.0	42.1 ± 5.7

Each value shows mean ± S.D. (g).

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 15. Functional findings of male rats at the last week of the dosing period

Group	Control (vehicle: corn oil)	2-DT 62.5 mg/kg	2-DT 250 mg/kg	2-DT 1000 mg/kg
<u>Male</u>				
Number of animals	5	5	5	5
Righting reflex	100	100	100	100
Visual placing	100	100	100	100
Pupillary reflex	100	100	100	100
Startle reaction	100	100	100	100
Preyer's reaction	100	100	100	100
Withdrawal reflex	100	100	100	100
Eyelid reflex	100	100	100	100

Values represent % of animals showing normal responses.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 16. Functional findings of female rats at the last week of the dosing period

Group	Control (vehicle: corn oil)	2-DT 62.5 mg/kg	2-DT 250 mg/kg	2-DT 1000 mg/kg
<u>Female, dam</u>				
Number of animals	5	5	5	5
Righting reflex	100	100	100	100
Visual placing	100	100	100	100
Pupillary reflex	100	100	100	100
Startle reaction	100	100	100	100
Preyer's reaction	100	100	100	100
Withdrawal reflex	100	100	100	100
Eyelid reflex	100	100	100	100
<u>Female, satelite group</u>				
Number of animals	5		5	
Righting reflex	100		100	
Visual placing	100		100	
Pupillary reflex	100		100	
Startle reaction	100		100	
Preyer's reaction	100		100	
Withdrawal reflex	100		100	
Eyelid reflex	100		100	

Values represent % of animals showing normal responses.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 17. Assessment of grip strength of male rats

Group	Control (vehicle: corn oil)	2-DT 62.5 mg/kg	2-DT 250 mg/kg	2-DT 1000 mg/kg
Number of males	5	5	5	5
<u>Administration period</u>				
Forelimb	1.195 ± 0.052	1.186 ± 0.062	1.185 ± 0.073	1.081 ± 0.050 *
Hindlimb	0.570 ± 0.072	0.528 ± 0.060	0.619 ± 0.050	0.580 ± 0.059
<u>Recovery period</u>				
Forelimb	1.157 ± 0.045			1.159 ± 0.044
Hindlimb	0.544 ± 0.081			0.548 ± 0.059

Each value shows mean (kg) ±S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 18. Assessment of grip strength of female rats at the last week of the dosing period

Group	Control (vehicle: corn oil)	2-DT 62.5 mg/kg	2-DT 250 mg/kg	2-DT 1000 mg/kg
Number of females	5	5	5	5
Forelimb	1.144 ± 0.011	1.194 ± 0.059	1.204 ± 0.073	1.213 ± 0.025
Hindlimb	0.511 ± 0.054	0.443 ± 0.051	0.437 ± 0.038	0.479 ± 0.077

Each value shows mean (kg) ±S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 19. Assessment of grip strength of female rats at the last week of the dosing period, satellite group

Group	Control (vehicle: corn oil)	2-DT 1000 mg/kg
Number of females	5	5
Forelimb	1.144 ± 0.081	1.174 ± 0.055
Hindlimb	0.458 ± 0.055	0.490 ± 0.064

Each value shows mean (kg) ±S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 20. Motor activity of male rats at the last week of the dosing period

Group	Control (vehicle: corn oil)	2-DT 62.5 mg/kg	2-DT 250 mg/kg	2-DT 1000 mg/kg
Number of males	5	5	5	5
Ambulation (counts)				
5min	1075 ± 169	1163 ± 53	1342 ± 185 *	1083 ± 159
10min	944 ± 192	1049 ± 102	1227 ± 256	998 ± 114
15min	875 ± 135	872 ± 80	1192 ± 247 *	946 ± 101
20min	772 ± 272	856 ± 167	971 ± 285	886 ± 162
Total	3667 ± 680	3941 ± 201	4733 ± 839 *	3913 ± 329
Rearing (counts)				
5min	36 ± 10	44 ± 15	43 ± 11	34 ± 12
10min	27 ± 17	29 ± 8	28 ± 7	31 ± 7
15min	26 ± 11	24 ± 6	26 ± 2	25 ± 4
20min	22 ± 17	20 ± 7	18 ± 6	22 ± 6
Total	111 ± 35	117 ± 26	116 ± 11	112 ± 15

Each value shows mean±S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 21. Motor activity of female rats at the last week of the dosing period

Group	Control (vehicle: corn oil)	2-DT 62.5 mg/kg	2-DT 250 mg/kg	2-DT 1000 mg/kg
Number of females	5	5	5	5
Ambulation (counts)				
5min	1058 ± 125	1163 ± 97	1243 ± 399	1056 ± 141
10min	889 ± 151	857 ± 179	996 ± 179	856 ± 224
15min	586 ± 109	646 ± 278	795 ± 237	687 ± 89
20min	574 ± 117	572 ± 377	542 ± 409	433 ± 164
Total	3106 ± 416	3238 ± 814	3577 ± 1131	3032 ± 494
Rearing (counts)				
5min	29 ± 2	42 ± 23	28 ± 10	31 ± 9
10min	25 ± 9	18 ± 13	21 ± 11	23 ± 13
15min	7 ± 3	15 ± 10	11 ± 9	12 ± 10
20min	8 ± 3	12 ± 9	5 ± 6	9 ± 14
Total	69 ± 14	87 ± 38	65 ± 23	75 ± 42

Each value shows mean±S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 22. Motor activity of female rats at the last week of the dosing period, satellite group

Group	Control (vehicle: corn oil)		2-DT 1000 mg/kg	
	5	5	5	5
Number of females				
Ambulation (counts)				
5min	1124 ± 215		1197 ± 80	
10min	1066 ± 228		1163 ± 93	
15min	964 ± 254		1117 ± 53	
20min	870 ± 329		1088 ± 80	
Total	4024 ± 937		4564 ± 186	
Rearing (counts)				
5min	37 ± 7		33 ± 7	
10min	34 ± 13		31 ± 13	
15min	29 ± 16		28 ± 9	
20min	22 ± 8		27 ± 10	
Total	122 ± 36		118 ± 26	

Each value shows mean±S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 23-1. Urinalysis in male rats

Group	Number of males	Quality ^{a)}																					
		Color		Turbidity		pH				Protein			Glucose		Ketone		Bilirubin	Occult blood	Urobilinogen				
		Light yellow	Yellow	-	+	6.5	7.0	7.5	8.0	-	±	+	2+	-	-	±	+	-	±	+			
Control (vehicle: corn oil)	5	4	1	5	0	1	3	1	0	0	0	4	1	5	0	2	3	5	5	0	3	1	1
2-DT 62.5 mg/kg	5	5	0	5	0	2	2	1	0	0	0	4	1	5	0	2	3	5	5	0	2	3	0
2-DT 250 mg/kg	5	3	2	5	0	2	2	0	1	0	0	2	3	5	0	1	4	5	5	0	2	3	0
2-DT 1000 mg/kg	5	5	0	4	1	4	1	0	0	0	0	2	3	5	0	1	4	5	4	1	1	3	1

Group	Number of males	Urinary sediments ^{a)}						Urine volume ^{b)} (mL/24hr)	Specific gravity ^{b)}	Electrolyte, density ^{b)} (mEq/L)			Electrolyte, gross volume ^{b)} (mEq/24 hr)		
		Red blood cells	White blood cells	Casts	Crystals	Epithelial cells	-			Na	K	Cl	Na	K	Cl
		-	-	-	-	±	-			(mL/24hr)	±8.4	1.050 ±0.027	90.4 ±65.5	173.3 ±75.4	97.0 ±65.4
Control (vehicle: corn oil)	5	5	5	5	1	4	5	18.0 ±8.4	1.050 ±0.027	90.4 ±65.5	173.3 ±75.4	97.0 ±65.4	1.25 ±0.45	2.62 ±0.23	1.33 ±0.45
2-DT 62.5 mg/kg	5	5	5	5	1	4	5	17.9 ±4.0	1.042 ±0.014	67.0 ±37.9	158.8 ±49.4	76.4 ±48.4	1.16 ±0.61	2.78 ±0.78	1.33 ±0.77
2-DT 250 mg/kg	5	5	5	5	2	3	5	12.6 ±3.9	1.065 ±0.015	118.4 ±23.1	226.9 ±32.5	135.9 ±32.9	1.42 ±0.14	2.77 ±0.42	1.62 ±0.22
2-DT 1000 mg/kg	5	5	5	5	1	4	5	11.5 ±2.8	1.071 ±0.022	127.4 ±51.1	214.3 ±52.8	140.2 ±68.4	1.38 ±0.50	2.39 ±0.54	1.51 ±0.68

Significantly different from the control group (*: P<0.05, **: P<0.01).

Turbidity, -: negative

Protein, -: negative; ±: 10≤ and <30 mg/dL; +: 30≤ and <100 mg/dL; 2+: 100≤ and <300 mg/dL

Glucose, -: negative

Ketone, -: negative; ±: 5≤ and <10 mg/dL; +: 10≤ and <40 mg/dL

Bilirubin, -: negative

Occult blood, -: negative; 2+: 0.20≤ and <1.00 mg/dL

Urobilinogen, -: normal; +: 2.0≤ and <4.0 mg/dL; 2+: 4.0≤ and <8.0 mg/dL

Red blood cells, White blood cells and Casts, -: not observed

Crystals and Epithelial cells, -: not observed; ±: a few

a), values represent as number of animals

b), values represent as mean ± S.D.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 23-2. Urinalysis in male rats of the recovery period

Group	Number of males	Quality ^{a)}																						
		Color		Turbidity		pH					Protein			Glucose		Ketone			Bilirubin		Occult blood		Urobilinogen	
		Light yellow	-	-	+	6.5	7.0	7.5	8.0	9.0	-	+	2+	-	-	-	±	+	-	-	-	-	±	+
Control (vehicle: corn oil)	5	5	5	0	0	3	1	0	1	0	3	2	5	0	2	3	5	5	5	1	3	1		
2-DT 1000 mg/kg	5	5	4	1	1	1	2	1	0	1	1	3	5	2	0	3	5	5	2	2	1			
Urinary sediments ^{a)}																		Electrolyte, density ^{b)} (mEq/L)			Electrolyte, gross volume ^{b)} (mEq/24 hr)			
Group	Number of males	Red blood cells	White blood cells	Casts	Crystals	Epithelial cells		Urine volume ^{b)} (mL/24hr)	Specific gravity ^{b)}	Electrolyte, density ^{b)} (mEq/L)			Electrolyte, gross volume ^{b)} (mEq/24 hr)											
		-	-	-	-	±	-			Na	K	Cl	Na	K	Cl									
Control (vehicle: corn oil)	5	5	5	5	0	5	5	16.2 ±5.1	1.063 ±0.015	91.9	203.6	116.2	1.42	3.20	1.79									
2-DT 1000 mg/kg	5	5	5	5	1	4	4	16.6 ±7.7	1.065 ±0.018	94.5	197.7	100.6	1.47	3.21	1.66									

Significantly different from the control group (*: P<0.05, **: P<0.01).

Turbidity, -: negative ; +: slight

Protein, -: negative; ±: 10≤and<30 mg/dL; +: 30≤and<100 mg/dL; 2+: 100≤and<300 mg/dL

Glucose, -: negative

Ketone, -: negative; ±: 5≤and<10 mg/dL; +: 10≤and<40 mg/dL

Bilirubin, -: negative

Occult blood, -: negative

Urobilinogen, ±: normal; +: 2.0≤and<4.0 mg/dL; 2+: 4.0≤and<8.0 mg/dL

Red blood cells, White blood cells and Casts, -: not observed

Crystals and Epithelial cells, -: not observed; ±: a few

a), values represent as number of animals

b), values represent as mean ± S.D.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 24-1. Urinalysis in female rats, satellite group

Group	Number of females	Quality ^{a)}																			
		Color		Turbidity		pH				Protein				Glucose		Ketone		Bilirubin	Occult blood	Urobilinogen	
		Light yellow	Yellow	-	6.0	6.5	7.0	7.5	8.0	-	±	+	2+	-	±	-	±	+	-	±	+
Control (vehicle: corn oil)	5	4	1	5	0	2	2	1	0	1	2	1	1	5	0	3	1	1	5	5	3 1 1
2-DT 1000 mg/kg	5	2	3	5	1	2	0	1	1	0	1	1	3	3	2	1	1	3	5	5	1 3 1

Group	Number of females	Urinary sediments ^{a)}						Urine volume ^{b)} (mL/24hr)	Specific gravity ^{b)}	Electrolyte, density ^{b)} (mEq/L)			Electrolyte, gross volume ^{b)} (mEq/24 hr)			
		Red blood cells	White blood cells	Casts	Crystals	Epithelial cells	-			Na	K	Cl	Na	K	Cl	
		-	-	-	-	±	-			±0.016	±31.0	±40.1	±44.4	±0.23	±0.31	±0.28
Control (vehicle: corn oil)	5	5	5	5	1	4	5	10.7 ±3.4	1.055 ±0.016	95.8 ±31.0	191.1 ±40.1	122.9 ±44.4	0.96 ±0.23	1.96 ±0.23	1.21 ±0.28	
2-DT 1000 mg/kg	5	5	5	5	3	2	5	5.8* ±2.7	1.073 ±0.020	107.1 ±27.8	192.6 ±19.9	91.0 ±31.9	0.57* ±0.18	1.10* ±0.18	0.57* ±0.52	±0.38

Significantly different from the control group (*: P<0.05, **: P<0.01).

Turbidity, -: negative

Protein, -: negative; ±: 10≤ and < 30 mg/dL; +: 30≤ and < 100 mg/dL; 2+: 100≤ and < 300 mg/dL

Glucose, -: negative; ±: 30≤ and < 70 mg/dL

Ketone, -: negative; ±: 5≤ and < 10 mg/dL; +: 10≤ and < 40 mg/dL

Bilirubin, -: negative

Occult blood, -: negative

Urobilinogen, -: normal ; +: 2.0≤ and < 4.0 mg/dL; 2+: 4.0≤ and < 8.0 mg/dL

Red blood cells, White blood cells and Casts, -: not observed

Crystals and Epithelial cells, -: not observed; ±: a few

a), values represent as number of animals

b), values represent as mean ± S.D.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 24-2. Urinalysis in female rats of the recovery period

Group	Number of females	Quality ^{a)}																
		Color		Turbidity		pH				Protein			Glucose		Ketone	Bilirubin	Occult blood	Urobilinogen
		Light yellow	-	-	-	6.0	6.5	7.0	7.5	8.0	-	±	+	-	-	±	-	±
Control (vehicle: corn oil)	5	5	5	1	0	2	2	0	2	2	1	5	4	1	5	5	3	2
2-DT 1000 mg/kg	5	5	5	0	1	2	1	1	2	2	1	5	4	1	5	5	4	1

Group	Number of females	Urinary sediments ^{a)}						Urine volume ^{b)} (mL/24hr)	Specific gravity ^{b)}	Electrolyte, density ^{b)} (mEq/L)			Electrolyte, gross volume ^{b)} (mEq/24 hr)		
		Red blood cells	White blood cells	Casts	Crystals	Epithelial cells	-			Na	K	Cl	Na	K	Cl
		-	-	-	-	±	-			(mL/24hr)	±4.6	±0.014	±23.0	±39.5	±37.9
Control (vehicle: corn oil)	5	5	5	5	1	4	5	15.4	1.053	99.1	208.7	126.1	1.45	3.09	1.81
2-DT 1000 mg/kg	5	5	5	5	2	3	5	16.0	1.045	79.2	168.3	100.3	1.22	2.62	1.52

Significantly different from the control group (*: P<0.05, **: P<0.01).

Turbidity, -: negative

Protein, -: negative; ±: 10≤ and < 30 mg/dL; +: 30≤ and < 100 mg/dL

Glucose, -: negative

Ketone, -: negative; ±: 5≤ and < 10 mg/dL

Bilirubin, -: negative

Occult blood, -: negative

Urobilinogen, ±: normal; +: 2.0≤ and < 4.0 mg/dL

Red blood cells, White blood cells and Casts, -: not observed

Crystals and Epithelial cells, -: not observed; ±: a few

a), values represent as number of animals

b), values represent as mean ± S.D.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 25-1. Hematological findings of male rats at the end of the dosing period

Group	Control (vehicle: corn oil)	2-DT 62.5 mg/kg	2-DT 250 mg/kg	2-DT 1000 mg/kg
Number of males	5	5	5	5
RBC ($\times 10^4/\mu\text{L}$)	829 ± 24	800 ± 68	842 ± 82	826 ± 38
Hemoglobin (g/dL)	15.2 ± 0.6	14.7 ± 1.2	15.4 ± 1.2	14.9 ± 0.8
Hematocrit (%)	43.3 ± 1.3	42.2 ± 2.7	43.8 ± 2.5	42.9 ± 2.6
MCV (fL)	52.2 ± 1.6	52.9 ± 2.0	52.3 ± 2.8	52.0 ± 1.5
MCH (pg)	18.3 ± 0.6	18.3 ± 0.4	18.3 ± 0.6	18.1 ± 0.4
MCHC (g/dL)	35.1 ± 0.5	34.7 ± 0.8	35.0 ± 1.0	34.8 ± 0.5
Platelet ($\times 10^4/\mu\text{L}$)	119.0 ± 13.2	100.0 ± 7.9	104.5 ± 16.6	102.3 ± 17.9
PT (sec)	15.3 ± 1.1	15.9 ± 4.4	21.7 ± 3.8 *	24.0 ± 2.8 **
APTT (sec)	24.6 ± 1.8	23.6 ± 3.3	27.9 ± 3.3	28.0 ± 2.9
WBC ($\times 10^2/\mu\text{L}$)	102.6 ± 31.4	93.6 ± 22.4	87.8 ± 14.6	82.2 ± 13.1
Differential leukocyte count (%)				
Neutrophil	17.5 ± 7.8	18.0 ± 8.0	20.4 ± 3.3	24.3 ± 10.5
Eosinophil	1.8 ± 0.9	1.5 ± 0.7	1.6 ± 0.5	1.7 ± 0.4
Basophil	0.1 ± 0.0	0.0 ± 0.1	0.0 ± 0.0	0.0 ± 0.0
Monocyte	4.6 ± 0.8	3.8 ± 1.3	4.3 ± 0.5	4.6 ± 0.7
Lymphocyte	75.9 ± 8.6	76.7 ± 9.2	73.6 ± 3.9	69.3 ± 11.1
Reticulocyte count (%)	2.91 ± 0.48	4.15 ± 2.81	3.33 ± 0.61	3.59 ± 1.28

Each value shows mean±S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 25-2. Hematological findings of male rats at the end of the recovery period

Group	Control (vehicle: corn oil)		2-DT 1000 mg/kg	
		5		5
Number of males				
RBC ($\times 10^4/\mu\text{L}$)	861	\pm 35	840	\pm 57
Hemoglobin (g/dL)	15.4	\pm 0.6	15.2	\pm 0.9
Hematocrit (%)	43.1	\pm 1.1	43.4	\pm 1.9
MCV (fL)	50.1	\pm 1.9	51.7	\pm 1.9
MCH (pg)	17.8	\pm 0.5	18.1	\pm 0.4
MCHC (g/dL)	35.6	\pm 0.6	35.0	\pm 0.7
Platelet ($\times 10^4/\mu\text{L}$)	114.6	\pm 6.7	109.9	\pm 5.9
PT (sec)	14.1	\pm 1.8	19.5	\pm 5.6
APTT (sec)	21.1	\pm 2.0	25.4	\pm 2.5 *
WBC ($\times 10^2/\mu\text{L}$)	87.2	\pm 19.0	78.7	\pm 20.8
Differential leukocyte count (%)				
Neutrophil	19.2	\pm 4.2	16.9	\pm 6.0
Eosinophil	2.3	\pm 0.9	2.0	\pm 0.7
Basophil	0.0	\pm 0.0	0.0	\pm 0.0
Monocyte	4.2	\pm 0.5	3.5	\pm 0.7
Lymphocyte	74.3	\pm 4.3	77.6	\pm 7.1
Reticulocyte count (%)	3.14	\pm 0.88	2.82	\pm 0.42

Each value shows mean \pm S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 26-1. Hematological findings of female rats at the end of the dosing period

Group	Control (vehicle: corn oil)		2-DT 62.5 mg/kg		2-DT 250 mg/kg		2-DT 1000 mg/kg							
Number of females			5			5								
RBC ($\times 10^4/\mu\text{L}$)	671	\pm	53	636	\pm	46	665	\pm	32	672	\pm	42		
Hemoglobin (g/dL)	13.1	\pm	0.7	12.5	\pm	0.7	12.9	\pm	0.7	13.2	\pm	0.4		
Hematocrit (%)	38.7	\pm	1.6	37.3	\pm	1.3	39.0	\pm	2.1	39.9	\pm	1.2		
MCV (fL)	57.8	\pm	2.7	58.9	\pm	3.0	58.7	\pm	0.9	59.5	\pm	3.0		
MCH (pg)	19.6	\pm	0.6	19.7	\pm	0.7	19.4	\pm	0.2	19.6	\pm	0.8		
MCHC (g/dL)	33.9	\pm	0.6	33.5	\pm	0.7	33.1	\pm	0.4	33.1	\pm	0.4		
Platelet ($\times 10^4/\mu\text{L}$)	138.0	\pm	25.0	110.8	\pm	6.8	107.3	\pm	7.1	106.6	\pm	8.7		
PT (sec)	12.7	\pm	0.3	12.6	\pm	0.7	12.6	\pm	0.5	12.2	\pm	0.7		
APTT (sec)	19.9	\pm	0.9	20.2	\pm	0.9	20.2	\pm	1.5	19.7	\pm	1.2		
WBC ($\times 10^2/\mu\text{L}$)	105.0	\pm	22.3	92.3	\pm	22.9	104.9	\pm	31.4	88.5	\pm	24.8		
Differential leukocyte count (%)														
Neutrophil	27.0	\pm	4.5	40.1	\pm	8.3	**	35.8	\pm	4.9	29.9	\pm	1.8	
Eosinophil	1.2	\pm	0.6	0.6	\pm	0.2		0.9	\pm	0.4	0.7	\pm	0.5	
Basophil	0.0	\pm	0.1	0.0	\pm	0.0		0.0	\pm	0.0	0.0	\pm	0.1	
Monocyte	3.9	\pm	1.0	2.4	\pm	0.8	*	4.0	\pm	0.2	3.4	\pm	0.8	
Lymphocyte	67.8	\pm	3.8	56.9	\pm	8.5	*	59.2	\pm	5.0	*	65.9	\pm	1.3
Reticulocyte count (%)	8.47	\pm	2.55	9.18	\pm	3.70		8.16	\pm	1.22	9.36	\pm	3.19	

Each value shows mean \pm S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 26-2. Hematological findings of female rats at the end of the dosing period, satellite group

Group Number of females	Control (vehicle: corn oil)		2-DT 1000 mg/kg	
	5	5	5	5
RBC ($\times 10^4/\mu\text{L}$)	778 ± 32		812 ± 51	
Hemoglobin (g/dL)	14.8 ± 0.6		14.6 ± 0.7	
Hematocrit (%)	41.7 ± 1.2		41.2 ± 1.6	
MCV (fL)	53.6 ± 0.7		50.9 ± 1.7 *	
MCH (pg)	19.0 ± 0.3		18.0 ± 0.4 **	
MCHC (g/dL)	35.4 ± 0.8		35.4 ± 0.4	
Platelet ($\times 10^4/\mu\text{L}$)	110.5 ± 3.4		111.9 ± 13.4	
PT (sec)	11.7 ± 0.7		11.9 ± 0.2	
APTT (sec)	19.6 ± 2.5		21.4 ± 2.8	
WBC ($\times 10^2/\mu\text{L}$)	62.0 ± 11.9		51.8 ± 10.8	
Differential leukocyte count (%)				
Neutrophil	13.5 ± 2.8		13.0 ± 4.7	
Eosinophil	1.8 ± 0.7		1.9 ± 0.4	
Basophil	0.0 ± 0.0		0.0 ± 0.0	
Monocyte	2.8 ± 0.9		3.1 ± 0.9	
Lymphocyte	81.9 ± 3.1		82.0 ± 5.6	
Reticulocyte count (%)	3.60 ± 1.26		3.02 ± 0.19	

Each value shows mean±S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 26-3. Hematological findings of female rats at the end of the recovery period

Group Number of females	Control (vehicle: corn oil)		2-DT 1000 mg/kg	
		5		5
RBC ($\times 10^4/\mu\text{L}$)	802	\pm 44	836	\pm 39
Hemoglobin (g/dL)	15.0	\pm 0.5	15.5	\pm 0.9
Hematocrit (%)	42.4	\pm 1.0	43.6	\pm 2.3
MCV (fL)	53.0	\pm 2.7	52.1	\pm 2.9
MCH (pg)	18.7	\pm 0.9	18.5	\pm 1.0
MCHC (g/dL)	35.3	\pm 0.6	35.5	\pm 0.7
Platelet ($\times 10^4/\mu\text{L}$)	107.9	\pm 11.3	110.4	\pm 17.3
PT (sec)	11.5	\pm 0.5	11.5	\pm 0.4
APTT (sec)	18.1	\pm 1.1	19.2	\pm 2.1
WBC ($\times 10^2/\mu\text{L}$)	64.3	\pm 13.1	65.1	\pm 22.1
Differential leukocyte count (%)				
Neutrophil	15.4	\pm 7.5	16.7	\pm 8.6
Eosinophil	1.4	\pm 0.2	1.4	\pm 0.8
Basophil	0.0	\pm 0.0	0.0	\pm 0.0
Monocyte	2.8	\pm 0.8	3.3	\pm 2.3
Lymphocyte	80.4	\pm 7.9	78.6	\pm 9.3
Reticulocyte count (%)	3.35	\pm 0.51	2.94	\pm 0.54

Each value shows mean \pm S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 27-1. Biochemical findings of male rats at the end of the dosing period

Group Number of males		Control (vehicle: corn oil) 5	2-DT 62.5 mg/kg 5	2-DT 250 mg/kg 5	2-DT 1000 mg/kg 5
Total protein	g/dL	5.8 ± 0.1	5.6 ± 0.2	5.6 ± 0.4	5.5 ± 0.3
Albumin	g/dL	3.8 ± 0.1	3.7 ± 0.1	3.8 ± 0.2	3.7 ± 0.2
A/G		1.94 ± 0.13	2.00 ± 0.12	2.05 ± 0.13	2.13 ± 0.13
Glucose	mg/dL	142 ± 8	146 ± 18	140 ± 19	143 ± 11
Total cholesterol	mg/dL	55 ± 11	59 ± 16	49 ± 9	44 ± 15
Triglyceride	mg/dL	46 ± 29	26 ± 5	47 ± 22	34 ± 19
Phospholipid	mg/dL	89 ± 12	87 ± 16	84 ± 15	77 ± 17
AST	U/L	56 ± 5	64 ± 23	57 ± 4	80 ± 46
ALT	U/L	26 ± 3	32 ± 17	28 ± 3	58 ± 65
γ-GTP	U/L	0 ± 0	0 ± 0	0 ± 0	0 ± 0
LDH	U/L	175 ± 34	211 ± 24	282 ± 89 *	345 ± 63 **
Bile acid	μmol/L	11.0 ± 2.7	12.7 ± 7.0	12.4 ± 5.2	14.6 ± 6.8
BUN	mg/dL	15 ± 2	13 ± 1	13 ± 1	14 ± 2
Creatinine	mg/dL	0.5 ± 0.0	0.5 ± 0.1	0.5 ± 0.1	0.4 ± 0.1
Total bilirubin	mg/dL	0.05 ± 0.00	0.05 ± 0.01	0.05 ± 0.01	0.05 ± 0.01
ALP	U/L	296 ± 58	362 ± 88	374 ± 23	382 ± 42
Inorganic phosphorus	mg/dL	5.4 ± 0.4	5.8 ± 0.4	6.0 ± 0.3	5.6 ± 0.2
Ca	mg/dL	9.5 ± 0.1	9.6 ± 0.2	9.5 ± 0.4	9.3 ± 0.2
Na	mEq/L	144 ± 0.9	144.4 ± 0.8	144.5 ± 0.7	143.8 ± 1.2
K	mEq/L	3.64 ± 0.18	3.74 ± 0.12	3.75 ± 0.16	3.75 ± 0.16
Cl	mEq/L	106.8 ± 1.6	107.3 ± 0.9	107.7 ± 1.2	108.1 ± 0.8

Each value shows mean ± S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 27-2. Biochemical findings of male rats at the end of the recovery period

Group Number of males	Control (vehicle: corn oil)		2-DT 1000 mg/kg 5
		5	
Total protein	g/dL	5.6 ± 0.1	5.5 ± 0.3
Albumin	g/dL	3.6 ± 0.2	3.5 ± 0.2
A/G		1.75 ± 0.12	1.80 ± 0.12
Glucose	mg/dL	149 ± 11	140 ± 12
Total cholesterol	mg/dL	54 ± 7	53 ± 8
Triglyceride	mg/dL	47 ± 16	33 ± 13
Phospholipid	mg/dL	91 ± 7	83 ± 8
AST	U/L	61 ± 12	58 ± 5
ALT	U/L	26 ± 3	24 ± 2
γ-GTP	U/L	0 ± 0	0 ± 0
LDH	U/L	82 ± 31	171 ± 156
Bile acid	μmol/L	20.0 ± 17.3	9.0 ± 4.3
BUN	mg/dL	15 ± 2	14 ± 1
Creatinine	mg/dL	0.5 ± 0.1	0.4 ± 0.1
Total bilirubin	mg/dL	0.05 ± 0.01	0.04 ± 0.00
ALP	U/L	226 ± 34	220 ± 32
Inorganic phosphorus	mg/dL	6.2 ± 0.4	6.2 ± 0.4
Ca	mg/dL	9.4 ± 0.2	9.6 ± 0.2
Na	mEq/L	144.7 ± 1.6	145.4 ± 1.1
K	mEq/L	3.79 ± 0.21	3.90 ± 0.30
Cl	mEq/L	107.9 ± 0.4	108.9 ± 1.1

Each value shows mean ± S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 28-1. Biochemical findings of female rats at the end of the dosing period

Group Number of females	Control (vehicle: corn oil)		2-DT 62.5 mg/kg	2-DT 250 mg/kg	2-DT 1000 mg/kg
		5	5	5	5
Total protein	g/dL	5.8 ± 0.2	6.0 ± 0.3	5.8 ± 0.3	5.8 ± 0.3
Albumin	g/dL	4.0 ± 0.2	4.0 ± 0.2	3.9 ± 0.2	4.0 ± 0.1
A/G		2.20 ± 0.12	2.05 ± 0.15	2.11 ± 0.16	2.31 ± 0.25
Glucose	mg/dL	125 ± 15	119 ± 19	126 ± 10	138 ± 10
Total cholesterol	mg/dL	60 ± 3	60 ± 16	55 ± 7	60 ± 12
Triglyceride	mg/dL	36 ± 12	25 ± 9	29 ± 10	43 ± 14
Phospholipid	mg/dL	111 ± 7	115 ± 18	106 ± 14	114 ± 16
AST	U/L	121 ± 68	180 ± 135	99 ± 12	87 ± 17
ALT	U/L	47 ± 15	65 ± 18	45 ± 4	41 ± 5
γ-GTP	U/L	0 ± 0	0 ± 0	0 ± 0	0 ± 1
LDH	U/L	137 ± 59	175 ± 48	211 ± 24	199 ± 80
Bile acid	μmol/L	15.4 ± 3.3	17.7 ± 7.7	15.8 ± 4.1	18.2 ± 20.0
BUN	mg/dL	15 ± 2	13 ± 2	13 ± 2	16 ± 3
Creatinine	mg/dL	0.5 ± 0.1	0.5 ± 0.0	0.5 ± 0.1	0.6 ± 0.1
Total bilirubin	mg/dL	0.05 ± 0.01	0.06 ± 0.01	0.06 ± 0.02	0.06 ± 0.01
ALP	U/L	138 ± 27	198 ± 67	182 ± 60	197 ± 99
Inorganic phosphorus	mg/dL	6.0 ± 0.6	6.1 ± 0.6	6.4 ± 0.5	6.3 ± 0.8
Ca	mg/dL	9.8 ± 0.3	10.1 ± 0.4	9.7 ± 0.2	9.7 ± 0.4
Na	mEq/L	142.6 ± 0.8	143.0 ± 1.4	142.6 ± 1.5	143.7 ± 1.1
K	mEq/L	3.84 ± 0.09	3.52 ± 0.36	3.67 ± 0.18	3.85 ± 0.50
Cl	mEq/L	108.5 ± 0.9	108.8 ± 1.7	107.8 ± 0.5	109.0 ± 3.1

Each value shows mean ± S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 28-2. Biochemical findings of female rats at the end of the dosing period, satellite group

Group Number of females	Control (vehicle: corn oil)		2-DT 1000 mg/kg
		5	5
Total protein	g/dL	6.0 ± 0.5	6.0 ± 0.6
Albumin	g/dL	4.1 ± 0.3	4.2 ± 0.4
A/G		2.23 ± 0.21	2.41 ± 0.31
Glucose	mg/dL	133 ± 17	127 ± 22
Total cholesterol	mg/dL	67 ± 9	67 ± 3
Triglyceride	mg/dL	17 ± 6	14 ± 7
Phospholipid	mg/dL	117 ± 14	119 ± 9
AST	U/L	71 ± 21	57 ± 7
ALT	U/L	31 ± 16	24 ± 8
γ-GTP	U/L	0 ± 0	0 ± 0
LDH	U/L	73 ± 9	77 ± 19
Bile acid	μmol/L	10.4 ± 6.2	16.0 ± 7.3
BUN	mg/dL	15 ± 2	16 ± 1
Creatinine	mg/dL	0.7 ± 0.1	0.6 ± 0.1
Total bilirubin	mg/dL	0.06 ± 0.02	0.06 ± 0.01
ALP	U/L	165 ± 39	206 ± 52
Inorganic phosphorus	mg/dL	4.8 ± 1.0	5.6 ± 0.7
Ca	mg/dL	9.6 ± 0.5	10.1 ± 0.4
Na	mEq/L	144.6 ± 0.9	143.1 ± 1.4
K	mEq/L	3.44 ± 0.23	3.68 ± 0.37
Cl	mEq/L	108.5 ± 1.4	107.8 ± 1.5

Each value shows mean ± S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 28-3. Biochemical findings of female rats at the end of the recovery period

Group Number of females	Control (vehicle: corn oil)		2-DT 1000 mg/kg
		5	5
Total protein	g/dL	6.1 ± 0.3	6.2 ± 0.5
Albumin	g/dL	4.1 ± 0.2	4.3 ± 0.4
A/G		2.08 ± 0.14	2.26 ± 0.11 *
Glucose	mg/dL	137 ± 15	156 ± 16
Total cholesterol	mg/dL	76 ± 7	83 ± 18
Triglyceride	mg/dL	16 ± 4	17 ± 4
Phospholipid	mg/dL	135 ± 12	140 ± 26
AST	U/L	53 ± 5	61 ± 15
ALT	U/L	21 ± 3	27 ± 13
γ-GTP	U/L	0 ± 0	0 ± 0
LDH	U/L	64 ± 23	101 ± 43
Bile acid	μmol/L	26.4 ± 13.4	15.2 ± 5.2
BUN	mg/dL	15 ± 1	14 ± 2
Creatinine	mg/dL	0.5 ± 0.1	0.5 ± 0.1
Total bilirubin	mg/dL	0.09 ± 0.03	0.07 ± 0.02
ALP	U/L	151 ± 35	138 ± 30
Inorganic phosphorus	mg/dL	6.5 ± 0.6	6.0 ± 0.6
Ca	mg/dL	9.6 ± 0.3	9.7 ± 0.5
Na	mEq/L	144.4 ± 0.8	144.1 ± 0.7
K	mEq/L	3.70 ± 0.26	3.72 ± 0.23
Cl	mEq/L	106.0 ± 0.9	107.1 ± 1.9

Each value shows mean ± S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 29-1. Organ weights of male rats at the end of the dosing period

Group Number of males	Control (vehicle: corn oil)		2-DT 62.5 mg/kg		2-DT 250 mg/kg		2-DT 1000 mg/kg	
		7		12		12		7
Body weight	(g)	522.5 ± 40.1		509.5 ± 33.3		513.0 ± 24.1		507.9 ± 25.6
Brain	(mg)	2062.4 ± 93.3		2025.5 ± 74.3		2035.8 ± 62.2		2027.5 ± 60.9
	(mg/g)	3.958 ± 0.192		3.991 ± 0.298		3.976 ± 0.217		4.003 ± 0.290
Thymus	(mg)	286.9 ± 57.6		237.1 ± 51.3		274.8 ± 83.4		319.3 ± 90.9
	(mg/g)	0.553 ± 0.120		0.469 ± 0.112		0.536 ± 0.159		0.636 ± 0.209
Heart	(mg)	1476.6 ± 189.1		1488.9 ± 189.8		1472.8 ± 114.8		1522.3 ± 113.2
	(mg/g)	2.824 ± 0.258		2.918 ± 0.255		2.874 ± 0.231		2.999 ± 0.201
Liver	(mg)	14262.9 ± 1781.2		14235.0 ± 1949.9		14548.9 ± 1777.3		13854.1 ± 1406.1
	(mg/g)	27.275 ± 2.435		27.879 ± 2.611		28.286 ± 2.476		27.242 ± 1.876
Kidney (R)	(mg)	1586.9 ± 254.9		1694.8 ± 156.5		1712.3 ± 179.7		1642.9 ± 105.6
	(mg/g)	3.028 ± 0.336		3.326 ± 0.202		3.340 ± 0.335		3.242 ± 0.269
Kidney (L)	(mg)	1622.9 ± 256.5		1640.9 ± 148.7		1694.8 ± 136.7		1653.7 ± 150.2
	(mg/g)	3.096 ± 0.325		3.219 ± 0.180		3.308 ± 0.270		3.263 ± 0.342
Kidney	(mg)	3209.8 ± 506.5		3335.7 ± 295.9		3407.1 ± 313.0		3296.6 ± 241.9
	(mg/g)	6.123 ± 0.649		6.545 ± 0.355		6.647 ± 0.597		6.505 ± 0.588
Spleen	(mg)	824.1 ± 76.3		878.4 ± 156.1		856.5 ± 83.1		799.4 ± 122.0
	(mg/g)	1.586 ± 0.198		1.724 ± 0.278		1.571 ± 0.156		1.572 ± 0.208
Testis (R)	(mg)	1695.4 ± 141.3		1706.7 ± 155.6		1650.3 ± 84.5		1692.4 ± 151.8
	(mg/g)	3.253 ± 0.271		3.361 ± 0.355		3.224 ± 0.229		3.338 ± 0.335
Testis (L)	(mg)	1693.7 ± 155.3		1702.3 ± 135.1		1643.8 ± 82.6		1692.5 ± 119.2
	(mg/g)	3.249 ± 0.282		3.352 ± 0.324		3.212 ± 0.233		3.339 ± 0.284
Testis	(mg)	3389.1 ± 294.8		3409.0 ± 288.5		3294.1 ± 161.0		3384.9 ± 269.0
	(mg/g)	6.502 ± 0.549		6.713 ± 0.675		6.436 ± 0.454		6.677 ± 0.613
Epididymis (R)	(mg)	625.0 ± 57.6		653.9 ± 52.0		639.6 ± 51.5		633.4 ± 40.2
	(mg/g)	1.200 ± 0.127		1.288 ± 0.125		1.250 ± 0.126		1.250 ± 0.099
Epididymis (L)	(mg)	611.0 ± 69.1		642.0 ± 62.1		650.4 ± 50.5		633.8 ± 40.8
	(mg/g)	1.175 ± 0.163		1.264 ± 0.139		1.273 ± 0.137		1.251 ± 0.110
Epididymis	(mg)	1236.0 ± 122.1		1295.9 ± 106.1		1290.0 ± 98.6		1267.1 ± 68.3
	(mg/g)	2.376 ± 0.284		2.552 ± 0.250		2.523 ± 0.258		2.500 ± 0.189

Each value shows mean ± S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 29-1(continued). Organ weights of male rats at the end of the dosing period

Group Number of males	Control (vehicle: corn oil)		2-DT 62.5 mg/kg		2-DT 250 mg/kg		2-DT 1000 mg/kg	
		7		12		12		7
Body weight	(g)	522.5 ± 40.1		509.5 ± 33.3		513.0 ± 24.1		507.9 ± 25.6
Prostate, ventral	(mg)	583.7 ± 106.8		626.6 ± 134.4		612.1 ± 139.0		785.6 ± 115.4 *
	(mg/g)	1.117 ± 0.190		1.236 ± 0.284		1.200 ± 0.296		1.546 ± 0.208 *
Seminal vesicles	(mg)	1514.2 ± 352.1		1710.9 ± 215.2		1844.3 ± 249.8		1786.0 ± 398.0
	(mg/g)	2.883 ± 0.559		3.364 ± 0.411		3.613 ± 0.582		3.531 ± 0.848
Thyroid gland	(mg)	18.7 ± 4.3		18.8 ± 4.3		18.7 ± 2.8		20.3 ± 4.4
	(mg/g)	0.036 ± 0.007		0.037 ± 0.009		0.036 ± 0.005		0.040 ± 0.008
Adrenal gland (R)	(mg)	28.2 ± 3.3		25.5 ± 3.8		27.1 ± 4.4		26.6 ± 7.4
	(mg/g)	0.054 ± 0.005		0.050 ± 0.009		0.053 ± 0.008		0.052 ± 0.014
Adrenal gland (L)	(mg)	29.1 ± 3.9		27.3 ± 4.1		28.0 ± 4.3		28.3 ± 6.8
	(mg/g)	0.056 ± 0.006		0.054 ± 0.008		0.055 ± 0.008		0.055 ± 0.013
Adrenal gland	(mg)	57.3 ± 6.9		52.8 ± 7.6		55.1 ± 8.6		54.8 ± 14.0
	(mg/g)	0.110 ± 0.010		0.104 ± 0.016		0.108 ± 0.016		0.108 ± 0.026

Each value shows mean ± S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 29-2. Organ weights of male rats at the end of the recovery period

Group Number of males	Control (vehicle: corn oil)		2-DT 1000 mg/kg	
		5		5
Body weight	(g)	504.6 ± 25.9		537.0 ± 29.0
Brain	(mg)	2062.4 ± 64.7		2037.3 ± 117.0
	(mg/g)	4.096 ± 0.252		3.794 ± 0.087 *
Thymus	(mg)	304.9 ± 72.2		280.1 ± 56.4
	(mg/g)	0.610 ± 0.164		0.524 ± 0.120
Heart	(mg)	1459.0 ± 96.9		1480.2 ± 72.5
	(mg/g)	2.891 ± 0.139		2.760 ± 0.136
Liver	(mg)	13210.5 ± 1100.7		13547.8 ± 1080.2
	(mg/g)	26.166 ± 1.414		25.235 ± 1.666
Kidney (R)	(mg)	1570.1 ± 92.3		1591.8 ± 140.5
	(mg/g)	3.113 ± 0.153		2.972 ± 0.317
Kidney (L)	(mg)	1556.6 ± 89.8		1587.7 ± 139.0
	(mg/g)	3.088 ± 0.177		2.962 ± 0.289
Kidney	(mg)	3126.6 ± 172.7		3179.5 ± 277.6
	(mg/g)	6.201 ± 0.312		5.934 ± 0.604
Spleen	(mg)	820.3 ± 146.1		841.5 ± 46.7
	(mg/g)	1.630 ± 0.324		1.572 ± 0.146
Testis (R)	(mg)	1685.2 ± 138.6		1610.4 ± 128.9
	(mg/g)	3.342 ± 0.262		3.014 ± 0.370
Testis (L)	(mg)	1678.5 ± 155.0		1608.8 ± 111.5
	(mg/g)	3.327 ± 0.269		3.010 ± 0.341
Testis	(mg)	3363.7 ± 292.1		3219.2 ± 238.3
	(mg/g)	6.669 ± 0.526		6.023 ± 0.708
Epididymis (R)	(mg)	668.7 ± 90.1		635.9 ± 23.4
	(mg/g)	1.322 ± 0.134		1.189 ± 0.104
Epididymis (L)	(mg)	659.2 ± 66.0		638.0 ± 18.9
	(mg/g)	1.305 ± 0.091		1.192 ± 0.090
Epididymis	(mg)	1327.9 ± 156.0		1273.9 ± 40.5
	(mg/g)	2.627 ± 0.224		2.381 ± 0.193

Each value shows mean ± S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 29-2(continued). Organ weights of male rats at the end of the recovery period

Group Number of males	Control (vehicle: corn oil)			2-DT 1000 mg/kg		
		5		5		5
Body weight	(g)	504.6 ± 25.9		537.0 ± 29.0		
Prostate, ventral	(mg)	735.1 ± 201.9		682.3 ± 148.1		
	(mg/g)	1.451 ± 0.375		1.278 ± 0.316		
Seminal vesicles	(mg)	1647.3 ± 390.6		1587.7 ± 238.0		
	(mg/g)	3.260 ± 0.757		2.960 ± 0.435		
Thyroid gland	(mg)	17.2 ± 4.5		20.0 ± 4.9		
	(mg/g)	0.034 ± 0.009		0.037 ± 0.010		
Adrenal gland (R)	(mg)	23.6 ± 3.1		23.3 ± 2.1		
	(mg/g)	0.047 ± 0.007		0.043 ± 0.003		
Adrenal gland (L)	(mg)	25.4 ± 2.2		22.9 ± 1.6		
	(mg/g)	0.051 ± 0.005		0.043 ± 0.003 *		
Adrenal glands	(mg)	49.0 ± 4.7		46.2 ± 3.6		
	(mg/g)	0.097 ± 0.011		0.086 ± 0.006		

Each value shows mean ± S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 30-1. Organ weights of female rats at the end of the dosing period

Group Number of females	Control (vehicle: corn oil)		2-DT 62.5 mg/kg		2-DT 250 mg/kg		2-DT 1000 mg/kg	
	11	12	12	12	12	12	12	12
Body weight	(g)	310.1 ± 14.7	316.2 ± 19.4	318.0 ± 12.5	313.7 ± 12.2			
Brain	(mg)	1932.2 ± 59.1	1921.7 ± 71.1	1897.2 ± 54.0	1909.9 ± 79.5			
	(mg/g)	6.240 ± 0.283	6.093 ± 0.334	5.975 ± 0.304	6.091 ± 0.212			
Thymus	(mg)	202.4 ± 49.5	228.8 ± 57.6	212.1 ± 68.3	245.3 ± 74.8			
	(mg/g)	0.651 ± 0.151	0.720 ± 0.165	0.663 ± 0.205	0.781 ± 0.242			
Heart	(mg)	978.8 ± 91.7	1014.8 ± 82.0	1022.6 ± 62.9	1018.7 ± 63.4			
	(mg/g)	3.155 ± 0.219	3.209 ± 0.146	3.217 ± 0.173	3.253 ± 0.255			
Liver	(mg)	9975.3 ± 1075.1	10272.1 ± 611.0	9929.9 ± 834.6	10063.9 ± 797.8			
	(mg/g)	32.167 ± 3.132	32.525 ± 1.632	31.229 ± 2.355	32.134 ± 2.994			
Kidney (R)	(mg)	968.3 ± 102.7	1085.9 ± 161.8	1002.8 ± 75.2	1016.9 ± 93.2			
	(mg/g)	3.124 ± 0.317	3.423 ± 0.329	3.153 ± 0.191	3.253 ± 0.383			
Kidney (L)	(mg)	959.3 ± 108.7	1069.5 ± 199.0	979.7 ± 85.6	1001.9 ± 74.0			
	(mg/g)	3.095 ± 0.329	3.366 ± 0.427	3.083 ± 0.253	3.203 ± 0.319			
Kidney	(mg)	1927.6 ± 205.3	2155.4 ± 360.2	1982.5 ± 150.7	2018.8 ± 163.5			
	(mg/g)	6.219 ± 0.626	6.788 ± 0.752	6.236 ± 0.412	6.455 ± 0.693			
Spleen	(mg)	696.1 ± 101.8	717.4 ± 126.5	677.7 ± 105.8	756.6 ± 134.5			
	(mg/g)	2.249 ± 0.359	2.269 ± 0.377	2.132 ± 0.330	2.409 ± 0.403			
Ovary (R)	(mg)	51.0 ± 6.0	55.0 ± 7.7	55.5 ± 7.1	53.9 ± 11.1			
	(mg/g)	0.164 ± 0.017	0.174 ± 0.024	0.175 ± 0.025	0.172 ± 0.035			
Ovary (L)	(mg)	49.7 ± 10.0	53.9 ± 8.3	56.8 ± 10.5	50.7 ± 6.7			
	(mg/g)	0.160 ± 0.029	0.171 ± 0.026	0.179 ± 0.035	0.162 ± 0.023			
Ovary	(mg)	100.7 ± 13.8	109.0 ± 10.1	112.2 ± 14.4	104.7 ± 13.4			
	(mg/g)	0.324 ± 0.038	0.345 ± 0.031	0.354 ± 0.050	0.334 ± 0.044			
Uterus	(mg)	602.7 ± 74.8	611.0 ± 81.8	568.5 ± 81.8	626.9 ± 76.5			
	(mg/g)	1.949 ± 0.273	1.933 ± 0.230	1.786 ± 0.234	1.999 ± 0.229			
Thyroid gland	(mg)	12.9 ± 4.9	15.3 ± 2.8	13.9 ± 2.4	14.9 ± 3.6			
	(mg/g)	0.041 ± 0.014	0.049 ± 0.009	0.044 ± 0.007	0.048 ± 0.012			
Adrenal gland (R)	(mg)	34.7 ± 6.7	36.6 ± 6.9	35.8 ± 5.1	38.4 ± 8.0			
	(mg/g)	0.112 ± 0.020	0.116 ± 0.025	0.113 ± 0.016	0.123 ± 0.025			
Adrenal gland (L)	(mg)	35.8 ± 6.7	39.2 ± 7.7	38.4 ± 5.8	39.8 ± 8.5			
	(mg/g)	0.115 ± 0.019	0.125 ± 0.027	0.121 ± 0.018	0.127 ± 0.026			
Adrenal gland	(mg)	70.4 ± 13.0	75.9 ± 14.2	74.3 ± 10.7	78.2 ± 15.7			
	(mg/g)	0.227 ± 0.038	0.241 ± 0.050	0.234 ± 0.033	0.249 ± 0.049			

Each value shows mean ± S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 30-2. Organ weights of female rats at the end of the dosing period, satellite group

Group		Control (vehicle: corn oil)	2-DT 1000 mg/kg
Number of females		5	5
Body weight	(g)	304.8 ± 26.5	269.7 ± 21.0 *
Brain	(mg)	1819.7 ± 63.8	1918.2 ± 46.6 *
	(mg/g)	5.991 ± 0.328	7.150 ± 0.619 **
Thymus	(mg)	310.8 ± 21.9	274.0 ± 75.6
	(mg/g)	1.025 ± 0.114	1.012 ± 0.255
Heart	(mg)	908.6 ± 58.0	875.3 ± 67.7
	(mg/g)	2.989 ± 0.192	3.253 ± 0.228
Liver	(mg)	7575.1 ± 754.4	7036.0 ± 357.3
	(mg/g)	24.848 ± 1.222	26.214 ± 2.366
Kidney (R)	(mg)	892.3 ± 70.4	873.2 ± 76.6
	(mg/g)	2.929 ± 0.064	3.238 ± 0.122 **
Kidney (L)	(mg)	865.2 ± 85.1	862.7 ± 76.6
	(mg/g)	2.840 ± 0.177	3.200 ± 0.161 **
Kidney	(mg)	1757.5 ± 142.1	1735.9 ± 151.6
	(mg/g)	5.769 ± 0.141	6.438 ± 0.272 **
Spleen	(mg)	542.9 ± 87.1	538.6 ± 31.6
	(mg/g)	1.788 ± 0.310	2.001 ± 0.082
Ovary (R)	(mg)	42.5 ± 6.8	48.6 ± 3.8
	(mg/g)	0.139 ± 0.018	0.181 ± 0.021 *
Ovary (L)	(mg)	47.9 ± 10.9	39.4 ± 5.0
	(mg/g)	0.157 ± 0.032	0.147 ± 0.022
Ovary	(mg)	90.4 ± 16.3	88.1 ± 8.5
	(mg/g)	0.296 ± 0.044	0.328 ± 0.042
Uterus	(mg)	946.9 ± 362.8	464.1 ± 38.8 *
	(mg/g)	3.171 ± 1.303	1.736 ± 0.265 *
Thyroid gland	(mg)	12.9 ± 5.1	11.4 ± 3.5
	(mg/g)	0.042 ± 0.014	0.043 ± 0.015
Adrenal gland (R)	(mg)	33.5 ± 7.2	30.9 ± 3.1
	(mg/g)	0.109 ± 0.017	0.115 ± 0.008
Adrenal gland (L)	(mg)	36.9 ± 6.0	31.6 ± 4.0
	(mg/g)	0.120 ± 0.013	0.117 ± 0.014
Adrenal gland	(mg)	70.3 ± 13.1	62.5 ± 6.6
	(mg/g)	0.230 ± 0.030	0.232 ± 0.020

Each value shows mean ± S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 30-3. Organ weights of female rats at the end of the recovery period

Group	Control (vehicle: corn oil)		2-DT 1000 mg/kg	
Number of females		5		5
Body weight	(g)	284.0 ± 20.7	301.8 ± 24.7	
Brain	(mg)	1877.5 ± 11.8	1933.8 ± 103.7	
	(mg/g)	6.643 ± 0.535	6.437 ± 0.565	
Thymus	(mg)	219.9 ± 45.0	269.1 ± 106.5	
	(mg/g)	0.782 ± 0.191	0.877 ± 0.281	
Heart	(mg)	825.2 ± 51.4	927.1 ± 43.2 **	
	(mg/g)	2.910 ± 0.121	3.088 ± 0.289	
Liver	(mg)	6842.7 ± 202.2	7483.3 ± 574.1 *	
	(mg/g)	24.215 ± 2.113	24.813 ± 0.810	
Kidney (R)	(mg)	829.5 ± 66.5	922.6 ± 36.6 *	
	(mg/g)	2.932 ± 0.290	3.074 ± 0.284	
Kidney (L)	(mg)	816.9 ± 72.0	905.8 ± 30.2 *	
	(mg/g)	2.887 ± 0.298	3.015 ± 0.238	
Kidney	(mg)	1646.4 ± 137.6	1828.4 ± 63.7 *	
	(mg/g)	5.819 ± 0.585	6.089 ± 0.518	
Spleen	(mg)	540.1 ± 48.5	593.0 ± 121.8	
	(mg/g)	1.908 ± 0.188	1.953 ± 0.265	
Ovary (R)	(mg)	45.1 ± 13.2	41.2 ± 8.1	
	(mg/g)	0.160 ± 0.048	0.137 ± 0.028	
Ovary (L)	(mg)	39.8 ± 3.4	43.2 ± 10.0	
	(mg/g)	0.141 ± 0.019	0.143 ± 0.027	
Ovary	(mg)	84.9 ± 13.2	84.4 ± 16.6	
	(mg/g)	0.300 ± 0.054	0.280 ± 0.050	
Uterus	(mg)	714.8 ± 380.0	550.3 ± 216.8	
	(mg/g)	2.513 ± 1.281	1.802 ± 0.591	
Thyroid gland	(mg)	17.1 ± 4.6	13.5 ± 2.4	
	(mg/g)	0.060 ± 0.015	0.045 ± 0.009	
Adrenal gland (R)	(mg)	27.1 ± 4.5	25.0 ± 4.2	
	(mg/g)	0.096 ± 0.015	0.083 ± 0.012	
Adrenal gland (L)	(mg)	28.5 ± 4.3	27.1 ± 4.8	
	(mg/g)	0.100 ± 0.013	0.090 ± 0.011	
Adrenal gland	(mg)	55.6 ± 8.6	52.2 ± 8.8	
	(mg/g)	0.196 ± 0.028	0.172 ± 0.021	

Each value shows mean ± S.D.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 31-1. Macroscopic findings of male rats at the end of the dosing period

Findings	Group Grade	Control (vehicle: corn oil)		2-DT 62.5 mg/kg		2-DT 250 mg/kg		2-DT 1000 mg/kg	
		-	P	-	P	-	P	-	P
Forestomach									
Edematous, mucosa		7	0	12	0	12	0	5	2
Prostate									
Small		6	1	12	0	12	0	7	0
Seminal vesicle									
Small		6	1	12	0	12	0	7	0

Notes) - : No abnormal changes P : Non-graded change

Numerals represent the number of animals.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 31-2. Macroscopic findings of male rats at the end of the recovery period

Findings	Group Grade	Control (vehicle: corn oil)		2-DT 1000 mg/kg	
		-	P	-	P
All organs and tissues		5		5	

Notes) - : No abnormal changes P : Non-graded change

Numerals represent the number of animals.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 32-1. Macroscopic findings of female rats at the end of the dosing period

Findings	Group Grade	Control (vehicle: corn oil)		2-DT 62.5 mg/kg		2-DT 250 mg/kg		2-DT 1000 mg/kg	
		-	P	-	P	-	P	-	P
Forestomach									
Edematous, mucosa		11	0	12	0	12	0	9	3
Glandular stomach									
Dark colored spot, mucosa		11	0	12	0	12	0	11	1
Recessed area, mucosa, dark		9	2	11	1	11	1	12	0

Notes) - : No abnormal changes P : Non-graded change

Numerals represent the number of animals.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 32-2. Macroscopic findings of female rats at the end of the dosing period, satellite group

Findings	Group Grade	Control (vehicle: corn oil)		2-DT 1000 mg/kg	
		-	P	-	P
Forestomach					
Edematous, mucosa		5	0	4	1

Notes) - : No abnormal changes P : Non-graded change

Numerals represent the number of animals.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 32-3. Macroscopic findings of female rats at the end of the recovery period

Findings	Group Grade	Control (vehicle: corn oil)		2-DT 1000 mg/kg	
		-	P	-	P
All organs and tissues		5		5	

Notes) - : No abnormal changes P : Non-graded change

Numerals represent the number of animals.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 33. Histopathological findings of male rats at the end of the dosing period

Findings	Group Grade	Control (vehicle: corn oil)						2-DT 1000 mg/kg						
		-	±	+	2+	3+	P	NE	-	±	+	2+	3+	P
Brain		5					7		5					7
Spinal cord		5					7		5					7
Pituitary gland		5					7		5					7
Submandibular gland														
Cellular infiltration, lymphocyte, interstitial		4	1	0	0	0		7	5	0	0	0	0	7
Sublingual gland		5					7		5					7
Lymph node, submandibular		5					7		5					7
Thyroid gland														
Ectopic thymic tissue		4					1	7	5				0	7
Parathyroid gland		4					8		5					7
Thymus		5					7		5					7
Heart														
Degeneration/fibrosis, myocardial a)		4	1	0	0	0		7	4	1	0	0	0	7
Trachea		5					7		5					7
Lung														
Accumulation, foam cell, alveolus		3	2	0	0	0		7	5	0	0	0	0	7
Bronchus		5					7		5					7
Liver														
Cellular infiltration, lymphocyte, periportal		4	1	0	0	0		7	5	0	0	0	0	7
Fatty change, hepatocyte, periportal		4	1	0	0	0		7	4	1	0	0	0	7
Hematopoiesis, extramedullary		5	0	0	0	0		7	4	1	0	0	0	7
Microgranuloma		2	3	0	0	0		7	1	3	1	0	0	7
Necrosis, focal		5	0	0	0	0		7	4	0	1	0	0	7
Pancreas		5					7		5					7
Stomach														
Cellular infiltration, mononuclear cell, submucosa, glandular stomach		3	2	0	0	0		7	5	0	0	0	0	7
Edema, lamina propria/submucosa, forestomach		5	0	0	0	0		7	4	1	0	0	0	7
Duodenum		5					7		5					7

Notes) - : No abnormal changes ±: Very slight +: Slight 2+: Moderate 3+: Marked

P : Non-graded change NE: Not examined a) right ventricle

Numerals represent the number of animals.

Not significantly different from control.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 33(continued). Histopathological findings of male rats at the end of the dosing period

Findings	Group Grade	Control (vehicle: corn oil)						2-DT 1000 mg/kg						
		-	±	+	2+	3+	P	NE	-	±	+	2+	3+	P
Jejunum		5					7		5					7
Ileum		5					7		5					7
Cecum		5					7		5					7
Colon		5					7		5					7
Rectum		5					7		5					7
Lymph node, mesenteric		5					7		5					7
Spleen														
Deposit, pigment, brown		0	3	2	0	0	7		0	4	1	0	0	7
Hematopoiesis, extramedullary		0	1	4	0	0	7		0	2	1	2	0	7
Kidney														
Basophilic tubule, cortex		1	4	0	0	0	7		2	3	0	0	0	7
Cast, hyalin, cortico-medullary junction/papilla		4	1	0	0	0	7		4	1	0	0	0	7
Eosinophilic body		5	0	0	0	0	7		4	1	0	0	0	7
Mineralization, cortex		4	1	0	0	0	7		5	0	0	0	0	7
Urinary bladder		5					7		5					7
Adrenal gland		5					7		5					7
Testis		5					7		5					7
Epididymis		5					7		5					7
Prostate														
Cellular infiltration, lymphocytic, interstitial		4	1	0	0	0	7		3	2	0	0	0	7
Seminal vesicle		5					7		5					7
Coagulating gland		5					7		5					7
Eyeball		5					7		5					7
Harderian gland		5					7		5					7
Sciatic nerve		5					7		5					7
Skeletal muscle														
Degeneration, muscle fiber, myogenic		4	1	0	0	0	7		5	0	0	0	0	7
Femur		5					7		5					7
Marrow, femur		5					7		5					7

Notes) - : No abnormal changes ±: Very slight +: Slight 2+: Moderate 3+: Marked

P : Non-graded change NE: Not examined

Numerals represent the number of animals.

Not significantly different from control.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 34-1. Histopathological findings of female rats at the end of the dosing period

Findings	Group Grade	Control (vehicle: corn oil)						2-DT 1000 mg/kg						
		-	±	+	2+	3+	P	NE	-	±	+	2+	3+	P
Brain		5						7	5					7
Spinal cord		5						7	5					7
Pituitary gland														
Remnant, Rathke's pouch		4				1	7		5			0	7	
Submandibular gland		5						7	5					7
Sublingual gland		5						7	5					7
Lymph node, submandibular		5						7	5					7
Thyroid gland														
Ultimobranchial rest		3				2	7		5			0	7	
Parathyroid gland		4						8	5					7
Thymus		5						7	5					7
Heart														
Degeneration/fibrosis, myocardial		4	1	0	0	0		7	4	1	0	0	0	7
Trachea		5						7	5					7
Lung														
Accumulation, foam cell, alveolus		3	2	0	0	0		7	3	2	0	0	0	7
Bronchus		5						7	5					7
Liver														
Fatty change, hepatocyte, periportal		4	1	0	0	0		7	5	0	0	0	0	7
Hematopoiesis, extramedullary		4	1	0	0	0		7	4	1	0	0	0	7
Microgranuloma		4	1	0	0	0		7	3	2	0	0	0	7
Necrosis, focal		4	1	0	0	0		7	4	1	0	0	0	7
Pancreas		5						7	5					7
Stomach														
Dilatation, lumen, fundic gland, focal, glandular stomach		5	1	0	0	0		6	7	0	0	0	0	5
Edema, lamina propria/ submucosa, forestomach		5	1	0	0	0		6	7	0	0	0	0	5
Erosion, focal, glandular stomach		5	1	0	0	0		6	6	1	0	0	0	5
Duodenum		5						7	5					7
Jejunum		5						7	5					7

Notes) - : No abnormal changes ±: Very slight +: Slight 2+: Moderate 3+: Marked

P : Non-graded change NE: Not examined

Numerals represent the number of animals.

Not significantly different from control.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 34-1(continued). Histopathological findings of female rats at the end of the dosing period

Findings	Group Grade	Control (vehicle: corn oil)						2-DT 1000 mg/kg						
		-	±	+	2+	3+	P	NE	-	±	+	2+	3+	P
Ileum		5						7	5					7
Cecum		5						7	5					7
Colon		5						7	5					7
Rectum		5						7	5					7
Lymph node, mesenteric		5						7	5					7
Spleen														
Deposit, pigment, brown		0	2	3	0	0		7	0	3	2	0	0	7
Hematopoiesis, extramedullary		0	0	2	3	0		7	0	0	2	3	0	7
Kidney														
Basophilic tubule, cortex		3	1	1	0	0		7	4	1	0	0	0	7
Cellular infiltration, lymphocyte, interstitial		4	1	0	0	0		7	4	1	0	0	0	7
Dilatation, pelvis, unilateral		4	0	1	0	0		7	5	0	0	0	0	7
Mineralization, cortex-medullary junction/ papilla		4	1	0	0	0		7	4	1	0	0	0	7
Urinary bladder														
Cellular infiltration, inflammatory, lamina propria		5	0	0	0	0		7	4	1	0	0	0	7
Adrenal gland		5						7	5					7
Ovary														
Cyst, follicular		4	1	0	0	0		7	5	0	0	0	0	7
Uterus		5						7	5					7
Vagina		5						7	5					7
Eyeball		5						7	5					7
Harderian gland		5						7	5					7
Sciatic nerve		5						7	5					7
Skeletal muscle														
Degeneration, muscle fiber, myogenic		4	1	0	0	0		7	4	1	0	0	0	7
Femur		5						7	5					7
Marrow, femur														
Hematopoiesis, increased		3	2	0	0	0		7	3	2	0	0	0	7

Notes) - : No abnormal changes ±: Very slight +: Slight 2+: Moderate 3+: Marked

P: Non-graded change NE: Not examined

Numerals represent the number of animals.

Not significantly different from control.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 34-2. Histopathological findings of female rats at the end of the dosing period, satellite group

Findings	Group Grade	Control (vehicle: corn oil)						2-DT 1000 mg/kg						
		-	±	+	2+	3+	P	NE	-	±	+	2+	3+	P
Brain		5					5		5				5	
Spinal cord		5					5		5				5	
Pituitary gland														
Remnant, Rathke's pouch		4					1	5	2			3	5	
Submandibular gland		5					5		5				5	
Sublingual gland		5					5		5				5	
Lymph node, submandibular		5					5		5				5	
Thyroid gland														
Ultimobranchial rest		3					2	5	4			1	5	
Parathyroid gland		5					5		5				5	
Thymus		5					5		5				5	
Heart														
Degeneration/fibrosis, myocardial		4	1	0	0	0	5		5	0	0	0	0	5
Trachea		5					5		5				5	
Lung														
Accumulation, foam cell, alveolus		4	1	0	0	0	5		2	3	0	0	0	5
Microgranuloma		5	0	0	0	0	5		3	2	0	0	0	5
Bronchus		5					5		5				5	
Liver														
Microgranuloma		1	4	0	0	0	5		0	5	0	0	0	5
Pancreas		5					5		5				5	
Stomach		5					5		5				5	
Duodenum		5					5		5				5	

Notes) - : No abnormal changes ± : Very slight + : Slight 2+ : Moderate 3+ : Marked

P : Non-graded change NE : Not examined

Numerals represent the number of animals.

Not significantly different from control.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 34-2(continued). Histopathological findings of female rats at the end of the dosing period, satellite group

Findings	Group Grade	Control (vehicle: corn oil)						2-DT 1000 mg/kg						
		-	±	+	2+	3+	P	NE	-	±	+	2+	3+	P
Jejunum		5					5	5					5	
Ileum		5					5	5					5	
Cecum		5					5	5					5	
Colon		5					5	5					5	
Rectum		5					5	5					5	
Lymph node, mesenteric		5					5	5					5	
Spleen														
Deposit, pigment, brown		0	1	4	0	0	5	0	3	2	0	0	5	
Hematopoiesis, extramedullary		0	3	2	0	0	5	0	2	3	0	0	5	
Kidney														
Basophilic tubule, cortex		4	1	0	0	0	5	4	1	0	0	0	5	
Mineralization, papilla		4	1	0	0	0	5	5	0	0	0	0	5	
Urinary bladder		5					5	5					5	
Adrenal gland		5					5	5					5	
Ovary		5					5	5					5	
Uterus														
Dilatation, lumen		2	0	3	0	0	5	5	0	0	0	0	5	
Vagina		5					5	5					5	
Eyeball		5					5	5					5	
Harderian gland		5					5	5					5	
Sciatic nerve		5					5	5					5	
Skeletal muscle		5					5	5					5	
Femur		5					5	5					5	
Marrow, femur		5					5	5					5	

Notes) - : No abnormal changes ±: Very slight +: Slight 2+: Moderate 3+: Marked

P : Non-graded change NE: Not examined

Numerals represent the number of animals.

Not significantly different from control.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 35. Results of observations about estrous cycle

Dose	Control (vehicle: corn oil)	2-DT 62.5 mg/kg	2-DT 250 mg/kg	2-DT 1000 mg/kg
Number of animals examined	12	12	12	12
<u>Pre-treatment period</u>				
Number of animals showing type of cycle				
4-day cycle	10	9	6	11
4-5-day cycle	1	1	2	0
5-day cycle	1	2	4	1
Mean length of estrous cycle in days; Mean±S.D. (N)	4.1 ± 0.3 (12)	4.2 ± 0.4 (12)	4.4 ± 0.5 (12)	4.1 ± 0.3 (12)
<u>Treatment period</u>				
Number of animals showing each type of cycle				
4-day cycle	10	8	4	11
4-5-day cycle	1	0	2	1
5-day cycle	0	3	4	0
Irregular cycle	1	1	2	0
Mean length of estrous cycle in days; Mean±S.D. (N)	4.0 ± 0.2 (12)	4.3 ± 0.5 (12)	4.7 ± 0.7 **(12)	4.0 ± 0.1 (12)
Frequency of animals that show abnormal estrous cycles after the treatment	1 / 12	1 / 12	2 / 12	0 / 12
Mean times of vaginal estrus during mating period; Mean±S.D. (N)	1.0 ± 0.0 (11)	1.0 ± 0.0 (12)	1.0 ± 0.0 (12)	1.0 ± 0.0 (12)

Significantly different from the control group (*: p<0.05, **: p<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 36. Results of observations about reproductive performance

Dose	Control (vehicle: corn oil)	2-DT 62.5 mg/kg	2-DT 250 mg/kg	2-DT 1000 mg/kg
Number of mated pairs [A]	12	12	12	12
Number of copulated pairs [B]	11	12	12	12
Copulation index [(B/A)×100,%]	91.7	100.0	100.0	100.0
Number of fertile males [C]	11	12	12	12
Fertility index [(C/B)×100,%]	100.0	100.0	100.0	100.0
Pairing days until copulation ;Mean±S.D.(N)	2.4 ± 1.3 (11)	2.2 ± 0.9 (12)	3.3 ± 3.5 (12)	2.0 ± 1.1 (12)

Significantly different from the control group (*: p<0.05, **: p<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 37. Observation of offspring (F_1)

Group	Control (vehicle: corn oil)	2-DT 62.5 mg/kg	2-DT 250 mg/kg	2-DT 1000 mg/kg
Number of dams	11	12	12	12
Gestation length (days)				
Mean ± S.D. per dam	22.1 ± 0.3	22.2 ± 0.4	22.1 ± 0.5	21.9 ± 0.5
Number of corpora lutea				
Total	172	192	197	198
Mean ± S.D. per dam	15.6 ± 1.9	16.0 ± 2.3	16.4 ± 2.4	16.5 ± 2.3
Number of implantation scars				
Total	169	190	192	194
Mean ± S.D. per dam	15.4 ± 1.8	15.8 ± 2.2	16.0 ± 2.5	16.2 ± 2.4
Implantation index (%) ^{a)}	98.4 ± 3.7	99.0 ± 2.4	97.3 ± 4.2	97.9 ± 3.1
Delivery index (dams, %) ^{b)}	100.0	100.0	100.0	100.0
Number of offspring at birth				
Total	156	176	182	174
Mean ± S.D. per dam	14.2 ± 1.4	14.7 ± 2.3	15.2 ± 2.5	14.5 ± 3.6
Number of live offspring at birth				
Male	79	90	77	104
Female	73	81	104	69
Total	152	171	181	173
Mean ± S.D. per dam	13.8 ± 1.7	14.3 ± 2.3	15.1 ± 2.7	14.4 ± 3.6
Sex ratio ^{c)}				
Mean ± S.D. per dam	0.52 ± 0.20	0.53 ± 0.12	0.43 ± 0.14	0.59 ± 0.15
Number of dead offspring				
Total	4	5	1	1
Mean ± S.D. per dam	0.4 ± 0.7	0.4 ± 1.0	0.1 ± 0.3	0.1 ± 0.3
Delivery index (offspring) ^{d)}				
Mean% ± S.D. per dam	92.8 ± 8.1	92.7 ± 6.6	94.8 ± 4.4	89.5 ± 17.1
Birth index ^{e)}				
Mean% ± S.D. per dam	90.5 ± 10.2	90.1 ± 7.4	94.1 ± 4.2	88.9 ± 17.0
Live birth index ^{f)}				
Mean% ± S.D. per dam	97.4 ± 4.9	97.3 ± 6.3	99.2 ± 2.6	99.4 ± 2.0
Number of offspring on day 4				
Male	78	89	69	103
Female	73	80	96	68
Sex ratio ^{c)}				
Mean ± S.D. per dam	0.52 ± 0.20	0.53 ± 0.11	0.43 ± 0.14 (11)	0.60 ± 0.15
Viability index ^{g)}				
Mean% ± S.D. per dam	99.3 ± 2.3	99.0 ± 2.5	92.2 ± 27.2	98.9 ± 2.5
Number of external abnormalities ^{h)}	0	0	0	0
Mean% ± S.D. per dam	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0

Significantly different from the control group (*: P<0.05, **: P<0.01).

a): (Number of implantation scars/Number of corpora lutea)×100.

b): (Number of dams with live offspring/number of pregnant dams)×100.

c): Number of male offspring/(number of male offspring + number of female offspring).

d): (Number of offspring at birth/Number of implantation scars)×100.

e): (Number of live offspring at birth/number of implantation scars)×100.

f): (Number of live offspring at birth/number of offspring at birth)×100.

g): (Number of live offspring 4 days after birth/number of live offspring at birth)×100.

h): Number of external abnormalities in live offspring at birth.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 38. Body weights of offspring (F_1) before weaning

Group	Control (vehicle: corn oil)	2-DT 62.5 mg/kg	2-DT 250 mg/kg	2-DT 1000 mg/kg
Number of dams	11	12	12	12
Male				
Days after birth				
0	7.0 ± 0.6	6.7 ± 0.6	6.6 ± 0.7	6.6 ± 0.5
4	10.9 ± 1.2	10.9 ± 1.3	10.7 ± 1.2 (11)	10.5 ± 1.5
Number of dams	11	12	12	12
Female				
Days after birth				
0	6.5 ± 0.6	6.5 ± 0.6	6.2 ± 0.7	6.2 ± 0.5
4	10.5 ± 1.3	10.9 ± 1.1	10.0 ± 1.6	10.1 ± 1.3

Each value shows mean ± S.D. per dam. (g).

Figures in parentheses indicate number of dams.

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 39. General conditions in offspring (F₁) before weaning

Group	Number of offspring and general conditions	Days after birth				
		0	1	2	3	4
Control (vehicle: corn oil)	Number of offspring	152	152	152	152	151
	General appearance, No abnormality	152	152	152	151	151
	General appearance, Death					1
2-DT 62.5 mg/kg	Number of offspring	171	171	170	170	169
	General appearance, No abnormality	171	170	170	169	169
	General appearance, Death			1		1
2-DT 250 mg/kg	Number of offspring	181	181	165	165	165
	General appearance, No abnormality	181	165	165	165	165
	General appearance, Death			16		
2-DT 1000 mg/kg	Number of offspring	173	173	173	172	172
	General appearance, No abnormality	173	173	172	172	171
	General appearance, Death			1		1

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Table 40. Morphological observations of offspring (F_1)

Group	Control (vehicle: corn oil)	2-DT 62.5 mg/kg	2-DT 250 mg/kg	2-DT 1000 mg/kg
Dead offspring				
Number of dead offspring ^{a)}	5	7	17	3
Number of missing offspring	0	1	11	0
Number of dead offspring examined ^{b)}	5 (2)	6 (3)	6 (5)	3 (1)
Number of dead offspring with external changes	0	0	0	0
Number of dead offspring with visceral changes	0	0	0	0
Live offspring				
Number of live offspring examined (postnatal day 0)	152	171	181	173
Number of live offspring with external changes	0	0	0	0
Number of live offspring examined (postnatal day 4)	151	169	165	171
Number of live offspring with external changes	0	0	0	0
Number of live offspring with visceral changes	0	0	0	0

Significantly different from the control group (*: p<0.05, **: p<0.01)

^{a)}including missing offspring^{b)}parenthesis indicates the number of offspring not examined because of their autolysis.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 1-1-1. General conditions of male rats

Control (vehicle: corn oil)

Male No.	Days of administration																									
	1 Pre	2 Post	3 Pre	4 Post	5 Pre	6 Post	7 Pre	8 Post	9 Pre	10 Post	11 Pre	12 Post	13 Pre	14 Post	15 Pre	16 Post	17 Pre	18 Post	19 Pre	20 Post	21 Pre	22 Post	23 Pre	24 Post	25 Pre	Post
M01001	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01002	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01003	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01004	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01005	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01006	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01007	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01008	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01009	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01010	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01011	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01012	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Number of males	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12
-	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12

(Continued)

Pre: Before administration, Post: after administration.

-: General appearance, No abnormality.

Control (vehicle: corn oil)

Male No.	Days of administration																									
	26 Pre	27 Post	28 Pre	29 Post	30 Pre	31 Post	32 Pre	33 Post	34 Pre	35 Post	36 Pre	37 Post	38 Pre	39 Post	40 Pre	41 Post	42 Pre	43 Post	Pre	Post	Pre	Post	Pre	Post	Pre	
M01001	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01002	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01003	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01004	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01005	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01006	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01007	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01008	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01009	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01010	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01011	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01012	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Number of males	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	7
-	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	7

Pre: Before administration, Post: after administration.

-: General appearance, No abnormality.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 1-1-2. General conditions of male rats

2-DT 62.5 mg/kg

Pre: Before administration, Post: after administration

-: General appearance. No abnormality.

(Continued)

2-DT 62.5 mg/kg

Pre: Before administration. Post: after administration

-: General appearance. No abnormality.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 1-1-3. General conditions of male rats

2-DT 250 mg/kg

Male No.	Days of administration																									
	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	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
M03025	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M03026	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M03027	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M03028	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M03029	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M03030	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M03031	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M03032	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M03033	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M03034	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M03035	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M03036	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Number of males	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	
-	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	

(Continued)

Pre: Before administration, Post: after administration.

-: General appearance, No abnormality.

2-DT 250 mg/kg

Male No.	Days of administration																									
	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	Pre	Post	Pre	Post	Pre	Post	Pre	Post
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
M03025	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M03026	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M03027	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M03028	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M03029	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M03030	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M03031	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M03032	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M03033	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M03034	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M03035	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M03036	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Number of males	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	
-	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	

Pre: Before administration, Post: after administration.

-: General appearance, No abnormality.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 1-1-4. General conditions of male rats

2-DT 1000 mg/kg

Male No.	Days of administration																									
	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	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
M04037	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M04038	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M04039	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M04040	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M04041	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M04042	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M04043	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M04044	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M04045	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M04046	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M04047	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M04048	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Number of males	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12
-	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12

Pre: Before administration, Post: after administration.

:: General appearance, No abnormality.

(Continued)

2-DT 1000 mg/kg

Male No.	Days of administration																									
	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43								
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
M04037	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M04038	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M04039	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M04040	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M04041	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M04042	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M04043	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M04044	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M04045	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M04046	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M04047	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
M04048	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Number of males	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	7
-	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	7

Pre: Before administration, Post: after administration.

:: General appearance, No abnormality.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 1-2-1. General conditions of male rats at the recovery period

Control (vehicle: corn oil)

Male No.	Days of recovery period														
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
M01008	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01009	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01010	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01011	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M01012	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Number of males	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
-	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5

-: General appearance, No abnormality.

2-DT 1000 mg/kg

Male No.	Days of recovery period														
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
M04044	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M04045	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M04046	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M04047	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
M04048	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Number of males	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
-	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5

-: General appearance, No abnormality.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 2-1-1. General conditions of female rats

Control (vehicle: corn oil)

Female No.	Days of administration																									
	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	
F01001	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01002	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01003	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01004	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01005	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01006	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01007	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01008	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01009	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01010	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01011	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01012	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Number of females	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12

Pre: Before administration, Post: after administration.

-: General appearance, No abnormality.

(Continued)

Control (vehicle: corn oil)

Female No.	Days of administration																									
	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	
F01005	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Number of females	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

Pre: Before administration, Post: after administration.

-: General appearance, No abnormality.

Control (vehicle: corn oil)

Female No.	Days of administration		
	51	52	53
	Pre	Post	Pre
F01005	-	-	-

Pre: Before administration, Post: after administration.

-: General appearance, No abnormality.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 2-1-2. General conditions of female rats

(Continued)

Pre: Before administration, **Post:** after administration

-: General appearance. No abnormality

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 2-1-3. General conditions of female rats

Female No.	Days of administration																									
	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	
F03025	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F03026	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F03027	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F03028	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F03029	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F03030	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F03031	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F03032	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F03033	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F03034	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F03035	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F03036	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Number of females	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12
-	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12

(Continued)

Pre: Before administration, Post: after administration.

-: General appearance, No abnormality.

Female No.	Days of administration																									
	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	
F03029	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Number of females	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
-	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Pre: Before administration, Post: after administration.

-: General appearance, No abnormality.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 2-1-4. General conditions of female rats

Pre: Before administration, **Post:** after administration

-: General appearance, No abnormality

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 2-2-1. General conditions of female rats, satellite group

Control (vehicle: corn oil)

Female No.	Days of administration																									
	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	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
F05049	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F05050	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F05051	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F05052	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F05053	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F05054	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F05055	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F05056	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F05057	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F05058	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Number of females	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
-	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10

Pre: Before administration, Post: after administration.

-: General appearance, No abnormality.

(Continued)

Control (vehicle: corn oil)

Female No.	Days of administration																									
	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43								
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
F05049	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F05050	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F05051	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F05052	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F05053	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F05054	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F05055	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F05056	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F05057	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F05058	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Number of females	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	5
-	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	5

Pre: Before administration, Post: after administration.

-: General appearance, No abnormality.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 2-2-2. General conditions of female rats, satellite group

(Continued)

Pre: Before administration, Post: after administration

-: General appearance, No abnormality.

Pre: Before administration, Post: after administration

-: General appearance, No abnormality.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 2-3-1. General conditions of female rats at the recovery period

Control (vehicle: corn oil)

Female No.	Days of recovery period														
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
F05054	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F05055	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F05056	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F05057	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F05058	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Number of females	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
-	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5

-: General appearance, No abnormality.

2-DT 1000 mg/kg

Female No.	Days of recovery period														
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
F06064	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F06065	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F06066	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F06067	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F06069	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Number of females	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
-	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5

-: General appearance, No abnormality.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 3-1. General conditions in dams during pregnancy

Control (vehicle: corn oil)

Female No.	Days of pregnancy																											
	0		1		2		3		4		5		6		7		8		9		10		11		12		13	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post		
F01001	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01002	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01003	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01004	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01006	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01007	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01008	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01009	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01010	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01011	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01012	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Number of females	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11
	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	

Pre: Before administration, Post: after administration.

(Continued)

-: General appearance, No abnormality.

Control (vehicle: corn oil)

Female No.	Days of pregnancy																										
	14		15		16		17		18		19		20		21		22										
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post									
F01001	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
F01002	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01003	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01004	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01006	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01007	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01008	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F01009	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F01010	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F01011	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F01012	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Number of females	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	4	4	4	4	4	4	4
	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Pre: Before administration, Post: after administration.

-: General appearance, No abnormality.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 3-2. General conditions in dams during pregnancy

2-DT 62.5 mg/kg

Female No.	Days of pregnancy																											
	0		1		2		3		4		5		6		7		8		9		10		11		12		13	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
F02013	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F02014	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F02015	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F02016	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F02017	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F02018	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F02019	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F02020	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F02021	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F02022	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F02023	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F02024	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Number of females	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	
	-	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	

Pre: Before administration, Post: after administration.

(Continued)

-: General appearance, No abnormality.

2-DT 62.5 mg/kg

Female No.	Days of pregnancy																										
	14		15		16		17		18		19		20		21		22										
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	
F02013	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F02014	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F02015	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F02016	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F02017	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F02018	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F02019	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F02020	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F02021	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F02022	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F02023	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F02024	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Number of females	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	5	5	
	-	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	5	5	

Pre: Before administration, Post: after administration.

-: General appearance, No abnormality.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 3-3. General conditions in dams during pregnancy

2-DT 250 mg/kg

Female No.	Days of pregnancy																											
	0		1		2		3		4		5		6		7		8		9		10		11		12		13	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post		
F03025	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
F03026	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
F03027	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
F03028	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
F03029	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
F03030	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
F03031	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
F03032	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
F03033	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
F03034	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
F03035	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
F03036	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
Number of females	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	
-	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	

Pre: Before administration, Post: after administration.

(Continued)

-: General appearance, No abnormality.

2-DT 250 mg/kg

Female No.	Days of pregnancy																									
	14		15		16		17		18		19		20		21		22									
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post								
F03025	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F03026	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F03027	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F03028	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F03029	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F03030	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F03031	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F03032	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F03033	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F03034	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F03035	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F03036	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Number of females	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	4	4						
-	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	4	4						

Pre: Before administration, Post: after administration.

-: General appearance, No abnormality.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 3-4. General conditions in dams during pregnancy

2-DT 1000 mg/kg

Female No.	Days of pregnancy																											
	0		1		2		3		4		5		6		7		8		9		10		11		12		13	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
F04037	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F04038	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F04039	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F04040	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F04041	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F04042	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F04043	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F04044	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F04045	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F04046	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F04047	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
F04048	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Number of females	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	
	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	

Pre: Before administration, Post: after administration.

-: General appearance, No abnormality.

(Continued)

2-DT 1000 mg/kg

Female No.	Days of pregnancy																										
	14		15		16		17		18		19		20		21		22										
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	
F04037	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F04038	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F04039	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F04040	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F04041	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F04042	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F04043	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F04044	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F04045	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F04046	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F04047	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
F04048	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Number of females	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	3	3	3	3
	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	3	3	3	3

Pre: Before administration, Post: after administration.

-: General appearance, No abnormality.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 4-1. General conditions in dams during lactation

Control (vehicle: corn oil)

Female No.	Days of lactation									
	0		1		2		3		4	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
F01001	-	-	-	-	-	-	-	-	-	-
F01002	-	-	-	-	-	-	-	-	-	-
F01003	-	-	-	-	-	-	-	-	-	-
F01004	-	-	-	-	-	-	-	-	-	-
F01006	-	-	-	-	-	-	-	-	-	-
F01007	#	#	-	-	-	-	-	-	-	-
F01008	-	-	-	-	-	-	-	-	-	-
F01009	-	-	-	-	-	-	-	-	-	-
F01010	#	#	-	-	-	-	-	-	-	-
F01011	#	#	-	-	-	-	-	-	-	-
F01012	-	-	-	-	-	-	-	-	-	-
Number of females	8	8	11	11	11	11	11	11	11	11
	-	8	8	11	11	11	11	11	11	11

Pre: Before administration, Post: after administration.

-: General appearance, No abnormality.

#, Animal was administered to dosing formulation before delivery, and no abnormality was observed on day 0 of lactation.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 4-2. General conditions in dams during lactation

2-DT 62.5 mg/kg

Female No.	Days of lactation									
	0		1		2		3		4	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
F02013	-	-	-	-	-	-	-	-	-	-
F02014	#	#	-	-	-	-	-	-	-	-
F02015	-	-	-	-	-	-	-	-	-	-
F02016	-	-	-	-	-	-	-	-	-	-
F02017	#	#	-	-	-	-	-	-	-	-
F02018	-	-	-	-	-	-	-	-	-	-
F02019	-	-	-	-	-	-	-	-	-	-
F02020	-	-	-	-	-	-	-	-	-	-
F02021	-	-	-	-	-	-	-	-	-	-
F02022	-	-	-	-	-	-	-	-	-	-
F02023	-	-	-	-	-	-	-	-	-	-
F02024	#	#	-	-	-	-	-	-	-	-
Number of females	9	9	12	12	12	12	12	12	12	12
	-	9	9	12	12	12	12	12	12	12

Pre: Before administration, Post: after administration.

-: General appearance, No abnormality.

#, Animal was administered to dosing formulation before delivery, and no abnormality was observed on day 0 of lactation.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 4-3. General conditions in dams during lactation

2-DT 250 mg/kg

Female No.	Days of lactation									
	0		1		2		3		4	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
F03025	-	-	-	-	-	-	-	-	-	-
F03026	-	-	-	-	-	-	-	-	-	-
F03027	-	-	-	-	-	-	-	-	-	-
F03028	-	-	-	-	-	-	-	-	-	-
F03029	#	#	-	-	-	-	-	-	-	-
F03030	-	-	-	-	-	-	-	-	-	-
F03031	-	-	-	-	-	-	-	-	-	-
F03032	-	-	-	-	-	-	-	-	-	-
F03033	#	#	-	-	-	-	-	-	-	-
F03034	#	#	-	-	-	-	-	-	-	-
F03035	-	-	-	-	-	-	-	-	-	-
F03036	-	-	-	-	-	-	-	-	-	-
Number of females	9	9	12	12	12	12	12	12	12	12
	-	9	9	12	12	12	12	12	12	12

Pre: Before administration, Post: after administration.

-: General appearance, No abnormality.

#, Animal was administered to dosing formulation before delivery, and no abnormality was observed on day 0 of lactation.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 4-4. General conditions in dams during lactation

2-DT 1000 mg/kg

Female No.	Days of lactation									
	0		1		2		3		4	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
F04037	-	-	-	-	-	-	-	-	-	-
F04038	-	-	-	-	-	-	-	-	-	-
F04039	#	#	-	-	-	-	-	-	-	-
F04040	-	-	-	-	-	-	-	-	-	-
F04041	-	-	-	-	-	-	-	-	-	-
F04042	-	-	-	-	-	-	-	-	-	-
F04043	#	#	-	-	-	-	-	-	-	-
F04044	-	-	-	-	-	-	-	-	-	-
F04045	#	#	-	-	-	-	-	-	-	-
F04046	-	-	-	-	-	-	-	-	-	-
F04047	-	-	-	-	-	-	-	-	-	-
F04048	#	#	-	-	-	-	-	-	-	-
Number of females	8	8	12	12	12	12	12	12	12	12
	-	8	8	12	12	12	12	12	12	12

Pre: Before administration, Post: after administration.

-: General appearance, No abnormality.

#, Animal was administered to dosing formulation before delivery, and no abnormality was observed on day 0 of lactation.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 5-1. Detailed clinical observations of male rats

Control (vehicle: corn oil)

Male No.	Open-field observations ^{c)}										Urination										Defecation											
	Stereotypy					Touch response					Urination					Defecation					Pre					T8						
	Pre ^a	T8 ^b	T15	T24	T30	T36	T42	R7 ^c	R14	Pre	T8	T15	T24	T30	T36	T42	R7	R14	Pre	T8	T15	T24	T30	T36	T42	R7	R14					
M01001	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0		
M01002	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	
M01003	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	
M01004	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	
M01005	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	
M01006	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	
M01007	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	
M01008	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	1	1	1	0	0	0	0	0	0	0	
M01009	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	
M01010	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	0	0	0	0	1	0	0	0	0	0	0	0	
M01011	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	
M01012	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	
Total (N)	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0	3: 0

^a pre-treatment; ^b day 8 of treatment; ^c day 7 of recovery

Stereotypy [2, not observed; 3, rearing]

Touch response [2, normal; 3, hypersensitivity (slight)]

Urination [frequency/30sec]

Defecation [frequency/30sec]

Except the above findings, there were no changes in all animals; a) Cage-side observation (posture in home-cage, locomoter activity in home-cage, vocalization, tremor, convulsion), b) Observations made while handling (behavior while removing from cage, handling behavior, heart beats, body temperature, fur, skin/mucous membranes color, lacrimation, exophthalmos, pupillary size, salivation), and c) Open-field observations (posture, exploration, piloerection, palpebral opening, tremor, convulsion, respiratory rate, gait, bizarre behavior, straub tail, grooming, vocalization, withdrawal reflex, pinna reflex).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 5-2. Detailed clinical observations of male rats

2-DT 62.5 mg/kg

Male No.	Open-field observations ^{c)}										Urination										Defecation									
	Stereotypy					Touch response						Urination					Defecation					Pre								
	Pre	^a T8	^b T15	T24	T30	T36	T42	Pre	T8	T15	T24	T30	T36	T42	Pre	T8	T15	T24	T30	T36	T42									
M02013	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	1	0	1	2	0	0	0	0	0	0	0	0	0	
M02014	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	1	2	0	0	0	0	0	0	0	0	0	
M02015	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0
M02016	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M02017	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M02018	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
M02019	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M02020	2	2	3	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M02021	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
M02022	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
M02023	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	0
M02024	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total score (N)	3: 0 (12)	3: 0 (12)	3: 1 (12)	3: 0 (12)	3: 0 (12)	3: 0 (12)	3: 0 (12)	3: 0 (12)	3: 0 (12)	3: 0 (12)	3: 0 (12)	3: 0 (12)	3: 0 (12)	3: 0 (12)	2 (12)	1 (12)	3 (12)	1 (12)	3 (12)	4 (12)	0 (12)	1 (12)	0 (12)							

^a pre-treatment; ^b day 8 of treatment; ^c day 7 of recovery

Stereotypy [2, not observed; 3, rearing]

Touch response [2, normal; 3, hypersensitivity (slight)]

Urination [frequency/30sec]

Defecation [frequency/30sec]

Except the above findings, there were no changes in all animals; a) Cage-side observation (posture in home-cage, locomoter activity in home-cage, vocalization, tremor, convulsion), b) Observations made while handling (behavior while removing from cage, handling behavir, heart beats, body temperature, fur, skin/mucous membranes color, lacrimation, exophthalmos, pupillary size, salivation), and c) Open-field observations (posture, exploration, piloerection, palpebral opening, tremor, convulsion, respiratory rate, gait, bizarre behavior, straub tail, grooming, vocalization, withdrawal reflex, pinna reflex).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 5-3. Detailed clinical observations of male rats

2-DT 250 mg/kg

Male No.	Open-field observations ^{c)}										Urination										Defecation									
	Stereotypy					Touch response					Urination					Defecation					Pre									
	Pre	T8	T15	T24	T30	T36	T42	Pre	T8	T15	T24	T30	T36	T42	Pre	T8	T15	T24	T30	T36	T42									
M03025	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	
M03026	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	
M03027	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
M03028	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	
M03029	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
M03030	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	1	0	0	0	1	1	0	0	0	0	0	0	0	0	
M03031	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
M03032	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
M03033	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
M03034	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
M03035	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
M03036	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Total score (N)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	1 (12)	2 (12)	0 (12)	0 (12)	1 (12)	2 (12)	1 (12)	0 (12)	0 (12)	0 (12)

^a pre-treatment; ^b day 8 of treatment; ^c day 7 of recovery

Stereotypy [2, not observed; 3, rearing]

Touch response [2, normal; 3, hypersensitivity (slight)]

Urination [frequency/30sec]

Defecation [frequency/30sec]

Except the above findings, there were no changes in all animals; a) Cage-side observation (posture in home-cage, locomotor activity in home-cage, vocalization, tremor, convulsion), b) Observations made while handling (behavior while removing from cage, handling behavior, heart beats, body temperature, fur, skin/mucous membranes color, lacrimation, exophthalmos, pupillary size, salivation), and c) Open-field observations (posture, exploration, piloerection, palpebral opening, tremor, convulsion, respiratory rate, gait, bizarre behavior, straub tail, grooming, vocalization, withdrawal reflex, pinna reflex).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 5-4. Detailed clinical observations of male rats

2-DT 1000 mg/kg

Male No.	Open-field observations ^{c)}										Urination										Defecation														
	Stereotypy					Touch response					Urination					Defecation					Pre					T8									
	Pre ^a	T8 ^b	T15	T24	T30	T36	T42	R7 ^c	R14	Pre	T8	T15	T24	T30	T36	T42	R7	R14	Pre	T8	T15	T24	T30	T36	T42	R7	R14								
M04037	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	0	0	0	0	0	0	0	0	0	0	0					
M04038	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	1	0	0	0	0	0	0				
M04039	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0				
M04040	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	2	0	0	0	0	0	0				
M04041	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	1	0	0	0	0	0	0	0	0	0				
M04042	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0				
M04043	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	0	0	0	0	0	2	0	1	0	0	0	0				
M04044	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0				
M04045	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0				
M04046	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0				
M04047	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	1	0	0	0	0	0	0	0	0	0	0				
M04048	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0				
Total score (N)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (5)	3:0 (5)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (5)	3:0 (5)	2 (12)	0 (12)	1 (12)	1 (12)	0 (12)	5 (12)	0 (12)	0 (5)	0 (5)	0 (5)	2 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (5)	0 (5)

^a pre-treatment; ^b day 8 of treatment; ^c day 7 of recovery

Stereotypy [2, not observed; 3, rearing]

Touch response [2, normal; 3, hypersensitivity (slight)]

Urination [frequency/30sec]

Defecation [frequency/30sec]

Except the above findings, there were no changes in all animals; a) Cage-side observation (posture in home-cage, locomoter activity in home-cage, vocalization, tremor, convulsion), b) Observations made while handling (behavior while removing from cage, handling behavir, heart beats, body temperature, fur, skin/mucous membranes color, lacrimation, exophthalmos, pupillary size, salivation), and c) Open-field observations (posture, exploration, piloerection, palpebral opening, tremor, convulsion, respiratory rate, gait, bizarre behavior, straub tail, grooming, vocalization, withdrawal reflex, pinna reflex).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 6-1-1. Detailed clinical observations of female rats

Control (vehicle: corn oil)

Female No.	Open-field observations ^{c)}										Stereotypy					Touch response					Urination					Defecation										
	Stereotypy					Touch response					Urination					Defecation					Urination					Defecation										
	Pre	T8 ^a	T15	T24	T30	T36	T42	T49	L ^c	Pre	T8	T15	T24	T30	T36	T42	T49	L	Pre	T8	T15	T24	T30	T36	T42	T49	L	Pre	T8	T15	T24	T30	T36	T42	T49	L
F01001	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
F01002	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
F01003	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
F01004	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
F01005	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
F01006	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
F01007	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
F01008	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
F01009	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
F01010	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
F01011	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
F01012	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Totalscore	3:0	3:0	3:0	3:0	3:0	3:0	3:0	3:0	3:0	3:0	3:0	3:0	3:0	3:0	3:0	3:0	3:0	3:0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
(N)	(12)	(12)	(12)	(12)	(12)	(12)	(1)	(1)	(11)	(12)	(12)	(12)	(12)	(12)	(1)	(1)	(11)	(12)	(12)	(12)	(12)	(12)	(1)	(1)	(11)	(12)	(12)	(12)	(12)	(12)	(1)	(1)	(11)	(12)		

^a pre-treatment; ^b day 8 of treatment; ^c lactation period

Stereotypy [2, not observed; 3, rearing]

Touch response [2, normal; 3, hypersensitivity (slight)]

Urination [frequency/30sec]

Defecation [frequency/30sec]

Except the above findings, there were no changes in all animals; a) Cage-side observation (posture in home-cage, locomotor activity in home-cage, vocalization, tremor, convulsion), b) Observations made while handling (behavior while removing from cage, handling behavior, heart beats, body temperature, fur, skin/mucous membranes color, lacrimation, exophthalmos, pupillary size, salivation), and c) Open-field observations (posture, exploration, piloerection, palpebral opening, tremor, convulsion, respiratory rate, gait, bizarre behavior, strabismus, tail grooming, vocalization, withdrawal reflex, pinna reflex).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 6-1-2. Detailed clinical observations of female rats

2-DT 62.5 mg/kg

Female No.	Open-field observations ^c										Urination										Defecation										
	Stereotypy					Touch response					Urination					Defecation															
	Pre	T8 ^a	T15 ^b	T24	T30	T36	L ^c	Pre	T8	T15	T24	T30	T36	L	Pre	T8	T15	T24	T30	T36	L										
F02013	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
F02014	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F02015	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F02016	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F02017	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F02018	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F02019	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F02020	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F02021	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F02022	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F02023	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F02024	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total score (N)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	3:0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)

^a pre-treatment; ^b day 8 of treatment; ^c lactation period

Stereotypy [2, not observed; 3, rearing]

Touch response [2, normal; 3, hypersensitivity (slight)]

Urination [frequency/30sec]

Defecation [frequency/30sec]

Except the above findings, there were no changes in all animals; a) Cage-side observation (posture in home-cage, locomotor activity in home-cage, vocalization, tremor, convulsion), b) Observations made while handling (behavior while removing from cage, handling behavior, heart beats, body temperature, fur, skin/mucous membranes color, lacrimation, exophthalmos, pupillary size, salivation), and c) Open-field observations (posture, exploration, piloerection, palpebral opening, tremor, convulsion, respiratory rate, gait, bizarre behavior, strabismus, grooming, vocalization, withdrawal reflex, pinna reflex).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 6-1-3. Detailed clinical observations of female rats

2-DT 250 mg/kg																						
Female No.	Open-field observations ^{c)}										Urination				Defecation							
	Stereotypy										Touch response				Urination							
	Pre ^a	T8 ^b	T15	T24	T30	T36	T42	T49	L ^c	Pre	T8	T15	T24	T30	T36	T42	T49	L				
F03025	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0
F03026	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0
F03027	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0
F03028	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0
F03029	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0
F03030	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0
F03031	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	1	0	0	0	0
F03032	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0
F03033	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0
F03034	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0
F03035	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0
F03036	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0	0	0	0
Total score (N)	3: 0 (12)	3: 0 (12)	3: 0 (12)	3: 0 (12)	3: 0 (12)	3: 0 (1)	3: 0 (1)	3: 0 (12)	3: 0 (12)	3: 0 (12)	3: 0 (12)	3: 0 (12)	3: 0 (12)	3: 0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (12)	0 (1)	0 (12)	

^a pre-treatment; ^b day 8 of treatment; ^c lactation period

Stereotypy [2, not observed; 3, rearing]

Touch response [2, normal; 3, hypersensitivity (slight)]

Urination [frequency/30sec]

Defecation [frequency/30sec]

Except the above findings, there were no changes in all animals; a) Cage-side observation (posture in home-cage, locomoter activity in home-cage, vocalization, tremor, convulsion), b) Observations made while handling (behavior while removing from cage, handling behavir, heart beats, body temperature, fur, skin/mucous membranes color, lachrimation, exophthalmos, pupillary size, salivation), and c) Open-field observations (posture, exploration, piloerection, palpebral opening, tremor, convulsion, respiratory rate, gait, bizarre behavior, straub tail, grooming, vocalization, withdrawal reflex, pinna reflex).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 6-1-4. Detailed clinical observations of female rats

^a pre-treatment; ^b day 8 of treatment; ^c lactation period

Stereotypy [2, not observed; 3, rearing]

Touch response [2, normal; 3, hypersensitivity (slight)]

Urination [frequency/30sec]

Defecation [frequency/30sec]

Except the above findings, there were no changes in all animals; a) Cage-side observation (posture in home-cage, locomotor activity in home-cage, vocalization, tremor, convulsion), b) Observations made while handling (behavior while removing from cage, handling behavior, heart beats, body temperature, fur, skin/mucous membranes color, lacrimation, exophthalmos, pupillary size, salivation), and c) Open-field observations (posture, exploration, piloerection, palpebral opening, tremor, convulsion, respiratory rate, gait, bizarre behavior, straub tail, grooming, vocalization, withdrawal reflex, pinna reflex).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 6-2-1. Detailed clinical observations of female rats, satellite group

Control (vehicle: corn oil)

Female No.	Open-field observations ^{c)}																	
	Urination					Defecation												
	Pre ^a	T8 ^b	T15	T24	T30	T36	T42	R7 ^c	R14	Pre	T8	T15	T24	T30	T36	T42	R7	R14
F05049	0	0	0	0	0	1	0			0	0	0	0	0	0	0	0	0
F05050	0	0	0	0	0	0	0			0	0	0	0	0	0	0	0	0
F05051	0	0	0	0	1	1	2			0	0	0	0	0	0	0	0	0
F05052	0	0	0	0	0	0	0			0	0	0	0	0	0	0	0	0
F05053	0	0	0	0	0	0	0			0	0	0	0	0	0	0	0	0
F05054	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F05055	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F05056	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F05057	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
F05058	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total score (N)	0 (10)	1 (10)	0 (10)	0 (10)	1 (10)	2 (10)	3 (10)	0 (5)	0 (5)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (5)	0 (5)	0 (5)

^a pre-treatment; ^b day 8 of treatment; ^c day 7 of recovery

Urination [frequency/30sec]

Defecation [frequency/30sec]

Except the above findings, there were no changes in all animals; a) Cage-side observation (posture in home-cage, locomoter activity in home-cage, vocalization, tremor, convulsion), b) Observations made while handling (behavior while removing from cage, handling behavior, heart beats, body temperature, fur, skin/mucous membranes color, lacrimation, exophthalmos, pupillary size, salivation), and c) Open-field observations (posture, exploration, piloerection, palpebral opening, tremor, convulsion, respiratory rate, gait, stereotypy, bizarre behavior, straub tail, grooming, vocalization, touch response, withdrawal reflex, pinna reflex).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 6-2-2. Detailed clinical observations of female rats, satellite group

2-DT 1000 mg/kg

Female No.	Open-field observations ^{c)}																	
	Urination					Defecation												
	Pre ^a	T8 ^b	T15	T24	T30	T36	T42	R7 ^c	R14	Pre	T8	T15	T24	T30	T36	T42	R7	R14
F06059	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F06060	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
F06061	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F06062	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F06063	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F06064	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F06065	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
F06066	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F06067	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
F06069	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total score (N)	0 (10)	0 (10)	0 (10)	0 (10)	1 (10)	0 (10)	1 (10)	0 (5)	0 (5)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (10)	0 (5)	0 (5)	0 (5)

^a pre-treatment; ^b day 8 of treatment; ^c day 7 of recovery

Urination [frequency/30sec]

Defecation [frequency/30sec]

Except the above findings, there were no changes in all animals; a) Cage-side observation (posture in home-cage, locomoter activity in home-cage, vocalization, tremor, convulsion), b) Observations made while handling (behavior while removing from cage, handling behavir, heart beats, body temperature, fur, skin/mucous membranes color, lacrimation, exophthalmos, pupillary size, salivation), and c) Open-field observations (posture, exploration, piloerection, palpebral opening, tremor, convulsion, respiratory rate, gait, stereotypy, bizarre behavior, straub tail, grooming, vocalization, touch response, withdrawal reflex, pinna reflex).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 7-1-1. Body weights of male rats

Control (vehicle: corn oil)

Male No.	Days of administration							
	1	4	7	14	21	28	35	42
M01001	417.5	426.9	444.0	470.7	501.2	529.9	568.5	574.8
M01002	415.2	418.0	423.0	430.4	438.2	468.1	475.6	481.1
M01003	409.5	420.3	432.0	455.4	477.1	498.1	516.3	523.5
M01004	415.8	430.6	438.9	474.0	509.5	539.9	558.6	558.9
M01005	422.7	434.1	441.3	453.2	473.7	502.7	521.0	537.3
M01006	437.8	448.4	463.0	493.6	510.3	516.3	562.4	540.8
M01007	424.7	442.8	460.0	498.2	516.1	539.6	577.1	603.5
M01008	394.3	406.9	425.3	454.0	477.9	508.2	528.0	550.4
M01009	384.9	393.1	400.5	418.0	434.9	461.7	485.3	507.5
M01010	408.1	425.2	441.0	457.0	470.0	494.8	514.2	524.5
M01011	390.6	404.8	414.0	396.0	450.7	429.0	492.1	508.8
M01012	392.5	400.8	417.9	433.7	450.8	470.9	486.3	501.9
Number of males	12	12	12	12	12	12	12	12
Mean	409.5	421.0	433.4	452.9	475.9	496.6	523.8	534.4
S.D.	16.0	17.1	18.4	29.9	28.6	33.9	35.6	34.1

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 7-1-2. Body weights of male rats

2-DT 62.5 mg/kg

Male No.	Days of administration							
	1	4	7	14	21	28	35	42
M02013	405.5	422.1	414.6	448.3	482.4	506.4	527.5	527.5
M02014	372.6	384.1	384.6	396.5	420.3	443.9	463.0	472.2
M02015	408.1	429.1	439.0	466.3	486.8	513.9	543.4	541.0
M02016	384.7	399.9	409.4	433.7	461.9	486.5	509.1	512.9
M02017	409.0	422.2	438.5	448.6	458.1	479.7	491.1	503.4
M02018	425.0	444.4	446.7	468.3	506.4	532.3	544.2	526.3
M02019	421.3	439.6	458.8	492.9	509.9	545.3	568.1	589.6
M02020	399.3	409.7	420.4	439.5	464.5	483.0	495.8	509.7
M02021	391.5	403.8	416.9	433.0	453.7	470.0	488.4	500.0
M02022	418.9	437.7	445.7	475.3	500.6	522.5	544.7	560.9
M02023	430.9	448.5	462.1	489.7	510.0	541.0	559.0	578.4
M02024	412.3	428.6	435.7	456.1	481.5	501.3	515.9	536.0
Number of males	12	12	12	12	12	12	12	12
Mean	406.6	422.5	431.0	454.0	478.0	502.2	520.9	529.8
S.D.	17.2	19.7	22.5	27.0	27.3	30.7	32.2	34.0
Significance	NS	NS	NS	NS	NS	NS	NS	NS
Statistical method	AN	AN	AN	AN	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 7-1-3. Body weights of male rats

2-DT 250 mg/kg

Male No.	Days of administration							
	1	4	7	14	21	28	35	42
M03025	408.8	420.1	437.8	459.1	486.6	512.4	528.4	535.1
M03026	416.2	431.0	442.8	446.3	467.9	489.5	502.0	506.1
M03027	407.9	424.4	434.5	461.3	488.6	513.0	536.0	555.0
M03028	425.5	439.0	452.8	482.1	503.7	522.4	549.3	544.4
M03029	429.9	441.9	460.2	480.8	490.3	498.2	507.1	516.7
M03030	390.0	390.3	398.2	412.8	440.9	466.4	477.0	471.6
M03031	416.4	431.5	446.6	469.3	491.8	507.7	527.8	548.4
M03032	378.1	398.9	418.0	438.1	452.2	478.2	503.0	523.1
M03033	396.6	411.9	427.8	451.2	482.3	508.0	532.6	547.3
M03034	400.5	409.0	422.9	456.6	481.1	518.4	550.7	579.2
M03035	423.6	436.0	453.6	425.1	493.2	526.4	546.6	567.0
M03036	413.1	418.4	427.1	445.0	475.7	499.5	527.5	554.6
Number of males	12	12	12	12	12	12	12	12
Mean	408.9	421.0	435.2	452.3	479.5	503.3	524.0	537.4
S.D.	15.3	16.2	17.6	20.7	18.0	18.0	22.5	29.3
Significance	NS	NS	NS	NS	NS	NS	NS	NS
Statistical method	AN	AN	AN	AN	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 7-1-4. Body weights of male rats

2-DT 1000 mg/kg

Male No.	Days of administration							
	1	4	7	14	21	28	35	42
M04037	386.2	398.2	375.6	422.8	451.3	467.8	499.2	512.1
M04038	398.9	413.3	417.8	441.0	467.7	488.0	508.3	510.3
M04039	420.5	439.6	455.9	487.5	509.6	542.4	564.3	575.5
M04040	404.2	431.0	443.0	473.1	501.0	528.8	552.2	544.8
M04041	409.5	417.5	431.6	460.9	485.2	519.6	544.2	552.4
M04042	428.8	442.9	449.1	469.6	488.8	513.1	539.5	528.9
M04043	398.6	403.5	414.5	425.3	445.1	475.5	495.7	514.0
M04044	407.4	431.4	436.7	454.9	481.1	503.9	508.1	525.5
M04045	416.1	437.1	452.6	476.2	490.9	511.7	534.1	560.9
M04046	408.0	424.7	442.3	466.0	488.6	516.1	539.1	550.2
M04047	395.3	406.6	414.5	438.8	458.4	479.0	500.2	485.3
M04048	423.1	436.9	449.9	464.6	489.5	519.1	558.3	575.6
Number of males	12	12	12	12	12	12	12	12
Mean	408.1	423.6	432.0	456.7	479.8	505.4	528.6	536.3
S.D.	12.5	15.3	23.1	20.5	19.9	23.0	24.9	28.2
Significance	NS	NS	NS	NS	NS	NS	NS	NS
Statistical method	AN	AN	AN	AN	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 7-2-1. Body weights of male rats at the recovery period

Control (vehicle: corn oil)

Male No.	Days of recovery period		
	1	7	14
M01008	553.6	568.5	568.1
M01009	514.7	514.9	510.8
M01010	527.7	529.2	542.9
M01011	511.3	524.7	525.7
M01012	501.6	504.3	500.1
Number of males	5	5	5
Mean	521.8	528.3	529.5
S.D.	20.1	24.4	26.9

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 7-2-2. Body weights of male rats at the recovery period

2-DT 1000 mg/kg

Male No.	Days of recovery period		
	1	7	14
M04044	529.4	540.8	524.5
M04045	563.6	568.1	577.2
M04046	546.7	558.3	565.6
M04047	514.0	520.1	537.0
M04048	582.1	595.0	601.4
Number of males	5	5	5
Mean	547.2	556.5	561.1
S.D.	27.0	28.2	30.9
Significance	NS	NS	NS
Statistical method	TT	TT	TT

Significantly different from the control group (*: P<0.05, **: P<0.01)

NS: Not significantly different from the control group.

TT: Analysis by Student's t-test.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 8-1-1. Body weights of female rats

Control (vehicle: corn oil)

Female No.	Days of administration								
	1	4	7	14	21	28	35	42	49
F01001	226.4	241.1	249.1	247.0					
F01002	245.4	256.9	256.4	271.0					
F01003	249.7	255.4	266.1	271.7					
F01004	235.9	235.7	245.1	252.7					
F01005	248.7	248.4	248.1	258.3	281.3	316.1	315.7	304.2	313.2
F01006	261.4	276.1	283.2	319.0					
F01007	244.7	252.6	260.3	263.5					
F01008	257.6	262.8	260.8	287.0					
F01009	246.7	239.3	248.7	236.3					
F01010	228.3	227.5	238.6	251.2					
F01011	237.5	240.6	240.7	248.6					
F01012	263.3	276.1	282.0	293.0					
Number of females	12	12	12	12					
Mean	245.5	251.0	256.6	266.6					
S.D.	11.9	15.4	14.7	23.4					

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 8-1-2. Body weights of female rats

2-DT 62.5 mg/kg

Female No.	Days of administration								
	1	4	7	14	21	28	35	42	49
F02013	250.1	255.6	253.5	274.6					
F02014	248.6	249.7	249.8	251.9					
F02015	259.5	252.6	257.6	261.9					
F02016	240.4	237.6	233.7	231.7					
F02017	249.3	246.9	259.8	268.9					
F02018	229.6	229.8	238.4	248.3					
F02019	233.4	230.5	238.9	252.6					
F02020	256.5	249.2	266.4	272.0					
F02021	260.1	262.6	267.0	273.9					
F02022	248.8	255.3	255.4	277.4					
F02023	238.8	243.7	242.4	246.5					
F02024	232.1	246.2	250.3	260.3					
Number of females	12	12	12	12					
Mean	245.6	246.6	251.1	260.0					
S.D.	10.6	10.0	11.0	14.1					
Significance	NS	NS	NS	NS	---	---	---	---	---
Statistical method	AN	AN	AN	AN	NA	NA	NA	NA	NA

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

NA: Not analyzed.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 8-1-3. Body weights of female rats

2-DT 250 mg/kg

Female No.	Days of administration								
	1	4	7	14	21	28	35	42	49
F03025	250.5	264.0	264.7	286.9					
F03026	238.9	245.5	246.5	262.0					
F03027	243.5	238.8	255.2	261.2					
F03028	241.7	244.9	250.5	264.9					
F03029	249.5	251.1	259.8	274.8	297.3	309.2			
F03030	250.8	255.5	259.6	261.7					
F03031	230.1	236.6	243.2	252.4					
F03032	255.1	257.3	259.9	274.1					
F03033	250.2	252.1	258.2	276.7					
F03034	253.5	263.1	261.2	271.9					
F03035	244.7	242.5	252.2	261.9					
F03036	266.9	275.9	278.5	294.9					
Number of females	12	12	12	12					
Mean	248.0	252.3	257.5	270.3					
S.D.	9.2	11.6	9.2	12.1					
Significance	NS	NS	NS	NS	--	--	--	--	--
Statistical method	AN	AN	AN	AN	NA	NA	NA	NA	NA

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

NA: Not analyzed.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 8-1-4. Body weights of female rats

2-DT 1000 mg/kg

Female No.	Days of administration								
	1	4	7	14	21	28	35	42	49
F04037	240.0	240.7	249.8	261.7					
F04038	253.8	254.4	267.1	281.5					
F04039	249.9	261.2	258.3	276.7					
F04040	225.9	238.7	238.7	254.0					
F04041	244.4	246.0	252.9	262.3					
F04042	236.0	243.3	239.6	254.0					
F04043	253.6	268.7	273.6	281.0					
F04044	245.6	244.6	258.4	263.7					
F04045	259.0	272.2	280.6	300.4					
F04046	249.0	264.7	272.3	281.3					
F04047	252.5	259.1	262.2	269.0					
F04048	241.4	244.5	249.9	266.0					
Number of females	12	12	12	12					
Mean	245.9	253.2	258.6	271.0					
S.D.	9.1	11.7	13.2	13.6					
Significance	NS	NS	NS	NS	--	--	--	--	--
Statistical method	AN	AN	AN	AN	NA	NA	NA	NA	NA

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

NA: Not analyzed.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 8-2-1. Body weights of female rats, satellite group

Control (vehicle: corn oil)

Female No.	Days of administration							
	1	4	7	14	21	28	35	42
F05049	262.3	267.7	276.9	295.2	311.2	323.5	329.4	340.7
F05050	236.9	243.8	254.5	267.4	273.3	284.9	300.1	306.1
F05051	267.0	279.0	284.3	302.8	330.4	345.9	356.5	358.9
F05052	246.8	248.9	260.4	274.1	284.8	289.1	298.6	304.9
F05053	257.7	258.0	269.2	277.4	288.8	288.5	304.2	308.7
F05054	223.2	226.6	226.1	225.5	238.9	246.4	249.2	257.2
F05055	240.7	250.2	254.1	260.6	278.2	281.4	289.6	296.8
F05056	236.5	243.0	246.8	266.0	282.4	288.1	294.1	306.5
F05057	244.9	256.8	263.0	271.3	274.3	288.8	293.9	298.5
F05058	244.5	246.0	261.9	269.8	285.6	293.1	304.0	307.3
Number of females	10	10	10	10	10	10	10	10
Mean	246.1	252.0	259.7	271.0	284.8	293.0	302.0	308.6
S.D.	13.2	14.4	16.2	20.7	24.0	26.2	27.5	26.8

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 8-2-2. Body weights of female rats, satellite group

2-DT 1000 mg/kg

Female No.	Days of administration							
	1	4	7	14	21	28	35	42
F06059	248.1	257.8	264.0	276.8	279.7	298.0	300.4	302.0
F06060	230.8	243.7	249.8	263.9	269.0	285.4	296.5	296.3
F06061	234.8	239.7	241.4	242.9	254.8	263.1	267.6	263.6
F06062	242.8	256.7	268.5	274.5	278.0	289.7	299.0	301.3
F06063	226.8	231.8	227.6	233.4	248.0	256.9	261.7	255.7
F06064	248.5	254.1	255.5	272.1	282.5	296.2	295.4	301.9
F06065	256.6	260.3	257.3	275.8	296.5	303.8	310.1	320.4
F06066	229.3	240.5	250.6	259.5	271.9	279.4	289.4	293.7
F06067	236.9	251.3	253.0	266.0	281.4	284.4	294.2	294.2
F06069	264.7	279.5	280.3	288.3	318.2	337.0	344.2	342.6
Number of females	10	10	10	10	10	10	10	10
Mean	241.9	251.5	254.8	265.3	278.0	289.4	295.9	297.2
S.D.	12.5	13.5	14.5	16.5	19.9	22.3	22.6	24.8
Significance	NS	NS	NS	NS	NS	NS	NS	NS
Statistical method	TT	TT	TT	TT	TT	TT	TT	TT

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

TT: Analysis by Student's t-test.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 8-3-1. Body weights of female rats at the recovery period

Control (vehicle: corn oil)

Female No.	Days of recovery period		
	1	7	14
F05054	254.1	262.9	264.3
F05055	297.4	306.2	314.6
F05056	302.3	317.3	318.5
F05057	299.7	304.0	310.6
F05058	307.9	313.3	320.1
Number of females	5	5	5
Mean	292.3	300.7	305.6
S.D.	21.7	21.8	23.4

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 8-3-2. Body weights of female rats at the recovery period

2-DT 1000 mg/kg

Female No.	Days of recovery period		
	1	7	14
F06064	301.4	310.4	306.6
F06065	313.6	330.2	333.7
F06066	297.9	299.6	299.7
F06067	294.8	300.5	285.7
F06069	351.6	353.9	365.1
Number of females	5	5	5
Mean	311.9	318.9	318.2
S.D.	23.3	23.1	31.5
Significance	NS	NS	NS
Statistical method	TT	TT	TT

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

TT: Analysis by Student's t-test.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 9-1. Body weights of dams during pregnancy

Control (vehicle: corn oil)

Dam No.	Days of pregnancy			
	0	7	14	20
F01001	272.7	313.8	352.4	442.9
F01002	286.6	327.1	359.1	434.3
F01003	268.6	305.0	339.7	411.7
F01004	256.2	292.1	332.8	422.8
F01006	315.2	342.1	371.3	451.8
F01007	274.1	307.6	347.0	423.9
F01008	298.7	332.5	380.7	468.2
F01009	241.9	287.4	324.3	405.3
F01010	256.9	292.1	333.3	411.7
F01011	261.2	295.5	332.1	401.2
F01012	293.6	323.7	355.4	439.5
Number of dams	11	11	11	11
Mean	275.1	310.8	348.0	428.5
S.D.	21.6	18.5	17.7	20.9

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 9-2. Body weights of dams during pregnancy

2-DT 62.5 mg/kg

Dam No.	Days of pregnancy			
	0	7	14	20
F02013	282.0	315.7	353.9	443.6
F02014	274.9	323.1	361.0	444.8
F02015	268.2	312.4	358.7	441.7
F02016	234.8	288.3	332.1	435.6
F02017	282.6	308.3	341.8	419.9
F02018	238.6	269.5	304.5	377.5
F02019	254.6	295.5	330.2	401.4
F02020	274.9	311.9	347.0	427.7
F02021	298.1	348.1	404.0	505.7
F02022	283.9	314.9	353.0	418.0
F02023	265.4	307.5	358.1	453.8
F02024	267.9	311.4	351.0	437.2
Number of dams	12	12	12	12
Mean	268.8	308.9	349.6	433.9
S.D.	18.6	19.1	23.5	31.0
Significance	NS	NS	NS	NS
Statistical method	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01)

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 9-3. Body weights of dams during pregnancy

2-DT 250 mg/kg

Dam No.	Days of pregnancy			
	0	7	14	20
F03025	282.7	324.7	369.0	439.9
F03026	269.8	309.6	358.3	438.6
F03027	284.9	328.4	378.7	474.3
F03028	272.7	310.2	351.2	454.4
F03029	305.7	317.6	343.4	406.2
F03030	276.7	313.1	350.1	450.1
F03031	263.1	292.8	330.3	408.3
F03032	288.2	319.4	347.2	427.4
F03033	275.9	319.0	365.1	443.8
F03034	281.8	318.2	358.3	455.6
F03035	259.0	297.2	333.4	407.0
F03036	299.4	331.7	367.5	456.9
Number of dams	12	12	12	12
Mean	280.0	315.2	354.4	438.5
S.D.	13.7	11.6	14.6	22.2
Significance	NS	NS	NS	NS
Statistical method	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01)

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 9-4. Body weights of dams during pregnancy

2-DT 1000 mg/kg

Dam No.	Days of pregnancy			
	0	7	14	20
F04037	266.0	298.8	333.2	405.1
F04038	283.8	324.3	356.4	438.3
F04039	264.6	318.0	354.5	446.2
F04040	258.9	290.6	331.5	426.5
F04041	264.0	303.1	334.5	428.6
F04042	270.9	300.7	332.7	420.8
F04043	285.4	322.5	357.4	443.1
F04044	260.9	295.1	330.3	394.9
F04045	297.6	343.0	384.1	491.8
F04046	294.6	334.2	378.1	483.1
F04047	289.3	314.3	344.8	426.3
F04048	271.3	297.0	332.1	375.1
Number of dams	12	12	12	12
Mean	275.6	311.8	347.5	431.7
S.D.	13.7	16.8	18.8	33.1
Significance	NS	NS	NS	NS
Statistical method	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01)

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 10-1. Body weights of dams during lactation

Control (vehicle: corn oil)

Dam No.	Days of lactation	
	0	4
F01001	342.3	346.4
F01002	340.1	346.8
F01003	337.4	339.5
F01004	304.4	318.3
F01006	333.4	368.8
F01007	341.5	337.6
F01008	345.8	381.1
F01009	331.9	320.1
F01010	250.6	315.1
F01011	309.7	316.7
F01012	316.7	342.7
Number of dams	11	11
Mean	323.1	339.4
S.D.	27.8	21.6

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 10-2. Body weights of dams during lactation

2-DT 62.5 mg/kg

Dam No.	Days of lactation	
	0	4
F02013	355.2	368.5
F02014	340.8	332.0
F02015	338.1	353.1
F02016	319.9	338.2
F02017	331.8	336.1
F02018	298.1	309.7
F02019	309.4	334.4
F02020	324.1	324.1
F02021	376.3	387.0
F02022	339.1	349.4
F02023	313.3	347.0
F02024	356.4	348.9
Number of dams	12	12
Mean	333.5	344.0
S.D.	22.3	20.2
Significance	NS	NS
Statistical method	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 10-3. Body weights of dams during lactation

2-DT 250 mg/kg

Dam No.	Days of lactation	
	0	4
F03025	327.3	353.8
F03026	344.8	351.5
F03027	351.7	368.9
F03028	311.3	342.1
F03029	343.9	341.6
F03030	330.5	345.6
F03031	328.4	329.3
F03032	328.1	331.4
F03033	367.4	367.5
F03034	359.9	347.3
F03035	326.3	354.2
F03036	321.9	348.4
Number of dams	12	12
Mean	336.8	348.5
S.D.	16.7	12.1
Significance	NS	NS
Statistical method	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 10-4. Body weights of dams during lactation

2-DT 1000 mg/kg

Dam No.	Days of lactation	
	0	4
F04037	317.8	328.2
F04038	330.6	350.3
F04039	353.6	335.7
F04040	291.4	329.5
F04041	329.7	342.9
F04042	308.7	349.0
F04043	359.8	357.0
F04044	310.7	330.9
F04045	382.9	363.5
F04046	302.4	339.4
F04047	325.5	337.3
F04048	345.4	335.9
Number of dams	12	12
Mean	329.9	341.6
S.D.	26.5	11.2
Significance	NS	NS
Statistical method	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 11-1-1. Food consumption of male rats

Control (vehicle: corn oil)

Male No.	Days of administration					
	1	7	14	29	35	41
M01001	22.0	27.3	24.8	27.6	26.5	27.3
M01002	29.2	23.1	20.5	21.3	20.5	22.6
M01003	27.4	25.7	23.8	24.8	23.3	25.2
M01004	26.6	26.3	21.8	25.8	24.1	23.6
M01005	24.8	25.2	24.9	26.5	28.1	27.9
M01006	28.8	29.2	26.2	28.4	24.5	17.9
M01007	28.4	28.5	28.1	29.8	27.3	32.2
M01008	27.1	30.4	25.8	26.7	22.8	24.9
M01009	26.8	25.5	22.1	26.1	24.8	26.7
M01010	28.4	26.9	22.8	23.2	23.1	26.7
M01011	28.6	24.8	26.2	27.4	27.3	26.2
M01012	27.6	25.1	23.7	25.3	21.8	26.2
Number of males	12	12	12	12	12	12
Mean	27.1	26.5	24.2	26.1	24.5	25.6
S.D.	2.0	2.1	2.2	2.3	2.4	3.4

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 11-1-2. Food consumption of male rats

2-DT 62.5 mg/kg

Male No.	Days of administration					
	1	7	14	29	35	41
M02013	32.3	27.7	23.1	22.9	20.8	17.5
M02014	21.3	19.1	19.3	19.1	18.0	20.5
M02015	26.8	23.0	23.1	22.7	23.0	21.4
M02016	26.5	25.8	22.8	25.1	24.7	25.5
M02017	29.9	24.0	23.1	24.1	26.1	21.3
M02018	28.2	23.5	23.0	21.6	25.1	9.4
M02019	30.6	23.0	28.0	26.1	25.8	27.4
M02020	26.0	24.8	23.3	23.6	21.1	21.7
M02021	25.1	23.3	21.7	22.3	22.6	23.6
M02022	29.4	22.8	24.6	27.1	26.1	28.4
M02023	26.3	27.7	24.8	25.6	26.3	28.0
M02024	31.0	28.4	28.2	26.0	24.4	27.2
Number of males	12	12	12	12	12	12
Mean	27.8	24.4	23.8	23.9	23.7	22.7
S.D.	3.1	2.6	2.5	2.3	2.6	5.4
Significance	NS	NS	NS	NS	NS	NS
Statistical method	AN	DU	DU	DU	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

DU: Analysis by Dunnett's test.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 11-1-3. Food consumption of male rats

2-DT 250 mg/kg

Male No.	Days of administration					
	1	7	14	29	35	41
M03025	28.7	22.8	21.6	23.8	23.3	26.3
M03026	30.6	26.0	20.2	26.3	21.3	24.4
M03027	26.1	26.2	24.1	27.6	22.8	26.5
M03028	28.0	30.2	26.3	30.8	28.0	26.6
M03029	31.7	27.4	25.0	29.8	23.0	25.6
M03030	25.4	24.7	23.7	23.2	21.5	10.7
M03031	29.0	29.9	27.8	25.1	25.7	29.6
M03032	30.0	29.8	24.4	27.2	27.1	24.5
M03033	29.3	30.6	26.7	24.4	24.8	25.2
M03034	24.9	26.9	25.1	27.6	27.3	28.8
M03035	36.4	30.1	31.9	28.6	24.9	24.3
M03036	27.3	23.9	23.6	24.5	22.4	24.5
Number of males	12	12	12	12	12	12
Mean	29.0	27.4	25.0	26.6	24.3	24.8
S.D.	3.1	2.7	3.0	2.4	2.3	4.7
Significance	NS	NS	NS	NS	NS	NS
Statistical method	AN	DU	DU	DU	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

DU: Analysis by Dunnett's test.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 11-1-4. Food consumption of male rats

2-DT 1000 mg/kg

Male No.	Days of administration					
	1	7	14	29	35	41
M04037	18.1	22.6	25.4	26.9	24.9	27.8
M04038	30.5	26.7	24.8	27.6	22.4	26.6
M04039	30.4	29.9	28.7	28.3	28.1	28.0
M04040	34.8	31.3	24.8	32.2	24.7	24.3
M04041	29.4	26.8	28.1	34.5	28.3	28.7
M04042	27.9	27.8	29.4	30.4	25.7	17.1
M04043	24.4	24.4	25.0	27.4	22.8	23.8
M04044	29.2	26.0	24.3	26.3	22.5	27.1
M04045	34.2	29.1	25.4	31.2	29.9	31.3
M04046	29.0	27.4	29.3	27.9	26.3	24.2
M04047	25.9	24.2	25.5	22.8	27.8	11.9
M04048	29.1	30.9	28.2	33.3	28.5	31.0
Number of males	12	12	12	12	12	12
Mean	28.6	27.3	26.6	29.1	26.0	25.2
S.D.	4.4	2.7	2.0	3.3	2.6	5.6
Significance	NS	NS	NS	*	NS	NS
Statistical method	AN	DU	DU	DU	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

DU: Analysis by Dunnett's test.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 11-2-1. Food consumption of male rats at the recovery period

Control (vehicle: corn oil)

Male No.	Days of recovery period	
	6	12
M01008	31.6	25.4
M01009	27.2	23.1
M01010	29.2	31.2
M01011	29.1	29.6
M01012	25.2	28.8
Number of males	5	5
Mean	28.5	27.6
S.D.	2.4	3.3

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 11-2-2. Food consumption of male rats at the recovery period

2-DT 1000 mg/kg

Male No.	Days of recovery period	
	6	12
M04044	29.1	27.8
M04045	29.6	25.4
M04046	27.9	29.2
M04047	28.0	29.7
M04048	32.3	31.3
Number of males	5	5
Mean	29.4	28.7
S.D.	1.8	2.2
Significance	NS	NS
Statistical method	TT	TT

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

TT: Analysis by Student's t-test.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 12-1-1. Food consumption of female rats

Control (vehicle: corn oil)

Female No.	Days of administration					
	1	7	14	29	35	41
F01001	16.9	20.3	17.1			
F01002	13.6	19.1	18.5			
F01003	20.6	16.2	21.0			
F01004	19.5	13.5	17.2			
F01005	17.9	20.4	14.2	25.9	18.2	11.3
F01006	18.3	21.1	16.7			
F01007	20.4	20.2	17.2			
F01008	17.9	21.9	17.5			
F01009	17.7	10.8	14.6			
F01010	19.0	14.8	18.2			
F01011	16.9	18.1	11.5			
F01012	18.6	19.9	22.5			
Number of females	12	12	12			
Mean	18.1	18.0	17.2			
S.D.	1.9	3.5	2.9			

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 12-1-2. Food consumption of female rats

2-DT 62.5 mg/kg

Female No.	Days of administration					
	1	7	14	29	35	41
F02013	16.2	21.1	19.4			
F02014	12.0	19.9	16.7			
F02015	21.0	14.0	17.8			
F02016	15.2	12.7	15.3			
F02017	19.6	16.8	21.7			
F02018	18.7	12.7	15.4			
F02019	19.7	13.3	18.1			
F02020	15.6	13.0	18.6			
F02021	12.0	21.4	18.7			
F02022	12.7	19.9	18.5			
F02023	19.3	18.8	13.3			
F02024	16.3	18.0	17.6			
Number of females	12	12	12			
Mean	16.5	16.8	17.6			
S.D.	3.2	3.5	2.2			
Significance	NS	NS	NS	---	---	---
Statistical method	DU	AN	AN	NA	NA	NA

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

DU: Analysis by Dunnett's test.

AN: Analysis by variance (one-way layout).

NA: Not analyzed.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 12-1-3. Food consumption of female rats

2-DT 250 mg/kg

Female No.	Days of administration					
	1	7	14	29	35	41
F03025	14.9	22.8	16.5			
F03026	16.5	13.7	18.0			
F03027	20.1	17.9	18.9			
F03028	12.5	12.1	19.5			
F03029	18.8	18.8	14.7			
F03030	11.0	18.6	17.4			
F03031	12.9	17.9	15.2			
F03032	19.1	17.8	20.9			
F03033	15.5	16.3	21.6			
F03034	14.4	22.6	18.0			
F03035	20.2	13.0	16.2			
F03036	22.1	17.2	20.3			
Number of females	12	12	12			
Mean	16.5	17.4	18.1			
S.D.	3.5	3.3	2.2			
Significance	NS	NS	NS	---	---	---
Statistical method	DU	AN	AN	NA	NA	NA

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

DU: Analysis by Dunnett's test.

AN: Analysis by variance (one-way layout).

NA: Not analyzed.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 12-1-4. Food consumption of female rats

2-DT 1000 mg/kg

Female No.	Days of administration						
	1	7	14	29	35	41	48
F04037	18.9	14.0	17.7				
F04038	23.2	15.4	20.8				
F04039	16.5	21.0	17.5				
F04040	16.8	18.1	15.8				
F04041	20.7	16.9	17.8				
F04042	18.3	17.7	16.2				
F04043	20.2	21.0	21.0				
F04044	19.3	15.5	19.2				
F04045	25.6	22.9	23.2				
F04046	20.6	22.8	23.6				
F04047	16.6	23.5	23.3				
F04048	18.2	19.4	15.0				
Number of females	12	12	12				
Mean	19.6	19.0	19.3				
S.D.	2.7	3.2	3.1				
Significance	NS	NS	NS	---	---	---	---
Statistical method	DU	AN	AN	NA	NA	NA	NA

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

DU: Analysis by Dunnett's test.

AN: Analysis by variance (one-way layout).

NA: Not analyzed.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 12-2-1. Food consumption of female rats, satellite group

Control (vehicle: corn oil)

Female No.	Days of administration						
	1	7	14	21	29	35	41
F05049	20.4	19.7	21.4	23.6	21.2	13.9	21.2
F05050	20.8	16.5	20.1	21.3	21.7	16.1	20.1
F05051	17.1	23.3	19.9	19.6	15.7	21.4	17.1
F05052	19.2	15.6	19.7	20.0	18.1	13.9	17.6
F05053	22.3	18.1	21.4	23.8	19.7	12.3	20.4
F05054	14.3	17.6	15.4	14.2	17.1	15.9	17.6
F05055	17.1	19.7	18.1	15.9	14.4	16.3	14.3
F05056	20.7	20.5	13.6	20.4	21.4	16.9	19.7
F05057	18.7	22.1	19.9	18.8	21.5	18.4	19.4
F05058	19.8	16.8	19.2	20.8	19.9	18.4	17.0
Number of females	10	10	10	10	10	10	10
Mean	19.0	19.0	18.9	19.8	19.1	16.4	18.4
S.D.	2.3	2.5	2.5	3.0	2.6	2.6	2.1

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 12-2-2. Food consumption of female rats, satellite group

2-DT 1000 mg/kg

Female No.	Days of administration						
	1	7	14	21	29	35	41
F06059	17.2	20.0	18.3	19.9	19.7	19.8	17.5
F06060	20.9	19.4	21.0	22.7	19.8	19.7	19.6
F06061	16.2	21.0	19.6	15.9	14.0	18.3	12.9
F06062	11.6	20.8	19.0	20.3	18.7	20.4	17.6
F06063	12.4	19.6	17.6	13.8	14.0	18.8	18.4
F06064	21.0	20.6	16.8	21.2	18.0	16.4	19.3
F06065	6.6	21.5	13.4	22.4	20.5	20.8	20.7
F06066	19.6	19.2	20.2	19.9	19.2	17.4	17.0
F06067	21.3	22.0	14.5	22.2	20.8	21.1	18.1
F06069	17.0	25.2	23.5	21.1	16.4	25.1	15.7
Number of females	10	10	10	10	10	10	10
Mean	16.4	20.9	18.4	19.9	18.1	19.8	17.7
S.D.	4.9	1.8	3.0	2.9	2.5	2.4	2.2
Significance	NS	NS	NS	NS	NS	**	NS
Statistical method	AW	TT	TT	TT	TT	TT	TT

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AW: Analysis by Aspin-Welch t-test.

TT: Analysis by Student's t-test.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 12-3-1. Food consumption of female rats at the recovery period

Control (vehicle: corn oil)

Female No.	Days of recovery period	
	6	12
F05054	20.1	18.4
F05055	19.4	20.1
F05056	20.6	14.9
F05057	18.8	22.8
F05058	19.8	20.9
Number of females	5	5
Mean	19.7	19.4
S.D.	0.7	3.0

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 12-3-2. Food consumption of female rats at the recovery period

2-DT 1000 mg/kg

Female No.	Days of recovery period	
	6	12
F06064	18.8	19.0
F06065	24.5	19.5
F06066	17.3	22.3
F06067	16.1	24.0
F06069	25.0	24.6
Number of females	5	5
Mean	20.3	21.9
S.D.	4.1	2.6
Significance	NS	NS
Statistical method	AW	TT

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AW: Analysis by Aspin-Welch t-test.

TT: Analysis by Student's t-test.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 13-1. Food consumption in dams during pregnancy

Control (vehicle: corn oil)

Dam No.	Days of pregnancy			
	0	7	14	20
F01001	21.5	25.8	21.7	22.9
F01002	18.7	24.5	20.1	17.2
F01003	18.2	23.4	24.8	23.0
F01004	17.9	25.3	22.7	14.6
F01006	17.8	23.8	23.4	19.2
F01007	19.0	22.1	26.4	18.5
F01008	19.1	26.8	25.7	21.2
F01009	16.3	21.4	26.3	23.5
F01010	17.1	26.4	23.9	19.5
F01011	17.3	26.0	21.2	29.4
F01012	20.9	22.3	21.2	19.3
Number of dams	11	11	11	11
Mean	18.5	24.3	23.4	20.8
S.D.	1.6	1.9	2.2	3.9

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 13-2. Food consumption in dams during pregnancy

2-DT 62.5 mg/kg

Dam No.	Days of pregnancy			
	0	7	14	20
F02013	18.7	21.8	25.5	23.3
F02014	23.4	28.2	19.5	19.9
F02015	21.3	25.9	24.3	22.1
F02016	17.2	23.2	28.7	23.9
F02017	20.5	26.4	24.6	20.9
F02018	15.8	23.0	24.3	23.3
F02019	18.8	23.2	23.8	19.1
F02020	19.7	23.9	19.6	21.6
F02021	23.9	27.4	27.0	23.2
F02022	19.0	24.0	22.9	22.9
F02023	22.4	25.1	29.3	17.8
F02024	21.1	27.2	27.1	20.6
Number of dams	12	12	12	12
Mean	20.2	24.9	24.7	21.6
S.D.	2.4	2.1	3.1	1.9
Significance	NS	NS	NS	NS
Statistical method	KW	AN	AN	KW

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

KW: Analysis by Kruskal-Wallis' test (one-way layout).

AN: Analysis by variance (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 13-3. Food consumption in dams during pregnancy

2-DT 250 mg/kg

Dam No.	Days of pregnancy			
	0	7	14	20
F03025	15.6	27.2	25.2	23.1
F03026	18.4	24.4	26.2	17.1
F03027	21.9	27.9	29.4	25.2
F03028	25.5	22.4	26.2	13.8
F03029	15.9	19.7	19.4	19.0
F03030	18.4	23.0	23.0	19.1
F03031	13.9	18.2	22.3	20.5
F03032	23.0	24.6	22.3	25.6
F03033	14.7	29.8	24.9	22.3
F03034	18.3	27.7	26.6	23.8
F03035	18.0	22.1	22.2	20.2
F03036	22.1	27.5	27.0	22.9
Number of dams	12	12	12	12
Mean	18.8	24.5	24.6	21.1
S.D.	3.6	3.6	2.8	3.5
Significance	NS	NS	NS	NS
Statistical method	KW	AN	AN	KW

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

KW: Analysis by Kruskal-Wallis' test (one-way layout).

AN: Analysis by variance (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 13-4. Food consumption in dams during pregnancy

2-DT 1000 mg/kg

Dam No.	Days of pregnancy			
	0	7	14	20
F04037	18.9	23.4	23.5	26.5
F04038	22.1	24.5	24.5	18.7
F04039	23.5	27.7	24.3	25.3
F04040	10.6	22.5	23.1	15.3
F04041	22.7	27.4	25.9	25.7
F04042	18.0	21.0	24.5	25.1
F04043	19.9	23.1	24.0	21.3
F04044	20.0	22.9	23.4	24.6
F04045	22.8	26.2	30.1	26.4
F04046	25.5	27.1	28.8	18.5
F04047	24.5	22.8	23.3	26.8
F04048	20.4	22.4	24.4	4.1
Number of dams	12	12	12	12
Mean	20.7	24.3	25.0	21.5
S.D.	3.9	2.3	2.2	6.7
Significance	NS	NS	NS	NS
Statistical method	KW	AN	AN	KW

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

KW: Analysis by Kruskal-Wallis' test (one-way layout).

AN: Analysis by variance (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 14-1. Food consumption in dams during lactation

Control (vehicle: corn oil)

Dam No.	Days of lactation
	3
F01001	34.9
F01002	30.6
F01003	37.2
F01004	44.1
F01006	45.5
F01007	31.0
F01008	53.7
F01009	35.2
F01010	37.2
F01011	32.0
F01012	42.0
Number of dams	11
Mean	38.5
S.D.	7.2

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 14-2. Food consumption in dams during lactation

2-DT 62.5 mg/kg

Dam No.	Days of lactation
	3
F02013	45.8
F02014	35.5
F02015	44.8
F02016	46.5
F02017	37.7
F02018	31.8
F02019	44.4
F02020	47.2
F02021	45.7
F02022	35.3
F02023	52.3
F02024	42.5
Number of dams	12
Mean	42.5
S.D.	6.0
Significance	NS
Statistical method	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 14-3. Food consumption in dams during lactation

2-DT 250 mg/kg

Dam No.	Days of lactation	
	3	
F03025	43.3	
F03026	43.3	
F03027	42.6	
F03028	53.4	
F03029	35.1	
F03030	39.1	
F03031	41.8	
F03032	19.4	
F03033	38.6	
F03034	40.6	
F03035	39.8	
F03036	46.3	
Number of dams	12	
Mean	40.3	
S.D.	8.0	
Significance	NS	
Statistical method	AN	

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 14-4. Food consumption in dams during lactation

2-DT 1000 mg/kg

Dam No.	Days of lactation	
	3	
F04037	40.5	
F04038	39.0	
F04039	32.8	
F04040	51.6	
F04041	42.1	
F04042	50.1	
F04043	43.9	
F04044	42.6	
F04045	45.1	
F04046	45.6	
F04047	36.4	
F04048	35.1	
Number of dams	12	
Mean	42.1	
S.D.	5.7	
Significance	NS	
Statistical method	AN	

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 15-1. Functional findings of male rats at the end of the dosing period

Control (vehicle: corn oil)

Male

Male No.	Righting reflex	Visual placing	Pupillary reflex	Startle reaction	Preyer's reaction	Withdrawal reflex	Eyelid reflex
M01001	2	2	2	2	+	+	+
M01002	2	2	2	2	+	+	+
M01003	2	2	2	2	+	+	+
M01004	2	2	2	2	+	+	+
M01005	2	2	2	2	+	+	+
Total	2:5	2:5	2:5	2:5	+; 5	+; 5	+; 5

2 or +, normal

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 15-2. Functional findings of male rats at the end of the dosing period

2-DT 62.5 mg/kg

Male

Male No.	Righting reflex	Visual placing	Papillary reflex	Startle reaction	Preyer's reaction	Withdrawal reflex	Eyelid reflex
M02013	2	2	2	2	+	+	+
M02014	2	2	2	2	+	+	+
M02015	2	2	2	2	+	+	+
M02016	2	2	2	2	+	+	+
M02017	2	2	2	2	+	+	+
Total	2:5	2:5	2:5	2:5	+; 5	+; 5	+; 5

2 or +, normal

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 15-3. Functional findings of male rats at the end of the dosing period

2-DT 250 mg/kg

Male

Male No.	Righting reflex	Visual placing	Papillary reflex	Startle reaction	Preyer's reaction	Withdrawal reflex	Eyelid reflex
M03025	2	2	2	2	+	+	+
M03026	2	2	2	2	+	+	+
M03027	2	2	2	2	+	+	+
M03028	2	2	2	2	+	+	+
M03029	2	2	2	2	+	+	+
Total	2: 5	2: 5	2: 5	2: 5	+: 5	+: 5	+: 5

2 or +, normal

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 15-4. Functional findings of male rats at the end of the dosing period

2-DT 1000 mg/kg

Male

Male No.	Righting reflex	Visual placing	Papillary reflex	Startle reaction	Preyer's reaction	Withdrawal reflex	Eyelid reflex
M04037	2	2	2	2	+	+	+
M04038	2	2	2	2	+	+	+
M04039	2	2	2	2	+	+	+
M04040	2	2	2	2	+	+	+
M04041	2	2	2	2	+	+	+
Total	2: 5	2: 5	2: 5	2: 5	+; 5	+; 5	+; 5

2 or +, normal

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 16-1. Functional findings of female rats at the end of the dosing period

Control (vehicle: corn oil)

Female, dam

Female No.	Righting reflex	Visual placing	Papillary reflex	Startle reaction	Preyer's reaction	Withdrawal reflex	Eyelid reflex
F01001	2	2	2	2	+	+	+
F01003	2	2	2	2	+	+	+
F01004	2	2	2	2	+	+	+
F01007	2	2	2	2	+	+	+
F01012	2	2	2	2	+	+	+
Total	2: 5	2: 5	2: 5	2: 5	+: 5	+: 5	+: 5

2 or +, normal

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 16-2. Functional findings of female rats at the end of the dosing period

2-DT 62.5 mg/kg

Female, dam

Female No.	Righting reflex	Visual placing	Papillary reflex	Startle reaction	Preyer's reaction	Withdrawal reflex	Eyelid reflex
F02013	2	2	2	2	+	+	+
F02014	2	2	2	2	+	+	+
F02015	2	2	2	2	+	+	+
F02016	2	2	2	2	+	+	+
F02018	2	2	2	2	+	+	+
Total	2:5	2:5	2:5	2:5	+;5	+;5	+;5

2 or +, normal

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 16-3. Functional findings of female rats at the end of the dosing period

2-DT 250 mg/kg

Female, dam

Female No.	Righting reflex	Visual placing	Papillary reflex	Startle reaction	Preyer's reaction	Withdrawal reflex	Eyelid reflex
F03026	2	2	2	2	+	+	+
F03027	2	2	2	2	+	+	+
F03028	2	2	2	2	+	+	+
F03030	2	2	2	2	+	+	+
F03035	2	2	2	2	+	+	+
Total	2:5	2:5	2:5	2:5	+:5	+:5	+:5

2 or +, normal

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 16-4. Functional findings of female rats at the end of the dosing period

2-DT 1000 mg/kg

Female, dam

Female No.	Righting reflex	Visual placing	Pupillary reflex	Startle reaction	Preyer's reaction	Withdrawal reflex	Eyelid reflex
F04037	2	2	2	2	+	+	+
F04038	2	2	2	2	+	+	+
F04040	2	2	2	2	+	+	+
F04043	2	2	2	2	+	+	+
F04047	2	2	2	2	+	+	+
Total	2: 5	2: 5	2: 5	2: 5	+: 5	+: 5	+: 5

2 or +, normal

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 16-5. Functional findings of female rats at the end of the dosing period

Control (vehicle: corn oil)

Female, satellite group

Female No.	Righting reflex	Visual placing	Papillary reflex	Startle reaction	Preyer's reaction	Withdrawal reflex	Eyelid reflex
F05049	2	2	2	2	+	+	+
F05050	2	2	2	2	+	+	+
F05051	2	2	2	2	+	+	+
F05052	2	2	2	2	+	+	+
F05053	2	2	2	2	+	+	+
Total	2: 5	2: 5	2: 5	2: 5	+; 5	+; 5	+; 5

2 or +, normal

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 16-6. Functional findings of female rats at the end of the dosing period

2-DT 1000 mg/kg

Female, satelite group

Female No.	Righting reflex	Visual placing	Papillary reflex	Startle reaction	Preyer's reaction	Withdrawal reflex	Eyelid reflex
F06059	2	2	2	2	+	+	+
F06060	2	2	2	2	+	+	+
F06061	2	2	2	2	+	+	+
F06062	2	2	2	2	+	+	+
F06063	2	2	2	2	+	+	+
Total	2: 5	2: 5	2: 5	2: 5	+; 5	+; 5	+; 5

2 or +, normal

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 17-1. Assessment of grip strength of male rats

Control (vehicle: corn oil)

Male at the administration period

Male No.	Administration period	
	Forelimb (kg)	Hindlimb (kg)
M01001	1.240	0.652
M01002	1.236	0.591
M01003	1.196	0.521
M01004	1.190	0.612
M01005	1.111	0.474
Number of males	5	5
Mean	1.195	0.570
S.D.	0.052	0.072

Significantly different from the control group (*: P<0.05, **: P<0.01).

2-DT 250 mg/kg

Male at the administration period

Male No.	Administration period	
	Forelimb (kg)	Hindlimb (kg)
M03025	1.140	0.676
M03026	1.164	0.542
M03027	1.286	0.645
M03028	1.104	0.620
M03029	1.230	0.613
Number of males	5	5
Mean	1.185	0.619
S.D.	0.073	0.050

Significantly different from the control group (*: P<0.05, **: P<0.01).

2-DT 62.5 mg/kg

Male at the administration period

Male No.	Administration period	
	Forelimb (kg)	Hindlimb (kg)
M02013	1.247	0.455
M02014	1.254	0.476
M02015	1.167	0.595
M02016	1.112	0.540
M02017	1.152	0.572
Number of males	5	5
Mean	1.186	0.528
S.D.	0.062	0.060

Significantly different from the control group (*: P<0.05, **: P<0.01).

2-DT 1000 mg/kg

Male at the administration period

Male No.	Administration period	
	Forelimb (kg)	Hindlimb (kg)
M04037	1.009	0.489
M04038	1.103	0.594
M04039	1.084	0.633
M04040	1.144	0.557
M04041	1.063	0.626
Number of males	5	5
Mean	1.081 *	0.580
S.D.	0.050	0.059

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 17-2. Assessment of grip strength of male rats

Control (vehicle: corn oil)

Male at the recovery period

Male No.	Recovery period	
	Forelimb (kg)	Hindlimb (kg)
M01008	1.191	0.553
M01009	1.112	0.404
M01010	1.218	0.569
M01011	1.136	0.587
M01012	1.127	0.606
Number of males	5	5
Mean	1.157	0.544
S.D.	0.045	0.081

Significantly different from the control group (*: P<0.05, **: P<0.01).

2-DT 1000 mg/kg

Male at the recovery period

Male No.	Recovery period	
	Forelimb (kg)	Hindlimb (kg)
M04044	1.173	0.613
M04045	1.133	0.564
M04046	1.125	0.577
M04047	1.134	0.457
M04048	1.231	0.531
Number of males	5	5
Mean	1.159	0.548
S.D.	0.044	0.059

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 18. Assessment of grip strength of female rats

Control (vehicle: corn oil)

Female No.	Administration period	
	Forelimb (kg)	Hindlimb (kg)
F01001	1.144	0.489
F01003	1.162	0.475
F01004	1.140	0.570
F01007	1.144	0.568
F01012	1.131	0.455
Number of females	5	5
Mean	1.144	0.511
S.D.	0.011	0.054

Significantly different from the control group (*: P<0.05, **: P<0.01).

2-DT 250 mg/kg

Female No.	Administration period	
	Forelimb (kg)	Hindlimb (kg)
F03026	1.217	0.390
F03027	1.130	0.471
F03028	1.126	0.414
F03030	1.274	0.479
F03035	1.272	0.429
Number of females	5	5
Mean	1.204	0.437
S.D.	0.073	0.038

Significantly different from the control group (*: P<0.05, **: P<0.01).

2-DT 62.5 mg/kg

Female No.	Administration period	
	Forelimb (kg)	Hindlimb (kg)
F02013	1.160	0.388
F02014	1.261	0.476
F02015	1.252	0.454
F02016	1.167	0.392
F02018	1.131	0.504
Number of females	5	5
Mean	1.194	0.443
S.D.	0.059	0.051

Significantly different from the control group (*: P<0.05, **: P<0.01).

2-DT 1000 mg/kg

Female No.	Administration period	
	Forelimb (kg)	Hindlimb (kg)
F04037	1.218	0.568
F04038	1.244	0.468
F04040	1.177	0.392
F04043	1.203	0.547
F04047	1.224	0.421
Number of females	5	5
Mean	1.213	0.479
S.D.	0.025	0.077

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 19. Assessment of grip strength of female rats, satellite group

Control (vehicle: corn oil)

Female No.	Administration period	
	Forelimb (kg)	Hindlimb (kg)
F05049	1.201	0.468
F05050	1.119	0.457
F05051	1.254	0.538
F05052	1.065	0.387
F05053	1.079	0.439
Number of females	5	5
Mean	1.144	0.458
S.D.	0.081	0.055

Significantly different from the control group (*: P<0.05, **: P<0.01).

2-DT 1000 mg/kg

Female No.	Administration period	
	Forelimb (kg)	Hindlimb (kg)
F06059	1.107	0.553
F06060	1.221	0.397
F06061	1.190	0.495
F06062	1.225	0.459
F06063	1.125	0.544
Number of females	5	5
Mean	1.174	0.490
S.D.	0.055	0.064

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 20-1. Motor activity of male rats

Control (vehicle: corn oil)

Male No.	Administration period									
	Ambulation (counts)					Rearing (counts)				
	5min	10min	15min	20min	Total	5min	10min	15min	20min	Total
M01001	1216	1120	885	1161	4382	21	29	29	51	130
M01002	1094	995	946	942	3977	34	21	14	19	88
M01003	1151	1081	983	612	3827	49	55	44	16	164
M01004	1131	882	918	649	3580	36	19	20	9	84
M01005	784	643	643	497	2567	40	12	23	15	90
Number of males	5	5	5	5	5	5	5	5	5	5
Mean	1075	944	875	772	3667	36	27	26	22	111
S.D.	169	192	135	272	680	10	17	11	17	35

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 20-2. Motor activity of male rats

2-DT 62.5 mg/kg

Male No.	Administration period									
	Ambulation (counts)					Rearing (counts)				
	5min	10min	15min	20min	Total	5min	10min	15min	20min	Total
M02013	1220	1097	889	869	4075	46	33	32	26	137
M02014	1197	1069	969	785	4020	49	31	24	9	113
M02015	1182	923	854	851	3810	63	38	28	20	149
M02016	1124	974	899	660	3657	39	18	19	17	93
M02017	1092	1181	751	1117	4141	23	26	17	26	92
Number of males	5	5	5	5	5	5	5	5	5	5
Mean	1163	1049	872	856	3941	44	29	24	20	117
S.D.	53	102	80	167	201	15	8	6	7	26

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 20-3. Motor activity of male rats

2-DT 250 mg/kg

Male No.	Administration period									
	Ambulation (counts)					Rearing (counts)				
	5min	10min	15min	20min	Total	5min	10min	15min	20min	Total
M03025	1646	1585	1485	1386	6102	27	30	24	20	101
M03026	1169	1084	997	964	4214	38	29	25	24	116
M03027	1277	1297	1407	966	4947	43	16	29	22	110
M03028	1245	901	923	959	4028	54	29	26	18	127
M03029	1374	1270	1148	580	4372	53	36	27	8	124
Number of males	5	5	5	5	5	5	5	5	5	5
Mean	1342 *	1227	1192 *	971	4733 *	43	28	26	18	116
S.D.	185	256	247	285	839	11	7	2	6	11

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 20-4. Motor activity of male rats

2-DT 1000 mg/kg

Male No.	Administration period									
	Ambulation (counts)					Rearing (counts)				
	5min	10min	15min	20min	Total	5min	10min	15min	20min	Total
M04037	1228	1029	779	798	3834	34	31	24	15	104
M04038	1031	929	965	696	3621	31	33	30	19	113
M04039	894	886	1055	831	3666	23	19	29	22	93
M04040	1267	1180	972	1014	4433	54	34	19	26	133
M04041	994	966	960	1091	4011	28	36	24	30	118
Number of males	5	5	5	5	5	5	5	5	5	5
Mean	1083	998	946	886	3913	34	31	25	22	112
S.D.	159	114	101	162	329	12	7	4	6	15

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 21-1. Motor activity of female rats

Control (vehicle: corn oil)

Female No.	Administration period									
	Ambulation (counts)					Rearing (counts)				
	5min	10min	15min	20min	Total	5min	10min	15min	20min	Total
F01001	864	659	648	411	2582	27	25	7	6	65
F01003	1021	811	414	530	2776	28	11	8	4	51
F01004	1112	976	543	560	3191	32	35	10	11	88
F01007	1097	983	643	715	3438	30	29	10	9	78
F01012	1195	1014	680	654	3543	27	26	2	8	63
Number of females	5	5	5	5	5	5	5	5	5	5
Mean	1058	889	586	574	3106	29	25	7	8	69
S.D.	125	151	109	117	416	2	9	3	3	14

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 21-2. Motor activity of female rats

2-DT 62.5 mg/kg

Female No.	Administration period									
	Ambulation (counts)					Rearing (counts)				
	5min	10min	15min	20min	Total	5min	10min	15min	20min	Total
F02013	1191	778	259	63	2291	74	12	4	0	90
F02014	1201	1066	990	741	3998	47	21	25	17	110
F02015	1151	833	540	752	3276	23	14	15	22	74
F02016	1266	995	819	995	4075	50	39	26	15	130
F02018	1005	614	623	309	2551	16	3	7	4	30
Number of females	5	5	5	5	5	5	5	5	5	5
Mean	1163	857	646	572	3238	42	18	15	12	87
S.D.	97	179	278	377	814	23	13	10	9	38

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 21-3. Motor activity of female rats

2-DT 250 mg/kg

Female No.	Administration period									
	Ambulation (counts)					Rearing (counts)				
	5min	10min	15min	20min	Total	5min	10min	15min	20min	Total
F03026	1412	1010	686	403	3511	44	16	2	2	64
F03027	868	959	717	541	3085	29	40	23	9	101
F03028	1850	1290	1208	1186	5534	17	15	9	1	42
F03030	946	817	756	523	3042	21	20	18	13	72
F03035	1139	905	610	57	2711	30	14	3	0	47
Number of females	5	5	5	5	5	5	5	5	5	5
Mean	1243	996	795	542	3577	28	21	11	5	65
S.D.	399	179	237	409	1131	10	11	9	6	23

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 21-4. Motor activity of female rats

2-DT 1000 mg/kg

Female No.	Administration period									
	Ambulation (counts)					Rearing (counts)				
	5min	10min	15min	20min	Total	5min	10min	15min	20min	Total
F04037	858	803	720	489	2870	34	35	21	11	101
F04038	997	532	585	230	2344	22	9	1	0	32
F04040	1064	1020	622	314	3020	24	16	3	0	43
F04043	1235	1110	695	651	3691	44	38	17	34	133
F04047	1127	814	814	480	3235	31	15	20	2	68
Number of females	5	5	5	5	5	5	5	5	5	5
Mean	1056	856	687	433	3032	31	23	12	9	75
S.D.	141	224	89	164	494	9	13	10	14	42

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 22-1. Motor activity of female rats, satellite group

Control (vehicle: corn oil)

Female No.	Administration period									
	Ambulation (counts)					Rearing (counts)				
	5min	10min	15min	20min	Total	5min	10min	15min	20min	Total
F05049	1153	1213	849	601	3816	30	44	21	15	110
F05050	1034	872	738	910	3554	35	17	9	18	79
F05051	1311	1168	1284	1233	4996	33	28	44	31	136
F05052	803	777	762	473	2815	39	31	24	18	112
F05053	1320	1300	1187	1133	4940	47	51	47	30	175
Number of females	5	5	5	5	5	5	5	5	5	5
Mean	1124	1066	964	870	4024	37	34	29	22	122
S.D.	215	228	254	329	937	7	13	16	8	36

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 22-2. Motor activity of female rats, satellite group

2-DT 1000 mg/kg

Female No.	Administration period									
	Ambulation (counts)					Rearing (counts)				
	5min	10min	15min	20min	Total	5min	10min	15min	20min	Total
F06059	1231	1100	1074	978	4383	29	22	22	20	93
F06060	1190	1125	1092	1192	4599	34	22	28	40	124
F06061	1312	1195	1182	1051	4740	44	30	38	29	141
F06062	1147	1310	1166	1118	4741	25	53	37	29	144
F06063	1105	1084	1069	1101	4359	32	26	16	15	89
Number of females	5	5	5	5	5	5	5	5	5	5
Mean	1197	1163	1117	1088	4564	33	31	28	27	118
S.D.	80	93	53	80	186	7	13	9	10	26

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 23-1-1. Urinalysis in male rats

Control (vehicle: corn oil)

Male No.	Quality								Urinary sediments					
	Color	Turbidity	pH	Protein	Glucose	Ketone	Bilirubin	Occult blood	Urobilinogen	Red blood cells	White blood cells	Casts	Crystals	Epithelial cells
M01001	Light yellow	-	7.5	+	-	+	-	-	±	-	-	-	±	-
M01002	Yellow	-	7.0	2+	-	+	-	-	2+	-	-	-	±	-
M01003	Light yellow	-	7.0	+	-	±	-	-	±	-	-	-	±	-
M01004	Light yellow	-	6.5	+	-	+	-	-	+	-	-	-	-	-
M01005	Light yellow	-	7.0	+	-	±	-	-	±	-	-	-	±	-

Male No.	Urine volume (mL/24hr)	Specific gravity	Electrolyte, density (mEq/L)			Electrolyte, gross volume (mEq/24 hr)		
			Na	K	Cl	Na	K	Cl
M01001	12.8	1.066	96.4	233.9§	110.8	1.23	2.99	1.42
M01002	12.7	1.064	97.5	201.9	121.5	1.24	2.56	1.54
M01003	27.6	1.022	30.4	96.3§	30.6	0.84	2.66	0.84
M01004	10.3	1.078	192.5	245.5§	186.9	1.98	2.53	1.93
M01005	26.6	1.021	35.2	89.0§	35.3	0.94	2.37	0.94
Number of males	5	5	5	5	5	5	5	5
Mean	18.0	1.050	90.4	173.3	97.0	1.25	2.62	1.33
±S.D.	8.4	0.027	65.5	75.4	65.4	0.45	0.23	0.45

Turbidity, -: negative

Protein, -: negative; ±: 10≤ and < 30 mg/dL; +: 30≤ and < 100 mg/dL; 2+: 100≤ and < 300 mg/dL

Glucose, -: negative

Ketone, -: negative; ±: 5≤ and < 10 mg/dL; +: 10≤ and < 40 mg/dL

Bilirubin, -: negative

Occult blood, -: negative; 2+: 0.20≤ and < 1.00 mg/dL

Urobilinogen, ±: normal; +: 2.0≤ and < 4.0 mg/dL; 2+: 4.0≤ and < 8.0 mg/dL

Red blood cells, White blood cells and Casts, -: not observed

Crystals and Epithelial cells, -: not observed; ±: a few

§, The re-measurement was carried out because the difference between two measured values exceeded the permissible limit. The re-measured values were employed as the data.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 23-1-2. Urinalysis in male rats

2-DT 62.5 mg/kg

Male No.	Quality								Urinary sediments					
	Color	Turbidity	pH	Protein	Glucose	Ketone	Bilirubin	Occult blood	Urobilinogen	Red blood cells	White blood cells	Casts	Crystals	Epithelial cells
M02013	Light yellow	-	7.0	2+	-	+	-	-	+	-	-	-	±	-
M02014	Light yellow	-	7.0	+	-	±	-	-	+	-	-	-	±	-
M02015	Light yellow	-	7.5	+	-	±	-	-	±	-	-	-	±	-
M02016	Light yellow	-	6.5	+	-	+	-	-	±	-	-	-	-	-
M02017	Light yellow	-	6.5	+	-	+	-	-	+	-	-	-	±	-

Male No.	Urine volume (mL/24hr)	Specific gravity	Electrolyte, density (mEq/L)			Electrolyte, gross volume (mEq/24 hr)		
			Na	K	Cl	Na	K	Cl
M02013	11.8	1.065	108.3	227.0§	129.7	1.28	2.68	1.53
M02014	21.6	1.034	63.6	149.8§	72.0	1.37	3.24	1.56
M02015	20.8	1.032	43.9	135.5	54.6	0.91	2.82	1.14
M02016	16.0	1.034	18.5§	97.0	9.5 b	0.30	1.55	0.15
M02017	19.5	1.044	100.6	184.9	116.1	1.96	3.61	2.26
Number of males	5	5	5	5	5	5	5	5
Mean	17.9	1.042	67.0	158.8	76.4	1.16	2.78	1.33
±S.D.	4.0	0.014	37.9	49.4	48.4	0.61	0.78	0.77

Significantly different from the control group (*: P<0.05, **: P<0.01).

Turbidity, -: negative

Protein, -: negative; ±: 10≤ and <30 mg/dL; +: 30≤ and <100 mg/dL; 2+: 100≤ and <300 mg/dL

Glucose, -: negative

Ketone, -: negative; ±: 5≤ and <10 mg/dL; +: 10≤ and <40 mg/dL

Bilirubin, -: negative

Occult blood, -: negative; 2+: 0.20≤ and <1.00 mg/dL

Urobilinogen, ±: normal; +: 2.0≤ and <4.0 mg/dL; 2+: 4.0≤ and <8.0 mg/dL

Red blood cells, White blood cells and Casts, -: not observed

Crystals and Epithelial cells, -: not observed; ±: a few

§, The re-measurement was carried out because the difference between two measured values exceeded the permissible limit. The re-measured values were employed as the data.

b, The re-measurement was carried out after mixing the specimen with standard solution because the first measured value exceeded the lower limit of quantitation range.

The re-measured value was employed as the measured value for the specimen.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 23-1-3. Urinalysis in male rats

2-DT 250 mg/kg

Male No.	Quality								Urinary sediments					
	Color	Turbidity	pH	Protein	Glucose	Ketone	Bilirubin	Occult blood	Urobilinogen	Red blood cells	White blood cells	Casts	Crystals	Epithelial cells
M03025	Light yellow	-	7.0	2+	-	+	-	-	+	-	-	-	±	-
M03026	Light yellow	-	7.0	+	-	+	-	-	±	-	-	-	-	-
M03027	Light yellow	-	8.0	+	-	±	-	-	±	-	-	-	±	-
M03028	Yellow	-	6.5	2+	-	+	-	-	+	-	-	-	±	-
M03029	Yellow	-	6.5	2+	-	+	-	-	+	-	-	-	-	-

Male No.	Urine volume (mL/24hr)	Specific gravity	Electrolyte, density (mEq/L)			Electrolyte, gross volume (mEq/24 hr)		
			Na	K	Cl	Na	K	Cl
M03025	10.1	1.077	128.8	258.9§	171.6	1.30	2.61	1.73
M03026	12.1	1.070	132.9	245.5§	153.9	1.61	2.97	1.86
M03027	19.4	1.039	79.2	174.2§	88.0	1.54	3.38	1.71
M03028	11.1	1.068	116.1	233.9§	118.3	1.29	2.60	1.31
M03029	10.2	1.070	135.1	222.1	147.5	1.38	2.27	1.50
Number of males	5	5	5	5	5	5	5	5
Mean	12.6	1.065	118.4	226.9	135.9	1.42	2.77	1.62
±S.D.	3.9	0.015	23.1	32.5	32.9	0.14	0.42	0.22

Significantly different from the control group (*: P<0.05, **: P<0.01).

Turbidity, -: negative

Protein, -: negative; ±: 10≤and<30 mg/dL; +: 30≤and<100 mg/dL; 2+: 100≤and<300 mg/dL

Glucose, -: negative

Ketone, -: negative; ±: 5≤and<10 mg/dL; +: 10≤and<40 mg/dL

Bilirubin, -: negative

Occult blood, -: negative; 2+: 0.20≤and<1.00 mg/dL

Urobilinogen, ±: normal; +: 2.0≤and<4.0 mg/dL; 2+: 4.0≤and<8.0 mg/dL

Red blood cells, White blood cells and Casts, -: not observed

Crystals and Epithelial cells, -: not observed; ±: a few

§, The re-measurement was carried out because the difference between two measured values exceeded the permissible limit. The re-measured values were employed as the data.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 23-1-4. Urinalysis in male rats

2-DT 1000 mg/kg

Male No.	Quality								Urinary sediments					
	Color	Turbidity	pH	Protein	Glucose	Ketone	Bilirubin	Occult blood	Urobilinogen	Red blood cells	White blood cells	Casts	Crystals	Epithelial cells
M04037	Light yellow	+	6.5	+	-	+	-	-	+	-	-	-	-	-
M04038	Light yellow	-	7.0	+	-	±	-	-	±	-	-	-	±	-
M04039	Light yellow	-	6.5	2+	-	+	-	2+	+	-	-	-	±	-
M04040	Light yellow	-	6.5	2+	-	+	-	-	+	-	-	-	±	-
M04041	Light yellow	-	6.5	2+	-	+	-	-	2+	-	-	-	±	-

Male No.	Urine volume (mL/24hr)	Specific gravity	Electrolyte, density (mEq/L)			Electrolyte, gross volume (mEq/24 hr)		
			Na	K	Cl	Na	K	Cl
M04037	12.0	1.069	99.9	212.6	128.2	1.20	2.55	1.54
M04038	15.3	1.036	50.5	127.6§	36.8	0.77	1.95	0.56
M04039	12.4	1.075	167.8	246.6§	164.4	2.08	3.06	2.04
M04040	7.9	1.084	152.2	220.0	146.1	1.20	1.74	1.15
M04041	10.0	1.092	166.4	264.7§	225.4	1.66	2.65	2.25
Number of males	5	5	5	5	5	5	5	5
Mean	11.5	1.071	127.4	214.3	140.2	1.38	2.39	1.51
±S.D.	2.8	0.022	51.1	52.8	68.4	0.50	0.54	0.68

Significantly different from the control group (*: P<0.05, **: P<0.01).

Turbidity, -: negative

Protein, -: negative; ±: 10≤and<30 mg/dL; +: 30≤and<100 mg/dL; 2+: 100≤and<300 mg/dL

Glucose, -: negative

Ketone, -: negative; ±: 5≤and<10 mg/dL; +: 10≤and<40 mg/dL

Bilirubin, -: negative

Occult blood, -: negative; 2+: 0.20≤and<1.00 mg/dL

Urobilinogen, ±: normal; +: 2.0≤and<4.0 mg/dL; 2+: 4.0≤and<8.0 mg/dL

Red blood cells, White blood cells and Casts, -: not observed

Crystals and Epithelial cells, -: not observed; ±: a few

§, The re-measurement was carried out because the difference between two measured values exceeded the permissible limit. The re-measured values were employed as the data.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 23-2-1. Urinalysis in male rats of the recovery period

Control (vehicle: corn oil)

Male No.	Quality								Urinary sediments					
	Color	Turbidity	pH	Protein	Glucose	Ketone	Bilirubin	Occult blood	Urobilinogen	Red blood cells	White blood cells	Casts	Crystals	Epithelial cells
M01008	Light yellow	-	7.0	2+	-	+	-	-	+	-	-	-	±	-
M01009	Light yellow	-	7.0	2+	-	+	-	-	2+	-	-	-	±	-
M01010	Light yellow	-	7.5	+	-	±	-	-	+	-	-	-	±	-
M01011	Light yellow	-	7.0	+	-	±	-	-	±	-	-	-	±	-
M01012	Light yellow	-	9.0	+	-	+	-	-	+	-	-	-	±	-

Male No.	Urine volume (mL/24hr)	Specific gravity	Electrolyte, density (mEq/L)			Electrolyte, gross volume (mEq/24 hr)		
			Na	K	Cl	Na	K	Cl
M01008	12.8	1.077	125.2	255.3§	160.0	1.60	3.27	2.05
M01009	11.2	1.079	88.8	213.9	120.1	0.99	2.40	1.35
M01010	23.6	1.043	51.9	159.1§	72.9	1.22	3.75	1.72
M01011	19.3	1.059	98.3	201.6§	110.0	1.90	3.89	2.12
M01012	14.3	1.058	95.5	188.1	117.9	1.37	2.69	1.69

Number of males	5	5	5	5	5	5	5	5
Mean	16.2	1.063	91.9	203.6	116.2	1.42	3.20	1.79
±S.D.	5.1	0.015	26.3	35.4	31.0	0.35	0.65	0.31

Turbidity, -: negative ; +: slight

Protein, -: negative; ±: 10≤and<30 mg/dL; +: 30≤and<100 mg/dL; 2+: 100≤and<300 mg/dL

Glucose, -: negative

Ketone, -: negative; ±: 5≤and<10 mg/dL; +: 10≤and<40 mg/dL

Bilirubin, -: negative

Occult blood, -: negative

Urobilinogen, ±: normal; +: 2.0≤and<4.0 mg/dL; 2+: 4.0≤and<8.0 mg/dL

Red blood cells, White blood cells and Casts, -: not observed

Crystals and Epithelial cells, -: not observed; ±: a few

§, The re-measurement was carried out because the difference between two measured values exceeded the permissible limit. The re-measured values were employed as the data.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 23-2-2. Urinalysis in male rats of the recovery period

2-DT 1000 mg/kg

Male No.	Quality								Urinary sediments					
	Color	Turbidity	pH	Protein	Glucose	Ketone	Bilirubin	Occult blood	Urobilinogen	Red blood cells	White blood cells	Casts	Crystals	Epithelial cells
M04044	Light yellow	+	7.5	2+	-	+	-	-	+	-	-	-	±	-
M04045	Light yellow	-	7.0	2+	-	+	-	-	2+	-	-	-	±	-
M04046	Light yellow	-	6.5	2+	-	+	-	-	+	-	-	-	±	±
M04047	Light yellow	-	7.5	-	-	-	-	-	±	-	-	-	-	-
M04048	Light yellow	-	8.0	+	-	-	-	-	±	-	-	-	±	-

Male No.	Urine volume (mL/24hr)	Specific gravity	Electrolyte, density (mEq/L)			Electrolyte, gross volume (mEq/24 hr)		
			Na	K	Cl	Na	K	Cl
M04044	8.0	1.075	72.1	163.4§	29.1	0.58	1.31	0.23
M04045	13.4	1.079	142.6	238.8	164.5	1.91	3.20	2.20
M04046	13.8	1.080	115.4	238.4§	145.9	1.59	3.29	2.01
M04047	28.1	1.039	56.4	165.1§	76.4	1.58	4.64	2.15
M04048	19.8	1.052	86.0	182.6	87.3	1.70	3.62	1.73
Number of males	5	5	5	5	5	5	5	5
Mean	16.6	1.065	94.5	197.7	100.6	1.47	3.21	1.66
±S.D.	7.7	0.018	34.6	38.1	54.8	0.52	1.21	0.82

Significantly different from the control group (*: P<0.05, **: P<0.01).

Turbidity, -: negative ; +: slight

Protein, -: negative; ±: 10≤ and < 30 mg/dL; +: 30≤ and < 100 mg/dL; 2+: 100≤ and < 300 mg/dL

Glucose, -: negative

Ketone, -: negative; ±: 5≤ and < 10 mg/dL; +: 10≤ and < 40 mg/dL

Bilirubin, -: negative

Occult blood, -: negative

Urobilinogen, ±: normal; +: 2.0≤ and < 4.0 mg/dL; 2+: 4.0≤ and < 8.0 mg/dL

Red blood cells, White blood cells and Casts, -: not observed

Crystals and Epithelial cells, -: not observed; ±: a few

§, The re-measurement was carried out because the difference between two measured values exceeded the permissible limit. The re-measured values were employed as the data.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 24-1-1. Urinalysis in female rats, satellite group

Control (vehicle: corn oil)

Female No.	Quality								Urinary sediments					
	Color	Turbidity	pH	Protein	Glucose	Ketone	Bilirubin	Occult blood	Urobilinogen	Red blood cells	White blood cells	Casts	Crystals	Epithelial cells
F05049	Yellow	-	6.5	2+	-	+	-	-	2+	-	-	-	±	-
F05050	Light yellow	-	6.5	±	-	-	-	-	±	-	-	-	±	-
F05051	Light yellow	-	7.0	±	-	-	-	-	±	-	-	-	-	-
F05052	Light yellow	-	7.0	+	-	±	-	-	+	-	-	-	±	-
F05053	Light yellow	-	7.5	-	-	-	-	-	±	-	-	-	±	-

Female No.	Urine volume (mL/24hr)	Specific gravity	Electrolyte, density (mEq/L)			Electrolyte, gross volume (mEq/24 hr)		
			Na	K	Cl	Na	K	Cl
F05049	6.9	1.075	104.4	210.0	164.8	0.72	1.45	1.14
F05050	11.4	1.053	92.6	182.3	125.0	1.06	2.08	1.43
F05051	9.2	1.059	117.9	213.1§	123.3	1.08	1.96	1.13
F05052	10.1	1.060	120.1	225.1§	151.2	1.21	2.27	1.53
F05053	16.1	1.030	44.1	125.2§	50.0	0.71	2.02	0.81

Number of females	5	5	5	5	5	5	5	5
Mean	10.7	1.055	95.8	191.1	122.9	0.96	1.96	1.21
±S.D.	3.4	0.016	31.0	40.1	44.4	0.23	0.31	0.28

Turbidity, -: negative

Protein, -: negative; ±: 10≤and<30 mg/dL; +: 30≤and<100 mg/dL; 2+: 100≤and<300 mg/dL

Glucose, -: negative; ±: 30≤and<70 mg/dL

Ketone, -: negative; ±: 5≤and<10 mg/dL; +: 10≤and<40 mg/dL

Bilirubin, -: negative

Occult blood, -: negative

Urobilinogen, ±: normal ; +: 2.0≤and<4.0 mg/dL ; 2+: 4.0≤and<8.0 mg/dL

Red blood cells, White blood cells and Casts, -: not observed

Crystals and Epithelial cells, -: not observed; ±: a few

§, The re-measurement was carried out because the difference between two measured values exceeded the permissible limit. The re-measured values were employed as the data.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 24-1-2. Urinalysis in female rats, satellite group

2-DT 1000 mg/kg

Female No.	Quality								Urinary sediments					
	Color	Turbidity	pH	Protein	Glucose	Ketone	Bilirubin	Occult blood	Urobilinogen	Red blood cells	White blood cells	Casts	Crystals	Epithelial cells
F06059	Yellow	-	6.5	2+	±	+	-	-	2+	-	-	-	-	-
F06060	Yellow	-	6.0	2+	-	+	-	-	+	-	-	-	-	-
F06061	Light yellow	-	7.5	+	-	±	-	-	+	-	-	-	±	-
F06062	Yellow	-	6.5	2+	±	+	-	-	+	-	-	-	±	-
F06063	Light yellow	-	8.0	±	-	-	-	-	±	-	-	-	-	-

Female No.	Urine volume (mL/24hr)	Specific gravity	Electrolyte, density (mEq/L)			Electrolyte, gross volume (mEq/24 hr)		
			Na	K	Cl	Na	K	Cl
F06059	2.8	1.098	130.2	208.7§	46.4	0.36	0.58	0.13
F06060	3.5	1.090	126.4	185.7§	77.6	0.44	0.65	0.27
F06061	8.6	1.051	92.5	167.6	88.9	0.80	1.44	0.76
F06062	8.3	1.061	65.1	216.7	127.8	0.54	1.80	1.06
F06063	5.7	1.063	121.4	184.1	114.1	0.69	1.05	0.65
Number of females	5	5	5	5	5	5	5	5
Mean	5.8*	1.073	107.1	192.6	91.0	0.57*	1.10*	0.57*
±S.D.	2.7	0.020	27.8	19.9	31.9	0.18	0.52	0.38

Significantly different from the control group (*: P<0.05, **: P<0.01).

Turbidity, -: negative

Protein, -: negative; ±: 10≤and<30 mg/dL; +: 30≤and<100 mg/dL; 2+: 100≤and<300 mg/dL

Glucose, -: negative; ±: 30≤and<70 mg/dL

Ketone, -: negative; ±: 5≤and<10 mg/dL; +: 10≤and<40 mg/dL

Bilirubin, -: negative

Occult blood, -: negative

Urobilinogen, ±: normal ; +: 2.0≤and<4.0 mg/dL ; 2+: 4.0≤and<8.0 mg/dL

Red blood cells, White blood cells and Casts, -: not observed

Crystals and Epithelial cells, -: not observed; ±: a few

§, The re-measurement was carried out because the difference between two measured values exceeded the permissible limit. The re-measured values were employed as the data.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 24-2-1. Urinalysis in female rats of the recovery period

Control (vehicle: corn oil)

Female No.	Quality								Urinary sediments					
	Color	Turbidity	pH	Protein	Glucose	Ketone	Bilirubin	Occult blood	Urobilinogen	Red blood cells ^{a)}	White blood cells ^{a)}	Casts ^{a)}	Crystals ^{b)}	Epithelial cells ^{b)}
F05054	Light yellow	-	7.0	±	-	-	-	-	+	-	-	-	±	-
F05055	Light yellow	-	7.0	+	-	±	-	-	+	-	-	-	±	-
F05056	Light yellow	-	6.0	-	-	-	-	-	±	-	-	-	±	-
F05057	Light yellow	-	7.5	-	-	-	-	-	±	-	-	-	-	-
F05058	Light yellow	-	7.5	±	-	-	-	-	±	-	-	-	±	-

Female No.	Urine volume (mL/24hr)	Specific gravity	Electrolyte, density (mEq/L)			Electrolyte, gross volume (mEq/24 hr)		
			Na	K	Cl	Na	K	Cl
F05054	13.6	1.059	109.5	231.2	139.7	1.49	3.14	1.90
F05055	11.3	1.072	130.5	259.3§	179.1	1.47	2.93	2.02
F05056	22.7	1.034	68.2	155.5§	75.1	1.55	3.53	1.70
F05057	17.0	1.049	93.0	207.1§	114.5	1.58	3.52	1.95
F05058	12.3	1.051	94.2	190.4	122.1	1.16	2.34	1.50

Number of females	5	5	5	5	5	5	5	5
Mean	15.4	1.053	99.1	208.7	126.1	1.45	3.09	1.81
±S.D.	4.6	0.014	23.0	39.5	37.9	0.17	0.49	0.21

Turbidity, -: negative

Protein, -: negative; ±: 10≤and<30 mg/dL; +: 30≤and<100 mg/dL; 2+: 100≤and<300 mg/dL

Glucose, -: negative

Ketone, -: negative; ±: 5≤and<10 mg/dL

Bilirubin, -: negative

Occult blood, -: negative

Urobilinogen, ±: normal; +: 2.0≤and<4.0 mg/dL

Red blood cells, White blood cells and Casts, -: not observed

Crystals and Epithelial cells, -: not observed; ±: a few

§, The re-measurement was carried out because the difference between two measured values exceeded the permissible limit. The re-measured values were employed as the data.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 24-2-2. Urinalysis in female rats of the recovery period

2-DT 1000 mg/kg

Female No.	Quality								Urinary sediments					
	Color	Turbidity	pH	Protein	Glucose	Ketone	Bilirubin	Occult blood	Urobilinogen	Red blood cells ^{a)}	White blood cells ^{a)}	Casts ^{a)}	Crystals ^{b)}	Epithelial cells ^{b)}
F06064	Light yellow	-	7.0	-	-	-	-	-	±	-	-	-	-	-
F06065	Light yellow	-	6.5	-	-	-	-	-	±	-	-	-	-	-
F06066	Light yellow	-	7.5	±	-	-	-	-	±	-	-	-	±	-
F06067	Light yellow	-	8.0	±	-	-	-	-	±	-	-	-	±	-
F06069	Light yellow	-	7.0	+	-	±	-	-	+	-	-	-	±	-

Female No.	Urine volume (mL/24hr)	Specific gravity	Electrolyte, density (mEq/L)			Electrolyte, gross volume (mEq/24 hr)		
			Na	K	Cl	Na	K	Cl
F06064	19.0	1.033	54.2	149.4§	67.5	1.03	2.84	1.28
F06065	20.3	1.041	77.7	171.3§	103.1	1.58	3.48	2.09
F06066	14.3	1.055	105.2	208.1§	135.3	1.50	2.98	1.93
F06067	15.2	1.024	43.5	64.1§	25.0	0.66	0.97	0.38
F06069	11.4	1.071	115.3	248.6§	170.6	1.31	2.83	1.94
Number of females	5	5	5	5	5	5	5	5
Mean	16.0	1.045	79.2	168.3	100.3	1.22	2.62	1.52
±S.D.	3.6	0.019	31.1	69.4	56.8	0.38	0.96	0.71

Significantly different from the control group (*: P<0.05, **: P<0.01).

Turbidity, -: negative

Protein, -: negative; ±: 10≤and<30 mg/dL; +: 30≤and<100 mg/dL; 2+: 100≤and<300 mg/dL

Glucose, -: negative

Ketone, -: negative; ±: 5≤and<10 mg/dL

Bilirubin, -: negative

Occult blood, -: negative

Urobilinogen, ±: normal; +: 2.0≤and<4.0 mg/dL

Red blood cells, White blood cells and Casts, -: not observed

Crystals and Epithelial cells, -: not observed; ±: a few

§, The re-measurement was carried out because the difference between two measured values exceeded the permissible limit. The re-measured values were employed as the data.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 25-1-1. Hematological findings of male rats at the end of the dosing period

Control (vehicle: corn oil)

Male No.	RBC ($\times 10^4/\mu\text{L}$)	HGB (g/dL)	HCT (%)	MCV (fL)	MCH (pg)	MCHC (g/dL)	PLT ($\times 10^4/\mu\text{L}$)	PT (sec)	APTT (sec)
M01001	806	15.5	44.3	55.0	19.2	35.0	132.0	13.7	23.1
M01002	868	16.1	44.9	51.7	18.5	35.9	122.2	14.7	23.8
M01003	817	14.5	42.0	51.4	17.7	34.5	99.0	15.8	23.9
M01004	832	14.9	42.6	51.2	17.9	35.0	128.4	15.7	27.6 §
M01005	823	15.0	42.5	51.6	18.2	35.3	113.6	16.7	24.6
Number of males	5	5	5	5	5	5	5	5	5
Mean	829	15.2	43.3	52.2	18.3	35.1	119.0	15.3	24.6
S.D.	24	0.6	1.3	1.6	0.6	0.5	13.2	1.1	1.8

Male No.	WBC ($\times 10^2/\mu\text{L}$)	NEUT (%)	EOSI (%)	BASO (%)	MONO (%)	LYMPH (%)	RET (%)
M01001	90.7	18.2	1.2	0.1	5.1	75.4	3.43
M01002	156.5	13.7	1.5	0.1	3.5	81.2	2.38
M01003	101.4	13.1	0.9	0.1	4.0	81.9	3.10
M01004	76.9	11.9	2.9	0.0	5.2	80.0	2.41
M01005	87.4	30.8	2.6	0.1	5.3	61.2	3.22
Number of males	5	5	5	5	5	5	5
Mean	102.6	17.5	1.8	0.1	4.6	75.9	2.91
S.D.	31.4	7.8	0.9	0.0	0.8	8.6	0.48

§, The re-measurement was carried out because the difference between two measured values exceeded the permissible limit.

The re-measured values were employed as the data.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 25-1-2. Hematological findings of male rats at the end of the dosing period

2-DT 62.5 mg/kg

Male No.	RBC	HGB	HCT	MCV	MCH	MCHC	PLT	PT	APTT
	($\times 10^4/\mu\text{L}$)	(g/dL)	(%)	(fL)	(pg)	(g/dL)	($\times 10^4/\mu\text{L}$)	(sec)	(sec)
M02013	866	16.3	46.0	53.1	18.8	35.4	88.7	23.5	29.2
M02014	818	14.9	43.1	52.7	18.2	34.6	106.5	13.9	23.0
M02015	788	14.2	41.1	52.2	18.0	34.5	96.1	16.0	22.8
M02016	689	12.9	38.6	56.0	18.7	33.4	101.1	12.4	20.8
M02017	837	15.0	42.2	50.4	17.9	35.5	107.8	13.7	22.0
Number of males	5	5	5	5	5	5	5	5	5
Mean	800	14.7	42.2	52.9	18.3	34.7	100.0	15.9	23.6
S.D.	68	1.2	2.7	2.0	0.4	0.8	7.9	4.4	3.3

Male No.	WBC	NEUT	EOSI	BASO	MONO	LYMPH	RET
	($\times 10^2/\mu\text{L}$)	(%)	(%)	(%)	(%)	(%)	(%)
M02013	122.8	9.6	1.4	0.1	2.7	86.2	2.81
M02014	101.2	19.2	2.5	0.0	2.5	75.8	3.33
M02015	101.4	15.5	0.4	0.1	4.5	79.5	2.64
M02016	75.3	14.7	1.5	0.0	3.6	80.2	9.16
M02017	67.1	31.0	1.6	0.0	5.7	61.7	2.83
Number of males	5	5	5	5	5	5	5
Mean	93.6	18.0	1.5	0.0	3.8	76.7	4.15
S.D.	22.4	8.0	0.7	0.1	1.3	9.2	2.81

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats
 Appendix 25-1-3. Hematological findings of male rats at the end of the dosing period

2-DT 250 mg/kg

Male No.	RBC	HGB	HCT	MCV	MCH	MCHC	PLT	PT	APTT
	($\times 10^4/\mu\text{L}$)	(g/dL)	(%)	(fL)	(pg)	(g/dL)	($\times 10^4/\mu\text{L}$)	(sec)	(sec)
M03025	859	16.0	46.2	53.8	18.6	34.6	115.8	22.5	30.6
M03026	867	15.9	44.8	51.7	18.3	35.5	93.5	25.1	28.8
M03027	759	13.8	40.6	53.5	18.2	34.0	96.8	16.7	24.9
M03028	959	16.7	45.7	47.7	17.4	36.5	127.9	25.3	31.1
M03029	767	14.5	41.9	54.6	18.9	34.6	88.6	18.7	24.0
Number of males	5	5	5	5	5	5	5	5	5
Mean	842	15.4	43.8	52.3	18.3	35.0	104.5	21.7 *	27.9
S.D.	82	1.2	2.5	2.8	0.6	1.0	16.6	3.8	3.3
Male No.	WBC	NEUT	EOSI	BASO	MONO	LYMPH	RET		
	($\times 10^2/\mu\text{L}$)	(%)	(%)	(%)	(%)	(%)	(%)		
M03025	106.8	16.0	0.8	0.0	4.1	79.1	3.48		
M03026	88.1	23.6	1.6	0.0	5.1	69.7	2.97		
M03027	69.5	22.9	2.0	0.0	4.3	70.8	4.33		
M03028	95.9	17.8	1.9	0.1	4.2	76.0	2.82		
M03029	78.5	21.9	1.9	0.0	3.8	72.4	3.03		
Number of males	5	5	5	5	5	5	5		
Mean	87.8	20.4	1.6	0.0	4.3	73.6	3.33		
S.D.	14.6	3.3	0.5	0.0	0.5	3.9	0.61		

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 25-1-4. Hematological findings of male rats at the end of the dosing period

2-DT 1000 mg/kg

Male No.	RBC	HGB	HCT	MCV	MCH	MCHC	PLT	PT	APTT
	($\times 10^4/\mu\text{L}$)	(g/dL)	(%)	(fL)	(pg)	(g/dL)	($\times 10^4/\mu\text{L}$)	(sec)	(sec)
M04037	860	15.6	44.7	52.0	18.1	34.9	99.2	21.7	27.1
M04038	795	14.6	41.1	51.7	18.4	35.5	99.0	21.0	23.4
M04039	775	13.8	40.1	51.7	17.8	34.4	133.2	28.0	31.0
M04040	853	15.9	46.3	54.3	18.6	34.3	91.9	24.5	29.6
M04041	847	14.8	42.5	50.2	17.5	34.8	88.1	24.9	28.9
Number of males	5	5	5	5	5	5	5	5	5
Mean	826	14.9	42.9	52.0	18.1	34.8	102.3	24.0 **	28.0
S.D.	38	0.8	2.6	1.5	0.4	0.5	17.9	2.8	2.9

Male No.	WBC	NEUT	EOSI	BASEO	MONO	LYMPH	RET
	($\times 10^2/\mu\text{L}$)	(%)	(%)	(%)	(%)	(%)	(%)
M04037	95.5	15.3	1.6	0.0	4.9	78.2	2.46
M04038	90.8	15.6	1.3	0.0	4.4	78.7	3.46
M04039	72.7	19.3	1.5	0.0	4.0	75.2	5.75
M04040	64.5	36.1	2.2	0.0	3.9	57.8	3.42
M04041	87.6	35.4	2.1	0.0	5.7	56.8	2.86
Number of males	5	5	5	5	5	5	5
Mean	82.2	24.3	1.7	0.0	4.6	69.3	3.59
S.D.	13.1	10.5	0.4	0.0	0.7	11.1	1.28

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 25-2-1. Hematological findings of male rats at the end of the recovery period

Control (vehicle: corn oil)

Male No.	RBC ($\times 10^4/\mu\text{L}$)	HGB (g/dL)	HCT (%)	MCV (fL)	MCH (pg)	MCHC (g/dL)	PLT ($\times 10^4/\mu\text{L}$)	PT (sec)	APTT (sec)
M01008	890	15.5	43.1	48.4	17.4	36.0	122.0	13.8	21.5
M01009	839	14.6	41.6	49.6	17.4	35.1	105.4	12.8	20.5
M01010	866	15.5	42.8	49.4	17.9	36.2	119.9	13.3	18.3
M01011	898	16.1	44.7	49.8	17.9	36.0	113.9	13.4	23.8
M01012	813	15.1	43.4	53.4	18.6	34.8	111.6	17.2	21.5
Number of males	5	5	5	5	5	5	5	5	5
Mean	861	15.4	43.1	50.1	17.8	35.6	114.6	14.1	21.1
S.D.	35	0.6	1.1	1.9	0.5	0.6	6.7	1.8	2.0

Male No.	WBC ($\times 10^2/\mu\text{L}$)	NEUT (%)	EOSI (%)	BASO (%)	MONO (%)	LYMPH (%)	RET (%)
M01008	98.9	13.9	1.9	0.1	4.7	79.4	4.34
M01009	66.9	20.1	2.4	0.0	4.3	73.2	1.89
M01010	68.5	19.5	3.8	0.0	4.4	72.3	2.97
M01011	110.3	25.2	1.6	0.0	4.3	68.9	3.41
M01012	91.2	17.1	1.6	0.0	3.4	77.9	3.07
Number of males	5	5	5	5	5	5	5
Mean	87.2	19.2	2.3	0.0	4.2	74.3	3.14
S.D.	19.0	4.2	0.9	0.0	0.5	4.3	0.88

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats
 Appendix 25-2-2. Hematological findings of male rats at the end of the recovery period

2-DT 1000 mg/kg

Male No.	RBC	HGB	HCT	MCV	MCH	MCHC	PLT	PT	APTT
	($\times 10^4/\mu\text{L}$)	(g/dL)	(%)	(fL)	(pg)	(g/dL)	($\times 10^4/\mu\text{L}$)	(sec)	(sec)
M04044	889	15.8	44.9	50.5	17.8	35.2	120.3	18.7	26.3
M04045	780	14.6	42.9	55.0	18.7	34.0	107.8	28.7	28.6
M04046	794	14.2	40.7	51.3	17.9	34.9	107.8	18.4	24.7
M04047	908	16.3	45.6	50.2	18.0	35.7	105.9	13.6	21.8
M04048	829	15.1	42.7	51.5	18.2	35.4	107.6	18.1	25.6
Number of males	5	5	5	5	5	5	5	5	5
Mean	840	15.2	43.4	51.7	18.1	35.0	109.9	19.5	25.4 *
S.D.	57	0.9	1.9	1.9	0.4	0.7	5.9	5.6	2.5

Male No.	WBC	NEUT	EOSI	BAZO	MONO	LYMPH	RET
	($\times 10^2/\mu\text{L}$)	(%)	(%)	(%)	(%)	(%)	(%)
M04044	82.2	19.5	2.9	0.0	3.9	73.7	2.43
M04045	84.6	11.6	1.3	0.0	4.0	83.1	2.84
M04046	106.1	9.4	1.3	0.0	2.2	87.1	2.52
M04047	71.3	20.9	1.8	0.0	3.8	73.5	3.49
M04048	49.1	23.0	2.6	0.0	3.7	70.7	2.84
Number of males	5	5	5	5	5	5	5
Mean	78.7	16.9	2.0	0.0	3.5	77.6	2.82
S.D.	20.8	6.0	0.7	0.0	0.7	7.1	0.42

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 26-1-1. Hematological findings of female rats at the end of the dosing period

Control (vehicle: corn oil)

Female No.	RBC	HGB	HCT	MCV	MCH	MCHC	PLT	PT	APTT
	($\times 10^4/\mu\text{L}$)	(g/dL)	(%)	(fL)	(pg)	(g/dL)	($\times 10^4/\mu\text{L}$)	(sec)	(sec)
F01001	626	12.7	38.3	61.2	20.3	33.2	161.6	12.9	19.1
F01003	759	14.2	40.8	53.8	18.7	34.8	133.7	12.4	19.4
F01004	675	13.5	39.8	59.0	20.0	33.9	99.9	13.2	21.4
F01007	656	12.9	37.9	57.8	19.7	34.0	159.5	12.6	19.9
F01012	638	12.3	36.6	57.4	19.3	33.6	135.5	12.4	19.7
Number of females	5	5	5	5	5	5	5	5	5
Mean	671	13.1	38.7	57.8	19.6	33.9	138.0	12.7	19.9
S.D.	53	0.7	1.6	2.7	0.6	0.6	25.0	0.3	0.9

Female No.	WBC	NEUT	EOSI	BASO	MONO	LYMPH	RET
	($\times 10^2/\mu\text{L}$)	(%)	(%)	(%)	(%)	(%)	(%)
F01001	125.6	25.6	0.8	0.1	3.3	70.2	12.33
F01003	111.2	26.3	1.2	0.1	2.9	69.5	6.31
F01004	66.9	22.7	2.1	0.0	4.8	70.4	6.86
F01007	107.7	25.7	1.4	0.0	5.2	67.7	7.04
F01012	113.5	34.7	0.7	0.0	3.2	61.4	9.81
Number of females	5	5	5	5	5	5	5
Mean	105.0	27.0	1.2	0.0	3.9	67.8	8.47
S.D.	22.3	4.5	0.6	0.1	1.0	3.8	2.55

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats
 Appendix 26-1-2. Hematological findings of female rats at the end of the dosing period

2-DT 62.5 mg/kg

Female No.	RBC	HGB	HCT	MCV	MCH	MCHC	PLT	PT	APTT
	($\times 10^4/\mu\text{L}$)	(g/dL)	(%)	(fL)	(pg)	(g/dL)	($\times 10^4/\mu\text{L}$)	(sec)	(sec)
F02013	665	12.7	37.1	55.8	19.1	34.2	109.9	11.6	21.1
F02014	577	12.1	36.7	63.6	21.0	33.0	114.6	13.1	20.3
F02015	665	12.9	38.0	57.1	19.4	33.9	117.7	12.8	19.8
F02016	676	13.3	39.2	58.0	19.7	33.9	111.9	12.2	18.9
F02018	597	11.6	35.7	59.8	19.4	32.5	99.8	13.2	21.0
Number of females	5	5	5	5	5	5	5	5	5
Mean	636	12.5	37.3	58.9	19.7	33.5	110.8	12.6	20.2
S.D.	46	0.7	1.3	3.0	0.7	0.7	6.8	0.7	0.9
Female No.	WBC	NEUT	EOSI	BASO	MONO	LYMPH	RET		
	($\times 10^2/\mu\text{L}$)	(%)	(%)	(%)	(%)	(%)	(%)		
F02013	129.3	50.9	0.6	0.0	2.1	46.4	6.72		
F02014	76.4	32.1	0.9	0.0	2.6	64.4	15.01		
F02015	82.4	37.8	0.6	0.0	2.7	58.9	7.61		
F02016	99.4	46.6	0.5	0.0	3.2	49.7	5.97		
F02018	74.0	33.3	0.4	0.0	1.2	65.1	10.60		
Number of females	5	5	5	5	5	5	5		
Mean	92.3	40.1 **	0.6	0.0	2.4 *	56.9 *	9.18		
S.D.	22.9	8.3	0.2	0.0	0.8	8.5	3.70		

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 26-1-3. Hematological findings of female rats at the end of the dosing period

2-DT 250 mg/kg

Female No.	RBC	HGB	HCT	MCV	MCH	MCHC	PLT	PT	APTT
	($\times 10^4/\mu\text{L}$)	(g/dL)	(%)	(fL)	(pg)	(g/dL)	($\times 10^4/\mu\text{L}$)	(sec)	(sec)
F03026	635	12.4	37.0	58.3	19.5	33.5	108.4	12.1	19.7
F03027	668	12.8	39.0	58.4	19.2	32.8	113.5	12.7	21.1
F03028	700	13.6	40.6	58.0	19.4	33.5	95.4	12.2	19.4
F03030	629	12.1	36.9	58.7	19.2	32.8	107.5	13.1	22.3
F03035	691	13.7	41.6	60.2	19.8	32.9	111.7	13.1	18.6
Number of females	5	5	5	5	5	5	5	5	5
Mean	665	12.9	39.0	58.7	19.4	33.1	107.3	12.6	20.2
S.D.	32	0.7	2.1	0.9	0.2	0.4	7.1	0.5	1.5

Female No.	WBC	NEUT	EOSI	BASO	MONO	LYMPH	RET
	($\times 10^2/\mu\text{L}$)	(%)	(%)	(%)	(%)	(%)	(%)
F03026	94.1	33.8	0.7	0.0	3.8	61.7	9.88
F03027	141.8	43.7	1.4	0.1	3.8	51.0	7.24
F03028	133.7	34.6	0.4	0.0	3.9	61.1	8.99
F03030	85.5	36.6	0.8	0.0	4.2	58.4	7.08
F03035	69.5	30.5	1.3	0.0	4.2	64.0	7.63
Number of females	5	5	5	5	5	5	5
Mean	104.9	35.8	0.9	0.0	4.0	59.2 *	8.16
S.D.	31.4	4.9	0.4	0.0	0.2	5.0	1.22

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats
 Appendix 26-1-4. Hematological findings of female rats at the end of the dosing period

2-DT 1000 mg/kg

Female No.	RBC	HGB	HCT	MCV	MCH	MCHC	PLT	PT	APTT
	($\times 10^4/\mu\text{L}$)	(g/dL)	(%)	(fL)	(pg)	(g/dL)	($\times 10^4/\mu\text{L}$)	(sec)	(sec)
F04037	730	13.6	40.6	55.6	18.6	33.5	104.3	12.8	19.0
F04038	669	13.5	41.3	61.7	20.2	32.7	95.0	12.7	21.8
F04040	612	12.6	38.7	63.2	20.6	32.6	115.0	11.2	19.4
F04043	665	12.8	38.7	58.2	19.2	33.1	115.5	11.7	19.3
F04047	683	13.4	40.1	58.7	19.6	33.4	103.1	12.6	18.9
Number of females	5	5	5	5	5	5	5	5	5
Mean	672	13.2	39.9	59.5	19.6	33.1	106.6	12.2	19.7
S.D.	42	0.4	1.2	3.0	0.8	0.4	8.7	0.7	1.2

Female No.	WBC	NEUT	EOSI	BASO	MONO	LYMPH	RET
	($\times 10^2/\mu\text{L}$)	(%)	(%)	(%)	(%)	(%)	(%)
F04037	71.8	30.2	0.3	0.0	3.5	66.0	6.98
F04038	60.1	30.9	0.7	0.0	2.3	66.1	11.42
F04040	84.1	31.2	0.2	0.0	3.7	64.9	13.74
F04043	121.1	30.5	1.4	0.1	3.3	64.7	8.61
F04047	105.4	26.8	0.7	0.1	4.4	68.0	6.03
Number of females	5	5	5	5	5	5	5
Mean	88.5	29.9	0.7	0.0	3.4	65.9	9.36
S.D.	24.8	1.8	0.5	0.1	0.8	1.3	3.19

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 26-2-1. Hematological findings of female rats at the end of the dosing period, satellite group

Control (vehicle: corn oil)

Female No.	RBC	HGB	HCT	MCV	MCH	MCHC	PLT	PT	APTT
	($\times 10^4/\mu\text{L}$)	(g/dL)	(%)	(fL)	(pg)	(g/dL)	($\times 10^4/\mu\text{L}$)	(sec)	(sec)
F05049	797	15.1	42.1	52.8	18.9	35.9	109.8	11.0	16.4
F05050	739	13.8	40.2	54.4	18.7	34.3	107.1	11.3	19.1
F05051	821	15.4	43.5	53.0	18.8	35.4	111.2	12.8	23.5
F05052	764	14.5	41.3	54.1	19.0	35.1	108.4	12.1	19.4
F05053	769	15.0	41.2	53.6	19.5	36.4	116.0	11.4	19.8
Number of females	5	5	5	5	5	5	5	5	5
Mean	778	14.8	41.7	53.6	19.0	35.4	110.5	11.7	19.6
S.D.	32	0.6	1.2	0.7	0.3	0.8	3.4	0.7	2.5

Female No.	WBC	NEUT	EOSI	BASO	MONO	LYMPH	RET
	($\times 10^2/\mu\text{L}$)	(%)	(%)	(%)	(%)	(%)	(%)
F05049	61.5	11.9	2.3	0.0	3.4	82.4	5.82
F05050	81.6	18.1	1.0	0.1	2.7	78.1	2.98
F05051	57.4	13.5	2.4	0.0	4.0	80.1	2.83
F05052	60.3	13.4	2.2	0.0	2.0	82.4	3.39
F05053	49.3	10.6	1.2	0.0	1.8	86.4	2.96
Number of females	5	5	5	5	5	5	5
Mean	62.0	13.5	1.8	0.0	2.8	81.9	3.60
S.D.	11.9	2.8	0.7	0.0	0.9	3.1	1.26

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 26-2-2. Hematological findings of female rats at the end of the dosing period, satellite group

2-DT 1000 mg/kg

Female No.	RBC	HGB	HCT	MCV	MCH	MCHC	PLT	PT	APTT
	($\times 10^4/\mu\text{L}$)	(g/dL)	(%)	(fL)	(pg)	(g/dL)	($\times 10^4/\mu\text{L}$)	(sec)	(sec)
F06059	844	15.2	42.8	50.7	18.0	35.5	129.4	11.8	20.5 §
F06060	743	13.7	39.1	52.6	18.4	35.0	114.8	11.6	19.5
F06061	781	14.1	39.9	51.1	18.1	35.3	114.4	11.9	21.5
F06062	872	15.1	42.0	48.2	17.3	36.0	108.7	11.9	19.2 §
F06063	818	15.0	42.4	51.8	18.3	35.4	92.3	12.1	26.1
Number of females	5	5	5	5	5	5	5	5	5
Mean	812	14.6	41.2	50.9 *	18.0 **	35.4	111.9	11.9	21.4
S.D.	51	0.7	1.6	1.7	0.4	0.4	13.4	0.2	2.8

Female No.	WBC	NEUT	EOSI	BASO	MONO	LYMPH	RET
	($\times 10^2/\mu\text{L}$)	(%)	(%)	(%)	(%)	(%)	(%)
F06059	63.8	18.7	2.2	0.0	3.6	75.5	2.82
F06060	38.3	8.3	1.6	0.0	3.7	86.4	3.14
F06061	60.2	9.8	1.5	0.0	2.0	86.7	3.28
F06062	43.4	17.3	2.5	0.0	3.9	76.3	2.97
F06063	53.3	11.0	1.7	0.0	2.3	85.0	2.90
Number of females	5	5	5	5	5	5	5
Mean	51.8	13.0	1.9	0.0	3.1	82.0	3.02
S.D.	10.8	4.7	0.4	0.0	0.9	5.6	0.19

Significantly different from the control group (*: P<0.05, **: P<0.01).

§, The re-measurement was carried out because the difference between two measured values exceeded the permissible limit.

The re-measured values were employed as the data.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 26-3-1. Hematological findings of female rats at the end of the recovery period

Control (vehicle: corn oil)

Female No.	RBC ($\times 10^4/\mu\text{L}$)	HGB (g/dL)	HCT (%)	MCV (fL)	MCH (pg)	MCHC (g/dL)	PLT ($\times 10^4/\mu\text{L}$)	PT (sec)	APTT (sec)
F05054	804	14.5	42.0	52.2	18.0	34.5	110.0	11.3	17.8
F05055	802	14.9	42.4	52.9	18.6	35.1	106.9	11.0	18.4
F05056	762	15.4	43.4	57.0	20.2	35.5	101.3	11.5	19.8
F05057	769	14.4	41.0	53.3	18.7	35.1	95.7	11.4	16.7
F05058	874	15.6	43.2	49.4	17.8	36.1	125.5	12.4	17.8
Number of females	5	5	5	5	5	5	5	5	5
Mean	802	15.0	42.4	53.0	18.7	35.3	107.9	11.5	18.1
S.D.	44	0.5	1.0	2.7	0.9	0.6	11.3	0.5	1.1

Female No.	WBC ($\times 10^2/\mu\text{L}$)	NEUT (%)	EOSI (%)	BASO (%)	MONO (%)	LYMPH (%)	RET (%)
F05054	61.0	12.6	1.5	0.0	3.4	82.5	3.36
F05055	53.4	23.1	1.5	0.0	2.2	73.2	3.33
F05056	61.3	23.7	1.5	0.0	3.8	71.0	2.96
F05057	87.0	8.8	1.1	0.0	2.9	87.2	2.90
F05058	59.0	8.6	1.4	0.0	1.9	88.1	4.19
Number of females	5	5	5	5	5	5	5
Mean	64.3	15.4	1.4	0.0	2.8	80.4	3.35
S.D.	13.1	7.5	0.2	0.0	0.8	7.9	0.51

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats
 Appendix 26-3-2. Hematological findings of female rats at the end of the recovery period

2-DT 1000 mg/kg

Female No.	RBC	HGB	HCT	MCV	MCH	MCHC	PLT	PT	APTT
	($\times 10^4/\mu\text{L}$)	(g/dL)	(%)	(fL)	(pg)	(g/dL)	($\times 10^4/\mu\text{L}$)	(sec)	(sec)
F06064	810	14.8	43.0	53.1	18.3	34.4	118.7	11.6	16.7
F06065	852	15.1	42.5	49.9	17.7	35.5	118.2	12.0	19.2
F06066	781	15.2	42.4	54.3	19.5	35.8	129.4	11.5	19.9
F06067	872	15.3	42.2	48.4	17.5	36.3	86.3	11.4	22.2
F06069	867	17.0	47.7	55.0	19.6	35.6	99.4	10.9	18.1
Number of females	5	5	5	5	5	5	5	5	5
Mean	836	15.5	43.6	52.1	18.5	35.5	110.4	11.5	19.2
S.D.	39	0.9	2.3	2.9	1.0	0.7	17.3	0.4	2.1

Female No.	WBC	NEUT	EOSI	BASO	MONO	LYMPH	RET
	($\times 10^2/\mu\text{L}$)	(%)	(%)	(%)	(%)	(%)	(%)
F06064	43.8	14.2	0.9	0.0	3.4	81.5	2.81
F06065	72.4	29.5	2.3	0.0	2.9	65.3	2.92
F06066	92.2	5.9	1.1	0.0	2.0	91.0	3.23
F06067	40.9	15.1	2.0	0.0	7.1	75.8	2.14
F06069	76.0	19.0	0.5	0.0	1.3	79.2	3.58
Number of females	5	5	5	5	5	5	5
Mean	65.1	16.7	1.4	0.0	3.3	78.6	2.94
S.D.	22.1	8.6	0.8	0.0	2.3	9.3	0.54

Significantly different from the control group (*: P<0.05, **: P<0.01).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 27-1-1. Biochemical findings of male rats at the end of the dosing period

Control (vehicle: corn oil)																
Male No.	Total protein g/dL	Albumin g/dL	A/G	Glucose mg/dL	Total cholesterol mg/dL	Triglyceride mg/dL	Phospholipid mg/dL	AST U/L	ALT U/L	γ-GTP U/L	LDH U/L	Bile acid μmol/L	BUN mg/dL	Creatinine mg/dL	Total bilirubin mg/dL	ALP U/L
M01001	5.8	3.8	1.90	143	49	28	80	63	30	0	226	10.4	13	0.5	0.05	283
M01002	5.8	3.8	1.90	153	58	43	90	55	25	0	147	8.2	16	0.5	0.05	373
M01003	5.7	3.9	2.17	130	72	43	105	60	26	0	140	15.3	13	0.5	0.05	332
M01004	5.7	3.7	1.85	142	45	23	74	51	23	0	182	9.4	14	0.4	0.05	225
M01005	5.8	3.8	1.90	142	50	95	96	51	26	0	180	11.5	17	0.5	0.06	266
Number of males	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Mean	5.8	3.8	1.94	142	55	46	89	56	26	0	175	11.0	15	0.5	0.05	296
S.D.	0.1	0.1	0.13	8	11	29	12	5	3	0	34	2.7	2	0.0	0.00	58

Control (vehicle: corn oil)					
Male No.	Inorganic phosphorus mg/dL	Ca mg/dL	Na mEq/L	K mEq/L	Cl mEq/L
M01001	6.0	9.6	144.5	3.85	108.1
M01002	5.0	9.6	143.9	3.65	107.5
M01003	5.1	9.4	145.1	3.64	107.8
M01004	5.3	9.4	143.7	3.70	106.7
M01005	5.7	9.6	142.7	3.35	104.1
Number of males	5	5	5	5	5
Mean	5.4	9.5	144	3.64	106.8
S.D.	0.4	0.1	0.9	0.18	1.6

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 27-1-2. Biochemical findings of male rats at the end of the dosing period

2-DT 62.5 mg/kg

Male No.	Total protein g/dL	Albumin g/dL	A/G	Glucose mg/dL	Total cholesterol mg/dL	Triglyceride mg/dL	Phospholipid mg/dL	AST U/L	ALT U/L	γ -GTP U/L	LDH U/L	Bile acid $\mu\text{mol}/\text{L}$	BUN mg/dL	Creatinine mg/dL	Total bilirubin mg/dL	ALP U/L
M02013	5.4	3.7	2.18	174	38	29	68	80	29	0	192	9.7	13	0.5	0.06	455
M02014	5.5	3.6	1.89	149	53	21	78	44	21	0	241	6.5	15	0.4	0.04	360
M02015	5.6	3.7	1.95	143	55	25	83	52	22	0	190	7.6	13	0.5	0.05	424
M02016	5.5	3.7	2.06	126	80	24	104	49	25	0	233	23.1	11	0.4	0.05	226
M02017	5.8	3.8	1.90	139	71	33	104	97	62	0	199	16.6	14	0.5	0.06	345
Number of males	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Mean	5.6	3.7	2.00	146	59	26	87	64	32	0	211	12.7	13	0.5	0.05	362
S.D.	0.2	0.1	0.12	18	16	5	16	23	17	0	24	7.0	1	0.1	0.01	88
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Statistical method	KW	AN	AN	AN	AN	KW	AN	KW	KW	AN	DU	AN	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

KW: Analysis by Kruskal-Wallis' test (one-way layout).

AN: Analysis by variance (one-way layout).

DU: Analysis by Dunnett's test.

2-DT 62.5 mg/kg

Male No.	Inorganic phosphorus mg/dL	Ca mg/dL	Na mEq/L	K mEq/L	Cl mEq/L
M02013	5.5	9.4	143.8	3.68	108.5
M02014	5.8	9.3	143.5	3.56	107.5
M02015	6.1	9.6	144.7	3.85	107.8
M02016	6.1	9.7	145.5	3.77	106.3
M02017	5.3	9.8	144.6	3.82	106.5
Number of males	5	5	5	5	5
Mean	5.8	9.6	144.4	3.74	107.3
S.D.	0.4	0.2	0.8	0.12	0.9
Significance	NS	NS	NS	NS	NS
Statistical method	AN	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

KW: Analysis by Kruskal-Wallis' test (one-way layout).

AN: Analysis by variance (one-way layout).

DU: Analysis by Dunnett's test.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 27-1-3. Biochemical findings of male rats at the end of the dosing period

2-DT 250 mg/kg

Male No.	Total protein g/dL	Albumin g/dL	A/G	Glucose mg/dL	Total cholesterol mg/dL	Triglyceride mg/dL	Phospholipid mg/dL	AST U/L	ALT U/L	γ -GTP U/L	LDH U/L	Bile acid μ mol/L	BUN mg/dL	Creatinine mg/dL	Total bilirubin mg/dL	ALP U/L
M03025	5.9	3.9	1.95	168	58	74	95	60	25	0	374	17.6	13	0.5	0.07	387
M03026	5.4	3.6	2.00	148	48	41	82	53	30	0	198	14.3	13	0.5	0.05	399
M03027	5.3	3.6	2.12	131	42	38	77	53	25	0	336	8.2	12	0.4	0.04	340
M03028	6.2	4.1	1.95	130	58	63	101	62	32	0	325	16.1	14	0.5	0.05	382
M03029	5.2	3.6	2.25	121	40	17	64	55	27	0	176	5.6	14	0.4	0.05	364
Number of males	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Mean	5.6	3.8	2.05	140	49	47	84	57	28	0	282	12.4	13	0.5	0.05	374
S.D.	0.4	0.2	0.13	19	9	22	15	4	3	0	89	5.2	1	0.1	0.01	23
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	*	NS	NS	NS	NS	NS
Statistical method	KW	AN	AN	AN	AN	KW	AN	KW	KW	AN	DU	AN	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

KW: Analysis by Kruskal-Wallis' test (one-way layout).

AN: Analysis by variance (one-way layout).

DU: Analysis by Dunnett's test.

2-DT 250 mg/kg

Male No.	Inorganic phosphorus mg/dL	Ca mg/dL	Na mEq/L	K mEq/L	Cl mEq/L
M03025	6.0	9.6	143.3	3.62	106.0
M03026	5.9	8.9	144.8	3.59	107.5
M03027	5.6	9.3	145.0	3.79	109.0
M03028	6.0	10.1	144.6	4.00	107.3
M03029	6.5	9.4	144.9	3.77	108.6
Number of males	5	5	5	5	5
Mean	6.0	9.5	144.5	3.75	107.7
S.D.	0.3	0.4	0.7	0.16	1.2
Significance	NS	NS	NS	NS	NS
Statistical method	AN	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

KW: Analysis by Kruskal-Wallis' test (one-way layout).

AN: Analysis by variance (one-way layout).

DU: Analysis by Dunnett's test.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 27-1-4. Biochemical findings of male rats at the end of the dosing period

2-DT 1000 mg/kg

Male No.	Total protein g/dL	Albumin g/dL	A/G	Glucose mg/dL	Total cholesterol mg/dL	Triglyceride mg/dL	Phospholipid mg/dL	AST U/L	ALT U/L	γ -GTP U/L	LDH U/L	Bile acid $\mu\text{mol}/\text{L}$	BUN mg/dL	Creatinine mg/dL	Total bilirubin mg/dL	ALP U/L
M04037	5.5	3.8	2.24	137	31	27	63	67	33	0	367	12.9	14	0.4	0.06	378
M04038	5.2	3.6	2.25	137	67	38	99	62	29	0	243	12.3	16	0.5	0.04	413
M04039	5.7	3.9	2.17	163	50	64	91	55	25	0	393	7.2	15	0.5	0.04	436
M04040	5.9	3.9	1.95	138	40	16	70	55	28	0	395	25.6	12	0.4	0.06	350
M04041	5.2	3.5	2.06	138	33	23	64	163	175 #	1	328	14.9	15	0.4	0.06	334
Number of males	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Mean	5.5	3.7	2.13	143	44	34	77	80	58	0	345	14.6	14	0.4	0.05	382
S.D.	0.3	0.2	0.13	11	15	19	17	46	65	0	63	6.8	2	0.1	0.01	42
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	**	NS	NS	NS	NS	NS	NS
Statistical method	KW	AN	AN	AN	AN	KW	AN	KW	AN	DU	AN	AN	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

KW: Analysis by Kruskal-Wallis' test (one-way layout).

AN: Analysis by variance (one-way layout).

DU: Analysis by Dunnett's test.

#, The first measured value was out of the control values stated in the standard operating procedures. One re-measurement was carried out, and the difference between the values in two measurements was not more than 10% of the lower value. The first measured value was employed as the measured value for the specimen.

2-DT 1000 mg/kg

Male No.	Inorganic phosphorus mg/dL	Ca mg/dL	Na mEq/L	K mEq/L	Cl mEq/L
M04037	5.8	9.3	143.8	3.94	107.9
M04038	5.3	9.0	143.1	3.60	107.3
M04039	5.8	9.4	142.8	3.91	107.8
M04040	5.6	9.5	145.8	3.63	109.5
M04041	5.7	9.2	143.7	3.65	107.8
Number of males	5	5	5	5	5
Mean	5.6	9.3	143.8	3.75	108.1
S.D.	0.2	0.2	1.2	0.16	0.8
Significance	NS	NS	NS	NS	NS
Statistical method	AN	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

KW: Analysis by Kruskal-Wallis' test (one-way layout).

AN: Analysis by variance (one-way layout).

DU: Analysis by Dunnett's test.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 27-2-1. Biochemical findings of male rats at the end of the recovery period

Control (vehicle: corn oil)																
Male No.	Total protein g/dL	Albumin g/dL	A/G	Glucose mg/dL	Total cholesterol mg/dL	Triglyceride mg/dL	Phospholipid mg/dL	AST U/L	ALT U/L	γ-GTP U/L	LDH U/L	Bile acid μmol/L	BUN mg/dL	Creatinine mg/dL	Total bilirubin mg/dL	ALP U/L
M01008	5.4	3.3	1.57	139	59	44	91	52	22	0	89	7.8	14	0.4	0.03	269
M01009	5.7	3.7	1.85	151	44	76	91	57	23	0	44	6.7	14	0.4	0.06	238
M01010	5.5	3.5	1.75	168	53	36	84	82	27	0	129	49.0	13	0.6	0.06	241
M01011	5.7	3.6	1.71	143	62	38	102	57	29	0	73	15.4	17	0.4	0.06	183
M01012	5.7	3.7	1.85	144	52	43	89	59	27	0	73	21.3	15	0.5	0.05	201
Number of males	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Mean	5.6	3.6	1.75	149	54	47	91	61	26	0	82	20.0	15	0.5	0.05	226
S.D.	0.1	0.2	0.12	11	7	16	7	12	3	0	31	17.3	2	0.1	0.01	34

Control (vehicle: corn oil)					
Male No.	Inorganic phosphorus mg/dL	Ca mg/dL	Na mEq/L	K mEq/L	Cl mEq/L
M01008	5.7	9.3	142.3	3.97	108.2
M01009	6.0	9.5	144.0	4.04	107.4
M01010	6.1	9.3	146.4	3.69	108.5
M01011	6.5	9.4	145.2	3.55	107.7
M01012	6.7	9.7	145.8	3.69	107.9
Number of males	5	5	5	5	5
Mean	6.2	9.4	144.7	3.79	107.9
S.D.	0.4	0.2	1.6	0.21	0.4

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 27-2-2. Biochemical findings of male rats at the end of the recovery period

2-DT 1000 mg/kg

Male No.	Total protein g/dL	Albumin g/dL	A/G	Glucose mg/dL	Total cholesterol mg/dL	Triglyceride mg/dL	Phospholipid mg/dL	AST U/L	ALT U/L	γ -GTP U/L	LDH U/L	Bile acid μ mol/L	BUN mg/dL	Creatinine mg/dL	Total bilirubin mg/dL	ALP U/L
M04044	5.8	3.7	1.76	140	57	18	80	53	25	0	45	9.1	13	0.5	0.04	237
M04045	5.2	3.4	1.89	160	43	49	78	62	22	0	74	6.1	14	0.4	0.04	177
M04046	5.1	3.2	1.68	131	48	33	77	55	22	0	344	4.2	15	0.4	0.04	194
M04047	5.7	3.6	1.71	129	64	42	96	55	25	0	52	15.3	14	0.4	0.04	241
M04048	5.6	3.7	1.95	141	52	22	86	64	24	0	338	10.5	16	0.5	0.04	250
Number of males	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Mean	5.5	3.5	1.80	140	53	33	83	58	24	0	171	9.0	14	0.4	0.04	220
S.D.	0.3	0.2	0.12	12	8	13	8	5	2	0	156	4.3	1	0.1	0.00	32
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Statistical method	TT	TT	TT	TT	TT	TT	TT	TT	TT	TT	AW	AW	TT	TT	TT	TT

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

TT: Analysis by Student's t-test.

AW: Analysis by Aspin-Welch t-test.

2-DT 1000 mg/kg

Male No.	Inorganic phosphorus mg/dL	Ca mg/dL	Na mEq/L	K mEq/L	Cl mEq/L
M04044	5.7	9.7	144.2	4.35	109.2
M04045	6.0	9.3	144.6	3.65	109.0
M04046	6.5	9.7	147.1	3.70	110.4
M04047	6.4	9.5	145.4	4.06	108.5
M04048	6.6	9.6	145.6	3.73	107.3
Number of males	5	5	5	5	5
Mean	6.2	9.6	145.4	3.90	108.9
S.D.	0.4	0.2	1.1	0.30	1.1
Significance	NS	NS	NS	NS	NS
Statistical method	TT	TT	TT	TT	TT

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

TT: Analysis by Student's t-test.

AW: Analysis by Aspin-Welch t-test.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 28-1-1. Biochemical findings of female rats at the end of the dosing period

Control (vehicle: corn oil)																
Female No.	Total protein g/dL	Albumin g/dL	A/G	Glucose mg/dL	Total cholesterol mg/dL	Triglyceride mg/dL	Phospholipid mg/dL	AST U/L	ALT U/L	γ -GTP U/L	LDH U/L	Bile acid $\mu\text{mol}/\text{L}$	BUN mg/dL	Creatinine mg/dL	Total bilirubin mg/dL	ALP U/L
F01001	5.6	3.8	2.11	105	61	28	111	97	41	0	183	17.8	14	0.5	0.05	147
F01003	5.6	3.8	2.11	120	56	24	100	240	73	0	201	15.6	17	0.6	0.05	182
F01004	5.6	3.8	2.11	118	64	33	113	75	36	0	60	9.7	17	0.5	0.04	118
F01007	6.0	4.2	2.33	142	61	39	114	80	38	0	148	16.0	12	0.5	0.06	130
F01012	6.0	4.2	2.33	139	58	54	118	115	49	0	94	17.8	13	0.6	0.06	115
Number of females	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Mean	5.8	4.0	2.20	125	60	36	111	121	47	0	137	15.4	15	0.5	0.05	138
S.D.	0.2	0.2	0.12	15	3	12	7	68	15	0	59	3.3	2	0.1	0.01	27

Control (vehicle: corn oil)					
Female No.	Inorganic phosphorus mg/dL	Ca mg/dL	Na mEq/L	K mEq/L	Cl mEq/L
F01001	6.8	9.6	142.7	3.82	108.1
F01003	5.7	10.1	143.2	3.93	110.0
F01004	6.3	9.5	141.3	3.94	108.0
F01007	6.0	10.0	142.2	3.78	108.0
F01012	5.3	9.7	143.4	3.74	108.5
Number of females	5	5	5	5	5
Mean	6.0	9.8	142.6	3.84	108.5
S.D.	0.6	0.3	0.8	0.09	0.9

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 28-1-2. Biochemical findings of female rats at the end of the dosing period

2-DT 62.5 mg/kg

Female No.	Total protein g/dL	Albumin g/dL	A/G	Glucose mg/dL	Total cholesterol mg/dL	Triglyceride mg/dL	Phospholipid mg/dL	AST U/L	ALT U/L	γ -GTP U/L	LDH U/L	Bile acid $\mu\text{mol}/\text{L}$	BUN mg/dL	Creatinine mg/dL	Total bilirubin mg/dL	ALP U/L
F02013	6.3	4.3	2.15	130	43	21	96	101	59	0	215	18.9	14	0.6	0.06	240
F02014	6.0	4.1	2.16	108	86	28	142	90	64	0	181	11.2	10	0.5	0.08	157
F02015	5.6	3.8	2.11	100	55	22	107	222	70	0	217	16.8	15	0.5	0.04	144
F02016	5.9	3.8	1.81	147	57	16	106	86	42	0	165	11.4	13	0.5	0.05	154
F02018	6.3	4.2	2.00	109	60	40	123	400	91	0	99	30.1	14	0.5	0.06	297
Number of females	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Mean	6.0	4.0	2.05	119	60	25	115	180	65	0	175	17.7	13	0.5	0.06	198
S.D.	0.3	0.2	0.15	19	16	9	18	135	18	0	48	7.7	2	0.0	0.01	67
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Statistical method	AN	AN	AN	AN	KW	AN	AN	KW	KW	AN	AN	KW	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

KW: Analysis by Kruskal-Wallis' test (one-way layout).

2-DT 62.5 mg/kg

Female No.	Inorganic phosphorus mg/dL	Ca mg/dL	Na mEq/L	K mEq/L	Cl mEq/L
F02013	6.2	10.6	142.4	3.42	107.1
F02014	5.7	10.0	141.3	4.02	108.3
F02015	6.3	10.0	142.8	3.72	110.7
F02016	5.4	9.7	143.4	3.34	107.4
F02018	7.0	10.4	145.2	3.09	110.6
Number of females	5	5	5	5	5
Mean	6.1	10.1	143.0	3.52	108.8
S.D.	0.6	0.4	1.4	0.36	1.7
Significance	NS	NS	NS	NS	NS
Statistical method	AN	AN	AN	KW	KW

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

KW: Analysis by Kruskal-Wallis' test (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 28-1-3. Biochemical findings of female rats at the end of the dosing period

2-DT 250 mg/kg

Female No.	Total protein g/dL	Albumin g/dL	A/G	Glucose mg/dL	Total cholesterol mg/dL	Triglyceride mg/dL	Phospholipid mg/dL	AST U/L	ALT U/L	γ -GTP U/L	LDH U/L	Bile acid μ mol/L	BUN mg/dL	Creatinine mg/dL	Total bilirubin mg/dL	ALP U/L
F03026	5.6	3.8	2.11	126	60	34	114	89	41	0	203	17.7	14	0.6	0.07	137
F03027	6.3	4.3	2.15	128	59	33	121	95	43	0	236	12.7	13	0.5	0.06	134
F03028	5.7	3.7	1.85	140	59	29	103	107	51	1	212	10.7	11	0.5	0.05	176
F03030	5.8	4.0	2.22	120	53	36	107	88	49	0	229	20.9	12	0.5	0.08	283
F03035	5.5	3.8	2.24	114	44	11	83	117	43	0	174	17.2	15	0.6	0.04	178
Number of females	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Mean	5.8	3.9	2.11	126	55	29	106	99	45	0	211	15.8	13	0.5	0.06	182
S.D.	0.3	0.2	0.16	10	7	10	14	12	4	0	24	4.1	2	0.1	0.02	60
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Statistical method	AN	AN	AN	AN	KW	AN	AN	KW	AN	AN	KW	AN	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

KW: Analysis by Kruskal-Wallis' test (one-way layout).

2-DT 250 mg/kg

Female No.	Inorganic phosphorus mg/dL	Ca mg/dL	Na mEq/L	K mEq/L	Cl mEq/L
F03026	6.2	9.9	142.7	3.70	107.9
F03027	6.5	9.8	141.2	3.49	107.6
F03028	7.1	9.5	143.3	3.85	107.2
F03030	5.8	9.4	141.2	3.46	107.9
F03035	6.2	9.8	144.8	3.83	108.6
Number of females	5	5	5	5	5
Mean	6.4	9.7	142.6	3.67	107.8
S.D.	0.5	0.2	1.5	0.18	0.5
Significance	NS	NS	NS	NS	NS
Statistical method	AN	AN	AN	KW	KW

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

KW: Analysis by Kruskal-Wallis' test (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 28-1-4. Biochemical findings of female rats at the end of the dosing period

2-DT 1000 mg/kg																
Female No.	Total protein g/dL	Albumin g/dL	A/G	Glucose mg/dL	Total cholesterol mg/dL	Triglyceride mg/dL	Phospholipid mg/dL	AST U/L	ALT U/L	γ-GTP U/L	LDH U/L	Bile acid μmol/L	BUN mg/dL	Creatinine mg/dL	Total bilirubin mg/dL	ALP U/L
F04037	5.5	3.8	2.24	130	49	27	97	83	38	0	174	8.4	16	0.6	0.05	217
F04038	5.5	4.0	2.67	129	73	30	131	67	34	0	82	9.8	19	0.7	0.05	105
F04040	6.3	4.2	2.00	132	65	50	122	75	41	1	264	54.0	17	0.5	0.08	165
F04043	5.8	4.0	2.22	149	65	44	123	106	47	0	193	9.2	14	0.6	0.05	357
F04047	5.8	4.1	2.41	149	46	62	97	103	46	1	284	9.8	12	0.5	0.06	139
Number of females	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Mean	5.8	4.0	2.31	138	60	43	114	87	41	0	199	18.2	16	0.6	0.06	197
S.D.	0.3	0.1	0.25	10	12	14	16	17	5	1	80	20.0	3	0.1	0.01	99
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Statistical method	AN	AN	AN	AN	KW	AN	AN	KW	KW	AN	AN	KW	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

KW: Analysis by Kruskal-Wallis' test (one-way layout).

2-DT 1000 mg/kg					
Female No.	Inorganic phosphorus mg/dL	Ca mg/dL	Na mEq/L	K mEq/L	Cl mEq/L
F04037	5.6	9.5	144.3	3.55	110.4
F04038	7.4	9.3	144.9	4.67	113.0
F04040	6.8	10.2	143.1	3.97	104.9
F04043	6.1	9.5	144.1	3.45	109.8
F04047	5.4	10.1	142.1	3.60	107.1
Number of females	5	5	5	5	5
Mean	6.3	9.7	143.7	3.85	109.0
S.D.	0.8	0.4	1.1	0.50	3.1
Significance	NS	NS	NS	NS	NS
Statistical method	AN	AN	AN	KW	KW

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

KW: Analysis by Kruskal-Wallis' test (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 28-2-1. Biochemical findings of female rats at the end of the dosing period, satellite group

Control (vehicle: corn oil)																
Female No.	Total protein g/dL	Albumin g/dL	A/G	Glucose mg/dL	Total cholesterol mg/dL	Triglyceride mg/dL	Phospholipid mg/dL	AST U/L	ALT U/L	γ-GTP U/L	LDH U/L	Bile acid μmol/L	BUN mg/dL	Creatinine mg/dL	Total bilirubin mg/dL	ALP U/L
F05049	6.0	4.2	2.33	150	53	15	102	45	18	0	72	11.7	13	0.6	0.08	149
F05050	5.9	4.2	2.47	109	73	8	124	92	58	0	82	6.2	13	0.7	0.06	232
F05051	6.4	4.2	1.91	145	69	18	119	75	29	0	66	8.4	16	0.7	0.04	138
F05052	5.2	3.6	2.25	124	62	24	104	54	20	0	63	5.1	16	0.6	0.04	142
F05053	6.4	4.4	2.20	138	77	18	136	88	28	0	82	20.6	17	0.7	0.08	166
Number of females	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Mean	6.0	4.1	2.23	133	67	17	117	71	31	0	73	10.4	15	0.7	0.06	165
S.D.	0.5	0.3	0.21	17	9	6	14	21	16	0	9	6.2	2	0.1	0.02	39

Control (vehicle: corn oil)					
Female No.	Inorganic phosphorus mg/dL	Ca mg/dL	Na mEq/L	K mEq/L	Cl mEq/L
F05049	4.9	9.5	145.1	3.37	107.1
F05050	6.4	9.9	145.4	3.62	107.5
F05051	4.7	10.1	143.1	3.71	108.2
F05052	4.5	8.8	144.9	3.36	110.6
F05053	3.5	9.8	144.7	3.12	109.3
Number of females	5	5	5	5	5
Mean	4.8	9.6	144.6	3.44	108.5
S.D.	1.0	0.5	0.9	0.23	1.4

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 28-2-2. Biochemical findings of female rats at the end of the dosing period, satellite group

2-DT 1000 mg/kg

Female No.	Total protein g/dL	Albumin g/dL	A/G	Glucose mg/dL	Total cholesterol mg/dL	Triglyceride mg/dL	Phospholipid mg/dL	AST U/L	ALT U/L	γ -GTP U/L	LDH U/L	Bile acid $\mu\text{mol}/\text{L}$	BUN mg/dL	Creatinine mg/dL	Total bilirubin mg/dL	ALP U/L
F06059	6.5	4.6	2.42	143	69	23	126	50	23	0	84	16.5	16	0.7	0.05	131
F06060	5.7	4.0	2.35	132	66	19	118	54	19	0	91	17.8	15	0.5	0.05	243
F06061	5.6	3.8	2.11	105	68	8	112	51	18	0	60	7.6	16	0.5	0.06	192
F06062	5.5	4.1	2.93	104	62	7	108	63	23	0	97	26.7	18	0.7	0.07	197
F06063	6.8	4.7	2.24	151	69	11	130	65	37	0	53	11.3	16	0.6	0.05	265
Number of females	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Mean	6.0	4.2	2.41	127	67	14	119	57	24	0	77	16.0	16	0.6	0.06	206
S.D.	0.6	0.4	0.31	22	3	7	9	7	8	0	19	7.3	1	0.1	0.01	52
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Statistical method	TT	TT	TT	TT	AW	TT	TT	TT	TT	TT	TT	TT	TT	TT	TT	TT

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

TT: Analysis by Student's t-test.

AW: Analysis by Aspin-Welch t-test.

2-DT 1000 mg/kg

Female No.	Inorganic phosphorus mg/dL	Ca mg/dL	Na mEq/L	K mEq/L	Cl mEq/L
F06059	5.4	10.2	141.9	3.85	107.4
F06060	5.4	10.2	142.0	3.40	109.4
F06061	5.4	9.4	145.2	3.25	109.1
F06062	6.8	10.3	143.6	4.18	105.8
F06063	5.1	10.2	142.6	3.70	107.3
Number of females	5	5	5	5	5
Mean	5.6	10.1	143.1	3.68	107.8
S.D.	0.7	0.4	1.4	0.37	1.5
Significance	NS	NS	NS	NS	NS
Statistical method	TT	TT	TT	TT	TT

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

TT: Analysis by Student's t-test.

AW: Analysis by Aspin-Welch t-test.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 28-3-1. Biochemical findings of female rats at the end of the recovery period

Control (vehicle: corn oil)																
Female No.	Total protein g/dL	Albumin g/dL	A/G	Glucose mg/dL	Total cholesterol mg/dL	Triglyceride mg/dL	Phospholipid mg/dL	AST U/L	ALT U/L	γ -GTP U/L	LDH U/L	Bile acid $\mu\text{mol}/\text{L}$	BUN mg/dL	Creatinine mg/dL	Total bilirubin mg/dL	ALP U/L
F05054	5.7	3.8	2.00	115	68	15	124	61	24	0	52	44.6	15	0.5	0.07	213
F05055	6.3	4.3	2.15	141	83	17	147	49	20	0	87	13.8	14	0.5	0.06	141
F05056	5.9	4.1	2.28	137	82	23	139	55	22	0	43	16.2	15	0.5	0.07	135
F05057	6.2	4.1	1.95	134	80	13	144	52	17	0	48	36.1	13	0.6	0.10	129
F05058	6.3	4.2	2.00	156	69	14	121	50	20	0	92	21.2	16	0.6	0.14	135
Number of females	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Mean	6.1	4.1	2.08	137	76	16	135	53	21	0	64	26.4	15	0.5	0.09	151
S.D.	0.3	0.2	0.14	15	7	4	12	5	3	0	23	13.4	1	0.1	0.03	35

Control (vehicle: corn oil)					
Female No.	Inorganic phosphorus mg/dL	Ca mg/dL	Na mEq/L	K mEq/L	Cl mEq/L
F05054	6.4	9.5	144.4	3.59	106.0
F05055	5.6	9.6	145.6	3.41	106.7
F05056	6.9	9.3	144.0	3.99	107.0
F05057	7.1	9.7	143.5	3.95	104.7
F05058	6.6	10.0	144.5	3.54	105.4
Number of females	5	5	5	5	5
Mean	6.5	9.6	144.4	3.70	106.0
S.D.	0.6	0.3	0.8	0.26	0.9

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 28-3-2. Biochemical findings of female rats at the end of the recovery period

2-DT 1000 mg/kg

Female No.	Total protein g/dL	Albumin g/dL	A/G	Glucose mg/dL	Total cholesterol mg/dL	Triglyceride mg/dL	Phospholipid mg/dL	AST U/L	ALT U/L	γ -GTP U/L	LDH U/L	Bile acid μ mol/L	BUN mg/dL	Creatinine mg/dL	Total bilirubin mg/dL	ALP U/L
F06064	5.8	4.0	2.22	151	65	21	116	53	21	0	47	23.5	16	0.5	0.07	174
F06065	6.1	4.3	2.39	150	86	12	138	58	21	0	113	13.0	14	0.6	0.08	145
F06066	7.0	4.9	2.33	159	106	20	177	55	25	0	75	16.3	15	0.6	0.10	155
F06067	5.9	4.1	2.28	183	63	18	116	88	51	0	112	9.8	11	0.5	0.05	114
F06069	6.2	4.2	2.10	139	93	12	155	50	19	0	160	13.4	13	0.5	0.06	100
Number of females	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Mean	6.2	4.3	2.26	156	83	17	140	61	27	0	101	15.2	14	0.5	0.07	138
S.D.	0.5	0.4	0.11	16	18	4	26	15	13	0	43	5.2	2	0.1	0.02	30
Significance	NS	NS	*	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Statistical method	TT	TT	TT	TT	TT	TT	TT	TT	AW	AW	TT	TT	AW	TT	TT	TT

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

TT: Analysis by Student's t-test.

AW: Analysis by Aspin-Welch t-test.

2-DT 1000 mg/kg

Female No.	Inorganic phosphorus mg/dL	Ca mg/dL	Na mEq/L	K mEq/L	Cl mEq/L
F06064	6.8	9.5	144.1	3.88	107.4
F06065	6.3	10.1	144.7	3.91	107.0
F06066	6.2	10.5	143.5	3.49	105.1
F06067	5.4	9.2	143.5	3.87	110.1
F06069	5.3	9.4	144.9	3.45	106.1
Number of females	5	5	5	5	5
Mean	6.0	9.7	144.1	3.72	107.1
S.D.	0.6	0.5	0.7	0.23	1.9
Significance	NS	NS	NS	NS	NS
Statistical method	TT	TT	TT	TT	TT

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

TT: Analysis by Student's t-test.

AW: Analysis by Aspin-Welch t-test.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 29-1-1. Organ weights of male rats at the end of the dosing period

Control (vehicle: corn oil)

Male No.	Body weight (g)	Brain		Thymus		Heart		Liver		Kidney (R)		Kidney (L)		Kidney		Spleen	
		(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
M01001	555.7	2085.0	3.752	170.2	0.306	1812.0	3.261	15798.0	28.429	1984.8	3.572	1911.1	3.439	3895.9	7.011	827.9	1.490
M01002	454.9	1952.6	4.292	280.3	0.616	1333.9	2.932	12048.0	26.485	1370.8	3.013	1424.7	3.132	2795.5	6.145	857.9	1.886
M01003	502.0	2008.2	4.000	311.2	0.620	1460.0	2.908	15755.2	31.385	1448.8	2.886	1463.4	2.915	2912.2	5.801	791.7	1.577
M01004	538.8	2184.7	4.055	317.6	0.589	1505.1	2.793	14623.7	27.141	1649.9	3.062	1677.5	3.113	3327.4	6.176	975.6	1.811
M01005	505.3	1955.2	3.869	274.9	0.544	1217.1	2.409	12909.1	25.547	1234.4	2.443	1247.0	2.468	2481.4	4.911	795.7	1.575
M01006	523.6	2091.8	3.995	353.2	0.675	1426.9	2.725	12408.0	23.697	1649.2	3.150	1703.6	3.254	3352.8	6.403	740.1	1.413
M01007	577.1	2159.6	3.742	300.9	0.521	1580.9	2.739	16298.4	28.242	1770.7	3.068	1932.8	3.349	3703.5	6.417	780.1	1.352
Number of males	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
Mean	522.5	2062.4	3.958	286.9	0.553	1476.6	2.824	14262.9	27.275	1586.9	3.028	1622.9	3.096	3209.8	6.123	824.1	1.586
S.D.	40.1	93.3	0.192	57.6	0.120	189.1	0.258	1781.2	2.435	254.9	0.336	256.5	0.325	506.5	0.649	76.3	0.198

Control (vehicle: corn oil)

Male No.	Testis (R)		Testis (L)		Testis		Epididymis (R)		Epididymis (L)		Epididymis	
	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
M01001	1940.7	3.492	1981.6	3.566	3922.3	7.058	638.6	1.149	604.7	1.088	1243.3	2.237
M01002	1693.4	3.723	1686.2	3.707	3379.6	7.429	620.7	1.364	666.0	1.464	1286.7	2.829
M01003	1534.9	3.058	1498.4	2.985	3033.3	6.042	585.9	1.167	528.5	1.053	1114.4	2.220
M01004	1757.3	3.262	1752.5	3.253	3509.8	6.514	605.5	1.124	619.4	1.150	1224.9	2.273
M01005	1627.1	3.220	1593.7	3.154	3220.8	6.374	548.2	1.085	512.2	1.014	1060.4	2.099
M01006	1551.5	2.963	1603.6	3.063	3155.1	6.026	732.7	1.399	698.1	1.333	1430.8	2.733
M01007	1763.2	3.055	1739.7	3.015	3502.9	6.070	643.1	1.114	648.4	1.124	1291.5	2.238
Number of males	7	7	7	7	7	7	7	7	7	7	7	7
Mean	1695.4	3.253	1693.7	3.249	3389.1	6.502	625.0	1.200	611.0	1.175	1236.0	2.376
S.D.	141.3	0.271	155.3	0.282	294.8	0.549	57.6	0.127	69.1	0.163	122.1	0.284

Control (vehicle: corn oil)

Male No.	Body weight (g)	Prostate, ventral		Seminal vesicles		Thyroid gland		Adrenal gland (R)		Adrenal gland (L)		Adrenal gland	
		(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
M01001	555.7	620.0	1.116	1897.6	3.415	21.2	0.038	29.4	0.053	28.3	0.051	57.7	0.104
M01002	454.9	482.1	1.060	1176.7	2.587	12.9	0.028	26.1	0.057	25.4	0.056	51.5	0.113
M01003	502.0	705.7	1.406	1576.1	3.140	22.4	0.045	25.5	0.051	24.6	0.049	50.1	0.100
M01004	538.8	613.9	1.139	1523.7	2.828	21.4	0.040	34.0	0.063	35.2	0.065	69.2	0.128
M01005	505.3	395.9	0.783	913.0	1.807	13.6	0.027	24.7	0.049	26.6	0.053	51.3	0.102
M01006	523.6	651.1	1.244	1775.3	3.391	16.4	0.031	27.6	0.053	31.8	0.061	59.4	0.113
M01007	577.1	617.5	1.070	1736.8	3.010	22.9	0.040	30.2	0.052	31.5	0.055	61.7	0.107
Number of males	7	7	7	7	7	7	7	7	7	7	7	7	7
Mean	522.5	583.7	1.117	1514.2	2.883	18.7	0.036	28.2	0.054	29.1	0.056	57.3	0.110
S.D.	40.1	106.8	0.190	352.1	0.559	4.3	0.007	3.3	0.005	3.9	0.006	6.9	0.010

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 29-1-2. Organ weights of male rats at the end of the dosing period

2-DT 62.5 mg/kg

Male No.	Body weight (g)	Brain		Thymus		Heart		Liver		Kidney (R)		Kidney (L)		Kidney		Spleen	
		(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
M02013	512.5	2011.8	3.925	259.8	0.507	1467.0	2.862	14165.6	27.640	1708.5	3.334	1686.7	3.291	3395.2	6.625	727.8	1.420
M02014	449.4	2072.4	4.611	297.1	0.661	1388.5	3.090	13295.0	29.584	1522.8	3.389	1451.4	3.230	2974.2	6.618	905.9	2.016
M02015	518.4	1920.2	3.704	212.3	0.410	1416.5	2.732	13645.4	26.322	1670.4	3.222	1811.8	3.495	3482.2	6.717	759.2	1.465
M02016	490.9	2075.9	4.229	166.2	0.339	1434.7	2.923	12424.8	25.310	1738.7	3.542	1657.8	3.377	3396.5	6.919	947.8	1.931
M02017	480.5	1913.4	3.982	250.0	0.520	1291.4	2.688	13808.5	28.738	1445.2	3.008	1401.4	2.917	2846.6	5.924	780.2	1.624
M02018	516.1	2018.7	3.911	228.4	0.443	1378.2	2.670	13651.8	26.452	1761.8	3.414	1639.3	3.176	3401.1	6.590	781.1	1.513
M02019	565.9	2110.5	3.729	228.3	0.403	1848.3	3.266	18470.4	32.639	1783.7	3.152	1783.5	3.152	3567.2	6.304	1050.6	1.857
M02020	487.6	1948.6	3.996	241.3	0.495	1335.5	2.739	11604.3	23.799	1532.3	3.143	1475.7	3.026	3008.0	6.169	940.3	1.928
M02021	485.2	2117.8	4.365	209.0	0.431	1360.9	2.805	13902.3	28.653	1632.9	3.365	1561.3	3.218	3194.2	6.583	702.6	1.448
M02022	537.7	2086.9	3.881	149.8	0.279	1880.6	3.497	16904.7	31.439	2034.2	3.783	1888.5	3.512	3922.7	7.295	1228.6	2.285
M02023	556.4	1958.5	3.520	269.6	0.485	1530.7	2.751	15986.1	28.731	1824.8	3.280	1696.2	3.049	3521.0	6.328	954.2	1.715
M02024	513.4	2071.8	4.035	333.8	0.650	1534.0	2.988	12960.6	25.245	1681.9	3.276	1637.7	3.190	3319.6	6.466	762.1	1.484
Number of males	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	
Mean	509.5	2025.5	3.991	237.1	0.469	1488.9	2.918	14235.0	27.879	1694.8	3.326	1640.9	3.219	3335.7	6.545	878.4	1.724
S.D.	33.3	74.3	0.298	51.3	0.112	189.8	0.255	1949.9	2.611	156.5	0.202	148.7	0.180	295.9	0.355	156.1	0.278
Significance Statistical method	NS AN	NS AN	NS AN	NS AN	NS AN	NS AN	NS AN	NS AN	NS AN	NS AN	NS AN	NS AN	NS AN	NS AN	NS AN	NS AN	

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

2-DT 62.5 mg/kg

Male No.	Testis (R)		Testis (L)		Testis		Epididymis (R)		Epididymis (L)		Epididymis	
	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
M02013	1940.9	3.787	1906.7	3.720	3847.6	7.508	793.1	1.548	757.0	1.477	1550.1	3.025
M02014	1736.4	3.864	1730.3	3.850	3466.7	7.714	605.9	1.348	607.4	1.352	1213.3	2.700
M02015	1663.8	3.209	1698.1	3.276	3361.9	6.485	626.6	1.209	588.6	1.135	1215.2	2.344
M02016	1790.6	3.648	1778.0	3.622	3568.6	7.270	688.2	1.402	735.5	1.498	1423.7	2.900
M02017	1511.3	3.145	1575.2	3.278	3086.5	6.424	602.1	1.253	567.8	1.182	1169.9	2.435
M02018	1702.2	3.298	1705.2	3.304	3407.4	6.602	633.5	1.227	684.6	1.326	1318.1	2.554
M02019	1600.9	2.829	1628.0	2.877	3228.9	5.706	665.7	1.176	647.8	1.145	1313.5	2.321
M02020	1494.6	3.065	1547.2	3.173	3041.8	6.238	656.7	1.347	597.9	1.226	1254.6	2.573
M02021	1824.4	3.760	1758.6	3.624	3583.0	7.385	678.1	1.398	670.8	1.383	1348.9	2.780
M02022	1935.8	3.600	1907.3	3.547	3843.1	7.147	640.1	1.190	585.0	1.088	1225.1	2.278
M02023	1766.5	3.175	1736.3	3.121	3502.8	6.295	608.5	1.094	668.5	1.201	1277.0	2.295
M02024	1513.0	2.947	1456.3	2.837	2969.3	5.784	647.9	1.262	593.5	1.156	1241.4	2.418
Number of males	12	12	12	12	12	12	12	12	12	12	12	12
Mean	1706.7	3.361	1702.3	3.352	3409.0	6.713	653.9	1.288	642.0	1.264	1295.9	2.552
S.D.	155.6	0.355	135.1	0.324	288.5	0.675	52.0	0.125	62.1	0.139	106.1	0.250
Significance Statistical method	NS AN	NS AN	NS AN	NS AN	NS AN	NS AN	NS AN	NS AN	NS AN	NS AN	NS AN	NS AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 29-1-2(continued). Organ weights of male rats at the end of the dosing period

2-DT 62.5 mg/kg

Male No.	Body weight (g)	Prostate, ventral		Seminal vesicles		Thyroid gland		Adrenal gland (R)		Adrenal gland (L)		Adrenal gland	
		(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
M02013	512.5	527.6	1.029	1832.1	3.575	26.0	0.051	30.6	0.060	31.8	0.062	62.4	0.122
M02014	449.4	708.9	1.577	1616.5	3.597	17.6	0.039	31.8	0.071	29.7	0.066	61.5	0.137
M02015	518.4	891.7	1.720	1864.5	3.597	17.1	0.033	27.0	0.052	28.6	0.055	55.6	0.107
M02016	490.9	579.6	1.181	1473.9	3.002	18.3	0.037	22.8	0.046	26.1	0.053	48.9	0.100
M02017	480.5	569.1	1.184	1407.8	2.930	19.1	0.040	19.2	0.040	22.6	0.047	41.8	0.087
M02018	516.1	745.7	1.445	1868.4	3.620	15.5	0.030	24.9	0.048	27.9	0.054	52.8	0.102
M02019	565.9	542.9	0.959	2009.7	3.551	26.1	0.046	28.7	0.051	32.8	0.058	61.5	0.109
M02020	487.6	743.7	1.525	1590.8	3.263	21.7	0.045	27.5	0.056	27.8	0.057	55.3	0.113
M02021	485.2	400.0	0.824	1975.2	4.071	20.9	0.043	22.5	0.046	20.3	0.042	42.8	0.088
M02022	537.7	699.9	1.302	1803.5	3.354	11.9	0.022	26.8	0.050	32.3	0.060	59.1	0.110
M02023	556.4	508.1	0.913	1383.4	2.486	14.0	0.025	22.3	0.040	25.5	0.046	47.8	0.086
M02024	513.4	601.4	1.171	1704.6	3.320	16.8	0.033	22.1	0.043	21.9	0.043	44.0	0.086
Number of males	12	12	12	12	12	12	12	12	12	12	12	12	12
Mean	509.5	626.6	1.236	1710.9	3.364	18.8	0.037	25.5	0.050	27.3	0.054	52.8	0.104
S.D.	33.3	134.4	0.284	215.2	0.411	4.3	0.009	3.8	0.009	4.1	0.008	7.6	0.016
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Statistical method	AN	DU	DU	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

DU: Analysis by Dunnett's test.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 29-1-3. Organ weights of male rats at the end of the dosing period

2-DT 250 mg/kg

Male No.	Body	Brain		Thymus		Heart		Liver		Kidney (R)		Kidney (L)		Kidney		Spleen	
	weight (g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
M03025	511.4	2132.2	4.169	345.6	0.676	1529.4	2.991	15716.2	30.732	1610.2	3.149	1617.1	3.162	3227.3	6.311	824.6	1.612
M03026	481.9	1977.3	4.103	249.0	0.517	1452.8	3.015	13243.6	27.482	1694.8	3.517	1662.2	3.449	3357.0	6.966	806.9	1.674
M03027	529.7	2038.3	3.848	428.9	0.810	1623.3	3.065	13392.4	25.283	1727.9	3.262	1693.5	3.197	3421.4	6.459	742.3	1.401
M03028	524.2	2037.1	3.886	198.5	0.379	1562.8	2.981	15202.0	29.000	1803.8	3.441	1750.1	3.339	3553.9	6.780	790.7	1.508
M03029	493.1	2094.6	4.248	238.1	0.483	1550.5	3.144	12598.3	25.549	1925.3	3.904	1881.8	3.816	3807.1	7.721	977.0	1.981
M03030	463.1	2016.3	4.354	203.3	0.439	1248.7	2.696	10754.1	23.222	1447.2	3.125	1510.0	3.261	2957.2	6.386	739.8	1.597
M03031	522.0	2044.8	3.917	277.6	0.532	1554.7	2.978	14802.4	28.357	1620.1	3.104	1537.2	2.945	3157.3	6.048	913.8	1.751
M03032	501.8	2070.8	4.127	408.9	0.815	1579.9	3.148	14440.8	28.778	1883.1	3.753	1851.2	3.689	3734.3	7.442	927.5	1.848
M03033	522.6	1922.5	3.679	270.1	0.517	1442.4	2.760	15806.8	30.246	1692.0	3.238	1659.6	3.176	3351.6	6.413	853.9	1.634
M03034	546.1	2116.2	3.875	303.6	0.556	1337.0	2.448	16877.5	30.906	2038.7	3.733	1940.6	3.554	3979.3	7.287	985.6	1.805
M03035	538.4	2013.5	3.740	204.6	0.380	1445.5	2.685	16620.2	30.870	1662.7	3.088	1657.7	3.079	3320.4	6.167	888.8	1.651
M03036	521.6	1965.4	3.768	169.8	0.326	1346.4	2.581	15132.3	29.011	1442.0	2.765	1576.7	3.023	3018.7	5.787	827.2	1.586
Number of males	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	
Mean	513.0	2035.8	3.976	274.8	0.536	1472.8	2.874	14548.9	28.286	1712.3	3.340	1694.8	3.308	3407.1	6.647	856.5	1.671
S.D.	24.1	62.2	0.217	83.4	0.159	114.8	0.231	1777.3	2.476	179.7	0.335	136.7	0.270	313.0	0.597	83.1	0.156
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Statistical method	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

2-DT 250 mg/kg

Male No.	Testis (R)		Testis (L)		Testis		Epididymis (R)		Epididymis (L)		Epididymis	
	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
M03025	1785.0	3.490	1792.6	3.505	3577.6	6.996	685.5	1.340	721.5	1.411	1407.0	2.751
M03026	1715.7	3.560	1752.1	3.636	3467.8	7.196	681.6	1.414	686.2	1.424	1367.8	2.838
M03027	1577.2	2.978	1504.2	2.840	3081.4	5.817	575.3	1.086	567.7	1.072	1143.0	2.158
M03028	1644.7	3.138	1671.9	3.189	3316.6	6.327	682.1	1.301	658.1	1.255	1340.2	2.557
M03029	1751.4	3.552	1684.3	3.416	3435.7	6.968	691.4	1.402	682.6	1.384	1374.0	2.786
M03030	1555.5	3.359	1542.1	3.330	3097.6	6.689	598.6	1.293	673.0	1.453	1271.6	2.746
M03031	1720.4	3.296	1659.7	3.180	3380.1	6.475	685.0	1.312	691.6	1.325	1376.6	2.637
M03032	1571.6	3.132	1628.1	3.245	3199.7	6.376	606.5	1.209	617.5	1.231	1224.0	2.439
M03033	1539.7	2.946	1588.3	3.039	3128.0	5.985	624.7	1.195	619.1	1.185	1243.8	2.380
M03034	1584.7	2.902	1591.8	2.915	3176.5	5.817	535.1	0.980	555.7	1.018	1090.8	1.997
M03035	1712.1	3.180	1689.5	3.138	3401.6	6.318	643.5	1.195	667.9	1.241	1311.4	2.436
M03036	1645.3	3.154	1621.0	3.108	3266.3	6.262	666.1	1.277	664.1	1.273	1330.2	2.550
Number of males	12	12	12	12	12	12	12	12	12	12	12	12
Mean	1650.3	3.224	1643.8	3.212	3294.1	6.436	639.6	1.250	650.4	1.273	1290.0	2.523
S.D.	84.5	0.229	82.6	0.233	161.0	0.454	51.5	0.126	50.5	0.137	98.6	0.258
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Statistical method	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 29-1-3(continued). Organ weights of male rats at the end of the dosing period

2-DT 250 mg/kg

Male No.	Body weight (g)	Prostate, ventral		Seminal vesicles		Thyroid gland		Adrenal gland (R)		Adrenal gland (L)		Adrenal gland	
		(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
M03025	511.4	947.6	1.853	2362.9	4.620	17.4	0.034	35.2	0.069	36.8	0.072	72.0	0.141
M03026	481.9	737.9	1.531	2076.2	4.308	22.7	0.047	27.9	0.058	30.1	0.062	58.0	0.120
M03027	529.7	645.7	1.219	1850.0	3.493	18.2	0.034	30.8	0.058	33.1	0.062	63.9	0.121
M03028	524.2	615.6	1.174	2032.7	3.878	21.2	0.040	22.8	0.043	25.7	0.049	48.5	0.093
M03029	493.1	611.9	1.241	1837.9	3.727	14.0	0.028	24.3	0.049	25.0	0.051	49.3	0.100
M03030	463.1	663.3	1.432	1889.6	4.080	15.7	0.034	22.9	0.049	25.7	0.055	48.6	0.105
M03031	522.0	473.1	0.906	1807.1	3.462	17.3	0.033	30.9	0.059	31.4	0.060	62.3	0.119
M03032	501.8	464.4	0.925	1953.3	3.893	16.8	0.033	23.3	0.046	24.3	0.048	47.6	0.095
M03033	522.6	657.3	1.258	1730.5	3.311	23.3	0.045	26.2	0.050	24.5	0.047	50.7	0.097
M03034	546.1	460.0	0.842	1572.2	2.879	20.9	0.038	33.0	0.060	30.8	0.056	63.8	0.117
M03035	538.4	565.2	1.050	1479.5	2.748	18.4	0.034	22.2	0.041	22.7	0.042	44.9	0.083
M03036	521.6	503.5	0.965	1540.0	2.952	19.0	0.036	25.4	0.049	26.3	0.050	51.7	0.099
Number of males	12	12	12	12	12	12	12	12	12	12	12	12	12
Mean	513.0	612.1	1.200	1844.3	3.613	18.7	0.036	27.1	0.053	28.0	0.055	55.1	0.108
S.D.	24.1	139.0	0.296	249.8	0.582	2.8	0.005	4.4	0.008	4.3	0.008	8.6	0.016
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Statistical method	AN	DU	DU	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

DU: Analysis by Dunnett's test.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 29-1-4. Organ weights of male rats at the end of the dosing period

2-DT 1000 mg/kg

Male No.	Body weight (g)	Brain		Thymus		Heart		Liver		Kidney (R)		Kidney (L)		Kidney		Spleen	
		(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
M04037	477.7	2104.3	4.405	399.5	0.836	1485.5	3.110	12262.0	25.669	1562.4	3.271	1629.5	3.411	3191.9	6.682	659.4	1.380
M04038	482.9	2084.3	4.316	480.9	0.996	1497.7	3.101	12260.5	25.389	1538.7	3.186	1520.9	3.150	3059.6	6.336	807.2	1.672
M04039	546.1	1964.2	3.597	236.7	0.433	1568.1	2.871	16342.6	29.926	1600.1	2.930	1642.8	3.008	3242.9	5.938	893.7	1.637
M04040	521.5	2086.9	4.002	244.1	0.468	1726.3	3.310	14198.3	27.226	1659.2	3.182	1549.2	2.971	3208.4	6.152	916.6	1.758
M04041	525.9	1982.3	3.769	309.8	0.589	1438.2	2.735	13518.7	25.706	1572.7	2.990	1526.4	2.902	3099.1	5.893	680.2	1.293
M04042	513.5	1983.2	3.862	252.7	0.492	1566.7	3.051	13946.1	27.159	1745.6	3.399	1924.7	3.748	3670.3	7.148	945.9	1.842
M04043	487.9	1987.2	4.073	311.6	0.639	1373.5	2.815	14450.6	29.618	1821.9	3.734	1782.2	3.653	3604.1	7.387	692.6	1.420
Number of males	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
Mean	507.9	2027.5	4.003	319.3	0.636	1522.3	2.999	13854.1	27.242	1642.9	3.242	1653.7	3.263	3296.6	6.505	799.4	1.572
S.D.	25.6	60.9	0.290	90.9	0.209	113.2	0.201	1406.1	1.876	105.6	0.269	150.2	0.342	241.9	0.588	122.0	0.208
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Statistical method	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

2-DT 1000 mg/kg

Male No.	Testis (R)		Testis (L)		Testis		Epididymis (R)		Epididymis (L)		Epididymis	
	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
M04037	1796.3	3.760	1749.3	3.662	3545.6	7.422	651.1	1.363	621.5	1.301	1272.6	2.664
M04038	1497.9	3.102	1552.4	3.215	3050.3	6.317	572.5	1.186	665.3	1.378	1237.8	2.563
M04039	1841.7	3.372	1824.4	3.341	3666.1	6.713	670.9	1.229	679.2	1.244	1350.1	2.472
M04040	1570.5	3.012	1596.4	3.061	3166.9	6.073	615.5	1.180	600.0	1.151	1215.5	2.331
M04041	1746.0	3.320	1681.4	3.197	3427.4	6.517	601.4	1.144	566.7	1.078	1168.1	2.221
M04042	1539.7	2.998	1591.6	3.100	3131.3	6.098	634.5	1.236	636.4	1.239	1270.9	2.475
M04043	1854.8	3.802	1852.0	3.796	3706.8	7.597	687.6	1.409	667.4	1.368	1355.0	2.777
Number of males	7	7	7	7	7	7	7	7	7	7	7	7
Mean	1692.4	3.338	1692.5	3.339	3384.9	6.677	633.4	1.250	633.8	1.251	1267.1	2.500
S.D.	151.8	0.335	119.2	0.284	269.0	0.613	40.2	0.099	40.8	0.110	68.3	0.189
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Statistical method	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 29-1-4(continued). Organ weights of male rats at the end of the dosing period

2-DT 1000 mg/kg

Male No.	Body weight (g)	Prostate, ventral		Seminal vesicles		Thyroid gland		Adrenal gland (R)		Adrenal gland (L)		Adrenal gland	
		(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
M04037	477.7	799.2	1.673	2065.6	4.324	21.6	0.045	24.5	0.051	27.9	0.058	52.4	0.110
M04038	482.9	674.7	1.397	1290.2	2.672	16.0	0.033	19.5	0.040	21.4	0.044	40.9	0.085
M04039	546.1	699.5	1.281	1710.6	3.132	16.2	0.030	24.8	0.045	25.6	0.047	50.4	0.092
M04040	521.5	913.1	1.751	1807.5	3.466	27.6	0.053	35.4	0.068	37.4	0.072	72.8	0.140
M04041	525.9	956.4	1.819	1246.6	2.370	22.7	0.043	22.1	0.042	26.2	0.050	48.3	0.092
M04042	513.5	791.3	1.541	2218.5	4.320	21.8	0.042	38.5	0.075	37.7	0.073	76.2	0.148
M04043	487.9	665.2	1.363	2163.1	4.433	16.0	0.033	21.2	0.043	21.7	0.044	42.9	0.088
Number of males	7	7	7	7	7	7	7	7	7	7	7	7	7
Mean	507.9	785.6	1.546	1786.0	3.531	20.3	0.040	26.6	0.052	28.3	0.055	54.8	0.108
S.D.	25.6	115.4	0.208	398.0	0.848	4.4	0.008	7.4	0.014	6.8	0.013	14.0	0.026
Significance	NS	*	*	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Statistical method	AN	DU	DU	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

DU: Analysis by Dunnett's test.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 29-2-1. Organ weights of male rats at the end of the recovery period

Control (vehicle: corn oil)

Male No.	Body weight (g)	Brain		Thymus		Heart		Liver		Kidney (R)		Kidney (L)		Kidney		Spleen	
		(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
M01008	543.2	2022.7	3.724	190.8	0.351	1574.3	2.898	14923.1	27.473	1711.9	3.152	1631.9	3.004	3343.8	6.156	882.5	1.625
M01009	487.3	2120.5	4.352	291.9	0.599	1314.9	2.698	12950.7	26.576	1599.2	3.282	1619.7	3.324	3218.9	6.606	660.3	1.355
M01010	514.3	2141.5	4.164	345.7	0.672	1509.1	2.934	13450.4	26.153	1539.4	2.993	1606.7	3.124	3146.1	6.117	758.6	1.475
M01011	502.1	1994.2	3.972	314.2	0.626	1428.6	2.845	11942.7	23.786	1466.0	2.920	1428.3	2.845	2894.3	5.764	759.7	1.513
M01012	476.3	2033.0	4.268	381.7	0.801	1467.9	3.082	12785.4	26.843	1533.8	3.220	1496.3	3.142	3030.1	6.362	1040.4	2.184
Number of males	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Mean	504.6	2062.4	4.096	304.9	0.610	1459.0	2.891	13210.5	26.166	1570.1	3.113	1556.6	3.088	3126.6	6.201	820.3	1.630
S.D.	25.9	64.7	0.252	72.2	0.164	96.9	0.139	1100.7	1.414	92.3	0.153	89.8	0.177	172.7	0.312	146.1	0.324

Control (vehicle: corn oil)

Male No.	Testis (R)		Testis (L)		Testis		Epididymis (R)		Epididymis (L)		Epididymis	
	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
M01008	1786.7	3.289	1800.7	3.315	3587.4	6.604	778.4	1.433	741.1	1.364	1519.5	2.797
M01009	1776.6	3.646	1787.8	3.669	3564.4	7.315	700.3	1.437	685.4	1.407	1385.7	2.844
M01010	1776.9	3.455	1782.6	3.466	3559.5	6.921	713.1	1.387	685.8	1.333	1398.9	2.720
M01011	1474.5	2.937	1478.5	2.945	2953.0	5.881	586.3	1.168	603.7	1.202	1190.0	2.370
M01012	1611.5	3.383	1542.7	3.239	3154.2	6.622	565.5	1.187	580.1	1.218	1145.6	2.405
Number of males	5	5	5	5	5	5	5	5	5	5	5	5
Mean	1685.2	3.342	1678.5	3.327	3363.7	6.669	668.7	1.322	659.2	1.305	1327.9	2.627
S.D.	138.6	0.262	155.0	0.269	292.1	0.526	90.1	0.134	66.0	0.091	156.0	0.224

Control (vehicle: corn oil)

Male No.	Body weight (g)	Prostate, ventral		Seminal vesicles		Thyroid gland		Adrenal gland (R)		Adrenal gland (L)		Adrenal glands	
		(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
M01008	543.2	715.0	1.316	1647.0	3.032	21.1	0.039	24.2	0.045	26.5	0.049	50.7	0.093
M01009	487.3	675.6	1.386	1714.9	3.519	22.6	0.046	19.0	0.039	24.7	0.051	43.7	0.090
M01010	514.3	977.2	1.900	1601.5	3.114	13.4	0.026	22.2	0.043	21.9	0.043	44.1	0.086
M01011	502.1	862.9	1.719	2185.7	4.353	16.5	0.033	26.4	0.053	27.3	0.054	53.7	0.107
M01012	476.3	444.9	0.934	1087.3	2.283	12.4	0.026	26.1	0.055	26.5	0.056	52.6	0.110
Number of males	5	5	5	5	5	5	5	5	5	5	5	5	5
Mean	504.6	735.1	1.451	1647.3	3.260	17.2	0.034	23.6	0.047	25.4	0.051	49.0	0.097
S.D.	25.9	201.9	0.375	390.6	0.757	4.5	0.009	3.1	0.007	2.2	0.005	4.7	0.011

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 29-2-2. Organ weights of male rats at the end of the recovery period

2-DT 1000 mg/kg															
Male No.	Body	Brain		Thymus		Heart		Liver		Kidney (R)		Kidney (L)		Kidney	
	weight (g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
M04044	513.0	1937.9	3.778	216.4	0.422	1485.4	2.896	11668.0	22.745	1390.7	2.711	1361.7	2.654	2752.4	5.365
M04045	548.1	2066.3	3.770	320.5	0.585	1398.0	2.551	14230.3	25.963	1625.4	2.966	1651.2	3.013	3276.6	5.978
M04046	542.6	2140.5	3.945	268.1	0.494	1478.8	2.725	13778.0	25.393	1724.1	3.177	1701.5	3.136	3425.6	6.313
M04047	504.5	1892.8	3.752	353.6	0.701	1444.7	2.864	13760.2	27.275	1707.4	3.384	1675.6	3.321	3383.0	6.706
M04048	576.7	2149.0	3.726	241.7	0.419	1594.2	2.764	14302.5	24.801	1511.3	2.621	1548.4	2.685	3059.7	5.306
Number of males	5	5	5	5	5	5	5	5	5	5	5	5	5	5	
Mean	537.0	2037.3	3.794	280.1	0.524	1480.2	2.760	13547.8	25.235	1591.8	2.972	1587.7	2.962	3179.5	5.934
S.D.	29.0	117.0	0.087	56.4	0.120	72.5	0.136	1080.2	1.666	140.5	0.317	139.0	0.289	277.6	0.604
Significance	NS	NS	*	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	
Statistical method	TT	TT	TT	TT	TT	TT	TT	TT	TT	TT	TT	TT	TT	TT	

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

TT: Analysis by Student's t-test.

AW: Analysis by Aspin-Welch t-test.

2-DT 1000 mg/kg												
Male No.	Testis (R)		Testis (L)		Testis		Epididymis (R)		Epididymis (L)		Epididymis	
	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
M04044	1593.1		3.105		1584.6		3.089		3177.7		6.194	
M04045	1648.7		3.008		1595.8		2.912		3244.5		5.920	
M04046	1666.3		3.071		1687.9		3.111		3354.2		6.182	
M04047	1743.2		3.455		1732.4		3.434		3475.6		6.889	
M04048	1400.9		2.429		1443.1		2.502		2844.0		4.932	
Number of males	5	5	5	5	5	5	5	5	5	5	5	5
Mean	1610.4	3.014	1608.8	3.010	3219.2	6.023	635.9	1.189	638.0	1.192	1273.9	2.381
S.D.	128.9	0.370	111.5	0.341	238.3	0.708	23.4	0.104	18.9	0.090	40.5	0.193
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Statistical method	TT	TT	TT	TT	TT	TT	AW	TT	AW	TT	AW	TT

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

TT: Analysis by Student's t-test.

AW: Analysis by Aspin-Welch t-test.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 29-2-2(continued). Organ weights of male rats at the end of the recovery period

2-DT 1000 mg/kg													
Male No.	Body weight (g)	Prostate, ventral		Seminal vesicles		Thyroid gland		Adrenal gland (R)		Adrenal gland (L)		Adrenal glands	
		(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
M04044	513.0	608.4	1.186	1709.6	3.333	17.6	0.034	24.7	0.048	24.8	0.048	49.5	0.096
M04045	548.1	488.3	0.891	1213.5	2.214	22.6	0.041	21.6	0.039	21.7	0.040	43.3	0.079
M04046	542.6	754.0	1.390	1658.4	3.056	12.8	0.024	24.0	0.044	22.8	0.042	46.8	0.086
M04047	504.5	881.0	1.746	1520.1	3.013	25.5	0.051	20.6	0.041	21.1	0.042	41.7	0.083
M04048	576.7	679.7	1.179	1837.0	3.185	21.3	0.037	25.5	0.044	24.2	0.042	49.7	0.086
Number of males	5	5	5	5	5	5	5	5	5	5	5	5	5
Mean	537.0	682.3	1.278	1587.7	2.960	20.0	0.037	23.3	0.043	22.9	0.043	46.2	0.086
S.D.	29.0	148.1	0.316	238.0	0.435	4.9	0.010	2.1	0.003	1.6	0.003	3.6	0.006
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	*	NS	NS
Statistical method	TT	TT	TT	TT	TT	TT	TT	TT	TT	TT	TT	TT	TT

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

TT: Analysis by Student's t-test.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 30-1-1. Organ weights of female rats at the end of the dosing period

Control (vehicle: corn oil)																	
Female No.	Body weight (g)	Brain		Thymus		Heart		Liver		Kidney (R)		Kidney (L)		Kidney		Spleen	
		(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
F01001	311.3	1954.3	6.278	164.2	0.527	1010.4	3.246	9681.3	31.100	1001.7	3.218	1022.0	3.283	2023.7	6.501	697.8	2.242
F01002	326.0	1950.0	5.982	207.9	0.638	994.7	3.051	9705.3	29.771	1046.7	3.211	1048.1	3.215	2094.8	6.426	688.7	2.113
F01003	316.1	1918.2	6.068	274.4	0.868	915.0	2.895	9856.6	31.182	849.3	2.687	875.5	2.770	1724.8	5.457	748.0	2.366
F01004	296.8	1926.4	6.491	144.4	0.487	884.1	2.979	10968.3	36.955	904.3	3.047	925.4	3.118	1829.7	6.165	767.7	2.587
F01005	319.6 a)	1994.7 a)	6.241 a)	320.4 a)	1.003 a)	1013.7 a)	3.172 a)	10700.5 a)	33.481 a)	1181.8 a)	3.698 a)	1098.7 a)	3.438 a)	2280.5 a)	7.135 a)	604.5 a)	1.891 a)
F01006	320.0	2037.4	6.367	231.9	0.725	1018.2	3.182	10949.0	34.216	1178.0	3.681	1137.9	3.556	2315.9	7.237	719.2	2.248
F01007	310.8	1927.9	6.203	221.0	0.711	910.7	2.930	8756.7	28.175	807.2	2.597	806.9	2.596	1614.1	5.193	537.4	1.729
F01008	335.4	1956.2	5.832	248.9	0.742	1219.7	3.637	12021.0	35.841	1018.0	3.035	1076.7	3.210	2094.7	6.245	738.7	2.202
F01009	290.9	1989.6	6.839	240.6	0.827	972.4	3.343	10328.2	35.504	1020.9	3.509	1012.4	3.480	2033.3	6.990	860.2	2.957
F01010	299.3	1815.4	6.065	215.9	0.721	984.2	3.288	9922.5	33.152	901.3	3.011	849.2	2.837	1750.5	5.849	758.9	2.536
F01011	289.2	1861.2	6.436	113.9	0.394	912.8	3.156	8158.1	28.209	954.0	3.299	959.3	3.317	1913.3	6.616	516.6	1.786
F01012	315.5	1917.9	6.079	162.8	0.516	944.3	2.993	9381.6	29.736	970.0	3.074	839.3	2.660	1809.3	5.735	624.1	1.978
Number of females	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	
Mean	310.1	1932.2	6.240	202.4	0.651	978.8	3.155	9975.3	32.167	968.3	3.124	959.3	3.095	1927.6	6.219	696.1	2.249
S.D.	14.7	59.1	0.283	49.5	0.151	91.7	0.219	1075.1	3.132	102.7	0.317	108.7	0.329	205.3	0.626	101.8	0.359

a) Excluded from data analysis (not copulated).

Control (vehicle: corn oil)																
Female No.	Ovary (R)		Ovary (L)		Ovary		Uterus		Thyroid gland		Adrenal gland (R)		Adrenal gland (L)		Adrenal gland	
	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
F01001	55.4	0.178	68.7	0.221	124.1	0.399	585.1	1.880	12.0	0.039	33.2	0.107	38.9	0.125	72.1	0.232
F01002	50.9	0.156	48.2	0.148	99.1	0.304	619.5	1.900	17.1	0.052	32.3	0.099	33.8	0.104	66.1	0.203
F01003	50.5	0.160	49.6	0.157	100.1	0.317	645.1	2.041	10.9	0.034	25.0	0.079	27.1	0.086	52.1	0.165
F01004	52.8	0.178	49.1	0.165	101.9	0.343	593.7	2.000	6.7	0.023	33.7	0.114	34.4	0.116	68.1	0.229
F01005	53.3 a)	0.167 a)	48.6 a)	0.152 a)	101.9 a)	0.319 a)	1104.3 a)	3.455 a)	13.1 a)	0.041 a)	29.6 a)	0.093 a)	29.9 a)	0.094 a)	59.5 a)	0.186 a)
F01006	64.3	0.201	50.4	0.158	114.7	0.358	439.2	1.373	14.0	0.044	38.5	0.120	41.5	0.130	80.0	0.250
F01007	45.8	0.147	51.8	0.167	97.6	0.314	590.3	1.899	21.9	0.070	24.8	0.080	26.6	0.086	51.4	0.165
F01008	55.6	0.166	59.8	0.178	115.4	0.344	634.1	1.891	18.7	0.056	48.5	0.145	50.1	0.149	98.6	0.294
F01009	47.7	0.164	47.9	0.165	95.6	0.329	745.1	2.561	8.9	0.031	35.6	0.122	39.1	0.134	74.7	0.257
F01010	42.3	0.141	35.5	0.119	77.8	0.260	595.2	1.989	14.4	0.048	37.6	0.126	31.0	0.104	68.6	0.229
F01011	48.9	0.169	32.0	0.111	80.9	0.280	540.8	1.870	8.3	0.029	32.2	0.111	33.7	0.117	65.9	0.228
F01012	46.9	0.149	53.3	0.169	100.2	0.318	641.3	2.033	8.5	0.027	39.9	0.126	37.2	0.118	77.1	0.244
Number of females	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	
Mean	51.0	0.164	49.7	0.160	100.7	0.324	602.7	1.949	12.9	0.041	34.7	0.112	35.8	0.115	70.4	0.227
S.D.	6.0	0.017	10.0	0.029	13.8	0.038	74.8	0.273	4.9	0.014	6.7	0.020	6.7	0.019	13.0	0.038

a) Excluded from data analysis (not copulated).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 30-1-2. Organ weights of female rats at the end of the dosing period

2-DT 62.5 mg/kg															
Female No.	Body weight (g)	Brain		Thymus		Heart		Liver		Kidney (R)		Kidney (L)		Kidney	
		(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
F02013	330.3	1876.2	5.680	279.1	0.845	1014.2	3.071	10498.0	31.783	1118.8	3.387	1103.1	3.340	2221.9	6.727
F02014	318.0	2020.2	6.353	250.4	0.787	1093.3	3.438	10398.7	32.700	1114.5	3.505	1070.0	3.365	2184.5	6.869
F02015	326.2	2004.8	6.146	301.8	0.925	961.4	2.947	10693.2	32.781	1002.8	3.074	1001.6	3.071	2004.4	6.145
F02016	297.1	1905.7	6.414	132.3	0.445	970.5	3.267	10747.7	36.175	978.8	3.295	928.0	3.124	1906.8	6.418
F02017	307.8	1885.7	6.126	187.0	0.608	1006.6	3.270	9918.1	32.223	995.3	3.234	946.7	3.076	1942.0	6.309
F02018	289.6	1854.9	6.405	182.9	0.632	888.5	3.068	9155.6	31.615	882.4	3.047	850.6	2.937	1733.0	5.984
F02019	293.5	1854.2	6.318	143.5	0.489	951.3	3.241	10276.0	35.012	1043.3	3.555	1016.9	3.465	2060.2	7.019
F02020	316.6	1980.4	6.255	207.7	0.656	1061.3	3.352	9707.1	30.660	1191.6	3.764	1204.8	3.805	2396.4	7.569
F02021	362.7	1973.9	5.442	226.9	0.626	1208.8	3.333	11483.4	31.661	1522.7	4.198	1628.4	4.490	3151.1	8.688
F02022	314.2	1971.4	6.274	281.6	0.896	1008.6	3.210	9817.7	31.247	999.4	3.181	978.9	3.116	1978.3	6.296
F02023	320.2	1790.1	5.591	272.2	0.850	1044.6	3.262	10652.8	33.269	1032.5	3.225	1003.8	3.135	2036.3	6.359
F02024	318.1	1942.7	6.107	279.8	0.880	967.9	3.043	9917.4	31.177	1148.6	3.611	1101.7	3.463	2250.3	7.074
Number of females	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12
Mean	316.2	1921.7	6.093	228.8	0.720	1014.8	3.209	10272.1	32.525	1085.9	3.423	1069.5	3.366	2155.4	6.788
S.D.	19.4	71.1	0.334	57.6	0.165	82.0	0.146	611.0	1.632	161.8	0.329	199.0	0.427	360.2	0.752
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Statistical method	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	KW	AN	KW	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

KW: Analysis by Kruskal-Wallis' test (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 30-1-2(continued). Organ weights of female rats at the end of the dosing period

2-DT 62.5 mg/kg

Female No.	Ovary (R)		Ovary (L)		Ovary		Uterus		Thyroid gland		Adrenal gland (R)		Adrenal gland (L)		Adrenal gland	
	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
F02013	42.1	0.127	60.8	0.184	102.9	0.312	517.1	1.566	21.0	0.064	43.6	0.132	51.3	0.155	94.9	0.287
F02014	58.2	0.183	44.9	0.141	103.1	0.324	588.5	1.851	15.0	0.047	33.3	0.105	30.5	0.096	63.8	0.201
F02015	54.5	0.167	54.1	0.166	108.6	0.333	706.1	2.165	13.5	0.041	33.7	0.103	37.7	0.116	71.4	0.219
F02016	50.9	0.171	51.1	0.172	102.0	0.343	687.7	2.315	14.8	0.050	51.9	0.175	56.9	0.192	108.8	0.366
F02017	58.6	0.190	64.2	0.209	122.8	0.399	528.2	1.716	14.1	0.046	34.6	0.112	39.4	0.128	74.0	0.240
F02018	44.3	0.153	46.3	0.160	90.6	0.313	516.0	1.782	19.2	0.066	28.3	0.098	30.3	0.105	58.6	0.202
F02019	53.9	0.184	64.2	0.219	118.1	0.402	609.2	2.076	14.4	0.049	44.9	0.153	41.3	0.141	86.2	0.294
F02020	54.6	0.172	60.1	0.190	114.7	0.362	648.2	2.047	15.3	0.048	29.5	0.093	37.1	0.117	66.6	0.210
F02021	60.9	0.168	63.9	0.176	124.8	0.344	761.8	2.100	17.8	0.049	37.7	0.104	37.0	0.102	74.7	0.206
F02022	70.8	0.225	42.5	0.135	113.3	0.361	640.4	2.038	10.8	0.034	32.1	0.102	35.8	0.114	67.9	0.216
F02023	50.8	0.159	48.9	0.153	99.7	0.311	518.6	1.620	14.9	0.047	36.1	0.113	38.3	0.120	74.4	0.232
F02024	60.9	0.191	46.0	0.145	106.9	0.336	610.5	1.919	13.0	0.041	33.9	0.107	35.3	0.111	69.2	0.218
Number of females	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12
Mean	55.0	0.174	53.9	0.171	109.0	0.345	611.0	1.933	15.3	0.049	36.6	0.116	39.2	0.125	75.9	0.241
S.D.	7.7	0.024	8.3	0.026	10.1	0.031	81.8	0.230	2.8	0.009	6.9	0.025	7.7	0.027	14.2	0.050
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Statistical method	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

KW: Analysis by Kruskal-Wallis' test (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 30-1-3. Organ weights of female rats at the end of the dosing period

2-DT 250 mg/kg																		
Female No.	Body		Brain		Thymus		Heart		Liver		Kidney (R)		Kidney (L)		Kidney		Spleen	
	weight (g)	(mg)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
F03025	314.7	1907.6	6.062	210.2	0.668	1048.7	3.332	10096.7	32.084	1086.8	3.453	1017.2	3.232	2104.0	6.686	519.2	1.650	
F03026	327.0	1826.8	5.587	244.6	0.748	1026.9	3.140	10562.0	32.300	926.1	2.832	899.7	2.751	1825.8	5.583	654.3	2.001	
F03027	333.6	1837.3	5.507	314.8	0.944	1082.5	3.245	11440.7	34.295	1019.2	3.055	979.5	2.936	1998.7	5.991	605.5	1.815	
F03028	307.5	1862.4	6.057	107.0	0.348	1040.0	3.382	11171.1	36.329	1024.8	3.333	980.4	3.188	2005.2	6.521	732.5	2.382	
F03029	321.4	1800.8	5.603	207.7	0.646	953.2	2.966	8983.6	27.951	998.1	3.105	968.2	3.012	1966.3	6.118	672.8	2.093	
F03030	321.8	1962.1	6.097	259.5	0.806	999.1	3.105	9512.9	29.562	968.8	3.011	875.0	2.719	1843.8	5.730	739.8	2.299	
F03031	295.1	1921.3	6.511	113.4	0.384	882.4	2.990	9319.6	31.581	906.4	3.072	955.4	3.238	1861.8	6.309	599.8	2.033	
F03032	302.6	1914.8	6.328	289.8	0.958	1038.1	3.431	8867.1	29.303	936.5	3.095	987.8	3.264	1924.3	6.359	694.6	2.295	
F03033	337.1	1975.6	5.861	230.2	0.683	1122.5	3.330	10434.4	30.953	1168.1	3.465	1222.3	3.626	2390.4	7.091	636.4	1.888	
F03034	320.0	1908.5	5.964	195.5	0.611	1019.0	3.184	9988.5	31.214	960.1	3.000	956.0	2.988	1916.1	5.988	890.4	2.783	
F03035	325.6	1929.0	5.924	251.9	0.774	986.8	3.031	9413.7	28.912	1063.6	3.267	940.8	2.889	2004.4	6.156	819.1	2.516	
F03036	309.5	1919.7	6.203	120.5	0.389	1071.6	3.462	9368.3	30.269	975.3	3.151	974.1	3.147	1949.4	6.299	567.4	1.833	
Number of females	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	
Mean	318.0	1897.2	5.975	212.1	0.663	1022.6	3.217	9929.9	31.229	1002.8	3.153	979.7	3.083	1982.5	6.236	677.7	2.132	
S.D.	12.5	54.0	0.304	68.3	0.205	62.9	0.173	834.6	2.355	75.2	0.191	85.6	0.253	150.7	0.412	105.8	0.330	
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	
Statistical method	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	KW	AN	KW	AN	AN	AN	AN	

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

KW: Analysis by Kruskal-Wallis' test (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 30-1-3(continued). Organ weights of female rats at the end of the dosing period

Female No.	Ovary (R)		Ovary (L)		Ovary		Uterus		Thyroid gland		Adrenal gland (R)		Adrenal gland (L)		Adrenal gland	
	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
F03025	53.3	0.169	46.0	0.146	99.3	0.316	519.5	1.651	12.6	0.040	35.9	0.114	39.2	0.125	75.1	0.239
F03026	43.0	0.131	63.3	0.194	106.3	0.325	491.1	1.502	12.7	0.039	45.2	0.138	50.8	0.155	96.0	0.294
F03027	55.3	0.166	69.8	0.209	125.1	0.375	726.1	2.177	12.4	0.037	35.4	0.106	37.4	0.112	72.8	0.218
F03028	60.3	0.196	63.8	0.207	124.1	0.404	511.8	1.664	15.7	0.051	45.3	0.147	44.8	0.146	90.1	0.293
F03029	53.8	0.167	57.3	0.178	111.1	0.346	513.9	1.599	11.0	0.034	32.5	0.101	36.7	0.114	69.2	0.215
F03030	42.7	0.133	39.8	0.124	82.5	0.256	550.5	1.711	13.0	0.040	34.5	0.107	37.0	0.115	71.5	0.222
F03031	61.2	0.207	51.7	0.175	112.9	0.383	485.2	1.644	10.5	0.036	32.9	0.111	33.6	0.114	66.5	0.225
F03032	64.2	0.212	70.1	0.232	134.3	0.444	677.0	2.237	15.6	0.052	29.5	0.097	32.7	0.108	62.2	0.206
F03033	65.0	0.193	57.8	0.171	122.8	0.364	663.4	1.968	17.9	0.053	34.5	0.102	37.3	0.111	71.8	0.213
F03034	55.2	0.173	42.6	0.133	97.8	0.306	596.1	1.863	14.7	0.046	38.8	0.121	44.0	0.138	82.8	0.259
F03035	58.0	0.178	51.1	0.157	109.1	0.335	589.3	1.810	13.7	0.042	30.2	0.093	29.7	0.091	59.9	0.184
F03036	53.4	0.173	67.7	0.219	121.1	0.391	498.4	1.610	17.4	0.056	35.4	0.114	37.9	0.122	73.3	0.237
Number of females	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12
Mean	55.5	0.175	56.8	0.179	112.2	0.354	568.5	1.786	13.9	0.044	35.8	0.113	38.4	0.121	74.3	0.234
S.D.	7.1	0.025	10.5	0.035	14.4	0.050	81.8	0.234	2.4	0.007	5.1	0.016	5.8	0.018	10.7	0.033
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Statistical method	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

KW: Analysis by Kruskal-Wallis' test (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 30-1-4. Organ weights of female rats at the end of the dosing period

2-DT 1000 mg/kg																		
Female No.	Body		Brain		Thymus		Heart		Liver		Kidney (R)		Kidney (L)		Kidney		Spleen	
	weight (g)	(mg)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
F04037	315.0	1855.8	5.891	233.6	0.742	988.1	3.137	9511.8	30.196	906.8	2.879	894.8	2.841	1801.6	5.719	609.6	1.935	
F04038	321.9	1876.1	5.828	237.4	0.737	916.1	2.846	9488.7	29.477	867.2	2.694	848.0	2.634	1715.2	5.328	853.7	2.652	
F04039	315.2	2016.0	6.396	284.7	0.903	981.4	3.114	9617.3	30.512	1087.1	3.449	1049.6	3.330	2136.7	6.779	739.2	2.345	
F04040	288.6	1827.2	6.331	106.2	0.368	1034.4	3.584	10804.8	37.439	1083.0	3.753	1050.1	3.639	2133.1	7.391	673.9	2.335	
F04041	324.4	1981.1	6.107	302.1	0.931	1039.0	3.203	10129.3	31.225	947.0	2.919	972.3	2.997	1919.3	5.916	859.5	2.650	
F04042	303.5	1867.4	6.153	196.2	0.646	992.3	3.270	9727.1	32.050	1017.5	3.353	1071.9	3.532	2089.4	6.884	676.0	2.227	
F04043	331.2	1930.9	5.830	208.0	0.628	993.9	3.001	10271.3	31.012	871.9	2.633	923.7	2.789	1795.6	5.421	729.0	2.201	
F04044	304.6	1854.0	6.087	352.8	1.158	960.6	3.154	8964.6	29.431	1093.3	3.589	1031.8	3.387	2125.1	6.977	621.7	2.041	
F04045	327.2	2075.3	6.343	252.7	0.772	1063.7	3.251	10677.2	32.632	1069.6	3.269	1043.5	3.189	2113.1	6.458	878.3	2.684	
F04046	319.8	1881.2	5.882	137.8	0.431	1042.2	3.259	10502.6	32.841	1052.0	3.290	1036.2	3.240	2088.2	6.530	907.9	2.839	
F04047	305.3	1819.9	5.961	328.9	1.077	1043.2	3.417	11807.6	38.675	1083.5	3.549	1045.2	3.424	2128.7	6.972	973.3	3.188	
F04048	307.6	1933.3	6.285	302.8	0.984	1169.9	3.803	9265.0	30.120	1123.9	3.654	1055.9	3.433	2179.8	7.086	556.7	1.810	
Number of females	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12		
Mean	313.7	1909.9	6.091	245.3	0.781	1018.7	3.253	10063.9	32.134	1016.9	3.253	1001.9	3.203	2018.8	6.455	756.6	2.409	
S.D.	12.2	79.5	0.212	74.8	0.242	63.4	0.255	797.8	2.994	93.2	0.383	74.0	0.319	163.5	0.693	134.5	0.403	
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS		
Statistical method	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	KW	AN	AN	AN	AN	AN		

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

KW: Analysis by Kruskal-Wallis' test (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 30-1-4(continued). Organ weights of female rats at the end of the dosing period

2-DT 1000 mg/kg

Female No.	Ovary (R)		Ovary (L)		Ovary		Uterus		Thyroid gland		Adrenal gland (R)		Adrenal gland (L)		Adrenal gland	
	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
F04037	55.9	0.177	53.2	0.169	109.1	0.346	548.3	1.741	15.4	0.049	51.5	0.163	40.6	0.129	92.1	0.292
F04038	33.1	0.103	51.9	0.161	85.0	0.264	583.2	1.812	7.4	0.023	28.7	0.089	31.4	0.098	60.1	0.187
F04039	56.8	0.180	48.2	0.153	105.0	0.333	671.8	2.131	16.8	0.053	41.2	0.131	45.6	0.145	86.8	0.275
F04040	46.2	0.160	57.5	0.199	103.7	0.359	598.8	2.075	16.2	0.056	40.4	0.140	40.5	0.140	80.9	0.280
F04041	48.2	0.149	35.2	0.109	83.4	0.257	560.9	1.729	14.0	0.043	33.0	0.102	39.4	0.121	72.4	0.223
F04042	53.4	0.176	46.5	0.153	99.9	0.329	534.2	1.760	15.1	0.050	38.4	0.127	45.6	0.150	84.0	0.277
F04043	57.5	0.174	55.3	0.167	112.8	0.341	615.5	1.858	10.5	0.032	32.7	0.099	35.1	0.106	67.8	0.205
F04044	45.0	0.148	55.7	0.183	100.7	0.331	595.4	1.955	19.7	0.065	29.3	0.096	27.2	0.089	56.5	0.185
F04045	63.9	0.195	60.1	0.184	124.0	0.379	812.1	2.482	19.0	0.058	52.1	0.159	58.5	0.179	110.6	0.338
F04046	57.6	0.180	49.9	0.156	107.5	0.336	675.8	2.113	16.0	0.050	43.2	0.135	41.5	0.130	84.7	0.265
F04047	78.3	0.256	50.1	0.164	128.4	0.421	661.1	2.165	17.4	0.057	40.0	0.131	42.8	0.140	82.8	0.271
F04048	51.4	0.167	44.9	0.146	96.3	0.313	665.7	2.164	11.2	0.036	30.0	0.098	29.1	0.095	59.1	0.192
Number of females	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12
Mean	53.9	0.172	50.7	0.162	104.7	0.334	626.9	1.999	14.9	0.048	38.4	0.123	39.8	0.127	78.2	0.249
S.D.	11.1	0.035	6.7	0.023	13.4	0.044	76.5	0.229	3.6	0.012	8.0	0.025	8.5	0.026	15.7	0.049
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Statistical method	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN	AN

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

KW: Analysis by Kruskal-Wallis' test (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 30-2-1. Organ weights of female rats at the end of the dosing period, satellite group

Control (vehicle: corn oil)																	
Female No.	Body weight (g)	Brain		Thymus		Heart		Liver		Kidney (R)		Kidney (L)		Kidney		Spleen	
		(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)		
F05049	319.7	1856.8	5.808	311.0	0.973	938.0	2.934	8134.4	25.444	947.0	2.962	912.9	2.855	1859.9	5.818	516.8	1.617
F05050	288.5	1775.5	6.154	285.8	0.991	856.4	2.968	7432.7	25.763	824.2	2.857	902.8	3.129	1727.0	5.986	670.3	2.323
F05051	344.6	1903.4	5.524	312.3	0.906	964.7	2.799	8450.5	24.523	986.7	2.863	958.4	2.781	1945.1	5.645	582.1	1.689
F05052	285.2	1742.7	6.110	344.9	1.209	836.4	2.933	6515.5	22.845	854.5	2.996	757.2	2.655	1611.7	5.651	441.1	1.547
F05053	286.1	1820.0	6.361	299.8	1.048	947.6	3.312	7342.4	25.664	849.0	2.967	794.8	2.778	1643.8	5.746	504.0	1.762
Number of females	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	
Mean	304.8	1819.7	5.991	310.8	1.025	908.6	2.989	7575.1	24.848	892.3	2.929	865.2	2.840	1757.5	5.769	542.9	1.788
S.D.	26.5	63.8	0.328	21.9	0.114	58.0	0.192	754.4	1.222	70.4	0.064	85.1	0.177	142.1	0.141	87.1	0.310

Control (vehicle: corn oil)																
Female No.	Ovary (R)		Ovary (L)		Ovary		Uterus		Thyroid gland		Adrenal gland (R)		Adrenal gland (L)		Adrenal gland	
	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
F05049	44.3	0.139	56.4	0.176	100.7	0.315	1138.5	3.561	8.8	0.028	40.1	0.125	41.7	0.130	81.8	0.256
F05050	45.5	0.158	39.4	0.137	84.9	0.294	1366.7	4.737	15.7	0.054	35.4	0.123	38.4	0.133	73.8	0.256
F05051	49.3	0.143	54.6	0.158	103.9	0.302	409.6	1.189	20.5	0.059	40.0	0.116	43.1	0.125	83.1	0.241
F05052	42.2	0.148	56.1	0.197	98.3	0.345	804.8	2.822	9.0	0.032	25.5	0.089	31.1	0.109	56.6	0.198
F05053	31.3	0.109	33.0	0.115	64.3	0.225	1014.9	3.547	10.5	0.037	26.3	0.092	30.1	0.105	56.4	0.197
Number of females	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	
Mean	42.5	0.139	47.9	0.157	90.4	0.296	946.9	3.171	12.9	0.042	33.5	0.109	36.9	0.120	70.3	0.230
S.D.	6.8	0.018	10.9	0.032	16.3	0.044	362.8	1.303	5.1	0.014	7.2	0.017	6.0	0.013	13.1	0.030

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 30-2-2. Organ weights of female rats at the end of the dosing period, satellite group

2-DT 1000 mg/kg															
Female No.	Body weight (g)	Brain		Thymus		Heart		Liver		Kidney (R)		Kidney (L)		Kidney	
		(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
F06059	287.4	1882.6	6.550	244.7	0.851	828.7	2.883	7352.0	25.581	889.3	3.094	854.3	2.973	1743.6	6.067
F06060	278.5	1987.1	7.135	380.7	1.367	899.5	3.230	7322.8	26.294	887.4	3.186	880.7	3.162	1768.1	6.349
F06061	249.4	1945.1	7.799	280.8	1.126	817.2	3.277	6715.4	26.926	823.5	3.302	793.9	3.183	1617.4	6.485
F06062	288.3	1880.1	6.521	291.3	1.010	982.4	3.408	6590.0	22.858	983.7	3.412	983.4	3.411	1967.1	6.823
F06063	244.8	1896.3	7.746	172.7	0.705	848.6	3.467	7199.8	29.411	782.0	3.194	801.2	3.273	1583.2	6.467
Number of females		5	5	5	5	5	5	5	5	5	5	5	5	5	
Mean	269.7	1918.2	7.150	274.0	1.012	875.3	3.253	7036.0	26.214	873.2	3.238	862.7	3.200	1735.9	6.438
S.D.	21.0	46.6	0.619	75.6	0.255	67.7	0.228	357.3	2.366	76.6	0.122	76.6	0.161	151.6	0.272
Significance	*	*	**	NS	NS	NS	NS	NS	NS	NS	**	NS	**	NS	NS
Statistical method	TT	TT	TT	AW	TT	TT	TT	TT	TT	TT	TT	TT	TT	TT	AW

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

TT: Analysis by Student's t-test.

AW: Analysis by Aspin-Welch t-test.

2-DT 1000 mg/kg																
Female No.	Ovary (R)		Ovary (L)		Ovary		Uterus		Thyroid gland		Adrenal gland (R)		Adrenal gland (L)		Adrenal gland	
	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
F06059	51.5	0.179	40.9	0.142	92.4	0.322	417.7	1.453	10.3	0.036	34.0	0.118	35.0	0.122	69.0	0.240
F06060	47.6	0.171	42.6	0.153	90.2	0.324	449.2	1.613	10.7	0.038	30.1	0.108	26.3	0.094	56.4	0.203
F06061	43.8	0.176	31.7	0.127	75.5	0.303	524.2	2.102	6.9	0.028	31.4	0.126	32.3	0.130	63.7	0.255
F06062	47.0	0.163	37.4	0.130	84.4	0.293	460.8	1.598	12.7	0.044	32.9	0.114	35.5	0.123	68.4	0.237
F06063	53.3	0.218	44.5	0.182	97.8	0.400	468.8	1.915	16.3	0.067	26.1	0.107	28.8	0.118	54.9	0.224
Number of females	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	
Mean	48.6	0.181	39.4	0.147	88.1	0.328	464.1	1.736	11.4	0.043	30.9	0.115	31.6	0.117	62.5	0.232
S.D.	3.8	0.021	5.0	0.022	8.5	0.042	38.8	0.265	3.5	0.015	3.1	0.008	4.0	0.014	6.6	0.020
Significance	NS	*	NS	NS	NS	NS	*	*	NS	NS	NS	NS	NS	NS	NS	
Statistical method	TT	TT	TT	TT	TT	TT	AW	AW	TT	TT	TT	TT	TT	TT	TT	

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

TT: Analysis by Student's t-test.

AW: Analysis by Aspin-Welch t-test.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 30-3-1. Organ weights of female rats at the end of the recovery period

Control (vehicle: corn oil)

Female No.	Body weight (g)	Brain		Thymus		Heart		Liver		Kidney (R)		Kidney (L)		Kidney		Spleen	
		(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
F05054	248.2	1880.8	7.578	245.5	0.989	747.2	3.010	6811.3	27.443	787.3	3.172	769.6	3.101	1556.9	6.273	511.4	2.060
F05055	291.5	1868.0	6.408	284.0	0.974	798.6	2.740	6830.7	23.433	796.8	2.733	771.7	2.647	1568.5	5.381	481.7	1.652
F05056	300.8	1891.5	6.288	176.1	0.585	856.6	2.848	6618.1	22.002	765.9	2.546	766.7	2.549	1532.6	5.095	530.5	1.764
F05057	286.0	1884.2	6.588	210.7	0.737	868.1	3.035	7171.8	25.076	923.1	3.228	931.5	3.257	1854.6	6.485	574.0	2.007
F05058	293.3	1863.0	6.352	183.2	0.625	855.7	2.917	6781.6	23.122	874.4	2.981	845.2	2.882	1719.6	5.863	602.8	2.055
Number of females	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Mean	284.0	1877.5	6.643	219.9	0.782	825.2	2.910	6842.7	24.215	829.5	2.932	816.9	2.887	1646.4	5.819	540.1	1.908
S.D.	20.7	11.8	0.535	45.0	0.191	51.4	0.121	202.2	2.113	66.5	0.290	72.0	0.298	137.6	0.585	48.5	0.188

Control (vehicle: corn oil)

Female No.	Ovary (R)		Ovary (L)		Ovary		Uterus		Thyroid gland		Adrenal gland (R)		Adrenal gland (L)		Adrenal gland	
	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
F05054	43.1	0.174	41.4	0.167	84.5	0.340	517.7	2.086	11.3	0.046	22.8	0.092	23.8	0.096	46.6	0.188
F05055	28.3	0.097	41.5	0.142	69.8	0.239	1359.8	4.665	21.3	0.073	26.8	0.092	28.1	0.096	54.9	0.188
F05056	45.6	0.152	33.7	0.112	79.3	0.264	382.3	1.271	15.4	0.051	24.1	0.080	24.7	0.082	48.8	0.162
F05057	65.4	0.229	40.5	0.142	105.9	0.370	709.7	2.481	22.4	0.078	34.3	0.120	33.6	0.117	67.9	0.237
F05058	43.2	0.147	41.7	0.142	84.9	0.289	604.7	2.062	15.1	0.051	27.7	0.094	32.1	0.109	59.8	0.204
Number of females	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Mean	45.1	0.160	39.8	0.141	84.9	0.300	714.8	2.513	17.1	0.060	27.1	0.096	28.5	0.100	55.6	0.196
S.D.	13.2	0.048	3.4	0.019	13.2	0.054	380.0	1.281	4.6	0.015	4.5	0.015	4.3	0.013	8.6	0.028

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 30-3-2. Organ weights of female rats at the end of the recovery period

2-DT 1000 mg/kg															
Female No.	Body weight (g)	Brain		Thymus		Heart		Liver		Kidney (R)		Kidney (L)		Kidney	
		(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
F06064	292.2	1852.9	6.341	154.2	0.528	896.7	3.069	6895.3	23.598	945.6	3.236	942.3	3.225	1887.9	6.461
F06065	312.0	2050.0	6.571	314.9	1.009	888.1	2.846	7750.8	24.842	892.2	2.860	894.3	2.866	1786.5	5.726
F06066	283.0	1818.9	6.427	261.3	0.923	906.9	3.205	7249.6	25.617	879.2	3.107	861.2	3.043	1740.4	6.150
F06067	281.6	2031.2	7.213	191.3	0.679	989.2	3.513	7171.7	25.468	967.2	3.435	915.3	3.250	1882.5	6.685
F06069	340.2	1916.2	5.633	423.9	1.246	954.4	2.805	8348.9	24.541	928.6	2.730	916.1	2.693	1844.7	5.422
Number of females		5	5	5	5	5	5	5	5	5	5	5	5	5	
Mean		301.8	1933.8	6.437	269.1	0.877	927.1	3.088	7483.3	24.813	922.6	3.074	905.8	3.015	
S.D.		24.7	103.7	0.565	106.5	0.281	43.2	0.289	574.1	0.810	36.6	0.284	30.2	0.238	
Significance		NS	NS	NS	NS	NS	**	NS	*	NS	*	NS	*	NS	
Statistical method		TT	AW	TT	TT	TT	TT	TT	TT	TT	TT	TT	TT	TT	

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

TT: Analysis by Student's t-test.

AW: Analysis by Aspin-Welch t-test.

2-DT 1000 mg/kg																
Female No.	Ovary (R)		Ovary (L)		Ovary		Uterus		Thyroid gland		Adrenal gland (R)		Adrenal gland (L)		Adrenal gland	
	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)	(mg)	(mg/g)
F06064	35.1	0.120	43.6	0.149	78.7	0.269	364.6	1.248	9.8	0.034	18.3	0.063	22.1	0.076	40.4	0.138
F06065	38.0	0.122	33.3	0.107	71.3	0.229	448.9	1.439	13.1	0.042	26.7	0.086	26.7	0.086	53.4	0.171
F06066	33.4	0.118	34.8	0.123	68.2	0.241	623.1	2.202	14.8	0.052	26.0	0.092	27.9	0.099	53.9	0.190
F06067	52.1	0.185	45.8	0.163	97.9	0.348	417.5	1.483	16.1	0.057	24.4	0.087	24.1	0.086	48.5	0.172
F06069	47.4	0.139	58.3	0.171	105.7	0.311	897.2	2.637	13.8	0.041	29.8	0.088	34.8	0.102	64.6	0.190
Number of females		5	5	5	5	5	5	5	5	5	5	5	5	5		
Mean		41.2	0.137	43.2	0.143	84.4	0.280	550.3	1.802	13.5	0.045	25.0	0.083	27.1	0.090	
S.D.		8.1	0.028	10.0	0.027	16.6	0.050	216.8	0.591	2.4	0.009	4.2	0.012	4.8	0.011	
Significance		NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS		
Statistical method		TT	TT	TT	TT	TT	TT	TT	TT	TT	TT	TT	TT	TT		

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

TT: Analysis by Student's t-test.

AW: Analysis by Aspin-Welch t-test.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 31-1. Macroscopic findings of male rats at the end of the dosing period

Findings	Group Animal No.	Control (vehicle: corn oil)	2-DT 62.5 mg/kg	2-DT 250 mg/kg	2-DT 1000 mg/kg
		M01 M01 M01 M01 M01 M01 001 002 003 004 005 006 007	M02 M02 M02 M02 M02 M02 M02 013 014 015 016 017 018 019	M03 M03 M03 M03 M03 M03 M03 025 026 027 028 029 030 031	M04 M04 M04 M04 M04 M04 M04 037 038 039 040 041 042 043
Forestomach					
Edematous, mucosa		- - - - -	- - - - -	- - - - -	P P - - - - -
Prostate					
Small		- - - - P	- - - - -	- - - - -	- - - - -
Seminal vesicle					
Small		- - - - P	- - - - -	- - - - -	- - - - -

Notes) - : No abnormal changes P : Non-graded change

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 31-2. Macroscopic findings of male rats at the end of the recovery period

Findings	Group	Control (vehicle: corn oil)		2-DT 1000 mg/kg									
		Animal No.		M01	M01	M01	M01	M01	M04	M04	M04	M04	M04
	All organs			008	009	010	011	012	044	045	046	047	048
		-	-	-	-	-	-	-	-	-	-	-	-

Notes) - : No abnormal changes P : Non-graded change

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 32-1. Macroscopic findings of female rats at the end of the dosing period

Notes) - : No abnormal changes P : Non-graded change

Fate : blanks, Subjected to autopsy on day 5 of lactation; NC, Not copulated.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats
Appendix 32-2. Macroscopic findings of female rats at the end of the dosing period, satellite group

Findings	Group	Control (vehicle: corn oil)					2-DT 1000 mg/kg				
		F05	F05	F05	F05	F05	F06	F06	F06	F06	F06
	Animal No.	049	050	051	052	053	059	060	061	062	063
Forestomach											
	Edematous, mucosa	-	-	-	-	-	-	-	P	-	-

Notes) - : No abnormal changes P : Non-graded change

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 32-3. Macroscopic findings of female rats at the end of the recovery period

Findings	Group	Control (vehicle: corn oil)					2-DT 1000 mg/kg				
		F05	F05	F05	F05	F05	F06	F06	F06	F06	F06
	Animal No.	054	055	056	057	058	064	065	066	067	069

All organs

Notes) - : No abnormal changes P : Non-graded change

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats
 Appendix 33. Histopathological findings of male rats at the end of the dosing period

Findings	Group Animal No.	Control (vehicle: corn oil)					2-DT 1000 mg/kg				
		M01 001	M01 002	M01 003	M01 004	M01 005	M04 037	M04 038	M04 039	M04 040	M04 041
Brain		-	-	-	-	-	-	-	-	-	-
Spinal cord		-	-	-	-	-	-	-	-	-	-
Pituitary gland		-	-	-	-	-	-	-	-	-	-
Submandibular gland		-	-	-	-	-	-	-	-	-	-
Cellular infiltration, lymphocyte, interstitial		-	-	-	±	-	-	-	-	-	-
Sublingual gland		-	-	-	-	-	-	-	-	-	-
Lymph node, submandibular		-	-	-	-	-	-	-	-	-	-
Thyroid gland		-	-	-	-	-	-	-	-	-	-
Ectopic thymic tissue		-	P	-	-	-	-	-	-	-	-
Parathyroid gland		-	-	M	-	-	-	-	-	-	-
Thymus		-	-	-	-	-	-	-	-	-	-
Heart		-	-	-	-	-	-	-	-	-	-
Degeneration/fibrosis, myocardial a)		±	-	-	-	-	-	-	-	±	-
Trachea		-	-	-	-	-	-	-	-	-	-
Lung		-	-	-	-	-	-	-	-	-	-
Accumulation, foam cell, alveolus		±	-	±	-	-	-	-	-	-	-
Bronchus		-	-	-	-	-	-	-	-	-	-
Liver		-	-	-	±	-	-	-	-	-	-
Cellular infiltration, lymphocyte, periportal		-	-	-	±	-	-	-	-	-	-
Fatty change, hepatocyte, periportal		-	-	-	±	-	-	-	±	-	-
Hematopoeisis, extramedullary		-	+	-	-	-	-	-	±	-	-
Microgranuloma		-	±	±	-	±	±	±	±	-	+
Necrosis, focal		-	-	-	-	-	-	-	-	-	+
Pancreas		-	-	-	-	-	-	-	-	-	-
Stomach		-	-	-	-	-	-	-	-	-	-
Cellular infiltration, mononuclear cell, submucosa, glandular stomach		±	-	-	-	±	-	-	-	-	-
Edema, lamina propria/ submucosa, forestomach		-	-	-	-	-	±	-	-	-	-
Duodenum		-	-	-	-	-	-	-	-	-	-
Jejunum		-	-	-	-	-	-	-	-	-	-

Notes) - : No abnormal changes ±: Very slight +: Slight 2+: Moderate 3+: Marked

P : Non-graded change NE: Not examined M: Missing A: Autolysis

a) right ventricle

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats
 Appendix 33(continued). Histopathological findings of male rats at the end of the dosing period

Findings	Group Animal No.	Control (vehicle: corn oil)					2-DT 1000 mg/kg				
		M01 001	M01 002	M01 003	M01 004	M01 005	M04 037	M04 038	M04 039	M04 040	M04 041
Ileum		-	-	-	-	-	-	-	-	-	-
Cecum		-	-	-	-	-	-	-	-	-	-
Colon		-	-	-	-	-	-	-	-	-	-
Rectum		-	-	-	-	-	-	-	-	-	-
Lymph node, mesenteric		-	-	-	-	-	-	-	-	-	-
Spleen		-	-	-	-	-	-	-	-	-	-
Deposit, pigment, brown		±	+	±	+	±	±	±	±	+	±
Hematopoiesis, extramedullary		+	+	+	+	±	+	2+	2+	±	±
Kidney		-	-	-	-	-	-	-	-	-	-
Basophilic tubule, cortex		±	±	±	-	±	±	±	-	±	-
Cast, hyalin, cortico-medullary junction/papilla		±	-	-	-	-	±	-	-	-	-
Eosinophilic body		-	-	-	-	-	-	±	-	-	-
Mineralization, cortex		-	-	±	-	-	-	-	-	-	-
Urinary bladder		-	-	-	-	-	-	-	-	-	-
Adrenal gland		-	-	-	-	-	-	-	-	-	-
Testis		-	-	-	-	-	-	-	-	-	-
Epididymis		-	-	-	-	-	-	-	-	-	-
Prostate		-	-	-	-	-	-	-	-	-	-
Cellular infiltration, lymphocyte, interstitial		-	-	-	-	±	-	-	-	±	±
Seminal vesicle		-	-	-	-	-	-	-	-	-	-
Coagulating gland		-	-	-	-	-	-	-	-	-	-
Eyeball		-	-	-	-	-	-	-	-	-	-
Harderian gland		-	-	-	-	-	-	-	-	-	-
Sciatic nerve		-	-	-	-	-	-	-	-	-	-
Skeletal muscle		-	-	-	-	-	-	-	-	-	-
Degeneration, muscle fiber, myogenic		-	-	±	-	-	-	-	-	-	-
Femur		-	-	-	-	-	-	-	-	-	-
Marrow, femur		-	-	-	-	-	-	-	-	-	-

Notes) - : No abnormal changes ±: Very slight +: Slight 2+: Moderate 3+: Marked

P : Non-graded change NE: Not examined M: Missing A: Autolysis

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 34-1. Histopathological findings of female rats at the end of the dosing period

Findings	Animal No.	Control (vehicle: corn oil)												2-DT 62.5 mg/kg		2-DT 250 mg/kg		2-DT 1000 mg/kg									
		F01 001	F01 002	F01 003	F01 004	F01 005	F01 006	F01 007	F01 008	F01 009	F01 010	F01 011	F01 012	F02 017	F03 027	F04 037	F04 038	F04 039	F04 040	F04 041	F04 042	F04 043	F04 044	F04 045	F04 046	F04 047	F04 048
		NC																									
Brain		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Spinal cord		-	-	-	-	-	-	-	-	-	-	-	-			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Pituitary gland		NE	-	NE	NE	-	NE	NE	NE	NE	-	-	-			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Remnant, Rathke's pouch		-	-	P	-	-	-	-	-	-	-	-	-			-	-	-	-	-	-	-	-	-	-	-	
Submandibular gland		NE	-	-	NE	NE	-	NE	NE	NE	NE	NE	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Sublingual gland		NE	-	-	NE	NE	-	NE	NE	NE	NE	NE	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Lymph node, submandibular		NE	-	-	NE	NE	-	NE	NE	NE	NE	NE	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Thyroid gland		NE	-	-	NE	NE	-	NE	NE	NE	NE	NE	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Ultimobranchial rest		-	P	-	-	-	-	-	-	-	-	-	P			-	-	-	-	-	-	-	-	-	-	-	
Parathyroid gland		NE	-	-	NE	NE	-	NE	NE	NE	NE	NE	M			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Thymus		-	-	NE	-	NE	-	NE	NE	NE	NE	NE	NE			-	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Heart		NE	-	NE	NE	-	NE			± b)	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE							
Degeneration/fibrosis, myocardial		± a)	-	-	-	-	-	-	-	-	-	-	-			± b)	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Trachea		NE	-	NE	NE	-	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE							
Lung		-	NE	-	NE	NE	-	NE	NE	NE	NE	NE	NE			-	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Accumulation, foam cell, alveolus		±	-	-	-	-	-	-	-	-	-	-	±			±	-	-	±	-	±	-	±	-	-	-	
Bronchus		NE	-	NE	NE	-	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE							
Liver		NE	-	NE	NE	-	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE							
Fatty change, hepatocyte, periportal		±	-	-	-	-	-	-	-	-	-	-	-			-	-	-	-	-	-	-	-	-	-	-	
Hematopoiesis, extramedullary		-	-	±	-	-	-	-	-	-	-	-	-			-	±	-	-	-	-	-	-	-	-	-	
Microgranuloma		-	-	±	-	-	-	-	-	-	-	-	-			±	-	-	±	-	±	-	-	-	-	-	
Necrosis, focal		-	±	-	-	-	-	-	-	-	-	-	-			-	±	-	-	-	-	-	-	-	-	-	
Pancreas		NE	-	NE	NE	-	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE							
Stomach		-	NE	-	NE	NE	-	NE	NE	NE	NE	NE	NE			-	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Dilatation, lumen, fundic gland, focal, glandular stomach		±	-	-	-	-	-	-	-	-	-	-	-			±	-	-	-	-	-	-	-	-	-	-	
Edema, lamina propria/submucosa, forestomach		-	-	-	-	-	-	-	±	-	-	-	-			-	-	-	-	-	-	-	-	-	-	-	
Erosion, focal, glandular stomach		-	-	-	-	-	-	-	±	-	-	±	-			-	-	-	±	-	-	-	-	-	-	-	
Duodenum		NE	-	NE	NE	-	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE							
Jejunum		NE	-	NE	NE	-	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE							

Notes) - : No abnormal changes ±: Very slight +: Slight 2+: Moderate 3+: Marked

P : Non-graded change NE: Not examined M: Missing A: Autopsy

a), septa; b), left ventricle

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 34-1(continued). Histopathological findings of female rats at the end of the dosing period

Findings	Group Animal No.	Control (vehicle: corn oil)										2-DT 62.5 mg/kg		2-DT 250 mg/kg		2-DT 1000 mg/kg											
		F01 001	F01 002	F01 003	F01 004	F01 005	F01 006	F01 007	F01 008	F01 009	F01 010	F01 011	F01 012	F02 017	F03 027	F04 037	F04 038	F04 039	F04 040	F04 041	F04 042	F04 043	F04 044	F04 045	F04 046	F04 047	F04 048
		NC												NC													
Ileum		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	-	-	-	-	-	-	-	-	-	-	-	NE	
Cecum		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	NE	
Colon		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	NE	
Rectum		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	NE	
Lymph node, mesenteric		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	NE	
Spleen		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	-	-	-	-	-	-	-	-	-	-	-	NE	
Deposit, pigment, brown		+	±	±	+	+	+	+	+	+	+	+	+	-	±	±	+	+	+	+	+	+	+	+	+	±	
Hematopoiesis, extramedullary		+	2+	2+	+	+	+	+	+	2+	2+	2+	2+	-	+	2+	2+	2+	+	+	+	+	+	+	+	2+	
Kidney		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	-	-	-	-	-	-	-	-	-	-	-	NE	
Basophilic tubule, cortex		-	-	±	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	±	
Cellular infiltration, lymphocyte, interstitial		-	-	-	-	-	-	-	-	-	-	-	-	-	±	-	-	-	-	-	-	-	-	-	-	-	
Dilatation, pelvis, unilateral		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Mineralization		-	-	± c)	-	-	-	-	-	-	-	-	-	-	-	-	± d)	-	-	-	-	-	-	-	-	-	
Urinary bladder		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	-	-	-	-	-	-	-	-	-	-	-	NE	
Cellular infiltration, inflammatory, lamina propria		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	±	
Adrenal gland		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	-	-	-	-	-	-	-	-	-	-	-	NE	
Ovary		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	-	-	-	-	-	-	-	-	-	-	-	NE	
Cyst, follicular		-	-	-	-	-	-	-	-	-	-	-	-	-	±	-	-	-	-	-	-	-	-	-	-	-	-
Uterus		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	-	-	-	-	-	-	-	-	-	-	-	NE	
Vagina		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	-	-	-	-	-	-	-	-	-	-	-	NE	
Eyeball		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	-	-	-	-	-	-	-	-	-	-	-	NE	
Harderian gland		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	-	-	-	-	-	-	-	-	-	-	-	NE	
Sciatic nerve		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	-	-	-	-	-	-	-	-	-	-	-	NE	
Skeletal muscle		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	-	-	-	-	-	-	-	-	-	-	-	NE	
Degeneration, muscle fiber, myogenic		±	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Femur		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	-	-	-	-	-	-	-	-	-	-	-	NE	
Marrow, femur		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	-	-	-	-	-	-	-	-	-	-	-	NE	
Hematopoiesis, increased		-	±	±	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	±	

Notes) - : No abnormal changes ±: Very slight +: Slight 2+: Moderate 3+: Marked

P : Non-graded change NE: Not examined M: Missing A: Autolysis

c) cortex-medullary junction, d) papilla

NC, Not copulated

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats
 Appendix 34-2. Histopathological findings of female rats at the end of the dosing period, satellite group

Findings	Group	Control (vehicle: corn oil)					2-DT 1000 mg/kg				
		F05 049	F05 050	F05 051	F05 052	F05 053	F06 059	F06 060	F06 061	F06 062	F06 063
Brain		-	-	-	-	-	-	-	-	-	-
Spinal cord		-	-	-	-	-	-	-	-	-	-
Pituitary gland											
Remnant, Rathke's pouch		-	-	-	-	P	-	P	P	-	P
Submandibular gland		-	-	-	-	-	-	-	-	-	-
Sublingual gland		-	-	-	-	-	-	-	-	-	-
Lymph node, submandibular		-	-	-	-	-	-	-	-	-	-
Thyroid gland											
Ultimobranchial rest		P	-	-	-	P	-	P	-	-	-
Parathyroid gland		-	-	-	-	-	-	-	-	-	-
Thymus		-	-	-	-	-	-	-	-	-	-
Heart											
Degeneration/fibrosis, myocardial		-	± a)	-	-	-	-	-	-	-	-
Trachea		-	-	-	-	-	-	-	-	-	-
Lung											
Accumulation, foam cell, alveolus		-	±	-	-	-	-	±	±	-	±
Microgranuloma		-	-	-	-	-	-	-	±	±	-
Bronchus		-	-	-	-	-	-	-	-	-	-
Liver											
Microgranuloma		±	±	-	±	±	±	±	±	±	±
Pancreas		-	-	-	-	-	-	-	-	-	-
Stomach		-	-	-	-	-	-	-	-	-	-
Duodenum		-	-	-	-	-	-	-	-	-	-

Notes) - : No abnormal changes ±: Very slight +: Slight 2+: Moderate 3+: Marked

P : Non-graded change NE: Not examined M: Missing A: Autolysis

a) left ventricle

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats
 Appendix 34-2(continued). Histopathological findings of female rats at the end of the dosing period, satellite group

Findings	Group	Control (vehicle: corn oil)					2-DT 1000 mg/kg				
		F05 049	F05 050	F05 051	F05 052	F05 053	F06 059	F06 060	F06 061	F06 062	F06 063
Jejunum		-	-	-	-	-	-	-	-	-	-
Ileum		-	-	-	-	-	-	-	-	-	-
Cecum		-	-	-	-	-	-	-	-	-	-
Colon		-	-	-	-	-	-	-	-	-	-
Rectum		-	-	-	-	-	-	-	-	-	-
Lymph node, mesenteric		-	-	-	-	-	-	-	-	-	-
Spleen		-	-	-	-	-	-	-	-	-	-
Deposit, pigment, brown		+	±	+	+	+	±	+	±	±	+
Hematopoiesis, extramedullary		±	±	+	±	+	+	±	+	±	+
Kidney		-	-	-	-	-	-	-	-	-	-
Basophilic tubule, cortex		±	-	-	-	-	-	-	-	±	-
Mineralization, papilla		-	-	-	±	-	-	-	-	-	-
Urinary bladder		-	-	-	-	-	-	-	-	-	-
Adrenal gland		-	-	-	-	-	-	-	-	-	-
Ovary		-	-	-	-	-	-	-	-	-	-
Uterus		-	-	-	-	-	-	-	-	-	-
Dilatation, lumen		-	+	-	+	+	-	-	-	-	-
Vagina		-	-	-	-	-	-	-	-	-	-
Eyeball		-	-	-	-	-	-	-	-	-	-
Harderian gland		-	-	-	-	-	-	-	-	-	-
Sciatic nerve		-	-	-	-	-	-	-	-	-	-
Skeletal muscle		-	-	-	-	-	-	-	-	-	-
Femur		-	-	-	-	-	-	-	-	-	-
Marrow, femur		-	-	-	-	-	-	-	-	-	-

Notes) - : No abnormal changes ±: Very slight +: Slight 2+: Moderate 3+: Marked

P : Non-graded change NE: Not examined M: Missing A: Autolysis

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 35-1. Results of observations about estrous cycle

Control (vehicle: corn oil)

Animal no.	Pre-mating period						Mating period			Times of vaginal estrus observed	
	Pre-treatment period			Treatment period							
	Stage	Type	Mean length (days)	Stage	Type	Mean length (days)	Stage				
F01001	E D D D P E D D P E D D D E	4-5-day	4.3	D D D E D D D E E D D P E D	4-5-day	4.5	D P PL		1		
F01002	D P E D D P E D D P E D D P	4-day	4.0	E D D P E D D D E D D P E D	4-day	4.0	D P PL		1		
F01003	E D D P E D D P E D D P E D	4-day	4.0	D D E D D D E D D P E D D D	4-day	4.0	PL		1		
F01004	E D D P E D D P E D D P E D	4-day	4.0	D P E D D D E D D P E D D P	4-day	4.0	PL		1		
F01005	D D P E D D D E D D D E D D	4-day	4.0	P E D D P E D D P E D D D E	4-day	4.0	D D P E D D D D D D D D D D D				
F01006	D D P E D D D P E D D D E E	5-day	5.0	D D D E E D D D D D D D D D	Irregular		D D P PL		1		
F01007	D D D P E D D P E D D D E D	4-day	4.0	D D E E D D D E D D P E D D	4-day	4.0	P PL		1		
F01008	D D P E D D P E D D P E D D	4-day	4.0	P E D D P E D D P E D D P E	4-day	4.0	D D P PL		1		
F01009	E D D P E D D P E D D P E D	4-day	4.0	D P E D D P E D D P E D D P	4-day	4.0	PL		1		
F01010	D D D E E D D P E D D P E D	4-day	4.0	D P E D D D E D D D E D D P	4-day	4.0	PL		1		
F01011	D P E E D D P E D D P E D D	4-day	4.0	P E D D P E D D D E D D P E	4-day	4.0	D D P PL		1		
F01012	P E D D P E D D P E D D D E	4-day	4.0	D D P E D D P E D D P E D D	4-day	4.0	P PL		1		
Mean			4.1			4.0			1.0		
S.D.			0.3			0.2			0.0		
(N)			(12)			(11)			(11)		

D, diestrus; P, proestrus; E, estrus; PL, vaginal plug

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 35-2. Results of observations about estrous cycle

2-DT 62.5 mg/kg

Animal no.	Pre-mating period						Mating period			Times of vaginal estrus observed	
	Pre-treatment period		Type	Mean length (days)	Treatment period		Type	Mean length (days)	Stage		
	Stage	Type			Stage	Type					
F02013	P E D D D E D D D E E D D P	4-5-day	4.5	E D D D P E D D D P E D D D	5-day	5.0	E PL			1	
F02014	D D E D D D E D D D E D D D	4-day	4.0	E D D P E D D D E D D P E D	4-day	4.0	D P PL			1	
F02015	E D D P E D D P E D D P E D	4-day	4.0	D D E D D P E D D P E D D P	4-day	4.0	PL			1	
F02016	D D P E D D P E D D P E D D	4-day	4.0	P E D D P E D D P E D D D D	Irregular	4.0	P PL			1	
F02017	P E D D D P E D D D D E D D	5-day	5.0	D P E D D D P E D D D P E D	5-day	5.0	D P PL			1	
F02018	E D D P E D D D E D D D E D	4-day	4.0	D D E D D D E D D D E D D D	4-day	4.0	PL			1	
F02019	E D D P E D D P E D D P E D	4-day	4.0	D P E D D D E D D D E D D D	4-day	4.0	PL			1	
F02020	D D D P E D D P E D D D E D	4-day	4.0	D D E D D D E D D D E E D D	4-5-day	4.5	P PL			1	
F02021	D P E D D P E D D P E D D P	4-day	4.0	E D D P E D D P E D D P E D	4-day	4.0	D P PL			1	
F02022	D D D D E D D D D E D D D P	5-day	5.0	E D D D P E D D D P E D D D	5-day	5.0	P PL			1	
F02023	D D P E D D P E D D D E D D	4-day	4.0	D E D D P E D D P E D D P E	4-day	4.0	D D P PL			1	
F02024	P E D D D E D D D D E D D D E	4-day	4.0	D D D E D D D E D D D E D D	4-day	4.0	D PL			1	
Mean			4.2				4.3			1.0	
S.D.			0.4				0.5			0.0	
(N)			(12)				(12)			(12)	

D, diestrus; P, proestrus; E, estrus; PL, vaginal plug

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 35-3. Results of observations about estrous cycle

2-DT 250 mg/kg

Animal no.	Pre-mating period						Mating period		Times of vaginal estrus observed	
	Pre-treatment period		Type	Mean length (days)	Treatment period		Type	Mean length (days)		
	Stage	Type			Stage	Type				
F03025	D D D D E D D D P E D D D P	5-day	5.0	E D D D D D D D D E D D D E	Irregular	6.5	PL		1	
F03026	E D D D D E D D D P E D D D	5-day	5.0	P E D D P E E D D D E E D D	5-day	5.0	P PL		1	
F03027	D P E D D P E D D D P E D D	4-5-day	4.5	D E E D D D E E D D P E E D	5-day	5.0	D P PL		1	
F03028	E D D D D E D D P E E D D P	5-day	5.0	E E D D P E E D D D P E D D	5-day	5.0	D PL		1	
F03029	D D P E D D D E D D D E D D	4-day	4.0	P E D D P E D D D E D D P E	4-day	4.0	D D D P D D D D D D D D D PL		1	
F03030	D P E D D P E D D P E D D P	4-day	4.0	E D D D E D D D E D D P E D	4-day	4.0	D P PL		1	
F03031	D P E D D P E D D P E D D D	4-day	4.0	E D D P E D D D P E D D P E	4-5-day	4.3	D D D PL		1	
F03032	D E D D P E E D D P E D D D	4-5-day	4.5	P E D D P E D D D P E E D D	Irregular	5.0	D E PL		1	
F03033	E D D D P E D D D P E D D D	5-day	5.0	P E D D D P E D D D P E D D	5-day	5.0	D E PL		1	
F03034	D P E D D P E D D P E D D P	4-day	4.0	E D D P E D D D E D D P E D	4-day	4.0	D P PL		1	
F03035	E D D P E D D P E D D P E D	4-day	4.0	D D E D D P E D D P E D D D	4-day	4.0	PL		1	
F03036	D D D E D D D E D D D E D D	4-day	4.0	D E D D D P E D D D E D D P	4-5-day	4.5	PL		1	
Mean			4.4			4.7	**		1.0	
S.D.			0.5			0.7			0.0	
(N)			(12)			(12)			(12)	

D, diestrus; P, proestrus; E, estrus; PL, vaginal plug

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 35-4. Results of observations about estrous cycle

2-DT 1000 mg/kg

Animal no.	Pre-mating period						Mating period		Times of vaginal estrus observed	
	Pre-treatment period		Type	Mean length (days)	Treatment period		Stage			
	Stage	Type			Stage	Type	Stage			
F04037	E D D P E D D P E D D P E D	4-day	4.0	D P E D D D E D D D E D D P	4-day	4.0	PL		1	
F04038	E D D P E D D P E D D P E D	4-day	4.0	D P E D D P E D D P E D D P	4-day	4.0	PL		1	
F04039	D D D D E D D P E E D D D P	5-day	5.0	E D D P E E D D P E D D D P	4-5-day	4.5	PL		1	
F04040	P E D D D E D D P E D D D E	4-day	4.0	D D D E D D D E D D P E D D	4-day	4.0	P PL		1	
F04041	E D D P E D D P E D D P E D	4-day	4.0	D D E D D P E D D P E D D P	4-day	4.0	PL		1	
F04042	D D P E D D P E D D P E D D	4-day	4.0	P E D D P E D D P E D D D E	4-day	4.0	D D D PL		1	
F04043	D E D D P E D D D E D D P E	4-day	4.0	D D D E D D D E D D P E D D	4-day	4.0	P PL		1	
F04044	E D D P E D D P E D D P E D	4-day	4.0	D D E D D P E D D D E D D D	4-day	4.0	PL		1	
F04045	P E D D P E D D P E D D P E	4-day	4.0	D D D E D D D E D D P E D D	4-day	4.0	P PL		1	
F04046	P E D D P E D D P E D D P E	4-day	4.0	D D D E D D P E D D P E D D	4-day	4.0	P PL		1	
F04047	D P E D D P E D D P E D D P	4-day	4.0	E D D P E D D P E D D P E D	4-day	4.0	D P PL		1	
F04048	D D P E D D D E D D P E D D	4-day	4.0	D E D D D E D D D E D D D E	4-day	4.0	D D P PL		1	
Mean			4.1			4.0			1.0	
S.D.			0.3			0.1			0.0	
(N)			(12)			(12)			(12)	

D, diestrus; P, proestrus; E, estrus; PL, vaginal plug

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 36-1. Results of observations about reproductive performance

Control (vehicle: corn oil)

Male no.	Female no.	Copulation	Conception	Pairing days until copulation
M01001	F01001	+	+	3
M01002	F01002	+	+	3
M01003	F01003	+	+	1
M01004	F01004	+	+	1
M01005	F01005	-		
M01006	F01006	+	+	4
M01007	F01007	+	+	2
M01008	F01008	+	+	4
M01009	F01009	+	+	1
M01010	F01010	+	+	1
M01011	F01011	+	+	4
M01012	F01012	+	+	2
Total		+; 11, -; 1	+; 11, -; 0	
Mean				2.4
S.D.				1.3
(N)				(11)

+, confirmed

-, not confirmed

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 36-2. Results of observations about reproductive performance

2-DT 62.5 mg/kg

Male no.	Female no.	Copulation	Conception	Pairing days until copulation
M02013	F02013	+	+	2
M02014	F02014	+	+	3
M02015	F02015	+	+	1
M02016	F02016	+	+	2
M02017	F02017	+	+	3
M02018	F02018	+	+	1
M02019	F02019	+	+	1
M02020	F02020	+	+	2
M02021	F02021	+	+	3
M02022	F02022	+	+	2
M02023	F02023	+	+	4
M02024	F02024	+	+	2
Total		+: 12, -: 0	+: 12, -: 0	
Mean				2.2
S.D.				0.9
(N)				(12)

+, confirmed

-, not confirmed

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 36-3. Results of observations about reproductive performance

2-DT 250 mg/kg

Male no.	Female no.	Copulation	Conception	Pairing days until copulation
M03025	F03025	+	+	1
M03026	F03026	+	+	2
M03027	F03027	+	+	3
M03028	F03028	+	+	2
M03029	F03029	+	+	14
M03030	F03030	+	+	3
M03031	F03031	+	+	4
M03032	F03032	+	+	3
M03033	F03033	+	+	3
M03034	F03034	+	+	3
M03035	F03035	+	+	1
M03036	F03036	+	+	1
Total		+: 12, -: 0	+: 12, -: 0	
Mean				3.3
S.D.				3.5
(N)				(12)

+, confirmed

-, not confirmed

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 36-4. Results of observations about reproductive performance

2-DT 1000 mg/kg

Male no.	Female no.	Copulation	Conception	Pairing days until copulation
M04037	F04037	+	+	1
M04038	F04038	+	+	1
M04039	F04039	+	+	1
M04040	F04040	+	+	2
M04041	F04041	+	+	1
M04042	F04042	+	+	4
M04043	F04043	+	+	2
M04044	F04044	+	+	1
M04045	F04045	+	+	2
M04046	F04046	+	+	2
M04047	F04047	+	+	3
M04048	F04048	+	+	4
Total		+: 12, -: 0	+: 12, -: 0	
Mean				2.0
S.D.				1.1
(N)				(12)

+, confirmed

-, not confirmed

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 37-1. Observation of offspring (F_1)

Dam No.	Gestation length (days)	Number of corpora lutea	Number of implantation scars	Implantation index (%)	Delivery index (dams)	Number of offspring at birth					Delivery index (offspring)	Birth index	Live birth index	Number of live offspring			External abnormalities ^{b)}		
						Number of offspring	Sex ratio			Dead offspring (%)	Male (%)	Female (%)	Ratio (%)	4 days (%)	Sex ratio (%)	Viability index (%)	(Number)	(%)	
							Male	Female	Total										
F01001	22	17	17	100.0	+	14	10	4	14	0.71	0	82.4	82.4	100.0	10	4	0.71	100.0	0 0.0
F01002	22	17	17	100.0	+	15	5	10	15	0.33	0	88.2	88.2	100.0	5	10	0.33	100.0	0 0.0
F01003	22	12	12	100.0	+	12	7	5	12	0.58	0	100.0	100.0	100.0	7	5	0.58	100.0	0 0.0
F01004	22	18	16	88.9	+	16	4	12	16	0.25	0	100.0	100.0	100.0	4	12	0.25	100.0	0 0.0
F01005	Not copulated																		
F01006	23	18	18	100.0	+	14	2	10	12	0.17	2	77.8	66.7	85.7	2	10	0.17	100.0	0 0.0
F01007	22	15	14	93.3	+	13	10	2	12	0.83	1	92.9	85.7	92.3	10	2	0.83	100.0	0 0.0
F01008	22	17	17	100.0	+	17	10	7	17	0.59	0	100.0	100.0	100.0	10	7	0.59	100.0	0 0.0
F01009	22	15	15	100.0	+	13	8	5	13	0.62	0	86.7	86.7	100.0	7	5	0.58	92.3	0 0.0
F01010	22	15	15	100.0	+	14	8	6	14	0.57	0	93.3	93.3	100.0	8	6	0.57	100.0	0 0.0
F01011	22	14	14	100.0	+	14	8	6	14	0.57	0	100.0	100.0	100.0	8	6	0.57	100.0	0 0.0
F01012	22	14	14	100.0	+	14	7	6	13	0.54	1	100.0	92.9	92.9	7	6	0.54	100.0	0 0.0
Number of dams	11	11	11	11	11 ^{a)}	11			11	11	11	11	11	11		11	11	11 11	
Total		172	169			156	79	73	152		4				78	73		0	
Mean	22.1	15.6	15.4	98.4		14.2	7.2	6.6	13.8	0.52	0.4	92.8	90.5	97.4	7.1	6.6	0.52	99.3	0.0
S.D.	0.3	1.9	1.8	3.7		1.4	2.6	2.9	1.7	0.20	0.7	8.1	10.2	4.9	2.6	2.9	0.20	2.3	0.0
%						100.0													

+: Dams with live offspring, -: dams without live offspring.

a): Number of dams with live offspring.

b): Number of external abnormalities in live offspring at birth.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 37-2. Observation of offspring (F₁)

2-DT 62.5 mg/kg																				
Dam No.	Gestation length (days)	Number of corpora lutea	Number of implan-tation scars (%)	Implan-tation index (%)	Delivery index (dams)	Number of offspring at birth					Delivery index	Birth index	Live birth index	Number of live offspring			External abnormalities ^{b)}			
						Number of offspring	Sex ratio			Dead offspring (%)	Male (%)	Female (%)	Total (%)	4 days Sex ratio			Viability index (%)	(Number)	(%)	
							Male	Female	Total					Male	Female					
F02013	22	16	16	100.0	+	15	8	7	15	0.53	0	93.8	93.8	100.0	7	7	0.50	93.3	0	0.0
F02014	22	19	19	100.0	+	17	8	9	17	0.47	0	89.5	89.5	100.0	8	8	0.50	94.1	0	0.0
F02015	22	15	15	100.0	+	15	9	6	15	0.60	0	100.0	100.0	100.0	9	6	0.60	100.0	0	0.0
F02016	22	17	17	100.0	+	16	7	9	16	0.44	0	94.1	94.1	100.0	7	9	0.44	100.0	0	0.0
F02017	22	16	16	100.0	+	15	6	7	13	0.46	2	93.8	81.3	86.7	6	7	0.46	100.0	0	0.0
F02018	22	14	13	92.9	+	11	6	5	11	0.55	0	84.6	84.6	100.0	6	5	0.55	100.0	0	0.0
F02019	23	16	16	100.0	+	14	9	5	14	0.64	0	87.5	87.5	100.0	9	5	0.64	100.0	0	0.0
F02020	22	16	16	100.0	+	14	10	4	14	0.71	0	87.5	87.5	100.0	10	4	0.71	100.0	0	0.0
F02021	23	16	16	100.0	+	16	4	9	13	0.31	3	100.0	81.3	81.3	4	9	0.31	100.0	0	0.0
F02022	22	11	11	100.0	+	11	7	4	11	0.64	0	100.0	100.0	100.0	7	4	0.64	100.0	0	0.0
F02023	22	20	19	95.0	+	19	8	11	19	0.42	0	100.0	100.0	100.0	8	11	0.42	100.0	0	0.0
F02024	22	16	16	100.0	+	13	8	5	13	0.62	0	81.3	81.3	100.0	8	5	0.62	100.0	0	0.0
Number of dams	12	12	12	12	12 ^{a)}	12	12	12	12	12	12	12	12	12	12	12	12	12	12	
Total		192	190			176	90	81	171		5				89	80			0	
Mean	22.2	16.0	15.8	99.0		14.7	7.5	6.8	14.3	0.53	0.4	92.7	90.1	97.3	7.4	6.7	0.53	99.0	0.0	
S.D.	0.4	2.3	2.2	2.4		2.3	1.6	2.3	2.3	0.12	1.0	6.6	7.4	6.3	1.6	2.2	0.11	2.5	0.0	
%					100.0															
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS		
Statistical method	AN	AN	AN	AN	AN	KW	AN	AN	AN	AN	KW	KW	KW	KW	AN	AN	AN	AN		

Significantly different from the control group (*: P<0.05, **: P<0.01).

+: Dams with live offspring, -: dams without live offspring.

a): Number of dams with live offspring.

b): Number of external abnormalities in live offspring at birth.

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 37-3. Observation of offspring (F_1)

Dam No.	Gestation length (days)	Number of corpora lutea	Number of implantation scars	Implantation index (%)	Delivery index (dams %)	Number of offspring at birth			Delivery index (offspring %)	Birth index (%)	Live birth index (%)	Number of live offspring			External abnormalities ^{b)}					
						Number of offspring						Male	Female	Total	Male	Female				
						Live	Dead	offspring				(%)	(%)	(%)	(%)	(%)				
F03025	23	17	15	88.2	+	14	6	8	14	0.43	0	93.3	93.3	100.0	6	8	0.43	100.0	0	0.0
F03026	22	15	15	100.0	+	14	4	10	14	0.29	0	93.3	93.3	100.0	4	10	0.29	100.0	0	0.0
F03027	22	17	17	100.0	+	17	3	14	17	0.18	0	100.0	100.0	100.0	3	14	0.18	100.0	0	0.0
F03028	22	20	20	100.0	+	20	5	15	20	0.25	0	100.0	100.0	100.0	5	15	0.25	100.0	0	0.0
F03029	22	12	11	91.7	+	11	5	5	10	0.50	1	100.0	90.9	90.9	5	5	0.50	100.0	0	0.0
F03030	22	15	15	100.0	+	14	9	5	14	0.64	0	93.3	93.3	100.0	9	5	0.64	100.0	0	0.0
F03031	22	16	15	93.8	+	15	7	8	15	0.47	0	100.0	100.0	100.0	7	8	0.47	100.0	0	0.0
F03032	22	19	19	100.0	+	17	8	9	17	0.47	0	89.5	89.5	100.0	0	1	5.9	0	0.0	
F03033	22	15	15	100.0	+	13	5	8	13	0.38	0	86.7	86.7	100.0	5	8	0.38	100.0	0	0.0
F03034	21	18	17	94.4	+	16	8	8	16	0.50	0	94.1	94.1	100.0	8	8	0.50	100.0	0	0.0
F03035	22	14	14	100.0	+	13	7	6	13	0.54	0	92.9	92.9	100.0	7	6	0.54	100.0	0	0.0
F03036	23	19	19	100.0	+	18	10	8	18	0.56	0	94.7	94.7	100.0	10	8	0.56	100.0	0	0.0
Number of dams	12	12	12	12	12 ^{a)}	12	12	12	12	12	12	12	12	12	11	12	12	12	12	
Total		197	192			182	77	104	181	1					69	96		0		
Mean	22.1	16.4	16.0	97.3		15.2	6.4	8.7	15.1	0.43	0.1	94.8	94.1	99.2	5.8	8.0	0.43	92.2	0.0	
S.D.	0.5	2.4	2.5	4.2		2.5	2.1	3.1	2.7	0.14	0.3	4.4	4.2	2.6	2.7	3.8	0.14	27.2	0.0	
%					100.0															
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS		
Statistical method	AN	AN	AN	AN	AN	KW	AN	AN	AN	KW	KW	KW	KW	AN	AN	AN	KW	AN		

Significantly different from the control group (*: P<0.05, **: P<0.01).

+: Dams with live offspring, -: dams without live offspring.

a): Number of dams with live offspring.

b): Number of external abnormalities in live offspring at birth.

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

KW: Analysis by Kruskal-Wallis' test (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 37-4. Observation of offspring (F_1)

2-DT 1000 mg/kg

Dam No.	Gestation length (days)	Number of corpora lutea	Number of implantation scars	Implantation index (%)	Delivery index (dams %)	Number of offspring at birth			Delivery index (offspring %)	Birth index (%)	Live birth index (%)	Number of live offspring			External abnormalities ^{b)}				
						Number of offspring						Male (%)	Female (%)	Ratio (%)	(Number) (%)	(%)			
						Male	Female	Total				Male	Female	Ratio					
F04037	22	15	14	93.3	+	13	7	6	13	0.54	0	92.9	92.9	100.0	7	6			
F04038	22	13	13	100.0	+	13	8	5	13	0.62	0	100.0	100.0	100.0	8	4			
F04039	21	17	17	100.0	+	17	13	4	17	0.76	0	100.0	100.0	100.0	13	4			
F04040	22	19	19	100.0	+	17	11	6	17	0.65	0	89.5	89.5	100.0	11	6			
F04041	22	15	14	93.3	+	14	9	5	14	0.64	0	100.0	100.0	100.0	9	5			
F04042	22	16	16	100.0	+	16	9	7	16	0.56	0	100.0	100.0	100.0	9	7			
F04043	22	18	18	100.0	+	14	10	4	14	0.71	0	77.8	77.8	100.0	10	4			
F04044	22	15	14	93.3	+	12	3	9	12	0.25	0	85.7	85.7	100.0	3	9			
F04045	21	20	19	95.0	+	18	9	9	18	0.50	0	94.7	94.7	100.0	9	9			
F04046	23	20	20	100.0	+	20	11	9	20	0.55	0	100.0	100.0	100.0	10	9			
F04047	22	15	15	100.0	+	14	11	2	13	0.85	1	93.3	86.7	92.9	11	2			
F04048	22	15	15	100.0	+	6	3	3	6	0.50	0	40.0	40.0	100.0	3	3			
Number of dams	12	12	12	12	12 ^{a)}	12			12	12	12	12	12	12	12	12			
Total		198	194			174	104	69	173		1			103	68	0			
Mean	21.9	16.5	16.2	97.9		14.5	8.7	5.8	14.4	0.59	0.1	89.5	88.9	99.4	8.6	5.7	0.60		
S.D.	0.5	2.3	2.4	3.1		3.6	3.1	2.4	3.6	0.15	0.3	17.1	17.0	2.0	3.0	2.4	0.15		
%					100.0														
Significance	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS		
Statistical method	AN	AN	AN	AN	AN	KW	AN	AN	AN	KW	KW	KW	KW	AN	AN	KW	AN		

Significantly different from the control group (*: P<0.05, **: P<0.01).

+: Dams with live offspring, -: dams without live offspring.

a): Number of dams with live offspring.

b): Number of external abnormalities in live offspring at birth.

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

KW: Analysis by Kruskal-Wallis' test (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 38-1. Body weights of offspring (F₁) before weaning

Control (vehicle: corn oil)

Dam No.	Days after birth					
	Male body weight		Female body weight		0	4
	0	4	0	4		
F01001	7.2 (10)	11.3 (10)	6.8 (4)	11.8 (4)		
F01002	6.4 (5)	10.3 (5)	5.9 (10)	10.0 (10)		
F01003	7.2 (7)	12.9 (7)	6.7 (5)	11.7 (5)		
F01004	6.7 (4)	10.1 (4)	6.2 (12)	9.5 (12)		
F01006	8.4 (2)	12.6 (2)	7.8 (10)	12.3 (10)		
F01007	6.6 (10)	9.8 (10)	6.6 (2)	10.0 (2)		
F01008	6.1 (10)	10.0 (10)	5.6 (7)	9.0 (7)		
F01009	7.4 (8)	12.1 (7)	7.0 (5)	12.0 (5)		
F01010	7.1 (8)	10.9 (8)	6.6 (6)	10.5 (6)		
F01011	6.6 (8)	9.1 (8)	6.1 (6)	8.5 (6)		
F01012	7.3 (7)	11.2 (7)	6.6 (6)	10.2 (6)		
Number of dams	11	11	11	11		
Mean	7.0	10.9	6.5	10.5		
S.D.	0.6	1.2	0.6	1.3		

Each value shows mean per dam (g).

Figures in parentheses indicate number of offspring.

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 38-2. Body weights of offspring (F_1) before weaning

2-DT 62.5 mg/kg

Dam No.	Days after birth							
	Male body weight				Female body weight			
	0	4	0	4				
F02013	6.5	(8)	10.8	(7)	6.3	(7)	11.0	(7)
F02014	6.5	(8)	9.7	(8)	5.9	(9)	9.5	(8)
F02015	6.5	(9)	11.3	(9)	6.1	(6)	10.4	(6)
F02016	6.7	(7)	9.9	(7)	6.4	(9)	9.9	(9)
F02017	6.9	(6)	11.4	(6)	6.4	(7)	11.1	(7)
F02018	6.4	(6)	10.7	(6)	5.9	(5)	10.3	(5)
F02019	7.6	(9)	12.0	(9)	7.7	(5)	12.6	(5)
F02020	6.6	(10)	10.8	(10)	6.6	(4)	10.9	(4)
F02021	7.2	(4)	12.8	(4)	6.5	(9)	11.8	(9)
F02022	7.2	(7)	12.1	(7)	7.2	(4)	12.5	(4)
F02023	5.4	(8)	7.9	(8)	5.4	(11)	9.3	(11)
F02024	7.4	(8)	11.6	(8)	7.0	(5)	11.6	(5)
Number of dams	12		12		12		12	
Mean	6.7		10.9		6.5		10.9	
S.D.	0.6		1.3		0.6		1.1	
Significance	NS		NS		NS		NS	
Statistical method	AN		AN		AN		AN	

Each value shows mean per dam (g).

Figures in parentheses indicate number of offspring.

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis of variance (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 38-3. Body weights of offspring (F_1) before weaning

2-DT 250 mg/kg

Dam No.	Days after birth					
	Male body weight		Female body weight		0	4
	0	4	0	4		
F03025	7.9 (6)	12.2 (6)	7.7 (8)	11.5 (8)		
F03026	7.1 (4)	11.9 (4)	6.3 (10)	10.8 (10)		
F03027	6.3 (3)	10.5 (3)	5.8 (14)	10.2 (14)		
F03028	6.1 (5)	8.9 (5)	5.7 (15)	8.5 (15)		
F03029	7.0 (5)	11.6 (5)	6.7 (5)	11.7 (5)		
F03030	7.0 (9)	11.3 (9)	6.5 (5)	11.3 (5)		
F03031	6.5 (7)	10.0 (7)	6.0 (8)	9.3 (8)		
F03032	5.0 (8)		5.0 (9)	6.7 (1)		
F03033	7.1 (5)	11.6 (5)	6.4 (8)	10.4 (8)		
F03034	5.8 (8)	9.0 (8)	5.5 (8)	7.9 (8)		
F03035	6.7 (7)	11.3 (7)	6.2 (6)	10.3 (6)		
F03036	6.6 (10)	9.9 (10)	7.0 (8)	11.1 (8)		
Number of dams	12	11	12	12		
Mean	6.6	10.7	6.2	10.0		
S.D.	0.7	1.2	0.7	1.6		
Significance	NS	NS	NS	NS		
Statistical method	AN	AN	AN	AN		

Each value shows mean per dam (g).

Figures in parentheses indicate number of offspring.

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 38-4. Body weights of offspring (F_1) before weaning

2-DT 1000 mg/kg

Dam No.	Days after birth					
	Male body weight		Female body weight		0	4
	0	4	0	4		
F04037	6.9 (7)	11.2 (7)	6.3 (6)	10.4 (6)		
F04038	7.1 (8)	11.4 (8)	7.0 (5)	11.2 (4)		
F04039	5.6 (13)	8.2 (13)	5.4 (4)	8.4 (4)		
F04040	6.1 (11)	9.5 (11)	5.7 (6)	8.9 (6)		
F04041	6.6 (9)	11.3 (9)	6.3 (5)	10.7 (5)		
F04042	6.3 (9)	10.1 (9)	5.9 (7)	9.6 (7)		
F04043	7.0 (10)	10.5 (10)	6.4 (4)	9.7 (4)		
F04044	6.7 (3)	11.1 (3)	6.2 (9)	10.4 (9)		
F04045	6.2 (9)	8.7 (9)	5.9 (9)	9.2 (9)		
F04046	6.1 (11)	9.1 (10)	5.6 (9)	8.9 (9)		
F04047	6.8 (11)	10.7 (11)	6.5 (2)	10.8 (2)		
F04048	7.6 (3)	13.8 (3)	7.1 (3)	13.1 (3)		
Number of dams	12	12	12	12		
Mean	6.6	10.5	6.2	10.1		
S.D.	0.5	1.5	0.5	1.3		
Significance	NS	NS	NS	NS		
Statistical method	AN	AN	AN	AN		

Each value shows mean per dam (g).

Figures in parentheses indicate number of offspring.

Significantly different from the control group (*: P<0.05, **: P<0.01).

NS: Not significantly different from the control group.

AN: Analysis by variance (one-way layout).

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 39-1. General conditions in offspring (F₁) before weaning

Control (vehicle: corn oil)

Dam No.	Number of offspring and general conditions	Days after birth				
		0	1	2	3	4
F01001	Number of offspring	14	14	14	14	14
	General appearance, No abnormality	14	14	14	14	14
F01002	Number of offspring	15	15	15	15	15
	General appearance, No abnormality	15	15	15	15	15
F01003	Number of offspring	12	12	12	12	12
	General appearance, No abnormality	12	12	12	12	12
F01004	Number of offspring	16	16	16	16	16
	General appearance, No abnormality	16	16	16	16	16
F01006	Number of offspring	12	12	12	12	12
	General appearance, No abnormality	12	12	12	12	12
F01007	Number of offspring	12	12	12	12	12
	General appearance, No abnormality	12	12	12	12	12
F01008	Number of offspring	17	17	17	17	17
	General appearance, No abnormality	17	17	17	17	17
F01009	Number of offspring	13	13	13	13	12
	General appearance, No abnormality	13	13	13	12	12
F01010	General appearance, Death	0	0	0	1	0
	Number of offspring	14	14	14	14	14
F01011	General appearance, No abnormality	14	14	14	14	14
	Number of offspring	14	14	14	14	14
F01012	General appearance, No abnormality	14	14	14	14	14
	Number of offspring	13	13	13	13	13
F01012	General appearance, No abnormality	13	13	13	13	13
	Number of offspring	152	152	152	152	151
	General appearance, No abnormality	152	152	152	151	151
	General appearance, Death					1

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 39-2. General conditions in offspring (F₁) before weaning

2-DT 62.5 mg/kg

Dam No.	Number of offspring and general conditions	Days after birth				
		0	1	2	3	4
F02013	Number of offspring	15	15	14	14	14
	General appearance, No abnormality	15	14	14	14	14
	General appearance, Death	0	1	0	0	0
F02014	Number of offspring	17	17	17	17	16
	General appearance, No abnormality	17	17	17	16	16
	General appearance, Death	0	0	0	1	0
F02015	Number of offspring	15	15	15	15	15
	General appearance, No abnormality	15	15	15	15	15
F02016	Number of offspring	16	16	16	16	16
	General appearance, No abnormality	16	16	16	16	16
F02017	Number of offspring	13	13	13	13	13
	General appearance, No abnormality	13	13	13	13	13
F02018	Number of offspring	11	11	11	11	11
	General appearance, No abnormality	11	11	11	11	11
F02019	Number of offspring	14	14	14	14	14
	General appearance, No abnormality	14	14	14	14	14
F02020	Number of offspring	14	14	14	14	14
	General appearance, No abnormality	14	14	14	14	14
F02021	Number of offspring	13	13	13	13	13
	General appearance, No abnormality	13	13	13	13	13
F02022	Number of offspring	11	11	11	11	11
	General appearance, No abnormality	11	11	11	11	11
F02023	Number of offspring	19	19	19	19	19
	General appearance, No abnormality	19	19	19	19	19
F02024	Number of offspring	13	13	13	13	13
	General appearance, No abnormality	13	13	13	13	13
		171	171	170	170	169
		171	170	170	169	169
				1	1	

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 39-3. General conditions in offspring (F₁) before weaning

2-DT 250 mg/kg

Dam No.	Number of offspring and general conditions	Days after birth				
		0	1	2	3	4
F03025	Number of offspring	14	14	14	14	14
	General appearance, No abnormality	14	14	14	14	14
F03026	Number of offspring	14	14	14	14	14
	General appearance, No abnormality	14	14	14	14	14
F03027	Number of offspring	17	17	17	17	17
	General appearance, No abnormality	17	17	17	17	17
F03028	Number of offspring	20	20	20	20	20
	General appearance, No abnormality	20	20	20	20	20
F03029	Number of offspring	10	10	10	10	10
	General appearance, No abnormality	10	10	10	10	10
F03030	Number of offspring	14	14	14	14	14
	General appearance, No abnormality	14	14	14	14	14
F03031	Number of offspring	15	15	15	15	15
	General appearance, No abnormality	15	15	15	15	15
F03032	Number of offspring	17	17	1	1	1
	General appearance, No abnormality	17	1	1	1	1
F03033	General appearance, Death	0	16	0	0	0
	Number of offspring	13	13	13	13	13
F03034	General appearance, No abnormality	13	13	13	13	13
	Number of offspring	16	16	16	16	16
F03035	General appearance, No abnormality	16	16	16	16	16
	Number of offspring	13	13	13	13	13
F03036	General appearance, No abnormality	13	13	13	13	13
	Number of offspring	18	18	18	18	18
	General appearance, No abnormality	18	18	18	18	18
	Number of offspring	181	181	165	165	165
	General appearance, No abnormality	181	165	165	165	165
	General appearance, Death				16	

Combined repeat dose and reproductive/developmental toxicity screening test of 2-Decyltetradecanol by oral administration in rats

Appendix 39-4. General conditions in offspring (F_1) before weaning

2-DT 1000 mg/kg

Dam No.	Number of offspring and general conditions	Days after birth				
		0	1	2	3	4
F04037	Number of offspring	13	13	13	13	13
	General appearance, No abnormality	13	13	13	13	13
F04038	Number of offspring	13	13	13	12	12
	General appearance, No abnormality	13	13	12	12	12
	General appearance, Death	0	0	1	0	0
F04039	Number of offspring	17	17	17	17	17
	General appearance, No abnormality	17	17	17	17	17
F04040	Number of offspring	17	17	17	17	17
	General appearance, No abnormality	17	17	17	17	17
F04041	Number of offspring	14	14	14	14	14
	General appearance, No abnormality	14	14	14	14	14
F04042	Number of offspring	16	16	16	16	16
	General appearance, No abnormality	16	16	16	16	16
F04043	Number of offspring	14	14	14	14	14
	General appearance, No abnormality	14	14	14	14	14
F04044	Number of offspring	12	12	12	12	12
	General appearance, No abnormality	12	12	12	12	12
F04045	Number of offspring	18	18	18	18	18
	General appearance, No abnormality	18	18	18	18	18
F04046	Number of offspring	20	20	20	20	20
	General appearance, No abnormality	20	20	20	20	19
	General appearance, Death	0	0	0	0	1
F04047	Number of offspring	13	13	13	13	13
	General appearance, No abnormality	13	13	13	13	13
F04048	Number of offspring	6	6	6	6	6
	General appearance, No abnormality	6	6	6	6	6
	Number of offspring	173	173	173	172	172
	General appearance, No abnormality	173	173	172	172	171
	General appearance, Death			1		1

信頼性保証書

表題 2-Decyltetradecanol のラットを用いる反復投与毒性・生殖発生毒性併合試験

試験番号 R-12-016

この試験に関する信頼性保証部門による査察および監査状況等は下記のとおりであった。

査察・監査項目	査察・監査年月日	運営管理者および試験責任者への報告年月日
試験計画書	2012年10月30日	2012年10月30日
試験計画書変更書 R-12-016-No.1	2012年12月4日	2012年12月4日
R-12-016-No.2	2013年1月9日	2013年1月9日
R-12-016-No.3	2013年3月21日	2013年3月21日
R-12-016-No.4	2013年4月1日	2013年4月1日
動物の受入れおよび検疫	2012年11月19日	2012年11月19日
媒体中の安定性 (安定性試験開始日)	2012年11月21日	2012年11月21日
群分け、検体調製および 含量試験	2012年12月3日	2012年12月3日
体重測定、給餌量測定、投与 および一般状態の観察	2012年12月4日	2012年12月4日
性周期観察	2012年12月5日	2012年12月5日
詳細な症状観察	2012年12月11日	2012年12月11日
交尾確認	2012年12月19日	2012年12月19日
尿検査	2013年1月9、10日	2013年1月15日
分娩状態および出生児の観察	2013年1月10日	2013年1月10日
機能検査	2013年1月11、14日	2013年1月15日
出生児剖検、血液学検査、 血液生化学検査、雄動物剖検、 器官重量測定および固定	2013年1月15日	2013年1月15日
病理組織学検査 (標本作製:切り出し)	2013年2月22日	2012年2月22日
報告書草案および生データ	2013年4月2~5、9日	2013年4月9日
最終報告書	2013年9月25日	2013年9月25日

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)を遵守して実施され、また、この報告書は試験に使用された方法および手順を正確に記載し、記載された結果は試験の生データを正確に反映していることを保証する。

2013年9月25日

一般財団法人食品薬品安全センター 秦野研究所
信頼性保証部門責任者