最終報告書

表　　題：ペルフルオロテトラデカン酸のラットにおける反復投与毒性･生殖発生毒性併合試験

試験番号：ＳＲ０７１２４

株式会社 化合物安全性研究所

陳 述 書

表　　題：ペルフルオロテトラデカン酸のラットにおける反復投与毒性･生殖発生毒性併合試験

試験番号：ＳＲ０７１２４

１．本試験は、「新規化学物質等に係る試験を実施する試験施設に関する基準について」(平成 23 年 3 月 31 日薬食発 0331 第 8 号・平成 23･03･29 製局第 6 号・環保企発第 110331010 号 厚生労働省医薬食品局長・経済産業省製造産業局長・環境省総合環境政策局長連名通知) に従い、試験方法は、OECD 試験法ガイドライン (OECD Guideline for Testing of Chemicals; Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (422), 1996.03.22) に基づいて実施したものであります。

２．本試験は、試験計画書に従って実施し、試験成績の信頼性に影響を及ぼしたと思われる環境要因は認められませんでした。

株式会社 化合物安全性研究所

試験責任者 [redacted] [redacted] 2012 年 3 月 12 日

信 頼 性 保 証 書

表題：ペルフルオロテトラデカン酸のラットにおける反復投与毒性･生殖発生毒性併合試験

試験番号：ＳＲ０７１２４

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

査察段階	査察日	試験責任者への報告日	運営管理者への報告日
試験計画書	2010 年 9 月 21 日	2010 年 9 月 21 日	2010 年 9 月 21 日
試験計画書変更書(No. 1)	2011 年 6 月 3 日	2011 年 6 月 6 日	2011 年 6 月 6 日
試験計画書変更書(No. 2)	2011 年 10 月 3 日	2011 年 10 月 3 日	2011 年 10 月 3 日
試験計画書変更書(No. 3)	2012 年 3 月 7 日	2012 年 3 月 7 日	2012 年 3 月 7 日
被験物質の受入・表示・保存	2010 年 9 月 21 日	2010 年 9 月 21 日	2010 年 9 月 21 日
投与液の調製	2010 年 10 月 5 日	2010 年 10 月 5 日	2010 年 10 月 5 日
投与液の化学分析	2010 年 10 月 5 日 2010 年 10 月 6 日 2010 年 10 月 7 日	2010 年 10 月 7 日	2010 年 10 月 7 日
動物受入・検疫・馴化	2010 年 9 月 22 日	2010 年 9 月 24 日	2010 年 9 月 24 日
群分け	2010 年 10 月 6 日	2010 年 10 月 6 日	2010 年 10 月 6 日
投与	2010 年 10 月 8 日	2010 年 10 月 8 日	2010 年 10 月 8 日
一般状態観察	2010 年 10 月 8 日	2010 年 10 月 8 日	2010 年 10 月 8 日
体重測定	2010 年 10 月 8 日	2010 年 10 月 8 日	2010 年 10 月 8 日
摂餌量測定	2010 年 10 月 8 日	2010 年 10 月 8 日	2010 年 10 月 8 日
性周期検査	2010 年 10 月 8 日	2010 年 10 月 8 日	2010 年 10 月 8 日
詳細な一般状態観察	2010 年 10 月 14 日	2010 年 10 月 14 日	2010 年 10 月 14 日
生殖能検査(交配)	2010 年 10 月 21 日 2010 年 10 月 22 日	2010 年 10 月 22 日	2010 年 10 月 22 日
機能検査	2010 年 11 月 16 日	2010 年 11 月 16 日	2010 年 11 月 16 日
尿検査	2010 年 11 月 12 日 2010 年 11 月 13 日	2010 年 11 月 15 日	2010 年 11 月 15 日
分娩および哺育状態観察	2010 年 11 月 13 日	2010 年 11 月 15 日	2010 年 11 月 15 日
新生児の剖検	2010 年 11 月 17 日	2010 年 11 月 17 日	2010 年 11 月 17 日
剖検・器官重量測定	2010 年 11 月 19 日	2010 年 11 月 19 日	2010 年 11 月 19 日
血液学的検査	2010 年 11 月 19 日	2010 年 11 月 19 日	2010 年 11 月 19 日

SR07124

査察段階	査察日	試験責任者への報告日	運営管理者への報告日
血液化学的検査	2010年11月19日 2010年11月22日	2010年11月24日	2010年11月24日
病理組織学的検査(標本作製)	2010年12月11日 2010年12月15日 2010年12月25日	2010年12月25日	2010年12月25日
病理組織学的検査(鏡検)	2011年1月5日	2011年1月5日	2011年1月5日
生データ	2011年3月17日	2011年3月17日	2011年3月17日
最終報告書(草案)：図表	2011年3月9日 2011年3月10日 2011年3月11日 2011年3月14日 2011年3月15日 2011年3月16日 2011年3月17日	2011年3月17日	2011年3月17日
	2011年3月22日	2011年3月22日	2011年3月22日
最終報告書(草案)：本文	2011年3月17日	2011年3月17日	2011年3月17日
最終報告書	2012年3月12日	2012年3月12日	2012年3月12日

1. 本試験は、「新規化学物質等に係る試験を実施する試験施設に関する基準について」(平成23年3月31日 薬食発0331第8号・平成23･03･29製局第6号・環保企発第110331010号 厚生労働省医薬食品局長・経済産業省製造産業局長・環境省総合環境政策局長連名通知)およびOECD試験法ガイドライン(OECD Guideline for Testing of Chemicals; Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (422), 1996.03.22) に従い実施された。

2. 本試験は、試験計画書に従って実施され、また、本報告書には当該試験に使用した方法および手順が正確に記載されており、試験成績には当該試験の実施過程において得られた生データが正確に反映していることを確認した。

株式会社 化合物安全性研究所

QAU責任者 [redacted] [redacted] 2012年3月12日

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表題：ペルフルオロテトラデカン酸のラットにおける反復投与毒性･生殖発生毒性併合試験

試験番号：ＳＲ０７１２４

試験目的：この試験は、ペルフルオロテトラデカン酸を雌雄ラットに反復経口投与してその毒性ならびに性腺機能、交尾行動、受胎および分娩等の生殖に及ぼす毒性を検討するために行われた。

試験実施基準（GLP）および試験法ガイドライン

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

試験法ガイドライン：OECD 試験法ガイドライン（OECD Guideline for Testing of Chemicals; Combined Repeated Dose Toxicity Study with the Reproduction/ Developmental Toxicity Screening Test (422), 1996.03.22）

動物愛護

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

法規および基準等　:「動物の愛護及び管理に関する法律」(昭和 48 年 10 月 1 日 法律第 105 号、最終改正 平成 18 年 6 月 2 日 法律第 50 号)

「実験動物の飼養及び保管並びに苦痛の軽減に関する基準」(平成 18 年 4 月 28 日 環境省告示第 88 号)

「動物実験に関する指針」(昭和62年5月22日承認 社団法人 日本実験動物学会)

試験委託者

名称　　：厚生労働省 医薬食品局

所在地　　：東京都千代田区霞が関 1-2-2（〒100-8916）

連絡先　　：審査管理課 化学物質安全対策室

試験施設

名称　　：株式会社　化合物安全性研究所

所在地　　：札幌市清田区真栄 363 番 24（〒004-0839）

運営管理者　　：[redacted]

試験責任者

氏名　　：[redacted]

所属　　：株式会社　化合物安全性研究所　安全性研究部

試験従事者およびその業務分担

被験物質管理　　：[redacted]

化学分析　　：

臨床検査　　：

動物管理　　：

検疫・馴化　　：

投与・観察・測定　　：

病理検査　　：

試験期間

試験開始日	: 2010 年　9 月　21 日
被験物質受入	: 2009 年　7 月　1 日
動物受入	: 2010 年　9 月　22 日
実験開始(投与開始)日	: 2010 年　10 月　8 日
交配開始	: 2010 年　10 月　21 日
新生児剖検開始	: 2010 年　11 月　17 日
母動物剖検開始	: 2010 年　11 月　19 日
雄動物および回復群雌動物投与終了	: 2010 年　11 月　18 日
雄動物投与終了時剖検	: 2010 年　11 月　19 日
回復群雌雄動物剖検	: 2010 年　12 月　3 日
病理組織学的検査終了(実験終了)	: 2011 年　1 月　19 日
試験終了日	: 2012 年　3 月　12 日

要　約

ペルフルオロテトラデカン酸の 0（対照､0.5%カルボキシメチルセルロースナトリウム水溶液）、1、3 および 10 mg/kg を 1 群雌雄各 12 匹の Crl:CD(SD) ラットに、雄に対しては交配前、交配期間および交配後を含む計 42 日間、雌に対しては交配前、交配および妊娠期間、ならびに分娩後 5 日までの期間（42－56 日間）経口投与し、雌雄動物への反復投与による影響、雌雄動物の生殖および新生児の発生に及ぼす影響について検討した。また、0（対照）および 10 mg/kg について、雄動物は各 5 匹を選抜し、雌動物は各 5 匹を別に設け、42 日間の投与終了後 14 日間の回復性についても併せて検討した。

1. 反復投与毒性

10 mg/kg 群では、機能検査で、投与 6 週に雄の後肢の握力に低値がみられた。体重および摂餌量については、雄では回復期間中の体重に低値がみられた。雌では、哺育期間の体重、体重増加量および体重増加率ならびに妊娠 5 日、10 日および哺育 4 日の摂餌量に低値がみられた。血液学的検査では、雌の回復群の回復期間終了時にヘモグロビン濃度およびヘマトクリット値に低値がみられた。血液化学的検査では、投与期間終了時に雄で総蛋白およびβ-グロブリン分画比に低値、アルカリホスファターゼおよび尿素窒素に高値、雌でβ-グロブリン分画比に低値、クロールに高値がみられた。回復期間終了時には、雄のアルカリホスファターゼには回復性は認められなかった。投与期間終了時の剖検では雄で肝臓の淡褐色化がみられ、器官重量では雌雄で肝臓の絶対または相対重量に高値がみられた。肝臓の病理組織学的検査では、小葉中心性肝細胞肥大が雌雄でみられた。その他に、雄で甲状腺の濾胞細胞の肥大ならびに雌で脾臓に髄外造血の低下および胸腺に皮質の萎縮がみられた。回復期間終了時には、雄で肝臓の淡褐色化がみられ、雌雄で肝臓の絶対または相対重量に高値がみられた。肝臓の病理組織学的検査では、小葉中心性肝細胞肥大が雌雄でみられ、雄ではびまん性脂肪化、雌ではびまん性肝細胞肥大もみられ、肝臓の障害についての回復性は認められなかった。

3 mg/kg 群では、雌の哺育 4 日の体重に低値がみられた。機能検査で投与 6 週に雄の後肢の握力に低値がみられた。器官重量では雄で肝臓の絶対および相対重量に高値がみられた。病理組織学的検査では、雄で肝臓の小葉中心性肝細胞肥大および甲状腺の濾胞細胞の肥大がみられた。

1 mg/kg 群では、被験物質投与に関連すると考えられる変化は認められなかった。

以上の結果から、本試験条件下におけるペルフルオロテトラデカン酸の無影響量（NOEL）は 1 mg/kg/day と考えられた。

2. 生殖発生毒性

生殖能検査では、いずれの項目にも変化はみられなかった。

新生児の体重では、10 mg/kg 群において、生後 1 および 4 日の体重に雌雄とも低値がみられた。新生児の一般状態および剖検では変化はみられなかった。

以上の結果から、本試験条件下におけるペルフルオロテトラデカン酸の反復投与による親動物の生殖に対する無影響量（NOEL）は 10 mg/kg/day、新生児の発生に対する無影響量（NOEL）は 3 mg/kg/day と考えられた。

緒　言

ペルフルオロテトラデカン酸を、0（対照、0.5%カルボキシメチルセルロースナトリウム水溶液）、1、3 および 10 mg/kg/day の用量で、1 群雌雄各 12 匹の Crl:CD(SD) ラットに、雄に対しては交配前、交配期間および交配後を含む計 42 日間、雌に対しては交配前、交配および妊娠期間、ならびに分娩後 5 日までの期間（42－56 日間）経口投与し、雌雄動物への反復投与による影響、雌雄動物の生殖および新生児の発生に及ぼす影響について検討した。また、0（対照）および 10 mg/kg について、雄動物は各 5 匹を選抜し、雌動物は各 5 匹を別に設け、42 日間の投与終了後 14 日間の回復性についても併せて検討した。

材料および方法

1. 被験物質

名称　：ペルフルオロテトラデカン酸

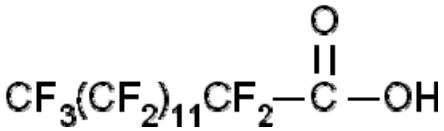
コード名　：PFTeDA

英名　：Perfluorotetradecanoic acid

CAS No.　：376-06-7

官報公示整理番号　：2-2658

構造式　：



分子式　：$C_{14}HF_{27}O_2$

分子量　：714.11

物理化学的性質　：外観　；白色粉末

沸点　；175～178℃/20-30mmHg

融点　；130～135℃

ロット番号　：3728

純度（GC）　：96.5%（Appendix 1-1）

不純物の濃度　：不明（データなし）

製造者　：名称 [redacted]

所在地

入手量　：957 g（関連試験と共に一括受入）

安定性および反応性：安定性；安定。
避けるべき条件；日光、熱、強酸化物
関連試験を含め全試験操作の終了後、使用した被験物質の純度に関する分析成績を入手し、被験物質の試験期間中の安定性を確認した(Appendix 1-2)。
危険有害な分解生成物；一酸化炭素、ハロゲン化物

危険有害性　：重要危険有害性；腐食性
有害性；腐食性が強く、眼、皮膚、粘膜に接触すると刺激作用がある。
吸入または飲み込んだ場合、有害である。

保存条件　：遮光、密閉、冷所（実測範囲：2～10℃）
酸化剤並びに酸化性の強い物質との保管は避ける。
安全な容器包装剤；ガラス

保存場所　：株式会社 化合物安全性研究所の被験物質保存室

取扱い上の注意　：強酸化剤との接触を避ける。
漏れ、溢れ、飛散などしないようにし、みだりに粉塵を発生させない。
使用後は容器を密閉する。取扱い後は、手、顔等を良く洗い、うがいをする。休憩場所では手袋その他汚染した保護具を持ち込んではならない。
吸い込んだり、目、皮膚及び衣類に触れないように、適切な保護具を着用する。屋内作業場における取扱い場所では、局所排気装置を使用する。

サンプリング　：被験物質サンプルとして、約１ｇを採取し、試験施設の資料保存室に保存した。

残余被験物質の処置：関連試験も含めすべての試験操作終了後、焼却処分するために、産業廃棄物として回収した。

参考文献　：製品安全データシート、和光純薬工業株式会社
Safety Data Sheet, SIGMA-ALDRICH
Material Safety Data Sheet, Exfluor Research Corporation

2. 媒体

名称　：0.5%カルボキシメチルセルロースナトリウム水溶液（0.5%CMC-Na）

調製方法　：日本薬局方カルメロースナトリウム（ロット番号 9X09、丸石製薬株式会社）を精秤し、日本薬局方精製水（ロット番号 006057、ヤクハン製薬株式会社）に、所定の濃度となるように溶解した。

保存条件　：遮光気密容器に入れ、冷蔵（実測範囲：2.6～6.9℃）で保存した。

使用期限　：調製後 15 日以内（調製後 14 日以内に使用した）。

3. 投与液の調製および化学分析

調製方法　　：被験物質を正確に秤量し、所定の濃度となるように媒体（0.5%CMC-Na）を加えて懸濁した。

調製頻度　　：15 日間に 1 回以上の頻度で調製した。

保存条件　　：遮光気密容器に入れ、冷蔵保存（実測範囲：2.6～6.9℃）し、14 日以内に使用した。

保存場所　　：株式会社 化合物安全性研究所の被験物質保存室

調製上の注意　　：被験物質はクリーンベンチ内で取扱い、調製の際にはゴム手袋およびマスクを着用し、吸い込んだり、眼、皮膚および衣類に触れないようにした。

残余調製液の処置　：残余の投与液は、焼却処分するために産業廃棄物として回収した。

調製液の安定性および均一性：投与開始前に、0.01 および 100 mg/mL の濃度の調製液について分析を実施し、被験物質の投与液中における均一性ならびに冷蔵保存 14 日間（調製日を 0 日として起算した）および室温保存 4 時間後の安定性を確認した（Appendix 2-1～2-4）。

調製液の濃度確認　：被験物質の全濃度に関する投与液中における濃度を、初回および最終回調製時の計 2 回分析し、その結果、含有率は設定濃度の 96.9～103.0%であり、判定基準を満たしていた（Appendix 2-5 および 2-6）。

被験物質調製液の濃度分析方法：

1) 使用機器

高速液体クロマトグラフ-質量分析計(LC-MS/MS)

	2695(LC 部)	Waters Corporation
	Quattro Micro(MS/MS 部)	Waters Corporation
データ処理装置	Mass Lynx V.4.0	Waters Corporation
電子天秤	xp205	METTLER TOLEDO
純水製造装置	Milli-Q Labo	日本ミリポア株式会社

2) 標準物質(気密容器に入れ、冷暗所に保存)

ペルフルオロテトラデカン酸(PFTeDA)(被験物質)

Lot. No.3728	Exfluor Research Corporation

3) 試薬

13C-ペルフルオロオクタン酸(13C-PFOA)(内標準物質)

Lot No.SCHG-007(50μg/mL メタノール溶液)

Cambridge Isotope Laboratories, Inc.

メタノール	高速液体クロマトグラフィー用	関東化学株式会社
酢酸アンモニウム	試薬特級	関東化学株式会社

4) 調製(以下の割合で調製、調製日を0日として起算)

a) 標準溶液

ペルフルオロテトラデカン酸0.010 gを正確に量りとり、100 mLメスフラスコに入れ、メタノールを加えて100μg/mL溶液を調製した。さらにこの液1 mLを正確に採取し、100 mLメスフラスコに入れ、メタノールを加えて1μg/mL溶液を調製した（標準原液)。標準原液をメタノールで希釈し、50、100、150、200および250 ng/mL溶液を調製した。各溶液に、それぞれ100 ng/mLとなるように13C-PFOAを内標準として添加したものを標準溶液とした（検量線)。

b) 試料溶液

被験物質調製液の採取点数は、濃度確認試験および安定性試験については被験物質調製液の中層付近から2点とし、均一性試験については被験物質調製液の上、中、下層付近から各2点の計6点とした。なお、均一性試験の中層の濃度を安定性試験の調製時の分析結果とした。

① 被験物質調製液を採取し、被験物質の濃度が検量線の範囲（100 ng/mL付近）となるようにメタノールで希釈した後、それぞれに100 ng/mLとなるように13C-PFOAを添加したものを試料溶液とした。

② 試料溶液の調製は、1点につき1回、HPLCへの注入は各1回とした。

c) 移動相

① 酢酸アンモニウム0.77 gを純水1 Lに溶解し、10 mmol/L酢酸アンモニウム水溶液とした。調製後は室温で保存し、使用期限は1ヵ月とした。

② メタノールおよび純水はそのまま用い、溶媒の混合（グラジエント）はLC装置で行った。

d) オートサンプラ洗浄液

メタノールおよび蒸留水は等量混合したものを使用した。調製後は室温で保存し、使用期限は1ヵ月とした。

e) 洗浄用注入液

メタノールを使用した。

5) HPLC 条件

カラム　　：Waters Atlantis dC18、3μm、2.1×150 mm

移動相　　：グラジエント(下記参照)

時間(分)	純水	メタノール	10 mmol/L 酢酸アンモニウム水溶液
0～15	15	80	5

オートサンプラ洗浄液　　：メタノール/蒸留水(1:1)の混合溶液

洗浄用注入液　　：メタノール

カラム温度　　：50℃

カラム流量　　：0.2 mL/min

注入量　　：5μL

オートサンプラ温度　　：20℃

イオン化モード　　：ESI－

キャピラリー電圧　　：1.0 kv

脱溶媒ガス　　：窒素

コーンガス流量　　：50 L/hr

ソース温度　　：110℃

コリジョンガス(MS/MS 部)　：ヘリウム

分析時間　　：15 分

6) システム適合性試験

測定日毎に標準溶液（100 ng/mL）を連続して 6 回注入した。ペルフルオロテトラデカン酸と 13C-PFOA の面積比および保持時間について変動係数を求めた。

7) 計算

Mass Lynx V.4.0 を用いて、各標準物質および内標準物質（子イオン）のピーク面積を求め、それぞれのピークの面積比（RES）と濃度から検量線を作成した。検量線から各試料溶液の被験物質濃度を求め、さらに変動係数、含有率および残存率を以下の式より算出した。

MS/MS によるモニターイオン

	親イオン	子イオン
ペルフルオロテトラデカン酸	713	669
13C-ペルフルオロオクタン酸	421	376

$$\text{面積比(RES)} = \frac{\text{測定対象物質(または標準物質)のピーク面積}}{\text{内標準物質のピーク面積}}$$

$$被験物質濃度(mg/mL) = \frac{測定濃度(ng/mL)\times希釈係数}{1,000,000}$$

$$変動係数(\%) = \frac{標準偏差}{平均値} \times 100$$

$$含有率(\%) = \frac{被験物質濃度平均値}{調製液の表示濃度} \times 100$$

$$残存率(\%) = \frac{保存後の被験物質濃度平均値}{調製時の被験物質濃度平均値} \times 100$$

8）数値の表示

a）標準溶液の濃度は秤量値より算出し、四捨五入して有効数字 3 桁に丸めた（計算値）。

b）調製液の被験物質濃度は四捨五入して有効数字 3 桁に丸めた。ただし、3 桁以上の整数となる場合は小数点以下第 1 位を四捨五入し、整数で表示した。

c）変動係数、含有率および残存率は四捨五入して小数点以下第 1 位に丸めた。

9）判定基準

a）濃度確認試験：含有率が 85～115％の場合を適とした。

b）安定性試験　：残存率が 85～115％の場合を適とした。

c）均一性試験　：変動係数が 5％以下の場合を適とした。

d）システム適合性試験：変動係数が 2％以下の場合を適とした。

4. 試験方法

(1) 試験系

種・系統　　：ラット、Crl:CD(SD)

微生物統御　　：SPF

生産業者　　：日本チャールス・リバー株式会社 厚木飼育センター

微生物モニタリング：動物生産業者よりデータを入手した。

動物選定理由　　：ラットはこの種の試験で通常用いられている動物種であり、繁殖成績が安定していることと当研究所における背景対照データが利用できることから、この系統を選定した。

発注動物数　　：雄 52 匹、雌 62 匹

受入動物数　　：雄 54 匹、雌 64 匹

発注動物週齢　　：雌雄とも 8 週齢

出荷体重基準　：雄は 240～330 g、雌は 160～230 g
受入時体重範囲　：雄は 278～319 g、雌は 181～209 g
投与開始時週齢　：雌雄とも 10 週齢
群数　：雌雄各 6 群（主試験群 雌雄各 4 群、回復群 雌雄各 2 群）
各群動物数　：主試験群 雌雄各 12 匹、回復群 雌雄各 5 匹

(2) 検疫および馴化

検疫方法　：一般状態を 1 日 1 回観察し、体重を動物受入日、検疫および馴化 8 日ならびに検疫および馴化期間終了日（投与開始前々日）に測定した。期間中一般状態に異常はみられなかったが、雌1例に体重の減少がみられた。
性周期検査　：雌動物について、群分け前の 9 日間に膣垢スメア塗抹法により性周期検査を行った。検査の結果、雌 1 例に性周期の異常がみられた。
期間　：14 日間

(3) 群分け

検疫および馴化期間終了日（投与開始前々日）に、性周期の異常がみられた雌 1 例と体重の減少がみられた雌 1 例を除くすべての動物の体重に基づいて、層化無作為抽出法により各群の平均体重が均一になるように群分けを行った。これらの動物の体重範囲は、雄で 382～448 g、雌で 232～272 g であり、平均体重（雄、411.7 g；雌、252.3 g）の±20%以内であった。選択された動物の投与開始前日の一般状態の観察では、異常はみられなかった。選抜から外れた動物は試験から除外後、標準操作手順書に従って取扱った。

(4) 動物およびケージの識別

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

(5) 動物飼育

1) 飼育環境

飼育室番号　：307 号室

温度・湿度　　：22±3℃，50±20％（実測範囲 20～24℃、29～55％）

換気回数　　：10～15 回／時間

照明時間　　：人工照明 12 時間（8：00～20：00）

2）飼育器材および飼育方法

ケージの種類　　：ブラケット式金属製金網床ケージ（260W×380D×180H，mm）

ただし、交尾成立雌動物については妊娠 17 日から哺育 4 日まで同ケージの金網床を小型受皿に代えて実験動物用床敷（ホワイトフレーク、日本チャールス･リバー株式会社）を使用して分娩と哺育を行わせた。

1 ケージあたりの収容動物数：

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

ケージおよび給餌器の交換：

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

受皿交換　　：週 2 回洗浄滅菌済みのものと交換した。

自動給水装置の水抜き：週 1 回実施した。

給水器の交換　　：尿検査時にのみ用いた。

小型受皿の交換　　：妊娠 20 日に実施した。

室内の清掃および清拭消毒：

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

3）飼料

種類・名称　　：固型飼料、CRF-1

ロット番号　　：100706、100907

製造業者　　：オリエンタル酵母工業株式会社

給餌方法　　：金属製給餌器を用いて自由に摂取させた。

ただし、剖検前日の夕刻からは全例を絶食させた。

汚染物質および微生物検査：

試験に悪影響を及ぼす恐れのある汚染物質の分析あるいは微生物検査を、使用した各ロットの飼料について実施した。汚染物質の分析は Eurofins Analytics 社が、微生物検査は飼料製造業者がそれぞれ行った。分析データを飼料製造業者からロット毎に入手した。分析項目と許容値は株式会社 化合物安全性研究所の標準操作手順書に

準拠した。分析の結果、いずれの項目にも規定された許容値を超える値は認められなかった（Appendix 3-1-1～3-2-2)。

4) 飲料水

種類　：札幌市水道水

給水方法　：自動給水装置を用いて自由に摂取させた。ただし、尿検査時は給水器を用いた。

汚染物質検査　：試験に悪影響を及ぼす恐れのある汚染物質の分析を、2010 年 7 月 1 日、2010 年 10 月 1 日および 2011 年 1 月 4 日に、当該飼育室と同系統配管の最末端（306 号室）から試料を採取して実施した。分析は日本衛生株式会社において行い、分析データを入手した。分析項目と許容値は株式会社 化合物安全性研究所の標準操作手順書に準拠した。分析の結果、いずれの項目にも規定された許容値を超える値は認められなかった（Appendix 4-1～4-3)。

(6) 被験物質の投与

1) 投与量の設定

投与量　：0（媒体のみ)、1、3 および 10 mg/kg/day とした。

設定理由　：先に実施した予備試験（ＳＲ０７１２４Ｐ）（投与量 0、2、10、30 および 50 mg/kg/day､雌雄各 4 匹/群､2 週間反復経口投与）の結果、体重および摂餌量については､30 mg/kg 群において雌の体重増加量、体重増加率の低値傾向および摂餌量の有意な低値、50 mg/kg 群において雌雄の体重の減少ならびに体重増加量、体重増加率および摂餌量の有意な低値または低値傾向がみられた。血液学的検査では、50 mg/kg 群において、雌雄で赤血球数およびヘモグロビン濃度に有意な高値がみられた。血液化学的検査では、30 mg/kg 群の雌および 50 mg/kg 群の雌雄で総コレステロールの有意な低値がみられた。30 および 50 mg/kg 群の雄でアルカリホスファターゼの有意な高値、30 および 50 mg/kg 群の雄および 50 mg/kg 群の雌で尿素窒素の有意な高値、50 mg/kg 群の雄で AST および ALT の有意な高値がみられた。さらに 50 mg/kg 群では、雌雄とも総蛋白に有意な低値、雄のカリウム、雌雄のクロールに有意な高値がみられた。肝臓重量の増加が、雌雄とも 10 mg/kg 以上の投与群でみられた。剖検では雌雄とも 50 mg/kg 群で肝臓の黄褐色化が観察された。したがって、本試験では投与期間の延長を考慮して、10 mg/kg/day を最高用量とし、以下公

比を約3として3および1 mg/kg/day を設定した。そのほかに媒体のみを同様の方法で投与する対照群を設けた。

試験群の構成と各群の動物番号は以下の通りとした。

試験群	投与量 (mg/kg)	濃度 (mg/mL)	動物数（動物番号） 雄	雌
＜主試験群＞				
対照群	0	0	12（101～112）	12（151～162）
低用量群	1	0.1	12（201～212）	12（251～262）
中用量群	3	0.3	12（301～312）	12（351～362）
高用量群	10	1	12（401～412）	12（451～462）
＜回復群＞				
対照群	0	0	5（103, 106, 107, 108, 109）	5（163～167）
高用量群	10	1	5（402, 405, 406, 409, 410）	5（463～467）

対照群の動物には、被験物質投与群と同様の方法で媒体のみを投与した。
回復群の雄は、主試験群から交配期間終了後に投与28日の体重に基づいて、全体の平均値に近似するよう集団の中央値の周辺に位置する動物を各群から5匹ずつ選抜した。

2）投与

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

投与回数　：1日1回、連日投与した。

投与時刻　：9：12～11：56

投与期間　：雄；交配14日前より42日間

雌；交配前14日間および交尾成立までの交配期間、さらに交尾成立例は妊娠期間および分娩後5日（哺育0日を分娩後0日として起算）までの期間、妊娠25日まで分娩が認められない交尾成立例については妊娠25日までの期間

回復群については42日間

回復期間　：投与期間終了後14日間

投与容量　：10 mL/kg とした。各個体の投与液量は投与日に最も近い測定日の体重に基づいて算出した。

投与方法、投与経路、投与回数および投与期間の選定理由：

試験法ガイドラインを参考にした。

(7) 観察、測定および検査項目

Ⅰ．反復投与毒性

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

1) 一般状態観察

例数　：全例

期間　：投与 1 日から剖検日まで。

頻度　：投与期間中は投与前および投与後の 1 日 2 回、回復期間中は午前および午後の 1 日 2 回、剖検日は午前中に 1 回観察した。

観察方法　：個々の動物の生死、外観、行動等について観察した。異常が認められる場合は、その症状ならびに症状の持続期間を記録した。

2) 詳細な一般状態観察

例数　：全例

時期　：投与開始前ならびに投与 7、14、21、28、35 および 42 日。
回復群の動物については、回復 7 および 14 日。

観察方法　：あらかじめ定めたスコアリング基準を用いてスコア化した観察結果を記録した。

観察項目およびその方法：

①体位・姿勢、呼吸状態、振戦・痙攣、常同行動（回転・旋回）、異常行動（自咬）をケージ外から観察した。

②取り出し易さ、取扱い易さ、筋収縮性、立毛、被毛の状態、皮膚、眼・眼球および粘膜の外観、瞳孔径、流涙、流涎、その他分泌物の有無について、ケージから取り出す時に観察した。

③歩行、運動協調性、環境刺激に対する反応、探索行動、排泄状態（排尿・排糞）、常同行動（身づくろい・くびふり）、異常行動（後ずさり・異常発声）、攻撃性について、オープンフィールド内で観察した。

3) 機能検査

例数　：各群の体重の平均値に近似するように選抜した雄(回復群を含む)および回復群の雌の各群 5 例ならびに主試験群の雌の分娩日の早いものから順に選抜した各群 5 例。

時期　　：投与 6 週（投与 40 日）および回復 2 週（回復 12 日）。
主試験群の雌は哺育 4 日。

観察／測定方法　　：あらかじめ定めたスコアリング基準を用いてスコア化した観察結果あるいは測定機器による測定値を記録した。

観察項目およびその方法：

①刺激に対する感覚運動反応：検査台上で以下を観察した。
視覚刺激、触覚刺激、聴覚刺激、痛覚刺激、固有受容器刺激、空中正向反射

②握力：CPU ゲージ（アイコーエンジニアリング株式会社）を用いて前肢および後肢について各 3 回測定し、1 g 単位で記録した。

③自発運動量：自発運動量測定装置（スーパーメックスおよび CompACT、室町機械株式会社）を用いて測定した。上記に引続き、10 分間隔で 1 時間測定した。

4）体重測定

例数　　：全例

測定日　　：投与 1、3、5、7、10、14、21、28、35 および 42 日の投与前、回復 7 および 14 日ならびに剖検日。
主試験群の雌は投与 1、3、5、7、10、14 日の投与前、妊娠 0、1、3、5、7、10、14、17 および 20 日の投与前、哺育 0、1 および 4 日の投与前ならびに剖検日。

測定方法　　：電子式上皿天秤（GX-2000、株式会社エー・アンド・デイ）を用いて測定し、1 g 単位で記録した。

体重増加量および体重増加率：

以下の式により算出した。

〈雄および回復群の雌〉

投与期間；

体重増加量(g)＝　投与 42 日体重(g)－投与 1 日体重(g)

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

回復期間；

体重増加量(g)＝　回復 14 日体重(g)－投与 42 日体重(g)

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

〈主試験群の雌〉

妊娠前投与期間；

体重増加量(g)＝　投与 14 日体重(g)－投与 1 日体重(g)

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

妊娠期間；

体重増加量(g)＝　妊娠 20 日体重(g)－妊娠 0 日体重(g)

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

哺育期間；

体重増加量(g)＝　哺育 4 日体重(g)－哺育 0 日体重(g)

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

5）摂餌量測定

例数　：全例

測定日　：雌雄とも剖検日および交配期間を除き、体重測定と同じ日に実施した。ただし、主試験群の雌については、妊娠 20 日は残量、哺育 0 日は給与量のみを測定した。

測定方法　：電子式上皿天秤（GX-2000、株式会社エー・アンド・デイ）を用いて測定し、1 g 単位で記録した。投与開始前日に適当量を測定後ケージ毎に給与し、その後は測定日に残量および給与量を測定した。ただし、最終回の測定は残量のみとした。

以下の式により、摂餌量（g/rat/day）を算出した。

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

6）尿検査

例数　：雄は機能検査と同一の各群 5 例について、雌は回復群の各群 5 例

時期　：投与 6 週（投与 36～37 日）および回復 2 週（回復 12～13 日）。

採尿方法　：非絶食下でラット用代謝ケージ（KN-646、B-1 型、株式会社夏目製作所）を用いて採尿し、投与直後から約 3 時間の蓄尿で①～⑧を、また約 21 時間の蓄尿で⑨および⑩を実施した。採取した尿は検査終了後廃棄した。

検査項目および検査方法：

①pH	試験紙法
②蛋白(Protein)	試験紙法

③糖　(Glucose)	試験紙法
④ケトン体(Ketone body)	試験紙法
⑤ウロビリノーゲン(Urobilinogen)	試験紙法
⑥ビリルビン(Bilirubin)	試験紙法
⑦潜血反応(Occult blood)	試験紙法
⑧色調(Color)	肉眼観察
⑨尿量(Urine Volume)	容量測定
⑩比重(Specific gravity)	屈折計法

①～⑦ マルティスティックス、シーメンスヘルスケア･ダイアグノスティクス
⑩ 尿比重屈折計ユリコン-S、アタゴ

7) 血液学的検査

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

時期　：剖検時（主試験群の雄は投与 42 日の翌日、雌は分娩後 6 日、回復群は回復 14 日の翌日）に採血した。

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

検査項目および検査方法：

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

①～⑩ 自動血球分析装置 XT-2000 iV、シスメックス
⑪⑫ 血液凝固自動測定装置 KC4 デルタ、トリニティ･バイオテック

8）血液化学的検査

例数　　：血液学的検査と同一の各群 5 例

時期　　：剖検時に採血した。

採血方法　　：16～22 時間の絶食下でラットをエーテル麻酔し、腹部大動脈より採血した。検査項目のうち、①および⑤については、血液 1 mL あたりヘパリンナトリウム（ヘパリンナトリウム注 N「味の素」、1000 単位/mL、味の素株式会社）約 20 単位で処理後、3500 回転/分で 10 分間の遠心分離で得られた血漿を用いて検査した。他の項目については分離剤入り試験管（セパクリーン A、栄研器材株式会社）に血液を採取し、3500 回転/分で 10 分間の遠心分離で得られた血清を用いて検査した。得られた血漿および血清は検査終了後-20℃以下で凍結保存し、試験終了日に廃棄した。

検査項目および検査方法：

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

①～⑯ 自動分析装置 7080 形、日立ハイテクノロジーズ
⑰ 自動電気泳動装置 AES320、三島オリンパス

9）剖検

例数　　：全例

時期　　：主試験群の雄は投与 42 日の翌日、雌の分娩例は分娩後 6 日（哺育 4 日の翌々日）に、妊娠 25 日まで分娩が認められない交尾成立例は妊娠 26 日に、回復群は雌雄とも回復 14 日の翌日に剖検した。死亡例は発見後速やかに、衰弱例は安楽死させた日に剖検した。

検査方法　　：体外表を観察し、エーテル麻酔下で採血後、放血により安楽死させ、全身の器官・組織を肉眼的に観察した。検査終了後、以下の器官・組織を 10％中性緩衝ホルマリンに固定・保存した。なお、眼球およびハーダー腺はデビッドソン液で固定・保存し、精巣および精巣上体はブアン液で固定、70％エタノールに保存した。肺については固定液を注入後浸漬固定した。左右のある器官については原則として左右とも固定・保存した。

器官・組織名　　：脳（大脳、小脳および脳橋）、脊髄、下垂体、胸腺、甲状腺（上皮小体を含む）、副腎、脾臓、心臓、食道、胃、肝臓、膵臓、十二指腸、空腸、回腸（パイエル板を含む）、盲腸、結腸、直腸、気管、肺、腎臓、膀胱、精巣、精巣上体、前立腺、精嚢（凝固腺含む）、卵巣、子宮（角部および頸部）、眼球およびハーダー腺、乳腺（右腹部）、大腿骨（骨髄を含む、右）、腸間膜リンパ節、顎下リンパ節、坐骨神経および肉眼的異常部位（正常組織との境界部含む）。

10）器官重量測定

例数　　：血液学的検査と同一の各群 5 例。
精巣および精巣上体については全例。

時期　　：剖検時

測定方法　　：電子式上皿天秤（ER-180A、株式会社エー・アンド・デイ）を用いて以下の器官について重量を測定した。左右のある器官については、左右併せて測定した。

検査器官　　：脳、下垂体、甲状腺（上皮小体含む）、心臓、肝臓、腎臓、脾臓、副腎、胸腺、精巣、精巣上体、前立腺（腹葉）、精嚢（凝固腺とともに分泌物含む）、卵巣

相対重量の算出　　：以下の式から相対重量を算出した。

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

11）病理組織学的検査

例数　　：剖検時に固定・保存した全例の全器官・組織について標本作製を実施し、対照群および高用量群の雌雄それぞれ5例（血液学的検査と同一例）について鏡検した。また、主試験群の精巣の精子形成について精査した。さらに、肝臓、脾臓、胸腺および甲状腺については、高用量群において剖検または病理組織学的検査で異常がみられたため全投与群の雌雄全例を検査した。また、剖検で異常がみられた部位の検査を実施した：1 mg/kg 群；精巣上体の黄白色腫瘤（動物番号 209）： 3 mg/kg 群；精巣上体の黄白色斑（動物番号 301）、腹大動脈の白色化（動物番号 351）： 10 mg/kg 群；前肢第3指欠損（動物番号 466）。

検査方法　　：パラフィン包埋後薄切し、ヘマトキシリン・エオジン染色標本を作製して鏡検した。なお、所見の確定のため、肝臓では Oil red O 染色標本を追加作製した。

Ⅱ．生殖発生毒性

1）性周期検査

例数　　：雌の全例

期間　　：投与開始日から主試験群は交尾成立まで、回復群は回復 14 日の翌日の剖検日までの連日。

方法　　：ギムザ染色による膣垢塗抹標本を作製し、光学顕微鏡下で性周期段階を観察した。

判定　　：性周期の各段階（発情前期、発情期、発情後期および発情休止期）を4日から6日の間隔で繰返すものを正常と判定し、発情期間隔を算出した。発情休止期が7日以上継続してみられる例は連続非発情とし異常と判定した。

2）生殖能検査

例数　　：主試験群の雌雄の全例

時期、方法　　：投与 14 日を交配開始日、交配開始日の翌日を交配1日とし、交配開始日の夕刻から、同試験群内の雌雄1対を交尾が確認されるまで 14 日間を限度として連続同居させた。

交配組み合せ　　：無作為組み合せ

交尾成立の確認方法：膣内または受皿上に落下した膣栓、あるいは膣垢スメア標本中の精子確認により判定した。いずれかが認められた日を妊娠0日とした。

次式から群毎に交尾率を算出した。

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

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

次式から群毎に受胎率を算出した。

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

3) 分娩および哺育状態観察

例数　　：受胎した雌の全例

分娩観察　　：交尾が確認された雌動物は全例自然分娩させた。

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

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

次式から群毎に出産率を算出した。

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

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

次式から腹毎に出生率を算出した。

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

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

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

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

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

妊娠期間の算出　：妊娠０日から哺育０日までの期間の日数を計数した。

分娩率の算出　：剖検時に各雌の子宮内の着床痕を肉眼的に計数した。
次式から腹毎に分娩率を算出した。

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

着床率の算出　：剖検時に各雌の卵巣の黄体数を計数した。
次式から腹毎に着床率を算出した。

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

哺育４日の哺育率の算出：次式から群毎に算出した。

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

4) 新生児の一般状態観察および生存率

例数　：全例

頻度　：１回／日

期間　：生後０日から生後４日（剖検日）までとした。

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

生後４日の新生児生存率の算出：
次式により１腹単位で算出した。

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

5) 新生児の体重測定

例数･時期　：生存児全例について、生後０、１および４日に実施した。

測定方法　：電子式上皿天秤（GX-2000、株式会社エー・アンド・デイ）を用いて雌雄別に１腹まとめて測定し、0.1 g まで記録した。
雌雄毎に腹当たりの平均体重を求めた。

6) 新生児の剖検

時期･例数　：生後４日に全例について実施した。

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

5. 統計学的方法

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

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

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

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

成　績

Ⅰ．反復投与毒性

1. 一般状態

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

(1) 主試験群雄

投与期間中、対照群を含むいずれの試験群の動物にも異常はみられなかった。

(2) 主試験群雌

妊娠前期間、妊娠期間、哺育期間を通じて、対照群を含むいずれの試験群の動物にも異常はみられなかった。

(3) 回復群雄

回復期間中、対照群および10 mg/kg群の動物には異常は認められなかった。

(4) 回復群雌

対照群では、投与期間および回復期間中に異常は認められなかった。10 mg/kg群では、回復期間中に外傷によると考えられる前肢(左)第3指欠損が1例にみられた。

2. 詳細な一般状態観察

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

(1) 主試験群雄

投与期間中の観察では、いずれの項目にも1、3および10 mg/kg群と対照群の間に有意な差はみられなかった。

(2) 主試験群雌

投与期間中の観察では、いずれの項目にも1、3および10 mg/kg群と対照群の間に有意な差はみられなかった。

(3) 回復群雄

10 mg/kg群の回復期間中の観察では、いずれの項目にも対照群と比較して有意な差はみられなかった。

(4) 回復群雌

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

3. 機能検査

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

(1) 主試験群雄

投与6週の検査では、3および10 mg/kg群で後肢の握力に対照群と比較して有意な低値がみられた。その他の項目では、被験物質各投与群と対照群の間に有意な差はみられなかった。

(2) 主試験群雌

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

(3) 回復群雄

回復2週の検査では、いずれの項目にも、10 mg/kg群と対照群の間に有意な差はみられなかった。

(4) 回復群雌

投与6週および回復2週の検査では、いずれの項目にも、10 mg/kg群と対照群の間に有意な差はみられなかった。

4. 体重推移

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

(1) 主試験群雄

1、3および10 mg/kg群では体重、体重増加量および体重増加率のいずれにも対照群と比較して有意な差はみられなかった。

(2) 主試験群雌

1 mg/kg群では、交配前、妊娠および哺育期間中を通して体重、体重増加量および体重増加率に対照群と比較して有意な差はみられなかった。3および10 mg/kg群では、交配前および妊娠期間の体重、体重増加量および体重増加率に対照群と比較して有意な差はみられなかったが、哺育期間において3 mg/kg群で哺育4日の体重に、10 mg/kg群で哺育期間を通じて体重、体重増加量および体重増加率に有意な低値がみられた。

(3) 回復群雄

10 mg/kg群では、回復期間中の体重は対照群と比較して有意な低値であった。体重増加量および体重増加率には有意な差はみられなかった。

(4) 回復群雌

10 mg/kg群では投与期間および回復期間中の体重、体重増加量および体重増加率のいずれにも対照群と比較して有意な差はみられなかった。

5. 摂餌量

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

(1) 主試験群雄

1、3 および 10 mg/kg 群では、投与期間中に対照群と比較して有意な差はみられなかった。

(2) 主試験群雌

1 および 3 mg/kg 群では、3 mg/kg 群の投与 10 日の一過性の偶発的な有意な低値を除き、交配前、妊娠および哺育期間中を通して有意な差はみられなかった。10 mg/kg 群では、交配前は有意な差はみられなかったが、妊娠 5 日、10 日および哺育 4 日に有意な低値がみられた。

(3) 回復群雄

10 mg/kg 群では、回復期間中に対照群と比較して有意な差はみられなかった。

(4) 回復群雌

10 mg/kg 群では、投与期間および回復期間中に対照群と比較して有意な差はみられなかった。

6. 尿検査

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

(1) 主試験群雄

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

(2) 回復群雄

10 mg/kg 群の回復 2 週の検査では、いずれの項目にも対照群と比較して有意な差はみられなかった。

(3) 回復群雌

10 mg/kg 群の投与 6 週および回復 2 週の検査では、いずれの項目にも対照群と比較して有意な差はみられなかった。

7. 血液学的検査

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

(1) 主試験群雄

投与期間終了時には、1 および 3 mg/kg 群ではいずれの検査項目にも対照群と比較して有意な差はみられなかった。10 mg/kg 群では、活性化部分トロンボプラスチン時間(APTT)に有意な短縮がみられた。

(2) 主試験群雌

投与期間終了時には、いずれの検査項目にも被験物質投与群と対照群の間に有意な差はみられなかった。

(3) 回復群雄

回復期間終了時の 10 mg/kg 群では、いずれの検査項目にも対照群と比較して有意な差はみられなかった。

(4) 回復群雌

回復期間終了時の 10 mg/kg 群では、ヘモグロビン濃度およびヘマトクリット値の有意な低値ならびにプロトロンビン時間(PT)に有意な短縮がみられた。

8. 血液化学的検査

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

(1) 主試験群雄

投与期間終了時には、1 および 3 mg/kg 群ではいずれの検査項目にも対照群と比較して有意な差はみられなかった。10 mg/kg 群では、総蛋白およびβ-グロブリン分画比に有意な低値、アルカリホスファターゼ(ALP)および尿素窒素に有意な高値がみられた。

(2) 主試験群雌

投与期間終了時には、1 mg/kg 群で総ビリルビンに有意な低値がみられたが、用量相関性がみられないことから、被験物質投与と関連性のない変化と考えられた。1 および 3 mg/kg 群では、その他の検査項目に対照群と比較して有意な差はみられなかった。10 mg/kg 群では、β-グロブリン分画比に有意な低値、クロールに有意な高値がみられた。

(3) 回復群雄

回復期間終了時の 10 mg/kg 群では、ALP および無機リンに有意な高値、トリグリセリドに有意な低値がみられた。

(4) 回復群雌

回復期間終了時の 10 mg/kg 群では、総コレステロールに有意な低値、尿素窒素に有意な高値がみられた。

9. 剖検所見

剖検所見を Table 29～31、INDIVIDUAL DATA 9-1-1～9-4-2 に示す。

(1) 主試験群雄

投与期間終了時の剖検では、対照群で腎盂拡張が 1 例、精巣上体尾部の黄白色腫瘤が 1 例、1 mg/kg 群で精巣上体尾部の黄白色腫瘤が 1 例、3 mg/kg 群で精巣上体尾部の黄白色斑が 1 例にみられた。10 mg/kg 群では、肝臓の淡褐色化が 7 例に観察された。

(2) 主試験群雌

投与期間終了時の剖検では、対照群および 1 mg/kg 群では異常所見はみられなかった。3 mg/kg 群では、腹大動脈の白色化が 1 例にみられた。10 mg/kg 群では、脾臓の脂肪組織との癒着が 1

例にみられた。

(3) 回復群雄

回復期間終了時の剖検では、対照群では異常所見はみられなかった。10 mg/kg 群では肝臓の淡褐色化が 4 例にみられた。

(4) 回復群雌

回復期間終了時の剖検では、対照群では異常所見はみられなかった。10 mg/kg 群では外傷によると考えられる前肢(左)第 3 指欠損が 1 例にみられた。

10. 器官重量

器官の絶対重量および相対重量の成績を Table 32-1～35、INDIVIDUAL DATA 10-1-1～10-4-4 に示す。

(1) 主試験群雄

投与期間終了時に、1 mg/kg 群では、精嚢の絶対重量の有意な低値を除き、対照群と比較して有意な差はみられなかった。3 mg/kg 群では、肝臓の絶対および相対重量に有意な高値がみられた。同群ではその他に、脾臓の相対重量、下垂体の絶対および相対重量、前立腺の絶対および相対重量、精嚢の絶対重量に有意な低値がみられた。10 mg/kg 群では、肝臓の絶対および相対重量に有意な高値がみられた。同群ではその他に、下垂体および精嚢の絶対重量に有意な低値がみられたが、相対重量には有意な差はみられなかった。

(2) 主試験群雌

投与期間終了時に、1 および 3 mg/kg 群では、対照群と比較して有意な差はみられなかった。10 mg/kg 群では、肝臓の相対重量に有意な高値がみられた。加えて、脳および卵巣の相対重量に有意な高値がみられた。

(3) 回復群雄

回復期間終了時に、10 mg/kg 群では、剖検時の体重に有意な低値がみられ、肝臓の絶対および相対重量に有意な高値がみられた。加えて、腎臓および脳の相対重量に有意な高値がみられた。

(4) 回復群雌

回復期間終了時に、10 mg/kg 群では、肝臓の相対重量に有意な高値がみられた。加えて、腎臓の絶対重量に有意な低値、脳の相対重量に有意な高値がみられた。

11. 病理組織学的検査

病理組織学的検査の成績を Table 36～39、INDIVIDUAL DATA 11-1-1～11-8-2 に示す。

(1) 主試験群雄

全例の検査を実施した肝臓では、小葉中心性肝細胞肥大が 3 mg/kg 群で、軽度および中等度

のグレードで 12 例中 8 例にみられ、10 mg/kg 群では中等度のグレードで 7 例全例にみられ、その発生頻度は有意に高かった。また、小肉芽腫は対照群を含む各群で、1～10 例にみられた。胸腺では、皮質の萎縮が対照群で 2 例、10 mg/kg 群で 1 例にみられた。甲状腺では、濾胞細胞の肥大が 3 および 10 mg/kg 群で各 4 例にみられた。

その他に、対照群または 10 mg/kg 群において肺の動脈の鉱質沈着、肺胞内マクロファージ集簇、膵臓の限局性の腺房細胞萎縮、腎盂拡張、精巣上体の精子肉芽腫、前立腺の炎症性細胞浸潤、下垂体中間葉の嚢胞の所見が散見された。剖検で異常がみられた部位の検査では、1 および 3 mg/kg 群において精巣上体の精子肉芽腫がみられた。

(2) 主試験群雌

全例の検査を実施した肝臓では、小葉中心性肝細胞肥大が 10 mg/kg 群で、軽度のグレードで 12 例中 9 例にみられ、その発生頻度は有意に高かった。小肉芽腫は、対照群、1 および 3 mg/kg 群で、軽度のグレードでそれぞれ 6、9 および 8 例にみられ、発生頻度に有意な差はなかったが、10 mg/kg 群では、グレードの増強がみられた（軽度 3 例、中等度 7 例）ため、その発生頻度は有意に高かった。また、限局性壊死が 10 mg/kg 群で 1 例にみられた。脾臓では、髄外造血の低下が対照群、3 および 10 mg/kg 群でそれぞれ 2、2 および 8 例にみられ、10 mg/kg 群における発生頻度は有意に増加した。また被膜炎が 10 mg/kg 群で 1 例にみられた。胸腺では、皮質の萎縮が対照群、1、3 および 10 mg/kg 群でそれぞれ 1、2、1 および 8 例にみられ、10 mg/kg 群における発生頻度は有意に増加した。

その他に、対照群または 10 mg/kg 群において肺の動脈の鉱質沈着、肺胞内マクロファージ集簇、肺胞内骨化生、膵臓の限局性の腺房細胞萎縮、腎盂粘膜の炎症性細胞浸潤、下垂体前葉の嚢胞の所見が散見された。

(3) 回復群雄

10 mg/kg 群では、肝臓の小葉中心性肝細胞肥大が軽度および中等度のグレードで 5 例全例にみられ、有意に高い発生頻度であった。また、びまん性脂肪化が 2 例にみられた。甲状腺では、濾胞細胞の肥大が 2 例にみられた。

その他に、対照群または 10 mg/kg 群において肺胞内マクロファージ集簇、動脈の鉱質沈着、肝臓の小肉芽腫、腎臓の近位尿細管上皮の硝子滴、前立腺の炎症性細胞浸潤等の所見が散見された。

(4) 回復群雌

10 mg/kg 群では、肝臓の小葉中心性肝細胞肥大が 2 例、びまん性肝細胞肥大が 2 例にみられた。小肉芽腫については、対照群で軽度のグレードで 4 例、10 mg/kg 群で軽度のグレードで 1 例、中等度のグレードで 3 例にみられた。

その他に、対照群または 10 mg/kg 群において肺胞内マクロファージ集簇、心臓の限局性心筋変性、腎盂粘膜の炎症性細胞浸潤等の所見が散見された。

Ⅱ．生殖発生毒性

(1)生殖能検査

生殖能検査の成績を Table 40 および 41、INDIVIDUAL DATA 12-1-1～12-2-2 および 13-1～13-4 に示す。

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

性周期検査では、連続非発情と判定された雌が主試験群の対照群および 1 mg/kg 群で 12 例中各 1 例に、回復群の 10 mg/kg 群で 5 例中 1 例にみられた。3 mg/kg 群では性周期の短縮が 1 例にみられた。対照群および 1 mg/kg 群では交尾が成立しなかった雄が各 1 例、3 mg/kg 群では妊娠が成立しなかった雌が 1 例にみられた。

(2)妊娠、分娩、哺育状態および新生児生存率

妊娠、分娩、哺育状態および新生児生存率の成績を Table 42、INDIVIDUAL DATA 14-1～14-4 に示す。

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

(3)新生児の一般状態

新生児の一般状態の成績を Table 43、INDIVIDUAL DATA 15-1～15-4 に示す。

対照群を含む全試験群において、生後 0 日から生後 4 日までの期間の死亡または不明（母動物に食されたと考えられる）児または授乳の証拠としてのミルクバンドのみられない児が散見された。

(4)新生児の体重推移

新生児の体重推移を Figure 7、Table 44、INDIVIDUAL DATA 16-1～16-4 に示す。

1 および 3 mg/kg 群では対照群と比較して有意な差はみられなかった。10 mg/kg 群では、生後 1 および 4 日の体重に雌雄とも対照群と比較して有意な低値がみられた。

(5)新生児の剖検

新生児の剖検の成績を Table 45、INDIVIDUAL DATA 17 および 18-1～18-4 に示す。

死亡児の剖検では、いずれの投与群においても異常はみられなかった。生後 4 日の生存児の剖検では、肝臓の 3 葉黄白色斑が 10 mg/kg 群の雄で 1 例にみられたのみであった。

考　察

ペルフルオロテトラデカン酸の 0（対照、0.5%CMC-Na）、1、3 および 10 mg/kg を 1 群雌雄各 12 匹の Crl:CD(SD) ラットに、雄に対しては交配前、交配期間および交配後を含む計 42 日間、雌に対しては交配前、交配および妊娠期間、ならびに分娩後 5 日までの期間（42－56 日間）経口投与し、雌雄動物への反復投与による影響、雌雄動物の生殖および新生児の発生に及ぼす影響について検討した。また、0（対照）および 10 mg/kg について、雄動物は各 5 匹を選抜し、雌動物は各 5 匹を別に設け、42 日間の投与終了後 14 日間の回復性についても併せて検討した。

1. 反復投与毒性

一般状態観察では、投与期間中いずれの動物にも被験物質投与に関連する変化はみられなかった。

詳細な一般状態観察では、雌雄とも被験物質投与に関連すると考えられる変化はいずれの投与群においてもみられなかった。機能検査では、投与 6 週の検査で、3 および 10 mg/kg 群の雄で後肢の握力に対照群と比較して有意な低値がみられ、被験物質投与との関連性が示唆されたが、回復 2 週には同じ変化はみられなかった。

体重および摂餌量については、雄では投与期間中はいずれの投与群においても対照群と比較して有意な差はみられなかったが、回復期間中の体重に 10 mg/kg 群で有意な低値がみられ、被験物質投与に関連した遅発性の変化と考えられた。雌の 1 mg/kg 群では被験物質投与の影響はみられなかった。3 mg/kg 群では哺育 4 日の体重に、10 mg/kg 群では哺育期間を通じて体重、体重増加量および体重増加率ならびに妊娠5日､10日および哺育4日の摂餌量に有意な低値がみられた。これらの変化については、回復群の雌においては有意な変化が認められなかったことから、妊娠および哺育に伴う生理的変化が毒性発現に関与していると考えられた。

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

血液学的検査では、10 mg/kg 群の雌で、回復群の回復期間終了時にヘモグロビン濃度およびヘマトクリット値の有意な低値がみられ、被験物質投与に関連した変化と考えられたが、主試験群の投与期間終了時には同じ変化はみられていないことから、非妊娠動物と妊娠動物の違いがあるものと推察された。なお、10 mg/kg 群でみられた活性化部分トロンボプラスチン時間およびプロトロンビン時間の有意な短縮については、短縮であることから毒性学的意義の乏しい変化と考えられた。

血液化学的検査では、投与期間終了時に 10 mg/kg 群の雄または雌で総蛋白および β-グロブリン分画比に有意な低値、アルカリホスファターゼ、尿素窒素、クロールに有意な高値がみられ、肝臓重量の増加や病理組織学的変化を考え合わせると肝機能への影響が示唆された。回復期間終

了時には、雄ではアルカリホスファターゼおよび無機リンに有意な高値、トリグリセリドに有意な低値、雌では総コレステロールに有意な低値、尿素窒素に有意な高値がみられた。雄のアルカリホスファターゼには回復性は認められなかった。他の項目では投与期間終了時に観察された変化はみられなかったことから、回復傾向にあるものと推察された。

投与期間終了時の剖検では 10 mg/kg 群の雄で肝臓の淡褐色化がみられ、器官重量の測定では 3 および 10 mg/kg 群の雄で肝臓の絶対および相対重量に有意な高値がみられた。10 mg/kg 群の雌では肝臓の相対重量に有意な高値がみられた。肝臓の病理組織学的検査では、小葉中心性肝細胞肥大が 3 および 10 mg/kg 群の雄で発生頻度が有意に増加し、肉眼所見に加えて器質的変化も認められた。雌でも小葉中心性肝細胞肥大が 10 mg/kg 群で発生頻度が有意に高かった。以上の変化は被験物質投与に関連したものと考えられた。小肉芽腫は、10 mg/kg 群の雌でグレードの憎悪化がみられ、被験物質投与との関連性が示唆された。その他に病理組織学的検査でみられた所見として甲状腺では、雄で濾胞細胞の肥大が 3 および 10 mg/kg 群でみられ、甲状腺の機能亢進が示唆された。雌の脾臓では髄外造血の低下が、胸腺では皮質の萎縮が、10 mg/kg 群で有意に増加し、ストレス性の変化と考えられた。

10 mg/kg 群の回復期間終了時の剖検では、肝臓の淡褐色化が雄 4 例にみられ、重量では、雄で絶対および相対重量に、雌で相対重量に有意な高値がみられた。病理組織学的検査では、小葉中心性肝細胞肥大、びまん性脂肪化、びまん性肝細胞肥大が雄または雌でみられ、肝臓の障害についての明らかな回復性は認められなかった。小肉芽腫は、雌でグレードの憎悪化がみられた。雄では甲状腺の濾胞細胞の肥大が引き続きみられた。

その他に剖検または病理組織学的検査でみられた所見は発生頻度が低いか用量相関性がみられないことから被験物質投与に関連のない変化と考えられた。

肝臓以外の器官重量の変化として、投与期間終了時に雄の 1 および 3 mg/kg 群で精嚢の絶対重量に有意な低値がみられたが、対照群において高値を示す 1 例(動物番号 101)の値を除いて統計処理した場合に有意な差は出なくなること、およびこれらの群の値は回復群の対照群に近い値であることから、偶発的なものと考えられた。3 mg/kg 群では、脾臓の相対重量、下垂体の絶対および相対重量、前立腺の絶対および相対重量に有意な低値がみられた。下垂体の変化については被験物質投与に関連した変化と考えられた。しかし、脾臓および前立腺の変化は用量相関性がみられないことから偶発的な変動と考えられた。10 mg/kg 群では、雄で下垂体および精嚢の絶対重量に有意な低値がみられ、被験物質投与に関連した変化と考えられた。雌では脳および卵巣の相対重量に有意な高値がみられたが、剖検時の体重低値に伴った変化と考えられた。回復期間終了時の腎臓または脳重量の変化も剖検時の体重低値に伴った変化あるいは二次的変化と考えられた。

以上をまとめると、ペルフルオロテトラデカン酸の反復投与により 1 mg/kg 群の雌雄では被験物質投与に関連した変化は認められなかった。3 mg/kg 群では雌の哺育期間の体重の低値、雄の

肝臓に重量の増加、ならびに肝臓および甲状腺に病理組織学的異常所見がみられた。10 mg/kg 群では雌の妊娠または哺育期間の体重および摂餌量の低値、雌雄の肝臓重量の増加、肝機能に関連する血液化学的検査項目の変化、剖検および病理組織学的検査における肝臓の異常所見が認められた。加えて、雄の甲状腺に病理組織学的異常所見がみられた。

したがって、本試験条件下におけるペルフルオロテトラデカン酸の無影響量（NOEL）は 1 mg/kg/day と考えられた。

2. 生殖発生毒性

生殖能検査では、いずれの項目にも、被験物質投与群と対照群との間に有意な差はみられなかった。

新生児の体重では、1 および 3 mg/kg 群において被験物質投与に関連した変化はみられなかった。10 mg/kg 群では、生後 1 および 4 日の体重に雌雄とも対照群と比較して有意な低値がみられた。新生児の一般状態および剖検では、被験物質投与に関連した変化はみられなかった。

したがって、本試験条件下におけるペルフルオロテトラデカン酸の反復投与による親動物の生殖に対する無影響量（NOEL）は 10 mg/kg/day、新生児の発生に対する無影響量（NOEL）は 3 mg/kg/day と考えられた。

参考文献

1）最終報告書：ペルフルオロテトラデカン酸のラットにおける反復投与毒性・生殖発生毒性併合試験(予備試験)(試験番号 SR07124P)，2010.

試験成績の信頼性に影響を及ぼしたと思われる環境要因

動物の飼育環境において、2010年12月2日に地震によるボイラーの緊急停止により、飼育室307号室の湿度が、試験計画書で規定した50±20%の範囲の下限を一時的に1%逸脱する事態が認められた。しかし、逸脱の幅は1%、時間は15分程度とわずかであり、復帰後の動物の一般状態に異常はみられなかったことから、試験成績の信頼性に対する影響はないと判断した。

その他に、試験成績の信頼性に影響を及ぼしたと思われる要因および試験計画書に従わなかったことはなかった。

資料の保存

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

① 試験計画書および試験計画書変更書

② 生データその他の記録文書

③ 最終報告書

④ 標本：膣垢塗抹標本

血液塗抹標本

固定器官・組織

病理組織標本(パラフィン包埋ブロックおよび光顕標本)

⑤ 被験物質サンプル

試験責任者の記名なつ印

試験責任者

[redacted] [redacted] 2012 年 3 月 12 日

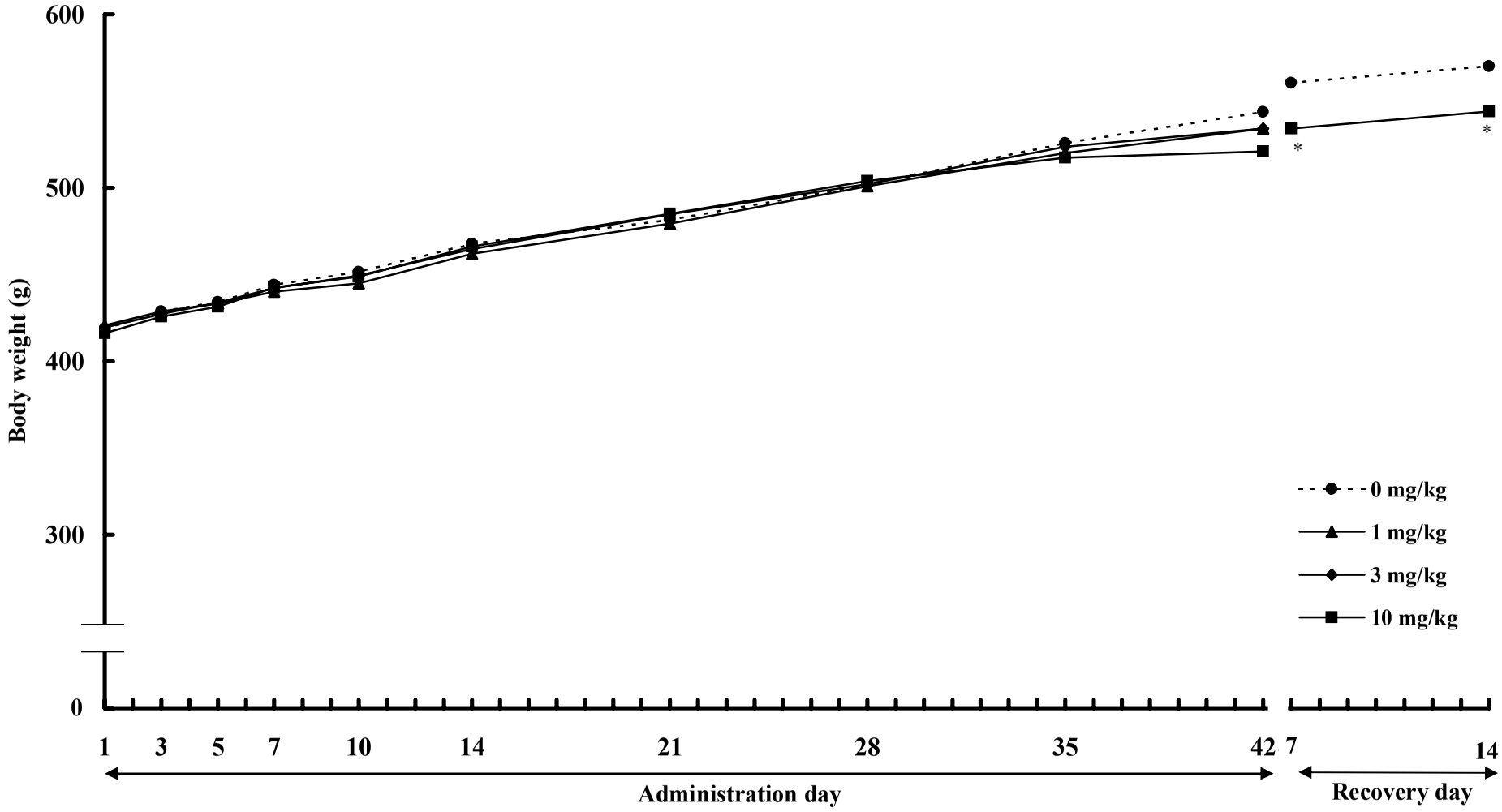


Figure 1 Body weight changes of male rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

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

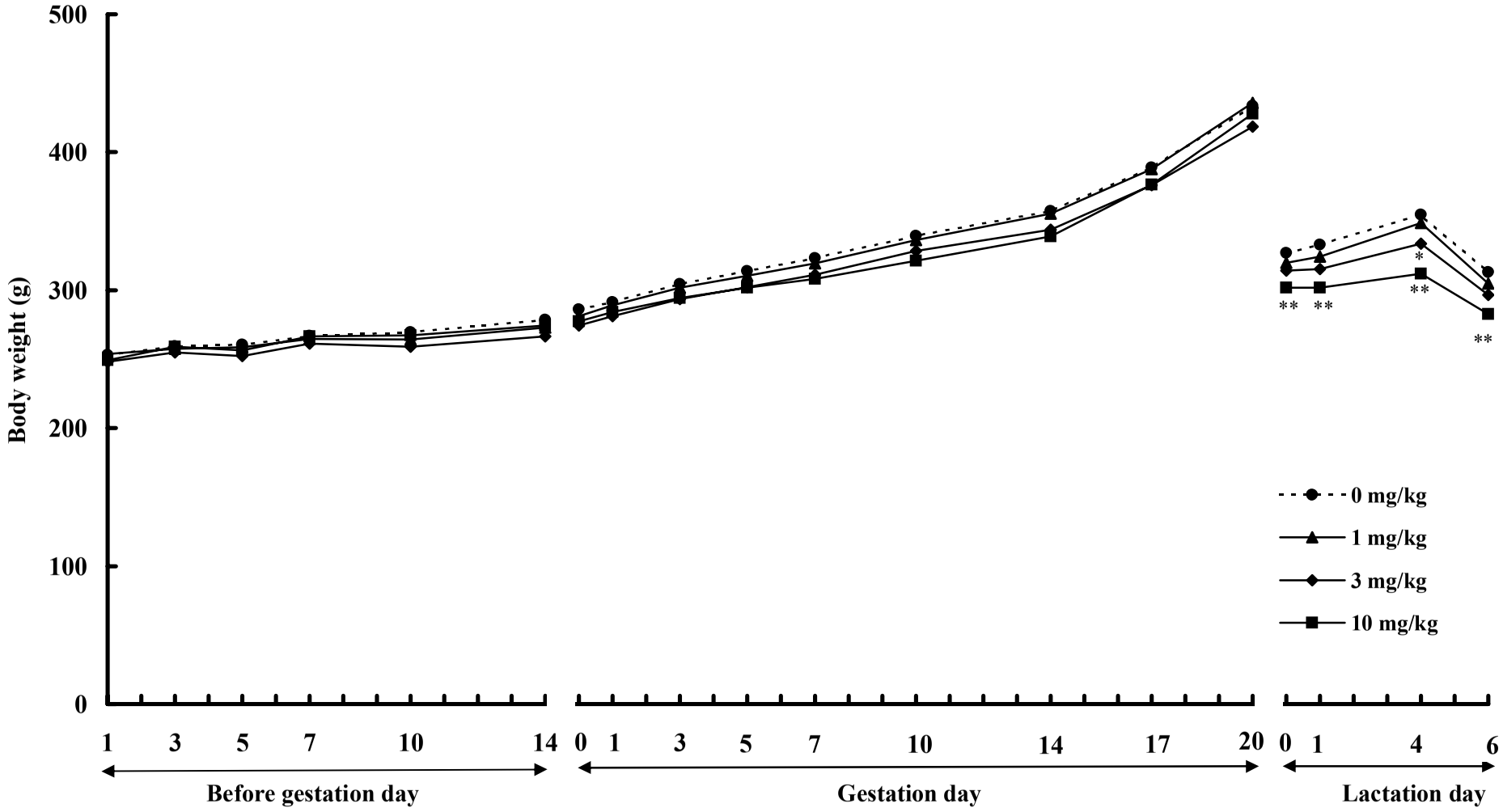


Figure 2 Body weight changes of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

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

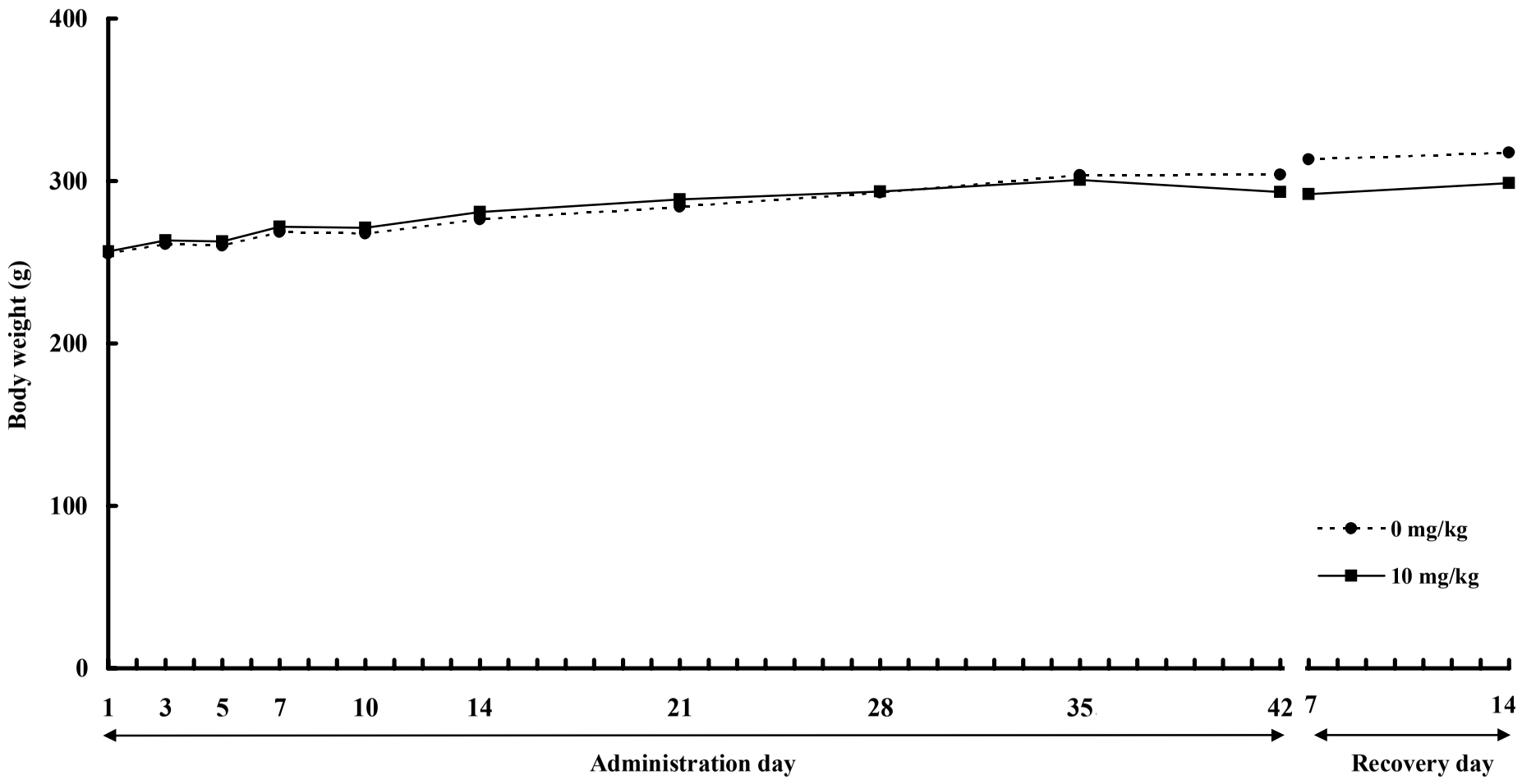


Figure 3 Body weight changes of female rats in 14-day recovery test following 42-day repeated oral dose with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

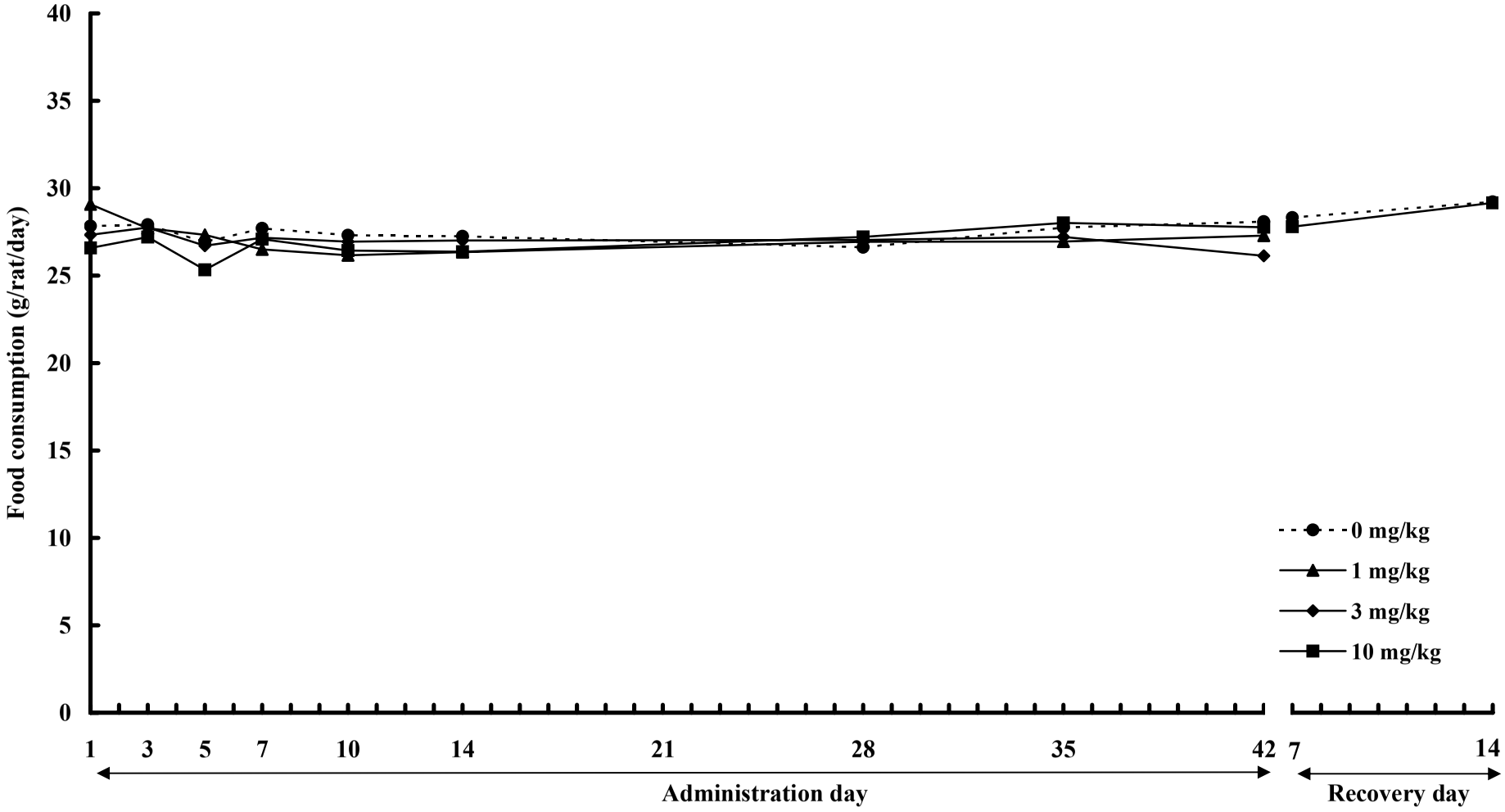


Figure 4 Food consumption of male rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

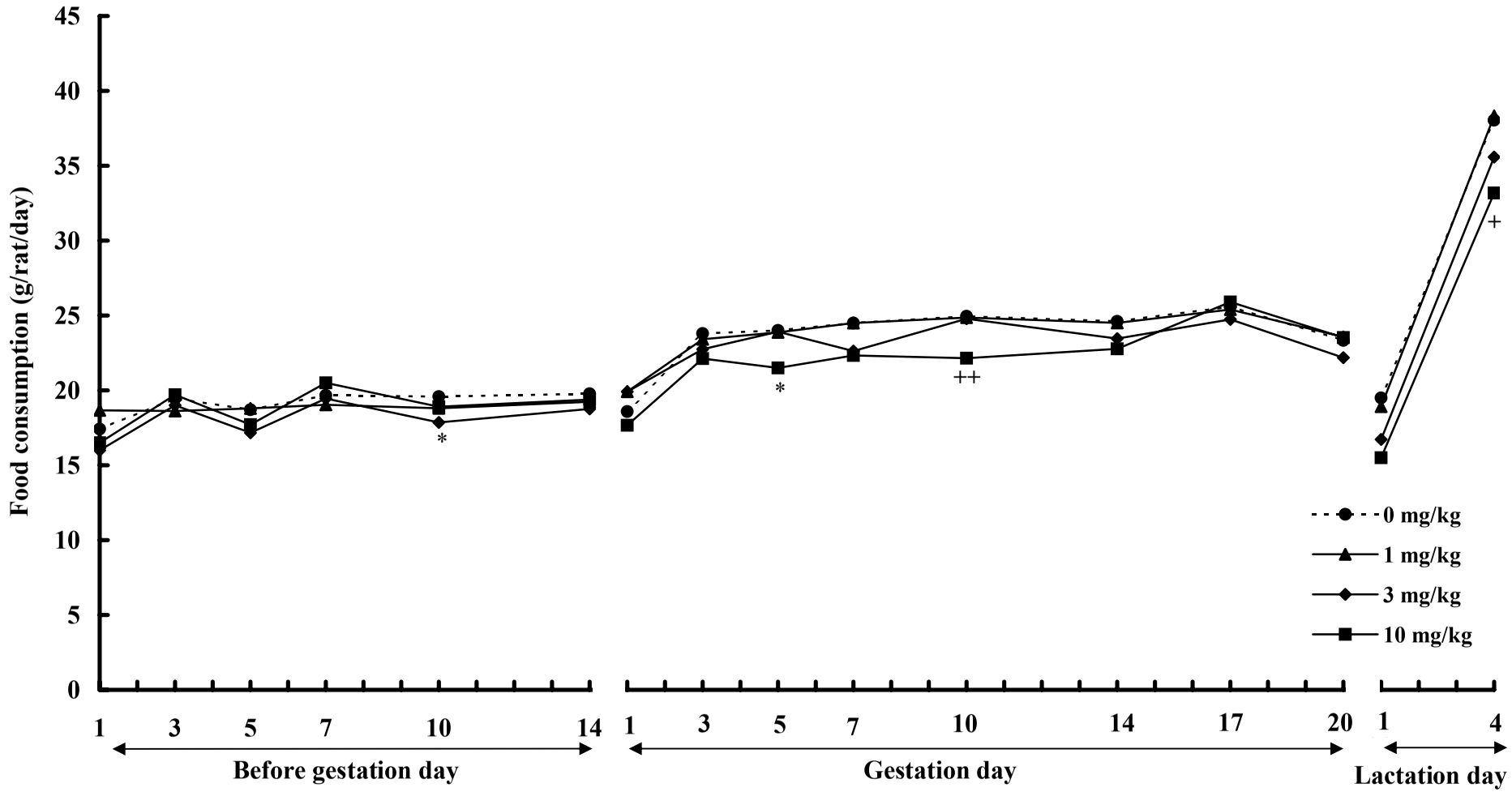


Figure 5 Food consumption of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

*: Significantly different from the 0 mg/kg group at p≦0.05 (Dunnett's test).
+: Significantly different from the 0 mg/kg group at p≦0.05 (Mann-Whitney's U-test).
++: Significantly different from the 0 mg/kg group at p≦0.01 (Mann-Whitney's U-test).

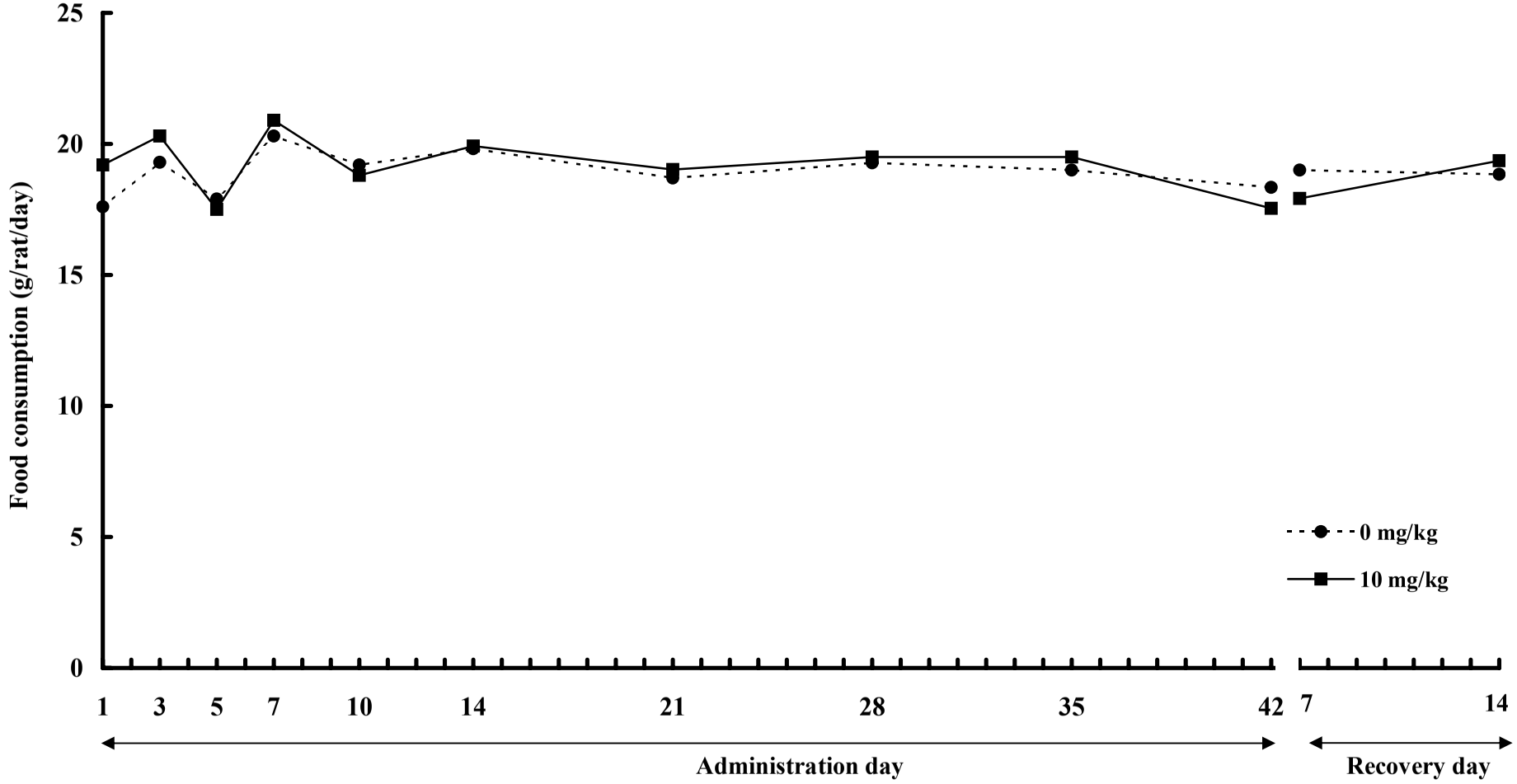


Figure 6 Food consumption of female rats in 14-day recovery test following 42-day repeated oral dose with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

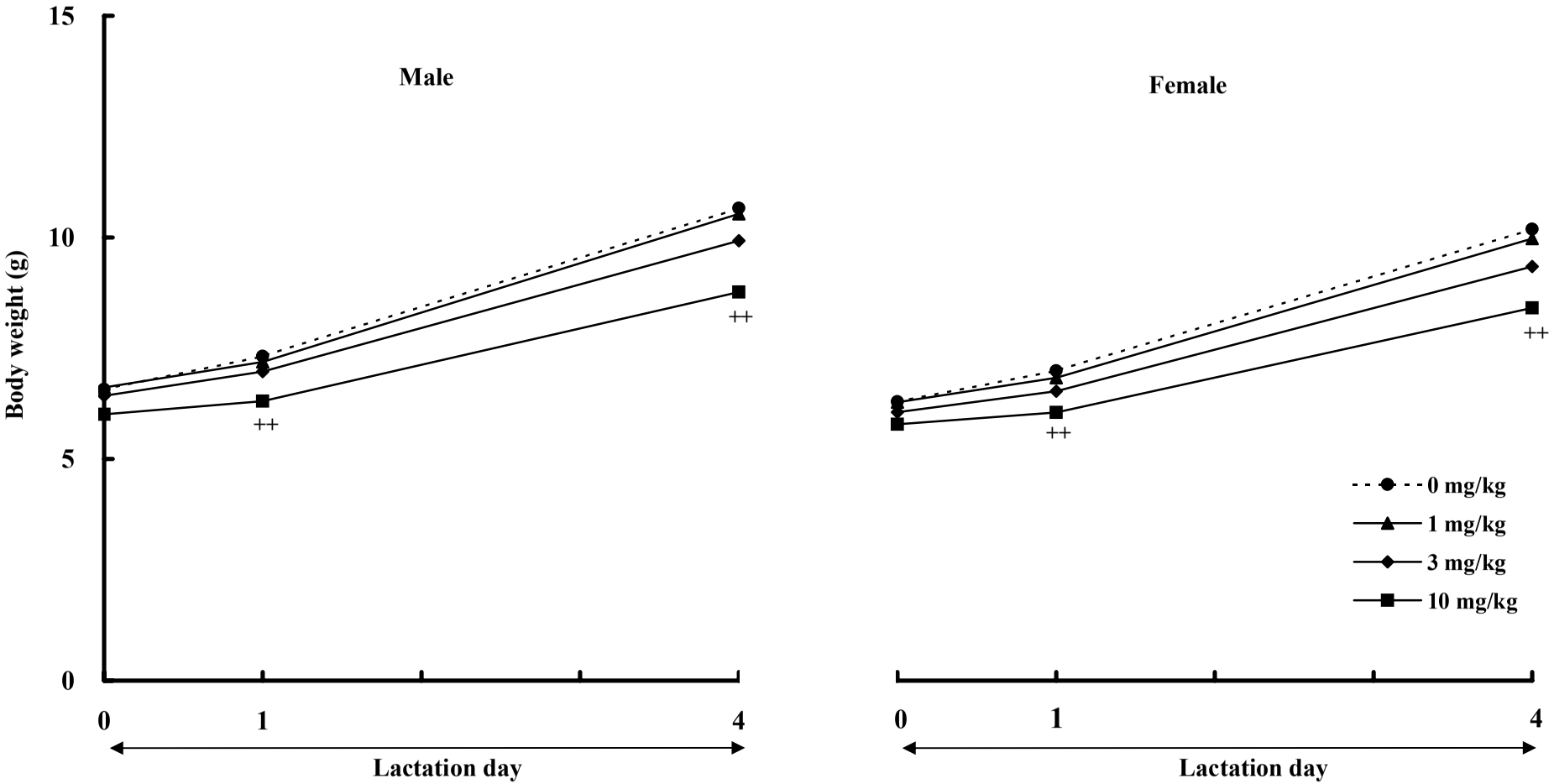


Figure 7 Body weight changes of pups in the combined repeated dose toxicity study with the reproduction/ developmental toxicity screening test of perfluorotetradecanoic acid in rats (SR07124)

++: Significantly different from the 0 mg/kg group at p ≦ 0.01 (Mann-Whitney's U-test).

Table 1 General appearance of male rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	Findings	Administration period [a]	Recovery period [a]
0 mg/kg	Number of animals examined	12	5
	No abnormal findings	12	5
1 mg/kg	Number of animals examined	12	-
	No abnormal findings	12	-
3 mg/kg	Number of animals examined	12	-
	No abnormal findings	12	-
10 mg/kg	Number of animals examined	12	5
	No abnormal findings	12	5

Values are the number of animals with findings.
a: Including autopsy day.
-: Blank.

Table 2 General appearance of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	Findings	Before gestation period	Gestation period	Lactation period [a]
0 mg/kg	Number of animals examined	12	12	12
	No abnormal findings	12	12	12
1 mg/kg	Number of animals examined	12	12	12
	No abnormal findings	12	12	12
3 mg/kg	Number of animals examined	12	12[b]	11
	No abnormal findings	12	12	11
10 mg/kg	Number of animals examined	12	12	12
	No abnormal findings	12	12	12

Values are the number of animals with findings.

(to be continued)

a: Including autopsy day.

b: One animal that delivered no pups until gestation day 25 was euthanized on the following day.

Table 2 General appearance of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124) (continued)

Group	Findings	Administration period	Recovery period [a]
0 mg/kg	Number of animals examined	5	5
	No abnormal findings	5	5
10 mg/kg	Number of animals examined	5	5
	No abnormal findings	5	4
	Loss of 3rd digit in left forelimb	0	1

Values are the number of animals with findings.
a: Including autopsy day.

Table 3-1 Detailed clinical observation of male rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

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

Category : The category number observed in each item.
Pre : Pre-administration.
Day 7, 14, 21 and 28 : Day 7, 14, 21 and 28 of administration.

(to be continued)

Table 3-1 Detailed clinical observation of male rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124) (continued-1)

							Stereotype		Bizarre behavior
Period	Group	Number of animals	Category No.	Body position/ Posture 1	Respiratory pattern 1	Tremor/ Convulsion 1	Rolling 0	Repetitive circling 0	Biting/ Selfmutilation 1
Day 35	0 mg/kg	12		12	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	12
Day 42	0 mg/kg	12		12	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	12
Recovery day 7	0 mg/kg	5		5	5	5	5	5	5
	10 mg/kg	5		5	5	5	5	5	5
Recovery day 14	0 mg/kg	5		5	5	5	5	5	5
	10 mg/kg	5		5	5	5	5	5	5

Category : The category number observed in each item.
Day 35 and 42 : Day 35 and 42 of administration.
Recovery day 7 and 14 : Day 7 and 14 of recovery.

Table 3-2 Detailed clinical observation of male rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Period	Group	Number of animals	Category No.	Ease of Removal 1	Ease of Handling 1	Muscle tone 2	Piloerection 1	Fur 1	Eyes 1	Mucous membranes 0	Skin 1	Pupil size 1	Lacrimation 1	Salivation 1	Secretions/ Excretions 0
Pre	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
Day 7	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
Day 14	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
Day 21	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
Day 28	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12

Category : The category number observed in each item.
Pre : Pre-administration.
Day 7, 14, 21 and 28 : Day 7, 14, 21 and 28 of administration.

(to be continued)

Table 3-2 Detailed clinical observation of male rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124) (continued-1)

Period	Group	Number of animals	Category No.	Ease of Removal 1	Ease of Handling 1	Muscle tone 2	Piloerection 1	Fur 1	Eyes 1	Mucous membranes 0	Skin 1	Pupil size 1	Lacrimation 1	Salivation 1	Secretions/ Excretions 0
Day 35	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
Day 42	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
Recovery day 7	0 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5	5
	10 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5	5
Recovery day 14	0 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5	5
	10 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5	5

Category : The category number observed in each item.
Day 35 and 42 : Day 35 and 42 of administration.
Recovery day 7 and 14 : Day 7 and 14 of recovery.

Table 3-3 Detailed clinical observation of male rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Period	Group	Number of animals	Category No.	Gait	Co-ordination of movement	Reactivity to environmental stimuli	Searching	Urination		Defecation		Stereotype		Bizarre behavior		Aggression
												Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	
				1	1	1	1	0	1	0	1	0	0	1	1	1
Pre	0 mg/kg	12		12	12	12	12	12	0	8	4	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	10	2	9	3	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	11	1	11	1	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	0	11	1	12	12	12	12	12
Day 7	0 mg/kg	12		12	12	12	12	11	1	11	1	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	10	2	11	1	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	11	1	10	2	12	12	12	12	12
Day 14	0 mg/kg	12		12	12	12	12	12	0	11	1	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	0	11	1	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	12	0	11	1	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12	12
Day 21	0 mg/kg	12		12	12	12	12	12	0	10	2	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	0	10	2	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	11	1	11	1	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	11	1	11	1	12	12	12	12	12
Day 28	0 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	10	2	11	1	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	11	1	12	0	12	12	12	12	12

Category : The category number observed in each item.
Pre : Pre-administration.
Day 7, 14, 21 and 28 : Day 7, 14, 21 and 28 of administration.

(to be continued)

Table 3-3 Detailed clinical observation of male rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124) (continued-1)

Period	Group	Number of animals	Category No.	Gait	Co-ordination of movement	Reactivity to environmental stimuli	Searching	Urination		Defecation		Stereotype		Bizarre behavior		Aggression
												Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	
				1	1	1	1	0	1	0	1	0	0	1	1	1
Day 35	0 mg/kg	12		12	12	12	12	11	1	12	0	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	11	1	12	0	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12	12
Day 42	0 mg/kg	12		12	12	12	12	10	2	12	0	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	9	3	10	2	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12	12
Recovery day 7	0 mg/kg	5		5	5	5	5	5	0	5	0	5	5	5	5	5
	10 mg/kg	5		5	5	5	5	5	0	5	0	5	5	5	5	5
Recovery day 14	0 mg/kg	5		5	5	5	5	5	0	5	0	5	5	5	5	5
	10 mg/kg	5		5	5	5	5	5	0	5	0	5	5	5	5	5

Category : The category number observed in each item.
Day 35 and 42 : Day 35 and 42 of administration.
Recovery day 7 and 14 : Day 7 and 14 of recovery.

Table 4-1-1 Detailed clinical observation of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

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

Category : The category number observed in each item.
Pre : Pre-administration.
Day 7, 14, 21 and 28 : Day 7, 14, 21 and 28 of administration.

(to be continued)

Table 4-1-1 Detailed clinical observation of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124) (continued-1)

							Stereotype		Bizarre behavior
Period	Group	Number of animals	Category No.	Body position/ Posture 1	Respiratory pattern 1	Tremor/ Convulsion 1	Rolling 0	Repetitive circling 0	Biting/ Selfmutilation 1
Day 35	0 mg/kg	12		12	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	12
Day 42	0 mg/kg	12		12	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	12
	3 mg/kg	11		11	11	11	11	11	11
	10 mg/kg	12		12	12	12	12	12	12

Category : The category number observed in each item.
Day 35 and 42 : Day 35 and 42 of administration.

Table 4-1-2 Detailed clinical observation of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Period	Group	Number of animals	Category No.	Ease of Removal 1	Ease of Handling 1	Muscle tone 2	Piloerection 1	Fur 1	Eyes 1	Mucous membranes 0	Skin 1	Pupil size 1	Lacrimation 1	Salivation 1	Secretions/ Excretions 0
Pre	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
Day 7	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
Day 14	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
Day 21	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
Day 28	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12

Category : The category number observed in each item.
Pre : Pre-administration.
Day 7, 14, 21 and 28 : Day 7, 14, 21 and 28 of administration.

(to be continued)

Table 4-1-2 Detailed clinical observation of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124) (continued-1)

Period	Group	Number of animals	Category No.	Ease of Removal 1	Ease of Handling 1	Muscle tone 2	Piloerection 1	Fur 1	Eyes 1	Mucous membranes 0	Skin 1	Pupil size 1	Lacrimation 1	Salivation 1	Secretions/ Excretions 0
Day 35	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
Day 42	0 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12
	3 mg/kg	11		11	11	11	11	11	11	11	11	11	11	11	11
	10 mg/kg	12		12	12	12	12	12	12	12	12	12	12	12	12

Category : The category number observed in each item.
Day 35 and 42 : Day 35 and 42 of administration.

Table 4-1-3 Detailed clinical observation of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Period	Group	Number of animals	Category No.	Gait	Co-ordination of movement	Reactivity to environmental stimuli	Searching	Urination		Defecation		Stereotype		Bizarre behavior		Aggression
												Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	
				1	1	1	1	0	1	0	1	0	0	1	1	1
Pre	0 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	11	1	12	0	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	10	2	12	0	12	12	12	12	12
Day 7	0 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	12	0	11	1	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12	12
Day 14	0 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12	12
Day 21	0 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	11	1	11	1	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12	12
Day 28	0 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12	12
	1 mg/kg	12		12	12	12	12	11	1	12	0	12	12	12	12	12
	3 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	0	12	0	12	12	12	12	12

Category : The category number observed in each item.
Pre : Pre-administration.
Day 7, 14, 21 and 28 : Day 7, 14, 21 and 28 of administration.

(to be continued)

Table 4-1-3 Detailed clinical observation of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124) (continued-1)

Period	Group	Number of animals	Category No.	Gait	Co-ordination of movement	Reactivity to environmental stimuli	Searching	Urination		Defecation		Stereotype			Bizarre behavior		Aggression
												Excessive grooming		Unusual head movement	Walking backward	Vocaliza-tion	
				1	1	1	1	0	1	0	1	0	1	0	1	1	1
Day 35	0 mg/kg	12		12	12	12	12	12	0	12	0	10	2	12	12	12	12
	1 mg/kg	12		12	12	12	12	11	1	11	1	12	0	12	12	12	12
	3 mg/kg	12		12	12	12	12	12	0	12	0	10	2	12	12	12	12
	10 mg/kg	12		12	12	12	12	12	0	12	0	11	1	12	12	12	12
Day 42	0 mg/kg	12		12	12	12	12	12	0	12	0	12	0	12	12	12	12
	1 mg/kg	12		12	12	12	12	12	0	12	0	12	0	12	12	12	12
	3 mg/kg	11		11	11	11	11	11	0	10	1	11	0	11	11	11	11
	10 mg/kg	12		12	12	12	12	12	0	12	0	11	1	12	12	12	12

Category : The category number observed in each item.
Day 35 and 42 : Day 35 and 42 of administration.

Table 4-2-1 Detailed clinical observation of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

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

Category : The category number observed in each item.
Pre : Pre-administration.
Day 7, 14, 21 and 28 : Day 7, 14, 21 and 28 of administration.

(to be continued)

Table 4-2-1 Detailed clinical observation of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124) (continued-1)

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

Category : The category number observed in each item.
Day 35 and 42 : Day 35 and 42 of administration.
Recovery day 7 and 14 : Day 7 and 14 of recovery.

Table 4-2-2 Detailed clinical observation of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

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

Category : The category number observed in each item.
Pre : Pre-administration.
Day 7, 14, 21 and 28 : Day 7, 14, 21 and 28 of administration.

(to be continued)

Table 4-2-2 Detailed clinical observation of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124) (continued-1)

Period	Group	Number of animals	Category No.	Ease of Removal 1	Ease of Handling 1	Muscle tone 2	Piloerection 1	Fur 1	Eyes 1	Mucous membranes 0	Skin 1	Pupil size 1	Lacrimation 1	Salivation 1	Secretions/ Excretions 0
Day 35	0 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5	5
	10 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5	5
Day 42	0 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5	5
	10 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5	5
Recovery day 7	0 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5	5
	10 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5	5
Recovery day 14	0 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5	5
	10 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5	5

Category : The category number observed in each item.
Day 35 and 42 : Day 35 and 42 of administration.
Recovery day 7 and 14 : Day 7 and 14 of recovery.

Table 4-2-3 Detailed clinical observation of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

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

Category : The category number observed in each item.
Pre : Pre-administration.
Day 7, 14, 21 and 28 : Day 7, 14, 21 and 28 of administration.

(to be continued)

Table 4-2-3 Detailed clinical observation of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124) (continued-1)

										Stereotype		Bizarre behavior		
Period	Group	Number of animals	Category No.	Gait	Co-ordination of movement	Reactivity to environmental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
				1	1	1	1	0	0	0	0	1	1	1
Day 35	0 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5
	10 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5
Day 42	0 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5
	10 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5
Recovery day 7	0 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5
	10 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5
Recovery day 14	0 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5
	10 mg/kg	5		5	5	5	5	5	5	5	5	5	5	5

Category : The category number observed in each item.
Day 35 and 42 : Day 35 and 42 of administration.
Recovery day 7 and 14 : Day 7 and 14 of recovery.

Table 5 Functional test of male rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

(Observation on the desk)		Number		Reactivity					Righting
		of	Category	Visual	Touch	Auditory	Pain	Proprioceptive	reflex
Period	Group	animals	No.	4	2	1	2	1	1
Administration	0 mg/kg	5		5	5	5	5	5	5
week 6	1 mg/kg	5		5	5	5	5	5	5
	3 mg/kg	5		5	5	5	5	5	5
	10 mg/kg	5		5	5	5	5	5	5
Recovery	0 mg/kg	5		5	5	5	5	5	5
week 2	10 mg/kg	5		5	5	5	5	5	5

Values are expressed as the number of animals.

(to be continued)

Table 5 Functional test of male rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124) (continued)

Period	Group	Number of animals		Grip strength (g)		Motor activity measurements						
				Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	0'-60'
Administration week 6	0 mg/kg	5	Mean	1222.18	778.12	421.2	264.2	151.6	106.2	79.6	56.8	1079.6
			S.D.	163.41	98.22	67.6	87.2	89.6	94.1	74.3	35.1	265.8
	1 mg/kg	5	Mean	1318.14	623.54	396.6	189.0	103.8	44.8	49.2	31.6	815.0
			S.D.	57.30	115.25	160.2	91.6	57.7	32.1	25.0	17.7	296.2
	3 mg/kg	5	Mean	1171.28	558.48*	593.6	417.6	215.0	173.8	136.0	112.4	1648.4
			S.D.	139.21	55.06	359.2	229.4	137.7	207.9	127.8	142.9	1082.6
	10 mg/kg	5	Mean	1143.26	536.52**	447.6	250.8	183.4	145.4	117.0	98.0	1242.2
			S.D.	214.05	148.04	243.9	103.5	111.1	92.8	45.9	54.1	573.5
Recovery week 2	0 mg/kg	5	Mean	1697.52	656.86	422.8	304.8	208.8	118.0	72.0	68.8	1195.2
			S.D.	216.63	86.37	112.5	92.8	100.2	23.8	38.0	25.7	300.0
	10 mg/kg	5	Mean	1545.34	579.14	365.8	261.8	171.6	151.8	118.4	102.8	1172.2
			S.D.	269.19	134.26	67.9	87.3	82.3	93.4	82.7	121.7	377.3

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

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

Table 6 Functional test of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

(Observation on the desk)		Number		Reactivity					Righting
		of	Category	Visual	Touch	Auditory	Pain	Proprioceptive	reflex
Period	Group	animals	No.	4	2	1	2	1	1
<Main group>									
Lactation	0 mg/kg	5		5	5	5	5	5	5
day 4	1 mg/kg	5		5	5	5	5	5	5
	3 mg/kg	5		5	5	5	5	5	5
	10 mg/kg	5		5	5	5	5	5	5
<Recovery group>									
Administration	0 mg/kg	5		5	5	5	5	5	5
week 6	10 mg/kg	5		5	5	5	5	5	5
Recovery	0 mg/kg	5		5	5	5	5	5	5
week 2	10 mg/kg	5		5	5	5	5	5	5

Values are expressed as the number of animals.

(to be continued)

Table 6 Functional test of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124) (continued)

Period	Group	Number of animals		Grip strength (g)		Motor activity measurements						
				Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	0'-60'
<Main group>												
Lactation day 4	0 mg/kg	5	Mean	979.40	631.20	544.8	286.8	164.4	118.6	74.2	74.6	1263.4
			S.D.	122.96	91.21	152.1	120.9	99.4	94.9	73.1	70.0	395.4
	1 mg/kg	5	Mean	1096.94	569.72	447.4	142.2	86.8	36.0	118.4	76.4	907.2
			S.D.	204.81	76.99	208.8	141.0	88.5	40.3	191.0	102.0	690.8
	3 mg/kg	5	Mean	1102.66	610.38	337.6	187.2	125.2	42.2	33.4	38.0	763.6
			S.D.	196.02	127.89	101.9	97.0	114.2	56.0	72.5	85.0	392.7
	10 mg/kg	5	Mean	1080.06	673.80	487.0	214.6	117.4	86.8	128.6	86.6	1121.0
			S.D.	109.07	118.21	133.1	124.5	86.9	99.3	172.0	147.9	650.1
<Recovery group>												
Administration week 6	0 mg/kg	5	Mean	906.16	528.28	700.6	493.6	300.0	215.4	56.0	17.8	1783.4
			S.D.	222.79	91.11	210.0	94.3	78.9	137.3	70.7	26.3	515.3
	10 mg/kg	5	Mean	770.92	550.86	577.8	424.4	341.8	185.0	62.6	76.8	1668.4
			S.D.	58.87	96.37	171.4	128.8	150.9	101.6	49.7	55.0	403.8
Recovery week 2	0 mg/kg	5	Mean	1310.92	481.12	615.8	450.8	338.0	214.8	271.8	175.0	2066.2
			S.D.	116.54	126.78	188.2	176.2	68.9	113.9	122.2	133.7	523.6
	10 mg/kg	5	Mean	1156.80	510.80	819.0	546.8	313.6	259.0	187.4	132.4	2258.2
			S.D.	122.73	84.64	206.0	73.7	171.9	97.2	85.8	90.5	288.2

Table 7 Body weight changes of male rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	Number of animals		Body weight (g) on administration period (day)										Body weight gain Days 1-42	
			1	3	5	7	10	14	21	28	35	42	(g)	(%)
0 mg/kg	12	Mean	418.4	428.8	434.2	444.1	451.4	467.6	481.4	501.7	525.8	543.7	125.3	29.818
		S.D.	19.7	21.8	21.3	21.7	22.2	23.3	27.5	38.8	38.1	41.5	25.3	5.161
1 mg/kg	12	Mean	420.7	428.8	433.3	440.2	444.9	462.1	479.3	500.8	519.9	534.0	113.3	26.944
		S.D.	19.0	20.2	20.5	21.9	22.5	23.9	23.0	25.6	28.9	29.3	17.3	3.978
3 mg/kg	12	Mean	419.6	427.3	433.8	442.2	449.1	464.6	484.6	505.2	523.7	534.0	114.4	27.325
		S.D.	20.8	19.5	22.1	22.0	22.2	23.4	24.4	24.4	26.2	29.1	20.1	4.881
10 mg/kg	12	Mean	416.3	425.7	431.5	442.6	448.8	466.2	484.9	504.0	517.3	520.9	104.7	25.148
		S.D.	14.6	18.6	18.7	20.9	21.8	26.3	27.4	30.0	34.6	35.8	30.9	7.239

Group	Number of animals		Body weight (g) on recovery period (day)		Body weight gain Day 42-R14	
			7	14	(g)	(%)
0 mg/kg	5	Mean	560.4	570.0	30.8	5.706
		S.D.	11.1	12.6	9.9	1.819
10 mg/kg	5	Mean	534.2 *	544.0 *	24.2	4.686
		S.D.	14.1	12.3	10.2	2.010

*: Significantly different from the 0 mg/kg group at $p \leqq 0.05$ (Dunnett's test).
R14: Recovery day 14.

Table 8 Body weight changes before gestation period of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	Number of animals		Body weight (g) on administration period (day)						Body weight gain Days 1-14	
			1	3	5	7	10	14	(g)	(%)
0 mg/kg	12	Mean	252.8	259.3	260.7	266.8	269.3	278.6	25.8	10.233
		S.D.	11.0	10.8	12.0	11.8	11.9	11.2	7.4	2.950
1 mg/kg	12	Mean	253.8	257.3	258.6	264.5	264.2	273.0	19.3	7.608
		S.D.	12.8	11.1	13.6	14.0	14.8	14.7	7.7	3.066
3 mg/kg	12	Mean	248.1	254.8	252.3	261.2	259.2	266.4	18.3	7.434
		S.D.	11.6	10.9	13.2	12.2	13.0	13.1	8.7	3.651
10 mg/kg	12	Mean	249.1	259.0	256.4	266.5	267.3	274.3	25.3	10.223
		S.D.	11.7	9.0	10.9	10.6	12.4	13.2	11.3	4.670

Table 9 Body weight changes during gestation period of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	Number of animals		Body weight (g) on gestation period (day)									Body weight gain Days 0-20	
			0	1	3	5	7	10	14	17	20	(g)	(%)
0 mg/kg	12	Mean	285.9	291.4	304.5	313.9	323.1	339.4	357.5	388.8	433.6	147.7	51.740
		S.D.	17.6	17.9	18.8	19.4	21.8	22.6	25.3	24.6	31.9	23.6	8.168
1 mg/kg	12	Mean	281.3	289.2	301.7	310.5	319.6	336.4	355.3	387.8	435.9	154.6	54.891
		S.D.	15.4	16.2	16.8	18.8	20.9	22.0	25.4	28.1	34.8	25.2	8.128
3 mg/kg	11	Mean	275.3	282.1	294.5	303.2	312.5	329.8	347.8	382.1	428.8	153.5	55.782
		S.D.	9.4	11.8	10.3	11.3	12.5	10.8	10.9	14.7	18.6	12.8	4.261
10 mg/kg	12	Mean	277.3	284.3	294.4	301.7	308.3	321.3	339.0	376.3	427.8	150.5	54.318
		S.D.	12.7	12.1	12.0	16.8	18.3	15.9	18.6	20.1	23.5	17.1	6.245

Table 10 Body weight changes during lactation period of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	Number of animals		Body weight (g) on lactation period (day)				Body weight gain Days 0-4	
			0	1	4	6	(g)	(%)
0 mg/kg	12	Mean	327.0	333.1	354.8	313.0	27.8	8.605
		S.D.	20.5	20.9	21.9	18.4	14.2	4.804
1 mg/kg	12	Mean	319.8	324.2	348.8	304.7	29.1	9.179
		S.D.	21.1	22.6	21.9	21.5	11.3	3.835
3 mg/kg	11	Mean	314.3	315.3	333.7 *	296.5	19.5	6.307
		S.D.	13.2	11.9	9.6	9.0	12.1	4.141
10 mg/kg	12	Mean	301.7 **	301.9 **	311.8 **	282.5 **	10.2 **	3.413 *
		S.D.	14.3	13.8	17.1	18.1	12.5	4.192

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

Table 11 Body weight changes of female rats in 14-day recovery test following 42-day repeated oral dose with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/ developmental toxicity screening test (SR07124)

Group	Number of animals		Body weight (g) on administration period (day)										Body weight gain Days 1-42	
			1	3	5	7	10	14	21	28	35	42	(g)	(%)
0 mg/kg	5	Mean	255.4	261.2	260.2	268.6	267.6	276.4	284.0	292.8	303.4	303.8	48.4	19.028
		S.D.	10.1	9.0	9.9	7.0	7.7	8.0	8.0	5.9	4.4	9.0	8.0	3.593
10 mg/kg	5	Mean	256.6	263.4	262.8	272.0	271.2	281.0	288.8	293.4	300.8	293.2	36.6	14.276
		S.D.	7.7	11.3	8.9	13.0	13.9	15.3	17.3	29.3	24.5	16.4	14.6	5.756

Group	Number of animals		Body weight (g) on recovery period (day)		Body weight gain Day 42-R14	
			7	14	(g)	(%)
0 mg/kg	5	Mean	313.4	317.4	13.6	4.490
		S.D.	8.9	9.7	6.3	2.074
10 mg/kg	5	Mean	291.8	298.6	5.4	1.818
		S.D.	26.6	20.0	7.9	2.677

R14: Recovery day 14.

Table 12 Food consumption of male rats dosed orally with perfluortetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	Number of animals		Food consumption (g/rat/day) on administration period (day)								
			1	3	5	7	10	14	28	35	42
0 mg/kg	12	Mean	27.83	27.92	26.92	27.71	27.31	27.25	(11) 26.62	(11) 27.75	28.09
		S.D.	2.76	2.88	2.13	2.23	1.87	2.11	3.66	2.04	2.11
1 mg/kg	12	Mean	29.08	27.71	27.33	26.50	26.17	26.34	(11) 26.94	(11) 26.95	27.29
		S.D.	1.88	1.76	3.88	2.20	1.93	2.01	2.11	2.14	2.30
3 mg/kg	12	Mean	27.33	27.75	26.71	27.17	26.94	27.01	27.04	27.22	26.13
		S.D.	2.27	1.59	2.10	1.76	1.35	1.78	2.13	1.90	2.41
10 mg/kg	12	Mean	26.58	27.21	25.33	27.08	26.43	26.37	27.22	28.02	27.77
		S.D.	3.94	2.02	1.99	1.52	2.38	1.69	1.79	2.54	2.36

Group	Number of animals		Food consumption (g/rat/day) on recovery period (day)	
			7	14
0 mg/kg	5	Mean	28.32	29.22
		S.D.	2.05	1.40
10 mg/kg	5	Mean	27.80	29.16
		S.D.	1.69	1.29

Values in parentheses are the number of animals examined.

Table 13 Food consumption before gestation period of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	Number of animals		Food consumption (g/rat/day) on administration period (day)					
			1	3	5	7	10	14
0 mg/kg	12	Mean	17.42	19.46	18.71	19.67	19.58	19.78
		S.D.	4.21	2.12	2.10	1.80	1.47	1.45
1 mg/kg	12	Mean	18.67	18.63	18.79	19.04	18.80	19.23
		S.D.	2.96	2.29	2.41	1.90	2.00	1.39
3 mg/kg	12	Mean	16.00	19.00	17.17	19.46	17.86 *	18.76
		S.D.	3.07	1.65	2.14	2.18	1.21	1.29
10 mg/kg	12	Mean	16.50	19.71	17.71	20.50	18.91	19.38
		S.D.	3.53	2.27	1.21	2.48	1.22	1.30

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

Table 14 Food consumption during gestation period of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	Number of animals		Food consumption (g/rat/day) on gestation period (day)							
			1	3	5	7	10	14	17	20
0 mg/kg	12	Mean	18.58	23.79	24.00	24.50	24.95	24.61	25.59	23.33
		S.D.	2.94	2.37	2.00	3.09	2.73	2.18	1.60	2.64
1 mg/kg	12	Mean	19.92	23.42	23.88	24.50	24.86	24.51	25.40	23.57
		S.D.	2.11	1.76	2.80	2.82	3.01	2.67	2.08	2.64
3 mg/kg	11	Mean	20.18	22.91	23.91	22.45	24.70	23.56	25.11	22.93
		S.D.	2.68	1.71	1.64	4.68	1.44	1.15	2.35	1.74
10 mg/kg	12	Mean	17.67	22.13	21.50 *	22.33	22.15 ++	22.78	25.90	23.53
		S.D.	2.23	1.90	3.04	2.30	1.38	1.81	1.62	1.68

*: Significantly different from the 0 mg/kg group at $p \leqq 0.05$ (Dunnett's test).
++: Significantly different from the 0 mg/kg group at $p \leqq 0.01$ (Mann-Whitney's U-test).

Table 15 Food consumption during lactation period of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	Number of animals		Food consumption (g/rat/day) on lactation period (day) 1	4
0 mg/kg	12	Mean	19.50	38.04
		S.D.	5.00	6.27
1 mg/kg	12	Mean	18.92	38.33
		S.D.	3.65	3.14
3 mg/kg	11	Mean	16.73	35.58
		S.D.	4.50	3.23
10 mg/kg	12	Mean	15.50	33.18 +
		S.D.	3.23	3.31

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

Table 16 Food consumption of female rats in 14-day recovery test following 42-day repeated oral dose with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/ developmental toxicity screening test (SR07124)

Group	Number of animals		Food consumption (g/day) on administration day									
			1	3	5	7	10	14	21	28	35	42
0 mg/kg	5	Mean	17.60	19.30	17.90	20.30	19.20	19.82	18.70	19.28	19.00	18.34
		S.D.	2.70	3.31	0.65	2.17	1.09	0.79	0.31	0.70	1.01	0.47
10 mg/kg	5	Mean	19.20	20.30	17.50	20.90	18.80	19.92	19.02	19.50	19.50	17.54
		S.D.	2.39	2.59	3.84	2.88	2.75	2.65	2.40	3.22	2.58	1.46

Group	Number of animals		Food consumption (g/rat/day) on recovery period (day)	
			7	14
0 mg/kg	5	Mean	19.00	18.84
		S.D.	1.41	1.36
10 mg/kg	5	Mean	17.92	19.36
		S.D.	3.37	0.92

Table 17 Urinary findings of male rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/ developmental toxicity screening test (SR07124)

Group	Number of animals	pH		Protein			Glucose	Ketone body	Urobilinogen	Bilirubin	Occult blood		Color
		8.0	8.5	−	±	+	−	−	0.1 EU/dL	−	−	±	A
0 mg/kg	5	2	3	2	1	2	5	5	5	5	5	0	5
1 mg/kg	5	1	4	1	3	1	5	5	5	5	5	0	5
3 mg/kg	5	0	5	0	5	0	5	5	5	5	3	2	5
10 mg/kg	5	2	3	2	0	3	5	5	5	5	5	0	5

Group	Number of animals	Specific gravity				Urine volume (mL/21hr., mean±S.D.)
		1.021-1.030	1.031-1.040	1.041-1.050	1.051≦	
0 mg/kg	5	2	2	1	0	19.70±5.54
1 mg/kg	5	1	1	2	1	19.30±14.02
3 mg/kg	5	1	2	2	0	15.60±6.80
10 mg/kg	5	1	2	2	0	14.90±1.64

Values are number of animals with findings.
Color: A = Pale yellow or yellow.
-; Negative, ±; slight, +; moderate.

Table 18 Urinary findings of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	Number of animals	pH						Protein			Glucose	Ketone body	Urobilinogen	Bilirubin	Occult blood	Color
		6.0	6.5	7.0	7.5	8.0	8.5	−	±	+	−	−	0.1 EU/dL	−	−	A
0 mg/kg	5	0	0	2	0	1	2	0	0	5	5	5	5	5	5	5
10 mg/kg	5	1	0	2	1	0	1	3	1	1	5	5	5	5	5	5

Group	Number of animals	Specific gravity					Urine volume (mL/21hr., mean±S.D.)
		1.011-1.020	1.021-1.030	1.031-1.040	1.041-1.050	1.051≦	
0 mg/kg	5	0	0	2	3	0	10.90±0.74
10 mg/kg	5	1	0	0	1	3	8.60±5.49

Values are number of animals with findings.
Color: A = Pale yellow or yellow.
-; Negative, ±; slight, +; moderate.

Table 19 Urinary findings of male rats in 14-day recovery test following 42-day repeated oral dose with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	Number of animals	pH	Protein		Glucose	Ketone body			Urobilinogen	Bilirubin	Occult blood	Color
		8.5	±	+	−	−	±	+	0.1 EU/dL	−	−	A
0 mg/kg	5	5	0	5	5	2	2	1	5	5	5	5
10 mg/kg	5	5	1	4	5	2	2	1	5	5	5	5

Group	Number of animals	Specific gravity				Urine volume (mL/21hr., mean±S.D.)
		1.021-1.030	1.031-1.040	1.041-1.050	1.051≦	
0 mg/kg	5	2	0	3	0	18.10±7.46
10 mg/kg	5	0	2	2	1	12.90±3.32

Values are number of animals with findings.
Color: A = Pale yellow or yellow.
-; Negative, ±; slight, +; moderate.

Table 20 Urinary findings of female rats in 14-day recovery test following 42-day repeated oral dose with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	Number of animals	pH				Protein			Glucose	Ketone body	Urobilinogen	Bilirubin	Occult blood	Color
		7.0	7.5	8.0	8.5	−	±	+	−	−	0.1 EU/dL	−	−	A
0 mg/kg	5	0	0	1	4	0	5	0	5	5	5	5	5	5
10 mg/kg	5	3	0	0	2	1	0	4	5	5	5	5	5	5

Group	Number of animals	Specific gravity				Urine volume (mL/21hr., mean±S.D.)
		1.021-1.030	1.031-1.040	1.041-1.050	1.051≦	
0 mg/kg	5	1	1	2	1	12.80±4.84
10 mg/kg	5	0	1	2	2	9.70±3.80

Values are number of animals with findings.
Color: A = Pale yellow or yellow.
-; Negative, ±; slight, +; moderate.

Table 21 Hematological findings of male rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/ developmental toxicity screening test (SR07124)

Group	Number of animals		WBC $10^2/\mu L$	RBC $10^4/\mu L$	HGB g/dL	HCT %	MCV fL	MCH pg	MCHC g/dL	Platelet $10^4/\mu L$
0 mg/kg	5	Mean	114.10	893.0	15.78	44.86	50.28	17.68	35.18	113.38
		S.D.	20.12	31.6	0.61	2.02	1.87	0.53	0.32	13.81
1 mg/kg	5	Mean	117.34	941.0	16.00	45.26	48.08	17.00	35.34	121.94
		S.D.	20.89	42.0	0.85	2.10	0.98	0.45	0.38	12.06
3 mg/kg	5	Mean	109.64	946.6	15.90	44.80	47.38	16.78	35.52	115.64
		S.D.	32.48	20.0	0.55	1.81	2.82	0.89	0.40	6.32
10 mg/kg	5	Mean	125.88	923.4	15.98	45.16	48.96	17.32	35.38	107.64
		S.D.	39.63	38.8	0.77	2.38	2.99	0.94	0.26	6.71

Group	Number of animals		Reticu-locyte %	PT sec	APTT sec	Differential count of WBC ($10^2/\mu L$)				
						Neutrophil	Lymphocyte	Monocyte	Eosinophil	Basophil
0 mg/kg	5	Mean	3.516	21.56	27.42	18.10	90.56	3.82	1.58	0.04
		S.D.	0.538	6.33	3.61	5.53	14.65	0.89	0.68	0.05
1 mg/kg	5	Mean	3.226	22.46	28.18	15.42	96.62	3.96	1.32	0.02
		S.D.	0.278	0.78	1.36	10.41	23.20	1.73	0.36	0.04
3 mg/kg	5	Mean	3.060	22.74	26.42	18.00	85.40	4.76	1.48	0.00
		S.D.	0.840	2.34	1.97	7.50	24.55	2.32	0.73	0.00
10 mg/kg	5	Mean	3.116	21.78	23.62 *	21.52	98.28	3.64	2.44	0.00
		S.D.	0.215	4.27	1.28	2.73	36.16	1.44	1.08	0.00

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

Table 22 Hematological findings of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/ developmental toxicity screening test (SR07124)

Group	Number of animals		WBC $10^2/\mu L$	RBC $10^4/\mu L$	HGB g/dL	HCT %	MCV fL	MCH pg	MCHC g/dL	Platelet $10^4/\mu L$
0 mg/kg	5	Mean	103.34	817.4	15.14	43.94	53.76	18.52	34.48	128.24
		S.D.	10.70	10.8	0.40	2.17	2.09	0.34	0.75	17.58
1 mg/kg	5	Mean	96.18	799.8	14.68	43.24	54.16	18.36	34.00	112.62
		S.D.	10.84	44.6	0.70	2.58	3.85	0.74	1.12	14.30
3 mg/kg	5	Mean	100.12	800.2	15.02	44.26	55.34	18.78	33.96	129.94
		S.D.	20.68	34.4	0.87	2.83	2.95	0.73	0.61	14.81
10 mg/kg	5	Mean	112.52	848.8	15.50	44.94	53.08	18.30	34.52	124.58
		S.D.	31.94	56.3	0.60	1.48	3.11	0.75	0.72	22.28

Group	Number of animals		Reticu-locyte %	PT sec	APTT sec	Differential count of WBC ($10^2/\mu L$)				
						Neutrophil	Lymphocyte	Monocyte	Eosinophil	Basophil
0 mg/kg	5	Mean	9.106	18.78	19.00	25.52	68.22	7.70	1.86	0.04
		S.D.	1.173	0.93	0.46	7.30	18.53	2.15	0.94	0.05
1 mg/kg	5	Mean	9.382	17.60	19.54	23.06	63.78	7.94	1.36	0.04
		S.D.	3.180	1.04	0.52	5.42	14.08	2.41	0.39	0.05
3 mg/kg	5	Mean	9.292	17.76	19.88	18.36	73.22	6.52	2.00	0.02
		S.D.	2.390	0.47	0.60	7.57	16.13	2.95	0.99	0.04
10 mg/kg	5	Mean	6.690	17.52	19.44	23.98	80.22	7.06	1.20	0.06
		S.D.	2.542	1.32	0.75	17.16	23.07	2.63	0.66	0.05

Table 23 Hematological findings of male rats in 14-day recovery test following 42-day repeated oral dose with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	Number of animals		WBC $10^2/\mu L$	RBC $10^4/\mu L$	HGB g/dL	HCT %	MCV fL	MCH pg	MCHC g/dL	Platelet $10^4/\mu L$
0 mg/kg	5	Mean	118.62	968.8	16.42	46.16	47.68	16.98	35.58	130.84
		S.D.	19.37	34.7	0.38	1.04	1.56	0.63	0.50	12.14
10 mg/kg	5	Mean	129.88	928.4	15.88	45.50	49.00	17.10	34.90	121.80
		S.D.	30.48	30.0	0.61	1.99	2.07	0.47	0.62	12.50

Group	Number of animals		Reticu-locyte %	PT sec	APTT sec	Differential count of WBC ($10^2/\mu L$)				
						Neutrophil	Lymphocyte	Monocyte	Eosinophil	Basophil
0 mg/kg	5	Mean	3.316	20.10	25.78	14.22	97.74	4.40	2.26	0.00
		S.D.	0.518	3.33	2.34	2.08	18.25	0.97	0.55	0.00
10 mg/kg	5	Mean	3.014	21.14	24.68	16.08	108.36	3.70	1.70	0.04
		S.D.	0.564	1.62	3.86	4.00	31.64	0.69	0.51	0.05

Table 24 Hematological findings of female rats in 14-day recovery test following 42-day repeated oral dose with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	Number of animals		WBC $10^2/\mu L$	RBC $10^4/\mu L$	HGB g/dL	HCT %	MCV fL	MCH pg	MCHC g/dL	Platelet $10^4/\mu L$
0 mg/kg	5	Mean	57.08	879.6	15.68	44.34	50.42	17.82	35.36	117.86
		S.D.	24.98	9.9	0.62	1.67	1.99	0.63	0.49	10.18
10 mg/kg	5	Mean	76.04	814.4	14.46 *	40.90 *	50.44	17.84	35.34	118.60
		S.D.	13.00	67.7	0.68	1.95	3.76	0.93	0.86	10.60

Group	Number of animals		Reticu-locyte %	PT sec	APTT sec	Differential count of WBC ($10^2/\mu L$)				
						Neutrophil	Lymphocyte	Monocyte	Eosinophil	Basophil
0 mg/kg	5	Mean	2.918	17.26	18.28	8.96	44.86	2.22	1.04	0.00
		S.D.	0.364	0.50	1.30	4.51	19.50	1.50	0.31	0.00
10 mg/kg	5	Mean	4.166	16.12 *	19.48	11.48	60.62	2.66	1.28	0.00
		S.D.	1.503	0.87	1.03	4.98	13.15	1.20	0.29	0.00

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

Table 25 Biochemical findings of male rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	Number of animals		TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%) Albumin	Globulin α_1	Globulin α_2	Globulin β	Globulin γ	AST IU/L	ALT IU/L	ALP IU/L	γ-GTP IU/L
0 mg/kg	5	Mean	5.74	2.822	0.970	49.22	21.56	7.24	17.12	4.86	70.6	31.4	363.2	0.60
		S.D.	0.19	0.108	0.063	1.58	2.03	0.42	0.91	0.81	3.1	5.1	81.5	0.14
1 mg/kg	5	Mean	5.66	2.808	0.986	49.62	22.46	7.18	16.14	4.60	70.4	28.8	352.6	0.56
		S.D.	0.21	0.135	0.090	2.16	1.93	0.78	0.80	0.87	10.9	2.6	113.1	0.15
3 mg/kg	5	Mean	5.78	2.848	0.970	49.26	22.28	7.02	16.24	5.20	72.2	31.8	355.0	0.56
		S.D.	0.30	0.129	0.065	1.62	2.18	0.59	0.57	0.48	6.6	3.6	51.8	0.22
10 mg/kg	5	Mean	5.26 **	2.734	1.084	52.02	19.56	7.20	15.68 *	5.54	72.4	31.0	520.8 *	0.48
		S.D.	0.11	0.080	0.091	2.13	1.40	0.36	0.99	0.76	6.4	5.1	75.6	0.29

Group	Number of animals		T-Bil mg/dL	Glucose mg/dL	T-Cho mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
0 mg/kg	5	Mean	0.064	154.8	60.0	36.0	14.26	0.546	145.4	4.618	106.8	9.44	6.36
		S.D.	0.021	15.5	9.9	9.4	1.43	0.038	1.1	0.232	1.3	0.23	0.47
1 mg/kg	5	Mean	0.058	157.0	53.8	50.4	14.02	0.546	145.6	4.604	107.4	9.42	6.04
		S.D.	0.004	8.6	6.0	22.1	1.47	0.029	0.5	0.218	1.8	0.33	0.50
3 mg/kg	5	Mean	0.056	162.6	44.0	46.4	16.00	0.540	145.4	4.820	107.0	9.48	6.42
		S.D.	0.015	12.0	11.2	17.1	1.71	0.022	0.9	0.125	0.7	0.33	0.60
10 mg/kg	5	Mean	0.080	157.2	50.8	21.8	19.88 **	0.542	145.6	4.914	108.4	9.08	6.98
		S.D.	0.022	11.4	14.7	6.3	1.99	0.055	1.3	0.258	2.3	0.22	0.44

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

Table 26 Biochemical findings of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	Number of animals		TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%) Albumin	Globulin α_1	Globulin α_2	Globulin β	Globulin γ	AST IU/L	ALT IU/L	ALP IU/L	γ-GTP IU/L
0 mg/kg	5	Mean	6.30	3.146	1.000	49.92	18.88	7.82	18.32	5.06	77.6	29.8	196.8	0.60
		S.D.	0.22	0.082	0.079	1.86	1.63	0.87	0.54	1.42	17.2	8.3	54.0	0.16
1 mg/kg	5	Mean	6.52	3.376	1.074	51.74	19.46	7.24	17.32	4.24	102.2	31.2	174.0	0.54
		S.D.	0.25	0.209	0.072	1.63	1.45	0.90	1.15	0.75	55.6	8.8	33.7	0.11
3 mg/kg	5	Mean	6.40	3.222	1.018	50.30	18.12	7.98	17.56	6.04	78.2	30.4	177.8	0.44
		S.D.	0.23	0.279	0.125	3.24	1.61	1.19	0.98	1.87	15.0	7.5	51.3	0.25
10 mg/kg	5	Mean	6.12	3.076	1.016	50.28	19.66	7.26	15.90 **	6.90	84.4	28.6	236.0	0.64
		S.D.	0.44	0.153	0.072	1.70	2.26	1.99	0.92	1.22	19.1	3.6	32.1	0.15

Group	Number of animals		T-Bil mg/dL	Glucose mg/dL	T-Cho mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
0 mg/kg	5	Mean	0.050	155.4	68.8	49.6	25.58	0.648	140.8	5.102	102.6	10.82	9.08
		S.D.	0.007	26.5	12.2	29.2	2.73	0.049	1.1	0.487	2.3	0.41	0.91
1 mg/kg	5	Mean	0.038 *	162.6	63.0	43.0	24.08	0.618	141.6	5.128	103.8	10.84	8.86
		S.D.	0.008	22.1	14.5	10.9	2.27	0.055	1.1	0.411	0.8	0.48	0.79
3 mg/kg	5	Mean	0.046	154.0	57.2	47.6	23.80	0.606	141.8	5.112	105.0	10.62	8.20
		S.D.	0.005	5.9	10.9	13.9	3.17	0.056	1.8	0.347	1.6	0.33	0.45
10 mg/kg	5	Mean	0.048	148.8	51.2	29.2	30.44	0.580	142.0	5.148	105.8 *	10.28	8.30
		S.D.	0.004	8.6	15.4	18.0	4.18	0.057	0.7	0.524	0.8	0.16	0.60

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

Table 27 Biochemical findings of male rats in 14-day recovery test following 42-day repeated oral dose with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/ developmental toxicity screening test (SR07124)

Group	Number of animals		TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%) Albumin	Globulin α_1	Globulin α_2	Globulin β	Globulin γ	AST IU/L	ALT IU/L	ALP IU/L	γ-GTP IU/L
0 mg/kg	5	Mean	5.80	2.792	0.930	48.16	23.26	7.04	16.40	5.14	62.6	26.4	334.2	0.70
		S.D.	0.12	0.089	0.074	1.98	3.09	0.65	0.72	0.80	10.5	2.4	51.7	0.12
10 mg/kg	5	Mean	5.52	2.788	1.028	50.58	20.60	6.34	16.36	6.12	67.0	31.2	470.4 **	0.68
		S.D.	0.34	0.180	0.106	2.53	3.18	0.76	0.51	1.02	3.4	4.4	67.3	0.16

Group	Number of animals		T-Bil mg/dL	Glucose mg/dL	T-Cho mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
0 mg/kg	5	Mean	0.064	177.8	63.8	59.2	14.82	0.562	143.4	4.710	105.4	9.52	6.20
		S.D.	0.005	14.5	18.9	14.2	1.04	0.045	1.5	0.351	1.1	0.26	0.33
10 mg/kg	5	Mean	0.060	170.0	50.6	31.8 **	16.20	0.526	143.6	4.988	106.6	9.40	6.68 *
		S.D.	0.019	14.9	10.7	8.9	2.11	0.037	1.1	0.270	1.1	0.23	0.29

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

Table 28 Biochemical findings of female rats in 14-day recovery test following 42-day repeated oral dose with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/ developmental toxicity screening test (SR07124)

Group	Number of animals		TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%) Albumin	Globulin α_1	Globulin α_2	Globulin β	Globulin γ	AST IU/L	ALT IU/L	ALP IU/L	γ-GTP IU/L
0 mg/kg	5	Mean	6.46	3.602	1.266	55.80	15.56	6.88	14.86	6.90	71.4	34.0	177.6	0.90
		S.D.	0.32	0.202	0.089	1.74	2.48	0.68	0.98	1.21	15.9	9.9	51.8	0.17
10 mg/kg	5	Mean	6.30	3.484	1.240	55.34	16.72	6.38	14.54	7.02	79.2	30.2	234.2	0.80
		S.D.	0.28	0.098	0.065	1.36	2.23	0.47	0.48	0.99	20.3	5.8	72.9	0.43

Group	Number of animals		T-Bil mg/dL	Glucose mg/dL	T-Cho mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
0 mg/kg	5	Mean	0.098	157.0	75.8	15.8	15.00	0.622	143.4	4.630	108.4	9.90	4.70
		S.D.	0.024	13.7	11.6	7.7	1.60	0.038	1.8	0.409	2.2	0.35	0.85
10 mg/kg	5	Mean	0.090	147.2	56.6 *	18.8	20.24 *	0.620	143.6	4.630	107.4	9.66	5.64
		S.D.	0.019	11.3	10.6	16.5	4.60	0.060	1.7	0.720	1.1	0.11	0.61

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

Table 29 Gross findings of male rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

	End of administration				End of recovery	
Group	0 mg/kg	1 mg/kg	3 mg/kg	10 mg/kg	0 mg/kg	10 mg/kg
Number of animals examined	7	12	12	7	5	5
No abnormal findings	5	11	11	0	5	1
Organ: Findings						
Liver: Pale brown discoloration	0	0	0	7	0	4
Kidney: Dilatation, renal pelvis	1	0	0	0	0	0
Epididymis: Yellowish white mass, cauda	1	1	0	0	0	0
Yellowish white patch, cauda	0	0	1	0	0	0

Values are the number of animals with findings.

Table 30 Gross findings of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	0 mg/kg			1 mg/kg			3 mg/kg			10 mg/kg		
	A	B	T	A	B	T	A	B	T	A	B	T
Number of animals examined	12	0	12	12	0	12	11	1	12	12	0	12
No abnormal findings	12	-	12	12	-	12	10	1	11	11	-	11
Organ: Findings												
Abdominal aorta: White discoloration	0	-	0	0	-	0	1	0	1	0	-	0
Spleen: Adhesion, adipose tissue	0	-	0	0	-	0	0	0	0	1	-	1

Values are the number of animals with findings.
Fate: A, animals nursing pups until lactation day 4; B, non-pregnant animals; T, total (A+B).
-: Blank.

Table 31 Gross findings of female rats in 14-day recovery test following 42-day repeated oral dose with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	0 mg/kg	10 mg/kg
Number of animals examined [a]	5	5
No abnormal findings	5	4
Organ: Findings		
Forelimb: Lost, 3rd digit	0	1

Values are the number of animals with findings.
a: Animals euthanized at the end of recovery.

Table 32-1 Absolute and relative organ weights of male rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	Number of animals		Body weight	Liver		Kidney		Spleen		Heart		Brain		Pituitary gland	
			g	g	%	g	%	g	%	g	%	g	%	mg	10^{-3}%
0 mg/kg	5	Mean	493.8	11.950	2.414	3.026	0.612	0.786	0.160	1.386	0.282	2.204	0.448	13.20	2.688
		S.D.	40.1	1.532	0.107	0.397	0.054	0.111	0.014	0.136	0.013	0.105	0.042	0.74	0.284
1 mg/kg	5	Mean	485.6	12.094	2.488	2.990	0.616	0.716	0.148	1.324	0.272	2.206	0.454	13.06	2.690
		S.D.	13.5	0.728	0.115	0.010	0.015	0.057	0.013	0.117	0.019	0.048	0.011	1.17	0.260
3 mg/kg	5	Mean	504.4	14.520 *	2.874 **	3.060	0.606	0.692	0.136 *	1.386	0.276	2.116	0.418	11.18 *	2.222 *
		S.D.	32.9	1.824	0.234	0.161	0.015	0.137	0.017	0.100	0.015	0.083	0.019	0.87	0.205
10 mg/kg	5	Mean	467.2	15.208 **	3.254 **	3.156	0.676	0.644	0.140	1.344	0.288	2.160	0.464	11.48 *	2.462
		S.D.	14.2	0.528	0.072	0.199	0.052	0.057	0.010	0.154	0.037	0.062	0.024	1.07	0.278

Group	Number of animals		Thymus		Thyroid		Adrenal		Prostate		Seminal vesicle	
			mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	g	%
0 mg/kg	5	Mean	282.2	56.414	20.36	4.108	61.2	12.410	899.6	183.174	2.526	0.512
		S.D.	104.5	17.739	3.69	0.483	4.1	0.528	280.2	58.899	0.508	0.102
1 mg/kg	5	Mean	356.4	73.500	21.22	4.380	61.6	12.710	835.2	171.996	2.002 *	0.412
		S.D.	65.6	14.200	2.77	0.665	6.4	1.513	114.7	23.439	0.185	0.035
3 mg/kg	5	Mean	291.6	57.384	19.34	3.810	54.2	10.738	603.0 *	119.934 *	2.008 *	0.402
		S.D.	87.5	14.829	4.80	0.819	12.1	2.324	172.0	36.071	0.286	0.077
10 mg/kg	5	Mean	244.4	52.126	23.46	5.014	56.2	12.042	748.4	160.526	1.908 *	0.408
		S.D.	73.1	15.142	4.91	0.986	8.4	1.903	94.5	22.351	0.152	0.023

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

Table 32-2 Absolute and relative organ weights of male rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	Number of animals		Body weight	Testis		Epididymis	
			g	g	%	g	%
0 mg/kg	7	Mean	515.7	3.141	0.610	1.254	0.244
		S.D.	49.8	0.287	0.049	0.124	0.024
1 mg/kg	12	Mean	503.9	3.318	0.661	1.295	0.258
		S.D.	26.6	0.295	0.061	0.057	0.016
3 mg/kg	12	Mean	505.3	3.345	0.663	1.248	0.248
		S.D.	26.8	0.228	0.041	0.086	0.014
10 mg/kg	7	Mean	494.9	3.347	0.683	1.316	0.270
		S.D.	48.7	0.273	0.090	0.105	0.040

Table 33 Absolute and relative organ weights of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	Number of animals		Body weight	Liver		Kidney		Spleen		Heart		Brain	
			g	g	%	g	%	g	%	g	%	g	%
0 mg/kg	5	Mean	304.4	10.140	3.328	2.088	0.688	0.794	0.260	1.014	0.334	1.982	0.652
		S.D.	13.4	0.753	0.174	0.221	0.075	0.080	0.019	0.058	0.009	0.038	0.031
1 mg/kg	5	Mean	313.6	10.960	3.494	2.096	0.670	0.710	0.228	1.020	0.324	2.022	0.648
		S.D.	26.5	1.134	0.208	0.240	0.067	0.162	0.045	0.089	0.011	0.046	0.054
3 mg/kg	5	Mean	297.4	10.166	3.422	1.980	0.668	0.710	0.238	1.034	0.350	2.090	0.702
		S.D.	10.6	0.190	0.160	0.080	0.044	0.181	0.049	0.046	0.019	0.088	0.027
10 mg/kg	5	Mean	282.8	10.436	3.698 *	2.024	0.718	0.604	0.212	0.946	0.334	2.074	0.738 *
		S.D.	21.4	0.894	0.292	0.109	0.060	0.117	0.036	0.131	0.039	0.114	0.068

Group	Number of animals		Pituitary gland		Thymus		Thyroid		Adrenal		Ovary	
			mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%
0 mg/kg	5	Mean	16.26	5.372	274.2	89.884	15.82	5.224	77.2	25.406	103.6	34.028
		S.D.	2.43	0.973	57.3	16.731	2.27	0.899	10.4	3.602	9.7	2.748
1 mg/kg	5	Mean	17.44	5.584	270.2	86.272	19.12	6.132	82.0	26.048	119.8	38.390
		S.D.	1.80	0.616	41.7	11.798	3.95	1.325	13.7	3.037	19.6	6.630
3 mg/kg	5	Mean	16.54	5.560	291.6	97.912	16.14	5.430	74.6	25.042	104.0	35.056
		S.D.	0.93	0.236	73.7	23.732	1.02	0.362	10.4	3.039	10.4	4.311
10 mg/kg	5	Mean	15.82	5.668	187.0	65.328	16.76	5.984	73.6	26.084	118.4	42.000 *
		S.D.	2.99	1.371	62.1	18.724	3.84	1.604	10.0	3.561	8.8	3.833

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

Table 34 Absolute and relative organ weights of male rats in 14-day recovery test following 42-day repeated oral dose with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/ developmental toxicity screening test (SR07124)

Group	Number of animals		Body weight	Liver		Kidney		Spleen		Heart		Brain		Pituitary gland		Thymus	
			g	g	%	g	%	g	%	g	%	g	%	mg	10^{-3}%	mg	10^{-3}%
0 mg/kg	5	Mean	539.0	13.086	2.428	3.172	0.590	0.812	0.150	1.452	0.268	2.206	0.408	13.10	2.430	262.2	48.732
		S.D.	11.0	0.947	0.152	0.270	0.048	0.074	0.017	0.124	0.026	0.098	0.023	2.46	0.437	28.2	6.115
10 mg/kg	5	Mean	516.6 *	16.406 **	3.178 **	3.618	0.698 *	0.762	0.148	1.474	0.288	2.282	0.440 *	13.70	2.652	322.2	62.516
		S.D.	13.6	0.480	0.155	0.399	0.059	0.047	0.013	0.189	0.029	0.062	0.016	1.04	0.205	110.1	22.305

Group	Number of animals		Thyroid		Adrenal		Testis		Epididymis		Prostate		Seminal vesicle	
			mg	10^{-3}%	mg	10^{-3}%	g	%	g	%	mg	10^{-3}%	g	%
0 mg/kg	5	Mean	23.14	4.292	64.0	11.862	3.486	0.648	1.446	0.268	865.8	160.556	2.178	0.402
		S.D.	1.72	0.299	11.7	2.068	0.218	0.054	0.128	0.020	147.9	26.827	0.124	0.029
10 mg/kg	5	Mean	24.82	4.812	56.0	10.808	3.178	0.616	1.326	0.256	787.8	152.584	2.142	0.414
		S.D.	5.34	1.084	15.2	2.779	0.525	0.103	0.143	0.026	208.7	40.979	0.417	0.074

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

Table 35 Absolute and relative organ weights of female rats in 14-day recovery test following 42-day repeated oral dose with perfluorooctadecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	Number of animals		Body weight	Liver		Kidney		Spleen		Heart		Brain	
			g	g	%	g	%	g	%	g	%	g	%
0 mg/kg	5	Mean	299.4	7.184	2.402	1.956	0.654	0.526	0.176	0.898	0.298	2.102	0.700
		S.D.	8.5	0.694	0.270	0.073	0.026	0.055	0.018	0.044	0.013	0.080	0.026
10 mg/kg	5	Mean	279.6	7.904	2.826 *	1.828 *	0.658	0.532	0.192	0.896	0.322	2.098	0.754 *
		S.D.	20.5	1.068	0.274	0.098	0.044	0.064	0.031	0.155	0.056	0.082	0.045

Group	Number of animals		Pituitary gland		Thymus		Thyroid		Adrenal		Ovary	
			mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%
0 mg/kg	5	Mean	16.32	5.440	299.6	99.930	15.06	5.042	71.0	23.768	88.8	29.676
		S.D.	2.29	0.630	41.4	11.891	3.92	1.359	8.1	3.121	12.7	4.367
10 mg/kg	5	Mean	18.06	6.426	275.4	98.252	16.44	5.880	66.0	23.618	100.6	35.910
		S.D.	3.75	1.041	96.9	33.775	2.58	0.785	10.6	3.563	22.7	7.674

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

Table 36 Histopathological findings of male rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

	Group	Control	1 mg/kg	3 mg/kg	10 mg/kg
Number of animals examined		7	12	12	7
Organ: Findings	Grade				
Lung: Aggregation, macrophage, alveolar	+	1 (5)	-	-	0 (5)
Mineralization, artery	+	1 (5)	-	-	2 (5)
Pancreas: Atrophy, acinar cell, focal	+	2 (5)	-	-	0 (5)
Liver: Hypertrophy, hepatocyte, centrilobular	+	0	0	6 *	0 **
	++	0	0	2	7
Microgranuloma	+	4	10	6	1
Kidney: Dilatation, renal pelvis	+	1 (5)	-	-	0 (5)
Epididymis: Spermatic granuloma	+	1 (5)	1 (1)	1 (1)	0 (5)
Prostate: Cellular infiltration, inflammatory cell	+	1 (5)	-	-	2 (5)
Thymus: Atrophy, cortex	+	2	0	0	1
Pituitary gland: Cyst, pars intermedia	+	1 (5)	-	-	0 (5)
Thyroid: Hypertrophy, follicular cell	+	0	0	4	4

Values are the number of animals with findings.
Values in parentheses are the number of animals examined.
-: Blank.
Grade; +: slight change, ++: moderate change.
*: Significantly different from the 0 mg/kg group at $p \leqq 0.05$ (Mann-Whitney's U-test).
**: Significantly different from the 0 mg/kg group at $p \leqq 0.01$ (Mann-Whitney's U-test).

Table 37 Histopathological findings of female rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

	Group	Control	1 mg/kg	3 mg/kg	10 mg/kg
Number of animals examined		12	12	12	12
Organ: Findings	Grade				
Lung: Aggregation, macrophage, alveolar	+	0 (5)	-	-	3 (5)
Mineralization, artery	+	1 (5)	-	-	0 (5)
Metaplasia, osseous, alveoli	+	1 (5)	-	-	0 (5)
Pancreas: Atrophy, acinar cell, focal	+	0 (5)	-	-	1 (5)
Liver: Hypertrophy, hepatocyte, centrilobular	+	0	0	0	9$^{\$\$}$
Microgranuloma	+	6	9	8	3 **
	++	0	0	0	7
Necrosis, focal	+	0	0	0	1
Kidney: Cellular infiltration, inflammatory cell, renal pelvic mucosa	+	1 (5)	-	-	0 (5)
Spleen: Decrease, extramedullary hematopoiesis	+	2	0	2	8$^{\$}$
Capsulitis	+	0	0	0	1
Thymus: Atrophy, cortex	+	1	2	1	8$^{\$\$}$
Pituitary gland: Cyst, pars distalis	+	0 (5)	-	-	1 (5)

Values are the number of animals with findings.
Values in parentheses are the number of animals examined.
-: Blank.
Grade; +: slight change, ++: moderate change.
**: Significantly different from the 0 mg/kg group at $p \leqq 0.01$ (Mann-Whitney's U-test).
$^{\$}$: Significantly different from the 0 mg/kg group at $p \leqq 0.05$ (Fisher's exact probability test).
$^{\$\$}$: Significantly different from the 0 mg/kg group at $p \leqq 0.01$ (Fisher's exact probability test).

Table 38 Histopathological findings of male rats in 14-day recovery test following 42-day repeated oral dose with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

	Group	Control	10 mg/kg
Number of animals examined		5	5
Organ: Findings	Grade		
Lung: Aggregation, macrophage, alveolar	+	0	1
Mineralization, artery	+	2	2
Fibrosis, pleura	+	0	1
Cellular infiltration, inflammatory cell, pleura	+	0	1
Liver: Hypertrophy, hepatocyte, centrilobular	+	0	2 **
	++	0	3
Microgranuloma	+	3	4
Fatty change, diffuse	+	0	2
Kidney: Hyaline droplet, proximal tubular epithelium	+	2	1
Eosinophilic body, proximal tubular epithelium	+	2	1
Regeneration, tubular epithelium	+	0	1
Cast, hyaline	+	1	1
Prostate: Cellular infiltration, inflammatory cell	+	1	2
Thyroid: Hypertrophy, follicular cell	+	0	2
Harderian gland: Cellular infiltration, inflammatory cell	+	1	0

Values are the number of animals with findings.
Grade; +: slight change, ++: moderate change.
**: Significantly different from the 0 mg/kg group at $p \leqq 0.01$ (Mann-Whitney's U-test).

Table 39 Histopathological findings of female rats in 14-day recovery test following 42-day repeated oral dose with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

	Group	Control	10 mg/kg
Number of animals examined		5	5
Organ: Findings	Grade		
Lung: Aggregation, macrophage, alveolar	+	0	2
Liver: Hypertrophy, hepatocyte, centrilobular	+	0	2
Hypertrophy, hepatocyte, diffuse	+	0	2
Microgranuloma	+	4	1
	++	0	3
Heart: Myocardial degeneration, focal	+	0	1
Kidney: Cellular infiltration, inflammatory cell, renal pelvic mucosa	+	0	1
Digit of forelimb: Fibrosis, subcutis	++	-	1 (1)
Cellular infiltration, inflammatory cell, subcutis	+	-	1 (1)

Values are the number of animals with findings.
Values in parentheses are the number of animals examined.
-: Blank.
Grade; +: slight change, ++: moderate change.

Table 40 Reproduction performance in parental rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	Estrous cycle Normality		Copulation index		Fertility index	Gestation index	Gestation length	Nursing index
			Male	Female				
	Incidence (%)	Length (days)[a]	Incidence (%)	Incidence (%)	Incidence (%)	Incidence (%)	(days)[a]	Incidence (%)
0 mg/kg	11/12 (91.7)	[11] 4.06 0.21	11/12 (91.7)	12/12 (100)	12/12 (100)	12/12 (100)	22.3 0.7	12/12 (100)
1 mg/kg	11/12 (91.7)	[11] 4.00 0.00	11/12 (91.7)	12/12 (100)	12/12 (100)	12/12 (100)	22.3 0.5	12/12 (100)
3 mg/kg	11/12 (91.7)	3.98 0.17	12/12 (100)	12/12 (100)	11/12 (91.7)	11/11 (100)	22.2 0.4	11/11 (100)
10 mg/kg	12/12 (100)	4.06 0.20	12/12 (100)	12/12 (100)	12/12 (100)	12/12 (100)	22.0 0.0	12/12 (100)

Normal estrous cycle = (number of females with normal estrous cycle / number of females examined) x 100.
Copulation index = (number of animals with successful copulation / number of animals mated) x 100.
Fertility index = (number of pregnant females / number of pairs with successful copulation) x 100.
Gestation index = (number of females with live pups / number of pregnant females) x 100.
Nursing index = (number of females nursing live pups on lactation day 4 / number of females with live pups delivery) x 100.
a: Values are means and S.D.
Values in square brackets are the number of animals examined.

Table 41 Estrus cycle of female rats in 14-day recovery test following 42-day repeated oral dose with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

	Administration period		Recovery period	
	Normality		Normality	
Group	Incidence (%)	Length (days)[a]	Incidence (%)	Length (days)[a]
0 mg/kg	5/5 (100)	4.34 0.47	5/5 (100)	4.40 0.89 [4]
10 mg/kg	5/5 (100)	4.00 0.00	4/5 (80.0)	4.08 0.15

Normal estrous cycle = (number of females with normal estrous cycle / number of females examined) x 100.

a: Values are means and S.D.

Values in square brackets are the number of animals examined.

Table 42 Pregnancy and litter data of rats dosed orally with perfluorotetradecanoic acid in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (SR07124)

Group	Number of pregnant animals		Number of corpora lutea	Number of implantation sites	Implantation index (%)	Delivery index (%)	Lactation day 0								Lactation day 4		
							Number of pups delivered					Sex ratio		Live birth index (%)	Number of live pups	Sex ratio	Viability index (%)
							Total	Male	Female	Alive	Dead	All pups	Live pups			All pups	
							Pup data										
0 mg/kg	12	Mean	16.7	16.0	96.208	89.467	14.5	7.1	7.4	14.5	0.0	0.470	0.470	100.000	14.1	0.467	97.536
		S.D.	1.9	1.7	4.995	19.627	3.8	2.7	2.0	3.8	0.0	0.113	0.113	0.000	3.6	0.112	3.059
1 mg/kg	12	Mean	16.4	16.2	98.564	94.727	15.3	8.1	7.3	15.3	0.0	0.532	0.532	100.000	15.0	0.525	98.001
		S.D.	1.8	1.6	2.623	5.972	2.0	1.6	2.1	2.0	0.0	0.101	0.101	0.000	1.9	0.102	3.882
3 mg/kg	11	Mean	16.1	15.9	98.825	95.928	15.3	7.4	7.9	15.2	0.1	0.481	0.485	99.465	15.1	0.487	99.522
		S.D.	1.6	1.8	2.615	5.831	2.1	2.4	2.1	2.0	0.3	0.132	0.135	1.773	1.8	0.138	1.586
10 mg/kg	12	Mean	17.0	16.4	96.838	96.633	15.8	8.7	7.2	15.8	0.0	0.547	0.547	100.000	15.2	0.543	96.120
		S.D.	2.2	2.0	5.930	4.504	1.8	2.1	2.0	1.8	0.0	0.116	0.116	0.000	1.3	0.137	4.496

Table 43 General appearance of pups in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test of perfluorotetradecanoic acid in rats (SR07124)

		Male					Female				
		Day of lactation					Day of lactation				
Group	Findings	0	1	2	3	4	0	1	2	3	4
0 mg/kg	Number of pups examined	85	85	82	82	82	89	89	88	88	87
	No abnormal findings	83	82	82	82	82	87	88	88	87	87
	Milk-band negative	2	0	0	0	0	2	0	0	0	0
	Death or missing	0	3	0	0	0	0	1	0	1	0
1 mg/kg	Number of pups examined	97	97	95	95	94	87	87	87	87	87
	No abnormal findings	97	95	95	94	94	87	87	87	87	86
	Death or missing	0	2	0	1	0	0	0	0	0	1
3 mg/kg	Number of pups examined	81	81	81	81	81	87	86	86	86	85
	No abnormal findings	81	81	81	81	81	86	86	86	85	85
	Death or missing	0	0	0	0	0	1	0	0	1	0
10 mg/kg	Number of pups examined	104	104	103	101	101	86	86	85	85	83
	No abnormal findings	104	102	101	100	99	86	85	85	83	83
	Milk-band negative	0	1	0	1	0	0	0	0	0	0
	Death or missing	0	1	2	0	2	0	1	0	2	0

Values are the number of pups with findings.

Table 44 Body weight changes of pups in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test of perfluorotetradecanoic acid in rats (SR07124)

Group	Number of litters		Male			Female		
			Body weight (g) on lactation day			Body weight (g) on lactation day		
			0	1	4	0	1	4
0 mg/kg	12	Mean	6.58	7.32	10.66	6.29	6.99	10.18
		S.D.	0.93	1.14	2.03	0.81	1.03	1.72
1 mg/kg	12	Mean	6.62	7.19	10.53	6.28	6.83	9.98
		S.D.	0.76	0.89	1.31	0.68	0.78	1.21
3 mg/kg	11	Mean	6.43	6.97	9.93	6.05	6.53	9.35
		S.D.	0.41	0.52	0.76	0.34	0.49	0.68
10 mg/kg	12	Mean	6.01	6.31 ++	8.77 ++	5.78	6.05 ++	8.41 ++
		S.D.	0.34	0.46	0.85	0.36	0.45	0.85

++: Significantly different from the 0 mg/kg group at $p \leqq 0.01$ (Mann-Whitney's U-test).

Table 45 Gross findings of pups in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test of perfluorotetradecanoic acid in rats (SR07124)

	Male				Female			
Group	0 mg/kg	1 mg/kg	3 mg/kg	10 mg/kg	0 mg/kg	1 mg/kg	3 mg/kg	10 mg/kg
Findings of dead pups during lactation days 0-4								
Number of pups examined	0	1	0	0	1	0	2	1
No abnormal findings	-	1	-	-	1	-	2	1
Findings of pups euthanized on lactation day 4								
Number of pups examined	82	94	81	99	87	86	85	83
No abnormal findings	82	94	81	98	87	86	85	83
Organ: Findings								
Liver: Yellowish white patch, middle lobe	0	0	0	1	0	0	0	0

Values are the number of pups with findings.
-: Blank.

INDIVIDUAL DATA 1-1-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
General appearance ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg

Animal No.	Administration period (day)																																							
	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15		16		17		18		19		20		21	
	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P
101	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
102	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
103	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
104	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
105	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
106	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
107	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
108	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
109	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
110	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
111	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
112	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

Animal No.	Administration period (day)																																								Autopsy day
	22		23		24		25		26		27		28		29		30		31		32		33		34		35		36		37		38		39		40		41		42		
	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A
101	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
102	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
103	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#
104	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
105	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
106	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#
107	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#
108	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#
109	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#
110	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
111	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
112	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

N : No abnormal findings. A : AM.
: Blank. P : PM.

(to be continued)

INDIVIDUAL DATA 1-1-1 (continued)

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
General appearance ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg

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

N : No abnormal findings. A : AM.
: Blank. P : PM.

INDIVIDUAL DATA 1-1-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
General appearance ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg

Animal No.	Administration period (day)																																							
	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15		16		17		18		19		20		21	
	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P
201	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
202	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
203	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
204	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
205	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
206	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
207	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
208	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
209	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
210	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
211	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
212	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

Animal No.	Administration period (day)																																								Autopsy day
	22		23		24		25		26		27		28		29		30		31		32		33		34		35		36		37		38		39		40		41		42		
	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A
201	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
202	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
203	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
204	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
205	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
206	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
207	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
208	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
209	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
210	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
211	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
212	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

N : No abnormal findings. A : AM.
P : PM.

INDIVIDUAL DATA 1-1-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
General appearance ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg

Animal No.	Administration period (day)																																							
	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15		16		17		18		19		20		21	
	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P
301	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
302	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
303	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
304	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
305	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
306	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
307	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
308	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
309	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
310	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
311	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
312	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

Animal No.	Administration period (day)																																								Autopsy day
	22		23		24		25		26		27		28		29		30		31		32		33		34		35		36		37		38		39		40		41		42		
	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A
301	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
302	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
303	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
304	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
305	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
306	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
307	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
308	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
309	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
310	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
311	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
312	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

N : No abnormal findings. A : AM.
P : PM.

INDIVIDUAL DATA 1-1-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
General appearance ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg

Animal No.	Administration period (day)																																							
	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15		16		17		18		19		20		21	
	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P
401	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
402	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
403	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
404	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
405	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
406	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
407	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
408	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
409	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
410	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
411	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
412	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

Animal No.	Administration period (day)																																								Autopsy day
	22		23		24		25		26		27		28		29		30		31		32		33		34		35		36		37		38		39		40		41		42		
	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A
401	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
402	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#
403	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
404	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
405	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#
406	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#
407	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
408	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
409	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#
410	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#
411	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
412	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

N : No abnormal findings. A : AM.
: Blank. P : PM.

(to be continued)

INDIVIDUAL DATA 1-1-4 (continued)

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
General appearance ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg

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

N : No abnormal findings. A : AM.
: Blank. P : PM.

INDIVIDUAL DATA 1-2-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
General appearance ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Pre-mating period (day)																																							
	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15		16		17		18		19		20		21	
	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P
151	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#	#	#	#	#	#	#	#	#
152	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#	#	#	#	#	#	#	#	#	#	#
153	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#	#	#	#	#	#	#
154	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#	#	#	#	#	#	#	#	#
155	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#	#	#	#	#	#	#
156	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
157	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#	#	#	#	#	#	#	#	#
158	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#	#	#	#	#	#	#	#	#
159	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#	#	#	#	#	#	#	#	#
160	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#	#	#	#	#	#	#
161	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#	#	#	#	#	#	#	#	#
162	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#	#	#	#	#

Animal No.	Pre-mating period (day)													
	22		23		24		25		26		27		28	
	A	P	A	P	A	P	A	P	A	P	A	P	A	P
151	#	#	#	#	#	#	#	#	#	#	#	#	#	#
152	#	#	#	#	#	#	#	#	#	#	#	#	#	#
153	#	#	#	#	#	#	#	#	#	#	#	#	#	#
154	#	#	#	#	#	#	#	#	#	#	#	#	#	#
155	#	#	#	#	#	#	#	#	#	#	#	#	#	#
156	N	N	N	N	N	N	N	N	N	N	N	N	N	N
157	#	#	#	#	#	#	#	#	#	#	#	#	#	#
158	#	#	#	#	#	#	#	#	#	#	#	#	#	#
159	#	#	#	#	#	#	#	#	#	#	#	#	#	#
160	#	#	#	#	#	#	#	#	#	#	#	#	#	#
161	#	#	#	#	#	#	#	#	#	#	#	#	#	#
162	#	#	#	#	#	#	#	#	#	#	#	#	#	#

N : No abnormal findings. A : AM.
: Blank (Copulated). P : PM.

(to be continued)

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

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
General appearance ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg

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

Animal No.	Gestation period (day)					
	21		22		23	
	A	P	A	P	A	P
151	N	N	N	N	N	N
152	N	N	#	#	#	#
153	N	N	#	#	#	#
154	N	N	#	#	#	#
155	N	N	#	#	#	#
156	N	N	#	#	#	#
157	N	N	N	N	#	#
158	N	N	#	#	#	#
159	N	N	N	N	#	#
160	N	N	#	#	#	#
161	N	N	#	#	#	#
162	N	N	#	#	#	#

N : No abnormal findings. A : AM.
: Blank (Delivered). P : PM.

(to be continued)

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

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
General appearance ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Lactation period (day)												
	0		1		2		3		4		5		6
	A	P	A	P	A	P	A	P	A	P	A	P	A
151	N	N	N	N	N	N	N	N	N	N	N	N	N
152	N	N	N	N	N	N	N	N	N	N	N	N	N
153	N	N	N	N	N	N	N	N	N	N	N	N	N
154	N	N	N	N	N	N	N	N	N	N	N	N	N
155	N	N	N	N	N	N	N	N	N	N	N	N	N
156	N	N	N	N	N	N	N	N	N	N	N	N	N
157	N	N	N	N	N	N	N	N	N	N	N	N	N
158	N	N	N	N	N	N	N	N	N	N	N	N	N
159	N	N	N	N	N	N	N	N	N	N	N	N	N
160	N	N	N	N	N	N	N	N	N	N	N	N	N
161	N	N	N	N	N	N	N	N	N	N	N	N	N
162	N	N	N	N	N	N	N	N	N	N	N	N	N

N : No abnormal findings. A : AM.
P : PM.

INDIVIDUAL DATA 1-2-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
General appearance ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg

Animal No.	Pre-mating period (day)																																							
	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15		16		17		18		19		20		21	
	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P
251	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#	#	#	#	#	#	#
252	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#	#	#	#	#	#	#	#	#
253	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#	#	#	#	#	#	#	#	#
254	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#	#	#	#	#	#	#	#	#	#	#
255	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#	#	#	#	#	#	#	#	#
256	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
257	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#	#	#	#	#
258	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#	#	#	#	#
259	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#	#	#	#	#
260	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#	#	#	#	#
261	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#	#	#	#	#	#	#
262	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#	#	#	#	#	#	#	#	#

Animal No.	Pre-mating period (day)													
	22		23		24		25		26		27		28	
	A	P	A	P	A	P	A	P	A	P	A	P	A	P
251	#	#	#	#	#	#	#	#	#	#	#	#	#	#
252	#	#	#	#	#	#	#	#	#	#	#	#	#	#
253	#	#	#	#	#	#	#	#	#	#	#	#	#	#
254	#	#	#	#	#	#	#	#	#	#	#	#	#	#
255	#	#	#	#	#	#	#	#	#	#	#	#	#	#
256	N	N	N	N	N	N	N	N	N	N	N	N	N	N
257	#	#	#	#	#	#	#	#	#	#	#	#	#	#
258	#	#	#	#	#	#	#	#	#	#	#	#	#	#
259	#	#	#	#	#	#	#	#	#	#	#	#	#	#
260	#	#	#	#	#	#	#	#	#	#	#	#	#	#
261	#	#	#	#	#	#	#	#	#	#	#	#	#	#
262	#	#	#	#	#	#	#	#	#	#	#	#	#	#

N : No abnormal findings. A : AM.
: Blank (Copulated). P : PM.

(to be continued)

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

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
General appearance ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg

Animal No.	Gestation period (day)																																											
	0		1		2		3		4		5		6		7		8		9		10		11		12		13		14		15		16		17		18		19		20		21		22	
	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P
251	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
252	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#
253	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#
254	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
255	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
256	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#
257	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#
258	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#
259	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#
260	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#
261	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
262	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#

N : No abnormal findings. A : AM.
: Blank (Delivered). P : PM.

(to be continued)

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

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
General appearance ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg

Animal No.	Lactation period (day)												
	0		1		2		3		4		5		6
	A	P	A	P	A	P	A	P	A	P	A	P	A
251	N	N	N	N	N	N	N	N	N	N	N	N	N
252	N	N	N	N	N	N	N	N	N	N	N	N	N
253	N	N	N	N	N	N	N	N	N	N	N	N	N
254	N	N	N	N	N	N	N	N	N	N	N	N	N
255	N	N	N	N	N	N	N	N	N	N	N	N	N
256	N	N	N	N	N	N	N	N	N	N	N	N	N
257	N	N	N	N	N	N	N	N	N	N	N	N	N
258	N	N	N	N	N	N	N	N	N	N	N	N	N
259	N	N	N	N	N	N	N	N	N	N	N	N	N
260	N	N	N	N	N	N	N	N	N	N	N	N	N
261	N	N	N	N	N	N	N	N	N	N	N	N	N
262	N	N	N	N	N	N	N	N	N	N	N	N	N

N : No abnormal findings. A : AM.
P : PM.

INDIVIDUAL DATA 1-2-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
General appearance ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg

Animal No.	Pre-mating period (day)																																	
	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15		16		17	
	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P
351	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#
352	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
353	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#
354	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#
355	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
356	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#	#	#
357	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
358	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#
359	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#	#	#
360	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#
361	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#
362	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#

N : No abnormal findings. A : AM.
: Blank (Copulated). P : PM.

(to be continued)

INDIVIDUAL DATA 1-2-3 (continued-1)

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
General appearance ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg

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

Animal No.	Gestation period (day)										
	21		22		23		24		25		26
	A	P	A	P	A	P	A	P	A	P	A
351	N	N	#	#	#	#	#	#	#	#	#
352	N	N	N	N	#	#	#	#	#	#	#
353	N	N	#	#	#	#	#	#	#	#	#
354	N	N	#	#	#	#	#	#	#	#	#
355	N	N	#	#	#	#	#	#	#	#	#
356	N	N	#	#	#	#	#	#	#	#	#
357	N	N	#	#	#	#	#	#	#	#	#
358	N	N	#	#	#	#	#	#	#	#	#
359	N	N	N	N	N	N	N	N	N	N	N
360	N	N	#	#	#	#	#	#	#	#	#
361	N	N	#	#	#	#	#	#	#	#	#
362	N	N	N	N	#	#	#	#	#	#	#

N : No abnormal findings. A : AM.
: Blank (Delivered). P : PM.

(to be continued)

INDIVIDUAL DATA 1-2-3 (continued-2)

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
General appearance ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg

Animal No.	Lactation period (day)												
	0		1		2		3		4		5		6
	A	P	A	P	A	P	A	P	A	P	A	P	A
351	N	N	N	N	N	N	N	N	N	N	N	N	N
352	N	N	N	N	N	N	N	N	N	N	N	N	N
353	N	N	N	N	N	N	N	N	N	N	N	N	N
354	N	N	N	N	N	N	N	N	N	N	N	N	N
355	N	N	N	N	N	N	N	N	N	N	N	N	N
356	N	N	N	N	N	N	N	N	N	N	N	N	N
357	N	N	N	N	N	N	N	N	N	N	N	N	N
358	N	N	N	N	N	N	N	N	N	N	N	N	N
359[a]	#	#	#	#	#	#	#	#	#	#	#	#	#
360	N	N	N	N	N	N	N	N	N	N	N	N	N
361	N	N	N	N	N	N	N	N	N	N	N	N	N
362	N	N	N	N	N	N	N	N	N	N	N	N	N

N : No abnormal findings. A : AM.
a: Non-pregnancy. P : PM.
: Blank.

INDIVIDUAL DATA 1-2-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
General appearance ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg

Animal No.	Pre-mating period (day)																																	
	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15		16		17	
	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P
451	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#
452	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
453	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#
454	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#
455	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#
456	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#
457	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#
458	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#
459	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#
460	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
461	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#	#	#
462	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	#	#

N : No abnormal findings. A : AM.
: Blank (Copulated). P : PM.

(to be continued)

INDIVIDUAL DATA 1-2-4 (continued-1)

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
General appearance ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg

Animal No.	Gestation period (day)																																									
	0		1		2		3		4		5		6		7		8		9		10		11		12		13		14		15		16		17		18		19		20		21	
	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P
451	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
452	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
453	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
454	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
455	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
456	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
457	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
458	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
459	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
460	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
461	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
462	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

N : No abnormal findings. A : AM.
P : PM.

(to be continued)

INDIVIDUAL DATA 1-2-4 (continued-2)

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
General appearance ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg

Animal No.	Lactation period (day)												
	0		1		2		3		4		5		6
	A	P	A	P	A	P	A	P	A	P	A	P	A
451	N	N	N	N	N	N	N	N	N	N	N	N	N
452	N	N	N	N	N	N	N	N	N	N	N	N	N
453	N	N	N	N	N	N	N	N	N	N	N	N	N
454	N	N	N	N	N	N	N	N	N	N	N	N	N
455	N	N	N	N	N	N	N	N	N	N	N	N	N
456	N	N	N	N	N	N	N	N	N	N	N	N	N
457	N	N	N	N	N	N	N	N	N	N	N	N	N
458	N	N	N	N	N	N	N	N	N	N	N	N	N
459	N	N	N	N	N	N	N	N	N	N	N	N	N
460	N	N	N	N	N	N	N	N	N	N	N	N	N
461	N	N	N	N	N	N	N	N	N	N	N	N	N
462	N	N	N	N	N	N	N	N	N	N	N	N	N

N : No abnormal findings. A : AM.
P : PM.

INDIVIDUAL DATA 1-3-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
General appearance ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Administration period (day)																																							
	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15		16		17		18		19		20		21	
	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P
163	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
164	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
165	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
166	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
167	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

Animal No.	Administration period (day)																																							
	22		23		24		25		26		27		28		29		30		31		32		33		34		35		36		37		38		39		40		41		42	
	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P
163	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
164	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
165	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
166	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
167	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

Animal No.	Recovery period (day)																												Autopsy day
	1		2		3		4		5		6		7		8		9		10		11		12		13		14		
	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A
163	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
164	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
165	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
166	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
167	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

N : No abnormal findings. A : AM.
P : PM.

INDIVIDUAL DATA 1-3-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
General appearance ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg

Animal No.	Administration period (day)																																							
	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15		16		17		18		19		20		21	
	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P
463	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
464	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
465	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
466	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
467	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

Animal No.	Administration period (day)																																							
	22		23		24		25		26		27		28		29		30		31		32		33		34		35		36		37		38		39		40		41		42	
	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P
463	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
464	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
465	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
466	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
467	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

Animal No.	Recovery period (day)																												Autopsy day
	1		2		3		4		5		6		7		8		9		10		11		12		13		14		
	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A	P	A
463	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
464	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
465	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
466	N	N	N	N	N	N	N	N	Ls	Ls	Ls	Ls	Ls	Ls	Ls	Ls	Ls	Ls	Ls	Ls	Ls	Ls	Ls	Ls	Ls	Ls	Ls	Ls	Ls
467	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

N : No abnormal findings. A : AM.
Ls : Loss of 3rd digit in left forelimb. P : PM.

INDIVIDUAL DATA 2-1-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Pre-administration

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

INDIVIDUAL DATA 2-1-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : Pre-administration

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

INDIVIDUAL DATA 2-1-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : Pre-administration

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

INDIVIDUAL DATA 2-1-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Pre-administration

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

INDIVIDUAL DATA 2-1-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Pre-administration

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

INDIVIDUAL DATA 2-1-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : Pre-administration

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

INDIVIDUAL DATA 2-1-7

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : Pre-administration

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

INDIVIDUAL DATA 2-1-8

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Pre-administration

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

INDIVIDUAL DATA 2-1-9

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Pre-administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
101	1	1	1	1	0	0	0	0	1	1	1
102	1	1	1	1	0	0	0	0	1	1	1
103	1	1	1	1	0	1	0	0	1	1	1
104	1	1	1	1	0	0	0	0	1	1	1
105	1	1	1	1	0	0	0	0	1	1	1
106	1	1	1	1	0	1	0	0	1	1	1
107	1	1	1	1	0	0	0	0	1	1	1
108	1	1	1	1	0	1	0	0	1	1	1
109	1	1	1	1	0	0	0	0	1	1	1
110	1	1	1	1	0	0	0	0	1	1	1
111	1	1	1	1	0	0	0	0	1	1	1
112	1	1	1	1	0	1	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	3.8296	3.6154	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-1-10

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : Pre-administration

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

INDIVIDUAL DATA 2-1-11

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : Pre-administration

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

INDIVIDUAL DATA 2-1-12

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Pre-administration

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

INDIVIDUAL DATA 2-2-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Pre-administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
151	1	1	1	0	0	1
152	1	1	1	0	0	1
153	1	1	1	0	0	1
154	1	1	1	0	0	1
155	1	1	1	0	0	1
156	1	1	1	0	0	1
157	1	1	1	0	0	1
158	1	1	1	0	0	1
159	1	1	1	0	0	1
160	1	1	1	0	0	1
161	1	1	1	0	0	1
162	1	1	1	0	0	1
N	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-2-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Pre-administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
251	1	1	1	0	0	1
252	1	1	1	0	0	1
253	1	1	1	0	0	1
254	1	1	1	0	0	1
255	1	1	1	0	0	1
256	1	1	1	0	0	1
257	1	1	1	0	0	1
258	1	1	1	0	0	1
259	1	1	1	0	0	1
260	1	1	1	0	0	1
261	1	1	1	0	0	1
262	1	1	1	0	0	1
N	12	12	12	12	12	12

INDIVIDUAL DATA 2-2-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Pre-administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
351	1	1	1	0	0	1
352	1	1	1	0	0	1
353	1	1	1	0	0	1
354	1	1	1	0	0	1
355	1	1	1	0	0	1
356	1	1	1	0	0	1
357	1	1	1	0	0	1
358	1	1	1	0	0	1
359	1	1	1	0	0	1
360	1	1	1	0	0	1
361	1	1	1	0	0	1
362	1	1	1	0	0	1
N	12	12	12	12	12	12

INDIVIDUAL DATA 2-2-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Pre-administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
451	1	1	1	0	0	1
452	1	1	1	0	0	1
453	1	1	1	0	0	1
454	1	1	1	0	0	1
455	1	1	1	0	0	1
456	1	1	1	0	0	1
457	1	1	1	0	0	1
458	1	1	1	0	0	1
459	1	1	1	0	0	1
460	1	1	1	0	0	1
461	1	1	1	0	0	1
462	1	1	1	0	0	1
N	12	12	12	12	12	12

INDIVIDUAL DATA 2-2-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Pre-administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
151	1	1	2	1	1	1	0	1	1	1	1	0
152	1	1	2	1	1	1	0	1	1	1	1	0
153	1	1	2	1	1	1	0	1	1	1	1	0
154	1	1	2	1	1	1	0	1	1	1	1	0
155	1	1	2	1	1	1	0	1	1	1	1	0
156	1	1	2	1	1	1	0	1	1	1	1	0
157	1	1	2	1	1	1	0	1	1	1	1	0
158	1	1	2	1	1	1	0	1	1	1	1	0
159	1	1	2	1	1	1	0	1	1	1	1	0
160	1	1	2	1	1	1	0	1	1	1	1	0
161	1	1	2	1	1	1	0	1	1	1	1	0
162	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-2-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Pre-administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
251	1	1	2	1	1	1	0	1	1	1	1	0
252	1	1	2	1	1	1	0	1	1	1	1	0
253	1	1	2	1	1	1	0	1	1	1	1	0
254	1	1	2	1	1	1	0	1	1	1	1	0
255	1	1	2	1	1	1	0	1	1	1	1	0
256	1	1	2	1	1	1	0	1	1	1	1	0
257	1	1	2	1	1	1	0	1	1	1	1	0
258	1	1	2	1	1	1	0	1	1	1	1	0
259	1	1	2	1	1	1	0	1	1	1	1	0
260	1	1	2	1	1	1	0	1	1	1	1	0
261	1	1	2	1	1	1	0	1	1	1	1	0
262	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-2-7

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Pre-administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
351	1	1	2	1	1	1	0	1	1	1	1	0
352	1	1	2	1	1	1	0	1	1	1	1	0
353	1	1	2	1	1	1	0	1	1	1	1	0
354	1	1	2	1	1	1	0	1	1	1	1	0
355	1	1	2	1	1	1	0	1	1	1	1	0
356	1	1	2	1	1	1	0	1	1	1	1	0
357	1	1	2	1	1	1	0	1	1	1	1	0
358	1	1	2	1	1	1	0	1	1	1	1	0
359	1	1	2	1	1	1	0	1	1	1	1	0
360	1	1	2	1	1	1	0	1	1	1	1	0
361	1	1	2	1	1	1	0	1	1	1	1	0
362	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-2-8

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Pre-administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
451	1	1	2	1	1	1	0	1	1	1	1	0
452	1	1	2	1	1	1	0	1	1	1	1	0
453	1	1	2	1	1	1	0	1	1	1	1	0
454	1	1	2	1	1	1	0	1	1	1	1	0
455	1	1	2	1	1	1	0	1	1	1	1	0
456	1	1	2	1	1	1	0	1	1	1	1	0
457	1	1	2	1	1	1	0	1	1	1	1	0
458	1	1	2	1	1	1	0	1	1	1	1	0
459	1	1	2	1	1	1	0	1	1	1	1	0
460	1	1	2	1	1	1	0	1	1	1	1	0
461	1	1	2	1	1	1	0	1	1	1	1	0
462	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-2-9

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Pre-administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
151	1	1	1	1	0	0	0	0	1	1	1
152	1	1	1	1	0	0	0	0	1	1	1
153	1	1	1	1	0	0	0	0	1	1	1
154	1	1	1	1	0	0	0	0	1	1	1
155	1	1	1	1	0	0	0	0	1	1	1
156	1	1	1	1	0	0	0	0	1	1	1
157	1	1	1	1	0	0	0	0	1	1	1
158	1	1	1	1	0	0	0	0	1	1	1
159	1	1	1	1	0	0	0	0	1	1	1
160	1	1	1	1	0	0	0	0	1	1	1
161	1	1	1	1	0	0	0	0	1	1	1
162	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	3.8296	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-2-10

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Pre-administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
251	1	1	1	1	0	0	0	0	1	1	1
252	1	1	1	1	0	0	0	0	1	1	1
253	1	1	1	1	0	0	0	0	1	1	1
254	1	1	1	1	0	0	0	0	1	1	1
255	1	1	1	1	0	0	0	0	1	1	1
256	1	1	1	1	0	0	0	0	1	1	1
257	1	1	1	1	0	0	0	0	1	1	1
258	1	1	1	1	0	0	0	0	1	1	1
259	1	1	1	1	0	0	0	0	1	1	1
260	1	1	1	1	0	0	0	0	1	1	1
261	1	1	1	1	0	0	0	0	1	1	1
262	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-2-11

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Pre-administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
351	1	1	1	1	0	0	0	0	1	1	1
352	1	1	1	1	0	0	0	0	1	1	1
353	1	1	1	1	0	0	0	0	1	1	1
354	1	1	1	1	1	0	0	0	1	1	1
355	1	1	1	1	0	0	0	0	1	1	1
356	1	1	1	1	0	0	0	0	1	1	1
357	1	1	1	1	0	0	0	0	1	1	1
358	1	1	1	1	0	0	0	0	1	1	1
359	1	1	1	1	0	0	0	0	1	1	1
360	1	1	1	1	0	0	0	0	1	1	1
361	1	1	1	1	0	0	0	0	1	1	1
362	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-2-12

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Pre-administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
451	1	1	1	1	0	0	0	0	1	1	1
452	1	1	1	1	0	0	0	0	1	1	1
453	1	1	1	1	0	0	0	0	1	1	1
454	1	1	1	1	0	0	0	0	1	1	1
455	1	1	1	1	0	0	0	0	1	1	1
456	1	1	1	1	0	0	0	0	1	1	1
457	1	1	1	1	0	0	0	0	1	1	1
458	1	1	1	1	0	0	0	0	1	1	1
459	1	1	1	1	0	0	0	0	1	1	1
460	1	1	1	1	0	0	0	0	1	1	1
461	1	1	1	1	1	0	0	0	1	1	1
462	1	1	1	1	1	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-2-13

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Pre-administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
163	1	1	1	0	0	1
164	1	1	1	0	0	1
165	1	1	1	0	0	1
166	1	1	1	0	0	1
167	1	1	1	0	0	1
N	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-2-14

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Pre-administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
463	1	1	1	0	0	1
464	1	1	1	0	0	1
465	1	1	1	0	0	1
466	1	1	1	0	0	1
467	1	1	1	0	0	1
N	5	5	5	5	5	5

INDIVIDUAL DATA 2-2-15

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Pre-administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
163	1	1	2	1	1	1	0	1	1	1	1	0
164	1	1	2	1	1	1	0	1	1	1	1	0
165	1	1	2	1	1	1	0	1	1	1	1	0
166	1	1	2	1	1	1	0	1	1	1	1	0
167	1	1	2	1	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-2-16

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Pre-administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
463	1	1	2	1	1	1	0	1	1	1	1	0
464	1	1	2	1	1	1	0	1	1	1	1	0
465	1	1	2	1	1	1	0	1	1	1	1	0
466	1	1	2	1	1	1	0	1	1	1	1	0
467	1	1	2	1	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5

INDIVIDUAL DATA 2-2-17

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Pre-administration

	In the open-field										
							Stereotype				
									Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
163	1	1	1	1	0	0	0	0	1	1	1
164	1	1	1	1	0	0	0	0	1	1	1
165	1	1	1	1	0	0	0	0	1	1	1
166	1	1	1	1	0	0	0	0	1	1	1
167	1	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-2-18

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Pre-administration

	In the open-field										
							Stereotype				
									Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
463	1	1	1	1	0	0	0	0	1	1	1
464	1	1	1	1	0	0	0	0	1	1	1
465	1	1	1	1	0	0	0	0	1	1	1
466	1	1	1	1	0	0	0	0	1	1	1
467	1	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5

INDIVIDUAL DATA 2-3-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 7 of administration

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

INDIVIDUAL DATA 2-3-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : Day 7 of administration

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

INDIVIDUAL DATA 2-3-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : Day 7 of administration

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

INDIVIDUAL DATA 2-3-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Day 7 of administration

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

INDIVIDUAL DATA 2-3-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 7 of administration

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

INDIVIDUAL DATA 2-3-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : Day 7 of administration

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

INDIVIDUAL DATA 2-3-7

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : Day 7 of administration

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

INDIVIDUAL DATA 2-3-8

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Day 7 of administration

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

INDIVIDUAL DATA 2-3-9

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 7 of administration

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

INDIVIDUAL DATA 2-3-10

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : Day 7 of administration

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

INDIVIDUAL DATA 2-3-11

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : Day 7 of administration

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

INDIVIDUAL DATA 2-3-12

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Day 7 of administration

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

INDIVIDUAL DATA 2-4-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 7 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
151	1	1	1	0	0	1
152	1	1	1	0	0	1
153	1	1	1	0	0	1
154	1	1	1	0	0	1
155	1	1	1	0	0	1
156	1	1	1	0	0	1
157	1	1	1	0	0	1
158	1	1	1	0	0	1
159	1	1	1	0	0	1
160	1	1	1	0	0	1
161	1	1	1	0	0	1
162	1	1	1	0	0	1
N	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-4-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 7 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
251	1	1	1	0	0	1
252	1	1	1	0	0	1
253	1	1	1	0	0	1
254	1	1	1	0	0	1
255	1	1	1	0	0	1
256	1	1	1	0	0	1
257	1	1	1	0	0	1
258	1	1	1	0	0	1
259	1	1	1	0	0	1
260	1	1	1	0	0	1
261	1	1	1	0	0	1
262	1	1	1	0	0	1
N	12	12	12	12	12	12

INDIVIDUAL DATA 2-4-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 7 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
351	1	1	1	0	0	1
352	1	1	1	0	0	1
353	1	1	1	0	0	1
354	1	1	1	0	0	1
355	1	1	1	0	0	1
356	1	1	1	0	0	1
357	1	1	1	0	0	1
358	1	1	1	0	0	1
359	1	1	1	0	0	1
360	1	1	1	0	0	1
361	1	1	1	0	0	1
362	1	1	1	0	0	1
N	12	12	12	12	12	12

INDIVIDUAL DATA 2-4-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 7 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
451	1	1	1	0	0	1
452	1	1	1	0	0	1
453	1	1	1	0	0	1
454	1	1	1	0	0	1
455	1	1	1	0	0	1
456	1	1	1	0	0	1
457	1	1	1	0	0	1
458	1	1	1	0	0	1
459	1	1	1	0	0	1
460	1	1	1	0	0	1
461	1	1	1	0	0	1
462	1	1	1	0	0	1
N	12	12	12	12	12	12

INDIVIDUAL DATA 2-4-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 7 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
151	1	1	2	1	1	1	0	1	1	1	1	0
152	1	1	2	1	1	1	0	1	1	1	1	0
153	1	1	2	1	1	1	0	1	1	1	1	0
154	1	1	2	1	1	1	0	1	1	1	1	0
155	1	1	2	1	1	1	0	1	1	1	1	0
156	1	1	2	1	1	1	0	1	1	1	1	0
157	1	1	2	1	1	1	0	1	1	1	1	0
158	1	1	2	1	1	1	0	1	1	1	1	0
159	1	1	2	1	1	1	0	1	1	1	1	0
160	1	1	2	1	1	1	0	1	1	1	1	0
161	1	1	2	1	1	1	0	1	1	1	1	0
162	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-4-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 7 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
251	1	1	2	1	1	1	0	1	1	1	1	0
252	1	1	2	1	1	1	0	1	1	1	1	0
253	1	1	2	1	1	1	0	1	1	1	1	0
254	1	1	2	1	1	1	0	1	1	1	1	0
255	1	1	2	1	1	1	0	1	1	1	1	0
256	1	1	2	1	1	1	0	1	1	1	1	0
257	1	1	2	1	1	1	0	1	1	1	1	0
258	1	1	2	1	1	1	0	1	1	1	1	0
259	1	1	2	1	1	1	0	1	1	1	1	0
260	1	1	2	1	1	1	0	1	1	1	1	0
261	1	1	2	1	1	1	0	1	1	1	1	0
262	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-4-7

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 7 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
351	1	1	2	1	1	1	0	1	1	1	1	0
352	1	1	2	1	1	1	0	1	1	1	1	0
353	1	1	2	1	1	1	0	1	1	1	1	0
354	1	1	2	1	1	1	0	1	1	1	1	0
355	1	1	2	1	1	1	0	1	1	1	1	0
356	1	1	2	1	1	1	0	1	1	1	1	0
357	1	1	2	1	1	1	0	1	1	1	1	0
358	1	1	2	1	1	1	0	1	1	1	1	0
359	1	1	2	1	1	1	0	1	1	1	1	0
360	1	1	2	1	1	1	0	1	1	1	1	0
361	1	1	2	1	1	1	0	1	1	1	1	0
362	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-4-8

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 7 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
451	1	1	2	1	1	1	0	1	1	1	1	0
452	1	1	2	1	1	1	0	1	1	1	1	0
453	1	1	2	1	1	1	0	1	1	1	1	0
454	1	1	2	1	1	1	0	1	1	1	1	0
455	1	1	2	1	1	1	0	1	1	1	1	0
456	1	1	2	1	1	1	0	1	1	1	1	0
457	1	1	2	1	1	1	0	1	1	1	1	0
458	1	1	2	1	1	1	0	1	1	1	1	0
459	1	1	2	1	1	1	0	1	1	1	1	0
460	1	1	2	1	1	1	0	1	1	1	1	0
461	1	1	2	1	1	1	0	1	1	1	1	0
462	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-4-9

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 7 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
151	1	1	1	1	0	0	0	0	1	1	1
152	1	1	1	1	0	0	0	0	1	1	1
153	1	1	1	1	0	0	0	0	1	1	1
154	1	1	1	1	0	0	0	0	1	1	1
155	1	1	1	1	0	0	0	0	1	1	1
156	1	1	1	1	0	0	0	0	1	1	1
157	1	1	1	1	0	0	0	0	1	1	1
158	1	1	1	1	0	0	0	0	1	1	1
159	1	1	1	1	0	0	0	0	1	1	1
160	1	1	1	1	0	0	0	0	1	1	1
161	1	1	1	1	0	0	0	0	1	1	1
162	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	3.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-4-10

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 7 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
251	1	1	1	1	0	0	0	0	1	1	1
252	1	1	1	1	0	0	0	0	1	1	1
253	1	1	1	1	0	0	0	0	1	1	1
254	1	1	1	1	0	0	0	0	1	1	1
255	1	1	1	1	0	0	0	0	1	1	1
256	1	1	1	1	0	0	0	0	1	1	1
257	1	1	1	1	0	0	0	0	1	1	1
258	1	1	1	1	0	0	0	0	1	1	1
259	1	1	1	1	0	0	0	0	1	1	1
260	1	1	1	1	0	0	0	0	1	1	1
261	1	1	1	1	0	0	0	0	1	1	1
262	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-4-11

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 7 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
351	1	1	1	1	0	0	0	0	1	1	1
352	1	1	1	1	0	0	0	0	1	1	1
353	1	1	1	1	0	0	0	0	1	1	1
354	1	1	1	1	0	0	0	0	1	1	1
355	1	1	1	1	0	0	0	0	1	1	1
356	1	1	1	1	0	1	0	0	1	1	1
357	1	1	1	1	0	0	0	0	1	1	1
358	1	1	1	1	0	0	0	0	1	1	1
359	1	1	1	1	0	0	0	0	1	1	1
360	1	1	1	1	0	0	0	0	1	1	1
361	1	1	1	1	0	0	0	0	1	1	1
362	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-4-12

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 7 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
451	1	1	1	1	0	0	0	0	1	1	1
452	1	1	1	1	0	0	0	0	1	1	1
453	1	1	1	1	0	0	0	0	1	1	1
454	1	1	1	1	0	0	0	0	1	1	1
455	1	1	1	1	0	0	0	0	1	1	1
456	1	1	1	1	0	0	0	0	1	1	1
457	1	1	1	1	0	0	0	0	1	1	1
458	1	1	1	1	0	0	0	0	1	1	1
459	1	1	1	1	0	0	0	0	1	1	1
460	1	1	1	1	0	0	0	0	1	1	1
461	1	1	1	1	0	0	0	0	1	1	1
462	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-4-13

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 7 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
163	1	1	1	0	0	1
164	1	1	1	0	0	1
165	1	1	1	0	0	1
166	1	1	1	0	0	1
167	1	1	1	0	0	1
N	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-4-14

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 7 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
463	1	1	1	0	0	1
464	1	1	1	0	0	1
465	1	1	1	0	0	1
466	1	1	1	0	0	1
467	1	1	1	0	0	1
N	5	5	5	5	5	5

INDIVIDUAL DATA 2-4-15

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 7 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
163	1	1	2	1	1	1	0	1	1	1	1	0
164	1	1	2	1	1	1	0	1	1	1	1	0
165	1	1	2	1	1	1	0	1	1	1	1	0
166	1	1	2	1	1	1	0	1	1	1	1	0
167	1	1	2	1	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-4-16

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 7 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
463	1	1	2	1	1	1	0	1	1	1	1	0
464	1	1	2	1	1	1	0	1	1	1	1	0
465	1	1	2	1	1	1	0	1	1	1	1	0
466	1	1	2	1	1	1	0	1	1	1	1	0
467	1	1	2	1	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5

INDIVIDUAL DATA 2-4-17

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 7 of administration

	In the open-field										
							Stereotype				
									Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
163	1	1	1	1	0	0	0	0	1	1	1
164	1	1	1	1	0	0	0	0	1	1	1
165	1	1	1	1	0	0	0	0	1	1	1
166	1	1	1	1	0	0	0	0	1	1	1
167	1	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-4-18

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 7 of administration

	In the open-field										
							Stereotype				
									Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
463	1	1	1	1	0	0	0	0	1	1	1
464	1	1	1	1	0	0	0	0	1	1	1
465	1	1	1	1	0	0	0	0	1	1	1
466	1	1	1	1	0	0	0	0	1	1	1
467	1	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5

INDIVIDUAL DATA 2-5-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 14 of administration

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

INDIVIDUAL DATA 2-5-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : Day 14 of administration

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

INDIVIDUAL DATA 2-5-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : Day 14 of administration

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

INDIVIDUAL DATA 2-5-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Day 14 of administration

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

INDIVIDUAL DATA 2-5-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 14 of administration

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

INDIVIDUAL DATA 2-5-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : Day 14 of administration

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

INDIVIDUAL DATA 2-5-7

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : Day 14 of administration

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

INDIVIDUAL DATA 2-5-8

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Day 14 of administration

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

INDIVIDUAL DATA 2-5-9

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 14 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
101	1	1	1	1	0	0	0	0	1	1	1
102	1	1	1	1	0	0	0	0	1	1	1
103	1	1	1	1	0	0	0	0	1	1	1
104	1	1	1	1	0	1	0	0	1	1	1
105	1	1	1	1	0	0	0	0	1	1	1
106	1	1	1	1	0	0	0	0	1	1	1
107	1	1	1	1	0	0	0	0	1	1	1
108	1	1	1	1	0	0	0	0	1	1	1
109	1	1	1	1	0	0	0	0	1	1	1
110	1	1	1	1	0	0	0	0	1	1	1
111	1	1	1	1	0	0	0	0	1	1	1
112	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	1.0444	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-5-10

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : Day 14 of administration

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

INDIVIDUAL DATA 2-5-11

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : Day 14 of administration

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

INDIVIDUAL DATA 2-5-12

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Day 14 of administration

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

INDIVIDUAL DATA 2-6-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 14 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
151	1	1	1	0	0	1
152	1	1	1	0	0	1
153	1	1	1	0	0	1
154	1	1	1	0	0	1
155	1	1	1	0	0	1
156	1	1	1	0	0	1
157	1	1	1	0	0	1
158	1	1	1	0	0	1
159	1	1	1	0	0	1
160	1	1	1	0	0	1
161	1	1	1	0	0	1
162	1	1	1	0	0	1
N	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-6-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 14 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
251	1	1	1	0	0	1
252	1	1	1	0	0	1
253	1	1	1	0	0	1
254	1	1	1	0	0	1
255	1	1	1	0	0	1
256	1	1	1	0	0	1
257	1	1	1	0	0	1
258	1	1	1	0	0	1
259	1	1	1	0	0	1
260	1	1	1	0	0	1
261	1	1	1	0	0	1
262	1	1	1	0	0	1
N	12	12	12	12	12	12

INDIVIDUAL DATA 2-6-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 14 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
351	1	1	1	0	0	1
352	1	1	1	0	0	1
353	1	1	1	0	0	1
354	1	1	1	0	0	1
355	1	1	1	0	0	1
356	1	1	1	0	0	1
357	1	1	1	0	0	1
358	1	1	1	0	0	1
359	1	1	1	0	0	1
360	1	1	1	0	0	1
361	1	1	1	0	0	1
362	1	1	1	0	0	1
N	12	12	12	12	12	12

INDIVIDUAL DATA 2-6-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 14 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
451	1	1	1	0	0	1
452	1	1	1	0	0	1
453	1	1	1	0	0	1
454	1	1	1	0	0	1
455	1	1	1	0	0	1
456	1	1	1	0	0	1
457	1	1	1	0	0	1
458	1	1	1	0	0	1
459	1	1	1	0	0	1
460	1	1	1	0	0	1
461	1	1	1	0	0	1
462	1	1	1	0	0	1
N	12	12	12	12	12	12

INDIVIDUAL DATA 2-6-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 14 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
151	1	1	2	1	1	1	0	1	1	1	1	0
152	1	1	2	1	1	1	0	1	1	1	1	0
153	1	1	2	1	1	1	0	1	1	1	1	0
154	1	1	2	1	1	1	0	1	1	1	1	0
155	1	1	2	1	1	1	0	1	1	1	1	0
156	1	1	2	1	1	1	0	1	1	1	1	0
157	1	1	2	1	1	1	0	1	1	1	1	0
158	1	1	2	1	1	1	0	1	1	1	1	0
159	1	1	2	1	1	1	0	1	1	1	1	0
160	1	1	2	1	1	1	0	1	1	1	1	0
161	1	1	2	1	1	1	0	1	1	1	1	0
162	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-6-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 14 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
251	1	1	2	1	1	1	0	1	1	1	1	0
252	1	1	2	1	1	1	0	1	1	1	1	0
253	1	1	2	1	1	1	0	1	1	1	1	0
254	1	1	2	1	1	1	0	1	1	1	1	0
255	1	1	2	1	1	1	0	1	1	1	1	0
256	1	1	2	1	1	1	0	1	1	1	1	0
257	1	1	2	1	1	1	0	1	1	1	1	0
258	1	1	2	1	1	1	0	1	1	1	1	0
259	1	1	2	1	1	1	0	1	1	1	1	0
260	1	1	2	1	1	1	0	1	1	1	1	0
261	1	1	2	1	1	1	0	1	1	1	1	0
262	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-6-7

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 14 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
351	1	1	2	1	1	1	0	1	1	1	1	0
352	1	1	2	1	1	1	0	1	1	1	1	0
353	1	1	2	1	1	1	0	1	1	1	1	0
354	1	1	2	1	1	1	0	1	1	1	1	0
355	1	1	2	1	1	1	0	1	1	1	1	0
356	1	1	2	1	1	1	0	1	1	1	1	0
357	1	1	2	1	1	1	0	1	1	1	1	0
358	1	1	2	1	1	1	0	1	1	1	1	0
359	1	1	2	1	1	1	0	1	1	1	1	0
360	1	1	2	1	1	1	0	1	1	1	1	0
361	1	1	2	1	1	1	0	1	1	1	1	0
362	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-6-8

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 14 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
451	1	1	2	1	1	1	0	1	1	1	1	0
452	1	1	2	1	1	1	0	1	1	1	1	0
453	1	1	2	1	1	1	0	1	1	1	1	0
454	1	1	2	1	1	1	0	1	1	1	1	0
455	1	1	2	1	1	1	0	1	1	1	1	0
456	1	1	2	1	1	1	0	1	1	1	1	0
457	1	1	2	1	1	1	0	1	1	1	1	0
458	1	1	2	1	1	1	0	1	1	1	1	0
459	1	1	2	1	1	1	0	1	1	1	1	0
460	1	1	2	1	1	1	0	1	1	1	1	0
461	1	1	2	1	1	1	0	1	1	1	1	0
462	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-6-9

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 14 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
151	1	1	1	1	0	0	0	0	1	1	1
152	1	1	1	1	0	0	0	0	1	1	1
153	1	1	1	1	0	0	0	0	1	1	1
154	1	1	1	1	0	0	0	0	1	1	1
155	1	1	1	1	0	0	0	0	1	1	1
156	1	1	1	1	0	0	0	0	1	1	1
157	1	1	1	1	0	0	0	0	1	1	1
158	1	1	1	1	0	0	0	0	1	1	1
159	1	1	1	1	0	0	0	0	1	1	1
160	1	1	1	1	0	0	0	0	1	1	1
161	1	1	1	1	0	0	0	0	1	1	1
162	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-6-10

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 14 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
251	1	1	1	1	0	0	0	0	1	1	1
252	1	1	1	1	0	0	0	0	1	1	1
253	1	1	1	1	0	0	0	0	1	1	1
254	1	1	1	1	0	0	0	0	1	1	1
255	1	1	1	1	0	0	0	0	1	1	1
256	1	1	1	1	0	0	0	0	1	1	1
257	1	1	1	1	0	0	0	0	1	1	1
258	1	1	1	1	0	0	0	0	1	1	1
259	1	1	1	1	0	0	0	0	1	1	1
260	1	1	1	1	0	0	0	0	1	1	1
261	1	1	1	1	0	0	0	0	1	1	1
262	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-6-11

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 14 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
351	1	1	1	1	0	0	0	0	1	1	1
352	1	1	1	1	0	0	0	0	1	1	1
353	1	1	1	1	0	0	0	0	1	1	1
354	1	1	1	1	0	0	0	0	1	1	1
355	1	1	1	1	0	0	0	0	1	1	1
356	1	1	1	1	0	0	0	0	1	1	1
357	1	1	1	1	0	0	0	0	1	1	1
358	1	1	1	1	0	0	0	0	1	1	1
359	1	1	1	1	0	0	0	0	1	1	1
360	1	1	1	1	0	0	0	0	1	1	1
361	1	1	1	1	0	0	0	0	1	1	1
362	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-6-12

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 14 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
451	1	1	1	1	0	0	0	0	1	1	1
452	1	1	1	1	0	0	0	0	1	1	1
453	1	1	1	1	0	0	0	0	1	1	1
454	1	1	1	1	0	0	0	0	1	1	1
455	1	1	1	1	0	0	0	0	1	1	1
456	1	1	1	1	0	0	0	0	1	1	1
457	1	1	1	1	0	0	0	0	1	1	1
458	1	1	1	1	0	0	0	0	1	1	1
459	1	1	1	1	0	0	0	0	1	1	1
460	1	1	1	1	0	0	0	0	1	1	1
461	1	1	1	1	0	0	0	0	1	1	1
462	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-6-13

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 14 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira- tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
163	1	1	1	0	0	1
164	1	1	1	0	0	1
165	1	1	1	0	0	1
166	1	1	1	0	0	1
167	1	1	1	0	0	1
N	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-6-14

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 14 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
463	1	1	1	0	0	1
464	1	1	1	0	0	1
465	1	1	1	0	0	1
466	1	1	1	0	0	1
467	1	1	1	0	0	1
N	5	5	5	5	5	5

INDIVIDUAL DATA 2-6-15

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 14 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
163	1	1	2	1	1	1	0	1	1	1	1	0
164	1	1	2	1	1	1	0	1	1	1	1	0
165	1	1	2	1	1	1	0	1	1	1	1	0
166	1	1	2	1	1	1	0	1	1	1	1	0
167	1	1	2	1	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-6-16

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 14 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
463	1	1	2	1	1	1	0	1	1	1	1	0
464	1	1	2	1	1	1	0	1	1	1	1	0
465	1	1	2	1	1	1	0	1	1	1	1	0
466	1	1	2	1	1	1	0	1	1	1	1	0
467	1	1	2	1	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5

INDIVIDUAL DATA 2-6-17

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 14 of administration

	In the open-field										
							Stereotype				
									Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
163	1	1	1	1	0	0	0	0	1	1	1
164	1	1	1	1	0	0	0	0	1	1	1
165	1	1	1	1	0	0	0	0	1	1	1
166	1	1	1	1	1	0	0	0	1	1	1
167	1	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	1.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-6-18

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 14 of administration

	In the open-field										
							Stereotype				
									Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
463	1	1	1	1	0	0	0	0	1	1	1
464	1	1	1	1	0	0	0	0	1	1	1
465	1	1	1	1	0	0	0	0	1	1	1
466	1	1	1	1	0	0	0	0	1	1	1
467	1	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5

INDIVIDUAL DATA 2-7-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 21 of administration

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

INDIVIDUAL DATA 2-7-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : Day 21 of administration

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

INDIVIDUAL DATA 2-7-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : Day 21 of administration

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

INDIVIDUAL DATA 2-7-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Day 21 of administration

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

INDIVIDUAL DATA 2-7-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 21 of administration

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

INDIVIDUAL DATA 2-7-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : Day 21 of administration

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

INDIVIDUAL DATA 2-7-7

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : Day 21 of administration

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

INDIVIDUAL DATA 2-7-8

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Day 21 of administration

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

INDIVIDUAL DATA 2-7-9

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 21 of administration

	In the open-field										
							Stereotype				
									Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
101	1	1	1	1	0	1	0	0	1	1	1
102	1	1	1	1	0	0	0	0	1	1	1
103	1	1	1	1	0	0	0	0	1	1	1
104	1	1	1	1	0	0	0	0	1	1	1
105	1	1	1	1	0	1	0	0	1	1	1
106	1	1	1	1	0	0	0	0	1	1	1
107	1	1	1	1	0	0	0	0	1	1	1
108	1	1	1	1	0	0	0	0	1	1	1
109	1	1	1	1	0	0	0	0	1	1	1
110	1	1	1	1	0	0	0	0	1	1	1
111	1	1	1	1	0	0	0	0	1	1	1
112	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	2.0435	0.7460	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-7-10

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : Day 21 of administration

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

INDIVIDUAL DATA 2-7-11

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : Day 21 of administration

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

INDIVIDUAL DATA 2-7-12

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Day 21 of administration

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

INDIVIDUAL DATA 2-8-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 21 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
151	1	1	1	0	0	1
152	1	1	1	0	0	1
153	1	1	1	0	0	1
154	1	1	1	0	0	1
155	1	1	1	0	0	1
156	1	1	1	0	0	1
157	1	1	1	0	0	1
158	1	1	1	0	0	1
159	1	1	1	0	0	1
160	1	1	1	0	0	1
161	1	1	1	0	0	1
162	1	1	1	0	0	1
N	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-8-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 21 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
251	1	1	1	0	0	1
252	1	1	1	0	0	1
253	1	1	1	0	0	1
254	1	1	1	0	0	1
255	1	1	1	0	0	1
256	1	1	1	0	0	1
257	1	1	1	0	0	1
258	1	1	1	0	0	1
259	1	1	1	0	0	1
260	1	1	1	0	0	1
261	1	1	1	0	0	1
262	1	1	1	0	0	1
N	12	12	12	12	12	12

INDIVIDUAL DATA 2-8-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 21 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
351	1	1	1	0	0	1
352	1	1	1	0	0	1
353	1	1	1	0	0	1
354	1	1	1	0	0	1
355	1	1	1	0	0	1
356	1	1	1	0	0	1
357	1	1	1	0	0	1
358	1	1	1	0	0	1
359	1	1	1	0	0	1
360	1	1	1	0	0	1
361	1	1	1	0	0	1
362	1	1	1	0	0	1
N	12	12	12	12	12	12

INDIVIDUAL DATA 2-8-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 21 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
451	1	1	1	0	0	1
452	1	1	1	0	0	1
453	1	1	1	0	0	1
454	1	1	1	0	0	1
455	1	1	1	0	0	1
456	1	1	1	0	0	1
457	1	1	1	0	0	1
458	1	1	1	0	0	1
459	1	1	1	0	0	1
460	1	1	1	0	0	1
461	1	1	1	0	0	1
462	1	1	1	0	0	1
N	12	12	12	12	12	12

INDIVIDUAL DATA 2-8-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 21 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
151	1	1	2	1	1	1	0	1	1	1	1	0
152	1	1	2	1	1	1	0	1	1	1	1	0
153	1	1	2	1	1	1	0	1	1	1	1	0
154	1	1	2	1	1	1	0	1	1	1	1	0
155	1	1	2	1	1	1	0	1	1	1	1	0
156	1	1	2	1	1	1	0	1	1	1	1	0
157	1	1	2	1	1	1	0	1	1	1	1	0
158	1	1	2	1	1	1	0	1	1	1	1	0
159	1	1	2	1	1	1	0	1	1	1	1	0
160	1	1	2	1	1	1	0	1	1	1	1	0
161	1	1	2	1	1	1	0	1	1	1	1	0
162	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-8-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 21 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
251	1	1	2	1	1	1	0	1	1	1	1	0
252	1	1	2	1	1	1	0	1	1	1	1	0
253	1	1	2	1	1	1	0	1	1	1	1	0
254	1	1	2	1	1	1	0	1	1	1	1	0
255	1	1	2	1	1	1	0	1	1	1	1	0
256	1	1	2	1	1	1	0	1	1	1	1	0
257	1	1	2	1	1	1	0	1	1	1	1	0
258	1	1	2	1	1	1	0	1	1	1	1	0
259	1	1	2	1	1	1	0	1	1	1	1	0
260	1	1	2	1	1	1	0	1	1	1	1	0
261	1	1	2	1	1	1	0	1	1	1	1	0
262	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-8-7

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 21 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
351	1	1	2	1	1	1	0	1	1	1	1	0
352	1	1	2	1	1	1	0	1	1	1	1	0
353	1	1	2	1	1	1	0	1	1	1	1	0
354	1	1	2	1	1	1	0	1	1	1	1	0
355	1	1	2	1	1	1	0	1	1	1	1	0
356	1	1	2	1	1	1	0	1	1	1	1	0
357	1	1	2	1	1	1	0	1	1	1	1	0
358	1	1	2	1	1	1	0	1	1	1	1	0
359	1	1	2	1	1	1	0	1	1	1	1	0
360	1	1	2	1	1	1	0	1	1	1	1	0
361	1	1	2	1	1	1	0	1	1	1	1	0
362	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-8-8

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 21 of administration

Animal No.	On the hand: Ease of Removal	Ease of Handling	Muscle tone	Pilo-erection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrima-tion	Salivation	Secretions/ Excretions
451	1	1	2	1	1	1	0	1	1	1	1	0
452	1	1	2	1	1	1	0	1	1	1	1	0
453	1	1	2	1	1	1	0	1	1	1	1	0
454	1	1	2	1	1	1	0	1	1	1	1	0
455	1	1	2	1	1	1	0	1	1	1	1	0
456	1	1	2	1	1	1	0	1	1	1	1	0
457	1	1	2	1	1	1	0	1	1	1	1	0
458	1	1	2	1	1	1	0	1	1	1	1	0
459	1	1	2	1	1	1	0	1	1	1	1	0
460	1	1	2	1	1	1	0	1	1	1	1	0
461	1	1	2	1	1	1	0	1	1	1	1	0
462	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-8-9

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 21 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
151	1	1	1	1	0	0	0	0	1	1	1
152	1	1	1	1	0	0	0	0	1	1	1
153	1	1	1	1	0	0	0	0	1	1	1
154	1	1	1	1	0	0	0	0	1	1	1
155	1	1	1	1	0	0	0	0	1	1	1
156	1	1	1	1	0	0	0	0	1	1	1
157	1	1	1	1	0	0	0	0	1	1	1
158	1	1	1	1	0	0	0	0	1	1	1
159	1	1	1	1	0	0	0	0	1	1	1
160	1	1	1	1	0	0	0	0	1	1	1
161	1	1	1	1	0	0	0	0	1	1	1
162	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	3.0000	3.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-8-10

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 21 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
251	1	1	1	1	0	0	0	0	1	1	1
252	1	1	1	1	0	0	0	0	1	1	1
253	1	1	1	1	1	1	0	0	1	1	1
254	1	1	1	1	0	0	0	0	1	1	1
255	1	1	1	1	0	0	0	0	1	1	1
256	1	1	1	1	0	0	0	0	1	1	1
257	1	1	1	1	0	0	0	0	1	1	1
258	1	1	1	1	0	0	0	0	1	1	1
259	1	1	1	1	0	0	0	0	1	1	1
260	1	1	1	1	0	0	0	0	1	1	1
261	1	1	1	1	0	0	0	0	1	1	1
262	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-8-11

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 21 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
351	1	1	1	1	0	0	0	0	1	1	1
352	1	1	1	1	0	0	0	0	1	1	1
353	1	1	1	1	0	0	0	0	1	1	1
354	1	1	1	1	0	0	0	0	1	1	1
355	1	1	1	1	0	0	0	0	1	1	1
356	1	1	1	1	0	0	0	0	1	1	1
357	1	1	1	1	0	0	0	0	1	1	1
358	1	1	1	1	0	0	0	0	1	1	1
359	1	1	1	1	0	0	0	0	1	1	1
360	1	1	1	1	0	0	0	0	1	1	1
361	1	1	1	1	0	0	0	0	1	1	1
362	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-8-12

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 21 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
451	1	1	1	1	0	0	0	0	1	1	1
452	1	1	1	1	0	0	0	0	1	1	1
453	1	1	1	1	0	0	0	0	1	1	1
454	1	1	1	1	0	0	0	0	1	1	1
455	1	1	1	1	0	0	0	0	1	1	1
456	1	1	1	1	0	0	0	0	1	1	1
457	1	1	1	1	0	0	0	0	1	1	1
458	1	1	1	1	0	0	0	0	1	1	1
459	1	1	1	1	0	0	0	0	1	1	1
460	1	1	1	1	0	0	0	0	1	1	1
461	1	1	1	1	0	0	0	0	1	1	1
462	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-8-13

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 21 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
163	1	1	1	0	0	1
164	1	1	1	0	0	1
165	1	1	1	0	0	1
166	1	1	1	0	0	1
167	1	1	1	0	0	1
N	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-8-14

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 21 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
463	1	1	1	0	0	1
464	1	1	1	0	0	1
465	1	1	1	0	0	1
466	1	1	1	0	0	1
467	1	1	1	0	0	1
N	5	5	5	5	5	5

INDIVIDUAL DATA 2-8-15

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 21 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
163	1	1	2	1	1	1	0	1	1	1	1	0
164	1	1	2	1	1	1	0	1	1	1	1	0
165	1	1	2	1	1	1	0	1	1	1	1	0
166	1	1	2	1	1	1	0	1	1	1	1	0
167	1	1	2	1	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-8-16

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 21 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
463	1	1	2	1	1	1	0	1	1	1	1	0
464	1	1	2	1	1	1	0	1	1	1	1	0
465	1	1	2	1	1	1	0	1	1	1	1	0
466	1	1	2	1	1	1	0	1	1	1	1	0
467	1	1	2	1	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5

INDIVIDUAL DATA 2-8-17

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 21 of administration

	In the open-field										
							Stereotype				
									Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
163	1	1	1	1	0	0	0	0	1	1	1
164	1	1	1	1	0	0	0	0	1	1	1
165	1	1	1	1	0	0	0	0	1	1	1
166	1	1	1	1	0	0	0	0	1	1	1
167	1	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-8-18

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 21 of administration

	In the open-field										
							Stereotype				
									Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
463	1	1	1	1	0	0	0	0	1	1	1
464	1	1	1	1	0	0	0	0	1	1	1
465	1	1	1	1	0	0	0	0	1	1	1
466	1	1	1	1	0	0	0	0	1	1	1
467	1	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5

INDIVIDUAL DATA 2-9-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 28 of administration

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

INDIVIDUAL DATA 2-9-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : Day 28 of administration

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

INDIVIDUAL DATA 2-9-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : Day 28 of administration

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

INDIVIDUAL DATA 2-9-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Day 28 of administration

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

INDIVIDUAL DATA 2-9-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 28 of administration

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

INDIVIDUAL DATA 2-9-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : Day 28 of administration

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

INDIVIDUAL DATA 2-9-7

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : Day 28 of administration

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

INDIVIDUAL DATA 2-9-8

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Day 28 of administration

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

INDIVIDUAL DATA 2-9-9

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 28 of administration

	In the open-field										
							Stereotype				
									Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
101	1	1	1	1	0	0	0	0	1	1	1
102	1	1	1	1	0	0	0	0	1	1	1
103	1	1	1	1	0	0	0	0	1	1	1
104	1	1	1	1	0	0	0	0	1	1	1
105	1	1	1	1	0	0	0	0	1	1	1
106	1	1	1	1	0	0	0	0	1	1	1
107	1	1	1	1	0	0	0	0	1	1	1
108	1	1	1	1	0	0	0	0	1	1	1
109	1	1	1	1	0	0	0	0	1	1	1
110	1	1	1	1	0	0	0	0	1	1	1
111	1	1	1	1	0	0	0	0	1	1	1
112	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	3.8296	3.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-9-10

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : Day 28 of administration

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

INDIVIDUAL DATA 2-9-11

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : Day 28 of administration

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

INDIVIDUAL DATA 2-9-12

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Day 28 of administration

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

INDIVIDUAL DATA 2-10-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 28 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
151	1	1	1	0	0	1
152	1	1	1	0	0	1
153	1	1	1	0	0	1
154	1	1	1	0	0	1
155	1	1	1	0	0	1
156	1	1	1	0	0	1
157	1	1	1	0	0	1
158	1	1	1	0	0	1
159	1	1	1	0	0	1
160	1	1	1	0	0	1
161	1	1	1	0	0	1
162	1	1	1	0	0	1
N	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-10-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 28 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
251	1	1	1	0	0	1
252	1	1	1	0	0	1
253	1	1	1	0	0	1
254	1	1	1	0	0	1
255	1	1	1	0	0	1
256	1	1	1	0	0	1
257	1	1	1	0	0	1
258	1	1	1	0	0	1
259	1	1	1	0	0	1
260	1	1	1	0	0	1
261	1	1	1	0	0	1
262	1	1	1	0	0	1
N	12	12	12	12	12	12

INDIVIDUAL DATA 2-10-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 28 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
351	1	1	1	0	0	1
352	1	1	1	0	0	1
353	1	1	1	0	0	1
354	1	1	1	0	0	1
355	1	1	1	0	0	1
356	1	1	1	0	0	1
357	1	1	1	0	0	1
358	1	1	1	0	0	1
359	1	1	1	0	0	1
360	1	1	1	0	0	1
361	1	1	1	0	0	1
362	1	1	1	0	0	1
N	12	12	12	12	12	12

INDIVIDUAL DATA 2-10-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 28 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
451	1	1	1	0	0	1
452	1	1	1	0	0	1
453	1	1	1	0	0	1
454	1	1	1	0	0	1
455	1	1	1	0	0	1
456	1	1	1	0	0	1
457	1	1	1	0	0	1
458	1	1	1	0	0	1
459	1	1	1	0	0	1
460	1	1	1	0	0	1
461	1	1	1	0	0	1
462	1	1	1	0	0	1
N	12	12	12	12	12	12

INDIVIDUAL DATA 2-10-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 28 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
151	1	1	2	1	1	1	0	1	1	1	1	0
152	1	1	2	1	1	1	0	1	1	1	1	0
153	1	1	2	1	1	1	0	1	1	1	1	0
154	1	1	2	1	1	1	0	1	1	1	1	0
155	1	1	2	1	1	1	0	1	1	1	1	0
156	1	1	2	1	1	1	0	1	1	1	1	0
157	1	1	2	1	1	1	0	1	1	1	1	0
158	1	1	2	1	1	1	0	1	1	1	1	0
159	1	1	2	1	1	1	0	1	1	1	1	0
160	1	1	2	1	1	1	0	1	1	1	1	0
161	1	1	2	1	1	1	0	1	1	1	1	0
162	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-10-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 28 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
251	1	1	2	1	1	1	0	1	1	1	1	0
252	1	1	2	1	1	1	0	1	1	1	1	0
253	1	1	2	1	1	1	0	1	1	1	1	0
254	1	1	2	1	1	1	0	1	1	1	1	0
255	1	1	2	1	1	1	0	1	1	1	1	0
256	1	1	2	1	1	1	0	1	1	1	1	0
257	1	1	2	1	1	1	0	1	1	1	1	0
258	1	1	2	1	1	1	0	1	1	1	1	0
259	1	1	2	1	1	1	0	1	1	1	1	0
260	1	1	2	1	1	1	0	1	1	1	1	0
261	1	1	2	1	1	1	0	1	1	1	1	0
262	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-10-7

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 28 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
351	1	1	2	1	1	1	0	1	1	1	1	0
352	1	1	2	1	1	1	0	1	1	1	1	0
353	1	1	2	1	1	1	0	1	1	1	1	0
354	1	1	2	1	1	1	0	1	1	1	1	0
355	1	1	2	1	1	1	0	1	1	1	1	0
356	1	1	2	1	1	1	0	1	1	1	1	0
357	1	1	2	1	1	1	0	1	1	1	1	0
358	1	1	2	1	1	1	0	1	1	1	1	0
359	1	1	2	1	1	1	0	1	1	1	1	0
360	1	1	2	1	1	1	0	1	1	1	1	0
361	1	1	2	1	1	1	0	1	1	1	1	0
362	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-10-8

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 28 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
451	1	1	2	1	1	1	0	1	1	1	1	0
452	1	1	2	1	1	1	0	1	1	1	1	0
453	1	1	2	1	1	1	0	1	1	1	1	0
454	1	1	2	1	1	1	0	1	1	1	1	0
455	1	1	2	1	1	1	0	1	1	1	1	0
456	1	1	2	1	1	1	0	1	1	1	1	0
457	1	1	2	1	1	1	0	1	1	1	1	0
458	1	1	2	1	1	1	0	1	1	1	1	0
459	1	1	2	1	1	1	0	1	1	1	1	0
460	1	1	2	1	1	1	0	1	1	1	1	0
461	1	1	2	1	1	1	0	1	1	1	1	0
462	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-10-9

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 28 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
151	1	1	1	1	0	0	0	0	1	1	1
152	1	1	1	1	0	0	0	0	1	1	1
153	1	1	1	1	0	0	0	0	1	1	1
154	1	1	1	1	0	0	0	0	1	1	1
155	1	1	1	1	0	0	0	0	1	1	1
156	1	1	1	1	0	0	0	0	1	1	1
157	1	1	1	1	0	0	0	0	1	1	1
158	1	1	1	1	0	0	0	0	1	1	1
159	1	1	1	1	0	0	0	0	1	1	1
160	1	1	1	1	0	0	0	0	1	1	1
161	1	1	1	1	0	0	0	0	1	1	1
162	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	3.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-10-10

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 28 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
251	1	1	1	1	0	0	0	0	1	1	1
252	1	1	1	1	0	0	0	0	1	1	1
253	1	1	1	1	1	0	0	0	1	1	1
254	1	1	1	1	0	0	0	0	1	1	1
255	1	1	1	1	0	0	0	0	1	1	1
256	1	1	1	1	0	0	0	0	1	1	1
257	1	1	1	1	0	0	0	0	1	1	1
258	1	1	1	1	0	0	0	0	1	1	1
259	1	1	1	1	0	0	0	0	1	1	1
260	1	1	1	1	0	0	0	0	1	1	1
261	1	1	1	1	0	0	0	0	1	1	1
262	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-10-11

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 28 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
351	1	1	1	1	0	0	0	0	1	1	1
352	1	1	1	1	0	0	0	0	1	1	1
353	1	1	1	1	0	0	0	0	1	1	1
354	1	1	1	1	0	0	0	0	1	1	1
355	1	1	1	1	0	0	0	0	1	1	1
356	1	1	1	1	0	0	0	0	1	1	1
357	1	1	1	1	0	0	0	0	1	1	1
358	1	1	1	1	0	0	0	0	1	1	1
359	1	1	1	1	0	0	0	0	1	1	1
360	1	1	1	1	0	0	0	0	1	1	1
361	1	1	1	1	0	0	0	0	1	1	1
362	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-10-12

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 28 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
451	1	1	1	1	0	0	0	0	1	1	1
452	1	1	1	1	0	0	0	0	1	1	1
453	1	1	1	1	0	0	0	0	1	1	1
454	1	1	1	1	0	0	0	0	1	1	1
455	1	1	1	1	0	0	0	0	1	1	1
456	1	1	1	1	0	0	0	0	1	1	1
457	1	1	1	1	0	0	0	0	1	1	1
458	1	1	1	1	0	0	0	0	1	1	1
459	1	1	1	1	0	0	0	0	1	1	1
460	1	1	1	1	0	0	0	0	1	1	1
461	1	1	1	1	0	0	0	0	1	1	1
462	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-10-13

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 28 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira- tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
163	1	1	1	0	0	1
164	1	1	1	0	0	1
165	1	1	1	0	0	1
166	1	1	1	0	0	1
167	1	1	1	0	0	1
N	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-10-14

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 28 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
463	1	1	1	0	0	1
464	1	1	1	0	0	1
465	1	1	1	0	0	1
466	1	1	1	0	0	1
467	1	1	1	0	0	1
N	5	5	5	5	5	5

INDIVIDUAL DATA 2-10-15

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 28 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
163	1	1	2	1	1	1	0	1	1	1	1	0
164	1	1	2	1	1	1	0	1	1	1	1	0
165	1	1	2	1	1	1	0	1	1	1	1	0
166	1	1	2	1	1	1	0	1	1	1	1	0
167	1	1	2	1	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-10-16

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 28 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
463	1	1	2	1	1	1	0	1	1	1	1	0
464	1	1	2	1	1	1	0	1	1	1	1	0
465	1	1	2	1	1	1	0	1	1	1	1	0
466	1	1	2	1	1	1	0	1	1	1	1	0
467	1	1	2	1	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5

INDIVIDUAL DATA 2-10-17

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 28 of administration

	In the open-field										
							Stereotype				
									Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
163	1	1	1	1	0	0	0	0	1	1	1
164	1	1	1	1	0	0	0	0	1	1	1
165	1	1	1	1	0	0	0	0	1	1	1
166	1	1	1	1	0	0	0	0	1	1	1
167	1	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-10-18

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 28 of administration

	In the open-field										
							Stereotype				
									Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
463	1	1	1	1	0	0	0	0	1	1	1
464	1	1	1	1	0	0	0	0	1	1	1
465	1	1	1	1	0	0	0	0	1	1	1
466	1	1	1	1	0	0	0	0	1	1	1
467	1	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5

INDIVIDUAL DATA 2-11-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 35 of administration

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

INDIVIDUAL DATA 2-11-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : Day 35 of administration

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

INDIVIDUAL DATA 2-11-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : Day 35 of administration

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

INDIVIDUAL DATA 2-11-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Day 35 of administration

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

INDIVIDUAL DATA 2-11-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 35 of administration

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

INDIVIDUAL DATA 2-11-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : Day 35 of administration

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

INDIVIDUAL DATA 2-11-7

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : Day 35 of administration

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

INDIVIDUAL DATA 2-11-8

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Day 35 of administration

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

INDIVIDUAL DATA 2-11-9

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 35 of administration

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

INDIVIDUAL DATA 2-11-10

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : Day 35 of administration

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

INDIVIDUAL DATA 2-11-11

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : Day 35 of administration

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

INDIVIDUAL DATA 2-11-12

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Day 35 of administration

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

INDIVIDUAL DATA 2-12-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 35 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira- tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
151	1	1	1	0	0	1
152	1	1	1	0	0	1
153	1	1	1	0	0	1
154	1	1	1	0	0	1
155	1	1	1	0	0	1
156	1	1	1	0	0	1
157	1	1	1	0	0	1
158	1	1	1	0	0	1
159	1	1	1	0	0	1
160	1	1	1	0	0	1
161	1	1	1	0	0	1
162	1	1	1	0	0	1
N	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-12-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 35 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
251	1	1	1	0	0	1
252	1	1	1	0	0	1
253	1	1	1	0	0	1
254	1	1	1	0	0	1
255	1	1	1	0	0	1
256	1	1	1	0	0	1
257	1	1	1	0	0	1
258	1	1	1	0	0	1
259	1	1	1	0	0	1
260	1	1	1	0	0	1
261	1	1	1	0	0	1
262	1	1	1	0	0	1
N	12	12	12	12	12	12

INDIVIDUAL DATA 2-12-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 35 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
351	1	1	1	0	0	1
352	1	1	1	0	0	1
353	1	1	1	0	0	1
354	1	1	1	0	0	1
355	1	1	1	0	0	1
356	1	1	1	0	0	1
357	1	1	1	0	0	1
358	1	1	1	0	0	1
359	1	1	1	0	0	1
360	1	1	1	0	0	1
361	1	1	1	0	0	1
362	1	1	1	0	0	1
N	12	12	12	12	12	12

INDIVIDUAL DATA 2-12-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 35 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
451	1	1	1	0	0	1
452	1	1	1	0	0	1
453	1	1	1	0	0	1
454	1	1	1	0	0	1
455	1	1	1	0	0	1
456	1	1	1	0	0	1
457	1	1	1	0	0	1
458	1	1	1	0	0	1
459	1	1	1	0	0	1
460	1	1	1	0	0	1
461	1	1	1	0	0	1
462	1	1	1	0	0	1
N	12	12	12	12	12	12

INDIVIDUAL DATA 2-12-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 35 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
151	1	1	2	1	1	1	0	1	1	1	1	0
152	1	1	2	1	1	1	0	1	1	1	1	0
153	1	1	2	1	1	1	0	1	1	1	1	0
154	1	1	2	1	1	1	0	1	1	1	1	0
155	1	1	2	1	1	1	0	1	1	1	1	0
156	1	1	2	1	1	1	0	1	1	1	1	0
157	1	1	2	1	1	1	0	1	1	1	1	0
158	1	1	2	1	1	1	0	1	1	1	1	0
159	1	1	2	1	1	1	0	1	1	1	1	0
160	1	1	2	1	1	1	0	1	1	1	1	0
161	1	1	2	1	1	1	0	1	1	1	1	0
162	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-12-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 35 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
251	1	1	2	1	1	1	0	1	1	1	1	0
252	1	1	2	1	1	1	0	1	1	1	1	0
253	1	1	2	1	1	1	0	1	1	1	1	0
254	1	1	2	1	1	1	0	1	1	1	1	0
255	1	1	2	1	1	1	0	1	1	1	1	0
256	1	1	2	1	1	1	0	1	1	1	1	0
257	1	1	2	1	1	1	0	1	1	1	1	0
258	1	1	2	1	1	1	0	1	1	1	1	0
259	1	1	2	1	1	1	0	1	1	1	1	0
260	1	1	2	1	1	1	0	1	1	1	1	0
261	1	1	2	1	1	1	0	1	1	1	1	0
262	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-12-7

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 35 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
351	1	1	2	1	1	1	0	1	1	1	1	0
352	1	1	2	1	1	1	0	1	1	1	1	0
353	1	1	2	1	1	1	0	1	1	1	1	0
354	1	1	2	1	1	1	0	1	1	1	1	0
355	1	1	2	1	1	1	0	1	1	1	1	0
356	1	1	2	1	1	1	0	1	1	1	1	0
357	1	1	2	1	1	1	0	1	1	1	1	0
358	1	1	2	1	1	1	0	1	1	1	1	0
359	1	1	2	1	1	1	0	1	1	1	1	0
360	1	1	2	1	1	1	0	1	1	1	1	0
361	1	1	2	1	1	1	0	1	1	1	1	0
362	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-12-8

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 35 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
451	1	1	2	1	1	1	0	1	1	1	1	0
452	1	1	2	1	1	1	0	1	1	1	1	0
453	1	1	2	1	1	1	0	1	1	1	1	0
454	1	1	2	1	1	1	0	1	1	1	1	0
455	1	1	2	1	1	1	0	1	1	1	1	0
456	1	1	2	1	1	1	0	1	1	1	1	0
457	1	1	2	1	1	1	0	1	1	1	1	0
458	1	1	2	1	1	1	0	1	1	1	1	0
459	1	1	2	1	1	1	0	1	1	1	1	0
460	1	1	2	1	1	1	0	1	1	1	1	0
461	1	1	2	1	1	1	0	1	1	1	1	0
462	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-12-9

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 35 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
151	1	1	1	1	0	0	0	0	1	1	1
152	1	1	1	1	0	0	0	0	1	1	1
153	1	1	1	1	0	0	0	0	1	1	1
154	1	1	1	1	0	0	0	0	1	1	1
155	1	1	1	1	0	0	0	0	1	1	1
156	1	1	1	1	0	0	0	0	1	1	1
157	1	1	1	1	0	0	0	0	1	1	1
158	1	1	1	1	0	0	1	0	1	1	1
159	1	1	1	1	0	0	0	0	1	1	1
160	1	1	1	1	0	0	1	0	1	1	1
161	1	1	1	1	0	0	0	0	1	1	1
162	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	3.0000	3.0000	2.4047	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-12-10

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 35 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
251	1	1	1	1	0	0	0	0	1	1	1
252	1	1	1	1	0	0	0	0	1	1	1
253	1	1	1	1	1	1	0	0	1	1	1
254	1	1	1	1	0	0	0	0	1	1	1
255	1	1	1	1	0	0	0	0	1	1	1
256	1	1	1	1	0	0	0	0	1	1	1
257	1	1	1	1	0	0	0	0	1	1	1
258	1	1	1	1	0	0	0	0	1	1	1
259	1	1	1	1	0	0	0	0	1	1	1
260	1	1	1	1	0	0	0	0	1	1	1
261	1	1	1	1	0	0	0	0	1	1	1
262	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-12-11

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 35 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
351	1	1	1	1	0	0	1	0	1	1	1
352	1	1	1	1	0	0	0	0	1	1	1
353	1	1	1	1	0	0	0	0	1	1	1
354	1	1	1	1	0	0	0	0	1	1	1
355	1	1	1	1	0	0	0	0	1	1	1
356	1	1	1	1	0	0	0	0	1	1	1
357	1	1	1	1	0	0	1	0	1	1	1
358	1	1	1	1	0	0	0	0	1	1	1
359	1	1	1	1	0	0	0	0	1	1	1
360	1	1	1	1	0	0	0	0	1	1	1
361	1	1	1	1	0	0	0	0	1	1	1
362	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-12-12

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 35 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
451	1	1	1	1	0	0	0	0	1	1	1
452	1	1	1	1	0	0	0	0	1	1	1
453	1	1	1	1	0	0	0	0	1	1	1
454	1	1	1	1	0	0	0	0	1	1	1
455	1	1	1	1	0	0	1	0	1	1	1
456	1	1	1	1	0	0	0	0	1	1	1
457	1	1	1	1	0	0	0	0	1	1	1
458	1	1	1	1	0	0	0	0	1	1	1
459	1	1	1	1	0	0	0	0	1	1	1
460	1	1	1	1	0	0	0	0	1	1	1
461	1	1	1	1	0	0	0	0	1	1	1
462	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-12-13

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 35 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
163	1	1	1	0	0	1
164	1	1	1	0	0	1
165	1	1	1	0	0	1
166	1	1	1	0	0	1
167	1	1	1	0	0	1
N	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-12-14

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 35 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira- tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
463	1	1	1	0	0	1
464	1	1	1	0	0	1
465	1	1	1	0	0	1
466	1	1	1	0	0	1
467	1	1	1	0	0	1
N	5	5	5	5	5	5

INDIVIDUAL DATA 2-12-15

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 35 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
163	1	1	2	1	1	1	0	1	1	1	1	0
164	1	1	2	1	1	1	0	1	1	1	1	0
165	1	1	2	1	1	1	0	1	1	1	1	0
166	1	1	2	1	1	1	0	1	1	1	1	0
167	1	1	2	1	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-12-16

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 35 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
463	1	1	2	1	1	1	0	1	1	1	1	0
464	1	1	2	1	1	1	0	1	1	1	1	0
465	1	1	2	1	1	1	0	1	1	1	1	0
466	1	1	2	1	1	1	0	1	1	1	1	0
467	1	1	2	1	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5

INDIVIDUAL DATA 2-12-17

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 35 of administration

	In the open-field										
							Stereotype				
									Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
163	1	1	1	1	0	0	0	0	1	1	1
164	1	1	1	1	0	0	0	0	1	1	1
165	1	1	1	1	0	0	0	0	1	1	1
166	1	1	1	1	0	0	0	0	1	1	1
167	1	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-12-18

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 35 of administration

	In the open-field										
							Stereotype				
									Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
463	1	1	1	1	0	0	0	0	1	1	1
464	1	1	1	1	0	0	0	0	1	1	1
465	1	1	1	1	0	0	0	0	1	1	1
466	1	1	1	1	0	0	0	0	1	1	1
467	1	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5

INDIVIDUAL DATA 2-13-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 42 of administration

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

INDIVIDUAL DATA 2-13-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : Day 42 of administration

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

INDIVIDUAL DATA 2-13-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : Day 42 of administration

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

INDIVIDUAL DATA 2-13-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Day 42 of administration

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

INDIVIDUAL DATA 2-13-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 42 of administration

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

INDIVIDUAL DATA 2-13-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : Day 42 of administration

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

INDIVIDUAL DATA 2-13-7

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : Day 42 of administration

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

INDIVIDUAL DATA 2-13-8

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Day 42 of administration

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

INDIVIDUAL DATA 2-13-9

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 42 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
101	1	1	1	1	1	0	0	0	1	1	1
102	1	1	1	1	0	0	0	0	1	1	1
103	1	1	1	1	0	0	0	0	1	1	1
104	1	1	1	1	1	0	0	0	1	1	1
105	1	1	1	1	0	0	0	0	1	1	1
106	1	1	1	1	0	0	0	0	1	1	1
107	1	1	1	1	0	0	0	0	1	1	1
108	1	1	1	1	0	0	0	0	1	1	1
109	1	1	1	1	0	0	0	0	1	1	1
110	1	1	1	1	0	0	0	0	1	1	1
111	1	1	1	1	0	0	0	0	1	1	1
112	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	5.9023	6.1304	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-13-10

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : Day 42 of administration

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

INDIVIDUAL DATA 2-13-11

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : Day 42 of administration

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

INDIVIDUAL DATA 2-13-12

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Day 42 of administration

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

INDIVIDUAL DATA 2-14-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 42 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
151	1	1	1	0	0	1
152	1	1	1	0	0	1
153	1	1	1	0	0	1
154	1	1	1	0	0	1
155	1	1	1	0	0	1
156	1	1	1	0	0	1
157	1	1	1	0	0	1
158	1	1	1	0	0	1
159	1	1	1	0	0	1
160	1	1	1	0	0	1
161	1	1	1	0	0	1
162	1	1	1	0	0	1
N	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-14-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 42 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira- tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
251	1	1	1	0	0	1
252	1	1	1	0	0	1
253	1	1	1	0	0	1
254	1	1	1	0	0	1
255	1	1	1	0	0	1
256	1	1	1	0	0	1
257	1	1	1	0	0	1
258	1	1	1	0	0	1
259	1	1	1	0	0	1
260	1	1	1	0	0	1
261	1	1	1	0	0	1
262	1	1	1	0	0	1
N	12	12	12	12	12	12

INDIVIDUAL DATA 2-14-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 42 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
351	1	1	1	0	0	1
352	1	1	1	0	0	1
353	1	1	1	0	0	1
354	1	1	1	0	0	1
355	1	1	1	0	0	1
356	1	1	1	0	0	1
357	1	1	1	0	0	1
358	1	1	1	0	0	1
360	1	1	1	0	0	1
361	1	1	1	0	0	1
362	1	1	1	0	0	1
N	11	11	11	11	11	11

INDIVIDUAL DATA 2-14-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 42 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira- tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
451	1	1	1	0	0	1
452	1	1	1	0	0	1
453	1	1	1	0	0	1
454	1	1	1	0	0	1
455	1	1	1	0	0	1
456	1	1	1	0	0	1
457	1	1	1	0	0	1
458	1	1	1	0	0	1
459	1	1	1	0	0	1
460	1	1	1	0	0	1
461	1	1	1	0	0	1
462	1	1	1	0	0	1
N	12	12	12	12	12	12

INDIVIDUAL DATA 2-14-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 42 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
151	1	1	2	1	1	1	0	1	1	1	1	0
152	1	1	2	1	1	1	0	1	1	1	1	0
153	1	1	2	1	1	1	0	1	1	1	1	0
154	1	1	2	1	1	1	0	1	1	1	1	0
155	1	1	2	1	1	1	0	1	1	1	1	0
156	1	1	2	1	1	1	0	1	1	1	1	0
157	1	1	2	1	1	1	0	1	1	1	1	0
158	1	1	2	1	1	1	0	1	1	1	1	0
159	1	1	2	1	1	1	0	1	1	1	1	0
160	1	1	2	1	1	1	0	1	1	1	1	0
161	1	1	2	1	1	1	0	1	1	1	1	0
162	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-14-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 42 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
251	1	1	2	1	1	1	0	1	1	1	1	0
252	1	1	2	1	1	1	0	1	1	1	1	0
253	1	1	2	1	1	1	0	1	1	1	1	0
254	1	1	2	1	1	1	0	1	1	1	1	0
255	1	1	2	1	1	1	0	1	1	1	1	0
256	1	1	2	1	1	1	0	1	1	1	1	0
257	1	1	2	1	1	1	0	1	1	1	1	0
258	1	1	2	1	1	1	0	1	1	1	1	0
259	1	1	2	1	1	1	0	1	1	1	1	0
260	1	1	2	1	1	1	0	1	1	1	1	0
261	1	1	2	1	1	1	0	1	1	1	1	0
262	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-14-7

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 42 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
351	1	1	2	1	1	1	0	1	1	1	1	0
352	1	1	2	1	1	1	0	1	1	1	1	0
353	1	1	2	1	1	1	0	1	1	1	1	0
354	1	1	2	1	1	1	0	1	1	1	1	0
355	1	1	2	1	1	1	0	1	1	1	1	0
356	1	1	2	1	1	1	0	1	1	1	1	0
357	1	1	2	1	1	1	0	1	1	1	1	0
358	1	1	2	1	1	1	0	1	1	1	1	0
360	1	1	2	1	1	1	0	1	1	1	1	0
361	1	1	2	1	1	1	0	1	1	1	1	0
362	1	1	2	1	1	1	0	1	1	1	1	0
N	11	11	11	11	11	11	11	11	11	11	11	11

INDIVIDUAL DATA 2-14-8

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 42 of administration

Animal No.	On the hand: Ease of Removal	Ease of Handling	Muscle tone	Pilo-erection	Fur	Eyes	Mucous membranes	Skin	Pupil size	Lacrima-tion	Salivation	Secretions/ Excretions
451	1	1	2	1	1	1	0	1	1	1	1	0
452	1	1	2	1	1	1	0	1	1	1	1	0
453	1	1	2	1	1	1	0	1	1	1	1	0
454	1	1	2	1	1	1	0	1	1	1	1	0
455	1	1	2	1	1	1	0	1	1	1	1	0
456	1	1	2	1	1	1	0	1	1	1	1	0
457	1	1	2	1	1	1	0	1	1	1	1	0
458	1	1	2	1	1	1	0	1	1	1	1	0
459	1	1	2	1	1	1	0	1	1	1	1	0
460	1	1	2	1	1	1	0	1	1	1	1	0
461	1	1	2	1	1	1	0	1	1	1	1	0
462	1	1	2	1	1	1	0	1	1	1	1	0
N	12	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-14-9

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 42 of administration

	In the open-field										
							Stereotype				
									Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
151	1	1	1	1	0	0	0	0	1	1	1
152	1	1	1	1	0	0	0	0	1	1	1
153	1	1	1	1	0	0	0	0	1	1	1
154	1	1	1	1	0	0	0	0	1	1	1
155	1	1	1	1	0	0	0	0	1	1	1
156	1	1	1	1	0	0	0	0	1	1	1
157	1	1	1	1	0	0	0	0	1	1	1
158	1	1	1	1	0	0	0	0	1	1	1
159	1	1	1	1	0	0	0	0	1	1	1
160	1	1	1	1	0	0	0	0	1	1	1
161	1	1	1	1	0	0	0	0	1	1	1
162	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12
H	0.0000	0.0000	0.0000	0.0000	0.0000	3.2727	2.9167	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-14-10

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 42 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
251	1	1	1	1	0	0	0	0	1	1	1
252	1	1	1	1	0	0	0	0	1	1	1
253	1	1	1	1	0	0	0	0	1	1	1
254	1	1	1	1	0	0	0	0	1	1	1
255	1	1	1	1	0	0	0	0	1	1	1
256	1	1	1	1	0	0	0	0	1	1	1
257	1	1	1	1	0	0	0	0	1	1	1
258	1	1	1	1	0	0	0	0	1	1	1
259	1	1	1	1	0	0	0	0	1	1	1
260	1	1	1	1	0	0	0	0	1	1	1
261	1	1	1	1	0	0	0	0	1	1	1
262	1	1	1	1	0	0	0	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-14-11

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 42 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
351	1	1	1	1	0	0	0	0	1	1	1
352	1	1	1	1	0	0	0	0	1	1	1
353	1	1	1	1	0	0	0	0	1	1	1
354	1	1	1	1	0	0	0	0	1	1	1
355	1	1	1	1	0	0	0	0	1	1	1
356	1	1	1	1	0	1	0	0	1	1	1
357	1	1	1	1	0	0	0	0	1	1	1
358	1	1	1	1	0	0	0	0	1	1	1
360	1	1	1	1	0	0	0	0	1	1	1
361	1	1	1	1	0	0	0	0	1	1	1
362	1	1	1	1	0	0	0	0	1	1	1
N	11	11	11	11	11	11	11	11	11	11	11

INDIVIDUAL DATA 2-14-12

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 42 of administration

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
451	1	1	1	1	0	0	0	0	1	1	1
452	1	1	1	1	0	0	0	0	1	1	1
453	1	1	1	1	0	0	0	0	1	1	1
454	1	1	1	1	0	0	0	0	1	1	1
455	1	1	1	1	0	0	0	0	1	1	1
456	1	1	1	1	0	0	0	0	1	1	1
457	1	1	1	1	0	0	0	0	1	1	1
458	1	1	1	1	0	0	0	0	1	1	1
459	1	1	1	1	0	0	0	0	1	1	1
460	1	1	1	1	0	0	0	0	1	1	1
461	1	1	1	1	0	0	0	0	1	1	1
462	1	1	1	1	0	0	1	0	1	1	1
N	12	12	12	12	12	12	12	12	12	12	12

INDIVIDUAL DATA 2-14-13

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 42 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira- tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
163	1	1	1	0	0	1
164	1	1	1	0	0	1
165	1	1	1	0	0	1
166	1	1	1	0	0	1
167	1	1	1	0	0	1
N	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-14-14

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 42 of administration

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
463	1	1	1	0	0	1
464	1	1	1	0	0	1
465	1	1	1	0	0	1
466	1	1	1	0	0	1
467	1	1	1	0	0	1
N	5	5	5	5	5	5

INDIVIDUAL DATA 2-14-15

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 42 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
163	1	1	2	1	1	1	0	1	1	1	1	0
164	1	1	2	1	1	1	0	1	1	1	1	0
165	1	1	2	1	1	1	0	1	1	1	1	0
166	1	1	2	1	1	1	0	1	1	1	1	0
167	1	1	2	1	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-14-16

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 42 of administration

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
463	1	1	2	1	1	1	0	1	1	1	1	0
464	1	1	2	1	1	1	0	1	1	1	1	0
465	1	1	2	1	1	1	0	1	1	1	1	0
466	1	1	2	1	1	1	0	1	1	1	1	0
467	1	1	2	1	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5

INDIVIDUAL DATA 2-14-17

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 42 of administration

	In the open-field										
							Stereotype				
									Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
163	1	1	1	1	0	0	0	0	1	1	1
164	1	1	1	1	0	0	0	0	1	1	1
165	1	1	1	1	0	0	0	0	1	1	1
166	1	1	1	1	0	0	0	0	1	1	1
167	1	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-14-18

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 42 of administration

	In the open-field										
							Stereotype				
									Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
463	1	1	1	1	0	0	0	0	1	1	1
464	1	1	1	1	0	0	0	0	1	1	1
465	1	1	1	1	0	0	0	0	1	1	1
466	1	1	1	1	0	0	0	0	1	1	1
467	1	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5

INDIVIDUAL DATA 2-15-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 7 of recovery

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
103	1	1	1	0	0	1
106	1	1	1	0	0	1
107	1	1	1	0	0	1
108	1	1	1	0	0	1
109	1	1	1	0	0	1
N	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-15-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Day 7 of recovery

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira- tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
402	1	1	1	0	0	1
405	1	1	1	0	0	1
406	1	1	1	0	0	1
409	1	1	1	0	0	1
410	1	1	1	0	0	1
N	5	5	5	5	5	5

INDIVIDUAL DATA 2-15-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 7 of recovery

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
103	1	1	2	1	1	1	0	1	1	1	1	0
106	1	1	2	1	1	1	0	1	1	1	1	0
107	1	1	2	1	1	1	0	1	1	1	1	0
108	1	1	2	1	1	1	0	1	1	1	1	0
109	1	1	2	1	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-15-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Day 7 of recovery

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
402	1	1	2	1	1	1	0	1	1	1	1	0
405	1	1	2	1	1	1	0	1	1	1	1	0
406	1	1	2	1	1	1	0	1	1	1	1	0
409	1	1	2	1	1	1	0	1	1	1	1	0
410	1	1	2	1	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5

INDIVIDUAL DATA 2-15-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 7 of recovery

	In the open-field										
							Stereotype				
									Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
103	1	1	1	1	0	0	0	0	1	1	1
106	1	1	1	1	0	0	0	0	1	1	1
107	1	1	1	1	0	0	0	0	1	1	1
108	1	1	1	1	0	0	0	0	1	1	1
109	1	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-15-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Day 7 of recovery

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
402	1	1	1	1	0	0	0	0	1	1	1
405	1	1	1	1	0	0	0	0	1	1	1
406	1	1	1	1	0	0	0	0	1	1	1
409	1	1	1	1	0	0	0	0	1	1	1
410	1	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5

INDIVIDUAL DATA 2-16-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 7 of recovery

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
163	1	1	1	0	0	1
164	1	1	1	0	0	1
165	1	1	1	0	0	1
166	1	1	1	0	0	1
167	1	1	1	0	0	1
N	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-16-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 7 of recovery

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira- tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
463	1	1	1	0	0	1
464	1	1	1	0	0	1
465	1	1	1	0	0	1
466	1	1	1	0	0	1
467	1	1	1	0	0	1
N	5	5	5	5	5	5

INDIVIDUAL DATA 2-16-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 7 of recovery

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
163	1	1	2	1	1	1	0	1	1	1	1	0
164	1	1	2	1	1	1	0	1	1	1	1	0
165	1	1	2	1	1	1	0	1	1	1	1	0
166	1	1	2	1	1	1	0	1	1	1	1	0
167	1	1	2	1	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-16-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 7 of recovery

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
463	1	1	2	1	1	1	0	1	1	1	1	0
464	1	1	2	1	1	1	0	1	1	1	1	0
465	1	1	2	1	1	1	0	1	1	1	1	0
466	1	1	2	1	1	1	0	1	1	1	1	0
467	1	1	2	1	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5

INDIVIDUAL DATA 2-16-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 7 of recovery

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
163	1	1	1	1	0	0	0	0	1	1	1
164	1	1	1	1	0	0	0	0	1	1	1
165	1	1	1	1	0	0	0	0	1	1	1
166	1	1	1	1	0	0	0	0	1	1	1
167	1	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-16-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 7 of recovery

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
463	1	1	1	1	0	0	0	0	1	1	1
464	1	1	1	1	0	0	0	0	1	1	1
465	1	1	1	1	0	0	0	0	1	1	1
466	1	1	1	1	0	0	0	0	1	1	1
467	1	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5

INDIVIDUAL DATA 2-17-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 14 of recovery

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira- tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
103	1	1	1	0	0	1
106	1	1	1	0	0	1
107	1	1	1	0	0	1
108	1	1	1	0	0	1
109	1	1	1	0	0	1
N	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-17-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Day 14 of recovery

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
402	1	1	1	0	0	1
405	1	1	1	0	0	1
406	1	1	1	0	0	1
409	1	1	1	0	0	1
410	1	1	1	0	0	1
N	5	5	5	5	5	5

INDIVIDUAL DATA 2-17-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 14 of recovery

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
103	1	1	2	1	1	1	0	1	1	1	1	0
106	1	1	2	1	1	1	0	1	1	1	1	0
107	1	1	2	1	1	1	0	1	1	1	1	0
108	1	1	2	1	1	1	0	1	1	1	1	0
109	1	1	2	1	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-17-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Day 14 of recovery

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
402	1	1	2	1	1	1	0	1	1	1	1	0
405	1	1	2	1	1	1	0	1	1	1	1	0
406	1	1	2	1	1	1	0	1	1	1	1	0
409	1	1	2	1	1	1	0	1	1	1	1	0
410	1	1	2	1	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5

INDIVIDUAL DATA 2-17-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Day 14 of recovery

	In the open-field										
							Stereotype				
									Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
103	1	1	1	1	0	0	0	0	1	1	1
106	1	1	1	1	0	0	0	0	1	1	1
107	1	1	1	1	0	0	0	0	1	1	1
108	1	1	1	1	0	0	0	0	1	1	1
109	1	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-17-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Day 14 of recovery

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
402	1	1	1	1	0	0	0	0	1	1	1
405	1	1	1	1	0	0	0	0	1	1	1
406	1	1	1	1	0	0	0	0	1	1	1
409	1	1	1	1	0	0	0	0	1	1	1
410	1	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5

INDIVIDUAL DATA 2-18-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 14 of recovery

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira-tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
163	1	1	1	0	0	1
164	1	1	1	0	0	1
165	1	1	1	0	0	1
166	1	1	1	0	0	1
167	1	1	1	0	0	1
N	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-18-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 14 of recovery

	In the cage					
				Stereotype		
Animal No.	Body position/ Posture	Respira- tory pattern	Tremor/ Convulsion	Rolling	Repetitive circling	Bizarre behavior Biting/Selfmutilation
463	1	1	1	0	0	1
464	1	1	1	0	0	1
465	1	1	1	0	0	1
466	1	1	1	0	0	1
467	1	1	1	0	0	1
N	5	5	5	5	5	5

INDIVIDUAL DATA 2-18-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 14 of recovery

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
163	1	1	2	1	1	1	0	1	1	1	1	0
164	1	1	2	1	1	1	0	1	1	1	1	0
165	1	1	2	1	1	1	0	1	1	1	1	0
166	1	1	2	1	1	1	0	1	1	1	1	0
167	1	1	2	1	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-18-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 14 of recovery

Animal No.	On the hand											
	Ease of		Muscle	Pilo-			Mucous			Lacrima-		Secretions/
	Removal	Handling	tone	erection	Fur	Eyes	membranes	Skin	Pupil size	tion	Salivation	Excretions
463	1	1	2	1	1	1	0	1	1	1	1	0
464	1	1	2	1	1	1	0	1	1	1	1	0
465	1	1	2	1	1	1	0	1	1	1	1	0
466	1	1	2	1	1	1	0	1	1	1	1	0
467	1	1	2	1	1	1	0	1	1	1	1	0
N	5	5	5	5	5	5	5	5	5	5	5	5

INDIVIDUAL DATA 2-18-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 14 of recovery

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
163	1	1	1	1	0	0	0	0	1	1	1
164	1	1	1	1	0	0	0	0	1	1	1
165	1	1	1	1	0	0	0	0	1	1	1
166	1	1	1	1	0	0	0	0	1	1	1
167	1	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 2-18-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Detailed clinical observation, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 14 of recovery

	In the open-field										
							Stereotype		Bizarre behavior		
Animal No.	Gait	Co-ordination of movement	Reactivity to environ-mental stimuli	Searching	Urination	Defecation	Excessive grooming	Unusual head movement	Walking backward	Vocaliza-tion	Aggression
463	1	1	1	1	0	0	0	0	1	1	1
464	1	1	1	1	0	0	0	0	1	1	1
465	1	1	1	1	0	0	0	0	1	1	1
466	1	1	1	1	0	0	0	0	1	1	1
467	1	1	1	1	0	0	0	0	1	1	1
N	5	5	5	5	5	5	5	5	5	5	5

INDIVIDUAL DATA 3-1-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Week 6 of administration

	On the desk					
	Reactivity					
Animal No.	Visual	Touch	Auditory	Pain	Proprio-ceptive	Righting reflex
103	4	2	1	2	1	1
106	4	2	1	2	1	1
107	4	2	1	2	1	1
108	4	2	1	2	1	1
109	4	2	1	2	1	1
N	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 3-1-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : Week 6 of administration

	On the desk					
	Reactivity					
Animal No.	Visual	Touch	Auditory	Pain	Proprio-ceptive	Righting reflex
204	4	2	1	2	1	1
206	4	2	1	2	1	1
207	4	2	1	2	1	1
208	4	2	1	2	1	1
210	4	2	1	2	1	1
N	5	5	5	5	5	5

INDIVIDUAL DATA 3-1-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : Week 6 of administration

	On the desk					
	Reactivity					
Animal No.	Visual	Touch	Auditory	Pain	Proprio-ceptive	Righting reflex
303	4	2	1	2	1	1
304	4	2	1	2	1	1
305	4	2	1	2	1	1
306	4	2	1	2	1	1
308	4	2	1	2	1	1
N	5	5	5	5	5	5

INDIVIDUAL DATA 3-1-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Week 6 of administration

	On the desk					
	Reactivity					
Animal No.	Visual	Touch	Auditory	Pain	Proprio-ceptive	Righting reflex
402	4	2	1	2	1	1
405	4	2	1	2	1	1
406	4	2	1	2	1	1
409	4	2	1	2	1	1
410	4	2	1	2	1	1
N	5	5	5	5	5	5

INDIVIDUAL DATA 3-2-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Week 6 of administration

	On the desk					
	Reactivity					
Animal No.	Visual	Touch	Auditory	Pain	Proprio-ceptive	Righting reflex
163	4	2	1	2	1	1
164	4	2	1	2	1	1
165	4	2	1	2	1	1
166	4	2	1	2	1	1
167	4	2	1	2	1	1
N	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 3-2-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Week 6 of administration

	On the desk					
	Reactivity					
Animal No.	Visual	Touch	Auditory	Pain	Proprio-ceptive	Righting reflex
463	4	2	1	2	1	1
464	4	2	1	2	1	1
465	4	2	1	2	1	1
466	4	2	1	2	1	1
467	4	2	1	2	1	1
N	5	5	5	5	5	5

INDIVIDUAL DATA 3-3-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 4 of lactation

	On the desk					
	Reactivity					
Animal No.	Visual	Touch	Auditory	Pain	Proprio-ceptive	Righting reflex
152	4	2	1	2	1	1
153	4	2	1	2	1	1
154	4	2	1	2	1	1
158	4	2	1	2	1	1
161	4	2	1	2	1	1
N	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 3-3-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 4 of lactation

	On the desk					
	Reactivity					
Animal No.	Visual	Touch	Auditory	Pain	Proprio-ceptive	Righting reflex
252	4	2	1	2	1	1
253	4	2	1	2	1	1
254	4	2	1	2	1	1
255	4	2	1	2	1	1
262	4	2	1	2	1	1
N	5	5	5	5	5	5

INDIVIDUAL DATA 3-3-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 4 of lactation

	On the desk					
	Reactivity					
Animal No.	Visual	Touch	Auditory	Pain	Proprio-ceptive	Righting reflex
351	4	2	1	2	1	1
353	4	2	1	2	1	1
356	4	2	1	2	1	1
358	4	2	1	2	1	1
361	4	2	1	2	1	1
N	5	5	5	5	5	5

INDIVIDUAL DATA 3-3-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 4 of lactation

	On the desk					
	Reactivity					
Animal No.	Visual	Touch	Auditory	Pain	Proprio-ceptive	Righting reflex
451	4	2	1	2	1	1
457	4	2	1	2	1	1
458	4	2	1	2	1	1
459	4	2	1	2	1	1
461	4	2	1	2	1	1
N	5	5	5	5	5	5

INDIVIDUAL DATA 3-4-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Week 2 of recovery

	On the desk					
	Reactivity					
Animal No.	Visual	Touch	Auditory	Pain	Proprio-ceptive	Righting reflex
103	4	2	1	2	1	1
106	4	2	1	2	1	1
107	4	2	1	2	1	1
108	4	2	1	2	1	1
109	4	2	1	2	1	1
N	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 3-4-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Week 2 of recovery

	On the desk					
	Reactivity					
Animal No.	Visual	Touch	Auditory	Pain	Proprio-ceptive	Righting reflex
402	4	2	1	2	1	1
405	4	2	1	2	1	1
406	4	2	1	2	1	1
409	4	2	1	2	1	1
410	4	2	1	2	1	1
N	5	5	5	5	5	5

INDIVIDUAL DATA 3-5-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Week 2 of recovery

	On the desk					
	Reactivity					
Animal No.	Visual	Touch	Auditory	Pain	Proprio-ceptive	Righting reflex
163	4	2	1	2	1	1
164	4	2	1	2	1	1
165	4	2	1	2	1	1
166	4	2	1	2	1	1
167	4	2	1	2	1	1
N	5	5	5	5	5	5
H	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

INDIVIDUAL DATA 3-5-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Week 2 of recovery

	On the desk					
	Reactivity					
Animal No.	Visual	Touch	Auditory	Pain	Proprio-ceptive	Righting reflex
463	4	2	1	2	1	1
464	4	2	1	2	1	1
465	4	2	1	2	1	1
466	4	2	1	2	1	1
467	4	2	1	2	1	1
N	5	5	5	5	5	5

INDIVIDUAL DATA 3-6-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Week 6 of administration

Animal No.	Grip strength (g) Forelimb	Hindlimb	Motor activity measurements 0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	0'-60'
103	1262.0	778.3	336	245	192	157	79	55	1064
106	1388.0	907.3	415	229	184	65	25	0	918
107	1041.3	839.3	379	413	66	28	104	95	1085
108	1359.3	684.0	500	250	263	247	190	63	1513
109	1060.3	681.7	476	184	53	34	0	71	818
N	5	5	5	5	5	5	5	5	5
MEAN	1222.18	778.12	421.2	264.2	151.6	106.2	79.6	56.8	1079.6
S.D.	163.41	98.22	67.6	87.2	89.6	94.1	74.3	35.1	265.8
S.E.	73.08	43.92	30.2	39.0	40.1	42.1	33.2	15.7	118.9
M/C	5.1278	3.1877	8.3154 *	5.2898	2.6338	10.2053 *	9.0021 *	15.1153 **	9.1182 *
F	1.2426	4.9707 *		2.3791	1.0552				
H			0.5919			3.9371	5.5197	5.4813	3.3429

INDIVIDUAL DATA 3-6-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : Week 6 of administration

Animal	Grip strength (g)		Motor activity measurements						
No.	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	0'-60'
204	1270.7	627.7	476	290	157	85	71	53	1132
206	1364.7	578.3	453	185	94	31	49	46	858
207	1390.7	632.0	222	155	170	62	45	21	675
208	1303.3	481.0	592	258	48	46	71	10	1025
210	1261.3	798.7	240	57	50	0	10	28	385
N	5	5	5	5	5	5	5	5	5
MEAN	1318.14	623.54	396.6	189.0	103.8	44.8	49.2	31.6	815.0
S.D.	57.30	115.25	160.2	91.6	57.7	32.1	25.0	17.7	296.2
S.E.	25.63	51.54	71.7	41.0	25.8	14.3	11.2	7.9	132.5
t'		2.2340							

INDIVIDUAL DATA 3-6-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : Week 6 of administration

Animal	Grip strength (g)		Motor activity measurements						
No.	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	0'-60'
303	1011.0	541.0	747	548	163	150	335	107	2050
304	1098.7	598.0	590	331	70	24	17	0	1032
305	1117.7	528.7	305	294	276	80	80	73	1108
306	1278.0	630.7	1110	747	423	537	188	357	3362
308	1351.0	494.0	216	168	143	78	60	25	690
N	5	5	5	5	5	5	5	5	5
MEAN	1171.28	558.48	593.6	417.6	215.0	173.8	136.0	112.4	1648.4
S.D.	139.21	55.06	359.2	229.4	137.7	207.9	127.8	142.9	1082.6
S.E.	62.26	24.62	160.6	102.6	61.6	93.0	57.2	63.9	484.2
t'		3.1742 *							

INDIVIDUAL DATA 3-6-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Week 6 of administration

Animal	Grip strength (g)		Motor activity measurements						
No.	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	0'-60'
402	1396.3	784.3	485	227	116	51	79	108	1066
405	881.3	429.0	443	212	76	144	101	67	1043
406	1009.3	542.3	372	176	140	70	105	50	913
409	1108.7	508.3	808	433	354	282	197	187	2261
410	1320.7	418.7	130	206	231	180	103	78	928
N	5	5	5	5	5	5	5	5	5
MEAN	1143.26	536.52	447.6	250.8	183.4	145.4	117.0	98.0	1242.2
S.D.	214.05	148.04	243.9	103.5	111.1	92.8	45.9	54.1	573.5
S.E.	95.73	66.21	109.1	46.3	49.7	41.5	20.5	24.2	256.5
t'		3.4916 **							

INDIVIDUAL DATA 3-7-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Week 6 of administration

Animal	Grip strength (g)		Motor activity measurements						
No.	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	0'-60'
163	755.0	623.3	491	373	172	64	15	0	1115
164	928.7	436.0	597	515	335	381	167	62	2057
165	924.7	508.7	1031	632	379	336	86	5	2469
166	1251.7	449.7	613	456	329	121	0	0	1519
167	670.7	623.7	771	492	285	175	12	22	1757
N	5	5	5	5	5	5	5	5	5
MEAN	906.16	528.28	700.6	493.6	300.0	215.4	56.0	17.8	1783.4
S.D.	222.79	91.11	210.0	94.3	78.9	137.3	70.7	26.3	515.3
S.E.	99.63	40.75	93.9	42.2	35.3	61.4	31.6	11.8	230.5
M/C	5.0150 *	0.0112	0.1457	0.3395	1.3999	0.3184	0.4300	1.7783	0.2093
F		0.1449	1.0258	0.9399	0.3012	0.1584	0.0292	4.6852 †	0.1543
H	1.3200								

INDIVIDUAL DATA 3-7-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Week 6 of administration

Animal	Grip strength (g)		Motor activity measurements						
No.	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	0'-60'
463	761.0	640.0	763	489	599	354	65	7	2277
464	748.0	653.3	372	237	232	136	115	98	1190
465	730.0	422.0	689	396	233	92	18	44	1472
466	741.3	511.3	643	414	335	197	108	83	1780
467	874.3	527.7	422	586	310	146	7	152	1623
N	5	5	5	5	5	5	5	5	5
MEAN	770.92	550.86	577.8	424.4	341.8	185.0	62.6	76.8	1668.4
S.D.	58.87	96.37	171.4	128.8	150.9	101.6	49.7	55.0	403.8
S.E.	26.33	43.10	76.7	57.6	67.5	45.4	22.2	24.6	180.6
t'								2.1645	

INDIVIDUAL DATA 3-8-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 4 of lactation

Animal	Grip strength (g)		Motor activity measurements						
No.	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	0'-60'
152	848.3	662.3	482	234	62	49	1	0	828
153	1006.7	537.7	474	213	166	181	75	140	1249
154	859.0	768.7	382	340	221	130	133	135	1341
158	1053.3	624.0	774	174	75	0	2	0	1025
161	1129.7	563.3	612	473	298	233	160	98	1874
N	5	5	5	5	5	5	5	5	5
MEAN	979.40	631.20	544.8	286.8	164.4	118.6	74.2	74.6	1263.4
S.D.	122.96	91.21	152.1	120.9	99.4	94.9	73.1	70.0	395.4
S.E.	54.99	40.79	68.0	54.1	44.5	42.4	32.7	31.3	176.8
M/C	2.1130	1.1366	1.9291	0.5021	0.3566	3.5821	5.4092	2.2984	1.9730
F	0.6203	0.8426	1.6118	1.2359	0.5326	1.2900	0.4994	0.2037	0.8138

INDIVIDUAL DATA 3-8-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 4 of lactation

Animal	Grip strength (g)		Motor activity measurements						
No.	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	0'-60'
252	859.0	548.3	677	348	73	42	449	207	1796
253	1139.3	667.3	251	23	18	18	0	0	310
254	1356.7	570.0	404	145	124	17	26	6	722
255	1206.0	605.0	654	195	219	103	117	167	1455
262	923.7	458.0	251	0	0	0	0	2	253
N	5	5	5	5	5	5	5	5	5
MEAN	1096.94	569.72	447.4	142.2	86.8	36.0	118.4	76.4	907.2
S.D.	204.81	76.99	208.8	141.0	88.5	40.3	191.0	102.0	690.8
S.E.	91.59	34.43	93.4	63.1	39.6	18.0	85.4	45.6	308.9

INDIVIDUAL DATA 3-8-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 4 of lactation

Animal	Grip strength (g)		Motor activity measurements						
No.	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	0'-60'
351	1360.3	638.3	395	335	210	7	0	0	947
353	877.7	412.3	478	185	156	85	4	0	908
356	937.3	609.3	238	159	3	0	0	0	400
358	1152.3	622.7	332	192	249	119	163	190	1245
361	1185.7	769.3	245	65	8	0	0	0	318
N	5	5	5	5	5	5	5	5	5
MEAN	1102.66	610.38	337.6	187.2	125.2	42.2	33.4	38.0	763.6
S.D.	196.02	127.89	101.9	97.0	114.2	56.0	72.5	85.0	392.7
S.E.	87.66	57.19	45.6	43.4	51.1	25.0	32.4	38.0	175.6

INDIVIDUAL DATA 3-8-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 4 of lactation

Animal	Grip strength (g)		Motor activity measurements						
No.	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	0'-60'
451	1016.0	535.7	556	276	118	231	402	350	1933
457	1019.3	839.0	390	86	54	2	0	0	532
458	1018.3	729.0	408	263	138	17	47	19	892
459	1269.7	672.0	391	84	27	35	1	24	562
461	1077.0	593.3	690	364	250	149	193	40	1686
N	5	5	5	5	5	5	5	5	5
MEAN	1080.06	673.80	487.0	214.6	117.4	86.8	128.6	86.6	1121.0
S.D.	109.07	118.21	133.1	124.5	86.9	99.3	172.0	147.9	650.1
S.E.	48.78	52.86	59.5	55.7	38.9	44.4	76.9	66.2	290.7

INDIVIDUAL DATA 3-9-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Week 2 of recovery

Animal	Grip strength (g)		Motor activity measurements						
No.	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	0'-60'
103	1556.3	722.3	297	230	146	86	105	48	912
106	1507.0	521.7	378	236	163	105	76	41	999
107	1908.7	737.3	429	416	362	139	26	85	1457
108	1957.3	671.0	407	246	117	117	41	103	1031
109	1558.3	632.0	603	396	256	143	112	67	1577
N	5	5	5	5	5	5	5	5	5
MEAN	1697.52	656.86	422.8	304.8	208.8	118.0	72.0	68.8	1195.2
S.D.	216.63	86.37	112.5	92.8	100.2	23.8	38.0	25.7	300.0
S.E.	96.88	38.63	50.3	41.5	44.8	10.6	17.0	11.5	134.2
M/C	0.1665	0.6705	0.8676	0.0133	0.1368	5.2501 *	1.9618	6.4404 *	0.1853
F	0.9699	1.1851	0.9410	0.5692	0.4115		1.2988		0.0114
H						0.0109		0.0982	

INDIVIDUAL DATA 3-9-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Week 2 of recovery

Animal	Grip strength (g)		Motor activity measurements						
No.	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	0'-60'
402	1990.3	564.7	400	264	73	113	72	86	1008
405	1390.7	649.3	399	208	202	58	78	33	978
406	1303.7	411.3	288	274	208	205	116	22	1113
409	1585.7	762.7	442	166	102	95	64	57	926
410	1456.3	507.7	300	397	273	288	262	316	1836
N	5	5	5	5	5	5	5	5	5
MEAN	1545.34	579.14	365.8	261.8	171.6	151.8	118.4	102.8	1172.2
S.D.	269.19	134.26	67.9	87.3	82.3	93.4	82.7	121.7	377.3
S.E.	120.38	60.04	30.4	39.1	36.8	41.8	37.0	54.4	168.7

INDIVIDUAL DATA 3-10-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Week 2 of recovery

Animal	Grip strength (g)		Motor activity measurements						
No.	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	0'-60'
163	1307.7	660.3	803	451	279	145	358	119	2155
164	1151.3	342.0	561	497	297	183	113	17	1668
165	1340.3	558.3	370	234	350	158	183	121	1416
166	1280.0	420.7	808	710	452	171	297	261	2699
167	1475.3	424.3	537	362	312	417	408	357	2393
N	5	5	5	5	5	5	5	5	5
MEAN	1310.92	481.12	615.8	450.8	338.0	214.8	271.8	175.0	2066.2
S.D.	116.54	126.78	188.2	176.2	68.9	113.9	122.2	133.7	523.6
S.E.	52.12	56.70	84.1	78.8	30.8	50.9	54.6	59.8	234.1
M/C	0.0095	0.5655	0.0292	2.4133	2.6340	0.0889	0.4353	0.5280	1.1990
F	4.1461 †	0.1895	2.6519	1.2628	0.0868	0.4355	1.5977	0.3479	0.5161

INDIVIDUAL DATA 3-10-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Functional test, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Week 2 of recovery

Animal	Grip strength (g)		Motor activity measurements						
No.	Forelimb	Hindlimb	0'-10'	10'-20'	20'-30'	30'-40'	40'-50'	50'-60'	0'-60'
463	1288.7	584.0	917	624	565	338	178	33	2655
464	1236.3	609.0	1030	571	138	230	139	93	2201
465	978.7	431.0	846	460	292	196	305	137	2236
466	1094.0	425.7	822	601	181	381	82	278	2345
467	1186.3	504.3	480	478	392	150	233	121	1854
N	5	5	5	5	5	5	5	5	5
MEAN	1156.80	510.80	819.0	546.8	313.6	259.0	187.4	132.4	2258.2
S.D.	122.73	84.64	206.0	73.7	171.9	97.2	85.8	90.5	288.2
S.E.	54.89	37.85	92.1	33.0	76.9	43.5	38.4	40.5	128.9
t'	2.0362								

INDIVIDUAL DATA 4-1-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg

Animal	Body weight (g) on administration period (day)										Body weight gain Days 1-42	
No.	1	3	5	7	10	14	21	28	35	42	(g)	(%)
101	391	401	410	416	428	447	463	481	498	521	130	33.25
102	397	402	410	423	434	452	465	426	470	482	85	21.41
103	402	413	416	426	432	441	463	495	515	536	134	33.33
104	403	413	416	432	432	448	465	473	495	509	106	26.30
105	409	420	422	425	432	443	464	475	490	501	92	22.49
106	417	422	433	438	446	462	476	485	518	532	115	27.58
107	420	428	437	448	447	466	444	504	524	542	122	29.05
108	423	436	435	452	456	472	485	508	521	541	118	27.90
109	424	435	439	447	458	476	485	512	536	545	121	28.54
110	434	443	451	460	475	495	508	541	567	596	162	37.33
111	443	462	466	478	487	505	525	554	582	606	163	36.79
112	458	470	475	484	490	504	534	566	594	613	155	33.84
N	12	12	12	12	12	12	12	12	12	12	12	12
MEAN	418.4	428.8	434.2	444.1	451.4	467.6	481.4	501.7	525.8	543.7	125.3	29.818
S.D.	19.7	21.8	21.3	21.7	22.2	23.3	27.5	38.8	38.1	41.5	25.3	5.161
S.E.	5.7	6.3	6.1	6.3	6.4	6.7	8.0	11.2	11.0	12.0	7.3	1.490
M/C	1.4148	0.2816	0.3127	0.0330	0.0114	0.2138	0.4992	2.9492	1.7954	1.9195	4.1384	4.1048
F	0.1228	0.0662	0.0395	0.0668	0.1774	0.1133	0.1329	0.0531	0.1658	0.8885	1.4860	1.4960

INDIVIDUAL DATA 4-1-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg

Animal	Body weight (g) on administration period (day)										Body weight gain Days 1-42	
No.	1	3	5	7	10	14	21	28	35	42	(g)	(%)
201	396	400	410	417	423	439	462	489	514	532	136	34.34
202	398	406	406	410	412	431	450	474	491	504	106	26.63
203	406	409	409	418	420	437	452	474	488	504	98	24.14
204	408	417	420	430	439	456	483	503	523	527	119	29.17
205	416	425	428	429	432	444	456	472	487	510	94	22.60
206	422	430	440	445	450	469	481	495	514	522	100	23.70
207	417	427	434	438	444	456	476	497	511	528	111	26.62
208	421	431	433	439	442	462	479	495	515	514	93	22.09
209	424	430	437	448	451	465	475	491	505	527	103	24.29
210	431	447	449	452	461	480	507	537	564	575	144	33.41
211	451	458	464	475	480	499	513	540	557	582	131	29.05
212	458	466	469	481	485	507	517	543	570	583	125	27.29
N	12	12	12	12	12	12	12	12	12	12	12	12
MEAN	420.7	428.8	433.3	440.2	444.9	462.1	479.3	500.8	519.9	534.0	113.3	26.944
S.D.	19.0	20.2	20.5	21.9	22.5	23.9	23.0	25.6	28.9	29.3	17.3	3.978
S.E.	5.5	5.8	5.9	6.3	6.5	6.9	6.6	7.4	8.3	8.5	5.0	1.148

INDIVIDUAL DATA 4-1-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg

Animal	Body weight (g) on administration period (day)										Body weight gain Days 1-42	
No.	1	3	5	7	10	14	21	28	35	42	(g)	(%)
301	387	402	399	409	418	433	445	465	482	506	119	30.75
302	398	408	409	418	423	432	444	464	486	504	106	26.63
303	412	419	425	433	438	457	493	513	531	544	132	32.04
304	414	424	437	442	451	470	492	512	526	537	123	29.71
305	410	416	426	436	439	454	473	507	526	520	110	26.83
306	411	419	425	433	443	454	477	500	513	492	81	19.71
307	417	423	425	431	435	446	471	480	496	518	101	24.22
308	420	423	429	440	446	465	485	508	523	526	106	25.24
309	426	432	442	449	462	477	499	534	553	571	145	34.04
310	426	433	444	454	463	488	504	522	553	568	142	33.33
311	450	460	467	471	473	490	504	517	530	536	86	19.11
312	464	469	478	490	498	509	528	540	565	586	122	26.29
N	12	12	12	12	12	12	12	12	12	12	12	12
MEAN	419.6	427.3	433.8	442.2	449.1	464.6	484.6	505.2	523.7	534.0	114.4	27.325
S.D.	20.8	19.5	22.1	22.0	22.2	23.4	24.4	24.4	26.2	29.1	20.1	4.881
S.E.	6.0	5.6	6.4	6.4	6.4	6.8	7.1	7.0	7.6	8.4	5.8	1.409

INDIVIDUAL DATA 4-1-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg

Animal	Body weight (g) on administration period (day)										Body weight gain Days 1-42	
No.	1	3	5	7	10	14	21	28	35	42	(g)	(%)
401	392	400	407	419	428	453	470	488	494	501	109	27.81
402	399	403	409	421	430	448	478	501	522	520	121	30.33
403	410	412	424	428	438	447	467	481	495	509	99	24.15
404	411	418	418	426	423	435	444	469	478	487	76	18.49
405	408	412	420	429	435	444	465	490	508	501	93	22.79
406	416	426	429	440	449	468	484	505	520	517	101	24.28
407	407	418	423	435	438	453	468	478	498	501	94	23.10
408	429	435	433	443	450	457	481	484	476	477	48	11.19
409	429	429	439	447	449	469	489	504	513	517	88	20.51
410	430	450	454	474	479	500	515	533	547	544	114	26.51
411	443	451	461	472	481	506	513	553	576	590	147	33.18
412	421	454	461	477	486	514	545	562	581	587	166	39.43
N	12	12	12	12	12	12	12	12	12	12	12	12
MEAN	416.3	425.7	431.5	442.6	448.8	466.2	484.9	504.0	517.3	520.9	104.7	25.148
S.D.	14.6	18.6	18.7	20.9	21.8	26.3	27.4	30.0	34.6	35.8	30.9	7.239
S.E.	4.2	5.4	5.4	6.0	6.3	7.6	7.9	8.7	10.0	10.3	8.9	2.090

INDIVIDUAL DATA 4-1-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg

Animal No.	Body weight (g) on recovery period (day) 7	14	Body weight gain Day 42-R14 (g)	(%)
103	551	551	15	2.80
106	546	565	33	6.20
107	566	584	42	7.75
108	569	575	34	6.28
109	570	575	30	5.50
N	5	5	5	5
MEAN	560.4	570.0	30.8	5.706
S.D.	11.1	12.6	9.9	1.819
S.E.	5.0	5.6	4.4	0.814
M/C	0.2047	0.0016	0.0032	0.0353
F	10.6260 *	10.9208 *	1.0814	0.7077

R14: Recovery day 14.

INDIVIDUAL DATA 4-1-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg

Animal No.	Body weight (g) on recovery period (day) 7	14	Body weight gain Day 42-R14 (g)	(%)
402	531	540	20	3.85
405	518	526	25	4.99
406	532	543	26	5.03
409	533	556	39	7.54
410	557	555	11	2.02
N	5	5	5	5
MEAN	534.2	544.0	24.2	4.686
S.D.	14.1	12.3	10.2	2.010
S.E.	6.3	5.5	4.6	0.899
t'	3.2598 *	3.3047 *		

R14: Recovery day 14.

INDIVIDUAL DATA 4-2-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Before gestation

Animal No.	Body weight (g) on administration period (day) 1	3	5	7	10	14	Body weight gain Days 1-14 (g)	(%)
151	242	241	244	246	252	263	21	8.68
152	251	249	259	254	262	278	27	10.76
153	235	251	242	258	252	260	25	10.64
154	242	253	253	262	264	271	29	11.98
155	248	255	250	262	263	273	25	10.08
156	254	254	258	264	259	269	15	5.91
157	259	265	267	271	276	287	28	10.81
158	255	266	267	274	280	285	30	11.76
159	257	260	267	267	278	286	29	11.28
160	253	271	266	281	278	288	35	13.83
161	260	268	272	274	285	295	35	13.46
162	278	279	283	289	283	288	10	3.60
N	12	12	12	12	12	12	12	12
MEAN	252.8	259.3	260.7	266.8	269.3	278.6	25.8	10.233
S.D.	11.0	10.8	12.0	11.8	11.9	11.2	7.4	2.950
S.E.	3.2	3.1	3.5	3.4	3.4	3.2	2.1	0.852
M/C	0.2471	0.5532	0.6336	0.8269	0.5633	0.7832	2.5328	2.9429
F	0.6662	0.4787	0.9791	0.5433	1.3731	1.7702	2.2907 †	2.2061

INDIVIDUAL DATA 4-2-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Before gestation

Animal No.	Body weight (g) on administration period (day) 1	3	5	7	10	14	Body weight gain Days 1-14 (g)	(%)
251	227	237	230	240	238	245	18	7.93
252	236	241	238	245	244	253	17	7.20
253	244	252	253	264	268	275	31	12.70
254	260	258	268	265	278	286	26	10.00
255	250	258	256	262	267	279	29	11.60
256	253	255	259	260	254	261	8	3.16
257	256	258	263	264	262	273	17	6.64
258	258	259	258	264	263	273	15	5.81
259	259	255	259	259	254	265	6	2.32
260	266	270	276	281	281	284	18	6.77
261	267	271	269	287	275	288	21	7.87
262	269	274	274	283	286	294	25	9.29
N	12	12	12	12	12	12	12	12
MEAN	253.8	257.3	258.6	264.5	264.2	273.0	19.3	7.608
S.D.	12.8	11.1	13.6	14.0	14.8	14.7	7.7	3.066
S.E.	3.7	3.2	3.9	4.0	4.3	4.3	2.2	0.885
t'							1.7853	

INDIVIDUAL DATA 4-2-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Before gestation

Animal No.	Body weight (g) on administration period (day) 1	3	5	7	10	14	Body weight gain Days 1-14 (g)	(%)
351	232	239	233	237	239	243	11	4.74
352	235	244	241	256	255	258	23	9.79
353	235	247	244	260	255	271	36	15.32
354	236	244	232	250	242	252	16	6.78
355	248	251	252	251	243	252	4	1.61
356	263	252	264	258	265	273	10	3.80
357	259	264	271	274	265	270	11	4.25
358	246	248	249	259	261	269	23	9.35
359	250	263	253	266	266	266	16	6.40
360	253	267	259	271	271	278	25	9.88
361	266	270	271	281	283	290	24	9.02
362	254	268	259	271	265	275	21	8.27
N	12	12	12	12	12	12	12	12
MEAN	248.1	254.8	252.3	261.2	259.2	266.4	18.3	7.434
S.D.	11.6	10.9	13.2	12.2	13.0	13.1	8.7	3.651
S.E.	3.3	3.2	3.8	3.5	3.8	3.8	2.5	1.054
t'							2.0371	

INDIVIDUAL DATA 4-2-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Before gestation

Animal No.	Body weight (g) on administration period (day) 1	3	5	7	10	14	Body weight gain Days 1-14 (g)	(%)
451	231	252	240	255	253	256	25	10.82
452	243	246	244	252	246	251	8	3.29
453	231	247	239	254	253	259	28	12.12
454	236	258	249	265	263	275	39	16.53
455	261	255	258	256	270	277	16	6.13
456	248	258	258	272	275	280	32	12.90
457	252	256	259	264	269	278	26	10.32
458	251	262	263	274	282	290	39	15.54
459	252	261	264	274	272	282	30	11.90
460	265	265	266	268	260	267	2	0.75
461	262	272	272	281	284	289	27	10.31
462	257	276	265	283	280	288	31	12.06
N	12	12	12	12	12	12	12	12
MEAN	249.1	259.0	256.4	266.5	267.3	274.3	25.3	10.223
S.D.	11.7	9.0	10.9	10.6	12.4	13.2	11.3	4.670
S.E.	3.4	2.6	3.1	3.1	3.6	3.8	3.3	1.348
t'							0.1373	

INDIVIDUAL DATA 4-3-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Gestation

Animal	Body weight (g) on gestation period (day)									Body weight gain Days 0-20	
No.	0	1	3	5	7	10	14	17	20	(g)	(%)
151	266	269	285	302	306	324	340	359	379	113	42.48
152	271	284	291	297	304	316	334	368	417	146	53.87
153	266	276	287	293	306	321	339	371	424	158	59.40
154	276	275	288	295	302	319	338	371	416	140	50.72
155	264	275	290	293	306	322	333	376	427	163	61.74
156	315	318	334	341	342	358	375	405	450	135	42.86
157	295	298	311	319	327	333	354	384	408	113	38.31
158	289	284	296	307	317	340	353	393	442	153	52.94
159	290	291	301	317	320	339	356	382	420	130	44.83
160	302	307	329	337	360	377	407	436	496	194	64.24
161	287	295	307	319	322	340	358	388	442	155	54.01
162	310	325	335	347	365	384	403	433	482	172	55.48
N	12	12	12	12	12	12	12	12	12	12	12
MEAN	285.9	291.4	304.5	313.9	323.1	339.4	357.5	388.8	433.6	147.7	51.740
S.D.	17.6	17.9	18.8	19.4	21.8	22.6	25.3	24.6	31.9	23.6	8.168
S.E.	5.1	5.2	5.4	5.6	6.3	6.5	7.3	7.1	9.2	6.8	2.358
M/C	4.0728	2.6475	4.5948	3.0719	3.2345	6.1659	7.6320	4.2980	4.6364	5.3238	4.8315
F	1.2786	0.9838	1.3627	1.4018	1.4959	2.2258 †	1.8851	0.7822	0.2216	0.2780	0.7330

INDIVIDUAL DATA 4-3-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Gestation

Animal	Body weight (g) on gestation period (day)									Body weight gain Days 0-20	
No.	0	1	3	5	7	10	14	17	20	(g)	(%)
251	251	254	269	267	274	295	307	334	375	124	49.40
252	250	261	269	279	281	294	305	339	374	124	49.60
253	281	288	300	320	330	351	379	420	485	204	72.60
254	288	302	313	321	325	350	364	395	448	160	55.56
255	286	293	313	325	336	365	390	428	485	199	69.58
256	290	296	305	312	322	330	354	382	422	132	45.52
257	283	289	300	314	322	338	362	388	429	146	51.59
258	280	290	300	310	321	335	353	388	439	159	56.79
259	282	287	301	306	317	331	352	378	428	146	51.77
260	297	303	320	326	337	349	364	397	448	151	50.84
261	294	305	312	322	338	349	368	396	447	153	52.04
262	294	302	318	324	332	350	366	409	451	157	53.40
N	12	12	12	12	12	12	12	12	12	12	12
MEAN	281.3	289.2	301.7	310.5	319.6	336.4	355.3	387.8	435.9	154.6	54.891
S.D.	15.4	16.2	16.8	18.8	20.9	22.0	25.4	28.1	34.8	25.2	8.128
S.E.	4.5	4.7	4.9	5.4	6.0	6.3	7.3	8.1	10.0	7.3	2.346
t'						0.3951					

INDIVIDUAL DATA 4-3-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Gestation

Animal	Body weight (g) on gestation period (day)									Body weight gain Days 0-20	
No.	0	1	3	5	7	10	14	17	20	(g)	(%)
351	259	263	276	289	296	316	335	374	413	154	59.46
352	270	278	294	302	311	332	341	365	405	135	50.00
353	278	281	296	300	309	327	346	380	427	149	53.60
354	260	265	279	286	292	309	331	356	400	140	53.85
355	279	286	293	302	313	328	352	402	456	177	63.44
356	271	275	287	290	306	324	337	369	418	147	54.24
357	285	289	303	309	323	331	350	383	427	142	49.82
358	276	283	299	312	308	339	358	393	443	167	60.51
359[a]	(265)	(269)	(283)	(292)	(297)	(314)	(302)	(310)	(307)	#	#
360	287	304	306	322	334	346	366	399	453	166	57.84
361	282	293	308	311	321	336	353	391	435	153	54.26
362	281	286	299	312	325	340	357	391	440	159	56.58
N	11	11	11	11	11	11	11	11	11	11	11
MEAN	275.3	282.1	294.5	303.2	312.5	329.8	347.8	382.1	428.8	153.5	55.782
S.D.	9.4	11.8	10.3	11.3	12.5	10.8	10.9	14.7	18.6	12.8	4.261
S.E.	2.8	3.6	3.1	3.4	3.8	3.3	3.3	4.4	5.6	3.9	1.285
t'						1.2364					

a: Non-pregnancy (values in parentheses are excluded from calculation).
#: Blank.

INDIVIDUAL DATA 4-3-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Gestation

Animal	Body weight (g) on gestation period (day)									Body weight gain Days 0-20	
No.	0	1	3	5	7	10	14	17	20	(g)	(%)
451	263	275	288	289	300	307	322	363	405	142	53.99
452	260	267	279	281	282	304	317	348	389	129	49.62
453	259	267	280	285	295	313	335	374	431	172	66.41
454	277	279	289	295	298	305	320	355	404	127	45.85
455	271	285	290	291	301	314	334	376	443	172	63.47
456	297	300	316	333	340	352	372	399	464	167	56.23
457	281	279	287	289	295	314	331	373	423	142	50.53
458	296	303	315	329	342	350	376	423	468	172	58.11
459	277	281	293	312	324	327	345	387	436	159	57.40
460	276	284	296	300	308	325	333	368	419	143	51.81
461	283	295	296	311	305	320	337	367	418	135	47.70
462	288	296	304	305	310	325	346	383	434	146	50.69
N	12	12	12	12	12	12	12	12	12	12	12
MEAN	277.3	284.3	294.4	301.7	308.3	321.3	339.0	376.3	427.8	150.5	54.318
S.D.	12.7	12.1	12.0	16.8	18.3	15.9	18.6	20.1	23.5	17.1	6.245
S.E.	3.7	3.5	3.5	4.9	5.3	4.6	5.4	5.8	6.8	4.9	1.803
t'						2.3816					

INDIVIDUAL DATA 4-4-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Lactation

Animal No.	Body weight (g) on lactation period (day) 0	1	4	6	Body weight gain Days 0-4 (g)	(%)
151	335	342	359	324	24	7.16
152	308	313	330	292	22	7.14
153	306	306	315	291	9	2.94
154	298	317	360	306	62	20.81
155	331	330	351	295	20	6.04
156	328	328	356	311	28	8.54
157	315	315	329	297	14	4.44
158	317	323	361	310	44	13.88
159	325	340	360	320	35	10.77
160	364	357	383	339	19	5.22
161	335	348	361	323	26	7.76
162	362	378	393	348	31	8.56
N	12	12	12	12	12	12
MEAN	327.0	333.1	354.8	313.0	27.8	8.605
S.D.	20.5	20.9	21.9	18.4	14.2	4.804
S.E.	5.9	6.0	6.3	5.3	4.1	1.387
M/C	3.4582	5.6406	7.0786	6.8336	0.6083	0.5718
F	4.3684 **	6.5308 **	12.8739 **	6.5551 **	5.7906 **	4.5369 **

INDIVIDUAL DATA 4-4-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Lactation

Animal No.	Body weight (g) on lactation period (day) 0	1	4	6	Body weight gain Days 0-4 (g)	(%)
251	275	286	317	270	42	15.27
252	297	292	311	268	14	4.71
253	337	340	374	319	37	10.98
254	317	324	358	319	41	12.93
255	351	359	376	337	25	7.12
256	313	312	338	299	25	7.99
257	332	339	354	311	22	6.63
258	314	324	354	301	40	12.74
259	305	309	342	286	37	12.13
260	339	340	368	320	29	8.55
261	321	314	327	301	6	1.87
262	336	351	367	325	31	9.23
N	12	12	12	12	12	12
MEAN	319.8	324.2	348.8	304.7	29.1	9.179
S.D.	21.1	22.6	21.9	21.5	11.3	3.835
S.E.	6.1	6.5	6.3	6.2	3.3	1.107
t'	1.0022	1.2132	0.7947	1.1620	0.2430	0.3301

INDIVIDUAL DATA 4-4-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Lactation

Animal No.	Body weight (g) on lactation period (day) 0	1	4	6	Body weight gain Days 0-4 (g)	(%)
351	323	320	329	292	6	1.86
352	297	305	323	290	26	8.75
353	307	304	331	289	24	7.82
354	308	312	314	284	6	1.95
355	309	298	336	298	27	8.74
356	307	311	340	290	33	10.75
357	333	332	346	305	13	3.90
358	331	329	347	314	16	4.83
359[a]	#	#	#	#	#	#
360	320	320	333	305	13	4.06
361	327	331	334	302	7	2.14
362	295	306	338	293	43	14.58
N	11	11	11	11	11	11
MEAN	314.3	315.3	333.7	296.5	19.5	6.307
S.D.	13.2	11.9	9.6	9.0	12.1	4.141
S.E.	4.0	3.6	2.9	2.7	3.7	1.249
t'	1.7207	2.3700	2.7342 *	2.2441	1.5933	1.2921

a: Non-pregnancy.
#: Blank.

INDIVIDUAL DATA 4-4-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Lactation

Animal No.	Body weight (g) on lactation period (day) 0	1	4	6	Body weight gain Days 0-4 (g)	(%)
451	296	295	304	276	8	2.70
452	277	279	299	268	22	7.94
453	304	311	330	302	26	8.55
454	294	294	313	270	19	6.46
455	294	288	288	261	-6	-2.04
456	316	319	337	303	21	6.65
457	289	296	300	272	11	3.81
458	334	329	337	316	3	0.90
459	300	303	315	290	15	5.00
460	305	311	325	294	20	6.56
461	302	295	292	260	-10	-3.31
462	309	303	302	278	-7	-2.27
N	12	12	12	12	12	12
MEAN	301.7	301.9	311.8	282.5	10.2	3.413
S.D.	14.3	13.8	17.1	18.1	12.5	4.192
S.E.	4.1	4.0	4.9	5.2	3.6	1.210
t'	3.5020 **	4.2404 **	5.6956 **	4.2531 **	3.4349 **	2.9855 *

INDIVIDUAL DATA 4-5-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal	Body weight (g) on administration period (day)										Body weight gain Days 1-42	
No.	1	3	5	7	10	14	21	28	35	42	(g)	(%)
163	252	248	251	257	257	265	278	292	297	295	43	17.06
164	242	258	249	270	262	273	274	290	301	297	55	22.73
165	255	261	263	268	275	283	290	291	306	314	59	23.14
166	258	270	266	273	271	276	293	288	305	300	42	16.28
167	270	269	272	275	273	285	285	303	308	313	43	15.93
N	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	255.4	261.2	260.2	268.6	267.6	276.4	284.0	292.8	303.4	303.8	48.4	19.028
S.D.	10.1	9.0	9.9	7.0	7.7	8.0	8.0	5.9	4.4	9.0	8.0	3.593
S.E.	4.5	4.0	4.4	3.1	3.5	3.6	3.6	2.6	2.0	4.0	3.6	1.607
M/C	0.2578	0.1800	0.0391	1.2715	1.1631	1.3747	1.9625	6.7540 **	7.5198 **	1.1989	1.2186	0.7620
F	0.0443	0.1166	0.1911	0.2648	0.2556	0.3541	0.3163			1.5987	2.5170	2.4525
H								0.5345	2.4545			

INDIVIDUAL DATA 4-5-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg

Animal	Body weight (g) on administration period (day)										Body weight gain Days 1-42	
No.	1	3	5	7	10	14	21	28	35	42	(g)	(%)
463	248	252	255	263	265	272	280	278	296	302	54	21.77
464	260	258	265	267	264	278	288	302	294	286	26	10.00
465	252	263	256	267	264	272	278	276	292	286	34	13.49
466	255	262	261	268	267	275	279	270	279	275	20	7.84
467	268	282	277	295	296	308	319	341	343	317	49	18.28
N	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	256.6	263.4	262.8	272.0	271.2	281.0	288.8	293.4	300.8	293.2	36.6	14.276
S.D.	7.7	11.3	8.9	13.0	13.9	15.3	17.3	29.3	24.5	16.4	14.6	5.756
S.E.	3.5	5.0	4.0	5.8	6.2	6.8	7.8	13.1	11.0	7.3	6.5	2.574

INDIVIDUAL DATA 4-5-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Body weight (g) on recovery period (day) 7	14	Body weight gain Day 42-R14 (g)	(%)
163	312	312	17	5.76
164	301	311	14	4.71
165	318	318	4	1.27
166	311	312	12	4.00
167	325	334	21	6.71
N	5	5	5	5
MEAN	313.4	317.4	13.6	4.490
S.D.	8.9	9.7	6.3	2.074
S.E.	4.0	4.3	2.8	0.927
M/C	3.6085	1.7273	0.1735	0.2292
F	2.9642	3.5766 †	3.2609	3.1140

R14: Recovery day 14.

INDIVIDUAL DATA 4-5-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg

Animal No.	Body weight (g) on recovery period (day) 7	14	Body weight gain Day 42-R14 (g)	(%)
463	301	298	-4	-1.32
464	296	294	8	2.80
465	289	299	13	4.55
466	250	273	-2	-0.73
467	323	329	12	3.79
N	5	5	5	5
MEAN	291.8	298.6	5.4	1.818
S.D.	26.6	20.0	7.9	2.677
S.E.	11.9	8.9	3.5	1.197
t'		1.8912		

R14: Recovery day 14.

INDIVIDUAL DATA 5-1-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Food consumption ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg

Animal No.	Food consumption (g/rat/day) on administration period (day) 1	3	5	7	10	14	28	35	42
101	24.0	27.0	26.5	26.0	27.0	28.0	27.6	#[a]	26.7
102	28.0	24.0	24.0	26.5	26.3	26.0	17.1	25.4	26.0
103	28.0	25.5	25.5	25.5	26.0	24.0	25.7	26.3	28.2
104	25.0	28.0	26.5	28.0	26.3	26.0	27.3	28.1	27.0
105	25.0	23.5	23.0	23.5	24.3	23.5	23.3	24.3	24.0
106	26.0	25.5	26.5	25.5	25.7	26.5	#[a]	27.9	27.3
107	28.0	28.0	28.0	29.5	27.0	27.3	27.9	27.0	27.8
108	28.0	30.0	26.5	29.0	27.7	28.0	27.6	26.7	28.5
109	28.0	31.5	28.5	29.5	29.7	28.8	27.7	29.0	30.2
110	29.0	29.0	30.5	30.0	30.7	29.8	29.1	30.6	31.7
111	34.0	31.5	29.0	30.5	29.7	29.8	29.4	29.6	30.0
112	31.0	31.5	28.5	29.0	27.3	29.3	30.1	30.4	29.7
N	12	12	12	12	12	12	11	11	12
MEAN	27.83	27.92	26.92	27.71	27.31	27.25	26.62	27.75	28.09
S.D.	2.76	2.88	2.13	2.23	1.87	2.11	3.66	2.04	2.11
S.E.	0.80	0.83	0.61	0.64	0.54	0.61	1.10	0.61	0.61
M/C	6.5905	4.6427	7.3316	2.0660	3.2759	0.6896	6.5145	0.9862	0.2180
F	1.6649	0.2483	1.2865	0.7720	0.8527	0.6940	0.1149	0.5756	1.6677

a: Data not determined (caged with a female).
#: Blank.
Food consumption of animal nos. 103, 106, 107, 108 and 109 on administration day 42 is the mean value of 6 days because of urinary examination.

INDIVIDUAL DATA 5-1-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Food consumption ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg

Animal No.	Food consumption (g/rat/day) on administration period (day) 1	3	5	7	10	14	28	35	42
201	31.0	26.0	28.5	27.0	26.3	26.0	27.6	#[a]	27.7
202	28.0	26.0	24.5	27.0	25.0	26.0	26.3	26.1	25.9
203	27.0	25.0	23.5	25.5	25.0	25.3	25.1	24.3	24.3
204	30.0	28.0	26.5	27.5	27.3	28.0	28.1	28.6	28.3
205	26.0	25.5	24.0	22.5	21.7	23.0	22.0	22.6	24.1
206	31.0	28.0	27.0	25.5	26.0	26.5	#[a]	26.0	26.2
207	29.0	29.0	26.5	24.5	26.7	25.8	27.6	27.6	29.2
208	27.0	27.5	26.5	25.0	25.0	27.0	27.7	27.6	27.2
209	30.0	30.5	28.5	30.5	26.3	23.0	25.4	26.6	31.7
210	28.0	28.0	26.0	25.5	27.0	27.5	29.1	28.6	24.9
211	30.0	29.5	38.5	28.5	29.0	28.0	28.3	28.4	29.4
212	32.0	29.5	28.0	29.0	28.7	30.0	29.1	30.1	28.6
N	12	12	12	12	12	12	11	11	12
MEAN	29.08	27.71	27.33	26.50	26.17	26.34	26.94	26.95	27.29
S.D.	1.88	1.76	3.88	2.20	1.93	2.01	2.11	2.14	2.30
S.E.	0.54	0.51	1.12	0.63	0.56	0.58	0.64	0.65	0.67

a: Data not determined (caged with a female).
#: Blank.
Food consumption of animal nos. 204, 206, 207, 208 and 209 on administration day 42 is the mean value of 6 days because of urinary examination.

INDIVIDUAL DATA 5-1-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Food consumption ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg

Animal No.	Food consumption (g/rat/day) on administration period (day)								
	1	3	5	7	10	14	28	35	42
301	25.0	26.0	22.5	25.0	26.7	26.8	24.3	26.4	26.0
302	28.0	27.0	25.0	26.5	26.3	25.3	25.3	25.6	25.4
303	26.0	26.5	26.0	26.5	26.0	27.3	26.9	28.0	28.3
304	26.0	28.0	27.5	26.5	27.7	27.5	26.3	25.9	27.7
305	25.0	27.5	28.5	27.5	27.7	27.8	30.1	28.4	25.8
306	27.0	26.5	24.5	27.0	25.7	25.0	25.1	24.9	19.8
307	28.0	27.0	25.5	25.0	24.7	24.0	24.7	25.4	26.9
308	27.0	26.5	26.5	25.0	25.7	26.3	26.4	25.9	24.3
309	28.0	28.0	28.5	29.0	27.7	27.8	28.4	28.3	27.7
310	25.0	29.0	28.0	29.5	29.7	30.8	31.0	31.6	29.1
311	32.0	31.5	30.0	28.5	27.7	28.5	28.4	27.6	25.7
312	31.0	29.5	28.0	30.0	27.7	27.0	27.6	28.6	26.9
N	12	12	12	12	12	12	12	12	12
MEAN	27.33	27.75	26.71	27.17	26.94	27.01	27.04	27.22	26.13
S.D.	2.27	1.59	2.10	1.76	1.35	1.78	2.13	1.90	2.41
S.E.	0.66	0.46	0.61	0.51	0.39	0.51	0.61	0.55	0.70

Food consumption of animal nos. 303, 304, 305, 306 and 308 on administration day 42 is the mean value of 6 days because of urinary examination.

INDIVIDUAL DATA 5-1-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Food consumption ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg

Animal No.	Food consumption (g/rat/day) on administration period (day)								
	1	3	5	7	10	14	28	35	42
401	25.0	25.5	26.5	27.5	26.7	28.0	26.6	27.4	25.9
402	28.0	24.5	24.0	26.0	25.0	25.5	26.1	26.9	27.2
403	29.0	27.0	25.5	26.0	25.3	24.3	25.3	26.9	27.0
404	27.0	29.0	24.5	26.5	24.0	24.3	26.6	26.1	27.6
405	27.0	24.5	24.0	25.0	24.7	25.8	27.6	28.3	26.3
406	31.0	26.5	26.0	27.0	26.7	26.3	27.1	27.3	27.8
407	22.0	27.0	24.5	25.5	24.7	24.8	24.9	25.9	26.4
408	28.0	27.0	20.5	27.0	26.7	25.3	25.9	24.7	24.1
409	30.0	26.5	26.5	27.5	24.7	26.3	26.7	27.0	27.3
410	30.0	31.0	27.0	30.5	30.0	28.8	30.0	31.1	31.0
411	25.0	28.0	27.5	27.5	26.7	28.0	30.1	33.0	32.7
412	17.0	30.0	27.5	29.0	32.0	29.0	29.7	31.6	29.9
N	12	12	12	12	12	12	12	12	12
MEAN	26.58	27.21	25.33	27.08	26.43	26.37	27.22	28.02	27.77
S.D.	3.94	2.02	1.99	1.52	2.38	1.69	1.79	2.54	2.36
S.E.	1.14	0.58	0.58	0.44	0.69	0.49	0.52	0.73	0.68

Food consumption of animal nos. 402, 405, 406, 409 and 410 on administration day 42 is the mean value of 6 days because of urinary examination.

INDIVIDUAL DATA 5-1-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Food consumption ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg

Animal No.	Food consumption (g/rat/day) on recovery period (day) 7	14
103	26.1	28.0
106	26.3	27.8
107	28.7	29.0
108	29.9	30.3
109	30.6	31.0
N	5	5
MEAN	28.32	29.22
S.D.	2.05	1.40
S.E.	0.92	0.63
M/C	0.1360	0.0240
F	0.1916	0.0049

Food consumption on recovery day 14 is the mean value of 6 days because of urinary examination.

INDIVIDUAL DATA 5-1-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Food consumption ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg

Animal No.	Food consumption (g/rat/day) on recovery period (day) 7	14
402	26.1	27.7
405	28.6	28.3
406	27.4	29.8
409	26.6	29.0
410	30.3	31.0
N	5	5
MEAN	27.80	29.16
S.D.	1.69	1.29
S.E.	0.75	0.58

Food consumption on recovery day 14 is the mean value of 6 days because of urinary examination.

INDIVIDUAL DATA 5-2-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Food consumption, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Before gestation

Animal No.	Food consumption (g/rat/day) on administration period (day) 1	3	5	7	10	14
151	19.0	17.5	15.5	18.0	18.3	18.5
152	20.0	17.5	19.5	16.5	20.0	19.0
153	9.0	20.0	15.5	20.5	16.0	17.5
154	16.0	20.5	18.5	20.0	19.7	18.8
155	16.0	18.5	17.0	19.5	18.7	18.8
156	21.0	16.5	20.0	18.0	20.0	21.3
157	21.0	22.5	19.5	21.5	21.0	21.8
158	20.0	21.5	19.5	21.0	20.7	20.3
159	15.0	16.5	20.0	17.5	21.3	18.5
160	11.0	21.5	17.5	22.5	18.7	21.5
161	18.0	21.5	19.0	20.5	20.3	21.3
162	23.0	19.5	23.0	20.5	20.3	20.0
N	12	12	12	12	12	12
MEAN	17.42	19.46	18.71	19.67	19.58	19.78
S.D.	4.21	2.12	2.10	1.80	1.47	1.45
S.E.	1.22	0.61	0.61	0.52	0.42	0.42
M/C	1.6700	1.3515	4.8544	1.3281	3.7671	0.1998
F	1.3603	0.6328	1.8429	1.0179	2.6603 †	1.1509

INDIVIDUAL DATA 5-2-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Food consumption, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Before gestation

Animal No.	Food consumption (g/rat/day) on administration period (day) 1	3	5	7	10	14
251	11.0	16.5	15.5	17.0	15.0	17.0
252	17.0	17.5	15.0	18.0	16.0	17.0
253	17.0	20.5	17.5	21.0	19.3	19.0
254	20.0	19.0	21.0	19.0	22.0	21.3
255	18.0	21.0	17.0	20.5	18.7	19.8
256	22.0	20.0	22.5	19.0	21.0	21.0
257	18.0	17.5	21.0	17.5	18.3	18.8
258	19.0	17.5	20.0	18.0	20.3	20.0
259	20.0	13.5	19.5	16.0	17.3	17.8
260	21.0	18.5	21.0	19.0	20.0	19.5
261	22.0	20.5	18.5	22.5	19.0	19.8
262	19.0	21.5	17.0	21.0	18.7	19.8
N	12	12	12	12	12	12
MEAN	18.67	18.63	18.79	19.04	18.80	19.23
S.D.	2.96	2.29	2.41	1.90	2.00	1.39
S.E.	0.86	0.66	0.69	0.55	0.58	0.40
t'					1.2728	

INDIVIDUAL DATA 5-2-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Food consumption, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Before gestation

Animal No.	Food consumption (g/rat/day) on administration period (day) 1	3	5	7	10	14
351	17.0	18.0	14.5	18.5	16.0	17.0
352	13.0	18.5	15.0	20.0	16.7	16.8
353	15.0	19.5	17.0	21.0	18.0	19.8
354	13.0	20.0	14.5	21.0	16.7	20.0
355	16.0	16.0	19.0	14.0	16.7	17.5
356	21.0	16.5	20.0	17.5	19.3	19.0
357	18.0	18.5	21.0	18.5	18.3	18.3
358	16.0	18.5	15.5	20.5	18.3	18.5
359	17.0	20.0	17.5	20.5	19.0	18.3
360	14.0	20.5	16.5	20.0	18.0	18.8
361	21.0	21.5	18.5	22.5	20.0	20.3
362	11.0	20.5	17.0	19.5	17.3	20.8
N	12	12	12	12	12	12
MEAN	16.00	19.00	17.17	19.46	17.86	18.76
S.D.	3.07	1.65	2.14	2.18	1.21	1.29
S.E.	0.89	0.48	0.62	0.63	0.35	0.37
t'					2.8029 *	

INDIVIDUAL DATA 5-2-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Food consumption, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Before gestation

Animal No.	Food consumption (g/rat/day) on administration period (day) 1	3	5	7	10	14
451	14.0	20.5	16.0	20.0	17.3	16.8
452	20.0	17.5	19.0	18.5	18.7	19.3
453	13.0	20.5	16.0	21.0	18.0	18.5
454	10.0	20.5	16.5	22.0	18.0	19.5
455	20.0	15.5	17.5	17.0	19.3	19.0
456	13.0	20.0	18.0	21.0	20.7	20.3
457	19.0	21.0	17.5	21.5	19.7	20.5
458	16.0	20.5	17.5	20.5	19.3	20.3
459	16.0	19.5	17.5	21.5	18.3	19.8
460	21.0	16.0	18.0	15.5	17.0	17.3
461	20.0	22.0	19.0	24.0	20.3	20.3
462	16.0	23.0	20.0	23.5	20.3	21.0
N	12	12	12	12	12	12
MEAN	16.50	19.71	17.71	20.50	18.91	19.38
S.D.	3.53	2.27	1.21	2.48	1.22	1.30
S.E.	1.02	0.66	0.35	0.72	0.35	0.37
t'					1.0968	

INDIVIDUAL DATA 5-3-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Food consumption, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Gestation

Animal No.	Food consumption (g/rat/day) on gestation period (day) 1	3	5	7	10	14	17	20
151	17.0	23.0	23.0	21.5	23.7	23.5	25.3	23.0
152	22.0	22.5	22.5	24.5	23.3	24.8	26.0	23.7
153	19.0	22.5	23.0	25.0	23.7	23.5	25.7	22.7
154	15.0	22.5	22.5	21.0	22.7	22.8	24.3	22.0
155	17.0	21.5	22.5	24.0	24.3	22.8	27.0	26.3
156	18.0	23.5	23.5	21.0	22.7	22.3	22.3	21.7
157	18.0	24.5	23.0	25.0	22.3	24.5	25.7	18.7
158	16.0	22.0	23.5	24.0	25.0	24.0	26.7	21.3
159	17.0	23.5	25.5	25.0	26.7	25.3	24.0	23.0
160	19.0	29.5	26.5	30.0	29.3	28.8	27.7	29.3
161	19.0	23.0	23.5	22.5	24.7	24.0	24.7	24.3
162	26.0	27.5	29.0	30.5	31.0	29.0	27.7	24.0
N	12	12	12	12	12	12	12	12
MEAN	18.58	23.79	24.00	24.50	24.95	24.61	25.59	23.33
S.D.	2.94	2.37	2.00	3.09	2.73	2.18	1.60	2.64
S.E.	0.85	0.68	0.58	0.89	0.79	0.63	0.46	0.76
M/C	1.5157	1.4416	4.7201	5.7791	9.7772 *	6.6692	2.2101	3.7469
F	2.5825 †	1.6274	2.9283 *	1.5956		2.1367	0.3424	0.1935
H					13.5958 **			

INDIVIDUAL DATA 5-3-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Food consumption, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Gestation

Animal No.	Food consumption (g/rat/day) on gestation period (day) 1	3	5	7	10	14	17	20
251	17.0	22.0	18.5	20.5	21.0	20.5	21.7	20.3
252	18.0	20.0	21.0	19.5	20.3	21.0	22.7	20.7
253	21.0	24.5	27.0	28.0	27.7	28.3	28.0	27.3
254	24.0	22.5	22.5	24.0	27.0	25.3	24.3	24.3
255	19.0	27.0	28.5	29.0	31.3	30.0	29.3	29.7
256	18.0	24.0	24.5	25.0	23.0	24.5	24.7	21.7
257	20.0	22.5	23.0	23.0	24.3	24.5	26.0	23.0
258	20.0	22.5	25.0	24.5	24.0	23.5	25.7	23.7
259	21.0	23.0	23.5	24.0	24.0	24.0	24.7	23.0
260	20.0	24.0	22.0	23.5	23.7	23.0	26.0	23.7
261	23.0	25.0	27.0	27.5	26.7	25.5	25.0	22.7
262	18.0	24.0	24.0	25.5	25.3	24.0	26.7	22.7
N	12	12	12	12	12	12	12	12
MEAN	19.92	23.42	23.88	24.50	24.86	24.51	25.40	23.57
S.D.	2.11	1.76	2.80	2.82	3.01	2.67	2.08	2.64
S.E.	0.61	0.51	0.81	0.81	0.87	0.77	0.60	0.76
t'	1.3030		0.1249					
U					67.0000			

INDIVIDUAL DATA 5-3-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Food consumption, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Gestation

Animal No.	Food consumption (g/rat/day) on gestation period (day)							
	1	3	5	7	10	14	17	20
351	20.0	22.5	24.0	22.5	24.7	23.8	27.0	22.3
352	21.0	24.5	24.5	25.0	26.7	21.3	20.3	19.7
353	19.0	25.0	23.5	24.0	24.3	23.0	23.3	22.3
354	20.0	22.0	23.0	21.5	24.0	23.0	24.3	21.3
355	21.0	20.5	23.5	23.0	25.3	24.5	29.0	24.3
356	19.0	20.5	22.0	9.0	25.0	24.0	25.3	24.7
357	17.0	22.0	21.5	24.0	21.7	23.5	25.7	24.7
358	21.0	24.0	25.0	22.0	26.3	26.0	27.0	25.3
359[a]	(17.0)	(21.0)	(24.0)	(24.5)	(25.7)	(22.3)	(20.7)	(14.0)
360	27.0	22.0	26.0	25.0	25.0	23.8	26.0	23.3
361	17.0	23.5	23.0	25.0	23.0	23.0	25.3	23.0
362	20.0	25.5	27.0	26.0	25.7	23.3	23.0	21.3
N	11	11	11	11	11	11	11	11
MEAN	20.18	22.91	23.91	22.45	24.70	23.56	25.11	22.93
S.D.	2.68	1.71	1.64	4.68	1.44	1.15	2.35	1.74
S.E.	0.81	0.52	0.49	1.41	0.43	0.35	0.71	0.53
t'	1.5278		0.0888					
U					55.5000			

a: Non-pregnancy (values in parentheses are excluded from calculation).

INDIVIDUAL DATA 5-3-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Food consumption, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Gestation

Animal No.	Food consumption (g/rat/day) on gestation period (day) 1	3	5	7	10	14	17	20
451	19.0	22.0	19.5	22.5	20.7	21.0	25.7	21.7
452	18.0	23.0	19.0	20.5	22.7	21.0	26.0	21.0
453	17.0	23.0	22.5	24.5	23.7	23.8	27.0	26.3
454	17.0	22.5	21.0	20.0	21.0	22.3	25.7	23.3
455	18.0	19.5	18.0	21.0	22.7	23.3	27.0	25.0
456	21.0	25.0	27.0	26.0	24.3	25.0	23.7	24.0
457	14.0	21.5	20.5	21.5	22.3	21.3	24.3	22.0
458	18.0	25.5	25.5	25.0	23.7	26.0	28.7	26.0
459	15.0	21.5	25.5	25.5	21.0	23.3	26.7	22.3
460	19.0	21.5	20.0	21.0	19.7	19.8	23.0	22.7
461	21.0	19.0	21.5	19.5	21.7	22.5	25.7	24.3
462	15.0	21.5	18.0	21.0	22.3	24.0	27.3	23.7
N	12	12	12	12	12	12	12	12
MEAN	17.67	22.13	21.50	22.33	22.15	22.78	25.90	23.53
S.D.	2.23	1.90	3.04	2.30	1.38	1.81	1.62	1.68
S.E.	0.64	0.55	0.88	0.66	0.40	0.52	0.47	0.49
t'	0.8958		2.4977 *					
U					21.5000 **			

INDIVIDUAL DATA 5-4-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Food consumption, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Lactation

Animal No.	Food consumption (g/rat/day) on lactation period (day) 1	4
151	16.0	26.7
152	19.0	38.3
153	13.0	32.7
154	25.0	40.7
155	22.0	38.7
156	18.0	41.3
157	18.0	30.7
158	19.0	40.7
159	27.0	52.0
160	10.0	38.3
161	24.0	37.7
162	23.0	38.7
N	12	12
MEAN	19.50	38.04
S.D.	5.00	6.27
S.E.	1.44	1.81
M/C	2.4060	8.1386 *
F	2.4263 †	
H		12.8197 **

INDIVIDUAL DATA 5-4-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Food consumption, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Lactation

Animal No.	Food consumption (g/rat/day) on lactation period (day) 1	4
251	19.0	37.3
252	19.0	33.0
253	18.0	41.3
254	17.0	42.3
255	16.0	39.0
256	18.0	37.0
257	22.0	39.3
258	23.0	43.0
259	23.0	39.0
260	20.0	38.0
261	10.0	33.0
262	22.0	37.7
N	12	12
MEAN	18.92	38.33
S.D.	3.65	3.14
S.E.	1.05	0.91
t'	0.3446	
U		68.0000

INDIVIDUAL DATA 5-4-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Food consumption, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Lactation

Animal No.	Food consumption (g/rat/day) on lactation period (day) 1	4
351	19.0	31.7
352	21.0	34.0
353	11.0	35.7
354	19.0	30.3
355	6.0	41.0
356	19.0	38.7
357	17.0	33.7
358	18.0	34.3
359[a]	#	#
360	16.0	37.3
361	21.0	35.7
362	17.0	39.0
N	11	11
MEAN	16.73	35.58
S.D.	4.50	3.23
S.E.	1.36	0.97
t'	1.6022	
U		46.0000

a: Non-pregnancy.
#: Blank.

INDIVIDUAL DATA 5-4-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Food consumption, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Lactation

Animal No.	Food consumption (g/rat/day) on lactation period (day) 1	4
451	16.0	30.7
452	12.0	32.3
453	18.0	37.3
454	18.0	35.0
455	13.0	31.3
456	15.0	36.0
457	19.0	31.0
458	11.0	37.0
459	16.0	32.0
460	21.0	33.3
461	11.0	26.0
462	16.0	36.3
N	12	12
MEAN	15.50	33.18
S.D.	3.23	3.31
S.E.	0.93	0.96
t'	2.3633	
U		27.5000 *

INDIVIDUAL DATA 5-5-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Food consumption, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal	Food consumption (g/rat/day) on administration period (day)									
No.	1	3	5	7	10	14	21	28	35	42
163	18.0	15.0	18.0	17.5	19.3	18.5	18.4	18.7	18.0	17.7
164	13.0	21.0	17.5	22.5	18.3	20.0	18.4	19.6	19.1	18.7
165	19.0	22.0	17.5	21.5	20.7	20.5	18.7	19.6	19.6	18.5
166	18.0	22.0	17.5	21.5	18.0	20.3	19.1	18.4	18.0	18.0
167	20.0	16.5	19.0	18.5	19.7	19.8	18.9	20.1	20.3	18.8
N	5	5	5	5	5	5	5	5	5	5
MEAN	17.60	19.30	17.90	20.30	19.20	19.82	18.70	19.28	19.00	18.34
S.D.	2.70	3.31	0.65	2.17	1.09	0.79	0.31	0.70	1.01	0.47
S.E.	1.21	1.48	0.29	0.97	0.49	0.35	0.14	0.32	0.45	0.21
M/C	0.0543	0.2124	7.8842 **	0.2837	2.6947	4.3231 *	9.7744 **	6.2044 *	2.7704	3.7934
F	0.9846	0.2833		0.1385	0.0911				0.1628	1.3640
H			0.2795			1.0976	0.0113	0.1800		

Food consumption on administration day 42 is the mean value of 6 days because of urinary examination.

INDIVIDUAL DATA 5-5-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Food consumption, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg

Animal	Food consumption (g/rat/day) on administration period (day)									
No.	1	3	5	7	10	14	21	28	35	42
463	17.0	19.0	15.5	21.0	18.7	18.3	18.9	19.6	19.9	19.7
464	23.0	17.0	21.0	17.0	18.7	19.8	18.9	18.7	17.3	16.2
465	18.0	21.0	13.0	21.5	16.0	19.0	17.4	18.6	19.4	17.3
466	18.0	20.5	16.0	20.0	17.3	18.0	16.9	15.9	17.3	16.3
467	20.0	24.0	22.0	25.0	23.3	24.5	23.0	24.7	23.6	18.2
N	5	5	5	5	5	5	5	5	5	5
MEAN	19.20	20.30	17.50	20.90	18.80	19.92	19.02	19.50	19.50	17.54
S.D.	2.39	2.59	3.84	2.88	2.75	2.65	2.40	3.22	2.58	1.46
S.E.	1.07	1.16	1.72	1.29	1.23	1.19	1.07	1.44	1.15	0.65

Food consumption on administration day 42 is the mean value of 6 days because of urinary examination.

INDIVIDUAL DATA 5-5-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Food consumption, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Food consumption (g/rat/day) on recovery period (day) 7	14
163	19.0	17.2
164	19.9	19.0
165	18.6	19.2
166	16.9	18.0
167	20.6	20.8
N	5	5
MEAN	19.00	18.84
S.D.	1.41	1.36
S.E.	0.63	0.61
M/C	2.4137	0.5341
F	0.4378	0.5024

Food consumption on recovery day 14 is the mean value of 6 days because of urinary examination.

INDIVIDUAL DATA 5-5-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Food consumption, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg

Animal No.	Food consumption (g/rat/day) on recovery period (day) 7	14
463	20.9	19.3
464	18.4	18.0
465	17.6	19.8
466	12.4	19.2
467	20.3	20.5
N	5	5
MEAN	17.92	19.36
S.D.	3.37	0.92
S.E.	1.51	0.41

Food consumption on recovery day 14 is the mean value of 6 days because of urinary examination.

INDIVIDUAL DATA 6-1-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Urinary findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Week 6 of administration

Animal No.	pH	Protein	Glucose	Ketone body	Urobili-nogen EU/dL	Bilirubin	Occult blood	Color	Specific gravity	Urine volume mL/21hr
103	8.0	+	−	−	0.1	−	−	A	1.026	25.0
106	8.5	±	−	−	0.1	−	−	A	1.038	17.0
107	8.5	−	−	−	0.1	−	−	A	1.032	19.5
108	8.0	−	−	−	0.1	−	−	A	1.026	25.0
109	8.5	+	−	−	0.1	−	−	A	1.045	12.0
N	5	5	5	5	5	5	5	5	5	5
MEAN										19.70
S.D.										5.54
S.E.										2.48
M/C										12.3727 **
H	2.7867	0.3191	0.0000	0.0000	0.0000	0.0000	6.3333 †	0.0000	2.6655	2.3847

Color: A = Pale yellow or yellow.
-; Negative, ±; slight, +; moderate.

INDIVIDUAL DATA 6-1-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Urinary findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : Week 6 of administration

Animal No.	pH	Protein	Glucose	Ketone body	Urobili-nogen EU/dL	Bilirubin	Occult blood	Color	Specific gravity	Urine volume mL/21hr
204	8.5	+	−	−	0.1	−	−	A	1.051[a]	10.0
206	8.5	±	−	−	0.1	−	−	A	1.040	16.5
207	8.0	−	−	−	0.1	−	−	A	1.024	44.0
208	8.5	±	−	−	0.1	−	−	A	1.044	12.0
210	8.5	±	−	−	0.1	−	−	A	1.046	14.0
N	5	5	5	5	5	5	5	5	5	5
MEAN										19.30
S.D.										14.02
S.E.										6.27
U							12.5000			

Color: A = Pale yellow or yellow.
a: Over the maximum value of scale.
-; Negative, ±; slight, +; moderate.

INDIVIDUAL DATA 6-1-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Urinary findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : Week 6 of administration

Animal No.	pH	Protein	Glucose	Ketone body	Urobili-nogen EU/dL	Bilirubin	Occult blood	Color	Specific gravity	Urine volume mL/21hr
303	8.5	±	—	—	0.1	—	—	A	1.026	27.0
304	8.5	±	—	—	0.1	—	—	A	1.041	12.5
305	8.5	±	—	—	0.1	—	±	A	1.037	12.0
306	8.5	±	—	—	0.1	—	—	A	1.044	10.0
308	8.5	±	—	—	0.1	—	±	A	1.037	16.5
N	5	5	5	5	5	5	5	5	5	5
MEAN										15.60
S.D.										6.80
S.E.										3.04
U							7.5000			

Color: A = Pale yellow or yellow.
-; Negative, ±; slight.

INDIVIDUAL DATA 6-1-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Urinary findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Week 6 of administration

Animal No.	pH	Protein	Glucose	Ketone body	Urobili-nogen EU/dL	Bilirubin	Occult blood	Color	Specific gravity	Urine volume mL/21hr
402	8.5	+	−	−	0.1	−	−	A	1.038	15.0
405	8.0	−	−	−	0.1	−	−	A	1.042	15.5
406	8.0	−	−	−	0.1	−	−	A	1.030	17.0
409	8.5	+	−	−	0.1	−	−	A	1.049	12.5
410	8.5	+	−	−	0.1	−	−	A	1.039	14.5
N	5	5	5	5	5	5	5	5	5	5
MEAN										14.90
S.D.										1.64
S.E.										0.73
U							12.5000			

Color: A = Pale yellow or yellow.
-; Negative, +; moderate.

INDIVIDUAL DATA 6-2-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Urinary findings, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Week 6 of administration

Animal No.	pH	Protein	Glucose	Ketone body	Urobili-nogen EU/dL	Bilirubin	Occult blood	Color	Specific gravity	Urine volume mL/21hr
163	8.5	+	−	−	0.1	−	−	A	1.047	10.0
164	7.0	+	−	−	0.1	−	−	A	1.033	11.0
165	8.5	+	−	−	0.1	−	−	A	1.043	11.0
166	8.0	+	−	−	0.1	−	−	A	1.035	12.0
167	7.0	+	−	−	0.1	−	−	A	1.045	10.5
N	5	5	5	5	5	5	5	5	5	5
MEAN										10.90
S.D.										0.74
S.E.										0.33
M/C										9.4389 **
H	0.9656	5.7143 *	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.9056	2.1778

Color: A = Pale yellow or yellow.
-; Negative, +; moderate.

INDIVIDUAL DATA 6-2-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Urinary findings, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Week 6 of administration

Animal No.	pH	Protein	Glucose	Ketone body	Urobili-nogen EU/dL	Bilirubin	Occult blood	Color	Specific gravity	Urine volume mL/21hr
463	7.0	+	−	−	0.1	−	−	A	1.051[a]	6.0
464	8.5	−	−	−	0.1	−	−	A	1.042	10.0
465	7.5	±	−	−	0.1	−	−	A	1.051[a]	6.0
466	6.0	−	−	−	0.1	−	−	A	1.019	17.5
467	7.0	−	−	−	0.1	−	−	A	1.051[a]	3.5
N	5	5	5	5	5	5	5	5	5	5
MEAN										8.60
S.D.										5.49
S.E.										2.46
U		2.5000								

Color: A = Pale yellow or yellow.
a: Over the maximum value of scale.
-; Negative, ±; slight, +; moderate.

INDIVIDUAL DATA 6-3-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Urinary findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : Week 2 of recovery

Animal No.	pH	Protein	Glucose	Ketone body	Urobili-nogen EU/dL	Bilirubin	Occult blood	Color	Specific gravity	Urine volume mL/21hr
103	8.5	+	−	+	0.1	−	−	A	1.026	20.0
106	8.5	+	−	±	0.1	−	−	A	1.047	12.5
107	8.5	+	−	±	0.1	−	−	A	1.049	11.5
108	8.5	+	−	−	0.1	−	−	A	1.023	30.0
109	8.5	+	−	−	0.1	−	−	A	1.043	16.5
N	5	5	5	5	5	5	5	5	5	5
MEAN										18.10
S.D.										7.46
S.E.										3.34
M/C										2.1081
F										2.0262
H	0.0000	1.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.2744	

Color: A = Pale yellow or yellow.
-; Negative, ±; slight, +; moderate.

INDIVIDUAL DATA 6-3-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Urinary findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : Week 2 of recovery

Animal No.	pH	Protein	Glucose	Ketone body	Urobili-nogen EU/dL	Bilirubin	Occult blood	Color	Specific gravity	Urine volume mL/21hr
402	8.5	+	−	+	0.1	−	−	A	1.048	8.5
405	8.5	±	−	−	0.1	−	−	A	1.042	17.0
406	8.5	+	−	±	0.1	−	−	A	1.038	13.0
409	8.5	+	−	±	0.1	−	−	A	1.051[a]	11.0
410	8.5	+	−	−	0.1	−	−	A	1.038	15.0
N	5	5	5	5	5	5	5	5	5	5
MEAN										12.90
S.D.										3.32
S.E.										1.49

Color: A = Pale yellow or yellow.
a: Over the maximum value of scale.
-; Negative, ±; slight, +; moderate.

INDIVIDUAL DATA 6-4-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Urinary findings, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Week 2 of recovery

Animal No.	pH	Protein	Glucose	Ketone body	Urobili-nogen EU/dL	Bilirubin	Occult blood	Color	Specific gravity	Urine volume mL/21hr
163	8.0	±	–	–	0.1	–	–	A	1.051[a]	7.5
164	8.5	±	–	–	0.1	–	–	A	1.040	12.0
165	8.5	±	–	–	0.1	–	–	A	1.043	13.5
166	8.5	±	–	–	0.1	–	–	A	1.030	20.5
167	8.5	±	–	–	0.1	–	–	A	1.047	10.5
N	5	5	5	5	5	5	5	5	5	5
MEAN										12.80
S.D.										4.84
S.E.										2.17
M/C										0.2064
F										1.2678
H	2.4143	3.0000 †	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	1.1250	

Color: A = Pale yellow or yellow.
a: Over the maximum value of scale.
-; Negative, ±; slight.

INDIVIDUAL DATA 6-4-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Urinary findings, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Week 2 of recovery

Animal No.	pH	Protein	Glucose	Ketone body	Urobili-nogen EU/dL	Bilirubin	Occult blood	Color	Specific gravity	Urine volume mL/21hr
463	7.0	+	−	−	0.1	−	−	A	1.047	10.0
464	7.0	+	−	−	0.1	−	−	A	1.051[a]	7.0
465	8.5	+	−	−	0.1	−	−	A	1.049	9.0
466	8.5	−	−	−	0.1	−	−	A	1.034	16.0
467	7.0	+	−	−	0.1	−	−	A	1.051[a]	6.5
N	5	5	5	5	5	5	5	5	5	5
MEAN										9.70
S.D.										3.80
S.E.										1.70
U		5.0000								

Color: A = Pale yellow or yellow.
a: Over the maximum value of scale.
-; Negative, +; moderate.

INDIVIDUAL DATA 7-1-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of administration

Animal No.	WBC $10^2/\mu L$	RBC $10^4/\mu L$	HGB g/dL	HCT %	MCV fL	MCH pg	MCHC g/dL	Platelet $10^4/\mu L$
101	114.9	883	16.4	47.3	53.6	18.6	34.7	93.6
102	128.5	927	16.1	45.5	49.1	17.4	35.4	118.0
104	100.3	890	15.7	44.3	49.8	17.6	35.4	120.6
105	138.1	918	15.9	45.4	49.5	17.3	35.0	128.9
110	88.7	847	14.8	41.8	49.4	17.5	35.4	105.8
N	5	5	5	5	5	5	5	5
MEAN	114.10	893.0	15.78	44.86	50.28	17.68	35.18	113.38
S.D.	20.12	31.6	0.61	2.02	1.87	0.53	0.32	13.81
S.E.	9.00	14.2	0.27	0.90	0.84	0.24	0.14	6.18
M/C	2.3772	2.0271	0.8790	0.2753	4.4003	2.8151	0.7552	3.2670
F	0.2717	2.4904 †	0.1002	0.0578	1.4650	1.4225	0.8344	1.6602

INDIVIDUAL DATA 7-1-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : End of administration

Animal No.	WBC $10^2/\mu L$	RBC $10^4/\mu L$	HGB g/dL	HCT %	MCV fL	MCH pg	MCHC g/dL	Platelet $10^4/\mu L$
201	138.3	889	15.3	43.2	48.6	17.2	35.4	104.7
202	97.5	960	16.3	46.5	48.4	17.0	35.1	116.3
203	95.5	967	15.9	44.9	46.4	16.4	35.4	123.2
205	138.2	904	15.2	43.5	48.1	16.8	34.9	135.7
209	117.2	985	17.3	48.2	48.9	17.6	35.9	129.8
N	5	5	5	5	5	5	5	5
MEAN	117.34	941.0	16.00	45.26	48.08	17.00	35.34	121.94
S.D.	20.89	42.0	0.85	2.10	0.98	0.45	0.38	12.06
S.E.	9.34	18.8	0.38	0.94	0.44	0.20	0.17	5.39
t'		2.2208						

INDIVIDUAL DATA 7-1-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : End of administration

Animal No.	WBC $10^2/\mu L$	RBC $10^4/\mu L$	HGB g/dL	HCT %	MCV fL	MCH pg	MCHC g/dL	Platelet $10^4/\mu L$
301	142.8	936	16.5	46.9	50.1	17.6	35.2	113.2
302	71.0	978	15.4	42.7	43.7	15.7	36.1	122.0
307	129.6	943	15.6	44.5	47.2	16.5	35.1	106.8
309	126.1	925	16.5	46.4	50.2	17.8	35.6	114.7
310	78.7	951	15.5	43.5	45.7	16.3	35.6	121.5
N	5	5	5	5	5	5	5	5
MEAN	109.64	946.6	15.90	44.80	47.38	16.78	35.52	115.64
S.D.	32.48	20.0	0.55	1.81	2.82	0.89	0.40	6.32
S.E.	14.52	8.9	0.25	0.81	1.26	0.40	0.18	2.83
t'		2.4799						

INDIVIDUAL DATA 7-1-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : End of administration

Animal No.	WBC $10^2/\mu L$	RBC $10^4/\mu L$	HGB g/dL	HCT %	MCV fL	MCH pg	MCHC g/dL	Platelet $10^4/\mu L$
401	139.6	925	14.9	41.8	45.2	16.1	35.6	113.7
403	144.3	862	16.0	45.6	52.9	18.6	35.1	103.9
404	173.8	969	16.7	47.0	48.5	17.2	35.5	98.3
407	97.1	924	15.6	43.8	47.4	16.9	35.6	108.2
408	74.6	937	16.7	47.6	50.8	17.8	35.1	114.1
N	5	5	5	5	5	5	5	5
MEAN	125.88	923.4	15.98	45.16	48.96	17.32	35.38	107.64
S.D.	39.63	38.8	0.77	2.38	2.99	0.94	0.26	6.71
S.E.	17.72	17.4	0.34	1.06	1.34	0.42	0.12	3.00
t'		1.4065						

INDIVIDUAL DATA 7-1-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of administration

Animal No.	Reticu-locyte %	PT sec	APTT sec	Differential count of WBC ($10^2/\mu L$) Neutrophil	Lymphocyte	Monocyte	Eosinophil	Basophil
101	3.10	22.2	28.7	15.8	94.0	3.4	1.7	0.0
102	4.30	16.3	21.5	25.9	95.5	5.0	2.0	0.1
104	3.84	19.9	28.5	16.6	78.5	4.0	1.1	0.1
105	3.06	32.1	31.2	20.9	110.7	4.1	2.4	0.0
110	3.28	17.3	27.2	11.3	74.1	2.6	0.7	0.0
N	5	5	5	5	5	5	5	5
MEAN	3.516	21.56	27.42	18.10	90.56	3.82	1.58	0.04
S.D.	0.538	6.33	3.61	5.53	14.65	0.89	0.68	0.05
S.E.	0.240	2.83	1.62	2.47	6.55	0.40	0.31	0.02
M/C	7.7030	12.0092 **	5.4114	5.6456	2.7889	3.0951	3.7953	∞ **
F	0.7380		3.9005 *	0.6180	0.2613	0.4356	2.1933	
H		1.7911						4.0980

INDIVIDUAL DATA 7-1-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : End of administration

Animal No.	Reticu-locyte %	PT sec	APTT sec	Differential count of WBC ($10^2/\mu L$) Neutrophil	Lymphocyte	Monocyte	Eosinophil	Basophil
201	3.57	21.9	30.4	10.7	123.5	2.9	1.2	0.0
202	3.03	23.3	28.5	6.3	87.3	3.0	0.9	0.0
203	3.08	21.7	27.0	13.7	77.3	3.2	1.3	0.0
205	3.48	23.3	27.4	13.1	119.5	3.7	1.9	0.0
209	2.97	22.1	27.6	33.3	75.5	7.0	1.3	0.1
N	5	5	5	5	5	5	5	5
MEAN	3.226	22.46	28.18	15.42	96.62	3.96	1.32	0.02
S.D.	0.278	0.78	1.36	10.41	23.20	1.73	0.36	0.04
S.E.	0.124	0.35	0.61	4.66	10.37	0.77	0.16	0.02
t'			0.5321					

INDIVIDUAL DATA 7-1-7

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : End of administration

Animal No.	Reticu-locyte %	PT sec	APTT sec	Differential count of WBC ($10^2/\mu L$) Neutrophil	Lymphocyte	Monocyte	Eosinophil	Basophil
301	2.60	21.9	27.9	24.0	113.6	3.6	1.6	0.0
302	4.46	21.6	24.8	7.1	60.3	2.8	0.8	0.0
307	2.78	24.8	28.4	24.9	94.2	8.6	1.9	0.0
309	2.31	19.9	23.9	20.2	99.9	3.6	2.4	0.0
310	3.15	25.5	27.1	13.8	59.0	5.2	0.7	0.0
N	5	5	5	5	5	5	5	5
MEAN	3.060	22.74	26.42	18.00	85.40	4.76	1.48	0.00
S.D.	0.840	2.34	1.97	7.50	24.55	2.32	0.73	0.00
S.E.	0.376	1.05	0.88	3.35	10.98	1.04	0.32	0.00
t'			0.7001					

INDIVIDUAL DATA 7-1-8

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : End of administration

Animal No.	Reticu-locyte %	PT sec	APTT sec	Differential count of WBC ($10^2/\mu L$) Neutrophil	Lymphocyte	Monocyte	Eosinophil	Basophil
401	3.03	28.7	24.4	19.4	113.4	4.1	2.7	0.0
403	2.84	18.7	22.8	25.8	112.1	4.7	1.7	0.0
404	3.43	23.1	25.1	22.2	142.7	5.0	3.9	0.0
407	3.17	19.7	23.9	21.2	70.2	2.9	2.8	0.0
408	3.11	18.7	21.9	19.0	53.0	1.5	1.1	0.0
N	5	5	5	5	5	5	5	5
MEAN	3.116	21.78	23.62	21.52	98.28	3.64	2.44	0.00
S.D.	0.215	4.27	1.28	2.73	36.16	1.44	1.08	0.00
S.E.	0.096	1.91	0.57	1.22	16.17	0.64	0.48	0.00
t'			2.6603 *					

INDIVIDUAL DATA 7-2-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Hematological findings, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 6 of lactation

Animal No.	WBC $10^2/\mu L$	RBC $10^4/\mu L$	HGB g/dL	HCT %	MCV fL	MCH pg	MCHC g/dL	Platelet $10^4/\mu L$
152	101.6	817	15.0	43.1	52.8	18.4	34.8	130.6
153	119.3	799	14.7	41.6	52.1	18.4	35.3	144.7
154	106.6	824	15.4	44.9	54.5	18.7	34.3	104.4
158	90.3	821	14.9	42.9	52.3	18.1	34.7	144.5
161	98.9	826	15.7	47.2	57.1	19.0	33.3	117.0
N	5	5	5	5	5	5	5	5
MEAN	103.34	817.4	15.14	43.94	53.76	18.52	34.48	128.24
S.D.	10.70	10.8	0.40	2.17	2.09	0.34	0.75	17.58
S.E.	4.79	4.8	0.18	0.97	0.94	0.15	0.34	7.86
M/C	6.0389	7.4253	2.0452	1.5400	1.2878	2.4111	1.5587	0.9416
F	0.5775	1.6408	1.2997	0.4627	0.4787	0.5251	0.6724	0.9927

INDIVIDUAL DATA 7-2-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Hematological findings, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 6 of lactation

Animal No.	WBC $10^2/\mu L$	RBC $10^4/\mu L$	HGB g/dL	HCT %	MCV fL	MCH pg	MCHC g/dL	Platelet $10^4/\mu L$
252	98.8	875	15.5	44.8	51.2	17.7	34.6	112.3
253	103.9	787	14.3	42.2	53.6	18.2	33.9	103.5
254	84.6	773	13.7	39.4	51.0	17.7	34.8	114.8
255	85.2	802	15.1	43.7	54.5	18.8	34.6	97.5
262	108.4	762	14.8	46.1	60.5	19.4	32.1	135.0
N	5	5	5	5	5	5	5	5
MEAN	96.18	799.8	14.68	43.24	54.16	18.36	34.00	112.62
S.D.	10.84	44.6	0.70	2.58	3.85	0.74	1.12	14.30
S.E.	4.85	20.0	0.31	1.15	1.72	0.33	0.50	6.39

INDIVIDUAL DATA 7-2-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Hematological findings, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 6 of lactation

Animal No.	WBC $10^2/\mu L$	RBC $10^4/\mu L$	HGB g/dL	HCT %	MCV fL	MCH pg	MCHC g/dL	Platelet $10^4/\mu L$
351	87.0	833	15.6	45.7	54.9	18.7	34.1	129.1
353	81.5	814	14.4	41.3	50.7	17.7	34.9	149.9
356	92.3	807	15.7	46.3	57.4	19.5	33.9	133.5
358	133.1	742	13.8	41.1	55.4	18.6	33.6	128.8
361	106.7	805	15.6	46.9	58.3	19.4	33.3	108.4
N	5	5	5	5	5	5	5	5
MEAN	100.12	800.2	15.02	44.26	55.34	18.78	33.96	129.94
S.D.	20.68	34.4	0.87	2.83	2.95	0.73	0.61	14.81
S.E.	9.25	15.4	0.39	1.26	1.32	0.32	0.27	6.62

INDIVIDUAL DATA 7-2-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Hematological findings, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 6 of lactation

Animal No.	WBC $10^2/\mu L$	RBC $10^4/\mu L$	HGB g/dL	HCT %	MCV fL	MCH pg	MCHC g/dL	Platelet $10^4/\mu L$
451	130.0	855	15.9	45.3	53.0	18.6	35.1	111.3
457	138.2	913	16.3	47.3	51.8	17.9	34.5	123.2
458	87.7	884	15.3	43.4	49.1	17.3	35.3	136.9
459	137.5	767	14.8	44.2	57.6	19.3	33.5	97.0
461	69.2	825	15.2	44.5	53.9	18.4	34.2	154.5
N	5	5	5	5	5	5	5	5
MEAN	112.52	848.8	15.50	44.94	53.08	18.30	34.52	124.58
S.D.	31.94	56.3	0.60	1.48	3.11	0.75	0.72	22.28
S.E.	14.29	25.2	0.27	0.66	1.39	0.34	0.32	9.96

INDIVIDUAL DATA 7-2-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Hematological findings, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 6 of lactation

Animal No.	Reticu-locyte %	PT sec	APTT sec	Differential count of WBC ($10^2/\mu L$) Neutrophil	Lymphocyte	Monocyte	Eosinophil	Basophil
152	8.06	19.6	18.9	20.3	70.2	9.5	1.5	0.1
153	7.81	19.7	18.4	20.1	90.5	5.7	2.9	0.1
154	9.92	18.6	19.6	23.2	77.0	5.8	0.6	0.0
158	9.20	17.4	19.3	37.8	40.5	10.4	1.6	0.0
161	10.54	18.6	18.8	26.2	62.9	7.1	2.7	0.0
N	5	5	5	5	5	5	5	5
MEAN	9.106	18.78	19.00	25.52	68.22	7.70	1.86	0.04
S.D.	1.173	0.93	0.46	7.30	18.53	2.15	0.94	0.05
S.E.	0.524	0.42	0.21	3.27	8.29	0.96	0.42	0.02
M/C	3.1494	3.3453	0.9502	6.0228	0.9859	0.3911	3.2709	0.2080
F	1.4069	1.7488	1.8822	0.4381	0.7459	0.3156	1.1984	0.4848

INDIVIDUAL DATA 7-2-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Hematological findings, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 6 of lactation

Animal No.	Reticu-locyte %	PT sec	APTT sec	Differential count of WBC ($10^2/\mu L$)				
				Neutrophil	Lymphocyte	Monocyte	Eosinophil	Basophil
252	6.86	18.6	19.7	29.5	59.8	8.2	1.3	0.0
253	7.89	18.0	20.1	19.3	73.1	10.4	1.0	0.1
254	9.01	18.4	19.1	28.3	46.5	7.9	1.9	0.0
255	8.25	16.3	18.9	17.9	57.1	9.2	1.0	0.0
262	14.90	16.7	19.9	20.3	82.4	4.0	1.6	0.1
N	5	5	5	5	5	5	5	5
MEAN	9.382	17.60	19.54	23.06	63.78	7.94	1.36	0.04
S.D.	3.180	1.04	0.52	5.42	14.08	2.41	0.39	0.05
S.E.	1.422	0.46	0.23	2.42	6.30	1.08	0.17	0.02

INDIVIDUAL DATA 7-2-7

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Hematological findings, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 6 of lactation

Animal No.	Reticu-locyte %	PT sec	APTT sec	Differential count of WBC ($10^2/\mu L$)				
				Neutrophil	Lymphocyte	Monocyte	Eosinophil	Basophil
351	6.01	17.9	19.4	11.2	68.9	3.8	3.1	0.0
353	9.29	17.6	19.3	18.4	49.5	10.7	2.9	0.0
356	8.06	18.4	19.9	13.9	72.2	4.5	1.7	0.0
358	11.13	17.8	20.0	30.9	92.0	8.5	1.6	0.1
361	11.97	17.1	20.8	17.4	83.5	5.1	0.7	0.0
N	5	5	5	5	5	5	5	5
MEAN	9.292	17.76	19.88	18.36	73.22	6.52	2.00	0.02
S.D.	2.390	0.47	0.60	7.57	16.13	2.95	0.99	0.04
S.E.	1.069	0.21	0.27	3.39	7.21	1.32	0.44	0.02

INDIVIDUAL DATA 7-2-8

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Hematological findings, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 6 of lactation

Animal No.	Reticu-locyte %	PT sec	APTT sec	Differential count of WBC ($10^2/\mu L$)				
				Neutrophil	Lymphocyte	Monocyte	Eosinophil	Basophil
451	6.53	17.3	18.8	30.3	92.4	5.9	1.4	0.0
457	5.54	19.6	19.7	14.6	112.8	8.6	2.1	0.1
458	5.20	17.8	20.1	15.5	60.6	10.2	1.3	0.1
459	11.12	16.1	18.5	51.1	78.1	7.3	0.9	0.1
461	5.06	16.8	20.1	8.4	57.2	3.3	0.3	0.0
N	5	5	5	5	5	5	5	5
MEAN	6.690	17.52	19.44	23.98	80.22	7.06	1.20	0.06
S.D.	2.542	1.32	0.75	17.16	23.07	2.63	0.66	0.05
S.E.	1.137	0.59	0.33	7.67	10.32	1.18	0.30	0.02

INDIVIDUAL DATA 7-3-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of recovery

Animal No.	WBC $10^2/\mu L$	RBC $10^4/\mu L$	HGB g/dL	HCT %	MCV fL	MCH pg	MCHC g/dL	Platelet $10^4/\mu L$
103	111.8	983	16.5	45.6	46.4	16.8	36.2	127.2
106	114.4	1001	16.0	45.7	45.7	16.0	35.0	116.8
107	123.5	931	16.4	45.6	49.0	17.6	36.0	123.2
108	148.1	997	17.0	48.0	48.1	17.1	35.4	143.2
109	95.3	932	16.2	45.9	49.2	17.4	35.3	143.8
N	5	5	5	5	5	5	5	5
MEAN	118.62	968.8	16.42	46.16	47.68	16.98	35.58	130.84
S.D.	19.37	34.7	0.38	1.04	1.56	0.63	0.50	12.14
S.E.	8.66	15.5	0.17	0.46	0.70	0.28	0.22	5.43
M/C	0.7065	0.0746	0.7730	1.4136	0.2732	0.2705	0.1489	0.0031
F	0.4861	3.8769 †	2.8644	0.4336	1.2960	0.1167	3.6582 †	1.3454

INDIVIDUAL DATA 7-3-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : End of recovery

Animal No.	WBC $10^2/\mu L$	RBC $10^4/\mu L$	HGB g/dL	HCT %	MCV fL	MCH pg	MCHC g/dL	Platelet $10^4/\mu L$
402	126.3	969	16.6	47.2	48.7	17.1	35.2	103.7
405	171.1	927	16.1	46.2	49.8	17.4	34.8	127.2
406	134.2	936	15.3	42.7	45.6	16.3	35.8	124.7
409	132.4	885	15.2	44.2	49.9	17.2	34.4	116.4
410	85.4	925	16.2	47.2	51.0	17.5	34.3	137.0
N	5	5	5	5	5	5	5	5
MEAN	129.88	928.4	15.88	45.50	49.00	17.10	34.90	121.80
S.D.	30.48	30.0	0.61	1.99	2.07	0.47	0.62	12.50
S.E.	13.63	13.4	0.27	0.89	0.92	0.21	0.28	5.59
t'		1.9690					1.9126	

INDIVIDUAL DATA 7-3-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of recovery

Animal No.	Reticu-locyte %	PT sec	APTT sec	Differential count of WBC ($10^2/\mu L$) Neutrophil	Lymphocyte	Monocyte	Eosinophil	Basophil
103	2.77	20.0	25.3	11.5	94.8	3.2	2.3	0.0
106	3.27	25.8	29.3	14.3	92.9	5.8	1.4	0.0
107	4.15	17.4	23.7	17.0	99.8	4.2	2.5	0.0
108	3.04	18.2	23.8	15.2	125.9	4.8	2.2	0.0
109	3.35	19.1	26.8	13.1	75.3	4.0	2.9	0.0
N	5	5	5	5	5	5	5	5
MEAN	3.316	20.10	25.78	14.22	97.74	4.40	2.26	0.00
S.D.	0.518	3.33	2.34	2.08	18.25	0.97	0.55	0.00
S.E.	0.232	1.49	1.05	0.93	8.16	0.43	0.25	0.00
M/C	0.0262	1.7004	0.8568	1.4195	1.0254	0.4063	0.0208	∞ **
F	0.7771	0.3938	0.2967	0.8501	0.4227	1.7314	2.7851	
H								2.2500

INDIVIDUAL DATA 7-3-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Hematological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : End of recovery

Animal No.	Reticu-locyte %	PT sec	APTT sec	Differential count of WBC ($10^2/\mu L$) Neutrophil	Lymphocyte	Monocyte	Eosinophil	Basophil
402	2.59	22.3	29.7	13.3	106.9	4.2	1.8	0.1
405	3.21	19.3	22.3	11.0	154.7	4.1	1.2	0.1
406	2.85	19.9	21.7	19.1	109.3	3.9	1.9	0.0
409	3.90	21.0	21.7	20.7	105.5	3.8	2.4	0.0
410	2.52	23.2	28.0	16.3	65.4	2.5	1.2	0.0
N	5	5	5	5	5	5	5	5
MEAN	3.014	21.14	24.68	16.08	108.36	3.70	1.70	0.04
S.D.	0.564	1.62	3.86	4.00	31.64	0.69	0.51	0.05
S.E.	0.252	0.73	1.73	1.79	14.15	0.31	0.23	0.02

INDIVIDUAL DATA 7-4-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Hematological findings, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : End of recovery

Animal No.	WBC $10^2/\mu L$	RBC $10^4/\mu L$	HGB g/dL	HCT %	MCV fL	MCH pg	MCHC g/dL	Platelet $10^4/\mu L$
163	54.8	892	16.1	44.6	50.0	18.0	36.1	124.1
164	69.3	876	16.5	47.0	53.7	18.8	35.1	124.4
165	93.0	886	15.6	43.9	49.5	17.6	35.5	121.1
166	34.0	878	15.0	42.5	48.4	17.1	35.3	119.7
167	34.3	866	15.2	43.7	50.5	17.6	34.8	100.0
N	5	5	5	5	5	5	5	5
MEAN	57.08	879.6	15.68	44.34	50.42	17.82	35.36	117.86
S.D.	24.98	9.9	0.62	1.67	1.99	0.63	0.49	10.18
S.E.	11.17	4.4	0.28	0.75	0.89	0.28	0.22	4.55
M/C	1.4213	8.8607 **	0.0285	0.0881	1.3462	0.5066	1.0947	0.0058
F	2.2666		8.7553 *	8.9676 *	0.0001	0.0016	0.0020	0.0127
H		2.4545						

INDIVIDUAL DATA 7-4-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Hematological findings, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : End of recovery

Animal No.	WBC $10^2/\mu L$	RBC $10^4/\mu L$	HGB g/dL	HCT %	MCV fL	MCH pg	MCHC g/dL	Platelet $10^4/\mu L$
463	91.8	923	15.1	41.4	44.9	16.4	36.5	116.8
464	80.1	833	14.9	41.8	50.2	17.9	35.6	127.2
465	79.7	793	14.8	43.1	54.4	18.7	34.3	106.8
466	56.5	754	14.0	40.3	53.4	18.6	34.7	131.6
467	72.1	769	13.5	37.9	49.3	17.6	35.6	110.6
N	5	5	5	5	5	5	5	5
MEAN	76.04	814.4	14.46	40.90	50.44	17.84	35.34	118.60
S.D.	13.00	67.7	0.68	1.95	3.76	0.93	0.86	10.60
S.E.	5.81	30.3	0.30	0.87	1.68	0.42	0.39	4.74
t'			2.9589 *	2.9946 *				

INDIVIDUAL DATA 7-4-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Hematological findings, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : End of recovery

Animal No.	Reticu-locyte %	PT sec	APTT sec	Differential count of WBC ($10^2/\mu L$) Neutrophil	Lymphocyte	Monocyte	Eosinophil	Basophil
163	2.66	17.6	17.5	7.8	43.9	2.4	0.7	0.0
164	3.13	17.4	18.3	9.1	57.0	1.9	1.3	0.0
165	2.41	16.6	20.5	16.2	70.8	4.7	1.3	0.0
166	3.14	17.8	17.3	7.9	23.9	1.0	1.2	0.0
167	3.25	16.9	17.8	3.8	28.7	1.1	0.7	0.0
N	5	5	5	5	5	5	5	5
MEAN	2.918	17.26	18.28	8.96	44.86	2.22	1.04	0.00
S.D.	0.364	0.50	1.30	4.51	19.50	1.50	0.31	0.00
S.E.	0.163	0.22	0.58	2.02	8.72	0.67	0.14	0.00
M/C	5.5646 *	1.0539	0.1826	0.0346	0.5390	0.1764	0.0126	0.0000
F		6.4657 *	2.6191	0.7022	2.2445	0.2616	1.5568	0.0000
H	3.9382 *							

INDIVIDUAL DATA 7-4-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Hematological findings, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : End of recovery

Animal No.	Reticu-locyte %	PT sec	APTT sec	Differential count of WBC ($10^2/\mu L$) Neutrophil	Lymphocyte	Monocyte	Eosinophil	Basophil
463	2.73	17.0	19.9	6.5	81.7	2.6	1.0	0.0
464	3.42	15.9	21.1	12.9	61.7	4.5	1.0	0.0
465	4.22	15.7	18.8	16.9	59.9	1.5	1.4	0.0
466	6.67	17.0	18.6	6.0	47.1	1.7	1.7	0.0
467	3.79	15.0	19.0	15.1	52.7	3.0	1.3	0.0
N	5	5	5	5	5	5	5	5
MEAN	4.166	16.12	19.48	11.48	60.62	2.66	1.28	0.00
S.D.	1.503	0.87	1.03	4.98	13.15	1.20	0.29	0.00
S.E.	0.672	0.39	0.46	2.23	5.88	0.54	0.13	0.00
t'		2.5428 *						
U	3.0000							

INDIVIDUAL DATA 8-1-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of administration

Animal No.	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%) Albumin	Globulin α_1	Globulin α_2	Globulin β	Globulin γ	AST IU/L	ALT IU/L	ALP IU/L	γ-GTP IU/L
101	6.0	2.96	0.97	49.4	22.3	7.1	16.8	4.4	74	38	468	0.5
102	5.8	2.85	0.97	49.2	18.9	7.3	18.4	6.2	70	33	357	0.7
104	5.8	2.80	0.94	48.3	21.5	7.7	17.6	4.9	73	30	421	0.7
105	5.5	2.84	1.07	51.7	20.7	7.5	16.0	4.1	66	24	286	0.7
110	5.6	2.66	0.90	47.5	24.4	6.6	16.8	4.7	70	32	284	0.4
N	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	5.74	2.822	0.970	49.22	21.56	7.24	17.12	4.86	70.6	31.4	363.2	0.60
S.D.	0.19	0.108	0.063	1.58	2.03	0.42	0.91	0.81	3.1	5.1	81.5	0.14
S.E.	0.09	0.048	0.028	0.71	0.91	0.19	0.41	0.36	1.4	2.3	36.5	0.06
M/C	3.1600	1.0626	0.8605	0.6240	0.7476	2.5483	1.1504	1.2701	4.8949	2.0069	2.1313	2.3867
F	6.1219 **	0.9040	2.4453	2.4974 †	2.4322	0.1479	2.6182 †	1.5010	0.1021	0.5012	4.8379 *	0.2929

INDIVIDUAL DATA 8-1-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : End of administration

Animal No.	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%) Albumin	Globulin α_1	Globulin α_2	Globulin β	Globulin γ	AST IU/L	ALT IU/L	ALP IU/L	γ-GTP IU/L
201	5.8	2.88	0.99	49.8	23.6	6.0	15.3	5.3	62	28	389	0.6
202	5.4	2.59	0.92	48.0	24.8	7.9	15.7	3.6	63	26	290	0.6
203	5.7	2.78	0.94	48.6	21.8	7.6	16.3	5.7	69	28	241	0.7
205	5.5	2.94	1.14	53.3	19.7	6.8	16.0	4.2	69	29	312	0.3
209	5.9	2.85	0.94	48.4	22.4	7.6	17.4	4.2	89	33	531	0.6
N	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	5.66	2.808	0.986	49.62	22.46	7.18	16.14	4.60	70.4	28.8	352.6	0.56
S.D.	0.21	0.135	0.090	2.16	1.93	0.78	0.80	0.87	10.9	2.6	113.1	0.15
S.E.	0.09	0.060	0.040	0.97	0.86	0.35	0.36	0.39	4.9	1.2	50.6	0.07
t'	0.5866			0.3339			1.8637				0.2009	

INDIVIDUAL DATA 8-1-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : End of administration

Animal No.	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%) Albumin	Globulin α_1	Globulin α_2	Globulin β	Globulin γ	AST IU/L	ALT IU/L	ALP IU/L	γ-GTP IU/L
301	5.4	2.80	1.07	51.7	19.1	7.8	16.7	4.7	70	32	321	0.5
302	6.0	3.00	1.00	50.0	22.5	7.0	15.4	5.1	70	36	380	0.6
307	5.5	2.66	0.93	48.3	21.7	7.4	16.6	6.0	84	33	394	0.9
309	6.0	2.86	0.91	47.6	25.1	6.4	15.9	5.0	68	26	281	0.3
310	6.0	2.92	0.94	48.7	23.0	6.5	16.6	5.2	69	32	399	0.5
N	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	5.78	2.848	0.970	49.26	22.28	7.02	16.24	5.20	72.2	31.8	355.0	0.56
S.D.	0.30	0.129	0.065	1.62	2.18	0.59	0.57	0.48	6.6	3.6	51.8	0.22
S.E.	0.14	0.057	0.029	0.72	0.97	0.27	0.25	0.22	3.0	1.6	23.1	0.10
t'	0.2933			0.0334			1.6735				0.1554	

INDIVIDUAL DATA 8-1-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : End of administration

Animal No.	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%) Albumin	Globulin α_1	Globulin α_2	Globulin β	Globulin γ	AST IU/L	ALT IU/L	ALP IU/L	γ-GTP IU/L
401	5.2	2.80	1.16	53.8	18.5	6.7	15.4	5.6	62	24	405	0.3
403	5.4	2.70	1.00	50.0	19.3	7.2	17.2	6.3	72	34	540	0.8
404	5.1	2.73	1.15	53.5	20.4	7.3	14.5	4.3	79	37	496	0.5
407	5.3	2.62	0.97	49.4	21.5	7.7	15.9	5.5	73	28	558	0.1
408	5.3	2.82	1.14	53.4	18.1	7.1	15.4	6.0	76	32	605	0.7
N	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	5.26	2.734	1.084	52.02	19.56	7.20	15.68	5.54	72.4	31.0	520.8	0.48
S.D.	0.11	0.080	0.091	2.13	1.40	0.36	0.99	0.76	6.4	5.1	75.6	0.29
S.E.	0.05	0.036	0.041	0.95	0.62	0.16	0.44	0.34	2.9	2.3	33.8	0.13
t'	3.5195 **			2.3371			2.7385 *				2.9871 *	

INDIVIDUAL DATA 8-1-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of administration

Animal No.	T-Bil mg/dL	Glucose mg/dL	T-Cho mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
101	0.08	180	52	36	12.8	0.55	145	4.49	106	9.7	6.2
102	0.07	154	76	30	15.3	0.60	144	4.60	106	9.2	5.7
104	0.08	143	58	29	15.3	0.56	146	4.31	106	9.5	6.4
105	0.03	156	52	33	15.3	0.52	147	4.82	109	9.2	6.5
110	0.06	141	62	52	12.6	0.50	145	4.87	107	9.6	7.0
N	5	5	5	5	5	5	5	5	5	5	5
MEAN	0.064	154.8	60.0	36.0	14.26	0.546	145.4	4.618	106.8	9.44	6.36
S.D.	0.021	15.5	9.9	9.4	1.43	0.038	1.1	0.232	1.3	0.23	0.47
S.E.	0.009	7.0	4.4	4.2	0.64	0.017	0.5	0.104	0.6	0.10	0.21
M/C	7.3746	1.2476	2.6918	6.0504	0.5320	3.2208	2.7971	1.8471	4.6149	1.1006	0.3716
F	2.0056	0.3731	1.8574	3.5877 *	13.2442 **	0.0309	0.0635	2.5446 †	0.9383	2.1463	2.9644 †

INDIVIDUAL DATA 8-1-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : End of administration

Animal No.	T-Bil mg/dL	Glucose mg/dL	T-Cho mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
201	0.05	170	63	35	12.3	0.57	145	4.53	106	9.2	6.4
202	0.06	158	49	42	13.5	0.51	146	4.44	108	9.0	6.0
203	0.06	146	48	28	13.3	0.52	146	4.98	109	9.7	5.9
205	0.06	155	55	67	15.0	0.56	146	4.59	109	9.4	5.3
209	0.06	156	54	80	16.0	0.57	145	4.48	105	9.8	6.6
N	5	5	5	5	5	5	5	5	5	5	5
MEAN	0.058	157.0	53.8	50.4	14.02	0.546	145.6	4.604	107.4	9.42	6.04
S.D.	0.004	8.6	6.0	22.1	1.47	0.029	0.5	0.218	1.8	0.33	0.50
S.E.	0.002	3.8	2.7	9.9	0.66	0.013	0.2	0.097	0.8	0.15	0.22
t'				1.5105	0.2281			0.1033			0.9971

INDIVIDUAL DATA 8-1-7

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : End of administration

Animal No.	T-Bil mg/dL	Glucose mg/dL	T-Cho mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
301	0.04	162	60	22	14.7	0.51	145	4.82	108	9.0	6.5
302	0.08	181	36	64	16.3	0.55	144	4.88	107	9.7	5.9
307	0.05	151	50	56	18.7	0.54	146	4.63	106	9.3	7.4
309	0.05	166	42	36	14.4	0.53	146	4.97	107	9.8	6.3
310	0.06	153	32	54	15.9	0.57	146	4.80	107	9.6	6.0
N	5	5	5	5	5	5	5	5	5	5	5
MEAN	0.056	162.6	44.0	46.4	16.00	0.540	145.4	4.820	107.0	9.48	6.42
S.D.	0.015	12.0	11.2	17.1	1.71	0.022	0.9	0.125	0.7	0.33	0.60
S.E.	0.007	5.4	5.0	7.6	0.76	0.010	0.4	0.056	0.3	0.15	0.27
t'				1.0909	1.6536			1.4911			0.1870

INDIVIDUAL DATA 8-1-8

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : End of administration

Animal No.	T-Bil mg/dL	Glucose mg/dL	T-Cho mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
401	0.05	162	31	16	20.9	0.55	144	4.92	106	8.8	7.0
403	0.09	163	67	28	21.3	0.62	145	4.64	106	9.0	7.5
404	0.08	152	54	29	20.1	0.48	147	4.78	109	9.1	6.9
407	0.07	140	41	20	16.4	0.56	145	5.33	110	9.4	6.3
408	0.11	169	61	16	20.7	0.50	147	4.90	111	9.1	7.2
N	5	5	5	5	5	5	5	5	5	5	5
MEAN	0.080	157.2	50.8	21.8	19.88	0.542	145.6	4.914	108.4	9.08	6.98
S.D.	0.022	11.4	14.7	6.3	1.99	0.055	1.3	0.258	2.3	0.22	0.44
S.E.	0.010	5.1	6.6	2.8	0.89	0.025	0.6	0.115	1.0	0.10	0.20
t'				1.4895	5.3410 **			2.1849			1.9318

INDIVIDUAL DATA 8-2-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Biochemical findings, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 6 of lactation

Animal No.	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%) Albumin	Globulin α_1	Globulin α_2	Globulin β	Globulin γ	AST IU/L	ALT IU/L	ALP IU/L	γ-GTP IU/L
152	6.3	3.06	0.95	48.6	20.3	8.6	17.9	4.6	74	30	169	0.5
153	6.2	3.07	0.98	49.5	18.7	7.2	18.3	6.3	101	41	206	0.8
154	6.4	3.15	0.97	49.3	18.4	6.7	19.0	6.6	89	32	278	0.4
158	6.6	3.25	0.96	49.0	20.5	8.7	18.7	3.1	64	28	199	0.7
161	6.0	3.20	1.14	53.2	16.5	7.9	17.7	4.7	60	18	132	0.6
N	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	6.30	3.146	1.000	49.92	18.88	7.82	18.32	5.06	77.6	29.8	196.8	0.60
S.D.	0.22	0.082	0.079	1.86	1.63	0.87	0.54	1.42	17.2	8.3	54.0	0.16
S.E.	0.10	0.037	0.035	0.83	0.73	0.39	0.24	0.64	7.7	3.7	24.1	0.07
M/C	2.4783	4.8921	1.7235	2.5631	0.8686	3.5497	1.9364	2.7608	9.3182 *	2.8105	1.5639	2.4398
F	1.5952	2.1790	0.6495	0.6659	0.7689	0.4168	5.9817 **	3.5393 *		0.1124	2.0892	1.2204
H									0.4435			

INDIVIDUAL DATA 8-2-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Biochemical findings, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 6 of lactation

Animal No.	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%) Albumin	Globulin α_1	Globulin α_2	Globulin β	Globulin γ	AST IU/L	ALT IU/L	ALP IU/L	γ-GTP IU/L
252	6.7	3.52	1.11	52.6	19.5	6.6	16.2	5.1	85	33	197	0.6
253	6.5	3.23	0.99	49.7	21.8	6.5	17.0	5.0	65	26	158	0.4
254	6.1	3.08	1.01	50.4	18.2	8.6	18.9	3.9	103	30	192	0.5
255	6.7	3.51	1.10	52.4	18.3	7.7	18.1	3.5	197	45	201	0.5
262	6.6	3.54	1.16	53.6	19.5	6.8	16.4	3.7	61	22	122	0.7
N	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	6.52	3.376	1.074	51.74	19.46	7.24	17.32	4.24	102.2	31.2	174.0	0.54
S.D.	0.25	0.209	0.072	1.63	1.45	0.90	1.15	0.75	55.6	8.8	33.7	0.11
S.E.	0.11	0.093	0.032	0.73	0.65	0.40	0.52	0.34	24.9	3.9	15.1	0.05
t'							1.7107	0.9425				

INDIVIDUAL DATA 8-2-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Biochemical findings, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 6 of lactation

Animal No.	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%) Albumin	Globulin α_1	Globulin α_2	Globulin β	Globulin γ	AST IU/L	ALT IU/L	ALP IU/L	γ-GTP IU/L
351	6.2	3.28	1.12	52.9	16.6	8.1	16.6	5.8	69	27	220	0.8
353	6.6	3.30	1.00	49.8	20.3	8.1	17.8	4.0	96	43	145	0.6
356	6.7	3.56	1.13	53.1	19.1	6.6	16.7	4.5	67	27	138	0.2
358	6.2	2.79	0.82	45.1	18.0	9.8	19.0	8.1	93	31	246	0.3
361	6.3	3.18	1.02	50.6	16.6	7.3	17.7	7.8	66	24	140	0.3
N	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	6.40	3.222	1.018	50.30	18.12	7.98	17.56	6.04	78.2	30.4	177.8	0.44
S.D.	0.23	0.279	0.125	3.24	1.61	1.19	0.98	1.87	15.0	7.5	51.3	0.25
S.E.	0.10	0.125	0.056	1.45	0.72	0.53	0.44	0.83	6.7	3.3	22.9	0.11
t'							1.3001	1.1264				

INDIVIDUAL DATA 8-2-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Biochemical findings, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 6 of lactation

Animal No.	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%) Albumin	Globulin α_1	Globulin α_2	Globulin β	Globulin γ	AST IU/L	ALT IU/L	ALP IU/L	γ-GTP IU/L
451	5.7	2.89	1.02	50.6	21.3	6.4	15.9	5.8	114	30	237	0.6
457	6.7	3.24	0.94	48.5	21.6	6.4	14.6	8.9	64	25	197	0.5
458	6.1	3.00	0.97	49.1	17.2	10.8	16.3	6.6	85	34	212	0.6
459	5.7	3.02	1.13	52.9	17.2	6.7	17.1	6.1	72	28	260	0.6
461	6.4	3.23	1.02	50.3	21.0	6.0	15.6	7.1	87	26	274	0.9
N	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	6.12	3.076	1.016	50.28	19.66	7.26	15.90	6.90	84.4	28.6	236.0	0.64
S.D.	0.44	0.153	0.072	1.70	2.26	1.99	0.92	1.22	19.1	3.6	32.1	0.15
S.E.	0.20	0.069	0.032	0.76	1.01	0.89	0.41	0.55	8.5	1.6	14.3	0.07
t'							4.1399 **	2.1149				

INDIVIDUAL DATA 8-2-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Biochemical findings, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 6 of lactation

Animal No.	T-Bil mg/dL	Glucose mg/dL	T-Cho mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
152	0.04	133	76	27	29.9	0.61	142	4.88	105	11.0	8.1
153	0.06	137	55	27	25.8	0.60	139	4.68	103	10.2	9.5
154	0.05	166	62	38	22.4	0.72	141	5.02	102	10.9	9.7
158	0.05	144	86	96	24.7	0.64	141	4.99	99	11.3	8.1
161	0.05	197	65	60	25.1	0.67	141	5.94	104	10.7	10.0
N	5	5	5	5	5	5	5	5	5	5	5
MEAN	0.050	155.4	68.8	49.6	25.58	0.648	140.8	5.102	102.6	10.82	9.08
S.D.	0.007	26.5	12.2	29.2	2.73	0.049	1.1	0.487	2.3	0.41	0.91
S.E.	0.003	11.9	5.5	13.1	1.22	0.022	0.5	0.218	1.0	0.18	0.41
M/C	1.5960	9.1785 *	0.5237	4.0268	1.4682	0.1025	3.0370	0.7091	5.2926	3.7629	1.9306
F	3.2549 *		1.5975	1.1350	4.7189 *	1.3526	0.8925	0.0101	4.2609 *	2.5268 †	1.8163
H		2.3321									

INDIVIDUAL DATA 8-2-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Biochemical findings, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 6 of lactation

Animal No.	T-Bil mg/dL	Glucose mg/dL	T-Cho mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
252	0.03	150	54	39	27.5	0.67	143	5.08	105	10.6	8.0
253	0.04	165	51	45	23.9	0.54	142	4.69	103	10.6	8.0
254	0.03	152	53	28	22.9	0.59	140	5.11	104	10.6	9.4
255	0.05	146	83	58	24.7	0.62	142	4.96	104	11.7	9.5
262	0.04	200	74	45	21.4	0.67	141	5.80	103	10.7	9.4
N	5	5	5	5	5	5	5	5	5	5	5
MEAN	0.038	162.6	63.0	43.0	24.08	0.618	141.6	5.128	103.8	10.84	8.86
S.D.	0.008	22.1	14.5	10.9	2.27	0.055	1.1	0.411	0.8	0.48	0.79
S.E.	0.004	9.9	6.5	4.9	1.02	0.025	0.5	0.184	0.4	0.22	0.35
t'	2.9104 *				0.7487				1.2511	0.0865	

INDIVIDUAL DATA 8-2-7

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Biochemical findings, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 6 of lactation

Animal No.	T-Bil mg/dL	Glucose mg/dL	T-Cho mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
351	0.05	158	51	45	19.5	0.59	143	4.76	105	10.4	8.3
353	0.05	157	72	70	25.1	0.55	140	5.50	103	11.1	8.4
356	0.04	159	59	39	23.7	0.59	144	4.77	106	10.8	7.7
358	0.04	151	61	34	28.1	0.70	140	5.12	104	10.5	8.8
361	0.05	145	43	50	22.6	0.60	142	5.41	107	10.3	7.8
N	5	5	5	5	5	5	5	5	5	5	5
MEAN	0.046	154.0	57.2	47.6	23.80	0.606	141.8	5.112	105.0	10.62	8.20
S.D.	0.005	5.9	10.9	13.9	3.17	0.056	1.8	0.347	1.6	0.33	0.45
S.E.	0.002	2.6	4.9	6.2	1.42	0.025	0.8	0.155	0.7	0.15	0.20
t'	0.9701				0.8884				2.5022	0.8655	

INDIVIDUAL DATA 8-2-8

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Biochemical findings, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 6 of lactation

Animal No.	T-Bil mg/dL	Glucose mg/dL	T-Cho mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
451	0.05	139	32	17	31.0	0.52	142	4.29	106	10.1	8.2
457	0.05	162	51	61	27.8	0.59	141	5.04	105	10.2	7.7
458	0.04	144	73	22	27.5	0.57	142	5.41	105	10.4	8.1
459	0.05	149	57	24	37.5	0.67	142	5.37	106	10.5	9.3
461	0.05	150	43	22	28.4	0.55	143	5.63	107	10.2	8.2
N	5	5	5	5	5	5	5	5	5	5	5
MEAN	0.048	148.8	51.2	29.2	30.44	0.580	142.0	5.148	105.8	10.28	8.30
S.D.	0.004	8.6	15.4	18.0	4.18	0.057	0.7	0.524	0.8	0.16	0.60
S.E.	0.002	3.8	6.9	8.0	1.87	0.025	0.3	0.234	0.4	0.07	0.27
t'	0.4851				2.4257				3.3362 *	2.3368	

INDIVIDUAL DATA 8-3-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of recovery

Animal No.	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%) Albumin	Globulin α_1	Globulin α_2	Globulin β	Globulin γ	AST IU/L	ALT IU/L	ALP IU/L	γ-GTP IU/L
103	5.7	2.74	0.92	48.0	26.6	6.0	15.3	4.1	51	25	328	0.7
106	5.7	2.94	1.06	51.6	18.2	6.9	17.3	6.0	78	27	423	0.6
107	6.0	2.81	0.88	46.7	24.4	7.4	16.3	5.2	66	28	322	0.9
108	5.8	2.72	0.89	47.1	23.4	7.2	16.5	5.8	63	29	291	0.7
109	5.8	2.75	0.90	47.4	23.7	7.7	16.6	4.6	55	23	307	0.6
N	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	5.80	2.792	0.930	48.16	23.26	7.04	16.40	5.14	62.6	26.4	334.2	0.70
S.D.	0.12	0.089	0.074	1.98	3.09	0.65	0.72	0.80	10.5	2.4	51.7	0.12
S.E.	0.05	0.040	0.033	0.89	1.38	0.29	0.32	0.36	4.7	1.1	23.1	0.05
M/C	3.2323	1.6327	0.4534	0.2118	0.0026	0.0911	0.4053	0.2159	3.8148	1.2536	0.2453	0.3028
F	2.9697	0.0020	2.8549	2.8347	1.7988	2.4354	0.0102	2.8499	0.7947	4.5176 †	12.8858 **	0.0476

INDIVIDUAL DATA 8-3-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : End of recovery

Animal No.	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%) Albumin	Globulin α_1	Globulin α_2	Globulin β	Globulin γ	AST IU/L	ALT IU/L	ALP IU/L	γ-GTP IU/L
402	5.7	2.80	0.97	49.1	22.0	6.2	16.1	6.6	69	33	378	0.8
405	5.8	3.00	1.08	51.9	19.4	6.9	16.5	5.3	66	35	481	0.9
406	5.8	2.81	0.93	48.3	24.2	5.1	16.8	5.6	62	24	440	0.5
409	5.2	2.83	1.19	54.4	15.8	6.5	15.6	7.7	71	34	493	0.6
410	5.1	2.50	0.97	49.2	21.6	7.0	16.8	5.4	67	30	560	0.6
N	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	5.52	2.788	1.028	50.58	20.60	6.34	16.36	6.12	67.0	31.2	470.4	0.68
S.D.	0.34	0.180	0.106	2.53	3.18	0.76	0.51	1.02	3.4	4.4	67.3	0.16
S.E.	0.15	0.081	0.048	1.13	1.42	0.34	0.23	0.46	1.5	2.0	30.1	0.07
t'										2.1255	3.5897 **	

INDIVIDUAL DATA 8-3-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of recovery

Animal No.	T-Bil mg/dL	Glucose mg/dL	T-Cho mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
103	0.06	197	67	57	14.5	0.54	141	4.51	104	9.6	5.9
106	0.06	161	36	54	13.9	0.60	143	4.37	106	9.1	6.7
107	0.07	169	83	42	14.1	0.62	144	4.49	105	9.6	5.9
108	0.06	174	55	62	15.1	0.53	144	5.10	107	9.5	6.2
109	0.07	188	78	81	16.5	0.52	145	5.08	105	9.8	6.3
N	5	5	5	5	5	5	5	5	5	5	5
MEAN	0.064	177.8	63.8	59.2	14.82	0.562	143.4	4.710	105.4	9.52	6.20
S.D.	0.005	14.5	18.9	14.2	1.04	0.045	1.5	0.351	1.1	0.26	0.33
S.E.	0.002	6.5	8.5	6.4	0.47	0.020	0.7	0.157	0.5	0.12	0.15
M/C	4.3908 *	0.0018	1.1072	0.7577	1.6218	0.1283	0.2855	0.2415	0.0000	0.0346	0.0488
F		0.7022	1.8477	13.3161 **	1.7213	1.9059	0.0556	1.9693	2.7692	0.5902	5.8477 *
H	1.0125										

INDIVIDUAL DATA 8-3-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Biochemical findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : End of recovery

Animal No.	T-Bil mg/dL	Glucose mg/dL	T-Cho mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
402	0.04	154	54	36	14.7	0.58	144	4.70	106	9.3	6.6
405	0.09	192	66	45	18.7	0.54	142	4.90	105	9.6	6.6
406	0.06	159	52	24	13.9	0.52	145	4.86	107	9.7	6.3
409	0.05	175	40	24	18.1	0.48	143	5.07	108	9.2	7.1
410	0.06	170	41	30	15.6	0.51	144	5.41	107	9.2	6.8
N	5	5	5	5	5	5	5	5	5	5	5
MEAN	0.060	170.0	50.6	31.8	16.20	0.526	143.6	4.988	106.6	9.40	6.68
S.D.	0.019	14.9	10.7	8.9	2.11	0.037	1.1	0.270	1.1	0.23	0.29
S.E.	0.008	6.7	4.8	4.0	0.94	0.017	0.5	0.121	0.5	0.10	0.13
t'				3.6491 **							2.4182 *

INDIVIDUAL DATA 8-4-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Biochemical findings, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : End of recovery

Animal No.	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%) Albumin	Globulin α_1	Globulin α_2	Globulin β	Globulin γ	AST IU/L	ALT IU/L	ALP IU/L	γ-GTP IU/L
163	6.2	3.44	1.25	55.6	15.0	6.8	15.1	7.5	61	29	110	1.0
164	6.5	3.45	1.14	53.3	17.5	6.4	14.4	8.4	58	28	142	0.9
165	7.0	3.92	1.28	56.1	17.4	6.3	13.4	6.8	65	37	242	0.6
166	6.3	3.52	1.27	55.8	16.4	6.9	15.8	5.1	97	50	198	1.0
167	6.3	3.68	1.39	58.2	11.5	8.0	15.6	6.7	76	26	196	1.0
N	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	6.46	3.602	1.266	55.80	15.56	6.88	14.86	6.90	71.4	34.0	177.6	0.90
S.D.	0.32	0.202	0.089	1.74	2.48	0.68	0.98	1.21	15.9	9.9	51.8	0.17
S.E.	0.14	0.090	0.040	0.78	1.11	0.30	0.44	0.54	7.1	4.4	23.2	0.08
M/C	0.0566	1.7354	0.3404	0.2213	0.0421	0.4821	1.6459	0.1535	0.2176	0.9853	0.4071	2.6077
F	0.6995	1.3827	0.2775	0.2171	0.6050	1.8546	0.4299	0.0294	0.4578	0.5524	2.0018	0.2326

INDIVIDUAL DATA 8-4-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Biochemical findings, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : End of recovery

Animal No.	TP g/dL	Albumin g/dL	A/G ratio	Protein fraction (%) Albumin	Globulin α_1	Globulin α_2	Globulin β	Globulin γ	AST IU/L	ALT IU/L	ALP IU/L	γ-GTP IU/L
463	6.1	3.49	1.33	57.2	14.3	6.7	14.5	7.3	100	30	263	0.3
464	6.1	3.43	1.28	56.2	16.2	5.9	13.8	7.9	54	25	145	0.4
465	6.5	3.52	1.18	54.2	18.1	6.3	15.1	6.3	98	40	168	1.0
466	6.1	3.36	1.23	55.1	15.2	7.0	14.8	7.9	64	28	304	1.3
467	6.7	3.62	1.18	54.0	19.8	6.0	14.5	5.7	80	28	291	1.0
N	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	6.30	3.484	1.240	55.34	16.72	6.38	14.54	7.02	79.2	30.2	234.2	0.80
S.D.	0.28	0.098	0.065	1.36	2.23	0.47	0.48	0.99	20.3	5.8	72.9	0.43
S.E.	0.13	0.044	0.029	0.61	1.00	0.21	0.22	0.44	9.1	2.6	32.6	0.19

INDIVIDUAL DATA 8-4-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Biochemical findings, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : End of recovery

Animal No.	T-Bil mg/dL	Glucose mg/dL	T-Cho mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
163	0.11	162	67	25	13.1	0.58	143	4.86	108	9.7	4.9
164	0.10	152	72	9	13.9	0.63	144	4.43	109	9.9	4.1
165	0.13	136	95	21	17.2	0.62	141	4.95	105	10.5	6.1
166	0.07	163	67	17	15.0	0.60	143	4.91	109	9.8	4.3
167	0.08	172	78	7	15.8	0.68	146	4.00	111	9.6	4.1
N	5	5	5	5	5	5	5	5	5	5	5
MEAN	0.098	157.0	75.8	15.8	15.00	0.622	143.4	4.630	108.4	9.90	4.70
S.D.	0.024	13.7	11.6	7.7	1.60	0.038	1.8	0.409	2.2	0.35	0.85
S.E.	0.011	6.1	5.2	3.4	0.72	0.017	0.8	0.183	1.0	0.16	0.38
M/C	0.2094	0.1295	0.0289	1.8989	3.3763	0.7216	0.0240	1.0752	1.4197	3.8220	0.3777
F	0.3478	1.5187	7.4024 *	0.1356	5.7847 *	0.0040	0.0328	0.0000	0.8197	2.0870	4.0421 †

INDIVIDUAL DATA 8-4-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Biochemical findings, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : End of recovery

Animal No.	T-Bil mg/dL	Glucose mg/dL	T-Cho mg/dL	TG mg/dL	UN mg/dL	Crea mg/dL	Na mEq/L	K mEq/L	Cl mEq/L	Ca mg/dL	IP mg/dL
463	0.11	141	69	8	17.7	0.57	144	4.75	108	9.5	5.3
464	0.10	151	67	12	20.7	0.58	143	5.09	107	9.7	5.6
465	0.07	143	46	11	16.5	0.69	145	3.95	109	9.7	5.2
466	0.10	136	52	15	28.0	0.58	141	5.51	106	9.6	6.7
467	0.07	165	49	48	18.3	0.68	145	3.85	107	9.8	5.4
N	5	5	5	5	5	5	5	5	5	5	5
MEAN	0.090	147.2	56.6	18.8	20.24	0.620	143.6	4.630	107.4	9.66	5.64
S.D.	0.019	11.3	10.6	16.5	4.60	0.060	1.7	0.720	1.1	0.11	0.61
S.E.	0.008	5.1	4.8	7.4	2.06	0.027	0.7	0.322	0.5	0.05	0.27
t'			2.7207 *		2.4051 *						2.0105

INDIVIDUAL DATA 9-1-1
STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Gross findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of administration

Animal No.	Findings	Day of euthanasia
101	Epididymis (right): Yellowish white mass, cauda (8 x 4 x 3, mm)	Next day of day 42 of administration
102	No abnormal findings	Next day of day 42 of administration
104	No abnormal findings	Next day of day 42 of administration
105	Kidney (right): Dilatation, renal pelvis	Next day of day 42 of administration
110	No abnormal findings	Next day of day 42 of administration
111	No abnormal findings	Next day of day 42 of administration
112	No abnormal findings	Next day of day 42 of administration

INDIVIDUAL DATA 9-1-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Gross findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : End of administration

Animal No.	Findings	Day of euthanasia
201	No abnormal findings	Next day of day 42 of administration
202	No abnormal findings	Next day of day 42 of administration
203	No abnormal findings	Next day of day 42 of administration
204	No abnormal findings	Next day of day 42 of administration
205	No abnormal findings	Next day of day 42 of administration
206	No abnormal findings	Next day of day 42 of administration
207	No abnormal findings	Next day of day 42 of administration
208	No abnormal findings	Next day of day 42 of administration
209	Epididymis (left): Yellowish white mass, cauda (7 x 3 x 2, mm)	Next day of day 42 of administration
210	No abnormal findings	Next day of day 42 of administration
211	No abnormal findings	Next day of day 42 of administration
212	No abnormal findings	Next day of day 42 of administration

INDIVIDUAL DATA 9-1-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Gross findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : End of administration

Animal No.	Findings	Day of euthanasia
301	Epididymis (right): Yellowish white patch, cauda (3 x 3, mm)	Next day of day 42 of administration
302	No abnormal findings	Next day of day 42 of administration
303	No abnormal findings	Next day of day 42 of administration
304	No abnormal findings	Next day of day 42 of administration
305	No abnormal findings	Next day of day 42 of administration
306	No abnormal findings	Next day of day 42 of administration
307	No abnormal findings	Next day of day 42 of administration
308	No abnormal findings	Next day of day 42 of administration
309	No abnormal findings	Next day of day 42 of administration
310	No abnormal findings	Next day of day 42 of administration
311	No abnormal findings	Next day of day 42 of administration
312	No abnormal findings	Next day of day 42 of administration

INDIVIDUAL DATA 9-1-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Gross findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : End of administration

Animal No.	Findings	Day of euthanasia
401	Liver: Pale brown discoloration	Next day of day 42 of administration
403	Liver: Pale brown discoloration	Next day of day 42 of administration
404	Liver: Pale brown discoloration	Next day of day 42 of administration
407	Liver: Pale brown discoloration	Next day of day 42 of administration
408	Liver: Pale brown discoloration	Next day of day 42 of administration
411	Liver: Pale brown discoloration	Next day of day 42 of administration
412	Liver: Pale brown discoloration	Next day of day 42 of administration

INDIVIDUAL DATA 9-2-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Gross findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 6 of lactation

Animal No.	Findings	Day of euthanasia
151	No abnormal findings	Day 6 of lactation
152	No abnormal findings	Day 6 of lactation
153	No abnormal findings	Day 6 of lactation
154	No abnormal findings	Day 6 of lactation
155	No abnormal findings	Day 6 of lactation
156	No abnormal findings	Day 6 of lactation
157	No abnormal findings	Day 6 of lactation
158	No abnormal findings	Day 6 of lactation
159	No abnormal findings	Day 6 of lactation
160	No abnormal findings	Day 6 of lactation
161	No abnormal findings	Day 6 of lactation
162	No abnormal findings	Day 6 of lactation

INDIVIDUAL DATA 9-2-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Gross findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 6 of lactation

Animal No.	Findings	Day of euthanasia
251	No abnormal findings	Day 6 of lactation
252	No abnormal findings	Day 6 of lactation
253	No abnormal findings	Day 6 of lactation
254	No abnormal findings	Day 6 of lactation
255	No abnormal findings	Day 6 of lactation
256	No abnormal findings	Day 6 of lactation
257	No abnormal findings	Day 6 of lactation
258	No abnormal findings	Day 6 of lactation
259	No abnormal findings	Day 6 of lactation
260	No abnormal findings	Day 6 of lactation
261	No abnormal findings	Day 6 of lactation
262	No abnormal findings	Day 6 of lactation

INDIVIDUAL DATA 9-2-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Gross findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 6 of lactation

Animal No.	Findings	Day of euthanasia
351	Abdominal aorta: White discoloration	Day 6 of lactation
352	No abnormal findings	Day 6 of lactation
353	No abnormal findings	Day 6 of lactation
354	No abnormal findings	Day 6 of lactation
355	No abnormal findings	Day 6 of lactation
356	No abnormal findings	Day 6 of lactation
357	No abnormal findings	Day 6 of lactation
358	No abnormal findings	Day 6 of lactation
359[a]	No abnormal findings	Day 26 of gestation
360	No abnormal findings	Day 6 of lactation
361	No abnormal findings	Day 6 of lactation
362	No abnormal findings	Day 6 of lactation

a: Non-pregnancy.

INDIVIDUAL DATA 9-2-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Gross findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 6 of lactation

Animal No.	Findings	Day of euthanasia
451	No abnormal findings	Day 6 of lactation
452	No abnormal findings	Day 6 of lactation
453	No abnormal findings	Day 6 of lactation
454	No abnormal findings	Day 6 of lactation
455	No abnormal findings	Day 6 of lactation
456	No abnormal findings	Day 6 of lactation
457	No abnormal findings	Day 6 of lactation
458	No abnormal findings	Day 6 of lactation
459	Spleen: Adhesion, adipose tissue	Day 6 of lactation
460	No abnormal findings	Day 6 of lactation
461	No abnormal findings	Day 6 of lactation
462	No abnormal findings	Day 6 of lactation

INDIVIDUAL DATA 9-3-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Gross findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of recovery

Animal No.	Findings	Day of euthanasia
103	No abnormal findings	Next day of day 14 of recovery
106	No abnormal findings	Next day of day 14 of recovery
107	No abnormal findings	Next day of day 14 of recovery
108	No abnormal findings	Next day of day 14 of recovery
109	No abnormal findings	Next day of day 14 of recovery

INDIVIDUAL DATA 9-3-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Gross findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : End of recovery

Animal No.	Findings	Day of euthanasia
402	Liver: Pale brown discoloration	Next day of day 14 of recovery
405	Liver: Pale brown discoloration	Next day of day 14 of recovery
406	Liver: Pale brown discoloration	Next day of day 14 of recovery
409	Liver: Pale brown discoloration	Next day of day 14 of recovery
410	No abnormal findings	Next day of day 14 of recovery

INDIVIDUAL DATA 9-4-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Gross findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : End of recovery

Animal No.	Findings	Day of euthanasia
163	No abnormal findings	Next day of day 14 of recovery
164	No abnormal findings	Next day of day 14 of recovery
165	No abnormal findings	Next day of day 14 of recovery
166	No abnormal findings	Next day of day 14 of recovery
167	No abnormal findings	Next day of day 14 of recovery

INDIVIDUAL DATA 9-4-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)

Gross findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : End of recovery

Animal No.	Findings	Day of euthanasia
463	No abnormal findings	Next day of day 14 of recovery
464	No abnormal findings	Next day of day 14 of recovery
465	No abnormal findings	Next day of day 14 of recovery
466	Forelimb (left): Lost, 3rd digit	Next day of day 14 of recovery
467	No abnormal findings	Next day of day 14 of recovery

INDIVIDUAL DATA 10-1-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of administration

Animal	Body weight	Liver		Kidney		Spleen		Heart		Brain		Pituitary gland	
No.	g	g	%	g	%	g	%	g	%	g	%	mg	10^{-3}%
101	489	11.78	2.41	2.83	0.58	0.68	0.14	1.26	0.26	2.14	0.44	12.6	2.58
102	457	10.75	2.35	2.48	0.54	0.76	0.17	1.32	0.29	2.17	0.47	12.9	2.82
104	486	11.36	2.34	3.29	0.68	0.71	0.15	1.41	0.29	2.39	0.49	14.3	2.94
105	475	11.25	2.37	3.03	0.64	0.82	0.17	1.33	0.28	2.18	0.46	13.6	2.86
110	562	14.61	2.60	3.50	0.62	0.96	0.17	1.61	0.29	2.14	0.38	12.6	2.24
N	5	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	493.8	11.950	2.414	3.026	0.612	0.786	0.160	1.386	0.282	2.204	0.448	13.20	2.688
S.D.	40.1	1.532	0.107	0.397	0.054	0.111	0.014	0.136	0.013	0.105	0.042	0.74	0.284
S.E.	17.9	0.685	0.048	0.178	0.024	0.050	0.006	0.061	0.006	0.047	0.019	0.33	0.127
M/C	6.1367	6.4731	5.5887	23.1784 **	9.2667 *	4.2144	0.9457	0.7393	5.1410	2.4590	5.9858	0.8963	0.4388
F	1.6041	8.5630 **	35.4706 **			1.8571	2.9867 †	0.2941	0.4579	1.5107	2.7509 †	5.7622 **	3.7150 *
H				2.5792	5.4889								

INDIVIDUAL DATA 10-1-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : End of administration

Animal	Body weight	Liver		Kidney		Spleen		Heart		Brain		Pituitary gland	
No.	g	g	%	g	%	g	%	g	%	g	%	mg	10^{-3}%
201	503	12.98	2.58	3.00	0.60	0.79	0.16	1.43	0.28	2.26	0.45	14.1	2.80
202	480	12.58	2.62	2.98	0.62	0.64	0.13	1.31	0.27	2.16	0.45	13.2	2.75
203	474	11.10	2.34	2.98	0.63	0.69	0.15	1.36	0.29	2.25	0.47	12.6	2.66
205	474	11.76	2.48	3.00	0.63	0.75	0.16	1.13	0.24	2.16	0.46	14.1	2.97
209	497	12.05	2.42	2.99	0.60	0.71	0.14	1.39	0.28	2.20	0.44	11.3	2.27
N	5	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	485.6	12.094	2.488	2.990	0.616	0.716	0.148	1.324	0.272	2.206	0.454	13.06	2.690
S.D.	13.5	0.728	0.115	0.010	0.015	0.057	0.013	0.117	0.019	0.048	0.011	1.17	0.260
S.E.	6.1	0.326	0.051	0.004	0.007	0.026	0.006	0.052	0.009	0.021	0.005	0.52	0.116
t'		0.1789	0.8040				1.3856				0.3554	0.2268	0.0122

INDIVIDUAL DATA 10-1-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : End of administration

Animal	Body weight	Liver		Kidney		Spleen		Heart		Brain		Pituitary gland	
No.	g	g	%	g	%	g	%	g	%	g	%	mg	10^{-3}%
301	477	12.91	2.71	3.02	0.63	0.67	0.14	1.41	0.30	2.11	0.44	12.3	2.58
302	473	14.32	3.03	2.85	0.60	0.50	0.11	1.26	0.27	1.99	0.42	10.4	2.20
307	493	12.79	2.59	2.99	0.61	0.64	0.13	1.32	0.27	2.14	0.43	10.2	2.07
309	539	15.45	2.87	3.19	0.59	0.83	0.15	1.42	0.26	2.12	0.39	11.5	2.13
310	540	17.13	3.17	3.25	0.60	0.82	0.15	1.52	0.28	2.22	0.41	11.5	2.13
N	5	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	504.4	14.520	2.874	3.060	0.606	0.692	0.136	1.386	0.276	2.116	0.418	11.18	2.222
S.D.	32.9	1.824	0.234	0.161	0.015	0.137	0.017	0.100	0.015	0.083	0.019	0.87	0.205
S.E.	14.7	0.816	0.105	0.072	0.007	0.061	0.007	0.045	0.007	0.037	0.009	0.39	0.092
t'		3.1925 *	4.9979 **				2.7713 *				1.7770	3.2717 *	2.8478 *

INDIVIDUAL DATA 10-1-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : End of administration

Animal	Body weight	Liver		Kidney		Spleen		Heart		Brain		Pituitary gland	
No.	g	g	%	g	%	g	%	g	%	g	%	mg	10^{-3}%
401	463	15.48	3.34	3.11	0.67	0.59	0.13	1.38	0.30	2.07	0.45	10.2	2.20
403	488	15.62	3.20	3.23	0.66	0.71	0.15	1.35	0.28	2.12	0.43	10.5	2.15
404	462	15.35	3.32	3.31	0.72	0.58	0.13	1.54	0.33	2.20	0.48	11.9	2.58
407	473	15.30	3.23	2.83	0.60	0.68	0.14	1.11	0.23	2.20	0.47	12.2	2.58
408	450	14.29	3.18	3.30	0.73	0.66	0.15	1.34	0.30	2.21	0.49	12.6	2.80
N	5	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	467.2	15.208	3.254	3.156	0.676	0.644	0.140	1.344	0.288	2.160	0.464	11.48	2.462
S.D.	14.2	0.528	0.072	0.199	0.052	0.057	0.010	0.154	0.037	0.062	0.024	1.07	0.278
S.E.	6.4	0.236	0.032	0.089	0.023	0.025	0.004	0.069	0.017	0.028	0.011	0.48	0.124
t'		4.0471 **	9.1267 **				2.3094				0.9478	2.7858 *	1.3811

INDIVIDUAL DATA 10-1-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of administration

Animal	Thymus		Thyroid		Adrenal		Prostate		Seminal vesicle	
No.	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	g	%
101	346	70.76	16.8	3.44	63	12.88	1391	284.46	3.31	0.68
102	169	36.98	17.3	3.79	59	12.91	784	171.55	2.16	0.47
104	184	37.86	20.8	4.28	61	12.55	854	175.72	2.60	0.53
105	300	63.16	20.9	4.40	56	11.79	698	146.95	2.00	0.42
110	412	73.31	26.0	4.63	67	11.92	771	137.19	2.56	0.46
N	5	5	5	5	5	5	5	5	5	5
MEAN	282.2	56.414	20.36	4.108	61.2	12.410	899.6	183.174	2.526	0.512
S.D.	104.5	17.739	3.69	0.483	4.1	0.528	280.2	58.899	0.508	0.102
S.E.	46.7	7.933	1.65	0.216	1.9	0.236	125.3	26.340	0.227	0.046
M/C	0.9199	0.2147	1.4139	1.8709	4.0558	6.2728	5.1206	4.6562	6.3795	8.5523 *
F	1.5346	1.8220	0.8999	2.2718	0.9845	1.3021	2.5293 †	2.6141 †	3.9594 *	
H										6.0771

INDIVIDUAL DATA 10-1-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : End of administration

Animal	Thymus		Thyroid		Adrenal		Prostate		Seminal vesicle	
No.	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	g	%
201	389	77.34	19.6	3.90	53	10.54	896	178.13	2.26	0.45
202	329	68.54	20.7	4.31	61	12.71	638	132.92	2.04	0.43
203	455	95.99	25.9	5.46	59	12.45	846	178.48	2.06	0.43
205	317	66.88	21.1	4.45	70	14.77	930	196.20	1.79	0.38
209	292	58.75	18.8	3.78	65	13.08	866	174.25	1.86	0.37
N	5	5	5	5	5	5	5	5	5	5
MEAN	356.4	73.500	21.22	4.380	61.6	12.710	835.2	171.996	2.002	0.412
S.D.	65.6	14.200	2.77	0.665	6.4	1.513	114.7	23.439	0.185	0.035
S.E.	29.4	6.350	1.24	0.297	2.9	0.677	51.3	10.482	0.083	0.016
t'							0.5644	0.4634	2.6291 *	

INDIVIDUAL DATA 10-1-7

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : End of administration

Animal	Thymus		Thyroid		Adrenal		Prostate		Seminal vesicle	
No.	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	g	%
301	189	39.62	11.9	2.49	63	13.21	800	167.71	2.37	0.50
302	304	64.27	17.8	3.76	36	7.61	374	79.07	2.18	0.46
307	237	48.07	22.0	4.46	57	11.56	668	135.50	1.78	0.36
309	421	78.11	24.4	4.53	66	12.24	481	89.24	2.04	0.38
310	307	56.85	20.6	3.81	49	9.07	692	128.15	1.67	0.31
N	5	5	5	5	5	5	5	5	5	5
MEAN	291.6	57.384	19.34	3.810	54.2	10.738	603.0	119.934	2.008	0.402
S.D.	87.5	14.829	4.80	0.819	12.1	2.324	172.0	36.071	0.286	0.077
S.E.	39.1	6.632	2.14	0.366	5.4	1.039	76.9	16.131	0.128	0.034
t'							2.5995 *	2.6216 *	2.5990 *	

INDIVIDUAL DATA 10-1-8

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : End of administration

Animal	Thymus		Thyroid		Adrenal		Prostate		Seminal vesicle	
No.	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	g	%
401	265	57.24	27.0	5.83	44	9.50	854	184.45	1.90	0.41
403	287	58.81	28.7	5.88	56	11.48	608	124.59	2.08	0.43
404	313	67.75	24.9	5.39	53	11.47	740	160.17	1.79	0.39
407	232	49.05	17.3	3.66	63	13.32	814	172.09	2.04	0.43
408	125	27.78	19.4	4.31	65	14.44	726	161.33	1.73	0.38
N	5	5	5	5	5	5	5	5	5	5
MEAN	244.4	52.126	23.46	5.014	56.2	12.042	748.4	160.526	1.908	0.408
S.D.	73.1	15.142	4.91	0.986	8.4	1.903	94.5	22.351	0.152	0.023
S.E.	32.7	6.772	2.20	0.441	3.8	0.851	42.3	9.996	0.068	0.010
t'							1.3252	0.9389	3.1007 *	

INDIVIDUAL DATA 10-1-9

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of administration

Animal No.	Body weight g	Testis g	Testis %	Epididymis g	Epididymis %
101	489	2.76	0.56	1.41	0.29
102	457	3.20	0.70	1.06	0.23
104	486	2.79	0.57	1.20	0.25
105	475	3.06	0.64	1.19	0.25
110	562	3.48	0.62	1.34	0.24
111	565	3.27	0.58	1.21	0.21
112	576	3.43	0.60	1.37	0.24
N	7	7	7	7	7
MEAN	515.7	3.141	0.610	1.254	0.244
S.D.	49.8	0.287	0.049	0.124	0.024
S.E.	18.8	0.108	0.018	0.047	0.009
M/C	5.8731	0.7466	5.3945	4.9976	11.4324 **
F	0.3890	1.0097	1.9172	1.1708	
H					3.8839

INDIVIDUAL DATA 10-1-10

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : End of administration

Animal No.	Body weight	Testis		Epididymis	
	g	g	%	g	%
201	503	4.00	0.80	1.33	0.26
202	480	3.24	0.68	1.23	0.26
203	474	3.03	0.64	1.25	0.26
204	499	2.87	0.58	1.18	0.24
205	474	3.31	0.70	1.33	0.28
206	495	3.33	0.67	1.33	0.27
207	495	3.36	0.68	1.37	0.28
208	495	3.20	0.65	1.32	0.27
209	497	3.28	0.66	1.25	0.25
210	548	3.37	0.61	1.28	0.23
211	549	3.13	0.57	1.31	0.24
212	538	3.70	0.69	1.36	0.25
N	12	12	12	12	12
MEAN	503.9	3.318	0.661	1.295	0.258
S.D.	26.6	0.295	0.061	0.057	0.016
S.E.	7.7	0.085	0.018	0.017	0.005

INDIVIDUAL DATA 10-1-11

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : End of administration

Animal No.	Body weight g	Testis g	Testis %	Epididymis g	Epididymis %
301	477	3.50	0.73	1.20	0.25
302	473	2.96	0.63	1.12	0.24
303	517	3.54	0.68	1.33	0.26
304	503	3.13	0.62	1.29	0.26
305	494	3.54	0.72	1.31	0.27
306	480	3.00	0.63	1.21	0.25
307	493	3.42	0.69	1.22	0.25
308	489	3.31	0.68	1.15	0.24
309	539	3.20	0.59	1.21	0.22
310	540	3.54	0.66	1.38	0.26
311	505	3.35	0.66	1.18	0.23
312	554	3.65	0.66	1.37	0.25
N	12	12	12	12	12
MEAN	505.3	3.345	0.663	1.248	0.248
S.D.	26.8	0.228	0.041	0.086	0.014
S.E.	7.7	0.066	0.012	0.025	0.004

INDIVIDUAL DATA 10-1-12

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : End of administration

Animal No.	Body weight	Testis		Epididymis	
	g	g	%	g	%
401	463	3.07	0.66	1.24	0.27
403	488	2.90	0.59	1.21	0.25
404	462	3.59	0.78	1.51	0.33
407	473	3.50	0.74	1.33	0.28
408	450	3.59	0.80	1.39	0.31
411	560	3.50	0.63	1.28	0.23
412	568	3.28	0.58	1.25	0.22
N	7	7	7	7	7
MEAN	494.9	3.347	0.683	1.316	0.270
S.D.	48.7	0.273	0.090	0.105	0.040
S.E.	18.4	0.103	0.034	0.040	0.015

INDIVIDUAL DATA 10-2-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 6 of lactation

Animal	Body weight	Liver		Kidney		Spleen		Heart		Brain	
No.	g	g	%	g	%	g	%	g	%	g	%
152	292	9.73	3.33	2.08	0.71	0.66	0.23	0.99	0.34	1.99	0.68
153	291	9.61	3.30	2.00	0.69	0.79	0.27	0.96	0.33	1.96	0.67
154	306	9.46	3.09	1.92	0.63	0.87	0.28	0.97	0.32	1.98	0.65
158	310	11.10	3.58	2.47	0.80	0.82	0.26	1.06	0.34	2.04	0.66
161	323	10.80	3.34	1.97	0.61	0.83	0.26	1.09	0.34	1.94	0.60
N	5	5	5	5	5	5	5	5	5	5	5
MEAN	304.4	10.140	3.328	2.088	0.688	0.794	0.260	1.014	0.334	1.982	0.652
S.D.	13.4	0.753	0.174	0.221	0.075	0.080	0.019	0.058	0.009	0.038	0.031
S.E.	6.0	0.337	0.078	0.099	0.034	0.036	0.008	0.026	0.004	0.017	0.014
M/C	3.5804	8.2234 *	1.6602	5.3593	1.0080	2.5502	3.2169	4.6446	9.3971 *	5.4513	4.0465
F	2.3204		2.6779 †	0.4844	0.6845	1.5313	1.3106	1.0083		2.0047	3.9700 *
H		3.2514							4.3069		

INDIVIDUAL DATA 10-2-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 6 of lactation

Animal	Body weight	Liver		Kidney		Spleen		Heart		Brain	
No.	g	g	%	g	%	g	%	g	%	g	%
252	268	9.20	3.43	1.80	0.67	0.55	0.21	0.87	0.32	1.98	0.74
253	319	12.31	3.86	2.41	0.76	0.75	0.24	1.09	0.34	1.98	0.62
254	319	10.97	3.44	2.24	0.70	0.66	0.21	1.06	0.33	2.08	0.65
255	337	11.43	3.39	1.94	0.58	0.62	0.18	1.07	0.32	2.01	0.60
262	325	10.89	3.35	2.09	0.64	0.97	0.30	1.01	0.31	2.06	0.63
N	5	5	5	5	5	5	5	5	5	5	5
MEAN	313.6	10.960	3.494	2.096	0.670	0.710	0.228	1.020	0.324	2.022	0.648
S.D.	26.5	1.134	0.208	0.240	0.067	0.162	0.045	0.089	0.011	0.046	0.054
S.E.	11.9	0.507	0.093	0.108	0.030	0.073	0.020	0.040	0.005	0.021	0.024
t'			1.2225								0.1310

INDIVIDUAL DATA 10-2-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 6 of lactation

Animal	Body weight	Liver		Kidney		Spleen		Heart		Brain	
No.	g	g	%	g	%	g	%	g	%	g	%
351	292	9.98	3.42	2.06	0.71	0.64	0.22	1.07	0.37	1.99	0.68
353	289	10.48	3.63	2.07	0.72	0.51	0.18	0.96	0.33	2.14	0.74
356	290	10.16	3.50	1.89	0.65	0.63	0.22	1.06	0.37	2.00	0.69
358	314	10.06	3.20	1.94	0.62	0.98	0.31	1.06	0.34	2.14	0.68
361	302	10.15	3.36	1.94	0.64	0.79	0.26	1.02	0.34	2.18	0.72
N	5	5	5	5	5	5	5	5	5	5	5
MEAN	297.4	10.166	3.422	1.980	0.668	0.710	0.238	1.034	0.350	2.090	0.702
S.D.	10.6	0.190	0.160	0.080	0.044	0.181	0.049	0.046	0.019	0.088	0.027
S.E.	4.7	0.085	0.072	0.036	0.020	0.081	0.022	0.020	0.008	0.039	0.012
t'			0.6922								1.6369

INDIVIDUAL DATA 10-2-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 6 of lactation

Animal	Body weight	Liver		Kidney		Spleen		Heart		Brain	
No.	g	g	%	g	%	g	%	g	%	g	%
451	276	8.99	3.26	2.07	0.75	0.48	0.17	0.83	0.30	1.92	0.70
457	272	10.74	3.95	2.12	0.78	0.57	0.21	0.99	0.36	2.00	0.74
458	316	11.23	3.55	2.11	0.67	0.63	0.20	0.99	0.31	2.13	0.67
459	290	11.01	3.80	1.87	0.64	0.79	0.27	1.12	0.39	2.11	0.73
461	260	10.21	3.93	1.95	0.75	0.55	0.21	0.80	0.31	2.21	0.85
N	5	5	5	5	5	5	5	5	5	5	5
MEAN	282.8	10.436	3.698	2.024	0.718	0.604	0.212	0.946	0.334	2.074	0.738
S.D.	21.4	0.894	0.292	0.109	0.060	0.117	0.036	0.131	0.039	0.114	0.068
S.E.	9.6	0.400	0.131	0.049	0.027	0.052	0.016	0.059	0.017	0.051	0.031
t'			2.7248 *								2.8155 *

INDIVIDUAL DATA 10-2-5

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : Day 6 of lactation

Animal	Pituitary gland		Thymus		Thyroid		Adrenal		Ovary	
No.	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%
152	16.6	5.68	227	77.74	16.7	5.72	67	22.95	107	36.64
153	18.5	6.36	297	102.06	16.8	5.77	80	27.49	90	30.93
154	17.9	5.85	261	85.29	18.5	6.05	93	30.39	98	32.03
158	16.0	5.16	224	72.26	14.4	4.65	77	24.84	115	37.10
161	12.3	3.81	362	112.07	12.7	3.93	69	21.36	108	33.44
N	5	5	5	5	5	5	5	5	5	5
MEAN	16.26	5.372	274.2	89.884	15.82	5.224	77.2	25.406	103.6	34.028
S.D.	2.43	0.973	57.3	16.731	2.27	0.899	10.4	3.602	9.7	2.748
S.E.	1.09	0.435	25.6	7.482	1.02	0.402	4.6	1.611	4.3	1.229
M/C	4.4161	8.9325 *	1.1349	1.7086	6.2450	6.6536	0.5132	0.1961	3.3432	2.9016
F	0.4940		3.0575 †	2.8964 †	1.2172	0.7170	0.5593	0.1172	2.3599	3.0666 †
H		0.0971								

INDIVIDUAL DATA 10-2-6

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : Day 6 of lactation

Animal	Pituitary gland		Thymus		Thyroid		Adrenal		Ovary	
No.	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%
252	16.9	6.31	231	86.19	18.8	7.01	61	22.76	117	43.66
253	18.2	5.71	316	99.06	23.2	7.27	99	31.03	141	44.20
254	15.0	4.70	244	76.49	19.8	6.21	80	25.08	113	35.42
255	19.9	5.91	245	72.70	21.1	6.26	86	25.52	136	40.36
262	17.2	5.29	315	96.92	12.7	3.91	84	25.85	92	28.31
N	5	5	5	5	5	5	5	5	5	5
MEAN	17.44	5.584	270.2	86.272	19.12	6.132	82.0	26.048	119.8	38.390
S.D.	1.80	0.616	41.7	11.798	3.95	1.325	13.7	3.037	19.6	6.630
S.E.	0.80	0.275	18.7	5.276	1.77	0.593	6.1	1.358	8.8	2.965
t'			0.1058	0.3129						1.4980

INDIVIDUAL DATA 10-2-7

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : Day 6 of lactation

Animal	Pituitary gland		Thymus		Thyroid		Adrenal		Ovary	
No.	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%
351	17.2	5.89	376	128.77	15.8	5.41	74	25.34	107	36.64
353	16.1	5.57	261	90.31	14.8	5.12	57	19.72	118	40.83
356	15.5	5.34	237	81.72	16.9	5.83	78	26.90	104	35.86
358	17.8	5.67	365	116.24	15.8	5.03	83	26.43	102	32.48
361	16.1	5.33	219	72.52	17.4	5.76	81	26.82	89	29.47
N	5	5	5	5	5	5	5	5	5	5
MEAN	16.54	5.560	291.6	97.912	16.14	5.430	74.6	25.042	104.0	35.056
S.D.	0.93	0.236	73.7	23.732	1.02	0.362	10.4	3.039	10.4	4.311
S.E.	0.42	0.105	32.9	10.613	0.46	0.162	4.7	1.359	4.7	1.928
t'			0.4600	0.6954						0.3530

INDIVIDUAL DATA 10-2-8

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : Day 6 of lactation

Animal	Pituitary gland		Thymus		Thyroid		Adrenal		Ovary	
No.	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%
451	14.4	5.22	223	80.80	14.9	5.40	81	29.35	105	38.04
457	19.6	7.21	172	63.24	23.4	8.60	75	27.57	114	41.91
458	11.7	3.70	255	80.70	15.1	4.78	69	21.84	125	39.56
459	16.0	5.52	194	66.90	13.8	4.76	84	28.97	123	42.41
461	17.4	6.69	91	35.00	16.6	6.38	59	22.69	125	48.08
N	5	5	5	5	5	5	5	5	5	5
MEAN	15.82	5.668	187.0	65.328	16.76	5.984	73.6	26.084	118.4	42.000
S.D.	2.99	1.371	62.1	18.724	3.84	1.604	10.0	3.561	8.8	3.833
S.E.	1.34	0.613	27.8	8.373	1.72	0.717	4.5	1.593	3.9	1.714
t'			2.3055	2.1270						2.7378 *

INDIVIDUAL DATA 10-3-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of recovery

Animal	Body weight	Liver		Kidney		Spleen		Heart		Brain		Pituitary gland		Thymus	
No.	g	g	%	g	%	g	%	g	%	g	%	mg	10^{-3}%	mg	10^{-3}%
103	525	13.16	2.51	3.13	0.60	0.74	0.14	1.56	0.30	2.10	0.40	11.0	2.10	309	58.86
106	531	11.69	2.20	3.04	0.57	0.93	0.18	1.33	0.25	2.31	0.44	11.3	2.13	259	48.78
107	549	13.29	2.42	2.85	0.52	0.83	0.15	1.60	0.29	2.11	0.38	12.3	2.24	260	47.36
108	540	12.95	2.40	3.27	0.61	0.77	0.14	1.43	0.26	2.29	0.42	17.0	3.15	249	46.11
109	550	14.34	2.61	3.57	0.65	0.79	0.14	1.34	0.24	2.22	0.40	13.9	2.53	234	42.55
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	539.0	13.086	2.428	3.172	0.590	0.812	0.150	1.452	0.268	2.206	0.408	13.10	2.430	262.2	48.732
S.D.	11.0	0.947	0.152	0.270	0.048	0.074	0.017	0.124	0.026	0.098	0.023	2.46	0.437	28.2	6.115
S.E.	4.9	0.423	0.068	0.121	0.022	0.033	0.008	0.055	0.012	0.044	0.010	1.10	0.195	12.6	2.735
M/C	0.1634	1.5263	0.0012	0.5337	0.1441	0.6859	0.2830	0.6166	0.0605	0.7145	0.4665	2.3480	1.8695	5.2150 *	4.7891 *
F	8.2041 *	48.8837 **	59.5995 **	4.2853 †	9.9353 *	1.6361	0.0426	0.0473	1.2987	2.1393	6.6494 *	0.2528	1.0584		
H														1.3200	1.3200

INDIVIDUAL DATA 10-3-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : End of recovery

Animal	Body weight	Liver		Kidney		Spleen		Heart		Brain		Pituitary gland		Thymus	
No.	g	g	%	g	%	g	%	g	%	g	%	mg	10^{-3}%	mg	10^{-3}%
402	510	17.14	3.36	3.25	0.64	0.76	0.15	1.32	0.26	2.23	0.44	14.2	2.78	180	35.29
405	500	16.46	3.29	3.42	0.68	0.84	0.17	1.33	0.27	2.30	0.46	12.9	2.58	486	97.20
406	513	16.44	3.20	3.41	0.66	0.72	0.14	1.36	0.27	2.23	0.43	14.7	2.87	297	57.89
409	525	15.85	3.02	3.76	0.72	0.76	0.14	1.66	0.32	2.38	0.45	12.3	2.34	304	57.90
410	535	16.14	3.02	4.25	0.79	0.73	0.14	1.70	0.32	2.27	0.42	14.4	2.69	344	64.30
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	516.6	16.406	3.178	3.618	0.698	0.762	0.148	1.474	0.288	2.282	0.440	13.70	2.652	322.2	62.516
S.D.	13.6	0.480	0.155	0.399	0.059	0.047	0.013	0.189	0.029	0.062	0.016	1.04	0.205	110.1	22.305
S.E.	6.1	0.215	0.069	0.179	0.027	0.021	0.006	0.085	0.013	0.028	0.007	0.47	0.092	49.2	9.975
t'	2.8643 *	6.9917 **	7.7201 **	2.0701	3.1520 *						2.5786 *				

INDIVIDUAL DATA 10-3-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of recovery

Animal	Thyroid		Adrenal		Testis		Epididymis		Prostate		Seminal vesicle	
No.	mg	10^{-3}%	mg	10^{-3}%	g	%	g	%	mg	10^{-3}%	g	%
103	21.2	4.04	56	10.67	3.81	0.73	1.52	0.29	963	183.43	2.38	0.45
106	23.1	4.35	55	10.36	3.45	0.65	1.32	0.25	654	123.16	2.11	0.40
107	24.2	4.41	56	10.20	3.24	0.59	1.44	0.26	1041	189.62	2.05	0.37
108	25.4	4.70	80	14.81	3.57	0.66	1.33	0.25	818	151.48	2.18	0.40
109	21.8	3.96	73	13.27	3.36	0.61	1.62	0.29	853	155.09	2.17	0.39
N	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	23.14	4.292	64.0	11.862	3.486	0.648	1.446	0.268	865.8	160.556	2.178	0.402
S.D.	1.72	0.299	11.7	2.068	0.218	0.054	0.128	0.020	147.9	26.827	0.124	0.029
S.E.	0.77	0.134	5.2	0.925	0.097	0.024	0.057	0.009	66.1	11.997	0.056	0.013
M/C	3.8440 *	4.7542 *	0.2472	0.3060	2.4598	1.4005	0.0467	0.2044	0.4146	0.6200	4.2768 *	2.6387
F			0.8684	0.4628	1.4669	0.3765	1.9587	0.6545	0.4649	0.1325		0.1143
H	0.7024	0.8836									0.2727	

INDIVIDUAL DATA 10-3-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : End of recovery

Animal	Thyroid		Adrenal		Testis		Epididymis		Prostate		Seminal vesicle	
No.	mg	10^{-3}%	mg	10^{-3}%	g	%	g	%	mg	10^{-3}%	g	%
402	18.1	3.55	67	13.14	3.06	0.60	1.14	0.22	1062	208.24	2.46	0.48
405	32.4	6.48	37	7.40	3.60	0.72	1.36	0.27	791	158.20	1.44	0.29
406	21.8	4.25	54	10.53	2.36	0.46	1.26	0.25	478	93.18	2.09	0.41
409	25.6	4.88	47	8.95	3.67	0.70	1.53	0.29	768	146.29	2.32	0.44
410	26.2	4.90	75	14.02	3.20	0.60	1.34	0.25	840	157.01	2.40	0.45
N	5	5	5	5	5	5	5	5	5	5	5	5
MEAN	24.82	4.812	56.0	10.808	3.178	0.616	1.326	0.256	787.8	152.584	2.142	0.414
S.D.	5.34	1.084	15.2	2.779	0.525	0.103	0.143	0.026	208.7	40.979	0.417	0.074
S.E.	2.39	0.485	6.8	1.243	0.235	0.046	0.064	0.012	93.4	18.326	0.186	0.033

INDIVIDUAL DATA 10-4-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : End of recovery

Animal	Body weight	Liver		Kidney		Spleen		Heart		Brain	
No.	g	g	%	g	%	g	%	g	%	g	%
163	297	6.66	2.24	1.97	0.66	0.47	0.16	0.87	0.29	2.06	0.69
164	289	8.25	2.85	2.00	0.69	0.56	0.19	0.90	0.31	2.15	0.74
165	306	7.53	2.46	2.01	0.66	0.60	0.20	0.93	0.30	2.17	0.71
166	295	6.70	2.27	1.83	0.62	0.48	0.16	0.84	0.28	1.98	0.67
167	310	6.78	2.19	1.97	0.64	0.52	0.17	0.95	0.31	2.15	0.69
N	5	5	5	5	5	5	5	5	5	5	5
MEAN	299.4	7.184	2.402	1.956	0.654	0.526	0.176	0.898	0.298	2.102	0.700
S.D.	8.5	0.694	0.270	0.073	0.026	0.055	0.018	0.044	0.013	0.080	0.026
S.E.	3.8	0.310	0.121	0.032	0.012	0.024	0.008	0.020	0.006	0.036	0.012
M/C	2.4610	0.6388	0.0007	0.3152	0.9176	0.0929	0.9869	4.5372 *	5.8449 *	0.0013	0.9634
F	3.9753 †	1.5984	6.0592 *	5.4980 *	0.0308	0.0254	0.9846			0.0061	5.3407 *
H								0.3951	0.2941		

INDIVIDUAL DATA 10-4-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : End of recovery

Animal	Body weight	Liver		Kidney		Spleen		Heart		Brain	
No.	g	g	%	g	%	g	%	g	%	g	%
463	288	7.19	2.50	1.95	0.68	0.57	0.20	0.90	0.31	2.10	0.73
464	274	7.07	2.58	1.85	0.68	0.60	0.22	1.15	0.42	1.99	0.73
465	276	8.44	3.06	1.87	0.68	0.53	0.19	0.76	0.28	2.10	0.76
466	252	7.28	2.89	1.69	0.67	0.53	0.21	0.78	0.31	2.08	0.83
467	308	9.54	3.10	1.78	0.58	0.43	0.14	0.89	0.29	2.22	0.72
N	5	5	5	5	5	5	5	5	5	5	5
MEAN	279.6	7.904	2.826	1.828	0.658	0.532	0.192	0.896	0.322	2.098	0.754
S.D.	20.5	1.068	0.274	0.098	0.044	0.064	0.031	0.155	0.056	0.082	0.045
S.E.	9.2	0.477	0.123	0.044	0.020	0.029	0.014	0.069	0.025	0.037	0.020
t'	1.9938		2.4615 *	2.3448 *							2.3110 *

INDIVIDUAL DATA 10-4-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : End of recovery

Animal	Pituitary gland		Thymus		Thyroid		Adrenal		Ovary	
No.	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%
163	16.0	5.39	269	90.57	16.3	5.49	80	26.94	105	35.35
164	13.5	4.67	283	97.92	11.7	4.05	69	23.88	73	25.26
165	16.1	5.26	280	91.50	14.9	4.87	63	20.59	85	27.78
166	16.1	5.46	294	99.66	21.0	7.12	79	26.78	98	33.22
167	19.9	6.42	372	120.00	11.4	3.68	64	20.65	83	26.77
N	5	5	5	5	5	5	5	5	5	5
MEAN	16.32	5.440	299.6	99.930	15.06	5.042	71.0	23.768	88.8	29.676
S.D.	2.29	0.630	41.4	11.891	3.92	1.359	8.1	3.121	12.7	4.367
S.E.	1.02	0.282	18.5	5.318	1.75	0.608	3.6	1.396	5.7	1.953
M/C	0.8292	0.8591	2.3034	3.3255	0.6092	1.0215	0.2486	0.0622	1.1438	1.0743
F	0.7854	3.2845	0.2638	0.0110	0.4323	1.4256	0.7062	0.0050	1.0268	2.4926

INDIVIDUAL DATA 10-4-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Absolute and relative organ weights, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : End of recovery

Animal	Pituitary gland		Thymus		Thyroid		Adrenal		Ovary	
No.	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%	mg	10^{-3}%
463	16.2	5.63	194	67.36	13.6	4.72	64	22.22	97	33.68
464	18.0	6.57	279	101.82	17.5	6.39	82	29.93	101	36.86
465	20.9	7.57	418	151.45	15.0	5.43	59	21.38	133	48.19
466	12.9	5.12	178	70.63	15.8	6.27	55	21.83	69	27.38
467	22.3	7.24	308	100.00	20.3	6.59	70	22.73	103	33.44
N	5	5	5	5	5	5	5	5	5	5
MEAN	18.06	6.426	275.4	98.252	16.44	5.880	66.0	23.618	100.6	35.910
S.D.	3.75	1.041	96.9	33.775	2.58	0.785	10.6	3.563	22.7	7.674
S.E.	1.68	0.465	43.3	15.105	1.15	0.351	4.7	1.594	10.2	3.432

INDIVIDUAL DATA 11-1-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Histopathological findings ANIMAL: Rat, Crl: CD (SD) SEX: Male GROUP: 0 mg/kg PERIOD: End of administration

Animal No.	101	102	104	105	110	111	112
Organ: Findings							
Lung: Aggregation, macrophage, alveolar	-	+	-	-	-	*	*
Mineralization, artery	-	-	-	+	-	*	*
Trachea:	N	N	N	N	N	*	*
Esophagus:	N	N	N	N	N	*	*
Forestomach:	N	N	N	N	N	*	*
Glandular stomach:	N	N	N	N	N	*	*
Duodenum:	N	N	N	N	N	*	*
Jejunum:	N	N	N	N	N	*	*
Ileum (including Peyer's patch):	N	N	N	N	N	*	*
Cecum:	N	N	N	N	N	*	*
Colon:	N	N	N	N	N	*	*
Rectum:	N	N	N	N	N	*	*
Pancreas: Atrophy, acinar cell, focal	-	-	-	+	+	*	*
Liver: Microgranuloma	-	+	+	+	+	-	-
Heart:	N	N	N	N	N	*	*
Right kidney: Dilatation, renal pelvis	-	-	-	+	-	*	*
Left kidney:	N	N	N	N	N	*	*
Urinary bladder:	N	N	N	N	N	*	*
Right testis:	N	N	N	N	N	*	*
Left testis:	N	N	N	N	N	*	*
Right epididymis: Spermatic granuloma	+	-	-	-	-	*	*
Left epididymis:	N	N	N	N	N	*	*
Prostate: Cellular infiltration, inflammatory cell	+	-	-	-	-	*	*
Right seminal vesicle:	N	N	N	N	N	*	*
Left seminal vesicle:	N	N	N	N	N	*	*
Right coagulating gland:	N	N	N	N	N	*	*
Left coagulating gland:	N	N	N	N	N	*	*

N: No abnormal findings, -: normal, +: slight change.
*: Not examined.

(to be continued)

INDIVIDUAL DATA 11-1-1 (continued)

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Histopathological findings ANIMAL: Rat, Crl: CD (SD) SEX: Male GROUP: 0 mg/kg PERIOD: End of administration

Animal No.	101	102	104	105	110	111	112
Organ: Findings							
Cerebrum:	N	N	N	N	N	*	*
Cerebellum:	N	N	N	N	N	*	*
Pons:	N	N	N	N	N	*	*
Spinal cord:	N	N	N	N	N	*	*
Sciatic nerve:	N	N	N	N	N	*	*
Spleen:	N	N	N	N	N	N	N
Thymus: Atrophy, cortex	-	+	+	-	-	-	-
Bone marrow of right femur:	N	N	N	N	N	*	*
Right submandibular lymph node:	N	N	N	N	N	*	*
Left submandibular lymph node:	N	N	N	N	N	*	*
Mesenteric lymph node:	N	N	N	N	N	*	*
Pituitary gland: Cyst, pars intermedia	-	-	-	+	-	*	*
Right thyroid:	N	N	N	N	N	N	N
Left thyroid:	N	N	N	N	N	N	N
Right parathyroid:	#	N	N	N	N	*	*
Left parathyroid:	N	N	N	N	N	*	*
Right adrenal:	N	N	N	N	N	*	*
Left adrenal:	N	N	N	N	N	*	*
Right eyeball:	N	N	N	N	N	*	*
Left eyeball:	N	N	N	N	N	*	*
Right Harderian gland:	N	N	N	N	N	*	*
Left Harderian gland:	N	N	N	N	N	*	*
Right femur:	N	N	N	N	N	*	*

N: No abnormal findings, -: normal, +: slight change.
*: Not examined.
#: Not examined because of missing.

INDIVIDUAL DATA 11-1-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Histopathological findings ANIMAL: Rat, Crl: CD (SD) SEX: Male GROUP: 1 mg/kg PERIOD: End of administration

Animal No.	201	202	203	204	205	206	207	208	209	210	211	212
Organ: Findings												
Liver: Microgranuloma	+	+	+	-	+	+	+	+	+	+	+	-
Left epididymis: Spermatic granuloma	*	*	*	*	*	*	*	*	+	*	*	*
Spleen:	N	N	N	N	N	N	N	N	N	N	N	N
Thymus:	N	N	N	N	N	N	N	N	N	N	N	N
Right thyroid:	N	N	N	N	N	N	N	N	N	N	N	N
Left thyroid:	N	N	N	N	N	N	N	N	N	N	N	N

N: No abnormal findings, -: normal, +: slight change.
*: Not examined.

INDIVIDUAL DATA 11-1-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Histopathological findings ANIMAL: Rat, Crl: CD (SD) SEX: Male GROUP: 3 mg/kg PERIOD: End of administration

Animal No.	301	302	303	304	305	306	307	308	309	310	311	312
Organ: Findings												
Liver: Hypertrophy, hepatocyte, centrilobular	+	++	-	+	-	-	+	+	-	++	+	+
Microgranuloma	-	-	+	+	-	+	+	-	-	-	+	+
Right epididymis: Spermatic granuloma	+	*	*	*	*	*	*	*	*	*	*	*
Spleen:	N	N	N	N	N	N	N	N	N	N	N	N
Thymus:	N	N	N	N	N	N	N	N	N	N	N	N
Right thyroid: Hypertrophy, follicular cell	-	-	-	-	-	-	-	+	+	-	+	+
Left thyroid: Hypertrophy, follicular cell	-	-	-	-	-	-	-	+	+	-	+	+

N: No abnormal findings, -: normal, +: slight change, ++: moderate change.
*: Not examined.

INDIVIDUAL DATA 11-1-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Histopathological findings ANIMAL: Rat, Crl: CD (SD) SEX: Male GROUP: 10 mg/kg PERIOD: End of administration

Animal No.	401	403	404	407	408	411	412
Organ: Findings							
Lung: Mineralization, artery	-	-	+	-	+	*	*
Trachea:	N	N	N	N	N	*	*
Esophagus:	N	N	N	N	N	*	*
Forestomach:	N	N	N	N	N	*	*
Glandular stomach:	N	N	N	N	N	*	*
Duodenum:	N	N	N	N	N	*	*
Jejunum:	N	N	N	N	N	*	*
Ileum (including Peyer's patch):	N	N	N	N	N	*	*
Cecum:	N	N	N	N	N	*	*
Colon:	N	N	N	N	N	*	*
Rectum:	N	N	N	N	N	*	*
Pancreas:	N	N	N	N	N	*	*
Liver: Hypertrophy, hepatocyte, centrilobular	++	++	++	++	++	++	++
Microgranuloma	-	-	-	+	-	-	-
Heart:	N	N	N	N	N	*	*
Right kidney:	N	N	N	N	N	*	*
Left kidney:	N	N	N	N	N	*	*
Urinary bladder:	N	N	N	N	N	*	*
Right testis:	N	N	N	N	N	*	*
Left testis:	N	N	N	N	N	*	*
Right epididymis:	N	N	N	N	N	*	*
Left epididymis:	N	N	N	N	N	*	*
Prostate: Cellular infiltration, inflammatory cell	-	+	-	+	-	*	*
Right seminal vesicle:	N	N	N	N	N	*	*
Left seminal vesicle:	N	N	N	N	N	*	*
Right coagulating gland:	N	N	N	N	N	*	*
Left coagulating gland:	N	N	N	N	N	*	*

N: No abnormal findings, -: normal, +: slight change, ++: moderate change.

(to be continued)

*: Not examined.

INDIVIDUAL DATA 11-1-4 (continued)

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Histopathological findings ANIMAL: Rat, Crl: CD (SD) SEX: Male GROUP: 10 mg/kg PERIOD: End of administration

Animal No.	401	403	404	407	408	411	412
Organ: Findings							
Cerebrum:	N	N	N	N	N	*	*
Cerebellum:	N	N	N	N	N	*	*
Pons:	N	N	N	N	N	*	*
Spinal cord:	N	N	N	N	N	*	*
Sciatic nerve:	N	N	N	N	N	*	*
Spleen:	N	N	N	N	N	N	N
Thymus: Atrophy, cortex	-	-	-	-	+	-	-
Bone marrow of right femur:	N	N	N	N	N	*	*
Right submandibular lymph node:	N	N	N	N	N	*	*
Left submandibular lymph node:	N	N	N	N	N	*	*
Mesenteric lymph node:	N	N	N	N	N	*	*
Pituitary gland:	N	N	N	N	N	*	*
Right thyroid: Hypertrophy, follicular cell	-	+	+	+	+	-	-
Left thyroid: Hypertrophy, follicular cell	-	+	+	+	+	-	-
Right parathyroid:	N	N	N	N	N	*	*
Left parathyroid:	N	N	N	N	N	*	*
Right adrenal:	N	N	N	N	N	*	*
Left adrenal:	N	N	N	N	N	*	*
Right eyeball:	N	N	N	N	N	*	*
Left eyeball:	N	N	N	N	N	*	*
Right Harderian gland:	N	N	N	N	N	*	*
Left Harderian gland:	N	N	N	N	N	*	*
Right femur:	N	N	N	N	N	*	*

N: No abnormal findings, -: normal, +: slight change.
*: Not examined.

INDIVIDUAL DATA 11-2-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Histopathological findings ANIMAL: Rat, Crl: CD (SD) SEX: Female GROUP: 0 mg/kg PERIOD: End of administration

Animal No.	151	152	153	154	155	156	157	158	159	160	161	162
Organ: Findings												
Lung: Mineralization, artery	*	-	+	-	*	*	*	-	*	*	-	*
Metaplasia, osseous, alveoli	*	-	-	-	*	*	*	-	*	*	+	*
Trachea:	*	N	N	N	*	*	*	N	*	*	N	*
Esophagus:	*	N	N	N	*	*	*	N	*	*	N	*
Forestomach:	*	N	N	N	*	*	*	N	*	*	N	*
Glandular stomach:	*	N	N	N	*	*	*	N	*	*	N	*
Duodenum:	*	N	N	N	*	*	*	N	*	*	N	*
Jejunum:	*	N	N	N	*	*	*	N	*	*	N	*
Ileum (including Peyer's patch):	*	N	N	N	*	*	*	N	*	*	N	*
Cecum:	*	N	N	N	*	*	*	N	*	*	N	*
Colon:	*	N	N	N	*	*	*	N	*	*	N	*
Rectum:	*	N	N	N	*	*	*	N	*	*	N	*
Pancreas:	*	N	N	N	*	*	*	N	*	*	N	*
Liver: Microgranuloma	-	-	-	+	-	+	+	+	-	+	-	+
Heart:	*	N	N	N	*	*	*	N	*	*	N	*
Right kidney: Cellular infiltration, inflammatory cell, renal pelvic mucosa	*	-	-	-	*	*	*	-	*	*	+	*
Left kidney:	*	N	N	N	*	*	*	N	*	*	N	*
Urinary bladder:	*	N	N	N	*	*	*	N	*	*	N	*
Right ovary:	*	N	N	N	*	*	*	N	*	*	N	*
Left ovary:	*	N	N	N	*	*	*	N	*	*	N	*
Right uterine horn:	*	N	N	N	*	*	*	N	*	*	N	*
Left uterine horn:	*	N	N	N	*	*	*	N	*	*	N	*
Uterine cervix:	*	N	N	N	*	*	*	N	*	*	N	*

N: No abnormal findings, -: normal, +: slight change.
*: Not examined.

(to be continued)

INDIVIDUAL DATA 11-2-1 (continued)

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Histopathological findings ANIMAL: Rat, Crl: CD (SD) SEX: Female GROUP: 0 mg/kg PERIOD: End of administration

Animal No.	151	152	153	154	155	156	157	158	159	160	161	162
Organ: Findings												
Cerebrum:	*	N	N	N	*	*	*	N	*	*	N	*
Cerebellum:	*	N	N	N	*	*	*	N	*	*	N	*
Pons:	*	N	N	N	*	*	*	N	*	*	N	*
Spinal cord:	*	N	N	N	*	*	*	N	*	*	N	*
Sciatic nerve:	*	N	N	N	*	*	*	N	*	*	N	*
Spleen: Decrease, extramedullary hematopoiesis	+	+	-	-	-	-	-	-	-	-	-	-
Thymus: Atrophy, cortex	-	-	-	-	-	-	-	-	-	-	-	+
Bone marrow of right femur:	*	N	N	N	*	*	*	N	*	*	N	*
Right submandibular lymph node:	*	N	N	N	*	*	*	N	*	*	N	*
Left submandibular lymph node:	*	N	N	N	*	*	*	N	*	*	N	*
Mesenteric lymph node:	*	N	N	N	*	*	*	N	*	*	N	*
Pituitary gland:	*	N	N	N	*	*	*	N	*	*	N	*
Right thyroid:	N	N	N	N	N	N	N	N	N	N	N	N
Left thyroid:	N	N	N	N	N	N	N	N	N	N	N	N
Right parathyroid:	*	#	#	N	*	*	*	N	*	*	N	*
Left parathyroid:	*	N	N	N	*	*	*	N	*	*	N	*
Right adrenal:	*	N	N	N	*	*	*	N	*	*	N	*
Left adrenal:	*	N	N	N	*	*	*	N	*	*	N	*
Right eyeball:	*	N	N	N	*	*	*	N	*	*	N	*
Left eyeball:	*	N	N	N	*	*	*	N	*	*	N	*
Right Harderian gland:	*	N	N	N	*	*	*	N	*	*	N	*
Left Harderian gland:	*	N	N	N	*	*	*	N	*	*	N	*
Right femur:	*	N	N	N	*	*	*	N	*	*	N	*
Mammary gland:	*	N	N	N	*	*	*	N	*	*	N	*

N: No abnormal findings, -: normal, +: slight change.
*: Not examined.
#: Not examined because of missing.

INDIVIDUAL DATA 11-2-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Histopathological findings ANIMAL: Rat, Crl: CD (SD) SEX: Female GROUP: 1 mg/kg PERIOD: End of administration

Animal No.	251	252	253	254	255	256	257	258	259	260	261	262
Organ: Findings												
Liver: Microgranuloma	+	-	+	+	-	+	+	-	+	+	+	+
Spleen:	N	N	N	N	N	N	N	N	N	N	N	N
Thymus: Atrophy, cortex	-	-	-	+	-	+	-	-	-	-	-	-
Right thyroid:	N	N	N	N	N	N	N	N	N	N	N	N
Left thyroid:	N	N	N	N	N	N	N	N	N	N	N	N

N: No abnormal findings, -: normal, +: slight change.

INDIVIDUAL DATA 11-2-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Histopathological findings ANIMAL: Rat, Crl: CD (SD) SEX: Female GROUP: 3 mg/kg PERIOD: End of administration

Animal No.	351	352	353	354	355	356	357	358	359	360	361	362
Organ: Findings												
Liver: Microgranuloma	+	+	-	+	+	+	-	+	-	+	+	-
Abdominal aorta:	N	*	*	*	*	*	*	*	*	*	*	*
Spleen: Decrease, extramedullary hematopoiesis	-	-	-	-	-	-	+	-	+	-	-	-
Thymus: Atrophy, cortex	-	-	-	-	-	-	-	-	-	-	-	+
Right thyroid:	N	N	N	N	N	N	N	N	N	N	N	N
Left thyroid:	N	N	N	N	N	N	N	N	N	N	N	N

N: No abnormal findings, -: normal, +: slight change.
*: Not examined.

INDIVIDUAL DATA 11-2-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Histopathological findings ANIMAL: Rat, Crl: CD (SD) SEX: Female GROUP: 10 mg/kg PERIOD: End of administration

Animal No.	451	452	453	454	455	456	457	458	459	460	461	462
Organ: Findings												
Lung: Aggregation, macrophage, alveolar	+	*	*	*	*	*	-	+	-	*	+	*
Trachea:	N	*	*	*	*	*	N	N	N	*	N	*
Esophagus:	N	*	*	*	*	*	N	N	N	*	N	*
Forestomach:	N	*	*	*	*	*	N	N	N	*	N	*
Glandular stomach:	N	*	*	*	*	*	N	N	N	*	N	*
Duodenum:	N	*	*	*	*	*	N	N	N	*	N	*
Jejunum:	N	*	*	*	*	*	N	N	N	*	N	*
Ileum (including Peyer's patch):	N	*	*	*	*	*	N	N	N	*	N	*
Cecum:	N	*	*	*	*	*	N	N	N	*	N	*
Colon:	N	*	*	*	*	*	N	N	N	*	N	*
Rectum:	N	*	*	*	*	*	N	N	N	*	N	*
Pancreas: Atrophy, acinar cell, focal	-	*	*	*	*	*	-	-	-	*	+	*
Liver: Hypertrophy, hepatocyte, centrilobular	-	+	-	+	+	+	+	+	+	+	+	-
Microgranuloma	+	++	+	++	++	-	+	++	++	++	++	-
Necrosis, focal	+	-	-	-	-	-	-	-	-	-	-	-
Heart:	N	*	*	*	*	*	N	N	N	*	N	*
Right kidney:	N	*	*	*	*	*	N	N	N	*	N	*
Left kidney:	N	*	*	*	*	*	N	N	N	*	N	*
Urinary bladder:	N	*	*	*	*	*	N	N	N	*	N	*
Right ovary:	N	*	*	*	*	*	N	N	N	*	N	*
Left ovary:	N	*	*	*	*	*	N	N	N	*	N	*
Right uterine horn:	N	*	*	*	*	*	N	N	N	*	N	*
Left uterine horn:	N	*	*	*	*	*	N	N	N	*	N	*
Uterine cervix:	N	*	*	*	*	*	N	N	N	*	N	*

N: No abnormal findings, -: normal, +: slight change, ++: moderate change.

(to be continued)

*: Not examined.

INDIVIDUAL DATA 11-2-4 (continued)

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Histopathological findings ANIMAL: Rat, Crl: CD (SD) SEX: Female GROUP: 10 mg/kg PERIOD: End of administration

Animal No.	451	452	453	454	455	456	457	458	459	460	461	462
Organ: Findings												
Cerebrum:	N	*	*	*	*	*	N	N	N	*	N	*
Cerebellum:	N	*	*	*	*	*	N	N	N	*	N	*
Pons:	N	*	*	*	*	*	N	N	N	*	N	*
Spinal cord:	N	*	*	*	*	*	N	N	N	*	N	*
Sciatic nerve:	N	*	*	*	*	*	N	N	N	*	N	*
Spleen: Decrease, extramedullary hematopoiesis	+	-	-	+	+	+	+	+	-	+	+	-
Capsulitis	-	-	-	-	-	-	-	-	+	-	-	-
Thymus: Atrophy, cortex	+	+	-	+	+	-	+	-	+	-	+	+
Bone marrow of right femur:	N	*	*	*	*	*	N	N	N	*	N	*
Right submandibular lymph node:	N	*	*	*	*	*	N	N	N	*	N	*
Left submandibular lymph node:	N	*	*	*	*	*	N	N	N	*	N	*
Mesenteric lymph node:	N	*	*	*	*	*	N	N	N	*	N	*
Pituitary gland: Cyst, pars distalis	-	*	*	*	*	*	-	-	+	*	-	*
Right thyroid:	N	N	N	N	N	N	N	N	N	N	N	N
Left thyroid:	N	N	N	N	N	N	N	N	N	N	N	N
Right parathyroid:	N	*	*	*	*	*	N	#	N	*	N	*
Left parathyroid:	N	*	*	*	*	*	N	N	N	*	N	*
Right adrenal:	N	*	*	*	*	*	N	N	N	*	N	*
Left adrenal:	N	*	*	*	*	*	N	N	N	*	N	*
Right eyeball:	N	*	*	*	*	*	N	N	N	*	N	*
Left eyeball:	N	*	*	*	*	*	N	N	N	*	N	*
Right Harderian gland:	N	*	*	*	*	*	N	N	N	*	N	*
Left Harderian gland:	N	*	*	*	*	*	N	N	N	*	N	*
Right femur:	N	*	*	*	*	*	N	N	N	*	N	*
Mammary gland:	N	*	*	*	*	*	N	N	N	*	N	*

N: No abnormal findings, -: normal, +: slight change.
*: Not examined.
#: Not examined because of missing.

INDIVIDUAL DATA 11-3-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Histopathological findings ANIMAL: Rat, Crl: CD (SD) SEX: Male GROUP: 0 mg/kg PERIOD: End of recovery

Animal No.	103	106	107	108	109
Organ: Findings					
Lung: Mineralization, artery	-	-	-	+	+
Trachea:	N	N	N	N	N
Esophagus:	N	N	N	N	N
Forestomach:	N	N	N	N	N
Glandular stomach:	N	N	N	N	N
Duodenum:	N	N	N	N	N
Jejunum:	N	N	N	N	N
Ileum (including Peyer's patch):	N	N	N	N	N
Cecum:	N	N	N	N	N
Colon:	N	N	N	N	N
Rectum:	N	N	N	N	N
Pancreas:	N	N	N	N	N
Liver: Microgranuloma	+	+	-	+	-
Heart:	N	N	N	N	N
Right kidney: Hyaline droplet, proximal tubular epithelium	-	+	+	-	-
Eosinophilic body, proximal tubular epithelium	-	+	+	-	-
Cast, hyaline	-	-	-	-	+
Left kidney: Hyaline droplet, proximal tubular epithelium	-	+	+	-	-
Eosinophilic body, proximal tubular epithelium	-	+	+	-	-
Urinary bladder:	N	N	N	N	N
Right testis:	N	N	N	N	N
Left testis:	N	N	N	N	N
Right epididymis:	N	N	N	N	N
Left epididymis:	N	N	N	N	N
Prostate: Cellular infiltration, inflammatory cell	-	+	-	-	-
Right seminal vesicle:	N	N	N	N	N
Left seminal vesicle:	N	N	N	N	N
Right coagulating gland:	N	N	N	N	N
Left coagulating gland:	N	N	N	N	N

N: No abnormal findings, -: normal, +: slight change.

(to be continued)

INDIVIDUAL DATA 11-3-1 (continued)

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Histopathological findings ANIMAL: Rat, Crl: CD (SD) SEX: Male GROUP: 0 mg/kg PERIOD: End of recovery

Animal No.	103	106	107	108	109
Organ: Findings					
Cerebrum:	N	N	N	N	N
Cerebellum:	N	N	N	N	N
Pons:	N	N	N	N	N
Spinal cord:	N	N	N	N	N
Sciatic nerve:	N	N	N	N	N
Spleen:	N	N	N	N	N
Thymus:	N	N	N	N	N
Bone marrow of right femur:	N	N	N	N	N
Right submandibular lymph node:	N	N	N	N	N
Left submandibular lymph node:	N	N	N	N	N
Mesenteric lymph node:	N	N	N	N	N
Pituitary gland:	N	N	N	N	N
Right thyroid:	N	N	N	N	N
Left thyroid:	N	N	N	N	N
Right parathyroid:	N	N	N	N	N
Left parathyroid:	N	N	N	N	N
Right adrenal:	N	N	N	N	N
Left adrenal:	N	N	N	N	N
Right eyeball:	N	N	N	N	N
Left eyeball:	N	N	N	N	N
Right Harderian gland: Cellular infiltration, inflammatory cell	-	-	-	+	-
Left Harderian gland:	N	N	N	N	N
Right femur:	N	N	N	N	N

N: No abnormal findings, -: normal, +: slight change.

INDIVIDUAL DATA 11-3-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Histopathological findings ANIMAL: Rat, Crl: CD (SD) SEX: Male GROUP: 10 mg/kg PERIOD: End of recovery

Animal No.	402	405	406	409	410
Organ: Findings					
Lung: Aggregation, macrophage, alveolar	-	-	-	-	+
Mineralization, artery	+	+	-	-	-
Fibrosis, pleura	-	-	-	-	+
Cellular infiltration, inflammatory cell, pleura	-	-	-	-	+
Trachea:	N	N	N	N	N
Esophagus:	N	N	N	N	N
Forestomach:	N	N	N	N	N
Glandular stomach:	N	N	N	N	N
Duodenum:	N	N	N	N	N
Jejunum:	N	N	N	N	N
Ileum (including Peyer's patch):	N	N	N	N	N
Cecum:	N	N	N	N	N
Colon:	N	N	N	N	N
Rectum:	N	N	N	N	N
Pancreas:	N	N	N	N	N
Liver: Hypertrophy, hepatocyte, centrilobular	+	++	++	+	++
Microgranuloma	+	+	+	+	-
Fatty change, diffuse	+	-	-	+	-
Heart:	N	N	N	N	N
Right kidney: Hyaline droplet, proximal tubular epithelium	+	-	-	-	-
Eosinophilic body, proximal tubular epithelium	+	-	-	-	-
Regeneration, tubular epithelium	-	-	+	-	-
Cast, hyaline	-	-	+	-	-
Left kidney: Hyaline droplet, proximal tubular epithelium	+	-	-	-	-
Eosinophilic body, proximal tubular epithelium	+	-	-	-	-
Urinary bladder:	N	N	N	N	N
Right testis:	N	N	N	N	N
Left testis:	N	N	N	N	N
Right epididymis:	N	N	N	N	N
Left epididymis:	N	N	N	N	N
Prostate: Cellular infiltration, inflammatory cell	-	-	+	-	+
Right seminal vesicle:	N	N	N	N	N
Left seminal vesicle:	N	N	N	N	N
Right coagulating gland:	N	N	N	N	N
Left coagulating gland:	N	N	N	N	N

N: No abnormal findings, -: normal, +: slight change, ++: moderate change.

(to be continued)

INDIVIDUAL DATA 11-3-2 (continued)

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Histopathological findings ANIMAL: Rat, Crl: CD (SD) SEX: Male GROUP: 10 mg/kg PERIOD: End of recovery

Animal No.	402	405	406	409	410
Organ: Findings					
Cerebrum:	N	N	N	N	N
Cerebellum:	N	N	N	N	N
Pons:	N	N	N	N	N
Spinal cord:	N	N	N	N	N
Sciatic nerve:	N	N	N	N	N
Spleen:	N	N	N	N	N
Thymus:	N	N	N	N	N
Bone marrow of right femur:	N	N	N	N	N
Right submandibular lymph node:	N	N	N	N	N
Left submandibular lymph node:	N	N	N	N	N
Mesenteric lymph node:	N	N	N	N	N
Pituitary gland:	N	N	N	N	N
Right thyroid: Hypertrophy, follicular cell	-	+	+	-	-
Left thyroid: Hypertrophy, follicular cell	-	+	+	-	-
Right parathyroid:	N	N	N	N	N
Left parathyroid:	N	N	N	N	N
Right adrenal:	N	N	N	N	N
Left adrenal:	N	N	N	N	N
Right eyeball:	N	N	N	N	N
Left eyeball:	N	N	N	N	N
Right Harderian gland:	N	N	N	N	N
Left Harderian gland:	N	N	N	N	N
Right femur:	N	N	N	N	N

N: No abnormal findings, -: normal, +: slight change.

INDIVIDUAL DATA 11-4-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Histopathological findings ANIMAL: Rat, Crl: CD (SD) SEX: Female GROUP: 0 mg/kg PERIOD: End of recovery

Animal No.	163	164	165	166	167
Organ: Findings					
Lung:	N	N	N	N	N
Trachea:	N	N	N	N	N
Esophagus:	N	N	N	N	N
Forestomach:	N	N	N	N	N
Glandular stomach:	N	N	N	N	N
Duodenum:	N	N	N	N	N
Jejunum:	N	N	N	N	N
Ileum (including Peyer's patch):	N	N	N	N	N
Cecum:	N	N	N	N	N
Colon:	N	N	N	N	N
Rectum:	N	N	N	N	N
Pancreas:	N	N	N	N	N
Liver: Microgranuloma	+	+	-	+	+
Heart:	N	N	N	N	N
Right kidney:	N	N	N	N	N
Left kidney:	N	N	N	N	N
Urinary bladder:	N	N	N	N	N
Right ovary:	N	N	N	N	N
Left ovary:	N	N	N	N	N
Right uterine horn:	N	N	N	N	N
Left uterine horn:	N	N	N	N	N
Uterine cervix:	N	N	N	N	N

N: No abnormal findings, -: normal, +: slight change.

(to be continued)

INDIVIDUAL DATA 11-4-1 (continued)

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Histopathological findings ANIMAL: Rat, Crl: CD (SD) SEX: Female GROUP: 0 mg/kg PERIOD: End of recovery

Animal No.	163	164	165	166	167
Organ: Findings					
Cerebrum:	N	N	N	N	N
Cerebellum:	N	N	N	N	N
Pons:	N	N	N	N	N
Spinal cord:	N	N	N	N	N
Sciatic nerve:	N	N	N	N	N
Spleen:	N	N	N	N	N
Thymus:	N	N	N	N	N
Bone marrow of right femur:	N	N	N	N	N
Right submandibular lymph node:	N	N	N	N	N
Left submandibular lymph node:	N	N	N	N	N
Mesenteric lymph node:	N	N	N	N	N
Pituitary gland:	N	N	N	N	N
Right thyroid:	N	N	N	N	N
Left thyroid:	N	N	N	N	N
Right parathyroid:	N	#	#	N	N
Left parathyroid:	N	N	N	N	N
Right adrenal:	N	N	N	N	N
Left adrenal:	N	N	N	N	N
Right eyeball:	N	N	N	N	N
Left eyeball:	N	N	N	N	N
Right Harderian gland:	N	N	N	N	N
Left Harderian gland:	N	N	N	N	N
Right femur:	N	N	N	N	N
Mammary gland:	N	N	N	N	N

N: No abnormal findings.
#: Not examined because of missing.

INDIVIDUAL DATA 11-4-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Histopathological findings ANIMAL: Rat, Crl: CD (SD) SEX: Female GROUP: 10 mg/kg PERIOD: End of recovery

Animal No.	463	464	465	466	467
Organ: Findings					
Lung: Aggregation, macrophage, alveolar	-	-	-	+	+
Trachea:	N	N	N	N	N
Esophagus:	N	N	N	N	N
Forestomach:	N	N	N	N	N
Glandular stomach:	N	N	N	N	N
Duodenum:	N	N	N	N	N
Jejunum:	N	N	N	N	N
Ileum (including Peyer's patch):	N	N	N	N	N
Cecum:	N	N	N	N	N
Colon:	N	N	N	N	N
Rectum:	N	N	N	N	N
Pancreas:	N	N	N	N	N
Liver: Hypertrophy, hepatocyte, centrilobular	-	+	+	-	-
Hypertrophy, hepatocyte, diffuse	+	-	-	+	-
Microgranuloma	++	++	+	++	-
Heart: Myocardial degeneration, focal	-	-	+	-	-
Right kidney: Cellular infiltration, inflammatory cell, renal pelvic mucosa	+	-	-	-	-
Left kidney:	N	N	N	N	N
Urinary bladder:	N	N	N	N	N
Right ovary:	N	N	N	N	N
Left ovary:	N	N	N	N	N
Right uterine horn:	N	N	N	N	N
Left uterine horn:	N	N	N	N	N
Uterine cervix:	N	N	N	N	N

N: No abnormal findings, -: normal, +: slight change, ++: moderate change.

(to be continued)

INDIVIDUAL DATA 11-4-2 (continued)

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Histopathological findings ANIMAL: Rat, Crl: CD (SD) SEX: Female GROUP: 10 mg/kg PERIOD: End of recovery

Animal No.	463	464	465	466	467
Organ: Findings					
Cerebrum:	N	N	N	N	N
Cerebellum:	N	N	N	N	N
Pons:	N	N	N	N	N
Spinal cord:	N	N	N	N	N
Sciatic nerve:	N	N	N	N	N
Spleen:	N	N	N	N	N
Thymus:	N	N	N	N	N
Bone marrow of right femur:	N	N	N	N	N
Right submandibular lymph node:	N	N	N	N	N
Left submandibular lymph node:	N	N	N	N	N
Mesenteric lymph node:	N	N	N	N	N
Pituitary gland:	N	N	N	N	N
Right thyroid:	N	N	N	N	N
Left thyroid:	N	N	N	N	N
Right parathyroid:	N	N	N	N	N
Left parathyroid:	N	N	N	N	N
Right adrenal:	N	N	N	N	N
Left adrenal:	N	N	N	N	N
Right eyeball:	N	N	N	N	N
Left eyeball:	N	N	N	N	N
Right Harderian gland:	N	N	N	N	N
Left Harderian gland:	N	N	N	N	N
Right femur:	N	N	N	N	N
Mammary gland:	N	N	N	N	N
3rd digit of left forelimb: Fibrosis, subcutis	*	*	*	++	*
Cellular infiltration, inflammatory cell, subcutis	*	*	*	+	*

N: No abnormal findings, +: slight change, ++: moderate change.
*: Not examined.

INDIVIDUAL DATA 11-5-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Statistical analysis in histopathological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of administration

Animal No.	A	B	C	D	E	F	G	H	I	J	K
101	−	−	−	−	−	−	+	+	−	−	−
102	+	−	−	−	+	−	−	−	+	−	−
104	−	−	−	−	+	−	−	−	+	−	−
105	−	+	+	−	+	+	−	−	−	+	−
110	−	−	+	−	+	−	−	−	−	−	−
111	#	#	#	−	−	#	#	#	−	#	−
112	#	#	#	−	−	#	#	#	−	#	−
N	5	5	5	7	7	5	5	5	7	5	7

H 28.5005 **
X2

A: Lung: Aggregation, macrophage, alveolar.
B: Lung: Mineralization, artery.
C: Pancreas: Atrophy, acinar cell, focal.
D: Liver: Hypertrophy, hepatocyte, centrilobular.
E: Liver: Microgranuloma.
F: Kidney: Dilatation, renal pelvis.
G: Epididymis: Spermatic granuloma.
H: Prostate: Cellular infiltration, inflammatory cell.
I: Thymus: Atrophy, cortex.
J: Pituitary gland: Cyst, pars intermedia.
K:Thyroid: Hypertrophy, follicular cell.
#: Blank.

INDIVIDUAL DATA 11-5-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Statistical analysis in histopathological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 1 mg/kg PERIOD : End of administration

Animal No.	A	B	C	D	E	F	G	H	I	J	K
201	#	#	#	−	+	#	#	#	−	#	−
202	#	#	#	−	+	#	#	#	−	#	−
203	#	#	#	−	+	#	#	#	−	#	−
204	#	#	#	−	−	#	#	#	−	#	−
205	#	#	#	−	+	#	#	#	−	#	−
206	#	#	#	−	+	#	#	#	−	#	−
207	#	#	#	−	+	#	#	#	−	#	−
208	#	#	#	−	+	#	#	#	−	#	−
209	#	#	#	−	+	#	+	#	−	#	−
210	#	#	#	−	+	#	#	#	−	#	−
211	#	#	#	−	+	#	#	#	−	#	−
212	#	#	#	−	−	#	#	#	−	#	−
N	0	0	0	12	12	0	1	0	12	0	12
U				42.0000							
p					0.2366		0.3333		0.1228		1.0000

A: Lung: Aggregation, macrophage, alveolar.
B: Lung: Mineralization, artery.
C: Pancreas: Atrophy, acinar cell, focal.
D: Liver: Hypertrophy, hepatocyte, centrilobular.
E: Liver: Microgranuloma.
F: Kidney: Dilatation, renal pelvis.
G: Epididymis: Spermatic granuloma.
H: Prostate: Cellular infiltration, inflammatory cell.
I: Thymus: Atrophy, cortex.
J: Pituitary gland: Cyst, pars intermedia.
K:Thyroid: Hypertrophy, follicular cell.
#: Blank.

INDIVIDUAL DATA 11-5-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Statistical analysis in histopathological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 3 mg/kg PERIOD : End of administration

Animal No.	A	B	C	D	E	F	G	H	I	J	K
301	#	#	#	+	−	#	+	#	−	#	−
302	#	#	#	2+	−	#	#	#	−	#	−
303	#	#	#	−	+	#	#	#	−	#	−
304	#	#	#	+	+	#	#	#	−	#	−
305	#	#	#	−	−	#	#	#	−	#	−
306	#	#	#	−	+	#	#	#	−	#	−
307	#	#	#	+	+	#	#	#	−	#	−
308	#	#	#	+	−	#	#	#	−	#	+
309	#	#	#	−	−	#	#	#	−	#	+
310	#	#	#	2+	−	#	#	#	−	#	−
311	#	#	#	+	+	#	#	#	−	#	+
312	#	#	#	+	+	#	#	#	−	#	+
N	0	0	0	12	12	0	1	0	12	0	12
U				14.0000 *							
p					0.5700		0.3333		0.1228		0.1277

A: Lung: Aggregation, macrophage, alveolar.
B: Lung: Mineralization, artery.
C: Pancreas: Atrophy, acinar cell, focal.
D: Liver: Hypertrophy, hepatocyte, centrilobular.
E: Liver: Microgranuloma.
F: Kidney: Dilatation, renal pelvis.
G: Epididymis: Spermatic granuloma.
H: Prostate: Cellular infiltration, inflammatory cell.
I: Thymus: Atrophy, cortex.
J: Pituitary gland: Cyst, pars intermedia.
K:Thyroid: Hypertrophy, follicular cell.
#: Blank.

INDIVIDUAL DATA 11-5-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Statistical analysis in histopathological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : End of administration

Animal No.	A	B	C	D	E	F	G	H	I	J	K
401	−	−	−	2+	−	−	−	−	−	−	−
403	−	−	−	2+	−	−	−	+	−	−	+
404	−	+	−	2+	−	−	−	−	−	−	+
407	−	−	−	2+	+	−	−	+	−	−	+
408	−	+	−	2+	−	−	−	−	+	−	+
411	#	#	#	2+	−	#	#	#	−	#	−
412	#	#	#	2+	−	#	#	#	−	#	−
N	5	5	5	7	7	5	5	5	7	5	7
U				0.0000 **							
p	0.5000	0.5000	0.2222		0.1329	0.5000	0.5000	0.5000	0.5000	0.5000	0.0350

A: Lung: Aggregation, macrophage, alveolar.
B: Lung: Mineralization, artery.
C: Pancreas: Atrophy, acinar cell, focal.
D: Liver: Hypertrophy, hepatocyte, centrilobular.
E: Liver: Microgranuloma.
F: Kidney: Dilatation, renal pelvis.
G: Epididymis: Spermatic granuloma.
H: Prostate: Cellular infiltration, inflammatory cell.
I: Thymus: Atrophy, cortex.
J: Pituitary gland: Cyst, pars intermedia.
K:Thyroid: Hypertrophy, follicular cell.
#: Blank.

INDIVIDUAL DATA 11-6-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Statistical analysis in histopathological findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : End of administration

Animal No.	A	B	C	D	E	F	G	H	I	J	K	L
151	#	#	#	#	−	−	−	#	+	−	−	#
152	−	−	−	−	−	−	−	−	+	−	−	−
153	−	+	−	−	−	−	−	−	−	−	−	−
154	−	−	−	−	−	+	−	−	−	−	−	−
155	#	#	#	#	−	−	−	#	−	−	−	#
156	#	#	#	#	−	+	−	#	−	−	−	#
157	#	#	#	#	−	+	−	#	−	−	−	#
158	−	−	−	−	−	+	−	−	−	−	−	−
159	#	#	#	#	−	−	−	#	−	−	−	#
160	#	#	#	#	−	+	−	#	−	−	−	#
161	−	−	+	−	−	−	−	+	−	−	−	−
162	#	#	#	#	−	+	−	#	−	−	+	#
N	5	5	5	5	12	12	12	5	12	12	12	5

H 11.5632 **
X2

A: Lung: Aggregation, macrophage, alveolar.
B: Lung: Mineralization, artery.
C: Lung: Metaplasis, osseous, alveoli.
D: Pancreas: Atrophy, acinar cell, focal.
E: Liver: Hypertrophy, hepatocyte, centrilobular.
F: Liver: Microgranuloma.
G: Liver: Necrosis, focal.
H: Kidney: Cellular infiltration, inflammatory cell, renal pelvic mucosa.
I: Spleen: Decrease, extramedullary hematopoiesis.
J: Spleen: Capsulitis.
K: Thymus: Atrophy, cortex.
L: Pituitary gland: Cyst, pars distalis.
#: Blank.

INDIVIDUAL DATA 11-6-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Statistical analysis in histopathological findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg PERIOD : End of administration

Animal No.	A	B	C	D	E	F	G	H	I	J	K	L
251	#	#	#	#	−	+	−	#	−	−	−	#
252	#	#	#	#	−	−	−	#	−	−	−	#
253	#	#	#	#	−	+	−	#	−	−	−	#
254	#	#	#	#	−	+	−	#	−	−	+	#
255	#	#	#	#	−	−	−	#	−	−	−	#
256	#	#	#	#	−	+	−	#	−	−	+	#
257	#	#	#	#	−	+	−	#	−	−	−	#
258	#	#	#	#	−	−	−	#	−	−	−	#
259	#	#	#	#	−	+	−	#	−	−	−	#
260	#	#	#	#	−	+	−	#	−	−	−	#
261	#	#	#	#	−	+	−	#	−	−	−	#
262	#	#	#	#	−	+	−	#	−	−	−	#
N	0	0	0	0	12	12	12	0	12	12	12	0
U						54.0000						
p					1.0000		1.0000		0.2391	1.0000	0.5000	

A: Lung: Aggregation, macrophage, alveolar.
B: Lung: Mineralization, artery.
C: Lung: Metaplasis, osseous, alveoli.
D: Pancreas: Atrophy, acinar cell, focal.
E: Liver: Hypertrophy, hepatocyte, centrilobular.
F: Liver: Microgranuloma.
G: Liver: Necrosis, focal.
H: Kidney: Cellular infiltration, inflammatory cell, renal pelvic mucosa.
I: Spleen: Decrease, extramedullary hematopoiesis.
J: Spleen: Capsulitis.
K: Thymus: Atrophy, cortex.
L: Pituitary gland: Cyst, pars distalis.
#: Blank.

INDIVIDUAL DATA 11-6-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Statistical analysis in histopathological findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg PERIOD : End of administration

Animal No.	A	B	C	D	E	F	G	H	I	J	K	L
351	#	#	#	#	−	+	−	#	−	−	−	#
352	#	#	#	#	−	+	−	#	−	−	−	#
353	#	#	#	#	−	−	−	#	−	−	−	#
354	#	#	#	#	−	+	−	#	−	−	−	#
355	#	#	#	#	−	+	−	#	−	−	−	#
356	#	#	#	#	−	+	−	#	−	−	−	#
357	#	#	#	#	−	−	−	#	+	−	−	#
358	#	#	#	#	−	+	−	#	−	−	−	#
359	#	#	#	#	−	−	−	#	+	−	−	#
360	#	#	#	#	−	+	−	#	−	−	−	#
361	#	#	#	#	−	+	−	#	−	−	−	#
362	#	#	#	#	−	−	−	#	−	−	+	#
N	0	0	0	0	12	12	12	0	12	12	12	0
U						60.0000						
p					1.0000		1.0000		0.7050	1.0000	0.7609	

A: Lung: Aggregation, macrophage, alveolar.
B: Lung: Mineralization, artery.
C: Lung: Metaplasis, osseous, alveoli.
D: Pancreas: Atrophy, acinar cell, focal.
E: Liver: Hypertrophy, hepatocyte, centrilobular.
F: Liver: Microgranuloma.
G: Liver: Necrosis, focal.
H: Kidney: Cellular infiltration, inflammatory cell, renal pelvic mucosa.
I: Spleen: Decrease, extramedullary hematopoiesis.
J: Spleen: Capsulitis.
K: Thymus: Atrophy, cortex.
L: Pituitary gland: Cyst, pars distalis.
#: Blank.

INDIVIDUAL DATA 11-6-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Statistical analysis in histopathological findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : End of administration

Animal No.	A	B	C	D	E	F	G	H	I	J	K	L
451	+	−	−	−	−	+	+	−	+	−	+	−
452	#	#	#	#	+	2+	−	#	−	−	+	#
453	#	#	#	#	−	+	−	#	−	−	−	#
454	#	#	#	#	+	2+	−	#	+	−	+	#
455	#	#	#	#	+	2+	−	#	+	−	+	#
456	#	#	#	#	+	−	−	#	+	−	−	#
457	−	−	−	−	+	+	−	−	+	−	+	−
458	+	−	−	−	+	2+	−	−	+	−	−	−
459	−	−	−	−	+	2+	−	−	−	+	+	+
460	#	#	#	#	+	2+	−	#	+	−	−	#
461	+	−	−	+	+	2+	−	−	+	−	+	−
462	#	#	#	#	−	−	−	#	−	−	+	#
N	5	5	5	5	12	12	12	5	12	12	12	5
U						27.0000 **						
p	0.0833	0.5000	0.5000	0.5000	0.0002 **		0.5000	0.5000	0.0180 *	0.5000	0.0047 **	0.5000

A: Lung: Aggregation, macrophage, alveolar.
B: Lung: Mineralization, artery.
C: Lung: Metaplasis, osseous, alveoli.
D: Pancreas: Atrophy, acinar cell, focal.
E: Liver: Hypertrophy, hepatocyte, centrilobular.
F: Liver: Microgranuloma.
G: Liver: Necrosis, focal.
H: Kidney: Cellular infiltration, inflammatory cell, renal pelvic mucosa.
I: Spleen: Decrease, extramedullary hematopoiesis.
J: Spleen: Capsulitis.
K: Thymus: Atrophy, cortex.
L: Pituitary gland: Cyst, pars distalis.
#: Blank.

INDIVIDUAL DATA 11-7-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Statistical analysis in histopathological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 0 mg/kg PERIOD : End of recovery

Animal No.	A	B	C	D	E	F	G	H	I	J	K	L	M	N
103	−	−	−	−	−	+	−	−	−	−	−	−	−	−
106	−	−	−	−	−	+	−	+	+	−	−	+	−	−
107	−	−	−	−	−	−	−	+	+	−	−	−	−	−
108	−	+	−	−	−	+	−	−	−	−	−	−	−	+
109	−	+	−	−	−	−	−	−	−	−	+	−	−	−
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5

H
X2 8.0357 **

A: Lung: Aggregation, macrophage, alveolar.
B: Lung: Mineralization, artery.
C: Lung: Fibrosis, pleura.
D: Lung: Cellular infiltration, inflammatory cell, pleura.
E: Liver: Hypertrophy, hepatocyte, centrilobular.
F: Liver: Microgranuloma.
G: Liver: Fatty change, diffuse.
H:Kidney: Hyaline droplet, proximal tubular epithelium.
I: Kidney: Eosinophilic body, proximal tubular epithelium.
J: Kidney: Regeneration, tubular epithelium.
K: Kidney: Cast, hyaline.
L: Prostate: Cellular infiltration, inflammatory cell.
M: Thyroid: Hypertrophy, follicular cell.
N: Harderian galnd: Cellular infiltration, inflammatory cell.

INDIVIDUAL DATA 11-7-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Statistical analysis in histopathological findings ANIMAL : Rat, Crl:CD(SD) SEX : Male GROUP : 10 mg/kg PERIOD : End of recovery

Animal No.	A	B	C	D	E	F	G	H	I	J	K	L	M	N
402	−	+	−	−	+	+	+	+	+	−	−	−	−	−
405	−	+	−	−	2+	+	−	−	−	−	−	−	+	−
406	−	−	−	−	2+	+	−	−	−	+	+	+	+	−
409	−	−	−	−	+	+	+	−	−	−	−	−	−	−
410	+	−	+	+	2+	−	−	−	−	−	−	+	−	−
N	5	5	5	5	5	5	5	5	5	5	5	5	5	5
U					0.0000 **									
p	0.5000	0.7381	0.5000	0.5000		0.5000	0.2222	0.5000	0.5000	0.5000	0.7778	0.5000	0.2222	0.5000

A: Lung: Aggregation, macrophage, alveolar.
B: Lung: Mineralization, artery.
C: Lung: Fibrosis, pleura.
D: Lung: Cellular infiltration, inflammatory cell, pleura.
E: Liver: Hypertrophy, hepatocyte, centrilobular.
F: Liver: Microgranuloma.
G: Liver: Fatty change, diffuse.
H:Kidney: Hyaline droplet, proximal tubular epithelium.
I: Kidney: Eosinophilic body, proximal tubular epithelium.
J: Kidney: Regeneration, tubular epithelium.
K: Kidney: Cast, hyaline.
L: Prostate: Cellular infiltration, inflammatory cell.
M: Thyroid: Hypertrophy, follicular cell.
N: Harderian galnd: Cellular infiltration, inflammatory cell.

INDIVIDUAL DATA 11-8-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Statistical analysis in histopathological findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg PERIOD : End of recovery

Animal No.	A	B	C	D	E	F
163	−	−	−	+	−	−
164	−	−	−	+	−	−
165	−	−	−	−	−	−
166	−	−	−	+	−	−
167	−	−	−	+	−	−
N	5	5	5	5	5	5
H				1.8514		
X2						

A: Lung: Aggregation, macrophage, alveolar.
B: Liver: Hypertrophy, hepatocyte, centrilobular.
C: Liver: Hypertrophy, hepatocyte, diffuse.
D: Liver: Microgranuloma.
E: Heart: Myocardial degeneration, focal.
F: Kidney: Cellular infiltration, inflammatory cell, renal pelvic mucosa.

INDIVIDUAL DATA 11-8-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Statistical analysis in histopathological findings ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg PERIOD : End of recovery

Animal No.	A	B	C	D	E	F
463	−	−	+	2+	−	+
464	−	+	−	2+	−	−
465	−	+	−	+	+	−
466	+	−	+	2+	−	−
467	+	−	−	−	−	−
N	5	5	5	5	5	5
p	0.2222	0.2222	0.2222		0.5000	0.5000

A: Lung: Aggregation, macrophage, alveolar.
B: Liver: Hypertrophy, hepatocyte, centrilobular.
C: Liver: Hypertrophy, hepatocyte, diffuse.
D: Liver: Microgranuloma.
E: Heart: Myocardial degeneration, focal.
F: Kidney: Cellular infiltration, inflammatory cell, renal pelvic mucosa.

INDIVIDUAL DATA 12-1-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Estrous cycle, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal	Administration day																											
	Before mating day														Mating day													Additional mating day
No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	1	2	3	4	5	6	7	8	9	10	11	12	13	14	1
151	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#	#	#	#	#	#	#	#	#	#	#	#	#
152	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#	#	#	#	#	#	#	#	#	#	#	#	#	#
153	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#	#	#	#	#	#	#	#	#	#	#	#
154	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#	#	#	#	#	#	#	#	#	#	#	#	#
155	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#	#	#	#	#	#	#	#	#	#	#	#
156	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	V	V	V	V	V	V	V	V	V	V	V	II	IIIC
157	IV	V	II	III	IV	V	II	III	IV	V	V	III	IV	V	II	IIIC	#	#	#	#	#	#	#	#	#	#	#	#	#
158	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#	#	#	#	#	#	#	#	#	#	#	#	#
159	III	III	IV	V	V	II	III	IV	V	V	II	III	IV	V	II	IIIC	#	#	#	#	#	#	#	#	#	#	#	#	#
160	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#	#	#	#	#	#	#	#	#	#	#	#
161	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#	#	#	#	#	#	#	#	#	#	#	#	#
162	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#	#	#	#	#	#	#	#	#	#	#

II: Proestrus. III: Estrus. IV: Metestrus. V: Diestrus. C: Copulated.
#: Blank.

INDIVIDUAL DATA 12-1-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Estrous cycle, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg

Animal	Administration day																											
	Before mating day														Mating day													Additional mating day
No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	1	2	3	4	5	6	7	8	9	10	11	12	13	14	1
251	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#	#	#	#	#	#	#	#	#	#	#	#
252	IV	V	II	III	IV	V	II	III	IV	V	V	III	IV	V	II	IIIC	#	#	#	#	#	#	#	#	#	#	#	#	#
253	IV	V	II	III	IV	V	II	III	IV	V	V	III	IV	V	II	IIIC	#	#	#	#	#	#	#	#	#	#	#	#	#
254	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#	#	#	#	#	#	#	#	#	#	#	#	#	#
255	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#	#	#	#	#	#	#	#	#	#	#	#	#
256	II	III	IV	V	V	III	IV	V	II	III	IV	V	II	III	IV	V	V	V	V	V	V	V	V	V	V	V	V	II	IIIC
257	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#	#	#	#	#	#	#	#	#	#	#
258	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#	#	#	#	#	#	#	#	#	#	#
259	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#	#	#	#	#	#	#	#	#	#	#
260	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#	#	#	#	#	#	#	#	#	#	#
261	V	V	II	III	III	IV	V	II	III	III	IV	V	III	IV	V	II	IIIC	#	#	#	#	#	#	#	#	#	#	#	#
262	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#	#	#	#	#	#	#	#	#	#	#	#	#

II: Proestrus. III: Estrus. IV: Metestrus. V: Diestrus. C: Copulated.
#: Blank.

INDIVIDUAL DATA 12-1-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Estrous cycle, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg

Animal	Administration day																	
	Before mating day														Mating day			
No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	1	2	3	4
351	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#	#
352	III	IV	V	II	III	IV	V	II	III	IV	V	V	II	III	IV	V	II	IIIC
353	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#
354	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#
355	II	III	IV	V	V	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC
356	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#	#	#
357	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC
358	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#	#
359	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	VC	#	#	#
360	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#
361	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#	#
362	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#

II: Proestrus. III: Estrus. IV: Metestrus. V: Diestrus. C: Copulated.
#: Blank.

INDIVIDUAL DATA 12-1-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Estrous cycle, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg

Animal	Administration day																	
	Before mating day														Mating day			
No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	1	2	3	4
451	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#
452	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC
453	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#
454	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#
455	V	V	III	IV	V	II	III	IV	V	V	II	III	IV	V	V	II	IIIC	#
456	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#
457	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#	#
458	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#	#
459	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#	#
460	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC
461	IV	V	II	III	IV	V	II	III	IV	V	V	III	IV	V	II	IIIC	#	#
462	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	IIIC	#

II: Proestrus. III: Estrus. IV: Metestrus. V: Diestrus. C: Copulated.
#: Blank.

INDIVIDUAL DATA 12-2-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Estrous cycle, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Administration day																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
163	II	III	IV	V	V	III	IV	V	II	III	IV	V	II	III	IV	V	V	III	IV	V	II	III	IV	V	II	III	IV	V
164	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II
165	IV	V	II	III	IV	V	II	III	IV	V	V	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III
166	IV	V	II	III	IV	V	II	II	III	IV	V	V	III	III	IV	V	V	III	IV	V	V	II	III	IV	V	V	III	III
167	II	III	IV	V	V	III	IV	V	II	III	III	IV	V	II	III	III	IV	V	V	II	III	IV	V	V	II	III	III	IV

Animal No.	Administration day														Estrous cycle	
	29	30	31	32	33	34	35	36	37	38	39	40	41	42	Normality	Length (days)
163	V	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	Normal	4.0
164	III	IV	V	V	III	IV	V	II	III	IV	V	II	III	IV	Normal	4.0
165	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	Normal	4.0
166	IV	V	V	II	III	IV	V	V	III	IV	V	V	II	III	Normal	4.8
167	V	II	III	IV	V	V	II	III	IV	V	V	II	III	IV	Normal	4.9

II: Proestrus. III: Estrus. IV: Metestrus. V: Diestrus.

Normal estrous cycle (%)		
	N	5
	MEAN	4.34
5/5 (100)	S.D.	0.47

Estrous cycle: Normal; Female rats cycling normally (defined as having a mean cycle length between 4 and 6 days).
Normal estrous cycle = (number of female with normal estrous cycle / number of females examined) x 100.

(to be continued)

INDIVIDUAL DATA 12-2-1 (continued)

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Estrous cycle, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Recovery day 1	2	3	4	5	6	7	8	9	10	11	12	13	14	A	Estrous cycle Normality	Length (days)
163	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	Normal	4.0
164	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	Normal	4.0
165	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	Normal	4.0
166	IV	V	V	II	III	IV	V	V	V	III	III	IV	V	V	II	Normal	6.0
167	V	II	III	IV	V	II	III	IV	V	V	III	IV	V	V	II	Normal	4.0

II: Proestrus. III: Estrus. IV: Metestrus. V: Diestrus.
A: Autopsy day.

Normal estrous cycle (%)		
5/5 (100)	N	5
	MEAN	4.40
	S.D.	0.89

Estrous cycle: Normal; Female rats cycling normally (defined as having a mean cycle length between 4 and 6 days).
Normal estrous cycle = (number of female with normal estrous cycle / number of females examined) x 100.

INDIVIDUAL DATA 12-2-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Estrous cycle, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg

Animal No.	Administration day																										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
463	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III
464	II	III	IV	V	V	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V
465	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III
466	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III
467	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II

Animal No.	Administration day														Estrous cycle	
	29	30	31	32	33	34	35	36	37	38	39	40	41	42	Normality	Length (days)
463	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	Normal	4.0
464	II	III	IV	V	V	III	IV	V	II	III	IV	V	II	III	Normal	4.0
465	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	Normal	4.0
466	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	Normal	4.0
467	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	Normal	4.0

II: Proestrus. III: Estrus. IV: Metestrus. V: Diestrus.

Normal estrous cycle (%)		
	N	5
	MEAN	4.00
5/5 (100)	S.D.	0.00

Estrous cycle: Normal; Female rats cycling normally (defined as having a mean cycle length between 4 and 6 days).
Normal estrous cycle = (number of female with normal estrous cycle / number of females examined) x 100.

(to be continued)

INDIVIDUAL DATA 12-2-2 (continued)

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Estrous cycle, Recovery group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg

Animal No.	Recovery day 1	2	3	4	5	6	7	8	9	10	11	12	13	14	A	Estrous cycle Normality	Length (days)
463	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	IV	Normal	4.0
464	IV	V	II	III	IV	V	II	III	IV	V	V	III	IV	V	V	Normal	4.0
465	II	III	IV	V	II	III	IV	V	II	II	III	IV	V	II	III	Normal	4.3
466	II	III	IV	V	II	III	IV	V	V	V	V	V	V	V	V	Abnormal (continuous diestrous)	#
467	V	II	III	IV	V	II	III	IV	V	II	III	IV	V	II	III	Normal	4.0

II: Proestrus. III: Estrus. IV: Metestrus. V: Diestrus.
A: Autopsy day.

Normal estrous cycle (%)		
	N	4
	MEAN	4.08
4/5 (80.0)	S.D.	0.15

Estrous cycle: Normal; Female rats cycling normally (defined as having a mean cycle length between 4 and 6 days).
Normal estrous cycle = (number of female with normal estrous cycle / number of females examined) x 100.
#: Blank.

INDIVIDUAL DATA 13-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Reproduction performance, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg

Female No.	Estrous cycle		Paired male No.	Copulation			Pregnancy	Parturition	Gestation length (days)	Nursing
				Mating week						
	Normality	Length (days)		1	2	3[a]				
151	Normal	4.0	101	+	#	#	+	+	24	+
152	Normal	4.0	102	+	#	#	+	+	22	+
153	Normal	4.0	103	+	#	#	+	+	22	+
154	Normal	4.0	104	+	#	#	+	+	22	+
155	Normal	4.0	105	+	#	#	+	+	22	+
156	Abnormal (continuous diestrous)	#	106	-	-	+	+	+	22	+
157	Normal	4.0	107	+	#	#	+	+	23	+
158	Normal	4.0	108	+	#	#	+	+	22	+
159	Normal	4.7	109	+	#	#	+	+	23	+
160	Normal	4.0	110	+	#	#	+	+	22	+
161	Normal	4.0	111	+	#	#	+	+	22	+
162	Normal	4.0	112	+	#	#	+	+	22	+
N		11							12	
MEAN		4.06							22.3	
S.D.		0.21							0.7	

Normal estrous cycle (%)	Copulation index (%) Male	Copulation index (%) Female	Fertility index (%)	Gestation index (%)	Nursing index (%)
11/12 (91.7)	11/12 (91.7)	12/12 (100)	12/12 (100)	12/12 (100)	12/12 (100)

Estrous cycle: Normal; Female rats cycling normally (defined as having a mean cycle length between 4 and 6 days).
Copulation and pregnancy : -, Negative; +, Positive.
Parturition and nursing : +, Normal.
Normal estrous cycle = (number of females with normal estrous cycle / number of females examined) x 100.
Copulation index = (number of animals with successful copulation / number of animals mated) x 100.
Fertility index = (number of pregnant females / number of pairs with successful copulation) x 100.
Gestation index = (number of females with live pups / number of pregnant females) x 100.
Nursing index = (number of females nursing live pups on lactation day 4 / number of females with live pups delivery) x 100.
a: Additional mating was performed in Animal number 156 (paired male number was 101).
#: Blank.

INDIVIDUAL DATA 13-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Reproduction performance, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg

Female No.	Estrous cycle		Paired male No.	Copulation			Pregnancy	Parturition	Gestation length (days)	Nursing
				Mating week						
	Normality	Length (days)		1	2	3[a]				
251	Normal	4.0	201	+	#	#	+	+	23	+
252	Normal	4.0	202	+	#	#	+	+	22	+
253	Normal	4.0	203	+	#	#	+	+	22	+
254	Normal	4.0	204	+	#	#	+	+	23	+
255	Normal	4.0	205	+	#	#	+	+	23	+
256	Abnormal (continuous diestrous)	#	206	-	-	+	+	+	22	+
257	Normal	4.0	207	+	#	#	+	+	22	+
258	Normal	4.0	208	+	#	#	+	+	22	+
259	Normal	4.0	209	+	#	#	+	+	22	+
260	Normal	4.0	210	+	#	#	+	+	22	+
261	Normal	4.0	211	+	#	#	+	+	23	+
262	Normal	4.0	212	+	#	#	+	+	22	+
N		11							12	
MEAN		4.00							22.3	
S.D.		0.00							0.5	

Normal estrous cycle (%)	Copulation index (%) Male	Copulation index (%) Female	Fertility index (%)	Gestation index (%)	Nursing index (%)
11/12 (91.7)	11/12 (91.7)	12/12 (100)	12/12 (100)	12/12 (100)	12/12 (100)

Estrous cycle: Normal; Female rats cycling normally (defined as having a mean cycle length between 4 and 6 days).
Copulation and pregnancy : -, Negative; +, Positive.
Parturition and nursing : +, Normal.
Normal estrous cycle = (number of females with normal estrous cycle / number of females examined) x 100.
Copulation index = (number of animals with successful copulation / number of animals mated) x 100.
Fertility index = (number of pregnant females / number of pairs with successful copulation) x 100.
Gestation index = (number of females with live pups / number of pregnant females) x 100.
Nursing index = (number of females nursing live pups on lactation day 4 / number of females with live pups delivery) x 100.
a: Additional mating was performed in Animal number 256 (paired male number was 201).
#: Blank.

INDIVIDUAL DATA 13-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Reproduction performance, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg

Female No.	Estrous cycle		Paired male No.	Copulation		Pregnancy	Parturition	Gestation length (days)	Nursing
				Mating week					
	Normality	Length (days)		1	2				
351	Normal	4.0	301	+	#	+	+	22	+
352	Normal	4.3	302	+	#	+	+	23	+
353	Normal	4.0	303	+	#	+	+	22	+
354	Normal	4.0	304	+	#	+	+	22	+
355	Normal	4.0	305	+	#	+	+	22	+
356	Normal	4.0	306	+	#	+	+	22	+
357	Normal	4.0	307	+	#	+	+	22	+
358	Normal	4.0	308	+	#	+	+	22	+
359	Abnormal (cycling shortened)	3.5	309	+	#	-	#	#	#
360	Normal	4.0	310	+	#	+	+	22	+
361	Normal	4.0	311	+	#	+	+	22	+
362	Normal	4.0	312	+	#	+	+	23	+
N		12						11	
MEAN		3.98						22.2	
S.D.		0.17						0.4	

Normal estrous cycle (%)	Copulation index (%) Male	Copulation index (%) Female	Fertility index (%)	Gestation index (%)	Nursing index (%)
11/12 (91.7)	12/12 (100)	12/12 (100)	11/12 (91.7)	11/11 (100)	11/11 (100)

Estrous cycle: Normal; Female rats cycling normally (defined as having a mean cycle length between 4 and 6 days).
Copulation and pregnancy : -, Negative; +, Positive.
Parturition and nursing : +, Normal.
Normal estrous cycle = (number of females with normal estrous cycle / number of females examined) x 100.
Copulation index = (number of animals with successful copulation / number of animals mated) x 100.
Fertility index = (number of pregnant females / number of pairs with successful copulation) x 100.
Gestation index = (number of females with live pups / number of pregnant females) x 100.
Nursing index = (number of females nursing live pups on lactation day 4 / number of females with live pups delivery) x 100.
#: Blank.

INDIVIDUAL DATA 13-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Reproduction performance, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg

Female No.	Estrous cycle		Paired male No.	Copulation		Pregnancy	Parturition	Gestation length (days)	Nursing
				Mating week					
	Normality	Length (days)		1	2				
451	Normal	4.0	401	+	#	+	+	22	+
452	Normal	4.0	402	+	#	+	+	22	+
453	Normal	4.0	403	+	#	+	+	22	+
454	Normal	4.0	404	+	#	+	+	22	+
455	Normal	4.7	405	+	#	+	+	22	+
456	Normal	4.0	406	+	#	+	+	22	+
457	Normal	4.0	407	+	#	+	+	22	+
458	Normal	4.0	408	+	#	+	+	22	+
459	Normal	4.0	409	+	#	+	+	22	+
460	Normal	4.0	410	+	#	+	+	22	+
461	Normal	4.0	411	+	#	+	+	22	+
462	Normal	4.0	412	+	#	+	+	22	+
N		12						12	
MEAN		4.06						22.0	
S.D.		0.20						0.0	

Normal estrous cycle (%)	Copulation index (%) Male	Copulation index (%) Female	Fertility index (%)	Gestation index (%)	Nursing index (%)
12/12 (100)	12/12 (100)	12/12 (100)	12/12 (100)	12/12 (100)	12/12 (100)

Estrous cycle: Normal; Female rats cycling normally (defined as having a mean cycle length between 4 and 6 days).
Copulation and pregnancy : +, Positive.
Parturition and nursing : +, Normal.
Normal estrous cycle = (number of females with normal estrous cycle / number of females examined) x 100.
Copulation index = (number of animals with successful copulation / number of animals mated) x 100.
Fertility index = (number of pregnant females / number of pairs with successful copulation) x 100.
Gestation index = (number of females with live pups / number of pregnant females) x 100.
Nursing index = (number of females nursing live pups on lactation day 4 / number of females with live pups delivery) x 100.
#: Blank.

INDIVIDUAL DATA 14-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Pregnancy and litter data, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 0 mg/kg

Animal No.	Number of corpora lutea	Number of implanta-tion sites	Implanta-tion index (%)	Delivery index (%)	Lactation day 0										Lactation day 4			
					Number of pups delivered					Sex ratio				Live birth index (%)	Number of live pups	Sex ratio		Viability index (%)
					Total	Male	Female	Alive	Dead	All pups		Live pups				All pups		
151	14	13	92.86	30.77	4	1	3	4	0	1/4	0.25	1/4	0.25	100.00	4	1/4	0.25	100.00
152	18	17	94.44	94.12	16	9	7	16	0	9/16	0.56	9/16	0.56	100.00	16	9/16	0.56	100.00
153	16	16	100.00	100.00	16	6	10	16	0	6/16	0.38	6/16	0.38	100.00	15	5/15	0.33	93.75
154	16	16	100.00	100.00	16	7	9	16	0	7/16	0.44	7/16	0.44	100.00	15	7/15	0.47	93.75
155	15	15	100.00	86.67	13	6	7	13	0	6/13	0.46	6/13	0.46	100.00	13	6/13	0.46	100.00
156	19	18	94.74	100.00	18	10	8	18	0	10/18	0.56	10/18	0.56	100.00	17	9/17	0.53	94.44
157	18	15	83.33	86.67	13	5	8	13	0	5/13	0.38	5/13	0.38	100.00	13	5/13	0.38	100.00
158	20	19	95.00	100.00	19	9	10	19	0	9/19	0.47	9/19	0.47	100.00	18	9/18	0.50	94.74
159	16	16	100.00	81.25	13	6	7	13	0	6/13	0.46	6/13	0.46	100.00	13	6/13	0.46	100.00
160	17	16	94.12	100.00	16	9	7	16	0	9/16	0.56	9/16	0.56	100.00	16	9/16	0.56	100.00
161	14	14	100.00	100.00	14	6	8	14	0	6/14	0.43	6/14	0.43	100.00	14	6/14	0.43	100.00
162	17	17	100.00	94.12	16	11	5	16	0	11/16	0.69	11/16	0.69	100.00	15	10/15	0.67	93.75
N	12	12	12	12	12	12	12	12	12		12		12	12	12		12	12
MEAN	16.7	16.0	96.208	89.467	14.5	7.1	7.4	14.5	0.0		0.470		0.470	100.000	14.1		0.467	97.536
S.D.	1.9	1.7	4.995	19.627	3.8	2.7	2.0	3.8	0.0		0.113		0.113	0.000	3.6		0.112	3.059
S.E.	0.5	0.5	1.442	5.666	1.1	0.8	0.6	1.1	0.0		0.033		0.033	0.000	1.0		0.032	0.883
M/C	0.8808	0.4841	10.5958 *	31.7218 **	8.5038 *	3.2638	0.0763	8.7296 *	∞ **		0.7004		0.8779	∞ **	11.7204 **		1.4013	9.7591 *
F	0.4817	0.1870				1.2152	0.2988				1.2490		1.1771				0.9596	
H			2.6863	1.0128	0.9679			1.0578	3.2727					3.2727	0.5021			5.4888

Implantation index = (number of implantation sites / number of corpora lutea) x 100.
Delivery index = (number of pups born / number of implantation sites) x 100.
Sex ratio on lactation day 0 = (number of male pups born / number of pups born) or (number of live male pups / number of live pups).
Sex ratio on lactation day 4 = number of live male pups / number of live pups.
Live birth index = (number of live pups on lactation day 0 / number of pups born) x 100.
Viability index on lactation day 4 = (number of live pups on lactation day 4 / number of live pups on lactation day 0) x 100.

INDIVIDUAL DATA 14-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Pregnancy and litter data, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 1 mg/kg

Animal No.	Number of corpora lutea	Number of implanta-tion sites	Implanta-tion index (%)	Delivery index (%)	Lactation day 0										Lactation day 4			
					Number of pups delivered					Sex ratio				Live birth index (%)	Number of live pups	Sex ratio		Viability index (%)
					Total	Male	Female	Alive	Dead	All pups		Live pups				All pups		
251	15	14	93.33	100.00	14	7	7	14	0	7/14	0.50	7/14	0.50	100.00	14	7/14	0.50	100.00
252	14	14	100.00	92.86	13	9	4	13	0	9/13	0.69	9/13	0.69	100.00	13	9/13	0.69	100.00
253	20	19	95.00	100.00	19	11	8	19	0	11/19	0.58	11/19	0.58	100.00	19	11/19	0.58	100.00
254	16	16	100.00	100.00	16	8	8	16	0	8/16	0.50	8/16	0.50	100.00	16	8/16	0.50	100.00
255	16	16	100.00	81.25	13	6	7	13	0	6/13	0.46	6/13	0.46	100.00	13	6/13	0.46	100.00
256	16	16	100.00	100.00	16	9	7	16	0	9/16	0.56	9/16	0.56	100.00	16	9/16	0.56	100.00
257	15	15	100.00	86.67	13	7	6	13	0	7/13	0.54	7/13	0.54	100.00	13	7/13	0.54	100.00
258	18	17	94.44	94.12	16	6	10	16	0	6/16	0.38	6/16	0.38	100.00	16	6/16	0.38	100.00
259	19	19	100.00	94.74	18	7	11	18	0	7/18	0.39	7/18	0.39	100.00	17	7/17	0.41	94.44
260	17	17	100.00	100.00	17	8	9	17	0	8/17	0.47	8/17	0.47	100.00	15	6/15	0.40	88.24
261	16	16	100.00	93.75	15	10	5	15	0	10/15	0.67	10/15	0.67	100.00	14	9/14	0.64	93.33
262	15	15	100.00	93.33	14	9	5	14	0	9/14	0.64	9/14	0.64	100.00	14	9/14	0.64	100.00
N	12	12	12	12	12	12	12	12	12		12		12	12	12		12	12
MEAN	16.4	16.2	98.564	94.727	15.3	8.1	7.3	15.3	0.0		0.532		0.532	100.000	15.0		0.525	98.001
S.D.	1.8	1.6	2.623	5.972	2.0	1.6	2.1	2.0	0.0		0.101		0.101	0.000	1.9		0.102	3.882
S.E.	0.5	0.5	0.757	1.724	0.6	0.5	0.6	0.6	0.0		0.029		0.029	0.000	0.5		0.029	1.121

Implantation index = (number of implantation sites / number of corpora lutea) x 100.
Delivery index = (number of pups born / number of implantation sites) x 100.
Sex ratio on lactation day 0 = (number of male pups born / number of pups born) or (number of live male pups / number of live pups).
Sex ratio on lactation day 4 = number of live male pups / number of live pups.
Live birth index = (number of live pups on lactation day 0 / number of pups born) x 100.
Viability index on lactation day 4 = (number of live pups on lactation day 4 / number of live pups on lactation day 0) x 100.

INDIVIDUAL DATA 14-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Pregnancy and litter data, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 3 mg/kg

Animal No.	Number of corpora lutea	Number of implanta-tion sites	Implanta-tion index (%)	Delivery index (%)	Lactation day 0										Lactation day 4			
					Number of pups delivered					Sex ratio				Live birth index (%)	Number of live pups	Sex ratio		Viability index (%)
					Total	Male	Female	Alive	Dead	All pups		Live pups				All pups		
351	13	13	100.00	100.00	13	7	6	13	0	7/13	0.54	7/13	0.54	100.00	13	7/13	0.54	100.00
352	15	15	100.00	100.00	15	6	9	15	0	6/15	0.40	6/15	0.40	100.00	15	6/15	0.40	100.00
353	17	17	100.00	100.00	17	9	8	17	0	9/17	0.53	9/17	0.53	100.00	17	9/17	0.53	100.00
354	15	14	93.33	92.86	13	8	5	13	0	8/13	0.62	8/13	0.62	100.00	13	8/13	0.62	100.00
355	19	19	100.00	100.00	19	11	8	19	0	11/19	0.58	11/19	0.58	100.00	18	11/18	0.61	94.74
356	15	15	100.00	93.33	14	5	9	14	0	5/14	0.36	5/14	0.36	100.00	14	5/14	0.36	100.00
357	16	16	100.00	81.25	13	5	8	13	0	5/13	0.38	5/13	0.38	100.00	13	5/13	0.38	100.00
358	16	15	93.75	93.33	14	8	6	14	0	8/14	0.57	8/14	0.57	100.00	14	8/14	0.57	100.00
359[a]	#	#	#	#	#	#	#	#	#	#/#	#	#/#	#	#	#	#/#	#	#
360	18	18	100.00	94.44	17	9	8	17	0	9/17	0.53	9/17	0.53	100.00	17	9/17	0.53	100.00
361	16	16	100.00	100.00	16	3	13	16	0	3/16	0.19	3/16	0.19	100.00	16	3/16	0.19	100.00
362	17	17	100.00	100.00	17	10	7	16	1	10/17	0.59	10/16	0.63	94.12	16	10/16	0.63	100.00
N	11	11	11	11	11	11	11	11	11		11		11	11	11		11	11
MEAN	16.1	15.9	98.825	95.928	15.3	7.4	7.9	15.2	0.1		0.481		0.485	99.465	15.1		0.487	99.522
S.D.	1.6	1.8	2.615	5.831	2.1	2.4	2.1	2.0	0.3		0.132		0.135	1.773	1.8		0.138	1.586
S.E.	0.5	0.5	0.788	1.758	0.6	0.7	0.6	0.6	0.1		0.040		0.041	0.535	0.5		0.042	0.478

Implantation index = (number of implantation sites / number of corpora lutea) x 100.
Delivery index = (number of pups born / number of implantation sites) x 100.
Sex ratio on lactation day 0 = (number of male pups born / number of pups born) or (number of live male pups / number of live pups).
Sex ratio on lactation day 4 = number of live male pups / number of live pups.
Live birth index = (number of live pups on lactation day 0 / number of pups born) x 100.
Viability index on lactation day 4 = (number of live pups on lactation day 4 / number of live pups on lactation day 0) x 100.
a: Non-pregnancy.
#: Blank.

INDIVIDUAL DATA 14-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Pregnancy and litter data, Main group ANIMAL : Rat, Crl:CD(SD) SEX : Female GROUP : 10 mg/kg

Animal No.	Number of corpora lutea	Number of implanta-tion sites	Implanta-tion index (%)	Delivery index (%)	Lactation day 0										Lactation day 4			
					Number of pups delivered					Sex ratio				Live birth index (%)	Number of live pups	Sex ratio		Viability index (%)
					Total	Male	Female	Alive	Dead	All pups		Live pups				All pups		
451	17	15	88.24	100.00	15	8	7	15	0	8/15	0.53	8/15	0.53	100.00	14	7/14	0.50	93.33
452	13	13	100.00	100.00	13	6	7	13	0	6/13	0.46	6/13	0.46	100.00	13	6/13	0.46	100.00
453	17	17	100.00	100.00	17	6	11	17	0	6/17	0.35	6/17	0.35	100.00	16	5/16	0.31	94.12
454	18	15	83.33	93.33	14	8	6	14	0	8/14	0.57	8/14	0.57	100.00	14	8/14	0.57	100.00
455	21	19	90.48	100.00	19	9	10	19	0	9/19	0.47	9/19	0.47	100.00	18	8/18	0.44	94.74
456	18	18	100.00	94.44	17	11	6	17	0	11/17	0.65	11/17	0.65	100.00	16	11/16	0.69	94.12
457	19	19	100.00	89.47	17	11	6	17	0	11/17	0.65	11/17	0.65	100.00	15	11/15	0.73	88.24
458	15	15	100.00	100.00	15	7	8	15	0	7/15	0.47	7/15	0.47	100.00	15	7/15	0.47	100.00
459	18	18	100.00	100.00	18	10	8	18	0	10/18	0.56	10/18	0.56	100.00	16	8/16	0.50	88.89
460	14	14	100.00	100.00	14	6	8	14	0	6/14	0.43	6/14	0.43	100.00	14	6/14	0.43	100.00
461	17	17	100.00	88.24	15	11	4	15	0	11/15	0.73	11/15	0.73	100.00	15	11/15	0.73	100.00
462	17	17	100.00	94.12	16	11	5	16	0	11/16	0.69	11/16	0.69	100.00	16	11/16	0.69	100.00
N	12	12	12	12	12	12	12	12	12		12		12	12	12		12	12
MEAN	17.0	16.4	96.838	96.633	15.8	8.7	7.2	15.8	0.0		0.547		0.547	100.000	15.2		0.543	96.120
S.D.	2.2	2.0	5.930	4.504	1.8	2.1	2.0	1.8	0.0		0.116		0.116	0.000	1.3		0.137	4.496
S.E.	0.6	0.6	1.712	1.300	0.5	0.6	0.6	0.5	0.0		0.033		0.033	0.000	0.4		0.040	1.298

Implantation index = (number of implantation sites / number of corpora lutea) x 100.
Delivery index = (number of pups born / number of implantation sites) x 100.
Sex ratio on lactation day 0 = (number of male pups born / number of pups born) or (number of live male pups / number of live pups).
Sex ratio on lactation day 4 = number of live male pups / number of live pups.
Live birth index = (number of live pups on lactation day 0 / number of pups born) x 100.
Viability index on lactation day 4 = (number of live pups on lactation day 4 / number of live pups on lactation day 0) x 100.

INDIVIDUAL DATA 15-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
General appearance, pups ANIMAL : Rat,Crl:CD(SD) SEX : Male, Female GROUP : 0 mg/kg

Dam No.	Day of lactation	Male		Female	
		Number of pups	Finding and number of pups with findings	Number of pups	Finding and number of pups with findings
151	0-4	1	No abnormal findings, 1	3	No abnormal findings, 3
152	0-4	9	No abnormal findings, 9	7	No abnormal findings, 7
153	0	6	Milk-band negative, 1; No abnormal findings, 5	10	No abnormal findings, 10
	1	6	Missing, 1; No abnormal findings, 5	10	No abnormal findings, 10
	2-4	5	No abnormal findings, 5	10	No abnormal findings, 10
154	0	7	No abnormal findings, 7	9	Milk-band negative, 1; No abnormal findings, 8
	1	7	No abnormal findings, 7	9	Missing, 1; No abnormal findings, 8
	2-4	7	No abnormal findings, 7	8	No abnormal findings, 8
155	0	6	No abnormal findings, 6	7	Milk-band negative, 1; No abnormal findings, 6
	1-4	6	No abnormal findings, 6	7	No abnormal findings, 7
156	0	10	No abnormal findings, 10	8	No abnormal findings, 8
	1	10	Missing, 1; No abnormal findings, 9	8	No abnormal findings, 8
	2-4	9	No abnormal findings, 9	8	No abnormal findings, 8
157	0-4	5	No abnormal findings, 5	8	No abnormal findings, 8
158	0-2	9	No abnormal findings, 9	10	No abnormal findings, 10
	3	9	No abnormal findings, 9	10	Death (milk-band not examined because of autolysis of abdominal cavity), 1; No abnormal findings, 9
	4	9	No abnormal findings, 9	9	No abnormal findings, 9
159	0-4	6	No abnormal findings, 6	7	No abnormal findings, 7
160	0-4	9	No abnormal findings, 9	7	No abnormal findings, 7
161	0-4	6	No abnormal findings, 6	8	No abnormal findings, 8
162	0	11	Milk-band negative, 1; No abnormal findings, 10	5	No abnormal findings, 5
	1	11	Missing, 1; No abnormal findings, 10	5	No abnormal findings, 5
	2-4	10	No abnormal findings, 10	5	No abnormal findings, 5

INDIVIDUAL DATA 15-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
General appearance, pups ANIMAL : Rat,Crl:CD(SD) SEX : Male, Female GROUP : 1 mg/kg

Dam No.	Day of lactation	Male		Female	
		Number of pups	Finding and number of pups with findings	Number of pups	Finding and number of pups with findings
251	0-4	7	No abnormal findings, 7	7	No abnormal findings, 7
252	0-4	9	No abnormal findings, 9	4	No abnormal findings, 4
253	0-4	11	No abnormal findings, 11	8	No abnormal findings, 8
254	0-4	8	No abnormal findings, 8	8	No abnormal findings, 8
255	0-4	6	No abnormal findings, 6	7	No abnormal findings, 7
256	0-4	9	No abnormal findings, 9	7	No abnormal findings, 7
257	0-4	7	No abnormal findings, 7	6	No abnormal findings, 6
258	0-4	6	No abnormal findings, 6	10	No abnormal findings, 10
259	0-3	7	No abnormal findings, 7	11	No abnormal findings, 11
	4	7	No abnormal findings, 7	11	Missing, 1; No abnormal findings, 10
260	0	8	No abnormal findings, 8	9	No abnormal findings, 9
	1	8	Missing, 2; No abnormal findings, 6	9	No abnormal findings, 9
	2-4	6	No abnormal findings, 6	9	No abnormal findings, 9
261	0-2	10	No abnormal findings, 10	5	No abnormal findings, 5
	3	10	Death (milk-band positive), 1; No abnormal findings, 9	5	No abnormal findings, 5
	4	9	No abnormal findings, 9	5	No abnormal findings, 5
262	0-4	9	No abnormal findings, 9	5	No abnormal findings, 5

INDIVIDUAL DATA 15-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
General appearance, pups ANIMAL : Rat,Crl:CD(SD) SEX : Male, Female GROUP : 3 mg/kg

Dam No.	Day of lactation	Male		Female	
		Number of pups	Finding and number of pups with findings	Number of pups	Finding and number of pups with findings
351	0-4	7	No abnormal findings, 7	6	No abnormal findings, 6
352	0-4	6	No abnormal findings, 6	9	No abnormal findings, 9
353	0-4	9	No abnormal findings, 9	8	No abnormal findings, 8
354	0-4	8	No abnormal findings, 8	5	No abnormal findings, 5
355	0-2	11	No abnormal findings, 11	8	No abnormal findings, 8
	3	11	No abnormal findings, 11	8	Death (milk-band negative), 1; No abnormal findings, 7
	4	11	No abnormal findings, 11	7	No abnormal findings, 7
356	0-4	5	No abnormal findings, 5	9	No abnormal findings, 9
357	0-4	5	No abnormal findings, 5	8	No abnormal findings, 8
358	0-4	8	No abnormal findings, 8	6	No abnormal findings, 6
359[a]	#	#	#	#	#
360	0-4	9	No abnormal findings, 9	8	No abnormal findings, 8
361	0-4	3	No abnormal findings, 3	13	No abnormal findings, 13
362	0	10	No abnormal findings, 10	7	Death (milk-band negative), 1; No abnormal findings, 6
	1-4	10	No abnormal findings, 10	6	No abnormal findings, 6

a: Non-pregnancy.
#: Blank.

INDIVIDUAL DATA 15-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
General appearance, pups ANIMAL : Rat,Crl:CD(SD) SEX : Male, Female GROUP : 10 mg/kg

Dam No.	Day of lactation	Male		Female	
		Number of pups	Finding and number of pups with findings	Number of pups	Finding and number of pups with findings
451	0	8	No abnormal findings, 8	7	No abnormal findings, 7
	1	8	Missing, 1; No abnormal findings, 7	7	No abnormal findings, 7
	2-4	7	No abnormal findings, 7	7	No abnormal findings, 7
452	0-4	6	No abnormal findings, 6	7	No abnormal findings, 7
453	0-2	6	No abnormal findings, 6	11	No abnormal findings, 11
	3	6	Milk-band negative, 1; No abnormal findings, 5	11	No abnormal findings, 11
	4	6	Missing, 1; No abnormal findings, 5	11	No abnormal findings, 11
454	0-4	8	No abnormal findings, 8	6	No abnormal findings, 6
455	0	9	No abnormal findings, 9	10	No abnormal findings, 10
	1	9	Milk-band negative, 1; No abnormal findings, 8	10	No abnormal findings, 10
	2	9	Missing, 1; No abnormal findings, 8	10	No abnormal findings, 10
	3-4	8	No abnormal findings, 8	10	No abnormal findings, 10
456	0	11	No abnormal findings, 11	6	No abnormal findings, 6
	1	11	No abnormal findings, 11	6	Death (milk-band positive), 1; No abnormal findings, 5
	2-4	11	No abnormal findings, 11	5	No abnormal findings, 5
457	0-2	11	No abnormal findings, 11	6	No abnormal findings, 6
	3	11	No abnormal findings, 11	6	Missing, 2; No abnormal findings, 4
	4	11	No abnormal findings, 11	4	No abnormal findings, 4
458	0-4	7	No abnormal findings, 7	8	No abnormal findings, 8
459	0-1	10	No abnormal findings, 10	8	No abnormal findings, 8
	2	10	Missing, 1; No abnormal findings, 9	8	No abnormal findings, 8
	3	9	No abnormal findings, 9	8	No abnormal findings, 8
	4	9	Missing, 1; No abnormal findings, 8	8	No abnormal findings, 8
460	0-4	6	No abnormal findings, 6	8	No abnormal findings, 8
461	0-4	11	No abnormal findings, 11	4	No abnormal findings, 4
462	0-4	11	No abnormal findings, 11	5	No abnormal findings, 5

INDIVIDUAL DATA 16-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight, pups ANIMAL : Rat, Crl:CD(SD) SEX : Male, Female GROUP : 0 mg/kg

Dam No.	Male Body weight (g) on lactation day 0	1	4	Female Body weight (g) on lactation day 0	1	4
151	9.0	10.3	15.9	8.3	9.6	14.5
152	6.2	6.6	9.3	5.8	6.2	9.1
153	5.9	6.7	9.6	5.6	6.2	8.8
154	6.1	6.5	9.5	5.6	6.1	8.6
155	6.6	7.5	11.8	6.1	6.8	11.0
156	5.7	6.4	8.5	5.6	6.2	8.9
157	7.1	8.1	11.5	6.9	7.8	11.0
158	5.5	6.0	8.5	5.5	6.0	8.4
159	7.2	7.9	12.0	6.9	7.6	11.6
160	6.7	7.5	10.6	6.7	7.4	10.2
161	6.7	7.4	10.6	6.2	6.9	9.8
162	6.2	6.9	10.1	6.3	7.1	10.3
N	12	12	12	12	12	12
MEAN	6.58	7.32	10.66	6.29	6.99	10.18
S.D.	0.93	1.14	2.03	0.81	1.03	1.72
S.E.	0.27	0.33	0.59	0.23	0.30	0.50
M/C	13.0280 **	11.0035 *	12.5963 **	11.3433 *	9.3099 *	9.9926 *
H	6.8664 †	12.1545 **	14.5070 **	5.4150	11.3129 *	14.2024 **

INDIVIDUAL DATA 16-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight, pups ANIMAL : Rat, Crl:CD(SD) SEX : Male, Female GROUP : 1 mg/kg

Dam No.	Male Body weight (g) on lactation day 0	1	4	Female Body weight (g) on lactation day 0	1	4
251	7.2	7.7	11.0	6.8	7.3	10.5
252	6.0	6.6	10.1	5.7	6.3	9.8
253	6.2	6.7	9.8	6.0	6.6	9.1
254	7.1	7.7	10.9	6.8	7.2	10.0
255	8.2	9.3	13.9	7.7	8.6	13.1
256	5.5	6.0	8.8	5.8	6.3	9.5
257	6.6	7.0	10.4	6.6	7.1	10.8
258	6.2	6.6	9.4	5.8	6.2	9.0
259	6.4	6.8	10.2	5.6	6.0	8.7
260	5.8	6.5	9.5	5.4	5.9	8.7
261	7.4	8.0	11.3	6.9	7.6	10.2
262	6.8	7.4	11.1	6.3	6.9	10.3
N	12	12	12	12	12	12
MEAN	6.62	7.19	10.53	6.28	6.83	9.98
S.D.	0.76	0.89	1.31	0.68	0.78	1.21
S.E.	0.22	0.26	0.38	0.20	0.23	0.35
U	65.0000	71.0000	70.0000		69.5000	70.0000

INDIVIDUAL DATA 16-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight, pups ANIMAL : Rat, Crl:CD(SD) SEX : Male, Female GROUP : 3 mg/kg

Dam No.	Male Body weight (g) on lactation day 0	1	4	Female Body weight (g) on lactation day 0	1	4
351	7.0	7.7	11.0	6.5	7.3	10.6
352	6.6	6.9	9.5	6.1	6.5	9.2
353	5.8	6.3	8.8	5.5	5.8	8.0
354	6.5	7.3	10.5	6.1	6.6	9.5
355	5.7	5.9	8.5	5.7	5.9	8.5
356	6.5	7.3	10.3	5.9	6.6	9.5
357	6.0	6.7	9.7	6.2	6.7	9.8
358	6.7	7.3	10.4	6.7	7.3	9.7
359[a]	#	#	#	#	#	#
360	6.7	7.3	10.0	6.1	6.6	9.1
361	6.6	7.1	10.5	6.0	6.5	9.3
362	6.6	6.9	10.0	5.8	6.0	9.6
N	11	11	11	11	11	11
MEAN	6.43	6.97	9.93	6.05	6.53	9.35
S.D.	0.41	0.52	0.76	0.34	0.49	0.68
S.E.	0.12	0.16	0.23	0.10	0.15	0.21
U	63.0000	55.5000	53.5000		46.5000	49.0000

a: Non-pregnancy.
#: Blank.

INDIVIDUAL DATA 16-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Body weight, pups ANIMAL : Rat, Crl:CD(SD) SEX : Male, Female GROUP : 10 mg/kg

Dam No.	Male Body weight (g) on lactation day 0	1	4	Female Body weight (g) on lactation day 0	1	4
451	5.8	7.1	9.9	6.2	6.6	9.3
452	6.0	6.2	8.7	5.7	5.7	8.4
453	6.4	6.7	10.2	5.9	6.6	10.0
454	5.8	5.9	8.9	5.4	5.5	7.9
455	5.5	5.7	7.4	5.4	5.6	7.3
456	6.1	6.4	9.1	5.7	5.9	8.8
457	5.7	5.9	8.3	5.4	5.6	7.4
458	6.8	7.1	9.7	6.6	6.9	9.5
459	5.8	5.9	8.4	5.6	5.9	8.1
460	6.1	6.3	8.7	6.0	6.2	8.5
461	6.0	6.1	7.7	5.8	6.1	7.8
462	6.1	6.4	8.2	5.7	6.0	7.9
N	12	12	12	12	12	12
MEAN	6.01	6.31	8.77	5.78	6.05	8.41
S.D.	0.34	0.46	0.85	0.36	0.45	0.85
S.E.	0.10	0.13	0.25	0.10	0.13	0.24
U	39.5000	22.5000 **	24.0000 **		22.0000 **	20.0000 **

INDIVIDUAL DATA 17

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Gross findings of dead pups on lactation days 0-4 ANIMAL : Rat,Crl:CD(SD) SEX : Male, Female

Group	Dam No.	Day of death	Number of pups		Findings
			Male	Female	
0 mg/kg	158	3	#	1	No abnomal findings (autolysis in abdominal cavity)
1 mg/kg	261	3	1	#	No abnormal findings
3 mg/kg	355	3	#	1	No abnormal findings
	362	0	#	1	No abnormal findings
10 mg/kg	456	1	#	1	No abnormal findings

#: Blank.

INDIVIDUAL DATA 18-1

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Gross findings of pups euthanized on lactation day 4 ANIMAL : Rat,Crl:CD(SD) SEX : Male, Female GROUP : 0 mg/kg

Dam No.	Number of pups		Findings
	Male	Female	
151	1	3	No abnormal findings
152	9	7	No abnormal findings
153	5	10	No abnormal findings
154	7	8	No abnormal findings
155	6	7	No abnormal findings
156	9	8	No abnormal findings
157	5	8	No abnormal findings
158	9	9	No abnormal findings
159	6	7	No abnormal findings
160	9	7	No abnormal findings
161	6	8	No abnormal findings
162	10	5	No abnormal findings

INDIVIDUAL DATA 18-2

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Gross findings of pups euthanized on lactation day 4 ANIMAL : Rat,Crl:CD(SD) SEX : Male, Female GROUP : 1 mg/kg

Dam No.	Number of pups		Findings
	Male	Female	
251	7	7	No abnormal findings
252	9	4	No abnormal findings
253	11	8	No abnormal findings
254	8	8	No abnormal findings
255	6	7	No abnormal findings
256	9	7	No abnormal findings
257	7	6	No abnormal findings
258	6	10	No abnormal findings
259	7	10	No abnormal findings
260	6	9	No abnormal findings
261	9	5	No abnormal findings
262	9	5	No abnormal findings

INDIVIDUAL DATA 18-3

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Gross findings of pups euthanized on lactation day 4 ANIMAL : Rat,Crl:CD(SD) SEX : Male, Female GROUP : 3 mg/kg

Dam No.	Number of pups		Findings
	Male	Female	
351	7	6	No abnormal findings
352	6	9	No abnormal findings
353	9	8	No abnormal findings
354	8	5	No abnormal findings
355	11	7	No abnormal findings
356	5	9	No abnormal findings
357	5	8	No abnormal findings
358	8	6	No abnormal findings
359[a]	#	#	#
360	9	8	No abnormal findings
361	3	13	No abnormal findings
362	10	6	No abnormal findings

a: Non-pregnancy.
#: Blank.

INDIVIDUAL DATA 18-4

STUDY NO. SR07124 TITLE : PFTeDA Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (p.o.)
Gross findings of pups euthanized on lactation day 4 ANIMAL : Rat,Crl:CD(SD) SEX : Male, Female GROUP : 10 mg/kg

Dam No.	Number of pups		Findings
	Male	Female	
451	7	7	No abnormal findings
452	6	7	No abnormal findings
453	5	11	No abnormal findings
454	8	6	No abnormal findings
455	8	10	No abnormal findings
456	11	5	No abnormal findings
457	11	4	No abnormal findings
458	7	8	No abnormal findings
459	8	8	No abnormal findings
460	6	8	No abnormal findings
461	11	4	No abnormal findings
462	1	0	Liver: Yellowish white patch, middle lobe (4 x 3, mm)
	10	5	No abnormal findings

EXFLUOR RESEARCH CORPORATION

2350 Double Creek Drive
Round Rock, Texas 78664
(512) 310-9044

CERTIFICATE OF ANALYSIS

Issue Date:	January 29, 2008
Product Name:	Perfluorotetradecanoic acid
CAS #	376-06-7
Chemical Formula:	$CF_3(CF_2)_{12}COOH$
Lot #	3728
Physical State	White solid

Products other than Perfluorotetradecanoic acid	$\leq$ 4 %
Perfluorotetradecanoic acid	96 % min.
Test Results	96.5 %

[redacted]

Exfluor Research Corporation

被験物質原体の純度試験 報告書

被験物質名 ： ペルフルオロテトラデカン酸
製造会社名 ： Exfluor Research Corporation
ロット番号 ： 3728
測定年月日 ： 2011年 1月 31日～2011年 2月 1日
保存条件 ： 遮光容器にて室温保存
測定方法 ： LC/MS/MS法(純度試験；定量法)
試験成績 ：

項目	結果				
純度試験(定量法)	測定の繰返し数	純度（%）			
		測定値(%)	平均値	標準偏差	変動係数(%)
	1	93.0	92.3	0.87	0.94
	2	92.5			
	3	91.3			

委託者 ：株式会社 化合物安全性研究所
試験施設：野外科学株式会社 環境計量部
〒065-0043 札幌市東区苗穂町 12丁目 2番 39号
TEL 011-751-5153 FAX 011-711-1541
分析担当者 [redacted]

[redacted]

分析証明書番号：1332

均一性試験 分析証明書

被験物質名：ペルフルオロテトラデカン酸
ロット番号：3728
媒　　体：0.5%カルボキシメチルセルロースナトリウム水溶液
調製年月日：2010年4月9日
分析試験実施時期：投与開始前
測定開始日：2010年4月9日
測定方法：LC-MS/MS法
試験成績：

調製液表示濃度	測定の繰返し数		被験物質濃度 (mg/mL)	平均値 ±標準偏差	変動係数 (%)
1 mg/mL	上層	1	1.04	1.04 ±0.008	0.8
		2	1.05		
	中層	1	1.03		
		2	1.03		
	下層	1	1.04		
		2	1.04		
100 mg/mL	上層	1	99.5	97.5 ±1.65	1.7
		2	96.8		
	中層	1	96.9		
		2	96.2		
	下層	1	96.0		
		2	99.7		

判定基準：変動係数が5%以下の場合を適とする。
合否判定：適
備　　考：
実施試験名；ペルフルオロテトラデカン酸のラットにおける反復投与毒性・生殖発生毒性併合試験（試験番号；SR07124）

試験施設　株式会社 化合物安全性研究所

化学分析責任者：[redacted]　2010 年 4 月 13 日

分析証明書番号：1357

均一性試験 分析証明書

被験物質名：ペルフルオロテトラデカン酸
ロット番号：3728
媒　　体：0.5%カルボキシメチルセルロースナトリウム水溶液
調製年月日：2010年8月27日
分析試験実施時期：投与開始前
測定開始日：2010年8月27日
測定方法：LC-MS/MS法
試験成績：

調製液表示濃度	測定の繰返し数		被験物質濃度 (mg/mL)	平均値 ±標準偏差	変動係数 (%)
0.01 mg/mL	上層	1	0.00967	0.00966 ±0.000331	3.4
		2	0.00954		
	中層	1	0.0103		
		2	0.00936		
	下層	1	0.00962		
		2	0.00948		

判定基準：変動係数が5%以下の場合を適とする。
合否判定：適
備　　考：
実施試験名；ペルフルオロテトラデカン酸のラットにおける反復投与毒性・生殖発生毒性併合試験（試験番号；SR07124）

試験施設　株式会社 化合物安全性研究所

化学分析責任者：[redacted]　2010 年 9 月 1 日

分析証明書番号：1333

安定性試験　分析証明書

被験物質名：ペルフルオロテトラデカン酸
ロット番号：3728
媒　　体：0.5%カルボキシメチルセルロースナトリウム水溶液
調製年月日：2010年4月9日
分析試験実施時期：投与開始前
測定開始日：2010年4月9日(調製時)、
2010年4月23日(冷蔵保存14日の室温保存6時間後)
保存条件：冷蔵保存後、室温保存
測定方法：LC-MS/MS法
試験成績：

調製液表示濃度	測定の繰返し数	被験物質濃度(mg/mL)	
		調製時	冷蔵保存14日の室温保存6時間後
1 mg/mL	1	1.03	0.965
	2	1.03	0.979
	平均値	1.03	0.972
	残存率(%)	−	94.4
100 mg/mL	1	96.9	93.6
	2	96.2	96.1
	平均値	96.6	94.9
	残存率(%)	−	98.2

判定基準：残存率が85～115%の場合を適とする。
合否判定：1および100 mg/mLの被験物質調製液について、冷蔵保存14日の室温保存6時間後まで安定性が認められた(調製日を0日として起算)。
備　　考：
実施試験名；ペルフルオロテトラデカン酸のラットにおける反復投与毒性・生殖発生毒性併合試験(試験番号；SR07124)

試験施設　株式会社 化合物安全性研究所

化学分析責任者：[redacted]　2010 年 4 月 27 日

分析証明書番号：1358

安定性試験　分析証明書

被験物質名：ペルフルオロテトラデカン酸
ロット番号：3728
媒　　体：0.5%カルボキシメチルセルロースナトリウム水溶液
調製年月日：2010年8月27日
分析試験実施時期：投与開始前
測定開始日：2010年8月27日(調製時)、
2010年9月10日(冷蔵保存14日の室温保存4時間後)
保存条件：冷蔵保存後、室温保存
測定方法：LC-MS/MS法
試験成績：

調製液表示濃度	測定の繰返し数	被験物質濃度(mg/mL)	
		調製時	冷蔵保存14日の室温保存4時間後
0.01 mg/mL	1	0.0103	0.0101
	2	0.00936	0.0102
	平均値	0.00983	0.0102
	残存率(%)	-	103.8

判定基準：残存率が85～115%の場合を適とする。
合否判定：0.01 mg/mLの被験物質調製液について、冷蔵保存14日の室温保存4時間後まで安定性が認められた(調製日を0日として起算)。
備　　考：
実施試験名；ペルフルオロテトラデカン酸のラットにおける反復投与毒性・生殖発生毒性併合試験(試験番号；SR07124)

試験施設　株式会社 化合物安全性研究所

化学分析責任者：[redacted]　2010 年 9 月 15 日

分析証明書番号：1361

濃度確認試験　分析証明書

被験物質名：ペルフルオロテトラデカン酸
ロット番号：3728
媒体：0.5%カルボキシメチルセルロースナトリウム水溶液
調製年月日：2010年10月5日
分析試験実施時期：初回調製時
測定年月日：2010年10月6日
測定方法：LC-MS/MS法
試験成績：

調製液 表示濃度 (mg/mL)	測定の 繰返し数	調製液 被験物質濃度 (mg/mL)	平均値 標準偏差	含有率 (%)
0.1	1	0.0962	0.0969	96.9
	2	0.0975	±0.00092	
0.3	1	0.298	0.301	100.3
	2	0.303	±0.0035	
1	1	1.01	1.00	100.0
	2	0.995	±0.011	

判定基準：含有率が85～115%の場合を適とする。
合否判定：適
備考：
実施試験名；ペルフルオロテトラデカン酸のラットにおける反復投与毒性・生殖発生毒性併合試験(試験番号 SR07124)

試験施設　株式会社 化合物安全性研究所

化学分析責任者：[redacted]　2010 年 10 月 7 日

分析証明書番号：1362

濃度確認試験　分析証明書

被験物質名　：ペルフルオロテトラデカン酸
ロット番号　：3728
媒　　体　：0.5%カルボキシメチルセルロースナトリウム水溶液
調製年月日　：2010年11月15日
分析試験実施時期　：最終回調製時
測定年月日　：2010年11月16日
測定方法　：LC-MS/MS法
試験成績　：

調製液表示濃度 (mg/mL)	測定の繰返し数	調製液 被験物質濃度 (mg/mL)	平均値 標準偏差	含有率 (%)
0.1	1	0.101	0.103 ±0.0021	103.0
	2	0.104		
0.3	1	0.310	0.307 ±0.0049	102.3
	2	0.303		
1	1	0.998	0.999 ±0.0007	99.9
	2	0.999		

判定基準　：含有率が85～115%の場合を適とする。
合否判定　：適
備　　考　：
実施試験名；ペルフルオロテトラデカン酸のラットにおける反復投与毒性・生殖発生毒性併合試験(試験番号 SR07124)

試験施設　株式会社 化合物安全性研究所

化学分析責任者：[redacted]　2010 年 11 月 18 日

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分析レポートコード AR-10-JP-000805-01

ユーロフィンズオーダーコード EUJPTO-00000859

報告日 20.07.2010

オリエンタル酵母工業株式会社

受領 09.07.2010

分析報告書

サンプルコード： 257-2010-07000009 分析 09.07.2010 – 19.07.2010

顧客コード： CRF-1,CRF-1粉末 Lot 100706

分析	結果	単位	定量限界
JJ0B5 ニトロソアミン			
ニトロソジエチルアミン	<0.010	ppm	0.010
ニトロソジメチルアミン	<0.010	ppm	0.010
J1003 ヒ素 (As として)			
ヒ素	0.11	ppm	0.10
J1005 カドミウム			
カドミウム	0.05	ppm	0.01
J1013 鉛			
鉛	0.11	ppm	0.05
J1014 セレン			
セレン	0.64	ppm	0.05
J1018 総水銀			
水銀	0.006	ppm	0.005
JJ006 アフラトキシン B1, B2, G1, G2			
アフラトキシン B1	0.4	ppb	0.1
アフラトキシン B2	<0.1	ppb	0.1
アフラトキシン G1	<0.1	ppb	0.1
アフラトキシン G2	<0.1	ppb	0.1
JJV17 エストラジオール			
エストラジオール	<0.005	ppm	0.005

報告結果の再生については分析所の許可が必要となります。報告結果は、分析したサンプルのみに適用されます。

Eurofins Analytics K.K Nittsu Keihin-Jima Center New Bldg. 2F 3-5-5 Keihin-Jima Ota-Ku 143-0003 Tokyo - JAPAN

eurofins

分析レポートコード AR-10-JP-000805-01

ユーロフィンズオーダーコード EUJPTO-00000859

SP001 ピレスロイドを含む有機塩素系農薬			
DDT及び代謝物（総計）	<0.01	ppm	
DDT, p,p'-	<0.001	ppm	0.001
DDT, o,p'-	<0.001	ppm	0.001
DDE,p,p'-	<0.002	ppm	0.002
DDE, o,p'-	<0.002	ppm	0.002
DDD, p,p'-	<0.002	ppm	0.002
DDD, o,p'-	<0.002	ppm	0.002
エンドリン	<0.002	ppm	0.002
ディルドリン	<0.001	ppm	0.001
γ-ＢＨＣ（リンデン）	<0.001	ppm	0.001
アルドリン	<0.001	ppm	0.001
ヘプタクロル	<0.001	ppm	0.001
SP004 有機リン系農薬			
パラチオン	<0.01	ppm	0.01
マラチオン（マラソン）	0.02	ppm	0.01
SP103 ポリ塩化　ビフェニル			
7 PCB測定総計	<0.07	ppm	
PCB IUPAC 28	<0.01	ppm	0.01
PCB IUPAC 52	<0.01	ppm	0.01
PCB IUPAC 101	<0.01	ppm	0.01
PCB IUPAC 118	<0.01	ppm	0.01
PCB IUPAC 138	<0.01	ppm	0.01
PCB IUPAC 153	<0.01	ppm	0.01
PCB IUPAC 180	<0.01	ppm	0.01

[redacted]

Chemistry Customer Services Manager

確認者署名

[redacted]

確認日付：2010年7月22日

Oriental Yeast Co., Ltd.

報告結果の再生については分析所の許可が必要となります。報告結果は、分析したサンプルのみに適用されます。

Eurofins Analytics K.K Nittsu Keihin-Jima Center New Bldg. 2F 3-5-5 Keihin-Jima Ota-Ku 143-0003 Tokyo - JAPAN

ページ 2/2

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分析レポートコード AR-10-JP-001058-01

ユーロフィンズオーダーコード EUJPTO-00000933

報告日 28.09.2010

オリエンタル酵母工業株式会社

受領 15.09.2010

分析報告書

サンプルコード： 257-2010-09000112 分析 15.09.2010 – 27.09.2010

顧客コード： CRF-1,CRF-1粉末 Lot 100907

分析	結果	単位	定量限界
JJ0B5 ニトロソアミン			
ニトロソジエチルアミン	<0.010	ppm	0.010
ニトロソジメチルアミン	<0.010	ppm	0.010
J1003 ヒ素 (As として)			
ヒ素	0.15	ppm	0.10
J8308 カドミウム			
カドミウム	0.07	ppm	0.01
J8306 鉛			
鉛	<0.05	ppm	0.05
J1014 セレン			
セレン	0.20	ppm	0.05
JCHG2 総水銀			
水銀	0.006	ppm	0.005
JJ006 アフラトキシン B1, B2, G1, G2			
アフラトキシン B1	0.2	ppb	0.1
アフラトキシン B2	<0.1	ppb	0.1
アフラトキシン G1	<0.1	ppb	0.1
アフラトキシン G2	<0.1	ppb	0.1
JJV17 エストラジオール			
エストラジオール	<0.005	ppm	0.005

報告結果の再生については分析所の許可が必要となります。報告結果は、分析したサンプルのみに適用されます。

Eurofins Analytics K.K Nittsu Keihin-Jima Center New Bldg. 2F 3-5-5 Keihin-Jima Ota-Ku 143-0003 Tokyo - JAPAN

eurofins

分析レポートコード AR-10-JP-001058-01

0550029000000003828

ユーロフィンズオーダーコード EUJPTO-00000933

SP001 ピレスロイドを含む有機塩素系農薬			
DDT及び代謝物（総計）	<0.01	ppm	
DDT, p,p'-	<0.001	ppm	0.001
DDT, o,p'-	<0.001	ppm	0.001
DDE,p,p'-	<0.002	ppm	0.002
DDE, o,p'-	<0.002	ppm	0.002
DDD, p,p'-	<0.002	ppm	0.002
DDD, o,p'-	<0.002	ppm	0.002
エンドリン	<0.002	ppm	0.002
ディルドリン	<0.001	ppm	0.001
γ-BHC（リンデン）	<0.001	ppm	0.001
アルドリン	<0.001	ppm	0.001
ヘプタクロル	<0.001	ppm	0.001
SP004 有機リン系農薬			
パラチオン	<0.01	ppm	0.01
マラチオン（マラソン）	0.01	ppm	0.01
SP103 ポリ塩化 ビフェニル			
7 PCB測定総計	<0.07	ppm	
PCB IUPAC 28	<0.01	ppm	0.01
PCB IUPAC 52	<0.01	ppm	0.01
PCB IUPAC 101	<0.01	ppm	0.01
PCB IUPAC 118	<0.01	ppm	0.01
PCB IUPAC 138	<0.01	ppm	0.01
PCB IUPAC 153	<0.01	ppm	0.01
PCB IUPAC 180	<0.01	ppm	0.01

[redacted]

Chemistry Customer Services Manager

確認者署名

[redacted]

確認日付：2010年9月28日

Oriental Yeast Co., Ltd.

報告結果の再生については分析所の許可が必要となります。報告結果は、分析したサンプルのみに適用されます。

Eurofins Analytics K.K Nittsu Keihin-Jima Center New Bldg. 2F 3-5-5 Keihin-Jima Ota-Ku 143-0003 Tokyo - JAPAN

ページ 2/2

分析試験報告書

No. 10G03-105

御中

〒261－0002
千葉県千葉市美浜区新港 8-2
オリエンタル酵母工業株式会社
千葉工場 品質管理室

検　体　名：　CRF－1・CRF－1粉末　Lot 100706
実施方法：　社内分析規格

報告年月日	2010－7－16
[redacted]	
責　任　者	

検査項目		結果	管理目標値
水分	（％）	8.5	9.9%以下
粗蛋白質	（％）	21.8	21.0%以上
粗脂肪	（％）	5.1	4.0%以上
粗灰分	（％）	6.0	8.0%以下
粗繊維	（％）	2.8	5.0%以下
可溶性無窒素物	（％）	55.8	－
一般生菌数	（個/g）	1.2×10^4	10^6個/g未満
サルモネラ	（個/20g）	陰性	陰性
大腸菌群	（個/g）	陰性	陰性
真菌類	（個/g）	10個/g以下	100個/g以下
記事	本製品は、弊社千葉工場管理目標値に照らし、異常なしと判定いたします。 2010.7.28 QA [redacted]		

分析試験報告書に関するお問い合わせは、バイオ事業本部ライフサイエンス部（TEL　03-3968-1192）へお願いいたします。

分析試験報告書

No. 10G03-139

御中

〒261－0002
千葉県千葉市美浜区新港 8-2
オリエンタル酵母工業株式会社
千葉工場 品質管理室

検　体　名：　CRF－1・CRF－1粉末　Lot 100907
実施方法：　社内分析規格

報告年月日	2010－9－24
[redacted]	
責任者	

検査項目		結果	管理目標値
水分	（％）	8.7	9.9%以下
粗蛋白質	（％）	22.1	21.0%以上
粗脂肪	（％）	5.2	4.0%以上
粗灰分	（％）	6.0	8.0%以下
粗繊維	（％）	2.6	5.0%以下
可溶性無窒素物	（％）	55.4	－
一般生菌数	（個/g）	1.4×10^4	10^6個/g未満
サルモネラ	（個/20g）	陰性	陰性
大腸菌群	（個/g）	陰性	陰性
真菌類	（個/g）	10個/g以下	100個/g以下
記事	本製品は、弊社千葉工場管理目標値に照らし、異常なしと判定いたします。 2010 9 28 QA [redacted]		

分析試験報告書に関するお問い合わせは、バイオ事業本部ライフサイエンス部（TEL　03-3968-1192）へお願いいたします。

SR07124

No. A220983

水質検査結果表

平成22年7月20日

株式会社化合物安全性研究所 様

建築物飲料水水質検査業[redacted]2号
札幌市清田区平岡1条[redacted]
電話 代表[redacted]22
日本衛生[redacted]社
代表取締役 [redacted]

採水場所：306号室
水源の種別：札幌市上水道
採水者：[redacted]
採水日時：7月1日 8時10分
試験目的：飲料水水質検査
検査日：7月1日 ～ 7月14日

気温：－ ℃
水温：16.0 ℃
残留塩素：0.3 mg/L

平成22年7月1日に提出された上記試料の検査結果は次のとおりです。

No.	項目	検査結果		No.	項目	検査結果	
1	一般細菌	0	CFU/mL	22	クロロホルム	0.0070	mg/L
2	大腸菌	不検出		28	ブロモジクロロメタン	0.0061	mg/L
45	有機物(全有機炭素TOCの量)	0.5	mg/L	24	ジブロモクロロメタン	0.0034	mg/L
46	pH値	7.5		29	ブロモホルム	0.0004	mg/L
47	味	異常なし		26	総トリハロメタン	0.0169	mg/L
48	臭気	異常なし		21	クロロ酢酸	< 0.002	mg/L
49	色度	2.0	度	23	ジクロロ酢酸	0.008	mg/L
50	濁度	< 0.1	度	27	トリクロロ酢酸	0.007	mg/L
37	塩化物イオン	14.3	mg/L	30	ホルムアルデヒド	< 0.008	mg/L
10	硝酸態窒素及び亜硝酸態窒素	< 0.5	mg/L	20	塩素酸	0.07	mg/L
33	鉄及びその化合物	< 0.01	mg/L	25	臭素酸	< 0.001	mg/L
34	銅及びその化合物	< 0.01	mg/L	9	シアン化物イオン及び塩化シアン	< 0.001	mg/L
31	亜鉛及びその化合物	< 0.01	mg/L	43	非イオン界面活性剤	< 0.005	mg/L
6	鉛及びその化合物	< 0.001	mg/L	32	アルミニウム及びその化合物	0.03	mg/L
39	蒸発残留物	82	mg/L	12	ホウ素及びその化合物	0.17	mg/L
11	フッ素及びその化合物	< 0.08	mg/L	14	1．4－ジオキサン	< 0.005	mg/L
3	カドミウム及びその化合物	< 0.0003	mg/L	44	フェノール類	< 0.0005	mg/L
8	六価クロム化合物	< 0.001	mg/L	7	ヒ素及びその化合物	0.002	mg/L
36	マンガン及びその化合物	< 0.001	mg/L	5	セレン及びその化合物	< 0.001	mg/L
16	ジクロロメタン	< 0.0002	mg/L	35	ナトリウム及びその化合物	9	mg/L
15	シス及びトランス－1．2－ジクロロエチレン	< 0.0002	mg/L	38	カルシウム、マグネシウム等(硬度)	22	mg/L
13	四塩化炭素	< 0.0002	mg/L	4	水銀及びその化合物	< 0.00005	mg/L
19	ベンゼン	< 0.0002	mg/L	40	陰イオン界面活性剤	< 0.02	mg/L
18	トリクロロエチレン	< 0.0002	mg/L	41	ジェオスミン	< 0.000001	mg/L
17	テトラクロロエチレン	< 0.0002	mg/L	42	2－メチルイソボルネオール	< 0.000001	mg/L
判定	上記検査項目については水質基準に適合します。						

理化学試験 ：[redacted] [redacted]　　細菌学試験 ：[redacted] [redacted]

Appendix 4-2

SR07124

No. A223084

水質検査結果表

平成22年10月13日

株式会社化合物安全性研究所 様

建築物飲料水水質検査業[redacted]第2号
札幌市清田区平岡1[redacted]40号
電話 代表(011)888－01[redacted]-0414
日本衛生[redacted]社
代表取締役 [redacted]

採水場所：306号室
水源の種別：札幌市上水道
採水者 [redacted]
採水日時： 10月1日 8時25分
試験目的：飲料水水質検査
検査日： 10月2日 ～ 10月8日
水温： 19.0 ℃
残留塩素： 0.3 mg/L

細菌学試験 [redacted]

理化学試験 [redacted]

平成22年10月2日に提出された上記試料の検査結果は次のとおりです。

番号	項目	基準	検査結果
1	一般細菌	100 CFU/mL 以下	0 CFU/mL
2	大腸菌	検出されないこと	不検出
45	有機物(全有機炭素TOCの量)	3 mg/L 以下	0.7 mg/L
46	pH値	5.8以上 8.6以下	7.4
47	味	異常でないこと	異常なし
48	臭気	異常でないこと	異常なし
49	色度	5 度 以下	0.7 度
50	濁度	2 度 以下	< 0.1 度
37	塩化物イオン	200 mg/L 以下	35.6 mg/L
10	硝酸態窒素及び亜硝酸態窒素	10 mg/L 以下	< 0.5 mg/L
33	鉄及びその化合物	0.3 mg/L 以下	< 0.01 mg/L
34	銅及びその化合物	1.0 mg/L 以下	－ mg/L
31	亜鉛及びその化合物	1.0 mg/L 以下	－ mg/L
6	鉛及びその化合物	0.01 mg/L 以下	－ mg/L
39	蒸発残留物	500 mg/L 以下	－ mg/L
22	クロロホルム	0.06 mg/L 以下	－ mg/L
28	ブロモジクロロメタン	0.03 mg/L 以下	－ mg/L
24	ジブロモクロロメタン	0.1 mg/L 以下	－ mg/L
29	ブロモホルム	0.09 mg/L 以下	－ mg/L
26	総トリハロメタン	0.1 mg/L 以下	－ mg/L
21	クロロ酢酸	0.02 mg/L 以下	－ mg/L
23	ジクロロ酢酸	0.04 mg/L 以下	－ mg/L
27	トリクロロ酢酸	0.2 mg/L 以下	－ mg/L
30	ホルムアルデヒド	0.08 mg/L 以下	－ mg/L
20	塩素酸	0.6 mg/L 以下	－ mg/L
25	臭素酸	0.01 mg/L 以下	－ mg/L
9	シアン化物イオン及び塩化シアン	0.01 mg/L 以下	－ mg/L
判定	上記検査項目については水質基準に適合します。		
備考	項目番号は、水質基準に関する厚生労働省の番号 CFU:コロニーの個数		

Appendix 4-3

SR07124

No. A224282

水質検査結果表

平成23年1月17日

株式会社化合物安全性研究所 様

建築物飲料水水質検査業[redacted]第2号
札幌市清田区平岡1[redacted]40号
電話 代表(011)888－012[redacted]-0414
日本衛生[redacted]社
代表取締役 [redacted]

採水場所：306号室
水源の種別：札幌市上水道
採水者 [redacted]
採水日時： 1月4日 8時46分
試験目的：飲料水水質検査
検査日： 1月4日 ～ 1月15日
水温： 16.0 ℃
残留塩素： 0.3 mg/L

細菌学試験 [redacted]

理化学試験 [redacted]

平成23年1月4日に提出された上記試料の検査結果は次のとおりです。

番号	項目	基準	検査結果
1	一般細菌	100 CFU/mL 以下	0 CFU/mL
2	大腸菌	検出されないこと	不検出
45	有機物(全有機炭素TOCの量)	3 mg/L 以下	0.6 mg/L
46	pH値	5.8以上 8.6以下	7.3
47	味	異常でないこと	異常なし
48	臭気	異常でないこと	異常なし
49	色度	5 度 以下	＜0.5 度
50	濁度	2 度 以下	＜0.1 度
37	塩化物イオン	200 mg/L 以下	28.4 mg/L
10	硝酸態窒素及び亜硝酸態窒素	10 mg/L 以下	＜0.5 mg/L
33	鉄及びその化合物	0.3 mg/L 以下	0.01 mg/L
34	銅及びその化合物	1.0 mg/L 以下	－ mg/L
31	亜鉛及びその化合物	1.0 mg/L 以下	－ mg/L
6	鉛及びその化合物	0.01 mg/L 以下	－ mg/L
39	蒸発残留物	500 mg/L 以下	－ mg/L
22	クロロホルム	0.06 mg/L 以下	－ mg/L
28	ブロモジクロロメタン	0.03 mg/L 以下	－ mg/L
24	ジブロモクロロメタン	0.1 mg/L 以下	－ mg/L
29	ブロモホルム	0.09 mg/L 以下	－ mg/L
26	総トリハロメタン	0.1 mg/L 以下	－ mg/L
21	クロロ酢酸	0.02 mg/L 以下	－ mg/L
23	ジクロロ酢酸	0.04 mg/L 以下	－ mg/L
27	トリクロロ酢酸	0.2 mg/L 以下	－ mg/L
30	ホルムアルデヒド	0.08 mg/L 以下	－ mg/L
20	塩素酸	0.6 mg/L 以下	－ mg/L
25	臭素酸	0.01 mg/L 以下	－ mg/L
9	シアン化物イオン及び塩化シアン	0.01 mg/L 以下	－ mg/L
判定	上記検査項目については水質基準に適合します。		
備考	項目番号は、水質基準に関する厚生労働省の番号 CFU:コロニーの個数		

Symbols and process for statistical analysis in individual data

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

$p \leqq 0.05$ → Kruskal-Wallis test

$p > 0.05$ → One way analysis of variance

F : Values for one way analysis of variance,

$p \leqq 0.10$ → Dunnett's procedure

H : Values for Kruskal-Wallis test,

$p \leqq 0.10$ → Mann-Whitney's U-test

† : Significant difference, $p \leqq 0.10$

* : Significant difference, $p \leqq 0.05$

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

---

t' : Values for Dunnett's procedure

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

* : Significant difference, $p \leqq 0.05$

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

X^2 : Values for chi-square test

p : Values for Fisher's exact probability test

* : Significant difference, $p \leqq 0.05$

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

Definitions for detailed clinical and functional observations

Item	Category No.					
In the cage:						
Body position/Posture						
	1; Normal (sitting, etc.)	2; Sleeping	3; Crouching	4; Prone, lateral	5; Standing, jumping	6; Cataleptic
Respiratory pattern						
	1; Normal	2; Slightly abnormal, rapid or slow	3; Moderately abnormal, difficult to breath	4; Severe abnormal, labored	5; Dyspnea	
Tremor / Convulsion						
	1; Not present	2; Irregularly, only the legs	3; Durable, only the legs	4; Clonic, systemic	5; Tonic, systemic	
Stereotype						
Rolling	0; Not present	1; Sometimes	2; Frequently			
Repetitive circling						
	0; Not present	1; Sometimes	2; Frequently			
Bizarre behavior						
Biting/Selfmutilation						
	1; Not present	2; Present				
On the hand: while removing the animal from its cage						
Ease of removal						
	1; Very easy	2; Easy	3; Slightly difficult	4; Difficult	5; Very difficult	
Ease of handling						
	1; Very easy	2; Easy	3; Slightly difficult	4; Difficult	5; Very difficult	
Muscle tone	1; Low	2; Normal	3; High			
Piloerection	1; Not present	2; Slightly present, around head and back	3; Slightly present, systemic	4; Severely present, systemic		
Fur	1; Normal	2; Slightly stained	3; Stained			
Eyes	1; Not present, normal	2; Slight ptosis, half closed	3; Ptosis	4; Closed		
Mucous membranes						
	-1; Dark purplish appearance, cyanosis		0; Normal	1; Red appearance		

(to be continued)

(Continued 1)

Item	Category No.			
Skin	0; Pale appearance, cyanosis	1; Normal	2; Red appearance	
Pupil size	1; Normal	2; Slightly mydriatic	3; Mydriatic	
Lacrimation	1; Not present	2; Wet around the eye	3; Wet	4; Severely wet
Salivation	1; Not present	2; Wet around the mouth	3; Wet	4; Severely wet
Secretions/Excretions				
	0; Not present	1; Present		
In the open-field: when placed the animal in an open-field				
Gait	0; Not moved	1; Normal	2; Difficult to walk	3; Unable to walk, paralytic
Co-ordination of movement				
	0; staggering (ataxic)	1; Normal		
Reactivity to environmental stimuli				
	0; Not present	1; present (to noise, etc.)		
Searching	0; Not present	1; present (sniffing, standing, etc.)		
Urination	0; Not present	1; Present		
Defecation	0; Not present	1; Present		
Stereotype				
Excessive grooming				
	0; Not present	1; Sometimes	2; Frequently	
Unusual head movement				
	0; Not present	1; Sometimes	2; Frequently	
Bizarre behavior				
Walking backward				
	1; Not present	2; Present		
Vocalization	1; Not present, sometimes	2; Present, frequently		
Aggression	1; Not present	2; Present		

(to be continued)

(Continued 2)

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