

TRADE SECRET

Study Title

H-24516:
Developmental Toxicity Study in Rats

Laboratory Project ID: DuPont-5991

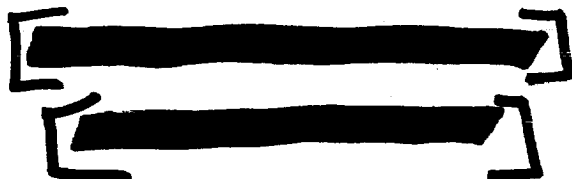
TEST GUIDELINES: U.S. EPA Health Effects Test Guidelines
OPPTS 870.3700 Prenatal Developmental Toxicity Study

OECD Guidelines for the Testing of Chemicals
Section 4, No. 414

AUTHOR: Susan M. Munley, M.A.

STUDY COMPLETED ON: December 12, 2001

PERFORMING LABORATORY: E.I. du Pont de Nemours and Company
Haskell Laboratory for Toxicology and Industrial Medicine
Elkton Road, P.O. Box 50
Newark, Delaware 19714-0050



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GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

This study was conducted in compliance with U.S. EPA TSCA (40 CFR part 792) Good Laboratory Practice Standards except for the item documented below. The item listed does not impact the validity of the study.

Test substance characterization and stability analyses were performed at Regional Analytical Services (RAS), a non-GLP laboratory. The test substance analyses performed were in compliance with regulatory guidelines. None of the aforementioned analyses were performed under Good Laboratory Practice Standards; however, the analyses were conducted in compliance with ISO9002 regulations. All of the analyses are considered valid and sufficient for the purposes of this study.

Applicant / Sponsor: E. I. du Pont de Nemours and Company
Wilmington, Delaware 19898
U.S.A.

Study Director: Susan M. Munley 12-Dec-2001
Susan M. Munley, M.A. Date
Research Scientist

Applicant / Sponsor: _____
DuPont Representative Date

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QUALITY ASSURANCE STATEMENT

Haskell Sample Number(s): 24516

Dates of Inspections:

Protocol: March 21, 2001

Conduct: March 20-21, 2001; April 30, 2001

Records, Reports: October 1,3-5,8-12,15, 2001

Dates Findings Reported to:

Study Director: October 10,19, 2001; December 5, 2001

Management: October 15, 2001; November 29, 2001; December 11, 2001

Reported by:

Wonda K. Kelly

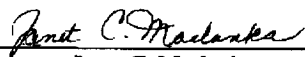
Wonda K. Kelly
Quality Assurance Auditor

12-Dec-2001
Date

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CERTIFICATION

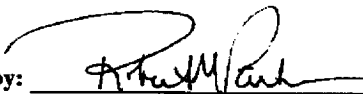
We, the undersigned, declare that this report provides an accurate evaluation of data obtained from this study.

Analytical Evaluations**Reported by:**

Janet C. Maslanka, B.S.
Staff Scientist

12-Dec-2001

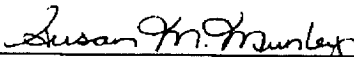
Date

Approved by:

Robert M. Parker, Ph.D., D.A.B.T.
Director
Developmental, Reproductive, and
Neurobehavioral Toxicology

12-Dec-2001

Date

Issued by Study**Director:**

Susan M. Munley, M.S.
Research Scientist
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12-Dec-2001

Date

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STUDY INFORMATION

Substance Tested:

Synonyms/Codes:

H-24516

Haskell Number: 24516

Composition:

Purity:

Known Impurities:

Note:

Physical Characteristics: Pale to medium tan waxy solid

Sponsor: E. I. du Pont de Nemours and Company
Wilmington, Delaware 19898
U.S.A.

Study Initiated/Completed: March 2, 2001 / (see report cover page)

In-Life Initiated/Completed: March 4, 2001 / May 8, 2001

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STUDY PERSONNEL

Study Director: Susan M. Munley, M.A.
Management: Robert M. Parker, Ph.D., D.A.B.T.
Primary Technician: Gregory L. Poindexter
Toxicology Report Preparation: Mary K. LaRoe
Analytical Chemist: Janet C. Maslanka, B.S.
Management: S. Mark Kennedy, Ph.D.
Laboratory Veterinarian: Wanda L. West, D.V.M., A.C.L.A.M.

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SUMMARY

The purpose of this study was to evaluate the potential maternal and developmental toxicity of H-24516, administered by gavage to pregnant rats from the time of implantation to the end of gestation.

Groups of 22 time-mated female Crl:CD[®](SD)IGS BR rats were administered suspensions of the test substance in 0.5% aqueous methylcellulose over days 6-20 of gestation (G) at daily dose levels of 0, 50, 200, or 500 mg/kg/day. During the in-life portion of the study, body weight, food consumption, and clinical observation data were collected. On day 21G, dams were euthanized; the thoracic and abdominal viscera were examined grossly. The uterus of each pregnant rat was removed and dissected to permit examination of uterine contents. The fetuses were removed, individually identified, weighed, sexed, and examined for external, visceral, head, and skeletal alterations.

Under the conditions of this study, minimal evidence of maternal toxicity including reduced body weight and weight gain, and increased perineal fur staining was observed at 500 mg/kg/day. Similarly, minimal evidence of developmental toxicity was evident at 500 mg/kg/day based on increased skeletal variations including retarded skull bone and pelvic bone ossification and wavy ribs. No toxicologically significant or adverse compound-related effects were seen in dams or fetuses at 50 or 200 mg/kg/day. Thus, the no-observed-effect level (NOEL)^a for maternal and developmental toxicity was considered 200 mg/kg/day.

^a The NOEL for this study is defined as the highest dose at which adverse effects attributable to the test substance were not detected. Thus, for this study, the NOEL is equivalent to the NOEL as defined by the U.S. EPA⁽¹²⁾ and to the no-observed-adverse-effect level (NOAEL) as defined by the European Union.⁽¹³⁾

OBJECTIVE

The purpose of this study was to evaluate the potential maternal and developmental toxicity of H-24516 in rats.

MATERIALS AND METHODS

A. Test Guidelines

The study design complies with following test guidelines:

- United States Environmental Protection Agency (EPA), Office of Prevention, Pesticides, and Toxic Substances (OPPTS) Health Effects Test Guidelines, OPPTS 870.3700 Prenatal Developmental Toxicity Study (1998).
- Organisation for Economic Cooperation and Development. Guidelines for Testing of Chemicals, Section 4 (No. 414). Paris, France (1981).

B. Test Substance

The test substance was supplied by the sponsor, the DuPont Chemical Solutions Enterprise (DCSE), E. I. Du Pont de Nemours and Company, Newark, Delaware. It was assigned the Haskell Laboratory Number 24516. The sponsor was responsible for the characterization and analysis of identity, concentration, and stability of the test substance. Test substance analyses were conducted by Regional Analytical Services (RAS), Jackson Laboratories, Deepwater, New Jersey. A reserve sample of the test substance was collected and retained by Haskell Laboratory.

C. Test Species

The Crl:CD[®](SD)IGS BR rat was selected for this study because it is a preferred species for developmental toxicity testing as recommended by the testing guidelines. The Crl:CD[®](SD)IGS BR strain was chosen because extensive background information is available from the literature, the supplier, and previous studies with other compounds at Haskell Laboratory. This strain is also considered suitable relative to hardiness and incidence of spontaneous disease.

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D. Animal Husbandry

2. Feed and Water

3. Identification

4. Health Monitoring Program

Certified animal feed is used, guaranteed by the manufacturer to meet specified nutritional requirements and not to exceed stated maximum concentrations of key contaminants, including

specified heavy metals, aflatoxin, chlorinated hydrocarbons, and organophosphates. The presence of these contaminants below the maximum concentration stated by the manufacturer would not be expected to impact the integrity of the study.

The animal health and environmental monitoring program is administered by the attending laboratory animal veterinarian. Evaluation of these data did not indicate any conditions that affected the validity of the study.

E. Quarantine and Pretest Period

Rats were quarantined according to procedures outlined in Haskell Laboratory [REDACTED] and then released for the study upon approval of the laboratory animal veterinarian.

F. Study Design

The experimental design is shown below:

<u>Group</u>	<u>Dose^a</u> <u>(mg/kg/day)</u>	<u>Concentration</u> <u>(mg/mL)</u>	<u>Time-Mated</u> <u>Females</u>
I	0 ^b	0	22
II	50	5.0	22
III	200	20.0	22
IV	500	50.0	22

a Suspensions of H-24516 were administered once daily, by gavage, over days 6-20 of gestation (days 6-20G) at a dosage volume of 10 mL/kg.

b Vehicle only (0.5% aqueous methylcellulose).

G. Selection of Dose Levels

The dose levels for the current study were based on a pilot study⁽¹⁾ conducted with H-24516 in the rat. In the pilot study, groups of 8 time-mated female CrI:CD®(SD)IGS BR rats were administered the test substance once daily by gavage during days 6-20 of gestation (days 6-20G) at daily dosages of 0, 125, 250, 500, or 1000 mg/kg/day. During the in-life portion of the study, maternal body weights, food consumption, and clinical signs data were collected. On day 21G, all dams were euthanatized and examined grossly. Gravid and empty uterine weights were recorded to permit calculation of the adjusted maternal final body weight. The uterine contents were examined and described; fetuses were weighed, sexed, and examined for any external alterations.

Maternal toxicity evident as reduced maternal body weights, weight gains, and food consumption occurred in rats administered dosages of ≥ 250 mg/kg/day. Overall weight values during the

dosing period (days 6-21G, adjusted for the products of conception) were 5.7%, 9.3%, and 14.2% lower than the control group value for females dosed with 250, 500, or 1000 mg/kg/day, respectively. Overall weight gain values during the dosing period (days 6-21G, adjusted for the products of conception) were 21.0%, 35.4%, or 66% lower than the control value for females dosed with 250, 500, or 1000 mg/kg/day, respectively. Overall mean maternal food consumption values during dosing (days 6-21G) were 7.3%, 6.5%, and 13.8% lower than the control value for females dosed with 250, 500, or 1000 mg/kg/day, respectively. One female dosed with 1000 mg/kg/day was sacrificed *in extremis* on day 13G due to persistent weight loss and not eating. There were no grossly observable postmortem findings in this animal, and she was not pregnant. It cannot be determined from these data whether the death of this animal is compound-related or whether it is incidental. Significantly increased incidences of clinical observations occurred in females dosed with 1000 mg/kg/day that included stained and/or wet fur on the perineum, and discharge on the neck. There were no compound-related gross postmortem findings, no effects on number of litters produced, no effects on fetal resorptions, no effects on nidations, no effects on corpora lutea.

With regard to fetal findings, compound-related toxicity at this exposure level was limited to a significant reduction in mean fetal weight 9.8% and 9.0% for 500, and 1000 mg/kg/day groups. There was no increase in any compound-related fetal external malformations or variations observed. Based on these findings, the dose levels listed above were selected for the current study.

H. Randomization

Dams were assigned to lots according to their gestation day. Then, they were ranked within their respective lots on the basis of day 0G body weights and assigned to control and experimental groups by random sampling from the ranked list. The distribution resulted in mean body weights for all groups that were not statistically different ($p > 0.05$).

I. Preparation, Administration, and Analysis of Test Suspensions

Suspensions of the test substance in the vehicle (0.5% aqueous methylcellulose) were prepared 2 or 3 times per week, and stored refrigerated until used. The method of mixing the test material with the vehicle was documented in the study records.

The dosing suspensions were administered by gavage because the oral route is the route that is recommended by regulatory agencies for this type of study. The volume administered (10 mL/kg) was based on the most recent body weight.

Samples of each test suspension were taken three times during the study, near the beginning, middle, and end of the dosing period. Analyses of the first sampling addressed homogeneity, concentration, and stability. For the second and third samplings, analyses addressed concentration. Samples were submitted, shortly after preparation to the Analytical Chemistry Group at Haskell Laboratory. The methods and results of these analyses are presented in Appendix H.

J. Animal Euthanasia

Females were euthanized by carbon dioxide inhalation. Fetuses were decapitated before proceeding with visceral examinations; those to be viscally examined without decapitation were injected with sodium pentobarbital. All other fetuses also were injected with sodium pentobarbital before fixation.

K. Parameters to be Studied

1. In-life Observations of Females

Body weights were recorded at least twice prior to dosing to provide data for quarantine release, and on days 6-21G. Food consumption was measured on days 4, 6, 8, 10, 12, 14, 16, 18, 20, and 21G. Clinical signs were recorded at least twice prior to dosing to provide data for quarantine release; signs were recorded once daily on days 4, 5, and 21G and twice daily on days 6-20G.

2. Postmortem Observations of Females Surviving to Scheduled Euthanasia

The abdominal and thoracic viscera were examined grossly immediately after euthanasia on day 21G. The intact and the empty uterus of each dam having at least one viable fetus was weighed to permit calculation of maternal body weight adjusted to exclude the products of conception. The corpora lutea count for each ovary of females with viable fetuses was recorded.

For each female with visible implantation sites, the types of implants (live and dead fetuses, and resorptions) and their relative positions were recorded. The uterus of each apparently "nonpregnant" female was stained with ammonium sulfide⁽²⁾ to detect very early resorptions.

3. Fetuses of Females Surviving to Scheduled Euthanasia

For each fetus, the following parameters were recorded: identification number, intrauterine location, sex, and body weight. The external alterations detected for each live fetus were also recorded.

For each litter, the first live fetus and every other live fetus thereafter were examined for visceral alterations.⁽³⁾ Retarded renal development was classified using the scheme of Woo and Hoar.⁽⁴⁾ In addition, all live fetuses with malformations visible at external examination were examined for soft tissue alterations; decapitation of these fetuses was at the discretion of the study director or a designee.

After fixation in Bouin's fixative, the heads of decapitated fetuses were examined and alterations were recorded. Examinations were based on the method of Barrow and Taylor.⁽⁵⁾ After alcohol fixation, the alizarin-stained skeletons were examined and skeletal alterations were recorded for all live fetuses, excluding the fetal heads fixed in Bouin's fixative.

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L. Control of Bias

In addition to random assignment to groups, all females were coded before scheduled euthanasia and remained coded during the collection of postmortem and fetal data.

M. Statistical Analyses

Sequential trend testing⁽⁶⁾ was applied to the data for each parameter as tabulated below. If a significant dose-response was detected, data from the top dose group was excluded and the test repeated until no significant trend was detected. For litter parameters, the proportion of affected fetuses per litter or the litter mean was used as the experimental unit for statistical evaluation.⁽⁷⁾ The level of significance selected was $p < 0.05$.

Where the data were tied and the standard large sample version of Jonckheere's test was not applicable, exact p values were calculated using permutation methodology.⁽⁸⁾

<u>Parameter</u>	<u>Trend Test</u>
Maternal weight Maternal weight changes Maternal food consumption	Linear contrast of means ⁽⁹⁾
Live fetuses Dead fetuses Resorptions Implantations Incidence of fetal alterations	Jonckheere's test ⁽¹⁰⁾
Incidence of pregnancy Clinical observations Maternal mortality Females with total resorptions Early deliveries	Cochran-Armitage test ⁽⁹⁾
Fetal weight (Covariates: litter size, sex ratio) Sex ratio (Covariate: litter size)	Linear contrast of least square means ⁽¹¹⁾

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RESULTS AND DISCUSSION

A. Maternal Findings

1. Mortality

There was no compound-related mortality at any level tested; all rats on study survived to scheduled sacrifice.

2. Body Weights (Table 1, Appendix A)

There was a minimal, compound-related reduction in mean maternal body weight at 500 mg/kg/day. Mean final body weight was 96% of the control and was statistically significant. There were no compound-related effects on mean maternal weight at 50 or 200 mg/kg/day.

3. Body Weight Changes (Table 2, Appendix B)

There were compound-related reductions in mean maternal body weight gain at 200 and 500 mg/kg/day. At 200 mg/kg/day, overall weight gain was 91%/79% of control using the absolute/adjusted final weight to calculate gain over days 6-21G. At 500 mg/kg/day, overall weight gain was 85%/63% of control using the absolute/adjusted final weight to calculate gain over days 6-21G. These overall reductions in body weight gain were statistically significant and considered the result of compound-related, statistically significant reductions in mean weight gain over days 6-8, 8-10, and 18-20G. While the effects on body weight gain at both 200 and 500 mg/kg/day were considered compound-related, the effect seen at 200 mg/kg/day was not considered adverse as the magnitude of the change was small and it had no adverse impact on mean body weight at this level. There were no compound-related effects on maternal body weight changes at 50 mg/kg/day.

4. Food Consumption (Table 3, Appendix C)

There were minimal, compound-related reductions in mean maternal food consumption at 50, 200, and 500 mg/kg/day. At 50 mg/kg/day, mean food consumption was significantly reduced over days 6-8G. This reduction was not considered adverse because it had no adverse impact on either overall mean food consumption or on body weight parameters. At 200 and 500 mg/kg/day, overall food consumption was 94 and 95% of control, respectively, when averaged over days 6-21G. These reductions in overall food consumption, which were not statistically significant, were considered the result of compound-related, statistically significant reductions in mean food consumption over days 6-8, 8-10, and 10-12G. Despite the statistical significance, these food consumption reductions at 200 and 500 mg/kg/day were not considered adverse because the reductions were transient and had no adverse impact on overall food consumption.

5. **Clinical Observations**
(Table 4, Appendix D)

Significant compound-related clinical observations were seen at 500 mg/kg/day and were limited to fur staining in the perineal area that was reported for 9/22 animals at this level. There were no compound-related clinical observations at 50 mg/kg/day.

6. **Postmortem Findings**
(Appendix E)

There were no compound-related gross postmortem findings at any level tested.

B. Fetal Findings

1. **Mortality**
(Table 5, Appendix F)

There was no compound-related embryofetal mortality evident as increased resorptions and/or dead fetuses at any level tested.

2. **Body Weight**
(Table 5, Appendices F and G)

There was a slight (97% of control) reduction in mean fetal weight at 200 and 500 mg/kg/day; at 500 mg/kg/day, the value was significantly different ($p=0.04$) whereas at 200 mg/kg/day, it was not significantly different ($p=0.07$). While these reductions were considered compound-related, they were not considered adverse based on the minimal magnitude of the reduction. Mean fetal weight at 50 mg/kg/day was equivalent to the control group value.

3. **Malformations**
(Table 6, Appendix G)

There were no compound-related fetal malformations at any level tested.

4. **Variations**
(Table 7, Appendix G)

Statistically significant increases in fetal skeletal variations were observed at 200 and 500 mg/kg/day. At 200 mg/kg/day, there was a significant increase in retarded skull bone ossification. This increase was not considered compound-related; rather, the incidence of this finding at 200 mg/kg/day (26 fetuses from 14 litters) appeared increased due to a relatively low value for the concurrent control group (7 fetuses from 7 litters). Recent historical control group values for retarded skull bone ossification are presented below for perspective:

Year Study Conducted	Reference	No. Affected Fetuses	No. Affected Litters
1997	1998-01367	19	10
1998	1998-01382	24	11
1998	DuPont-1165	11	8
1998	DuPont-1559	37	13
1999	1998-01500	18	8
1999	DuPont-2287	19	12
1999	DuPont-1454	21	10
1999	DuPont-3378	36	14
2000	DuPont-4177	47	14
2000	DuPont-4341	6	6
2001	DuPont-5676	58	19

At 500 mg/kg/day, there were significant increases in the following fetal skeletal variations: retarded skull bone ossification, retarded pelvic ossification, and wavy ribs. These observations were all considered compound-related.

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CONCLUSIONS

Under the conditions of this study, minimal evidence of maternal toxicity including reduced body weight and weight gain, and increased perineal fur staining was observed at 500 mg/kg/day. Similarly, minimal evidence of developmental toxicity was evident at 500 mg/kg/day based on increased skeletal variations including retarded skull bone and pelvic bone ossification and wavy ribs. No toxicologically significant or adverse compound-related effects were seen in dams or fetuses at 50 or 200 mg/kg/day. Thus, the no-observed-effect level (NOEL)^a for maternal and developmental toxicity was considered 200 mg/kg/day.

RECORDS AND SAMPLE STORAGE

Laboratory-specific or site-specific raw data such as personnel files and equipment records will be retained at the facility where the work was done.

A sample of the test substance was collected for archive purposes and retained at Haskell Laboratory. Specimens, raw data, and the final report will be retained at Haskell Laboratory, Newark, Delaware, or at Iron Mountain Records Management, Wilmington, Delaware. Characterization data will be stored at Regional Analytical Services (RAS), Jackson Laboratories, Deepwater, New Jersey.

^a The NOEL for this study is defined as the highest dose at which adverse effects attributable to the test substance were not detected. Thus, for this study, the NOEL is equivalent to the NOEL as defined by the U.S. EPA⁽¹²⁾ and to the no-observed-adverse-effect level (NOAEL) as defined by the European Union.⁽¹³⁾

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TABLES

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TABLE 1

MEAN MATERNAL BODY WEIGHTS (GRAMS)

Days Of Gestation	Group:		I	II	III	IV
	Dose (mg/kg/day):		0	50	200	500
	n:		22	22	22	22
0			240.6 (8.40) ^a	241.9 (9.56)	242.7 (9.12)	242.2 (8.99)
4 ^b			243.3 (20.24)	252.3 (12.89)	250.9 (19.39)	253.2 (7.46)
6			260.1 (13.13)	264.5 (12.16)	264.3 (18.07)	266.3 (9.12)
7			265.8 (14.03)	264.3 (14.51)	265.2 (15.61)	264.4 (9.22)
8			270.2 (14.92)	270.2 (16.00)	268.3 (19.66)	269.0 (11.55)
9			275.0 (16.97)	275.7 (13.98)	272.9 (17.31)	272.0 (11.57)
10			281.6 (19.01)	281.0 (13.44)	274.8 (20.20)	275.2 (11.75)
11			289.7 (18.36)	288.7 (14.38)	283.5 (18.33)	284.3 (12.01)
12			296.7 (18.54)	296.0 (15.22)	291.0 (18.26)	290.0 (12.89)
13			302.9 (17.28)	302.0 (16.33)	296.5 (17.71)	298.1 (13.34)
14			310.7 (17.98)	307.8 (15.80)	304.1 (17.42)	304.7 (14.09)
15			318.8 (19.58)	316.0 (16.91)	312.9 (18.46)	311.8 (15.11)
16			329.1 (19.22)	326.7 (16.70)	322.4 (18.95)	326.4 (14.98)
17			342.5 (20.67)	341.3 (18.97)	337.2 (20.95)	339.8 (17.54)
18			359.8 (20.64)	358.6 (19.22)	354.0 (21.44)	357.2 (17.65)
19			374.9 (23.64)	373.1 (20.57)	367.9 (22.91)	369.7 (20.51)
20			393.4 (24.74)	391.4 (22.83)	383.5 (22.88)	383.1 (24.38)
21			416.8 (27.86)	415.9 (23.54)	407.5 (28.74)	399.4 (28.51) *
21 ^c			319.0 (19.75)	315.3 (17.44)	310.9 (21.05)	303.4 (18.99) *

^a Standard deviation is presented in parentheses.

^b Day 4: Group I - N = 16; Group II - N = 17; Group III - N = 16; Group IV - N = 17.

^c Body weight calculated using the final body weight minus the weight of the products of conception.

* Significant trend (linear contrast of means); $p < 0.05$.

TABLE 2

MEAN MATERNAL BODY WEIGHT CHANGES (GRAMS)

Days Of Gestation	Group:		I	II	III	IV
	Dose (mg/kg/day) :		0	50	200	500
	n:		22	22	22	22
0-4 ^a			2.6 (17.68) ^b	10.2 (11.03)	7.9 (17.39)	11.2 (10.88)
4-6 ^a			15.3 (11.33)	13.4 (10.61)	13.4 (6.76)	12.9 (9.10)
6-8			10.2 (7.79)	5.7 (10.35)	4.0 (8.52)*	2.7 (6.79)*
8-10			11.4 (5.82)	10.8 (8.31)	6.5 (9.60)*	6.2 (5.27)*
10-12			15.1 (4.69)	15.0 (4.79)	16.2 (5.51)	14.9 (5.62)
12-14			14.0 (6.42)	11.8 (4.95)	13.0 (7.27)	14.7 (5.74)
14-16			18.4 (4.50)	18.9 (3.81)	18.4 (3.96)	21.7 (7.26)
16-18			30.7 (4.77)	31.9 (5.25)	31.6 (6.14)	30.8 (6.62)
18-20			33.6 (5.68)	32.9 (5.12)	29.6 (6.03)*	25.8 (15.00)*
20-21			23.4 (4.86)	24.5 (6.78)	24.0 (7.44)	16.4 (17.83)
6-21			156.7 (22.42)	151.4 (15.78)	143.2 (21.08)*	133.1 (27.54)*
6-21 ^c			58.9 (14.88)	50.8 (12.39)	46.6 (15.74)*	37.1 (18.48)*

^a Day 4: Group I - N = 16; Group II - N = 17; Group III - N = 16; Group IV - N = 17.

^b Standard deviation is presented in parentheses.

^c Body weight calculated using the final body weight minus the weight of the products of conception.

* Significant trend (linear contrast of means); $p < 0.05$.

TABLE 3

MEAN MATERNAL FOOD CONSUMPTION (GRAMS/DAY)

Days Of Gestation	Group:	I	II	III	IV
	Dose (mg/kg/day) :	0	50	200	500
	n:	22	22	22	22
4-6		22.7 (5.99) ^a	23.6 (5.01)	23.6 (4.89)	23.1 (2.16)
6-8		24.6 (4.21)	20.6 (5.01)*	20.3 (4.84)*	20.6 (2.94)*
8-10		25.3 (4.13)	23.5 (2.42)	20.8 (4.32)*	20.8 (3.20)*
10-12		27.6 (3.99)	26.4 (3.12)	24.5 (2.85)*	24.8 (2.83)*
12-14		27.9 (2.87) ^b	26.5 (3.18)	26.1 (2.12)	26.1 (2.89)
14-16		28.4 (3.44)	26.9 (3.89)	26.9 (2.65)	27.8 (3.84)
16-18		30.4 (3.09)	29.1 (3.50)	28.3 (3.05)	30.2 (3.43)
18-20		28.6 (3.95)	28.1 (3.40)	27.2 (2.85)	27.6 (4.81)
20-21		27.1 (4.68)	26.6 (3.94)	25.5 (4.28)	24.8 (9.93)
4-21		26.1 (4.12)	25.6 (2.73)	24.8 (2.18)	25.1 (1.75)
6-21		26.6 (4.71)	25.9 (2.67)	24.9 (2.13)	25.4 (1.91)

^a Standard deviation is presented in parentheses.

^b N=21

* Significant trend (linear contrast of means); $p < 0.05$.

TABLE 4

CLINICAL OBSERVATIONS

DAY OF GESTATION	OBSERVATION:	GROUP :	I	II	III	IV
		DOSE (mg/kg/day) :	0	50	200	500
		NO. EXAMINED :	22	22	22	22
=====						
4- 5	ALOPECIA		1	1	0	0
6-21	ALOPECIA		6	11	11	10
	DEHYDRATED		0	1	0	0
	SORE		1	0	1	0
	STAINED BOTH SHOULDER		0	1	0	0
	STAIN PERINEUM		0	0	1	9*
	STAIN PERIORAL		0	0	0	1
	TEETH MISSING		1	0	1	0
	WET PERINEUM		0	0	0	1

* Significant trend (Cochran-Armitage test); $p \leq 0.05$.

TABLE 5

REPRODUCTIVE OUTCOME

Group:		I	II	III	IV
Dose (mg/kg/day):		0	50	200	500
No. Mated		22	22	22	22
No. Pregnant		22	22	22	22
No. Deaths		0	0	0	0
No. With Total Resorptions		0	0	0	0
No. Litters		22	22	22	22
<u>Means Per Litter</u>					
Mean Corpora Lutea ^a		16.7 (1.93) ^b	16.6 (2.32)	16.6 (3.02)	15.8 (1.77)
Implantations		14.2 (1.31)	14.8 (1.82)	14.2 (2.29)	14.4 (1.81)
Resorptions:	Total	0.4 (0.58)	0.4 (0.59)	0.2 (0.39)	0.4 (0.91)
	Early	0.4 (0.58)	0.3 (0.57)	0.2 (0.39)	0.4 (0.91)
	Late	0	0.1 (0.29)	0	0
Dead Fetuses		0	0	0	0
Live Fetuses ^c :	Total	13.9 (1.49)	14.4 (1.71)	14.0 (2.44)	14.0 (2.24)
	Males	6.3 (2.29)	6.5 (2.22)	6.9 (2.31)	6.5 (1.79)
	Females	7.6 (1.94)	8.0 (2.24)	7.1 (2.29)	7.5 (1.71)
Mean Fetal Weight:	Total	5.53 (0.30)	5.52 (0.26)	5.36 (0.20)	5.38 (0.44)*
Sex Ratio ^d		0.45 (0.14)	0.45 (0.14)	0.49 (0.15)	0.46 (0.09)

^a Statistical analyses are not conducted on mean corpora lutea data; these data are presented for information only.

^b Standard deviation is reported in parentheses.

^c Statistical analyses are only conducted on the mean total number of live fetuses per litter. The mean number of males and females are presented for information only.

^d Number male fetuses/total number fetuses per litter.

* Significant trend; $p < 0.05$.

TABLE 6
INCIDENCE OF FETAL MALFORMATIONS

	Group:	I	II	III	IV
	Dose (mg/kg/day):	0	50	200	500
<u>EXTERNAL</u>					
No. Examined ^a		305 (22)	317 (22)	309 (22)	307 (22)
Umbilical hernia		---- ^b	1 (1)	----	----
Micrognathia		----	1 (1)	----	----
No. Affected		----	2 (2)	----	----
<u>VISCERAL</u>					
No. Examined		160 (22)	165 (22)	159 (22)	158 (22)
No. Affected		----	----	----	----
<u>HEAD</u>					
No. Examined		160 (22)	164 (22)	159 (22)	158 (22)
Brain - Distended Ventricles		----	1 (1)	1 (1)	----
No. Affected		----	1 (1)	1 (1)	----
<u>SKELETAL</u>					
No. Examined		302 (22)	316 (22)	306 (22)	303 (22)
Rib - Fused		----	1 (1)	----	----
Micrognathia		----	1 (1)	----	----
Vertebra					
Fused		----	1 (1)	----	----
Hemi		----	1 (1)	----	----
No. Affected		----	2 (2)	----	----
<u>TOTAL NUMBER AFFECTED</u>		0 (0)	4 (4)	1 (1)	0 (0)

a Number examined and affected, including the number affected with the listed malformations are expressed as Fetuses (Litters).

b For ease of reading, zeros have been replaced with dashes for the listed malformations.

No significant trends were detected.

Note: Statistical analyses are only conducted on the individual endpoints. The overall total and totals by exam type are presented for information only.

TABLE 7
INCIDENCE OF FETAL VARIATIONS

	Group:	I	II	III	IV
	Dose (mg/kg/day):	0	50	200	500
<u>DEVELOPMENTAL VARIATIONS</u>					
<u>EXTERNAL</u>					
No. Examined ^a		305 (22)	317 (22)	309 (22)	307 (22)
No. Affected		---- ^b	----	----	----
<u>VISCERAL</u>					
No. Examined		160 (22)	164 (22)	159 (22)	158 (22)
No. Affected		----	----	----	----
<u>HEAD</u>					
No. Examined		160 (22)	164 (22)	159 (22)	158 (22)
No. Affected		----	----	----	----
<u>SKELETAL</u>					
No. Examined		302 (22)	316 (22)	306 (22)	303 (22)
Rib - Rudimentary Cervical		1 (1)	1 (1)	1 (1)	1 (1)
Rib - Supernumerary		16 (5)	6 (6)	25 (7)	16 (6)
Scapula - Misshapen		----	1 (1)	----	----
Sternebra - Fused		---	---	1 (1)	---
No. Affected		17 (6)	8 (8)	26 (7)	17 (6)
TOTAL WITH DEVELOPMENTAL VARIATIONS		17 (6)	8 (8)	26 (7)	17 (6)

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TABLE 7 (Continued)

INCIDENCE OF FETAL VARIATIONS

	Group: I	II	III	IV
Dose (mg/kg/day):	0	50	200	500
<u>VARIATIONS DUE TO RETARDED DEVELOPMENT</u>				
<u>EXTERNAL</u>				
No. Examined	305 (22)	317 (22)	309 (22)	307 (22)
No. Affected	----	----	----	----
<u>VISCERAL</u>				
No. Examined	160 (22)	165 (22)	159 (22)	158 (22)
Heart &/or Greater Vessels -				
Patent Ductus Arteriosis	----	2 (2)	----	----
Kidney, Papillae				
Small Papilla - Size 1	----	2 (2)	1 (1)	----
Small Papilla - Size 2	12 (12)	11 (8)	2 (2)	2 (2)
Papilla - Size 3	16 (12)	11 (10)	9 (6)	12 (11)
No. Affected	28 (18)	26 (16)	12 (8)	14 (12)
<u>HEAD</u>				
No. Examined	160 (22)	164 (22)	159 (22)	158 (22)
No. Affected	----	----	----	----
<u>SKELETAL</u>				
No. Examined	302 (22)	316 (22)	306 (22)	303 (22)
Femur - Retarded Ossification	----	----	1 (1)	----
Pelvis - Retarded Ossification	1 (1)	----	1 (1)	6 (3)*
Rib - Wavy	----	1 (1)	1 (1)	10 (4)*
Skull - Retarded Ossification	7 (7)	10 (8)	26 (14)*	65 (18)*
Sternebra - Retarded Ossification	1 (1)	2 (2)	4 (3)	5 (2)
Vertebra - Retarded Ossification	110 (21)	146 (21)	124 (21)	69 (19)
No. Affected	116 (21)	149 (21)	136 (22)	125 (21)

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TABLE 7 (Continued)

INCIDENCE OF FETAL VARIATIONS

	Group:	I	II	III	IV
	Dose (mg/kg/day):	0	50	200	500
TOTAL WITH VARIATIONS DUE TO RETARDED DEVELOPMENT		136 (22)	166 (22)	145 (22)	135 (21)
TOTAL NUMBER FETUSES WITH VARIATIONS		145 (22)	169 (22)	160 (22)	147 (21)

a Number examined and affected, including the number affected with the listed variations, are expressed as Fetuses (Litters).

b For ease of reading, zeros have been replaced with dashes for the listed variations.

* Significant trend (Jonckheere's test); $p < 0.05$

Note: Statistical analyses are only conducted on the individual endpoints. The overall total and totals by exam are presented for information only.

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APPENDICES

Company Sanitized. Does not contain TSCA CBI

APPENDIX A

Individual Body Weights

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Individual Body Weights

Explanatory Notes

Footnotes

- a* Day 0G body weights are provided by the vendor; the vendor-supplied body weight data are only recorded to 3 significant figures and are reported in this appendix accordingly
- b* Maternal body weight minus the weight of the products of conception.

Abbreviations

--- = No Data

~~Company Sanitized. Does not contain TSCA CBI~~

INDIVIDUAL BODY WEIGHTS (grams)

GROUP I: 0 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION						
	0 ^a	4	6	7	8	9	10
646224	247	255.6	261.9	275.7	279.7	288.7	298.0
646225	230	237.3	249.2	254.0	258.1	262.6	268.0
646226	260	271.6	291.2	294.7	297.7	305.4	313.0
646230	252	241.0	265.0	273.2	285.4	289.5	293.0
646236	230	252.1	268.7	267.9	275.2	283.4	291.3
646241	245	259.9	271.4	282.3	290.4	296.4	305.8
646251	246	259.9	267.6	272.7	275.5	276.9	289.5
646252	235	246.5	255.2	265.3	266.5	270.3	284.7
646256	250	258.6	257.4	269.4	278.8	281.8	286.2
646257	244	246.9	259.0	264.0	264.9	268.6	272.5
646261	235	228.8	261.0	266.4	269.2	276.9	282.2
646265	234	---	250.6	254.9	257.5	261.7	267.6
646272	235	---	263.8	266.7	271.3	276.7	281.9
646276	243	---	276.8	272.2	274.7	287.5	294.1
646278	235	---	260.4	265.6	268.4	272.4	280.0
646282	252	---	274.3	275.9	282.8	288.2	292.9
646284	242	---	258.2	268.4	270.9	274.3	280.1
646288	236	260.7	264.9	275.2	280.4	286.1	294.4
646290	226	227.4	240.3	243.7	247.2	249.2	252.5
646292	236	195.4	238.8	225.7	228.8	226.8	222.8
646294	240	243.2	252.4	261.4	263.1	264.3	267.9
646308	240	208.6	233.7	251.9	258.8	261.6	276.9

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL BODY WEIGHTS (grams)

GROUP I: 0 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION						
	11	12	13	14	15	16	17
646224	301.1	309.1	313.9	327.0	330.5	340.5	357.3
646225	278.8	282.7	285.4	295.2	302.1	313.9	326.6
646226	324.4	326.0	337.9	350.4	361.8	376.0	394.3
646230	301.5	307.6	313.4	323.2	327.9	338.4	352.0
646236	299.6	305.4	309.0	321.4	323.2	334.0	349.6
646241	312.5	319.1	320.5	332.0	348.9	352.5	365.6
646251	294.1	295.0	303.7	310.6	315.9	326.8	331.8
646252	292.4	297.5	305.9	312.6	316.0	329.2	343.9
646256	301.4	302.0	318.6	316.9	325.2	340.3	348.1
646257	281.0	283.9	294.3	297.2	302.2	313.7	322.9
646261	286.4	293.9	303.6	304.6	309.0	315.2	324.2
646265	273.4	280.7	284.5	289.6	299.8	302.5	314.9
646272	286.2	305.9	304.0	307.7	313.0	327.0	326.9
646276	299.7	315.1	314.5	321.8	341.1	347.6	359.9
646278	288.2	298.4	302.2	308.2	319.3	334.0	343.4
646282	302.3	313.4	314.6	320.9	333.3	340.0	360.6
646284	285.9	303.0	301.1	306.7	319.1	329.2	347.9
646288	303.8	308.5	318.6	329.9	333.5	345.8	364.3
646290	263.5	265.9	273.9	280.2	285.6	299.9	318.2
646292	235.5	245.5	261.0	273.9	279.8	296.2	311.9
646294	274.2	277.3	283.9	291.8	300.1	305.6	319.3
646308	287.6	291.7	299.5	313.4	326.5	332.7	350.8

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL BODY WEIGHTS (grams)

GROUP I: 0 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION				
	18	19	20	21	21 ^b
646224	373.9	386.1	405.3	432.6	335.6
646225	340.3	350.5	372.2	395.0	301.4
646226	409.7	424.1	448.0	471.4	353.0
646230	368.7	388.9	402.9	419.2	321.0
646236	362.0	378.3	394.2	418.5	321.0
646241	384.1	405.1	429.5	459.1	342.8
646251	354.0	365.7	385.0	404.4	307.8
646252	358.5	379.4	401.7	430.8	325.7
646256	368.8	381.3	398.8	427.8	339.4
646257	340.4	354.1	368.3	391.5	306.6
646261	339.1	348.4	365.3	382.2	305.8
646265	334.9	344.0	361.2	383.5	302.8
646272	347.5	364.1	385.5	409.0	312.5
646276	381.2	403.8	417.7	444.8	342.5
646278	360.4	377.4	389.5	417.2	328.9
646282	376.2	393.9	413.2	440.7	327.4
646284	360.0	380.2	397.1	420.8	325.1
646288	382.8	402.3	420.0	443.1	331.3
646290	331.2	342.4	358.6	369.3	276.5
646292	334.1	345.0	365.8	387.1	283.2
646294	335.4	343.4	360.8	378.6	296.3
646308	373.2	388.9	414.5	442.4	330.5

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL BODY WEIGHTS (grams)

GROUP II: 50 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION						
	0 ^a	4	6	7	8	9	10
646227	252	267.3	285.6	285.5	286.5	296.4	301.2
646229	230	237.6	257.1	258.8	266.4	272.7	277.6
646231	255	263.2	282.3	284.9	285.3	295.9	298.6
646235	246	260.6	272.6	278.5	273.5	287.0	287.4
646242	251	256.5	264.1	265.7	267.2	271.7	272.1
646245	235	250.9	252.4	247.2	259.3	263.4	266.2
646246	253	266.7	279.5	268.1	283.0	296.5	293.0
646249	233	218.6	252.1	253.0	262.3	261.3	268.3
646250	239	259.3	272.9	278.1	288.6	285.6	296.7
646253	245	258.9	272.6	272.0	283.4	288.7	292.9
646264	257	238.3	277.1	274.9	289.2	291.3	298.6
646267	248	---	270.6	275.2	278.6	277.9	282.8
646274	232	---	253.1	253.8	261.2	262.5	270.5
646279	233	---	247.8	249.3	252.1	262.0	260.2
646280	258	---	256.7	227.0	220.1	248.3	264.5
646286	235	---	273.9	276.5	278.4	282.4	293.6
646291	230	243.0	244.2	249.5	254.5	256.8	261.4
646296	230	246.5	253.3	257.0	263.8	267.1	272.1
646297	243	251.7	256.5	259.6	266.8	267.7	268.6
646298	233	248.1	264.7	269.4	280.8	279.8	288.6
646300	238	254.2	254.7	255.9	263.1	266.9	277.7
646306	245	267.7	274.9	275.7	280.8	283.7	288.8

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL BODY WEIGHTS (grams)

GROUP II: 50 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION						
	11	12	13	14	15	16	17
646227	312.8	320.7	327.8	335.4	340.5	353.9	368.9
646229	284.2	292.3	302.2	313.3	328.1	335.3	355.3
646231	307.6	308.1	318.1	327.1	330.6	339.9	359.3
646235	294.8	302.2	309.8	320.3	325.4	334.6	357.0
646242	280.2	282.3	286.3	295.1	295.9	306.0	321.8
646245	268.5	277.7	286.7	287.0	292.2	306.4	310.7
646246	307.4	320.1	323.8	323.3	337.8	348.5	361.4
646249	274.3	283.6	294.8	296.6	302.7	316.5	330.3
646250	305.1	315.0	321.7	327.8	336.2	346.0	361.9
646253	299.2	308.8	320.6	321.6	330.5	344.8	361.1
646264	300.6	314.9	320.7	321.2	335.7	344.1	360.1
646267	289.6	296.7	298.5	302.1	315.5	322.1	337.0
646274	276.6	283.9	295.9	301.8	306.1	322.0	332.7
646279	271.4	279.6	273.7	285.5	293.3	304.2	310.6
646280	273.4	289.4	292.3	299.2	309.0	315.1	330.0
646286	301.2	305.1	311.2	318.0	330.1	337.2	349.9
646291	268.0	269.5	270.8	276.5	286.7	296.8	305.4
646296	277.0	282.9	290.9	297.3	310.0	320.1	333.8
646297	276.3	278.6	286.3	290.0	294.6	304.2	324.2
646298	298.7	306.7	310.0	313.1	325.1	336.6	351.4
646300	284.5	290.8	294.7	307.5	310.5	321.5	338.9
646306	299.3	303.4	307.6	311.5	315.0	331.3	347.1

Company Sanitized. Does not contain TSCA CB

INDIVIDUAL BODY WEIGHTS (grams)

GROUP II: 50 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION				
	18	19	20	21	21 ^b
646227	390.5	402.3	423.2	447.1	348.5
646229	377.8	391.6	411.1	438.5	340.8
646231	368.2	382.9	406.5	437.3	333.3
646235	371.7	385.7	406.9	435.2	331.0
646242	338.1	348.8	362.8	385.2	296.3
646245	324.0	338.7	357.0	379.0	295.8
646246	379.8	394.4	421.0	450.2	332.0
646249	347.9	357.1	377.2	404.4	314.1
646250	376.4	395.5	411.6	432.5	319.4
646253	375.4	392.5	413.1	430.8	319.9
646264	377.7	397.1	418.3	443.6	336.2
646267	352.9	367.6	380.2	404.3	307.9
646274	352.5	373.0	387.1	393.1	295.5
646279	329.4	350.0	361.0	396.1	301.8
646280	350.8	369.4	384.7	408.8	303.5
646286	371.8	388.7	410.0	432.7	310.4
646291	321.4	328.4	345.4	364.5	284.8
646296	356.2	364.9	380.6	417.4	326.6
646297	341.6	349.6	368.0	399.3	292.7
646298	369.4	380.1	404.0	424.3	316.1
646300	355.9	374.4	392.1	407.5	304.8
646306	359.4	375.8	389.9	418.4	325.4

Company Sealed. Does not contain TSCA CB.

INDIVIDUAL BODY WEIGHTS (grams)

GROUP III: 200 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION						
	0 ^a	4	6	7	8	9	10
646222	252	252.8	264.3	263.8	272.8	268.6	270.6
646228	257	273.6	291.4	292.0	301.2	307.4	306.7
646232	236	248.4	259.4	239.5	228.3	249.6	260.5
646234	251	252.8	268.0	270.0	270.3	278.0	282.5
646237	246	255.3	265.5	269.5	272.3	281.9	266.4
646238	239	246.2	260.2	260.8	266.1	269.1	273.9
646243	243	257.9	269.2	261.7	266.1	263.0	271.9
646248	260	242.8	278.8	284.8	285.5	294.9	295.7
646254	234	249.9	264.1	261.3	270.1	267.9	270.1
646258	241	260.9	271.5	278.6	275.6	275.7	280.2
646259	250	256.3	272.2	270.8	279.5	282.4	286.9
646266	255	---	278.0	275.9	280.5	289.4	292.0
646268	230	---	248.4	242.9	251.4	254.5	265.1
646269	245	---	265.8	270.1	274.9	275.8	279.2
646271	244	---	263.9	264.6	273.8	275.6	282.8
646273	242	---	268.9	268.5	272.5	274.6	278.8
646285	236	---	261.3	269.5	272.1	276.1	281.6
646299	230	255.6	262.7	266.0	267.9	276.9	275.5
646302	230	186.7	195.5	221.0	205.4	235.4	209.9
646303	249	276.8	285.8	283.6	287.7	299.7	304.7
646305	231	250.1	257.9	255.7	262.8	263.5	264.0
646307	238	247.7	262.2	263.8	266.7	243.8	246.6

Company Sanitized. Does not contain TSCA CRI

INDIVIDUAL BODY WEIGHTS (grams)

GROUP III: 200 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION						
	11	12	13	14	15	16	17
646222	276.0	288.0	291.0	302.6	304.7	314.5	335.9
646228	315.9	319.7	327.7	337.8	347.3	358.7	376.0
646232	261.1	273.3	279.9	288.7	292.7	301.2	316.4
646234	290.3	298.8	303.5	312.7	311.2	328.6	344.4
646237	275.0	287.8	301.0	315.8	320.8	335.4	346.7
646238	277.2	283.3	288.8	298.6	305.1	311.7	327.3
646243	281.7	292.5	301.4	305.8	311.7	325.9	336.1
646248	305.6	315.2	323.7	329.6	336.1	351.4	366.8
646254	275.9	278.8	287.6	290.2	301.2	313.9	325.0
646258	289.0	295.9	306.3	309.7	319.9	333.5	345.1
646259	298.4	302.9	317.2	319.6	326.1	336.6	351.5
646266	300.3	310.3	303.8	320.2	333.4	339.1	352.4
646268	267.8	277.1	279.4	289.7	297.3	310.4	319.6
646269	287.8	298.3	302.4	306.3	321.1	329.9	344.1
646271	289.0	300.3	299.7	302.4	311.0	317.5	339.1
646273	284.6	295.1	295.0	301.3	312.1	322.5	336.8
646285	288.1	298.5	293.8	292.8	310.4	312.5	324.2
646299	289.2	293.1	296.1	303.7	320.9	321.2	337.8
646302	244.3	244.7	250.9	265.3	273.1	282.4	289.7
646303	316.3	315.0	319.9	330.0	346.5	349.5	375.0
646305	274.6	276.7	281.4	283.3	290.4	293.0	303.3
646307	249.4	257.6	272.9	283.6	291.8	304.1	325.0

Company Sanitized. Does not contain TSCA CB1

INDIVIDUAL BODY WEIGHTS (grams)

GROUP III: 200 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION				
	18	19	20	21	21 ^b
646222	349.2	360.9	381.0	403.6	318.7
646228	394.8	411.0	425.2	460.9	358.2
646232	333.9	346.3	358.6	371.3	289.7
646234	360.0	373.0	393.2	414.8	314.8
646237	359.5	371.0	383.2	416.3	304.3
646238	344.7	355.3	367.2	389.0	311.1
646243	353.3	367.3	381.8	394.9	306.9
646248	389.5	407.7	426.9	460.2	355.4
646254	349.4	367.7	387.9	407.0	288.4
646258	360.0	377.4	387.2	407.1	314.9
646259	368.1	386.3	402.5	438.7	338.3
646266	368.4	382.5	397.4	424.1	330.3
646268	336.1	354.8	375.4	403.0	296.8
646269	352.1	371.5	393.2	423.2	304.3
646271	350.1	368.0	377.9	403.8	306.6
646273	357.2	370.6	388.7	410.9	300.4
646285	336.1	350.3	365.1	389.8	310.0
646299	354.7	365.7	373.4	397.2	302.3
646302	316.5	325.5	343.9	363.8	279.8
646303	398.3	407.8	420.3	449.3	331.5
646305	316.0	322.4	338.5	345.3	291.8
646307	339.9	351.6	369.6	391.1	285.5

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL BODY WEIGHTS (grams)

GROUP IV: 500 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION						
	0 ^a	4	6	7	8	9	10
646221	245	255.5	273.0	264.8	277.6	280.0	275.6
646223	257	262.4	280.9	272.0	286.5	293.3	290.6
646233	253	246.6	269.9	270.6	280.1	288.0	283.4
646239	248	260.8	273.3	264.9	278.8	278.7	285.6
646240	239	258.8	271.1	263.0	275.2	274.7	272.7
646244	250	251.1	261.5	263.1	261.7	263.4	264.9
646247	239	257.5	257.6	272.2	276.4	281.4	288.3
646255	243	260.7	275.4	270.5	266.3	274.1	272.6
646260	255	241.3	279.9	282.5	285.4	282.2	289.4
646262	226	248.4	261.1	264.9	268.0	269.3	273.1
646263	243	253.7	271.8	264.0	262.8	261.0	255.5
646270	229	---	255.2	254.5	257.3	263.8	273.1
646275	236	---	266.4	264.5	260.0	267.9	268.6
646277	250	---	277.8	276.3	280.5	284.9	292.4
646281	250	---	271.5	272.3	280.5	276.9	287.4
646283	250	---	264.2	263.8	277.2	275.3	284.0
646287	236	252.4	255.7	252.0	252.2	256.5	259.7
646289	233	253.5	263.1	261.7	260.4	266.6	271.3
646293	240	242.4	255.0	246.5	254.6	254.4	261.1
646295	231	260.2	267.4	268.2	268.9	277.1	279.0
646301	246	259.9	261.2	260.8	262.2	268.9	273.5
646304	230	238.6	245.9	243.2	244.9	245.8	251.5

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL BODY WEIGHTS (grams)

GROUP IV: 500 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION						17
	11	12	13	14	15	16	
646221	286.1	285.9	291.5	298.0	299.4	312.8	330.6
646223	300.1	310.4	316.2	322.9	325.4	336.9	351.6
646233	289.1	293.4	308.1	317.5	329.6	335.4	356.5
646239	297.0	302.6	313.8	328.8	332.9	347.7	361.1
646240	283.1	288.2	302.4	306.2	318.2	333.9	351.1
646244	271.0	273.8	282.5	280.5	285.2	298.7	302.4
646247	292.5	301.7	310.1	313.9	310.4	314.1	333.0
646255	275.7	281.9	292.4	295.1	304.7	319.1	331.6
646260	301.4	297.6	313.9	317.1	328.6	342.8	360.8
646262	280.2	290.4	298.6	304.7	313.9	330.5	346.0
646263	260.4	275.9	288.2	296.7	306.2	329.4	346.2
646270	284.0	280.7	288.9	294.1	300.6	315.4	310.2
646275	283.2	295.8	297.5	298.4	308.9	319.4	339.3
646277	293.9	309.0	310.0	317.1	330.5	341.5	338.9
646281	298.1	312.7	316.2	325.9	338.1	351.7	364.4
646283	296.7	301.8	310.4	316.3	317.4	338.0	354.8
646287	265.1	275.4	281.3	289.0	295.0	312.7	324.0
646289	286.0	288.8	287.9	300.2	308.5	323.7	348.5
646293	277.4	280.0	296.5	303.6	313.0	337.7	349.2
646295	290.4	289.0	297.2	304.4	313.6	330.9	342.4
646301	281.8	280.3	288.6	298.1	296.6	310.0	324.8
646304	262.1	265.2	265.7	275.3	282.8	298.6	308.3

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL BODY WEIGHTS (grams)

GROUP IV: 500 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION				
	18	19	20	21	21 ^b
646221	341.3	344.4	362.4	377.1	303.8
646223	364.8	380.9	401.4	428.6	327.4
646233	370.6	386.6	407.1	432.4	330.4
646239	383.8	395.0	416.2	441.4	340.2
646240	361.1	372.9	382.1	390.4	282.9
646244	315.8	321.3	336.4	357.4	301.4
646247	349.9	367.4	376.8	397.0	297.5
646255	350.4	366.4	376.3	400.8	307.6
646260	381.6	391.2	411.8	430.6	313.9
646262	359.2	367.5	322.6	353.6	276.1
646263	365.2	388.8	401.9	421.1	309.0
646270	351.4	371.0	388.0	414.4	303.0
646275	359.3	363.8	378.9	396.0	297.3
646277	361.0	379.3	393.4	363.3	276.2
646281	377.1	395.8	399.0	358.3	272.6
646283	369.1	383.5	398.8	421.2	326.4
646287	337.7	346.3	363.4	376.2	280.0
646289	367.9	374.6	396.1	423.0	309.4
646293	369.5	389.1	403.2	426.4	305.2
646295	362.6	371.3	393.2	426.0	324.5
646301	335.7	343.4	365.6	384.6	303.3
646304	323.7	333.7	352.7	367.5	286.9

Company Sanitized. Does not contain TSCA CBI

APPENDIX B

Individual Body Weight Changes

Company Sanitized. Does not contain TSCA CB1

Company Sanitized. Does not contain TSCA CB1

Explanatory Notes

a Maternal body weight minus the weight of the products of conception.

--- = No Data

SECRET

INDIVIDUAL BODY WEIGHT CHANGES (grams)

GROUP I: 0 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION						
	0-4	4-6	6-8	8-10	10-12	12-14	14-16
646224	8.6	6.3	17.8	18.3	11.1	17.9	13.5
646225	7.3	11.9	8.9	9.9	14.7	12.5	18.7
646226	11.6	19.6	6.5	15.3	13.0	24.4	25.6
646230	-11.0	24.0	20.4	7.6	14.6	15.6	15.2
646236	22.1	16.6	6.5	16.1	14.1	16.0	12.6
646241	14.9	11.5	19.0	15.4	13.3	12.9	20.5
646251	13.9	7.7	7.9	14.0	5.5	15.6	16.2
646252	11.5	8.7	11.3	18.2	12.8	15.1	16.6
646256	8.6	-1.2	21.4	7.4	15.8	14.9	23.4
646257	2.9	12.1	5.9	7.6	11.4	13.3	16.5
646261	-6.2	32.2	8.2	13.0	11.7	10.7	10.6
646265	---	---	6.9	10.1	13.1	8.9	12.9
646272	---	---	7.5	10.6	24.0	1.8	19.3
646276	---	---	-2.1	19.4	21.0	6.7	25.8
646278	---	---	8.0	11.6	18.4	9.8	25.8
646282	---	---	8.5	10.1	20.5	7.5	19.1
646284	---	---	12.7	9.2	22.9	3.7	22.5
646288	24.7	4.2	15.5	14.0	14.1	21.4	15.9
646290	1.4	12.9	6.9	5.3	13.4	14.3	19.7
646292	-40.6	43.4	-10.0	-6.0	22.7	28.4	22.3
646294	3.2	9.2	10.7	4.8	9.4	14.5	13.8
646308	-31.4	25.1	25.1	18.1	14.8	21.7	19.3

Company Sanitized. Does not contain TSCA CBI

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL BODY WEIGHT CHANGES (grams)

GROUP I: 0 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION				
	16-18	18-20	20-21	6-21	6-21 ^a
646224	33.4	31.4	27.3	170.7	73.7
646225	26.4	31.9	22.8	145.8	52.2
646226	33.7	38.3	23.4	180.2	61.8
646230	30.3	34.2	16.3	154.2	56.1
646236	28.0	32.2	24.3	149.8	52.3
646241	31.6	45.4	29.6	187.7	71.4
646251	27.2	31.0	19.4	136.8	40.2
646252	29.3	43.2	29.1	175.6	70.5
646256	28.5	30.0	29.0	170.4	82.0
646257	26.7	27.9	23.2	132.5	47.6
646261	23.9	26.2	16.9	121.2	44.8
646265	32.4	26.3	22.3	132.9	52.2
646272	20.5	38.0	23.5	145.2	48.7
646276	33.6	36.5	27.1	168.0	65.7
646278	26.4	29.1	27.7	156.8	68.5
646282	36.2	37.0	27.5	166.4	53.1
646284	30.8	37.1	23.7	162.6	66.9
646288	37.0	37.2	23.1	178.2	66.4
646290	31.3	27.4	10.7	129.0	36.2
646292	37.9	31.7	21.3	148.3	44.4
646294	29.8	25.4	17.8	126.2	43.9
646308	40.5	41.3	27.9	208.7	96.8

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL BODY WEIGHT CHANGES (grams)

GROUP II: 50 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION						
	0-4	4-6	6-8	8-10	10-12	12-14	14-16
646227	15.3	18.3	0.9	14.7	19.5	14.7	18.5
646229	7.6	19.5	9.3	11.2	14.7	21.0	22.0
646231	8.2	19.1	3.0	13.3	9.5	19.0	12.8
646235	14.6	12.0	0.9	13.9	14.8	18.1	14.3
646242	5.5	7.6	3.1	4.9	10.2	12.8	10.9
646245	15.9	1.5	6.9	6.9	11.5	9.3	19.4
646246	13.7	12.8	3.5	10.0	27.1	3.2	25.2
646249	-14.4	33.5	10.2	6.0	15.3	13.0	19.9
646250	20.3	13.6	15.7	8.1	18.3	12.8	18.2
646253	13.9	13.7	10.8	9.5	15.9	12.8	23.2
646264	-18.7	38.8	12.1	9.4	16.3	6.3	22.9
646267	---	---	8.0	4.2	13.9	5.4	20.0
646274	---	---	8.1	9.3	13.4	17.9	20.2
646279	---	---	4.3	8.1	19.4	5.9	18.7
646280	---	---	-36.6	44.4	24.9	9.8	15.9
646286	---	---	4.5	15.2	11.5	12.9	19.2
646291	13.0	1.2	10.3	6.9	8.1	7.0	20.3
646296	16.5	6.8	10.5	8.3	10.8	14.4	22.8
646297	8.7	4.8	10.3	1.8	10.0	11.4	14.2
646298	15.1	16.6	16.1	7.8	18.1	6.4	23.5
646300	16.2	0.5	8.4	14.6	13.1	16.7	14.0
646306	22.7	7.2	5.9	8.0	14.6	8.1	19.8

Company Sanitized. Does not contain TSCA CB

INDIVIDUAL BODY WEIGHT CHANGES (grams)

GROUP II: 50 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION				
	16-18	18-20	20-21	6-21	6-21 ^a
646227	36.6	32.7	23.9	161.5	62.9
646229	42.5	33.3	27.4	181.4	83.7
646231	28.3	38.3	30.8	155.0	51.0
646235	37.1	35.2	28.3	162.6	58.4
646242	32.1	24.7	22.4	121.1	32.2
646245	17.6	33.0	22.0	126.6	43.4
646246	31.3	41.2	29.2	170.7	52.5
646249	31.4	29.3	27.2	152.3	62.0
646250	30.4	35.2	20.9	159.6	46.5
646253	30.6	37.7	17.7	158.2	47.3
646264	33.6	40.6	25.3	166.5	59.1
646267	30.8	27.3	24.1	133.7	37.3
646274	30.5	34.6	6.0	140.0	42.4
646279	25.2	31.6	35.1	148.3	54.0
646280	35.7	33.9	24.1	152.1	46.8
646286	34.6	38.2	22.7	158.8	36.5
646291	24.6	24.0	19.1	120.3	40.6
646296	36.1	24.4	36.8	164.1	73.3
646297	37.4	26.4	31.3	142.8	36.2
646298	32.8	34.6	20.3	159.6	51.4
646300	34.4	36.2	15.4	152.8	50.1
646306	28.1	30.5	28.5	143.5	50.5

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL BODY WEIGHT CHANGES (grams)

GROUP III: 200 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION						
	0-4	4-6	6-8	8-10	10-12	12-14	14-16
646222	0.8	11.5	8.5	-2.2	17.4	14.6	11.9
646228	16.6	17.8	9.8	5.5	13.0	18.1	20.9
646232	12.4	11.0	-31.1	32.2	12.8	15.4	12.5
646234	1.8	15.2	2.3	12.2	16.3	13.9	15.9
646237	9.3	10.2	6.8	-5.9	21.4	28.0	19.6
646238	7.2	14.0	5.9	7.8	9.4	15.3	13.1
646243	14.9	11.3	-3.1	5.8	20.6	13.3	20.1
646248	-17.2	36.0	6.7	10.2	19.5	14.4	21.8
646254	15.9	14.2	6.0	0.0	8.7	11.4	23.7
646258	19.9	10.6	4.1	4.6	15.7	13.8	23.8
646259	6.3	15.9	7.3	7.4	16.0	16.7	17.0
646266	---	---	2.5	11.5	18.3	9.9	18.9
646268	---	---	3.0	13.7	12.0	12.6	20.7
646269	---	---	9.1	4.3	19.1	8.0	23.6
646271	---	---	9.9	9.0	17.5	2.1	15.1
646273	---	---	3.6	6.3	16.3	6.2	21.2
646285	---	---	10.8	9.5	16.9	-5.7	19.7
646299	25.6	7.1	5.2	7.6	17.6	10.6	17.5
646302	-43.3	8.8	9.9	4.5	34.8	20.6	17.1
646303	27.8	9.0	1.9	17.0	10.3	15.0	19.5
646305	19.1	7.8	4.9	1.2	12.7	6.6	9.7
646307	9.7	14.5	4.5	-20.1	11.0	26.0	20.5

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL BODY WEIGHT CHANGES (grams)

GROUP III: 200 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION				
	16-18	18-20	20-21	6-21	6-21 ^a
646222	34.7	31.8	22.6	139.3	54.4
646228	36.1	30.4	35.7	169.5	66.8
646232	32.7	24.7	12.7	111.9	30.3
646234	31.4	33.2	21.6	146.8	46.8
646237	24.1	23.7	33.1	150.8	38.8
646238	33.0	22.5	21.8	128.8	50.9
646243	27.4	28.5	13.1	125.7	37.7
646248	38.1	37.4	33.3	181.4	76.6
646254	35.5	38.5	19.1	142.9	24.3
646258	26.5	27.2	19.9	135.6	43.4
646259	31.5	34.4	36.2	166.5	66.1
646266	29.3	29.0	26.7	146.1	52.3
646268	25.7	39.3	27.6	154.6	48.4
646269	22.2	41.1	30.0	157.4	38.5
646271	32.6	27.8	25.9	139.9	42.7
646273	34.7	31.5	22.2	142.0	31.5
646285	23.6	29.0	24.7	128.5	48.7
646299	33.5	18.7	23.8	134.5	39.6
646302	34.1	27.4	19.9	168.3	84.3
646303	48.8	22.0	29.0	163.5	45.7
646305	23.0	22.5	6.8	87.4	33.9
646307	35.8	29.7	21.5	128.9	23.3

Company Sanitized. Does not contain TSCA CB.

Company Sanitized. Does not contain TSCA CB.

INDIVIDUAL BODY WEIGHT CHANGES (grams)

GROUP IV: 500 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION						
	0-4	4-6	6-8	8-10	10-12	12-14	14-16
646221	10.5	17.5	4.6	-2.0	10.3	12.1	14.8
646223	5.4	18.5	5.6	4.1	19.8	12.5	14.0
646233	-6.4	23.3	10.2	3.3	10.0	24.1	17.9
646239	12.8	12.5	5.5	6.8	17.0	26.2	18.9
646240	19.8	12.3	4.1	-2.5	15.5	18.0	27.7
646244	1.1	10.4	0.2	3.2	8.9	6.7	18.2
646247	18.5	0.1	18.8	11.9	13.4	12.2	0.2
646255	17.7	14.7	-9.1	6.3	9.3	13.2	24.0
646260	-13.7	38.6	5.5	4.0	8.2	19.5	25.7
646262	22.4	12.7	6.9	5.1	17.3	14.3	25.8
646263	10.7	18.1	-9.0	-7.3	20.4	20.8	32.7
646270	---	---	2.1	15.8	7.6	13.4	21.3
646275	---	---	-6.4	8.6	27.2	2.6	21.0
646277	---	---	2.7	11.9	16.6	8.1	24.4
646281	---	---	9.0	6.9	25.3	13.2	25.8
646283	---	---	13.0	6.8	17.8	14.5	21.7
646287	16.4	3.3	-3.5	7.5	15.7	13.6	23.7
646289	20.5	9.6	-2.7	10.9	17.5	11.4	23.5
646293	2.4	12.6	-0.4	6.5	18.9	23.6	34.1
646295	29.2	7.2	1.5	10.1	10.0	15.4	26.5
646301	13.9	1.3	1.0	11.3	6.8	17.8	11.9
646304	8.6	7.3	-1.0	6.6	13.7	10.1	23.3

INDIVIDUAL BODY WEIGHT CHANGES (grams)

GROUP IV: 500 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION				
	16-18	18-20	20-21	6-21	6-21 ^a
646221	28.5	21.1	14.7	104.1	30.8
646223	27.9	36.6	27.2	147.7	46.5
646233	35.2	36.5	25.3	162.5	60.5
646239	36.1	32.4	25.2	168.1	66.9
646240	27.2	21.0	8.3	119.3	11.8
646244	17.1	20.6	21.0	95.9	39.9
646247	35.8	26.9	20.2	139.4	39.9
646255	31.3	25.9	24.5	125.4	32.2
646260	38.8	30.2	18.8	150.7	34.0
646262	28.7	-36.6	31.0	92.5	15.0
646263	35.8	36.7	19.2	149.3	37.2
646270	36.0	36.6	26.4	159.2	47.8
646275	39.9	19.6	17.1	129.6	30.9
646277	19.5	32.4	-30.1	85.5	-1.6
646281	25.4	21.9	-40.7	86.8	1.1
646283	31.1	29.7	22.4	157.0	62.1
646287	25.0	25.7	12.8	120.5	24.3
646289	44.2	28.2	26.9	159.9	46.3
646293	31.8	33.7	23.2	171.4	50.2
646295	31.7	30.6	32.8	158.6	57.1
646301	25.7	29.9	19.0	123.4	42.1
646304	25.1	29.0	14.8	121.6	41.0

Company Sanitized. Does not contain TSCA CBI

APPENDIX C

Individual Food Consumption

Company Sanitized. Does not contain TSCA CBI

Individual Food Consumption

Explanatory Notes

Abbreviations

--- = No Data

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FOOD CONSUMPTION (grams/day)

GROUP I: 0 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION						
	4-6	6-8	8-10	10-12	12-14	14-16	
646224	20.1	36.1	29.7	30.9	29.7	29.0	31.6
646225	23.2	24.4	22.6	27.4	25.3	30.3	29.7
646226	23.2	27.6	28.2	32.5	33.5	34.7	35.9
646230	15.1	28.0	25.3	30.9	30.6	29.5	29.6
646236	27.7	22.9	24.5	28.1	28.0	27.9	28.7
646241	24.0	28.0	29.3	31.2	31.0	34.1	34.0
646251	22.0	21.8	23.5	24.1	23.8	23.3	26.8
646252	40.4	24.7	28.0	28.9	28.9	26.0	31.6
646256	8.4	24.1	27.0	30.9	29.8	29.7	33.2
646257	23.3	21.0	21.4	24.4	24.7	25.6	26.1
646261	26.6	22.2	23.9	25.2	24.4	23.8	25.4
646265	20.3	19.9	23.2	22.1	24.8	23.9	26.9
646272	23.5	23.8	24.9	29.3	27.4	29.9	28.9
646276	26.8	26.7	30.2	31.4	---	32.5	34.5
646278	23.2	22.6	24.3	26.4	26.6	29.3	29.7
646282	23.7	23.3	25.7	26.3	29.1	25.8	30.4
646284	24.2	27.7	28.7	31.6	27.6	31.4	33.5
646288	26.0	28.3	31.0	29.2	31.9	31.1	35.2
646290	19.5	20.8	20.3	20.8	22.9	23.2	25.8
646292	23.7	14.6	12.4	18.6	29.5	26.3	30.6
646294	21.5	24.4	23.9	23.7	25.8	26.4	30.0
646308	13.9	27.3	28.3	32.4	31.1	31.6	31.3

Company Sanitized. Does not contain TSCA CB1

INDIVIDUAL FOOD CONSUMPTION (grams/day)

GROUP I: 0 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION			
	18-20	20-21	4-21	6-21
646224	31.6	31.1	29.9	31.2
646225	28.7	25.5	26.4	26.8
646226	30.7	32.0	30.8	31.9
646230	29.2	24.4	27.1	28.7
646236	29.8	26.7	27.2	27.1
646241	34.3	32.9	30.9	31.8
646251	25.9	22.9	23.8	24.1
646252	29.9	28.6	29.7	28.3
646256	32.0	30.8	27.1	29.6
646257	27.9	22.9	24.2	24.4
646261	23.8	19.9	24.1	23.8
646265	26.9	24.5	23.6	24.0
646272	31.1	26.9	27.3	27.8
646276	36.3	26.9	12.3	10.4
646278	28.3	32.6	26.7	27.1
646282	31.6	32.5	27.3	27.8
646284	30.5	34.2	29.7	30.4
646288	30.6	28.6	30.3	30.9
646290	22.6	17.8	21.7	22.0
646292	22.4	24.8	22.4	22.2
646294	24.2	19.9	24.7	25.1
646308	21.1	30.3	27.3	29.1

Company Sanitized. Does not contain TSCA CBI

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FOOD CONSUMPTION (grams/day)

GROUP II: 50 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION						
	4-6	6-8	8-10	10-12	12-14	14-16	
646227	26.5	22.3	25.1	29.9	29.1	30.7	33.8
646229	26.1	23.9	22.8	29.0	31.3	34.7	37.8
646231	25.0	19.9	21.9	24.5	25.7	25.7	27.9
646235	23.6	20.2	22.3	25.8	26.9	28.6	30.4
646242	20.3	17.9	20.7	22.9	22.0	17.1	23.1
646245	20.6	17.3	20.9	24.9	25.6	23.3	25.0
646246	22.4	15.6	23.8	28.7	26.1	28.5	28.1
646249	24.6	22.9	24.4	27.5	29.7	31.9	30.9
646250	29.6	27.0	28.6	33.6	31.3	30.3	32.8
646253	21.4	23.1	24.7	29.4	30.1	29.9	32.5
646264	25.1	23.9	23.0	28.3	27.6	27.3	31.2
646267	22.0	20.4	21.4	23.0	24.2	27.0	28.8
646274	24.0	23.8	24.4	25.0	27.6	27.2	28.8
646279	18.4	17.1	19.1	23.2	22.2	21.8	23.2
646280	12.6	2.1	24.4	31.8	30.9	27.6	28.8
646286	26.9	23.6	27.4	26.4	28.7	28.6	28.0
646291	21.5	19.9	21.2	21.7	20.7	22.9	24.8
646296	23.6	24.1	24.3	25.8	25.2	29.7	28.6
646297	20.9	20.9	21.1	22.3	23.3	22.2	27.9
646298	21.9	24.0	24.0	25.4	24.3	24.6	28.8
646300	39.9	23.4	28.0	26.6	27.4	26.4	32.3
646306	22.1	20.8	22.9	24.6	23.0	26.1	27.6

Company Sanitized. Does not contain TSCA C

INDIVIDUAL FOOD CONSUMPTION (grams/day)

GROUP II: 50 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION			
	18-20	20-21	4-21	6-21
646227	30.4	27.4	28.4	28.7
646229	33.4	31.6	30.0	30.5
646231	27.3	30.4	25.1	25.1
646235	29.0	30.2	26.1	26.4
646242	23.0	22.5	20.9	21.0
646245	25.8	21.9	22.8	23.1
646246	30.3	26.7	25.5	25.9
646249	31.8	30.1	28.1	28.6
646250	31.1	28.7	30.4	30.5
646253	32.0	23.1	27.6	28.5
646264	32.4	27.0	27.3	27.6
646267	26.4	25.2	24.2	24.5
646274	30.1	19.2	25.9	26.2
646279	23.4	28.3	21.5	21.9
646280	28.6	23.0	23.3	24.8
646286	29.4	30.7	27.6	27.7
646291	22.6	19.3	21.8	21.8
646296	25.0	31.2	26.1	26.4
646297	23.5	28.7	23.1	23.4
646298	26.2	25.8	24.9	25.3
646300	31.8	22.7	29.1	27.6
646306	25.6	31.2	24.5	24.8

Company Sanitized. Does not contain TSCA CRI

INDIVIDUAL FOOD CONSUMPTION (grams/day)

GROUP III: 200 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION						
	4-6	6-8	8-10	10-12	12-14	14-16	
646222	20.8	17.8	16.7	23.8	25.3	27.4	29.2
646228	26.4	23.4	23.3	25.3	26.6	30.4	31.9
646232	21.0	1.3	19.3	21.7	27.2	26.2	26.3
646234	22.4	19.3	21.4	24.8	25.8	26.0	28.4
646237	23.3	21.9	15.6	22.7	28.1	27.6	27.6
646238	19.9	19.9	18.3	22.7	23.7	25.5	29.4
646243	20.4	17.8	18.1	25.1	26.1	24.7	25.1
646248	27.4	24.7	25.7	29.1	29.2	29.0	31.9
646254	22.3	20.1	18.5	21.6	23.9	22.2	24.4
646258	26.1	21.4	21.3	26.4	28.3	27.7	27.9
646259	26.6	21.6	25.0	29.1	31.3	28.1	30.7
646266	23.1	21.0	23.1	26.6	27.9	29.6	32.3
646268	21.1	19.2	21.8	22.9	23.7	26.2	25.5
646269	22.9	24.0	22.6	25.9	26.8	25.9	24.7
646271	22.2	20.6	22.9	25.6	24.8	25.2	28.4
646273	36.0	20.4	23.9	26.1	27.9	29.3	29.6
646285	30.1	25.5	25.3	24.8	24.9	23.3	26.8
646299	24.9	22.7	24.1	26.1	25.4	26.7	31.9
646302	10.1	17.5	15.1	25.3	24.9	33.9	21.5
646303	22.1	20.7	26.7	26.2	25.1	27.3	33.8
646305	20.9	20.6	20.1	22.4	22.6	22.6	26.9
646307	28.6	25.5	8.3	15.7	23.8	27.4	28.4

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FOOD CONSUMPTION (grams/day)

GROUP III: 200 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION			
	18-20	20-21	4-21	6-21
646222	29.1	27.2	24.0	24.4
646228	29.8	32.7	27.5	27.6
646232	25.1	20.4	21.0	21.0
646234	28.3	24.1	24.5	24.8
646237	20.7	25.9	23.6	23.6
646238	27.8	24.7	23.5	24.0
646243	26.5	17.2	22.6	22.9
646248	31.3	35.3	28.9	29.1
646254	27.1	24.8	22.7	22.7
646258	29.4	21.7	25.8	25.8
646259	32.4	32.3	28.3	28.6
646266	31.0	28.2	26.9	27.4
646268	26.3	25.3	23.5	23.8
646269	27.7	26.5	25.1	25.4
646271	27.5	23.4	24.6	24.9
646273	28.6	24.0	27.5	26.4
646285	26.2	27.8	26.0	25.4
646299	22.4	24.5	25.5	25.5
646302	26.7	24.5	22.0	23.6
646303	26.3	27.7	26.1	26.7
646305	23.0	18.6	22.2	22.3
646307	25.7	25.1	23.1	22.3

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FOOD CONSUMPTION (grams/day)

GROUP IV: 500 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION						
	4-6	6-8	8-10	10-12	12-14	14-16	
646221	23.4	19.8	18.7	20.8	21.4	26.2	27.3
646223	24.3	21.4	22.7	26.8	25.9	27.3	27.2
646233	20.1	23.8	22.1	24.3	27.4	30.5	32.8
646239	24.3	20.6	21.8	27.3	32.1	30.6	34.7
646240	26.8	21.3	20.9	25.6	25.8	30.3	29.0
646244	20.7	16.8	15.6	19.2	22.1	22.6	24.6
646247	18.4	25.0	24.8	26.8	27.9	18.1	29.2
646255	24.8	17.1	16.9	20.0	23.2	25.9	28.4
646260	24.9	27.3	22.9	28.4	29.3	30.3	32.8
646262	25.5	22.2	23.9	28.0	30.9	32.7	35.4
646263	24.8	16.8	11.8	19.6	27.3	34.9	35.6
646270	22.0	19.2	23.9	25.3	23.5	25.6	28.3
646275	24.0	17.7	19.4	26.0	26.4	27.2	32.3
646277	24.7	22.8	24.9	26.7	28.1	29.7	24.0
646281	24.3	21.8	21.3	28.4	30.3	32.3	31.8
646283	20.0	21.1	21.4	24.7	25.5	25.0	28.0
646287	21.6	16.3	18.1	26.1	24.6	25.9	27.6
646289	24.8	22.4	22.0	26.2	23.8	28.1	34.1
646293	22.2	16.4	18.1	24.4	26.6	29.5	33.8
646295	22.3	22.7	23.3	25.3	25.4	28.9	31.5
646301	20.8	19.8	20.8	21.6	22.6	21.9	27.0
646304	24.6	20.7	21.4	24.6	24.2	27.1	28.7

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FOOD CONSUMPTION (grams/day)

GROUP IV: 500 MG/KG/DAY

ANIMAL NUMBER	DAYS OF GESTATION			
	18-20	20-21	4-21	6-21
646221	25.1	24.5	22.9	22.9
646223	27.7	28.6	25.6	25.8
646233	31.9	31.0	26.9	27.8
646239	32.4	31.4	28.2	28.7
646240	24.4	19.3	25.1	24.9
646244	22.9	26.0	20.9	20.9
646247	28.2	25.4	24.8	25.7
646255	25.1	24.2	22.8	22.5
646260	27.8	24.5	27.7	28.1
646262	16.1	50.6	28.2	28.6
646263	31.8	25.0	25.3	25.4
646270	29.6	30.8	25.0	25.4
646275	26.2	18.1	24.5	24.6
646277	30.1	0.7	24.9	24.9
646281	30.9	1.6	26.1	26.3
646283	26.0	24.1	24.0	24.5
646287	28.1	24.1	23.6	23.8
646289	22.7	29.7	25.7	25.9
646293	34.1	24.7	25.6	26.0
646295	22.4	31.8	25.6	26.1
646301	38.8	24.4	24.2	24.6
646304	25.3	24.6	24.6	24.6

Company Sanitized. Does not contain TSCA CBI

APPENDIX D

Individual Clinical Observations

Company Sanitized. Does not contain TSCA CBI

Individual Clinical Observations

Explanatory Notes

Footnotes

- a* The first observation recorded each day is indicated by "a"; the second by "b". Observations were made twice daily on days 6-20G. If no signs were observed during the study examinations, the "b" entries are omitted from the printout.

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL CLINICAL OBSERVATIONS^a

GROUP I: 0 MG/KG/DAY

ANIMAL OBSERVATION

NUMBER:

DAYS OF GESTATION ON WHICH SIGN WAS OBSERVED
1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22

646224

ALOPECIA LEFT FRONT PAW

a: , , , , , , , , , , 13, 14, , , , , , , ,
b: , , , , , , , , , , 13, 14, , , , , , , ,

ALOPECIA BOTH FRONT PAW

a: , , , , , , , , , , , 15, 16, 17, 18, 19, 20, 21, ,
b: , , , , , , , , , , , 15, 16, 17, 18, 19, 20, ,

ALOPECIA BOTH FRONT LEG

a: , , , , , , , , , , , 15, 16, 17, 18, 19, 20, 21, ,
b: , , , , , , , , , , , 15, 16, 17, 18, 19, 20, ,

SACRIFICED BY DESIGN 03/19/01

a: , 21,

646225

SACRIFICED BY DESIGN 03/19/01

a: , 21,

646226

SACRIFICED BY DESIGN 03/19/01

a: , 21,

646230

SACRIFICED BY DESIGN 03/19/01

a: , 21,

646236

SACRIFICED BY DESIGN 03/19/01

a: , 21,

646241

ALOPECIA RIGHT FRONT LEG

a: , , , , , , , , , , , , , , , 15, , 17, 18, 19, 20, ,
b: , , , , , , , , , , , , , , , , , , , 17, 18, 19, 20, ,

ALOPECIA BOTH FRONT LEG

a: , , , , , , , , , , , , , , , , 16, , , , , 21,
b: , , , , , , , , , , , , , , , , 15, 16, , , , ,

SACRIFICED BY DESIGN 03/19/01

a: , 21,

646251

SACRIFICED BY DESIGN 03/20/01

a: , 21,

646252

SACRIFICED BY DESIGN 03/20/01

a: , 21,

INDIVIDUAL CLINICAL OBSERVATIONS^a

GROUP II: 50 MG/KG/DAY

ANIMAL OBSERVATION

NUMBER:

DAYS OF GESTATION ON WHICH SIGN WAS OBSERVED

646250

SACRIFICED BY DESIGN 03/20/01

[illegible]

646253

ALOPECIA RIGHT FRONT PAW

[illegible]

STAIN BOTH SHOULDER YELLOW

[illegible]

STAIN BOTH SHOULDER BROWN

a: , , , , , , , , , ,
a: , , , , , , , , , ,

, 20, 21,

SACRIFICED BY DESIGN 03/20/01

21,

646264

ALOPECIA ABDOMINAL

a: , , , 5, 6, 7, , 9, 10, 11, , , , , 20, 21,

SACRIFICED BY DESIGN 03/20/01

α_0 , β_0 , γ_0

646267

SACRIFICED BY DESIGN 3/21/01

[illegible]

646274

ALOPECIA RIGHT FRONT PAW

[illegible]

SACRIFICED BY DESIGN 3/21/01

[illegible]

646279

SACRIFICED BY DESIGN 3/21/01

[illegible]

646280

DEHYDRATED

8

SACRIFICED BY DESIGN 3/21/01

[illegible]

INDIVIDUAL CLINICAL OBSERVATIONS^a

GROUP II: 50 MG/KG/DAY

ANIMAL OBSERVATION
 NUMBER: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22
 DAYS OF GESTATION ON WHICH SIGN WAS OBSERVED

646300

ALOPECIA BOTH FRONT PAW

ALOPECIA RIGHT FRONT LEG

ALOPECIA BOTH FRONT LEG

SACRIFICED BY DESIGN 03/22/01

a: , , , , , , , , , 12, 13, 14, 15, 16, 17, 18, 19, 20, 21,
 b: , , , , , , , , , 12, 13, 14, 15, 16, 17, 18, 19, 20, ,
 a: ,
 b: , , , , , , , , , , , , , , , 15, , , , , , , ,
 a: , , , , , , , , , , , , , , , 16, 17, 18, 19, 20, 21,
 b: , , , , , , , , , , , , , , , 16, 17, 18, 19, 20, ,
 a: , 21,

646306

ALOPECIA RIGHT FRONT PAW

ALOPECIA BOTH FRONT PAW

SACRIFICED BY DESIGN 03/22/01

a: , , , , , , , , , 15, , , , , , , , ,
 a: , 21,
 a: , 21,

INDIVIDUAL CLINICAL OBSERVATIONS^a

GROUP III: 200 MG/KG/DAY

ANIMAL OBSERVATION

NUMBER:

DAYS OF GESTATION ON WHICH SIGN WAS OBSERVED
1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22

=====

646248

SACRIFICED BY DESIGN 03/20/01

a: , 21,

646254

ALOPECIA BOTH FRONT PAW

a: , , , , , , , , , , , , , , , 15, 16, 17, 18, 19, 20, 21,

b: , , , , , , , , , , , , , , , 15, 16, 17, 18, 19, 20,

SACRIFICED BY DESIGN 03/20/01

a: , , , , , , , , , , , , , , , , 21,

646258

SORE MOUTH

a: , , , , , , , , , , , , , , , 20, 21,

b: , , , , , , , , , , , , , , , 20,

SACRIFICED BY DESIGN 03/20/01

a: , , , , , , , , , , , , , , , 21,

646259

SACRIFICED BY DESIGN 03/20/01

a: , , , , , , , , , , , , , , , 21,

646266

ALOPECIA ABDOMINAL

a: , , , , , , , , , , 11, 12, 13, 14, 15, 16, 17, 18, 19, , ,

b: , , , , , , , , , , 11, 12, 13, 14, 15, 16, 17, 18, 19, , ,

ALOPECIA RIGHT HIND QUARTERS

a: , , , , , , , , , , 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21,

b: , , , , , , , , , , 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, ,

ALOPECIA RIGHT SIDE

a: , , , , , , , , , , 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21,

b: , , , , , , , , , , 16, 17, 18, 19, 20, , ,

ALOPECIA BOTH FRONT PAW

a: , , , , , , , , , , , 20, 21,

b: , , , , , , , , , , , 20,

SACRIFICED BY DESIGN 3/21/01

a: , , , , , , , , , , , , 21,

646268

SACRIFICED BY DESIGN 3/21/01

a: , , , , , , , , , , , , , 21,

646269

ALOPECIA BOTH FRONT LEG

a: , , , , , , , , , , , 13, 14, 15, 16, 17, 18, 19, 20, 21,

b: , , , , , , , , , , , 13, 14, 15, 16, 17, 18, 19, 20, ,

SACRIFICED BY DESIGN 3/21/01

a: , , , , , , , , , , , , , 21,

INDIVIDUAL CLINICAL OBSERVATIONS^a

GROUP III: 200 MG/KG/DAY

ANIMAL OBSERVATION
NUMBER:

DAYS OF GESTATION ON WHICH SIGN WAS OBSERVED
1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22

=====

646307

TOP TEETH MISSING

a: , , , , , , 9, 10, 11, 12, 13, 14, 15, , , , , ,
b: , , , , , , 9, 10, 11, 12, 13, 14, , , , , ,
a: , , , , , , , , , , , , , , , 21,

SACRIFICED BY DESIGN 03/22/01

INDIVIDUAL CLINICAL OBSERVATIONS^a

GROUP IV: 500 MG/KG/DAY

ANIMAL OBSERVATION

NUMBER:

DAYS OF GESTATION ON WHICH SIGN WAS OBSERVED

646221

STAIN PERINEUM YELLOW

SACRIFICED BY DESIGN 03/19/01

[illegible]

646223

STAIN PERINEUM YELLOW

SACRIFICED BY DESIGN 03/19/01

[illegible]

646233

ALOPECIA BOTH FRONT PAW

SACRIFICED BY DESIGN 03/19/01

[illegible]

646239

SACRIFICED BY DESIGN 03/19/01

[illegible]

646240

ALOPECIA BOTH FRONT PAW

a: , , , , , , , , , , , , , , ,
 ,15,
 ,15,

STAIN PERINEUM YELLOW

SACRIFICED BY DESIGN 03/19/01

[illegible]

646244

SACRIFICED BY DESIGN 03/20/01

a:²¹,

646247

SACRIFICED BY DESIGN 03/20/01

$\alpha_0 = \frac{1}{\sqrt{\pi}} e^{-x^2}$

646255

SACRIFICED BY DESIGN 03/20/01

$\alpha_1, \dots, \alpha_{2l}, \beta_1, \dots, \beta_{2l}$

INDIVIDUAL CLINICAL OBSERVATIONS^a

GROUP IV: 500 MG/KG/DAY

ANIMAL OBSERVATION

NUMBER: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22

646260

ALOPECIA BOTH FRONT LEG

ALOPECIA BOTH FRONT PAW

SACRIFICED BY DESIGN 03/20/01

a: , , , , , 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21,
 b: , , , , , 7, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, ,
 a: , , , , , 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21,
 b: , , , , , 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, ,
 a: , 21,

646262

ALOPECIA BOTH FRONT PAW

STAIN PERINEUM YELLOW

WET PERINEUM

SACRIFICED BY DESIGN 03/20/01

a: , , , , , , , , , 12, 13, 14, 15, 16, 17, 18, 19, 20, 21,
 b: , , , , , , , , , 12, 13, 14, 15, 16, 17, 18, 19, 20, ,
 a: , , , , , , , , , 15, , , , 19, 20, 21,
 b: , , , , , , , , , , , , , , , 20,
 a: , , , , , , , , , , , , , , , 20,
 b: , , , , , , , , , , , , , , , 20,
 a: , , , , , , , , , , , , , , , 21,

646263

SACRIFICED BY DESIGN 03/20/01

a: , , , , , , , , , , , , , , , , 21,

646270

ALOPECIA BOTH FRONT PAW

SACRIFICED BY DESIGN 3/21/01

a: , , , , , 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21,
 b: , , , , , 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, ,
 a: , , , , , , , , , , , , , , , 21,

646275

STAIN PERINEUM YELLOW

SACRIFICED BY DESIGN 3/21/01

a: , , , , , , , , , , , , , , , 20, 21,
 b: , , , , , , , , , , , , , , , 20,
 a: , , , , , , , , , , , , , , , 21,

646277

STAIN PERINEUM YELLOW

STAIN PERIORAL RED
 SACRIFICED BY DESIGN 3/21/01

a: , , , , , , , , , 11, 12, , 15, , , 19, 20, 21,
 b: , , , , , , , , , 11, 12, 13, 15, , , 19, 20, ,
 a: , , , , , , , , , , , , , , , 21,
 a: , , , , , , , , , , , , , , , 21,

INDIVIDUAL CLINICAL OBSERVATIONS^a

GROUP IV: 500 MG/KG/DAY

ANIMAL OBSERVATION

ANIMAL NUMBER:	OBSERVATION	DAYS OF GESTATION ON WHICH SIGN WAS OBSERVED																					
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
646281	ALOPECIA BOTH FRONT PAW							8						13	14	15	16	17	18	19	20	21	
	ALOPECIA RIGHT FRONT PAW							8						13	14	15	16	17	18	19	20		
	ALOPECIA BOTH FRONT LEG											11	12										
	STAIN PERINEUM YELLOW											11	12										
	SACRIFICED BY DESIGN 3/21/01																						
646283	SACRIFICED BY DESIGN 3/21/01																						
646287	ALOPECIA RIGHT FRONT PAW																						
	ALOPECIA BOTH FRONT PAW																15						
	STAIN PERINEUM YELLOW																						
	SACRIFICED BY DESIGN 03/22/01																						
646289	ALOPECIA RIGHT SHOULDER																						
	STAIN PERINEUM YELLOW																						
	SACRIFICED BY DESIGN 03/22/01																						
646293	ALOPECIA LEFT FRONT PAW																						
	SACRIFICED BY DESIGN 03/22/01																						

Company Sanitized. Does not contain TSCA CBI

Company Sanitized. Does not contain TSCA CBI

GROUP IV: 500 MG/KG/DAY

ANIMAL OBSERVATION

NUMBER:

DAYS OF GESTATION ON WHICH SIGN WAS OBSERVED

1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22

646295

ALOPECIA BOTH FRONT PAW

SACRIFICED BY DESIGN 03/22/01

a: , , , , , , , , , ,
b: , , , , , , , , , ,
c: , , , , , , , , , ,

646301

SACRIFICED BY DESIGN 03/22/01

[illegible]

646304

SACRIFICED BY DESIGN 03/22/01

[illegible]

APPENDIX E

Gross Postmortem Findings

Company Sanitized. Does not contain TSCA CBI

Gross Postmortem Findings

Explanatory Notes

Abbreviations

NAD = No Abnormalities Detected

Company Sanitized. Does not contain TSCA CBI

GROSS POSTMORTEM FINDINGS

Group I: 0 mg/kg/day

<u>Animal Number</u>	<u>Dam Code</u>	<u>Structure(s)</u>	<u>Finding(s)</u>
646224	7		NAD
646225	21		NAD
646226	12		NAD
646230	11		NAD
646236	20		NAD
646241	2	Perineum	Mass 2 x 1.5 cm
646251	40		NAD
646252	43		NAD
646256	31		NAD
646257	34		NAD
646261	23		NAD
646265	48		NAD
646272	46		NAD
646276	51		NAD
646278	52		NAD
646282	50		NAD
646284	56		NAD
646288	72		NAD
646290	69		NAD
646292	84		NAD
646294	82		NAD
646308	87		NAD

Company Sanitized. Does not contain TSCA

GROSS POSTMORTEM FINDINGS

Group II: 50 mg/kg/day

<u>Animal Number</u>	<u>Dam Code</u>	<u>Structure(s)</u>	<u>Finding(s)</u>
646227	4		NAD
646229	17		NAD
646231	13		NAD
646235	5		NAD
646242	6		NAD
646245	28		NAD
646246	25		NAD
646249	33		NAD
646250	24		NAD
646253	27		NAD
646264	26		NAD
646267	63		NAD
646274	54		NAD
646279	58		NAD
646280	62		NAD
646286	55		NAD
646291	83		NAD
646296	86		NAD
646297	81		NAD
646298	78		NAD
646300	85		NAD
646306	80		NAD

Company Sanitized. Does not contain TSCA

GROSS POSTMORTEM FINDINGS

Group III: 200 mg/kg/day

<u>Animal Number</u>	<u>Dam Code</u>	<u>Structure(s)</u>	<u>Finding(s)</u>
646222	19		NAD
646228	15		NAD
646232	22		NAD
646234	3		NAD
646237	9		NAD
646238	10		NAD
646243	44		NAD
646248	41		NAD
646254	42		NAD
646258	36		NAD
646259	30		NAD
646266	57		NAD
646268	53		NAD
646269	47		NAD
646271	49		NAD
646273	61		NAD
646285	45		NAD
646299	70		NAD
646302	67		NAD
646303	88		NAD
646305	68		NAD
646307	76		NAD

Company Sanitized. Does not contain TSCA CBI

GROSS POSTMORTEM FINDINGS

Group IV: 500 mg/kg/day

<u>Animal Number</u>	<u>Dam Code</u>	<u>Structure(s)</u>	<u>Finding(s)</u>
646221	1		NAD
646223	8		NAD
646233	16		NAD
646239	18		NAD
646240	14		NAD
644244	37		NAD
646247	38		NAD
646255	32		NAD
646260	39		NAD
646262	35		NAD
646263	29		NAD
646270	64		NAD
646275	59		NAD
646277	65		NAD
646281	60		NAD
646283	66		NAD
646287	71		NAD
646289	73		NAD
646293	77		NAD
646295	74		NAD
646301	75		NAD
646304	79		NAD

Company Sanitized. Does not contain TSCA CBI

APPENDIX F

Individual Reproductive Data

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL REPRODUCTIVE DATA

GROUP I: 0 MG/KG/DAY

ANIMAL NUMBER	CORPORA LUTEA	NIDA- TIONS	TOTAL	RESORPTIONS EARLY	LATE	DEAD FETUSES	LIVE FETUSES TOTAL	MALE	MEAN FETAL WEIGHT (G)
646224	17	14	1	1	0	0	13	6	5.70
646225	15	14	1	1	0	0	13	9	5.69
646226	18	17	0	0	0	0	17	7	5.59
646230	23	15	0	0	0	0	15	9	5.28
646236	15	13	0	0	0	0	13	8	5.94
646241	17	16	0	0	0	0	16	7	5.68
646251	19	14	0	0	0	0	14	11	5.51
646252	16	15	0	0	0	0	15	5	5.26
646256	13	13	1	1	0	0	12	6	5.79
646257	16	14	2	2	0	0	12	5	5.67
646261	16	12	1	1	0	0	11	8	5.63
646265	18	12	0	0	0	0	12	6	5.13
646272	15	13	0	0	0	0	13	8	5.80
646276	17	15	0	0	0	0	15	6	5.29
646278	15	13	0	0	0	0	13	11	5.52
646282	17	15	0	0	0	0	15	11	5.91
646284	18	13	0	0	0	0	13	7	5.76
646288	17	15	0	0	0	0	15	8	5.55
646290	16	14	0	0	0	0	14	6	5.30
646292	17	15	0	0	0	0	15	8	5.25
646294	16	15	1	1	0	0	14	5	4.67
646308	17	16	1	1	0	0	15	10	5.82

INDIVIDUAL REPRODUCTIVE DATA

GROUP II: 50 MG/KG/DAY	ANIMAL NUMBER	CORPORA LUTEA	NIDA- TIONS	RESORPTIONS		DEAD FETUSES	LIVE FETUSES		MEAN FETAL WEIGHT (G)
				TOTAL	LATE		TOTAL	MALE	
					EARLY			FEMALE	
646227	17	16	1	0	0	0	15	12	3
646229	16	14	0	0	0	0	14	11	3
646231	20	18	2	0	0	0	16	12	4
646235	17	14	0	0	0	0	14	9	5
646242	14	14	1	1	0	0	13	6	7
646245	14	12	0	0	0	0	12	8	4
646246	17	16	0	0	0	0	16	8	8
646249	12	12	0	0	0	0	12	6	6
646250	20	18	1	0	1	0	17	10	7
646253	16	15	0	0	0	0	15	7	8
646264	17	15	0	0	0	0	15	10	5
646267	17	16	1	1	0	0	15	7	8
646274	17	14	0	0	0	0	14	5	9
646279	18	15	0	0	0	0	15	7	8
646280	16	15	0	0	0	0	15	9	6
646286	17	17	0	0	0	0	17	7	10
646291	14	11	1	1	0	0	10	6	4
646296	15	13	0	0	0	0	13	5	8
646297	16	16	1	1	0	0	15	5	10
646298	17	16	0	0	0	0	16	7	9
646300	16	15	0	0	0	0	15	11	4
646306	23	14	1	0	1	0	13	7	6

INDIVIDUAL REPRODUCTIVE DATA

GROUP III: 200 MG/KG/DAY	ANIMAL NUMBER	CORPORA LUTEA	NIDA- TIONS	RESORPTIONS		DEAD FETUSES	LIVE FETUSES		MEAN FETAL WEIGHT (G)
				TOTAL	LATE		TOTAL	MALE	
646222	13	12	0	0	0	0	12	6	5.40
646228	14	14	0	0	0	0	14	8	5.90
646232	19	12	0	0	0	0	12	7	5.27
646234	17	15	0	0	0	0	15	10	5.14
646237	21	17	0	0	0	0	17	9	5.20
646238	12	11	0	0	0	0	11	3	5.52
646243	20	14	0	0	0	0	14	7	5.20
646248	16	15	0	0	0	0	15	5	5.52
646254	19	18	0	0	0	0	18	10	5.11
646258	17	14	0	0	0	0	14	8	5.19
646259	22	14	0	0	0	0	14	8	5.50
646266	18	15	1	1	0	0	14	8	5.25
646268	18	15	0	0	0	0	15	3	5.35
646269	21	18	0	0	0	0	18	10	5.29
646271	15	13	0	0	0	0	13	7	5.49
646273	16	15	0	0	0	0	15	8	5.40
646285	14	12	1	1	0	0	11	5	5.56
646299	15	15	1	1	0	0	14	5	5.38
646302	12	12	0	0	0	0	12	11	5.46
646303	17	17	0	0	0	0	17	9	5.40
646305	12	9	1	1	0	0	8	4	4.99
646307	17	16	0	0	0	0	16	6	5.26

H-24516: Developmental Toxicity Study in Rats

INDIVIDUAL REPRODUCTIVE DATA

ANIMAL NUMBER	CORPORA LUTEA	NIDA- TIONS	RESORPTIONS		DEAD FETUSES	LIVE FETUSES		MEAN FETAL WEIGHT (G)
			TOTAL	EARLY	LATE	TOTAL	MALE	
646221	13	11	1	1	0	10	6	5.46
646223	16	14	0	0	0	14	8	5.65
646233	16	15	0	0	0	15	10	5.40
646239	16	15	1	1	0	14	6	5.70
646240	18	15	0	0	0	15	9	5.66
646244	15	12	4	4	0	8	5	5.54
646247	18	15	0	0	0	15	7	5.13
646255	16	13	0	0	0	13	5	5.88
646260	19	18	0	0	0	18	10	5.02
646262	15	14	1	1	0	13	6	4.51
646263	17	17	1	1	0	16	7	5.36
646270	15	15	0	0	0	15	9	5.58
646275	16	15	1	1	0	14	7	5.48
646277	15	15	0	0	0	15	7	4.61
646281	15	15	0	0	0	15	11	4.29
646283	14	12	0	0	0	12	7	6.15
646287	14	14	0	0	0	14	8	5.42
646289	18	16	0	0	0	16	6	5.69
646293	19	17	0	0	0	17	10	5.57
646295	15	14	0	0	0	14	6	5.59
646301	14	12	0	0	0	12	7	5.35
646304	13	12	0	0	0	12	7	5.26

Company Sanitized. Does not contain TSCA ch.

APPENDIX G

Individual Fetal Weights and Alterations

Company Sanitized. Does not contain TSCA CRI

Individual Fetal Weights and Alterations

Explanatory Notes

a No skeletal evaluation was done for these fetuses; due to technical error, the fetal skeletons marked with this footnote were disarticulated.

For ease of recording, many of the findings have been abbreviated or coded, as listed below:

ar	=	arch(es)
bil	=	bilateral
cen	=	centrum or centra
lt	=	left
lu	=	lumbar
NAD	=	No Abnormalities Detected
rt	=	right
th	=	thoracic
---	=	No Data

* Subcutaneous hemorrhage that was not present *in utero*.

Renal papillary sizes refer to papillary development using the scheme of Woo and Hoar.⁽³⁾

Alterations are classed as:

N	=	Notes
DV	=	Developmental Variations
VR	=	Variation due to Retarded Development
M	=	Malformations

Numbers are used to:

- Indicate renal papillary size
- Identify specific sternebra
- Refer to skeletal position for ribs or vertebra
- Specify skull bones according to the following key:

1. Interparietal	8. Squamosal
2. Parietal	9. Tympanic annulus
3. Frontal	10. Basioccipital
4. Nasal	11. Exoccipital
5. Premaxilla	12. Supreoccipital
6. Maxilla	13. Hyoid
7. Zygoma	

Company Sanitized. Does not contain TSCA CRT

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP I: 0 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646224				
1	5.60	Vertebra	Retarded Ossification (cen th11,12)	VR
2	5.60	Vertebra	Retarded Ossification (cen th11,12)	VR
3	5.83	Sternebra	Retarded Ossification (4)	VR
4	5.74	Vertebra	Retarded Ossification (cen th12)	VR
5	5.90	Kidney	Papilla - Size 3 (rt)	VR
6	5.43	Vertebra	Retarded Ossification (cen th12)	VR
7	5.79		NAD	
8	5.96	Vertebra	Retarded Ossification (cen th11)	VR
9	5.61		NAD	
10	5.31	Vertebra	Retarded Ossification (cen th12)	VR
11	5.63		NAD	
12	5.59	Vertebra	Retarded Ossification (cen th11)	VR
13	6.12	Vertebra	Retarded Ossification (cen th8,11)	VR
646225				
1	6.01		NAD	
2	5.69	Vertebra	Retarded Ossification (cen th12)	VR
3	5.76		NAD	
4	5.94	Vertebra	Retarded Ossification (cen th12)	VR
5	5.77		NAD	
6	5.64	Vertebra	Retarded Ossification (cen th13)	VR
7	6.21	Vertebra	Retarded Ossification (cen th11-12)	VR
8	5.48	Vertebra	Retarded Ossification (cen th11-12)	VR

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP I: 0 MG/KG/DAY

DAM NO./

FETUS NO. FETUS WT. STRUCTURE FINDING(S) CLASSIFICATION

646225 (Cont.)

9	5.34	Vertebra	Retarded Ossification (cen th12)	VR
10	5.79		NAD	
11	5.70	Vertebra	Retarded Ossification (cen th11)	VR
12	4.74		NAD	
13	5.94	Kidney	Small Papilla - Size 2 (bilateral)	VR
		Vertebra	Retarded Ossification (cen th10,11)	VR

646226

1	5.63		NAD	
2	5.33		NAD	
3	5.54		NAD	
4	5.66	Vertebra	Retarded Ossification (cen th11)	VR
5	5.43		NAD	
6	4.68	Rib	Supernumerary (site th14 bil)	DV
7	5.67	Kidney	Small Papilla - Size 2 (bil)	VR
		Vertebra	Retarded Ossification (cen th12)	VR
8	5.45		NAD	
9	5.25		NAD	
10	5.55		NAD	
11	6.10	Vertebra	Retarded Ossification (cen th10,12)	VR
12	5.87		NAD	
13	5.70	Vertebra	Retarded Ossification (cen th12)	VR
14	5.73		NAD	
15	5.62	Rib	Supernumerary (site th14 lt)	DV
16	5.98	Rib	Supernumerary (site th14 lt)	DV
17	5.85		NAD	

646230

1	5.61		NAD	
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Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP I: 0 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646230 (Cont.)				
2	5.36	Vertebra	Retarded Ossification (cen th8,10-12)	VR
3	5.15		NAD	
4	5.28		NAD	
5	5.15	Vertebra	Retarded Ossification (cen th10)	VR
6	5.43		NAD	
7	5.31		NAD	
8	4.96		NAD	
9	5.14		NAD	
10	5.26		NAD	
11	5.94	Kidney	Papilla - Size 3 (left)	VR
12	5.01	Vertebra	Retarded Ossification (cen th10)	VR
13	5.25		NAD	
14	4.90		NAD	
15	5.48	Kidney Vertebra	Papilla - Size 3 (bilateral) Retarded Ossification (cen th10)	VR VR
646236				
1	5.88		NAD	
2	6.20		NAD	
3	5.97		NAD	
4	5.83		NAD	
5	5.67		NAD	
6	5.57	Vertebra	Retarded Ossification (cen th11)	VR
7	5.81	Vertebra	Retarded Ossification (cen th9)	VR
8	6.25		NAD	
9	5.31	Kidney Rib	Papilla - Size 3 (bil) Rudimentary Cervical (7 rt)	VR DV
10	6.15		NAD	
11	6.36		NAD	
12	6.34		NAD	
13	5.83	Kidney	Papilla - Size 3 (bil)	VR

Company Sanitized. Does not contain TSCA CB!

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP I: 0 MG/KG/DAY

DAM NO./		FETUS NO. FETUS WT. STRUCTURE		FINDING(S)	CLASSIFICATION
646236 (Cont.)					
		Vertebra		Retarded Ossification (cen th11)	VR
646241					
1	5.53	Rib		Supernumerary (th14 site bil)	DV
2	5.39	Vertebra		Retarded Ossification (cen th11)	VR
3	5.35			NAD	
4	5.78	Vertebra		Retarded Ossification (cen th10)	VR
5	5.85	Rib		Supernumerary (th14 site lt)	DV
		Vertebra		Retarded Ossification (cen th10-12)	VR
6	5.63			NAD	
7	6.25			NAD	
8	6.24	Vertebra		Retarded Ossification (cen th11-12)	VR
9	5.54			NAD	
10	5.53			NAD	
11	5.70	Vertebra		Retarded Ossification (cen th12)	VR
12	5.76			NAD	
13	5.75			NAD	
14	5.42			NAD	
15	5.19	Vertebra		Retarded Ossification (cen th11)	VR
16	6.02	Vertebra		Retarded Ossification (cen th11)	VR
646251					
1	5.12			NAD	
2	5.51			NAD	
3	5.61	Subcutis		Hemorrhage (back*)	N
4	5.98			NAD	
5	5.49			NAD	
6	5.21	Vertebra		Retarded Ossification (cen th12)	VR
7	5.80			NAD	

Company Sanitized. Does not contain TSCA CB

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP I: 0 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646251 (Cont.)				
8	5.18	Skull	Retarded Ossification (6 bil)	VR
9	5.25		NAD	
10	5.26		NAD	
11	5.59		NAD	
12	5.99		NAD	
13	5.81		NAD	
14	5.32	Vertebra	Retarded Ossification (cen th13)	VR
646252				
1	5.15		NAD	
2	5.33		NAD	
3	5.59		NAD	
4	4.90	Vertebra	Retarded Ossification (cen th12)	VR
5	5.62	Kidney	Papilla - Size 3 (rt)	VR
6	5.86		NAD	
7	4.92		NAD	
8	5.05	Vertebra	Retarded Ossification (cen th12-13)	VR
9	5.70		NAD	
10	5.67	Vertebra	Retarded Ossification (cen th11)	VR
11	5.24	Vertebra	Retarded Ossification (cen th11)	VR
12	4.41	Skull	Retarded Ossification (2 bil)	VR
13	4.76		NAD	
14	5.48	Vertebra	Retarded Ossification (cen th12)	VR
15	5.19		NAD	
646256				
1	5.85	Vertebra	Retarded Ossification (cen th11,12,13)	VR
2	6.28	Vertebra	Retarded Ossification (cen th12,13)	VR
3	5.73	Kidney	Small Papilla - Size 2 (bil)	VR
4	5.79		NAD	

Company Sanitized. Does not contain TSCA CS

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP I: 0 MG/KG/DAY

DAM NO./ FETUS NO.		FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646256 (Cont.)					
5		6.00	Vertebra	Retarded Ossification (cen th11,12)	VR
6		5.79	Vertebra	Retarded Ossification (cen th11)	VR
7		5.61	Vertebra	Retarded Ossification (cen th10,11,12,13)	VR
8		6.20	Vertebra	Retarded Ossification (cen th11)	VR
9		5.74	Vertebra	Retarded Ossification (cen th13)	VR
10		5.01	Vertebra	Retarded Ossification (cen th12)	VR
11		5.77	Vertebra	Retarded Ossification (cen th12,13)	VR
12		5.72	Vertebra	Retarded Ossification (cen th10,13)	VR
646257					
1		5.61		NAD	
2		5.94		NAD	
3		6.12	Kidney	Papilla - Size 3 (bil)	VR
4		6.02	Vertebra	Retarded Ossification (cen th11)	VR
5		5.43		NAD	
6		6.44	Vertebra	Retarded Ossification (cen th11)	VR
7		5.03	Vertebra	Retarded Ossification (cen th11)	VR
8		5.46		NAD	
9		5.42		NAD	
10		5.52	Vertebra	Retarded Ossification (cen th11-12)	VR
11		5.20	Kidney	Small Papilla - Size 2 (left)	VR
12		5.90	Vertebra	Retarded Ossification (cen th11)	VR
646261					
1		5.56		NAD	

Company Sanitized. Does not contain TSCA C.

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP I: 0 MG/KG/DAY

DAM NO./

FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646261 (Cont.)				
2	5.94		NAD	
3	5.74		NAD	
4	5.78	Vertebra	Retarded Ossification (cen th11-13)	VR
5	5.12		NAD	
6	6.09	Skull	Retarded Ossification (6bil)	VR
7	5.81		NAD	
8	5.36	Vertebra	Retarded Ossification (cen th12)	VR
9	5.30	Kidney	Papilla - Size 3 (bil)	VR
10	5.61	Vertebra	Retarded Ossification (cen th12)	VR
11	5.60		NAD	
646265				
1	5.62		NAD	
2	5.18	Vertebra	Retarded Ossification (cen th10)	VR
3	4.67	Kidney	Small Papilla - Size 2 (bilateral)	VR
4	5.28		NAD	
5	5.19	Vertebra	Retarded Ossification (cen th11)	VR
6	4.85	Vertebra	Retarded Ossification (cen th11-13)	VR
7	5.08		NAD	
8	5.22	Vertebra	Retarded Ossification (cen th12)	VR
9	5.13		NAD	
10	5.42		NAD	
11	4.82		NAD	
12	5.11	Vertebra	Retarded Ossification (cen th11)	VR
646272				
1	5.66	Rib	Supernumerary (th14 site bil)	DV

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP I: 0 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646272 (Cont.)				
2	5.07	Vertebra	Retarded Ossification (cen th11-12)	VR
3	6.14	Vertebra	Retarded Ossification (cen th13)	VR
4	5.20	Vertebra	Retarded Ossification (cen th10)	VR
5	5.51		NAD	
6	5.60	Rib	Supernumerary (th14 site rt)	DV
		Vertebra	Retarded Ossification (cen th11)	VR
7	5.67		NAD	
8	5.94	Rib	Supernumerary (th14 site lt)	DV
		Vertebra	Retarded Ossification (cen th12)	VR
9	5.97	Kidney	Papilla - Size 3 (lt)	VR
		Rib	Supernumerary (th14 site rt short lt)	DV
10	5.92	Rib	Supernumerary (th14 site lt)	DV
11	6.06	Kidney	Papilla - Size 3 (bil)	VR
12	6.06	Rib	Supernumerary (th14 site bil)	DV
		Vertebra	Retarded Ossification (cen th11)	VR
13	6.63	Kidney	Small Papilla - Size 2 (bil)	VR
646276				
1	5.54		NAD	
2	5.47		NAD	
3	5.18		NAD	
4	5.36		NAD	
5	4.41	Vertebra	Retarded Ossification (cen th11, lu1)	VR
6	5.47	Vertebra	Retarded Ossification (cen th11)	VR
7	5.54	Rib	Supernumerary (th site 14rt)	DV
8	5.46		NAD	
9	4.50		NAD	
10	5.64	Rib	Supernumerary (th site 14bil)	DV

Company Sanitized. Does not contain TSCA CB1

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP I: 0 MG/KG/DAY

DAM NO. / FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646276 (Cont.)				
		Vertebra	Retarded Ossification (cen th12)	VR
11	5.42		NAD	
12	5.38		NAD	
13	5.16		NAD	
14	5.28		NAD	
15	5.54		NAD	
646278				
1	6.31		NAD	
2	5.70		NAD	
3	5.34		NAD	
4	5.70	Vertebra	Retarded Ossification (cen th11-12)	VR
5	5.38		NAD	
6	5.28		NAD	
7	5.40	Kidney Vertebra	Papilla - Size 3 (bil) Retarded Ossification (cen th11)	VR VR
8	5.56		NAD	
9	5.53	Vertebra	Retarded Ossification (cen th11-12)	VR
10	5.81		NAD	
11	5.22	Vertebra	Retarded Ossification (cen th12)	VR
12	5.06		NAD	
13	5.45		NAD	
646282				
1	5.71	Kidney Vertebra	Papilla - Size 3 (bil) Retarded Ossification (cen th11)	VR VR
2	6.27		NAD	
3	5.98		NAD	
4	5.43		NAD	
5	6.12	Kidney	Small Papilla - Size 2 (left)	VR
6	6.25		NAD	
7	5.64		NAD	

Company Sanitized. Does not contain TSCA CR1

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP I: 0 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646282 (Cont.)				
8	6.01		NAD	
9	6.10	Vertebra	Retarded Ossification (cen th11,12)	VR
10	5.24	Skull Vertebra	Retarded Ossification (2 bil) Retarded Ossification (cen th12)	VR VR
11	5.93	Vertebra	Retarded Ossification (cen th10)	VR
12	5.46	Vertebra	Retarded Ossification (cen th12)	VR
13	6.10	Vertebra	Retarded Ossification (cen th11)	VR
14	6.48		NAD	
15	5.98		NAD	
646284				
1	5.66	Kidney	Papilla - Size 3 (bil)	VR
2	5.59	Skull Vertebra	Retarded Ossification (6 bil) Retarded Ossification (cen th10-11)	VR VR
3	5.61	Vertebra	Retarded Ossification (cen th12)	VR
4	5.14	Vertebra	Retarded Ossification (cen th11-12)	VR
5	5.45	Kidney Vertebra	Papilla - Size 3 (bil) Retarded Ossification (cen th11)	VR VR
6	6.14	Vertebra	Retarded Ossification (cen th13)	VR
7	5.69	Vertebra	Retarded Ossification (cen th12)	VR
8	6.48	Vertebra	Retarded Ossification (cen th13)	VR
9	5.44	Kidney Vertebra	Small Papilla - Size 2 (bil) Retarded Ossification (cen th10-12)	VR VR

Company Sanitized. Does Not contain TSCA CR1

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP I: 0 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646284 (Cont.)				
10	5.87	Vertebra	Retarded Ossification (cen th11-12)	VR
11	5.57		NAD	
12	6.26	Vertebra	Retarded Ossification (cen th11-13)	VR
13	5.94		NAD	
646288				
1	5.47	Kidney	Small Papilla - Size 2 (left)	VR
2	5.84		NAD	
3	5.65	Kidney	Papilla - Size 3 (bil)	VR
4	5.61	Vertebra	Retarded Ossification (cen th11)	VR
5	4.87		NAD	
6	5.33	Vertebra	Retarded Ossification (cen th10)	VR
7	5.63	Vertebra	Retarded Ossification (cen th10,11)	VR
8	5.65	Vertebra	Retarded Ossification (cen th12)	VR
9	5.73	Vertebra	Retarded Ossification (cen th10,12)	VR
10	5.58		NAD	
11	5.17	Vertebra	Retarded Ossification (cen th10,12)	VR
12	5.42		NAD	
13	5.46		NAD	
14	5.94	Skull	Retarded Ossification (6 lt)	VR
15	5.85	Vertebra	Retarded Ossification (cen th11)	VR
646290				
1	5.41	Kidney	Small Papilla - Size 2 (bil)	VR
2	5.66	Vertebra	Retarded Ossification (cen th12)	VR
3	5.27		NAD	

Company Sanitized. Does not contain TSCA CB:

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP I: 0 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646290 (Cont.)				
4	5.67	Vertebra	Retarded Ossification (cen th12)	VR
5	5.50		NAD	
6	4.91	Subcutis Vertebra	Hemorrhage (back*) Retarded Ossification (cen th11)	N VR
7	5.27		NAD	
8	5.33		NAD	
9	4.81	Vertebra	Retarded Ossification (cen th11)	VR
10	4.94		NAD	
11	5.56		NAD	
12	5.14		NAD	
13	5.42		NAD	
14	5.26		NAD	
646292				
1	5.15	Kidney Rib	Small Papilla - Size 2 (bil) Supernumerary (th14 site lt)	VR DV
2	5.43		NAD	
3	5.43		NAD	
4	5.56	Rib	Supernumerary (th14 site bil)	DV
5	5.52		NAD	
6	5.21		NAD	
7	5.05		NAD	
8	4.74		NAD	
9	5.37	Kidney	Papilla - Size 3 (bilateral)	VR
10	5.37		NAD	
11	5.05		NAD	
12 ^a	5.29		NAD	
13	5.13		NAD	
14	5.48		NAD	
15	4.96	Rib	Supernumerary (th14 site lt)	DV
646294				
1	4.89		NAD	

Company Sanitized. Does not contain TSCA CB.

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP I: 0 MG/KG/DAY

DAM NO. / FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646294 (Cont.)				
2	4.92	Vertebra	Retarded Ossification (cen th11-12)	VR
3	4.02		NAD	
4	4.48		NAD	
5	5.25		NAD	
6	4.61	Vertebra	Retarded Ossification (cen th12)	VR
7	4.57		NAD	
8	4.44		NAD	
9	4.82		NAD	
10	4.85	Vertebra	Retarded Ossification (cen th10-11)	VR
11	4.75	Vertebra	Retarded Ossification (cen th12)	VR
12	4.79		NAD	
13	4.26	Vertebra	Retarded Ossification (cen th12)	VR
14	4.69	Pelvis	Retarded Ossification (pubis bil)	VR
		Skull	Retarded Ossification (2 bil)	VR
646308				
1	5.59		NAD	
2 ^a	6.02		NAD	
3	6.49		NAD	
4	5.65		NAD	
5	5.80	Subcutis	Hemorrhage (nose*)	N
6 ^a	5.96		NAD	
7	5.85		NAD	
8	5.71		NAD	
9	5.37		NAD	
10	5.85		NAD	
11	5.97		NAD	
12	5.92		NAD	
13	5.60		NAD	
14	5.65	Vertebra	Retarded Ossification (cen th11)	VR

Company Sanitized. Does not contain TSCA CF

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP I: 0 MG/KG/DAY

DAM NO. /

FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
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646308 (Cont.)

15

5.82 Kidney

Small Papilla - Size 2 (bil) VR

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP II: 50 MG/KG/DAY

DAM NO. / FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646227				
1	5.38	Vertebra	Retarded Ossification (cen th10)	VR
2	5.17		NAD	
3	5.23		NAD	
4	5.42		NAD	
5	5.48		NAD	
6	5.03		NAD	
7	5.35	Vertebra	Retarded Ossification (cen th11)	VR
8	3.18	Skull	Retarded Ossification (3 bil)	VR
		Sternebra	Retarded Ossification (1,4,6)	VR
9	5.36		NAD	
10	5.31	Vertebra	Retarded Ossification (cen th11,13)	VR
11	5.01		NAD	
12	5.33		NAD	
13	4.91		NAD	
14	5.35		NAD	
15	5.40	Brain	Distended (ventricles)	M
646229				
1	5.53	Vertebra	Retarded Ossification (cen th11-12)	VR
2	5.88	Vertebra	Retarded Ossification (cen th10-12)	VR
3	5.67	Vertebra	Retarded Ossification (cen th11)	VR
4	5.58		NAD	
5	5.49	Kidney	Small Papilla - Size 2 (left)	VR
6	5.78	Vertebra	Retarded Ossification (cen th7,9-12)	VR
7	5.17	Vertebra	Retarded Ossification (cen th10-12)	VR
8	4.96	Vertebra	Retarded Ossification (cen th11)	VR
9	5.40		NAD	

Company Sanitized. Does not contain TSCA C

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP II: 50 MG/KG/DAY

DAM NO./

FETUS NO. FETUS WT. STRUCTURE FINDING(S) CLASSIFICATION

646229 (Cont.)

10	5.45	Vertebra	Retarded Ossification (cen th12)	VR
11	5.65		NAD	
12	5.48	Skull	Retarded Ossification (12,6bil)	VR
		Vertebra	Retarded Ossification (cen th11-12)	VR
13	5.26	Vertebra	Retarded Ossification (cen th10-11)	VR
14	6.14	Rib	Supernumerary (th site 14lt)	DV
		Skull	Retarded Ossification (6bil)	VR

646231

1	5.46		NAD	
2	5.79		NAD	
3	5.48		NAD	
4	5.24		NAD	
5	5.77		NAD	
6	5.43		NAD	
7	5.46		NAD	
8	4.68		NAD	
9	5.13		NAD	
10	5.48		NAD	
11	4.95		NAD	
12	4.77	Rib	Supernumerary (th short 13rt)	DV
13	5.57		NAD	
14	5.13	Vertebra	Retarded Ossification (cen th9)	VR
15	4.93		NAD	
16	5.26		NAD	

646235

1	5.89		NAD	
2	5.71		NAD	
3	5.26	Vertebra	Retarded Ossification (cen th4)	VR
4	5.44		NAD	
5	5.39		NAD	

Company Sanitized. Does not contain TSCA C

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP II: 50 MG/KG/DAY

DAM NO./

FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646235 (Cont.)				
6	5.81	Skull	Retarded Ossification (2 bil)	VR
7	5.99	Kidney	Papilla - Size 3 (lt)	VR
8	5.55		NAD	
9	5.95		NAD	
10	5.81		NAD	
11	5.38	Vertebra	Retarded Ossification (cen th11)	VR
12	5.95	Vertebra	Retarded Ossification (cen th12)	VR
13	5.62	Vertebra	Retarded Ossification (cen th11)	VR
14	5.94	Vertebra	Retarded Ossification (cen th11,12)	VR
646242				
1	5.93	Kidney	Small Papilla - Size 2 (bil)	VR
		Vertebra	Retarded Ossification (cen th12)	VR
2	5.04	Vertebra	Retarded Ossification (cen th10)	VR
3	5.76	Kidney	Papilla - Size 3 (bil)	VR
		Vertebra	Retarded Ossification (cen th11)	VR
4	5.35	Vertebra	Retarded Ossification (cen th11)	VR
5	5.01		NAD	
6	5.53	Scapula	Misshapen (bil)	DV
		Rib	Wavy (5-13 bil)	VR
		Skull	Retarded Ossification (1,12 bil)	VR
		Vertebra	Retarded Ossification (cen th13)	VR
7	4.79	Kidney	Papilla - Size 3 (bil)	VR
		Vertebra	Retarded Ossification (cen th11)	VR
8	4.23		NAD	

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP II: 50 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646242 (Cont.)				
9	5.63	Vertebra	Retarded Ossification (cen th12)	VR
10	5.15		NAD	
11	5.21		NAD	
12	5.55	Skull	Retarded Ossification (1,6 bil)	VR
		Vertebra	Retarded Ossification (cen th12)	VR
13	4.52		NAD	
646245				
1	5.00	Kidney	Small Papilla - Size 2 (lt;size 3rt)	VR
		Vertebra	Retarded Ossification (cen th12)	VR
2	5.55		NAD	
3	5.28	Kidney	Small Papilla - Size 2 (rt)	VR
4	5.46		NAD	
5	5.77	Kidney	Papilla - Size 3 (lt)	VR
6	5.66		NAD	
7	5.51	Vertebra	Retarded Ossification (cen th12)	VR
8	3.02	Rib	Fused (th3-5 lt)	M
		Vertebra	Fused (th3-5 arch lt)	M
		Vertebra	Hemi (cen th3,7)	M
		Skull	Retarded Ossification (3 bil)	VR
		Sternebra	Retarded Ossification (1,3-4,6)	VR
		Vertebra	Retarded Ossification (cen th9-10,12)	VR
9	6.34	Vertebra	Retarded Ossification (cen th10)	VR
10	5.04	Rib	Supernumerary (th14 site rt)	DV
		Vertebra	Retarded Ossification (cen th12)	VR
11	5.43		NAD	

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP II: 50 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646245 (Cont.)				
12	5.59	Vertebra	Retarded Ossification (cen th11)	VR
646246				
1	5.77	Vertebra	Retarded Ossification (cen th11)	VR
2	5.83	Vertebra	Retarded Ossification (cen th10-12)	VR
3	5.72	Sternebra Vertebra	Retarded Ossification (3) Retarded Ossification (cen th10,11)	VR VR
4	5.80	Vertebra	Retarded Ossification (cen th11)	VR
5	5.36	Vertebra	Retarded Ossification (cen th11,13)	VR
6	5.66	Vertebra	Retarded Ossification (cen th12)	VR
7	5.52	Vertebra	Retarded Ossification (cen th10-13)	VR
8	5.62	Vertebra	Retarded Ossification (cen th12)	VR
9	5.23	Heart &/or Greater Vessels Vertebra	Patent Ductus Arteriosus Retarded Ossification (cen th10)	VR VR
10	5.04	Vertebra	Retarded Ossification (cen th10-13)	VR
11	5.79	Vertebra	Retarded Ossification (cen th11,12)	VR
12	5.60	Vertebra	Retarded Ossification (cen th12)	VR
13	5.90	Subcutis	Hemorrhage (chin*)	N
14	5.43	Vertebra	Retarded Ossification (cen th11-13)	VR
15	6.06	Vertebra	Retarded Ossification (cen th11-13)	VR
16	6.31	Skull	Retarded Ossification (6 lt)	VR

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP II: 50 MG/KG/DAY

DAM NO. / FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646246 (Cont.)				
		Vertebra	Retarded Ossification (cen th12-13)	VR
646249				
1	4.25	Vertebra	Retarded Ossification (cen th12)	VR
2	6.50		NAD	
3	5.80		NAD	
4	5.47	Vertebra	Retarded Ossification (cen th11-12)	VR
5	5.79	Kidney	Papilla - Size 3 (left)	VR
6	5.73		NAD	
7	6.14	Vertebra	Retarded Ossification (cen th12)	VR
8	6.30		NAD	
9	6.39	Vertebra	Retarded Ossification (cen th11)	VR
10	5.61	Vertebra	Retarded Ossification (cen th11-12)	VR
11	5.90		NAD	
12	5.47	Vertebra	Retarded Ossification (cen th11)	VR
646250				
1	4.90	Vertebra	Retarded Ossification (cen th12)	VR
2	5.08		NAD	
3	5.16	Vertebra	Retarded Ossification (cen th12)	VR
4	5.66		NAD	
5	5.36		NAD	
6	5.43		NAD	
7	4.99	Vertebra	Retarded Ossification (cen th11)	VR
8	5.20	Vertebra	Retarded Ossification (cen th11-12)	VR

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP II: 50 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646250 (Cont.)				
9	5.34	Vertebra	Retarded Ossification (cen th12)	VR
10	4.99	Vertebra	Retarded Ossification (cen th12)	VR
11	5.42		NAD	
12	5.79		NAD	
13	5.34		NAD	
14	5.24	Vertebra	Retarded Ossification (cen th11)	VR
15	5.13		NAD	
16	5.65	Rib	Supernumerary (site 14rt)	DV
17	5.08	Vertebra	Retarded Ossification (cen th12)	VR
646253				
1	5.45		NAD	
2	5.71		NAD	
3	6.31	Vertebra	Retarded Ossification (cen th11,12)	VR
4	6.03		NAD	
5	5.94		NAD	
6	5.89	Vertebra	Retarded Ossification (cen th11)	VR
7	5.35	Vertebra	Retarded Ossification (cen th11)	VR
8	5.40		NAD	
9	5.65		NAD	
10	5.72	Vertebra	Retarded Ossification (cen th12)	VR
11	6.22	Vertebra	Retarded Ossification (cen th11)	VR
12	5.57		NAD	
13	5.73	Vertebra	Retarded Ossification (cen th11)	VR
14	5.82	Vertebra	Retarded Ossification (cen th12)	VR
15	5.85		NAD	

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP II: 50 MG/KG/DAY

DAM NO. / FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646264				
1	5.51		NAD	
2	5.60	Vertebra	Retarded Ossification (cen th12)	VR
3	5.96	Kidney	Papilla - Size 3 (bil)	VR
		Vertebra	Retarded Ossification (cen th11,12)	VR
4	5.46		NAD	
5	5.15	Vertebra	Retarded Ossification (cen th11)	VR
6	5.27	Rib	Supernumerary (th13 site rt)	DV
		Vertebra	Retarded Ossification (cen th12)	VR
7	5.21		NAD	
8	5.18		NAD	
9	5.16	Kidney	Small Papilla - Size 2 (lt)	VR
10	5.31	Vertebra	Retarded Ossification (cen th11)	VR
11	5.50		NAD	
12	5.62	Vertebra	Retarded Ossification (cen th11)	VR
13	5.17		NAD	
14	5.34		NAD	
15	5.53	Vertebra	Retarded Ossification (cen th11)	VR
646267				
1	5.26	Vertebra	Retarded Ossification (cen th11)	VR
2	5.11		NAD	
3	4.92	Vertebra	Retarded Ossification (cen th11-12)	VR
4	5.30		NAD	
5	4.64	Vertebra	Retarded Ossification (cen th10)	VR
6	5.27		NAD	
7	5.16		NAD	
8	5.01	Skull	Retarded Ossification (6 bil)	VR

Company Sanitized. Does not contain TSCA CRT

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP II: 50 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646267 (Cont.)				
9	4.71	Kidney Vertebra	Small Papilla - Size 1 (left) Retarded Ossification (cen th12-13)	VR VR
10	5.29	Vertebra	Retarded Ossification (cen th10,12)	VR
11	5.50	Vertebra	Retarded Ossification (cen th10,11)	VR
12	5.29	Vertebra	Retarded Ossification (cen th12)	VR
13	4.86	Vertebra	Retarded Ossification (cen th10,13)	VR
14	4.91		NAD	
15	5.37	Vertebra	Retarded Ossification (cen th11)	VR
646274				
1	5.55		NAD	
2	5.46		NAD	
3	5.35		NAD	
4	5.33	Vertebra	Retarded Ossification (cen th11)	VR
5	5.33		NAD	
6	5.50		NAD	
7	6.06	Vertebra	Retarded Ossification (cen th10)	VR
8	5.35		NAD	
9	5.50		NAD	
10	5.05	Vertebra	Retarded Ossification (cen th12)	VR
11	5.24	Kidney Vertebra	Papilla - Size 3 (bil) Retarded Ossification (cen th12)	VR VR
12	6.02	Vertebra	Retarded Ossification (cen th11-12)	VR
13	5.13	Vertebra	Retarded Ossification (cen th12)	VR
14	5.53		NAD	

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP II: 50 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646279				
1	5.17		NAD	
2	5.71		NAD	
3	5.24	Vertebra	Retarded Ossification (cen th11)	VR
4	5.36		NAD	
5	5.53	Vertebra	Retarded Ossification (cen th12)	VR
6	4.99		NAD	
7	5.25		NAD	
8	5.56		NAD	
9	5.31	Vertebra	Retarded Ossification (cen th11)	VR
10	5.54		NAD	
11	5.89		NAD	
12	5.38		NAD	
13	5.44	Heart &/or Greater Vessels	Patent Ductus Arteriosus	VR
14	5.61		NAD	
15	5.19	Vertebra	Retarded Ossification (cen th11,13)	VR
		Vertebra	Retarded Ossification (cen th12)	VR
646280				
1	5.55	Kidney Vertebra	Small Papilla - Size 2 (rt) Retarded Ossification (cen th11)	VR
2	5.77	Vertebra	Retarded Ossification (cen th12)	VR
3	5.83	Vertebra	Retarded Ossification (cen th12)	VR
4	5.76	Vertebra	Retarded Ossification (cen th12)	VR
5	5.67	Vertebra	Retarded Ossification (cen th11-13)	VR
6	5.53	Vertebra	Retarded Ossification (cen th12)	VR

Company Sanitized. Does not contain TSCA CB

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP II: 50 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646280 (Cont.)				
7	5.79	Vertebra	Retarded Ossification (cen th11-12)	VR
8	6.08	Vertebra	Retarded Ossification (cen th12)	VR
9	5.61	Vertebra	Retarded Ossification (cen th12)	VR
10	5.40	Vertebra	Retarded Ossification (cen th13)	VR
11	5.95	Vertebra	Retarded Ossification (cen th12)	VR
12	4.99	Vertebra	Retarded Ossification (cen th12)	VR
13	5.45	Vertebra	Retarded Ossification (cen th10-12)	VR
14	5.53	Vertebra	Retarded Ossification (cen th11-12)	VR
15	5.19	Kidney	Papilla - Size 3 (bil)	VR
646286				
1	6.30		NAD	
2	5.91		NAD	
3	6.21		NAD	
4	6.01		NAD	
5	5.70		NAD	
6	5.51		NAD	
7	5.77		NAD	
8	6.08		NAD	
9	5.43		NAD	
10	5.84		NAD	
11	5.58		NAD	
12	5.81		NAD	
13	6.06		NAD	
14	5.75		NAD	
15	5.74	Kidney	Papilla - Size 3 (rt)	VR
16	6.13		NAD	
17	5.24	Rib	Supernumerary (site 14 lt)	DV

Company Sanitized. Does not contain TSCA CH

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP II: 50 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646291				
1	6.01		NAD	
2	6.09	Vertebra	Retarded Ossification (cen th11)	VR
		Vertebra	Retarded Ossification (cen th12)	VR
3	6.42		NAD	
4	6.32	Vertebra	Retarded Ossification (cen th12-13)	VR
5	6.21	Vertebra	Retarded Ossification (cen th11)	VR
6	6.16	Vertebra	Retarded Ossification (cen th11-12)	VR
7	6.36	Vertebra	Retarded Ossification (cen th11)	VR
		Vertebra	Retarded Ossification (cen th12)	VR
8	6.34	Vertebra	Retarded Ossification (cen th11)	VR
9	6.51	Vertebra	Retarded Ossification (cen th11)	VR
10	6.26	Vertebra	Retarded Ossification (cen th11-12)	VR
646296				
1	5.17	Vertebra	Retarded Ossification (cen th12)	VR
2	5.31	Vertebra	Retarded Ossification (cen th11)	VR
3	5.67	Vertebra	Retarded Ossification (cen th10-12)	VR
4	5.72		NAD	
5	5.61	Vertebra	Retarded Ossification (cen th12-13)	VR
6	5.39	Vertebra	Retarded Ossification (cen th10-13)	VR
7	5.28	Vertebra	Retarded Ossification (cen th11)	VR

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP II: 50 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646296 (Cont.)				
8	5.05	Vertebra	Retarded Ossification (cen th10)	VR
9	5.65	Kidney	Papilla - Size 3 (bil)	VR
		Vertebra	Retarded Ossification (cen th11-12)	VR
10	5.34		NAD	
11	5.55	Vertebra	Retarded Ossification (cen th11-12)	VR
12	5.57	Vertebra	Retarded Ossification (cen th10-13)	VR
13	5.68	Rib	Rudimentary Cervical (7 lt)	DV
		Vertebra	Retarded Ossification (cen th10)	VR
646297				
1	5.67	Kidney	Small Papilla - Size 2 (rt)	VR
2 ^a	5.63		NAD	
3	5.80		NAD	
4	5.95		NAD	
5	5.71		NAD	
6	6.25		NAD	
7	5.68	Vertebra	Retarded Ossification (cen th12)	VR
8	5.89	Vertebra	Retarded Ossification (cen th11-12)	VR
9	5.73	Kidney	Small Papilla - Size 2 (bil)	VR
10	5.61		NAD	
11	5.82		NAD	
12	5.75		NAD	
13	5.69	Abdomen	Malformation (umbilical hernia)	M
		Vertebra	Retarded Ossification (cen th9-12)	VR
14	4.69	Vertebra	Retarded Ossification (cen th11-12)	VR
15	5.71	Vertebra	Retarded Ossification (cen th11-12)	VR

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP II: 50 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646298				
1	5.29	Kidney	Small Papilla - Size 2 (right)	VR
2	5.33		NAD	
3	5.00	Vertebra	Retarded Ossification (cen th11)	VR
4	5.65		NAD	
5	5.28	Vertebra	Retarded Ossification (cen th10)	VR
6	5.06		NAD	
7	5.71	Kidney	Papilla - Size 3 (bil)	VR
		Vertebra	Retarded Ossification (cen th10-13)	VR
8	5.28	Vertebra	Retarded Ossification (cen th11)	VR
9	5.28	Vertebra	Retarded Ossification (cen th11)	VR
10	5.19		NAD	
11	5.51		NAD	
12	5.64		NAD	
13	5.10		NAD	
14	4.96		NAD	
15	5.01		NAD	
16	5.60	Vertebra	Retarded Ossification (cen th10-13)	VR
646300				
1	5.70		NAD	
2	5.58	Skull	Retarded Ossification (2 bil)	VR
3	5.45		NAD	
4	5.58		NAD	
5	5.79		NAD	
6	5.16	Vertebra	Retarded Ossification (cen th10)	VR
7	5.03		NAD	
8	5.55		NAD	
9	5.14		NAD	
10	5.47		NAD	
11	5.32		NAD	
12	5.37		NAD	

Company Sanitized. Does not contain TSCA CRV

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP II: 50 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646300 (Cont.)				
13	5.37		NAD	
14	5.32	Vertebra	Retarded Ossification (cen th11-12)	VR
15	5.39	Chin	Micrognathia	M
		Skull	Micrognathia	M
646306				
1	5.50	Kidney	Small Papilla - Size 2 (lt)	VR
2	6.08	Skull	Retarded Ossification (2 bil)	VR
3	5.54	Vertebra	Retarded Ossification (cen th12)	VR
4	5.86	Vertebra	Retarded Ossification (cen th12)	VR
5	5.25	Vertebra	Retarded Ossification (cen th11-13)	VR
6	5.51	Vertebra	Retarded Ossification (cen th11)	VR
7	6.00		NAD	
8	5.53	Vertebra	Retarded Ossification (cen th11)	VR
9	5.69	Kidney	Small Papilla - Size 2 (lt;size 3rt)	VR
10	5.53		NAD	
11	5.30	Kidney	Small Papilla - Size 1 (left)	VR
12	5.27		NAD	
13	5.41		NAD	

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP III: 250 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646222				
1	4.85	Vertebra	Retarded Ossification (cen th11, lu2)	VR
2	5.06	Vertebra	Retarded Ossification (cen th11-13)	VR
3	5.94		NAD	
4	5.30	Skull	Retarded Ossification (6rt)	VR
		Vertebra	Retarded Ossification (cen th10-11)	VR
5	5.05	Rib	Supernumerary (th13 short rt)	DV
		Vertebra	Retarded Ossification (cen th10-12)	VR
6	4.08	Sternebra	Retarded Ossification (6)	VR
		Vertebra	Retarded Ossification (cen th10-13, lu1)	VR
7	5.67	Vertebra	Retarded Ossification (cen th12)	VR
8	6.30	Rib	Supernumerary (th13 short rt)	DV
		Sternebra	Fused (1,2)	DV
		Vertebra	Retarded Ossification (cen th10-13)	VR
9	5.95	Rib	Rudimentary Cervical (7rt)	DV
		Vertebra	Retarded Ossification (cen th13)	VR
10	5.66		NAD	
11	5.83	Kidney	Small Papilla - Size 1 (bil)	VR
12	5.09	Rib	Supernumerary (th13 short lt)	DV
		Sternebra	Retarded Ossification (6)	VR
		Vertebra	Retarded Ossification (cen th9-13)	VR
646228				
1	5.69	Vertebra	Retarded Ossification (cen th11,12)	VR
2	5.81	Vertebra	Retarded Ossification (cen th12)	VR
3	6.13	Vertebra	Retarded Ossification (cen th11)	VR

Company Sanitized. Does not contain TSCA CRT

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP III: 250 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646228 (Cont.)				
4	6.10	Vertebra	Retarded Ossification (cen th11)	VR
5	5.84		NAD	
6	5.69	Vertebra	Retarded Ossification (cen th12)	VR
		Vertebra	Retarded Ossification (cen th5)	VR
7	5.86	Vertebra	Retarded Ossification (cen th12)	VR
8	5.17	Sternebra	Retarded Ossification (5)	VR
		Vertebra	Retarded Ossification (arches cel 1t)	VR
		Vertebra	Retarded Ossification (cen th11 lul)	VR
9	5.93		NAD	
10	5.93	Vertebra	Retarded Ossification (cen th11,12)	VR
11	5.92	Vertebra	Retarded Ossification (cen th11)	VR
12	6.06	Vertebra	Retarded Ossification (cen th11)	VR
13	6.11	Vertebra	Retarded Ossification (cen th12)	VR
14	6.30	Skull	Retarded Ossification (8,2 bil)	VR
		Vertebra	Retarded Ossification (cen th12)	VR
646232				
1	5.13		NAD	
2	5.20	Skull	Retarded Ossification (2 bil)	VR
3	5.26	Vertebra	Retarded Ossification (cen th11-12)	VR
4	4.69	Skull	Retarded Ossification (6 bil)	VR
5	5.14	Vertebra	Retarded Ossification (cen th10,12)	VR
6	5.35		NAD	

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP III: 250 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646232 (Cont.)				
7	5.33	Vertebra	Retarded Ossification (cen th11-12)	VR
8	5.42		NAD	
9	5.64		NAD	
10	5.59	Vertebra	Retarded Ossification (cen th11,13)	VR
11	5.42	Vertebra	Retarded Ossification (cen th10-11)	VR
12	5.05	Vertebra	Retarded Ossification (cen th11-12)	VR
646234				
1	5.23		NAD	
2	5.39		NAD	
3	4.46	Vertebra	Retarded Ossification (cen th11)	VR
4	5.22		NAD	
5	5.16		NAD	
6	5.01	Vertebra	Retarded Ossification (cen th12,13)	VR
7	4.94	Vertebra	Retarded Ossification (cen th10)	VR
8	5.28		NAD	
9	4.93		NAD	
10	5.26		NAD	
11	5.63		NAD	
12	5.31		NAD	
13	4.84		NAD	
14	5.19		NAD	
15	5.28		NAD	
646237				
1	5.25		NAD	
2	5.36		NAD	
3	5.07	Vertebra	Retarded Ossification (cen th12)	VR
4	5.59		NAD	
5	5.46		NAD	

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP III: 250 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646237 (Cont.)				
6	4.91		NAD	
7	4.84		NAD	
8	5.45		NAD	
9	4.60		NAD	
10	5.38		NAD	
11	5.46		NAD	
12	5.21		NAD	
13	5.33		NAD	
14	4.74		NAD	
15	5.53	Vertebra	Retarded Ossification (cen th11)	VR
16	5.06		NAD	
17	5.24	Kidney	Papilla - Size 3 (bil)	VR
646238				
1	5.41	Rib	Supernumerary (th14 site bil)	DV
2	5.10	Rib	Supernumerary (th14 site bil)	DV
3	5.56		NAD	
4	5.81	Rib	Supernumerary (th14 site bil)	DV
		Skull	Retarded Ossification (6bil)	VR
5	5.94	Rib	Supernumerary (th14 site bil)	DV
6	5.96	Rib	Supernumerary (th14 site bil)	DV
7	5.73		NAD	
8	5.05	Rib	Supernumerary (th14 site bil)	DV
9	5.26	Rib	Supernumerary (th14 site bil)	DV
10	5.68	Skull	Retarded Ossification (6lt)	VR
11	5.24	Rib	Supernumerary (th14 site rt;short lt)	DV
646243				
1	4.73	Vertebra	Retarded Ossification (cen th11)	VR
2	5.34	Skull	Retarded Ossification (2,6 bil)	VR
		Vertebra	Retarded Ossification (cen th11)	VR
3	5.61		NAD	

Company Sanitized. Does not contain TSCA CRI

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP III: 250 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646243 (Cont.)				
4	5.71	Vertebra	Retarded Ossification (cen th11)	VR
5	5.30	Vertebra	Retarded Ossification (cen th10-11)	VR
6	5.43	Skull	Retarded Ossification (6 bil)	VR
		Vertebra	Retarded Ossification (cen th10-11)	VR
7	5.54		NAD	
8	4.19	Skull	Retarded Ossification (2 bil)	VR
		Vertebra	Retarded Ossification (cen th11-12)	VR
9	6.26		NAD	
10	5.95		NAD	
11	4.60		NAD	
12	4.88		NAD	
13	4.71	Vertebra	Retarded Ossification (cen th12)	VR
14	4.59	Skull	Retarded Ossification (6 bil)	VR
646248				
1	5.52		NAD	
2	5.33		NAD	
3	5.95	Kidney	Papilla - Size 3 (bilateral)	VR
4	5.74	Vertebra	Retarded Ossification (cen th10,13)	VR
5	5.69		NAD	
6	5.20	Vertebra	Retarded Ossification (cen th12)	VR
7	5.68		NAD	
8	5.56		NAD	
9	5.51		NAD	
10	5.61	Skull	Retarded Ossification (6bil)	VR
		Vertebra	Retarded Ossification (cen th13)	VR
11	4.99	Vertebra	Retarded Ossification (cen th12)	VR
12	5.20	Skull	Retarded Ossification (6bil)	VR
13	6.16		NAD	

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP III: 250 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646248 (Cont.)				
14	5.43		NAD	
15	5.20		NAD	
646254				
1	5.20	Vertebra	Retarded Ossification (cen th10-11)	VR
2	4.37	Vertebra	Retarded Ossification (cen th11)	VR
3	4.43	Vertebra	Retarded Ossification (cen th12)	VR
4	4.69	Skull	Retarded Ossification (1,12,6bil)	VR
		Vertebra	Retarded Ossification (cen th10-11,lul)	VR
5	4.38		NAD	
6	5.82		NAD	
7	5.53		NAD	
8	4.99	Skull	Retarded Ossification (1,12;2,6-8bil)	VR
		Vertebra	Retarded Ossification (cen th11)	VR
9	5.32		NAD	
10	5.04	Vertebra	Retarded Ossification (cen th12)	VR
11	4.73		NAD	
12	5.82		NAD	
13	5.62		NAD	
14	5.61	Skull	Retarded Ossification (6bil)	VR
15	5.43		NAD	
16	5.16		NAD	
17	4.87	Vertebra	Retarded Ossification (cen th12)	VR
18	4.95	Skull	Retarded Ossification (12;6bil)	VR
646258				
1	4.97	Kidney	Papilla - Size 3 (bil)	VR

Company Sanitized. Does not contain TSCA CRI

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP III: 250 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646258 (Cont.)				
2	5.00	Vertebra	Retarded Ossification (cen th10-11)	VR
3	5.18	Vertebra	Retarded Ossification (cen th9-10,12)	VR
4	5.32	Vertebra	Retarded Ossification (cen th12-13)	VR
5	5.10	Vertebra	Retarded Ossification (cen th12)	VR
6	4.60	Skull Vertebra	Retarded Ossification (2 bil) Retarded Ossification (cen th11,13)	VR VR
7	4.75	Vertebra	Retarded Ossification (cen th11-12)	VR
8	5.19	Vertebra	Retarded Ossification (cen th11-12)	VR
9	5.18	Vertebra	Retarded Ossification (cen th12)	VR
10	5.26	Vertebra	Retarded Ossification (cen th11-12)	VR
11	6.38		NAD	
12	5.83	Vertebra	Retarded Ossification (cen th12)	VR
13	4.54		NAD	
14	5.38	Vertebra	Retarded Ossification (cen th11-12)	VR
646259				
1	4.84	Subcutis	Hemorrhage (back*)	N
2	5.19		NAD	
3	4.83	Vertebra	Retarded Ossification (cen th11)	VR
4	5.59		NAD	
5	5.58		NAD	
6	5.72	Vertebra	Retarded Ossification (cen th11)	VR
7	5.53		NAD	
8	5.69		NAD	
9	6.08		NAD	

Company Sanitized. Does not contain TSCA CB1

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP III: 250 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646259 (Cont.)				
10	5.75	Subcutis	Hemorrhage (back*)	N
11	5.55	Subcutis	Hemorrhage (back*)	N
		Vertebra	Retarded Ossification (cen th13)	VR
12	5.65		NAD	
13	5.82		NAD	
14	5.16	Skull	Retarded Ossification (6bil,7rt)	VR
646266				
1	4.56		NAD	
2	5.00	Vertebra	Retarded Ossification (cen th11)	VR
3	5.32	Vertebra	Retarded Ossification (cen th12)	VR
4	4.97		NAD	
5	5.29		NAD	
6	6.01		NAD	
7	5.61		NAD	
8	5.14		NAD	
9	5.41		NAD	
10	5.29	Vertebra	Retarded Ossification (cen th11)	VR
11	5.50	Vertebra	Retarded Ossification (cen th10)	VR
12	4.91		NAD	
13	5.04	Subcutis	Hemorrhage (head*)	N
14	5.46	Vertebra	Retarded Ossification (cen th11)	VR
646268				
1	4.95		NAD	
2	5.46	Vertebra	Retarded Ossification (cen th11)	VR
3	4.70	Vertebra	Retarded Ossification (cen th11)	VR
4	6.58		NAD	
5	4.45		NAD	

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP III: 250 MG/KG/DAY

DAM NO./

FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646268 (Cont.)				
6	5.40	Rib	Supernumerary (site th14 lt)	DV
7	5.64		NAD	
8	4.83	Subcutis	Hemorrhage (chin*)	N
		Rib	Supernumerary (site th14 bil)	DV
9	5.83	Kidney	Papilla - Size 3 (bil)	VR
		Rib	Supernumerary (short th13 lt)	DV
10	5.24		NAD	
11	5.49	Kidney	Small Papilla - Size 2 (bil)	VR
		Vertebra	Retarded Ossification (cen th11)	VR
12	5.09		NAD	
13	6.98		NAD	
14	4.58	Vertebra	Retarded Ossification (cen th12)	VR
15	5.07	Vertebra	Retarded Ossification (cen th12)	VR
646269				
1	5.97	Rib	Supernumerary (th14 site rt)	DV
		Vertebra	Retarded Ossification (cen th11)	VR
2	5.13	Skull	Retarded Ossification (2 bil)	VR
3	5.12	Kidney	Small Papilla - Size 2 (bilateral)	VR
		Rib	Supernumerary (th14 site bil)	DV
4	5.24		NAD	
5	5.42		NAD	
6	5.01	Vertebra	Retarded Ossification (cen th12-13)	VR
7	5.35	Vertebra	Retarded Ossification (cen th11-12)	VR
8	5.19	Vertebra	Retarded Ossification (cen th12)	VR
9	5.13	Rib	Supernumerary (th14 site bil)	DV
10	4.71	Vertebra	Retarded Ossification (cen th11)	VR

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP III: 250 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646269 (Cont.)				
11	5.36	Vertebra	Retarded Ossification (cen th11-12)	VR
12	6.06	Vertebra	Retarded Ossification (cen th12)	VR
13	5.87	Vertebra	Retarded Ossification (cen th11)	VR
14	5.35	Vertebra	Retarded Ossification (cen th12)	VR
15	5.22	Rib Vertebra	Supernumerary (th14 site lt) Retarded Ossification (cen th13)	DV VR
16	5.34	Rib Vertebra	Supernumerary (th14 site lt) Retarded Ossification (cen th10-12)	DV VR
17	4.81	Vertebra	Retarded Ossification (cen th11-12)	VR
18	4.99		NAD	
646271				
1	5.52	Brain	Distended (ventricles)	M
2	5.67		NAD	
3	5.62		NAD	
4	5.83	Vertebra	Retarded Ossification (cen th11)	VR
5	5.20	Kidney Vertebra	Papilla - Size 3 (lt) Retarded Ossification (cen th11-12)	VR VR
6	5.53		NAD	
7	5.50		NAD	
8	5.36	Vertebra	Retarded Ossification (cen th11)	VR
9	5.15	Kidney	Papilla - Size 3 (bil)	VR
10	5.57		NAD	
11	5.45	Vertebra	Retarded Ossification (cen th10)	VR
12	5.40		NAD	
13	5.61	Kidney	Papilla - Size 3 (lt)	VR

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP III: 250 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646273				
1	5.32		NAD	
2	5.41		NAD	
3	5.11	Vertebra	Retarded Ossification (cen th11)	VR
4	5.42	Skull	Retarded Ossification (12;6bil)	VR
5	5.61	Vertebra	Retarded Ossification (cen th10-11)	VR
6	5.27	Rib	Supernumerary (th site 14bil)	DV
7	6.07	Kidney	Papilla - Size 3 (lt)	VR
		Vertebra	Retarded Ossification (cen th11)	VR
8	5.61	Skull	Retarded Ossification (6rt)	VR
		Vertebra	Retarded Ossification (cen th11-13)	VR
9	5.45	Kidney	Papilla - Size 3 (right)	VR
		Rib	Supernumerary (th site 14lt)	DV
10	5.50	Vertebra	Retarded Ossification (cen th10)	VR
11	5.14	Rib	Supernumerary (th site 14lt)	DV
12	5.45		NAD	
13	4.83	Rib	Supernumerary (th site 14rt)	DV
14	5.32	Skull	Retarded Ossification (6bil)	VR
		Vertebra	Retarded Ossification (cen th12)	VR
15	5.56		NAD	
646285				
1	5.77	Vertebra	Retarded Ossification (cen th12)	VR
2	5.50	Skull	Retarded Ossification (6 bil)	VR
3	6.11		NAD	
4	5.51		NAD	
5	5.41	Vertebra	Retarded Ossification (cen th11,12)	VR
6	5.54		NAD	
7	5.72		NAD	

Company Sanitized. Does not contain TSCA CB

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP III: 250 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646285 (Cont.)				
8	5.40	Rib	Supernumerary (th14 site rt)	DV
9	4.78	Femur	Retarded Ossification (bil)	VR
		Pelvis	Retarded Ossification (pubis,bil)	VR
		Rib	Wavy (7-11bil;6rt)	VR
		Vertebra	Retarded Ossification (cen th11)	VR
10	5.40		NAD	
11	6.00		NAD	
646299				
1	5.46	Vertebra	Retarded Ossification (cen th11)	VR
2	6.07		NAD	
3	5.49		NAD	
4	5.63		NAD	
5	5.38		NAD	
6	5.23	Vertebra	Retarded Ossification (cen th11)	VR
7	5.40		NAD	
8	4.94	Vertebra	Retarded Ossification (cen th12)	VR
9	5.02		NAD	
10	5.31		NAD	
11	5.31	Vertebra	Retarded Ossification (cen th11)	VR
12	5.12	Skull	Retarded Ossification (2 bil)	VR
		Vertebra	Retarded Ossification (cen th11)	VR
13	5.27	Vertebra	Retarded Ossification (cent th11-12)	VR
14	5.64	Skull	Retarded Ossification (6 left)	VR
646302				
1	5.19	Vertebra	Retarded Ossification (cen th12)	VR

Company Sanitized. Does not contain TSCA CR

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP III: 250 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646302 (Cont.)				
2	5.70	Vertebra	Retarded Ossification (cen th11,13)	VR
3	5.43	Vertebra	Retarded Ossification (cen th11)	VR
4	5.87		NAD	
5	5.54	Rib	Supernumerary (th14 site lt)	DV
6	5.61		NAD	
7	5.36		NAD	
8	5.37		NAD	
9	5.36	Sternebra Vertebra	Retarded Ossification (5) Retarded Ossification (cen th11)	VR VR
10	5.67	Vertebra	Retarded Ossification (cen th10,12)	VR
11	5.25		NAD	
12	5.16		NAD	
646303				
1	5.52		NAD	
2	5.57	Vertebra	Retarded Ossification (cen th11)	VR
3	3.25		NAD	
4	5.60		NAD	
5	5.71		NAD	
6	6.08	Vertebra	Retarded Ossification (cen th11-12)	VR
7	5.75		NAD	
8	5.14		NAD	
9	5.19		NAD	
10	5.17		NAD	
11	5.73	Vertebra	Retarded Ossification (cen th11)	VR
12	5.10		NAD	
13	5.48	Vertebra	Retarded Ossification (cen th11)	VR
14	5.59	Vertebra	Retarded Ossification (cen th10)	VR
15	5.91		NAD	

Company Sanitized. Does not contain TSCA CS.

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP III: 250 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646303 (Cont.)				
16	5.36		NAD	
17	5.71		NAD	
646305				
1	5.28		NAD	
2	4.35	Vertebra	Retarded Ossification (cen th11-12)	VR
3	5.19	Vertebra	Retarded Ossification (cen th10-13)	VR
4	4.91	Vertebra	Retarded Ossification (cen th11)	VR
5	5.13		NAD	
6	4.70		NAD	
7	4.87	Vertebra	Retarded Ossification (cen th10)	VR
8	5.45	Vertebra	Retarded Ossification (cen th11-12)	VR
646307				
1	5.34		NAD	
2	5.13	Skull	Retarded Ossification (6 lt)	VR
3	5.19		NAD	
4	5.23		NAD	
5	5.44	Vertebra	Retarded Ossification (cen th12-13)	VR
6	5.32		NAD	
7	5.65		NAD	
8 ^a	5.27		NAD	
9	5.21		NAD	
10	5.69		NAD	
11	5.29	Vertebra	Retarded Ossification (cen th10)	VR
12	5.02		NAD	
13	5.09		NAD	
14	4.90		NAD	
15 ^a	5.39		NAD	
16 ^a	4.99		NAD	

Company Sanitized. Does not contain TSCA CBI

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP IV: 500 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646221				
1	5.03	Vertebra	Retarded Ossification (cen th11)	VR
2	6.16	Skull	Retarded Ossification (6,7,2 bil)	VR
		Vertebra	Retarded Ossification (cen th11)	VR
3	4.84	Vertebra	Retarded Ossification (cen th12)	VR
4	5.34	Skull	Retarded Ossification (2,6 bil)	VR
5	5.78		NAD	
6	4.99	Skull	Retarded Ossification (6 bil)	VR
		Vertebra	Retarded Ossification (cen th12)	VR
7	5.93		NAD	
8	4.86	Vertebra	Retarded Ossification (cen th12)	VR
9	6.07	Pelvis	Retarded Ossification (pubis bil)	VR
		Rib	Wavy (10-11 rt)	VR
		Vertebra	Retarded Ossification (cen th12)	VR
10	5.61	Pelvis	Retarded Ossification (pubis bil)	VR
		Rib	Wavy (9-12 bil;5-8 rt)	VR
		Skull	Retarded Ossification (1,2,6 bil)	VR
646223				
1	5.78		NAD	
2	5.74	Skull	Retarded Ossification (1;6 lt)	VR
		Vertebra	Retarded Ossification (cen th13)	VR
3	5.61	Vertebra	Retarded Ossification (cen th10,12)	VR
4	5.91		NAD	
5	5.38	Rib	Supernumerary (th14 site lt)	DV
6	5.56		NAD	

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP IV: 500 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646223 (Cont.)				
7	5.55		NAD	
8	5.68	Vertebra	Retarded Ossification (cen th12)	VR
9	5.71		NAD	
10	5.90		NAD	
11	5.30		NAD	
12	5.75	Skull	Retarded Ossification (1;2,6 bil;7-8 lt)	VR
13	5.56	Rib	Supernumerary (th14 site lt)	DV
14	5.67		NAD	
646233				
1	4.87		NAD	
2	5.20		NAD	
3	5.82		NAD	
4	5.72		NAD	
5	4.79		NAD	
6	4.94	Vertebra	Retarded Ossification (cen th12)	VR
7	5.29		NAD	
8	5.62		NAD	
9	6.07		NAD	
10	5.24		NAD	
11	5.14	Rib	Wavy (th8-11lt, 6-9 rt)	VR
12	5.93		NAD	
13	5.93	Kidney	Papilla - Size 3 (bilateral)	VR
14	5.43		NAD	
15	4.99		NAD	
646239				
1	6.07		NAD	
2	5.54	Skull	Retarded Ossification (2,6 bil)	VR
3	5.45		NAD	
4	6.18	Skull	Retarded Ossification (6 bil)	VR
		Vertebra	Retarded Ossification (cen th10,12)	VR

Company Sanitized. Does not contain TSCA CB

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP IV: 500 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646239 (Cont.)				
5	5.45	Vertebra	Retarded Ossification (cen th10)	VR
6	5.87		NAD	
7	5.51		NAD	
8	5.74	Vertebra	Retarded Ossification (cen th11-12)	VR
9	5.95	Vertebra	Retarded Ossification (cen th11-12)	VR
10	5.19	Skull	Retarded Ossification (6 bil)	VR
11	5.87	Kidney	Papilla - Size 3 (lt)	VR
12	5.70	Skull	Retarded Ossification (2 bil)	VR
		Vertebra	Retarded Ossification (cen th11)	VR
13	5.53		NAD	
14	5.68	Skull	Retarded Ossification (2,6 bil)	VR
		Vertebra	Retarded Ossification (cen th11)	VR
646240				
1	6.01	Vertebra	Retarded Ossification (cen th11)	VR
2	5.50	Skull	Retarded Ossification (6 lt)	VR
3	5.52		NAD	
4	5.97		NAD	
5	5.12		NAD	
6	5.78		NAD	
7	5.90	Vertebra	Retarded Ossification (cen th11)	VR
8	5.89		NAD	
9	5.31	Vertebra	Retarded Ossification (cen th11)	VR
10	5.48		NAD	
11	5.57		NAD	
12	5.78	Skull	Retarded Ossification (6 lt)	VR
13	5.59	Kidney	Papilla - Size 3 (bil)	VR
14	5.82		NAD	
15	5.59		NAD	

Company Sanitized. Does not contain TSCA CB

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP IV: 500 MG/KG/DAY

DAM NO. / FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646244				
1	5.48	Vertebra	Retarded Ossification (cen th11-13)	VR
2	5.42	Skull	Retarded Ossification (6 bil)	VR
3	5.79	Vertebra	Retarded Ossification (cen th12)	VR
4	5.37		NAD	
5	5.68		NAD	
6	5.43		NAD	
7	5.44		NAD	
8	5.73		NAD	
646247				
1	4.71	Rib	Supernumerary (th13 site lt)	DV
2	4.98		NAD	
3	4.80		NAD	
4	5.27		NAD	
5	5.05		NAD	
6	5.21	Skull	Retarded Ossification (2,6 bil)	VR
7	4.92		NAD	
8	4.89	Skull	Retarded Ossification (7,8 bil)	VR
9	5.26	Vertebra	Retarded Ossification (cen th11)	VR
10	5.43	Skull Vertebra	Retarded Ossification (6 bil) Retarded Ossification (cen th11)	VR VR
11	4.86		NAD	
12	5.41	Skull	Retarded Ossification (6 lt)	VR
13	5.19		NAD	
14	5.35	Skull Vertebra	Retarded Ossification (8 lt) Retarded Ossification (cen th12)	VR VR
15	5.62	Kidney Vertebra	Papilla - Size 3 (rt) Retarded Ossification (cen th12)	VR VR

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INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP IV: 500 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646255				
1	5.45		NAD	
2	6.15	Skull	Retarded Ossification (6lt)	VR
3	7.05		NAD	
4	5.47		NAD	
5	5.62		NAD	
6	5.81	Vertebra	Retarded Ossification (cen th10-11)	VR
7	5.81		NAD	
8	5.64	Skull	Retarded Ossification (6bil)	VR
9	5.49	Vertebra	Retarded Ossification (cen th11)	VR
10	5.87	Skull Vertebra	Retarded Ossification (6bil) Retarded Ossification (cen th11)	VR VR
11	6.05	Vertebra	Retarded Ossification (cen th11)	VR
12	5.41	Skull	Retarded Ossification (6bil)	VR
13	6.57		NAD	
646260				
1	4.94		NAD	
2	5.15	Skull	Retarded Ossification (2 bil)	VR
3	5.08		NAD	
4	4.66	Skull	Retarded Ossification (6 bil)	VR
5	5.66	Rib	Supernumerary (th13 site lt)	DV
6	5.47	Skull	Retarded Ossification (6,8,2 bil)	VR
7	5.44	Rib Vertebra	Wavy (th7,9-11 rt) Retarded Ossification (cen th12)	VR VR
8	4.28	Pelvis Rib Skull	Retarded Ossification (pubis bil) Wavy (th9-11 bil, th1-8 rt) Retarded Ossification (6 bil)	VR VR VR
9	4.85	Vertebra	Retarded Ossification (cen th11)	VR

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INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP IV: 500 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646260 (Cont.)				
10	5.01	Vertebra	Retarded Ossification (cen th11)	VR
11	4.99	Kidney Pelvis	Papilla - Size 3 (right) Retarded Ossification (pubis bil, ischium bil)	VR VR
12	4.86		NAD	
13	5.35	Rib	Wavy (th7-12 rt)	VR
14	5.18	Skull	Retarded Ossification (2,3,6 bil)	VR
15	4.55	Rib	Wavy (th6-11 rt)	VR
16	4.94	Skull	Retarded Ossification (2,6 bil)	VR
		Vertebra	Retarded Ossification (cen th11-13)	VR
17	4.52	Rib	Wavy (th8-12 bil)	VR
18	5.48	Rib	Wavy (th10-12 bil, th8-9 rt)	VR
		Skull	Retarded Ossification (3,6 bil)	VR
646262				
1	4.60	Kidney Pelvis	Papilla - Size 3 (lt) Retarded Ossification (ischium, pubis bil)	VR VR
		Sternebra Vertebra	Retarded Ossification (3-4) Retarded Ossification (cen th12,13)	VR VR
2	4.64	Skull	Retarded Ossification (2,3,7 bil)	VR
3	4.69		NAD	
4	4.81	Skull	Retarded Ossification (2,3 bil)	VR
		Sternebra	Retarded Ossification (3,4)	VR
5	4.51	Vertebra	Retarded Ossification (cen th11)	VR
6	4.70	Skull	Retarded Ossification (2,6,7,8 bil)	VR
7	5.01	Sternebra	Retarded Ossification (3-4)	VR

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INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP IV: 500 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646262 (Cont.)				
8	4.32	Skull	Retarded Ossification (2,3,7,8 bil)	VR
		Vertebra	Retarded Ossification (cen th13)	VR
9	4.28	Pelvis	Retarded Ossification (pubis bil)	VR
		Vertebra	Retarded Ossification (cen th10,11,12)	VR
10	4.34	Skull	Retarded Ossification (2,3,8 bil)	VR
11	4.12	Vertebra	Retarded Ossification (cen th12)	VR
12	4.30	Skull	Retarded Ossification (2,3 bil;12)	VR
		Vertebra	Retarded Ossification (cen th3)	VR
13	4.33	Sternebra	Retarded Ossification (4-5)	VR
646263				
1	5.50	Kidney	Papilla - Size 3 (bilateral)	VR
2	5.27		NAD	
3	5.10		NAD	
4	5.21	Vertebra	Retarded Ossification (cen th11,12)	VR
5	5.21		NAD	
6	4.81	Skull	Retarded Ossification (2 bil)	VR
7	5.36		NAD	
8	5.17		NAD	
9	5.90	Vertebra	Retarded Ossification (cen th12)	VR
10	5.15		NAD	
11	5.77	Vertebra	Retarded Ossification (cen th11)	VR
12	5.23	Skull	Retarded Ossification (2 bil)	VR
13	5.20		NAD	
14	5.24	Vertebra	Retarded Ossification (cen th12)	VR
15	5.94		NAD	

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INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP IV: 500 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646263 (Cont.)				
16	5.72		NAD	
646270				
1	5.79		NAD	
2	5.74	Vertebra	Retarded Ossification (cen th11)	VR
3	5.33	Rib Vertebra	Rudimentary Cervical (7lt) Retarded Ossification (cen th10-11)	DV VR
4	5.60	Vertebra	Retarded Ossification (cen th11)	VR
5	5.54		NAD	
6	5.78		NAD	
7	5.27		NAD	
8	5.50	Skull	Retarded Ossification (6bil)	VR
9	5.87	Rib	Supernumerary (th site 14lt)	DV
10	5.57		NAD	
11	5.35	Kidney Rib	Small Papilla - Size 2 (bil) Supernumerary (th site 14bil)	VR DV
12	5.16	Vertebra	Retarded Ossification (cen th13)	VR
13	5.94	Rib	Supernumerary (th short 14lt;site rt)	DV
14	5.62	Rib Skull Vertebra	Wavy (3-13bil) Retarded Ossification (1,2;6-8bil) Retarded Ossification (cen th11-12)	VR VR VR
15	5.57		NAD	
646275				
1	5.40		NAD	
2	5.47		NAD	
3	5.65	Vertebra	Retarded Ossification (cen th11)	VR
4	5.83		NAD	
5	5.53		NAD	

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INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP IV: 500 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646275 (Cont.)				
6	5.54	Skull Vertebra	Retarded Ossification (6 bil) Retarded Ossification (cen th12)	VR VR
7	5.25		NAD	
8	5.66		NAD	
9	5.11		NAD	
10	5.15	Vertebra	Retarded Ossification (cen th12-13)	VR
11	5.56		NAD	
12	6.06		NAD	
13	5.24		NAD	
14	5.29		NAD	
646277				
1	4.34		NAD	
2	5.09	Skull	Retarded Ossification (6bil)	VR
3	5.19		NAD	
4	4.08		NAD	
5	4.76	Kidney	Papilla - Size 3 (bil)	VR
6	3.68	Skull	Retarded Ossification (1,12;6bil)	VR
7	4.49		NAD	
8	4.24	Skull	Retarded Ossification (6bil)	VR
9	4.31		NAD	
10	4.79	Skull	Retarded Ossification (6bil)	VR
11	4.77		NAD	
12	4.89	Skull	Retarded Ossification (6bil)	VR
13	4.84	Kidney	Papilla - Size 3 (bil)	VR
14	4.78	Skull	Retarded Ossification (12;6bil)	VR
15	4.85		NAD	
646281				
1	4.15		NAD	
2	4.17	Skull	Retarded Ossification (6 bil)	VR
3	4.70		NAD	

Company Sanitized. Does not contain TSCA CBI

INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP IV: 500 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646281 (Cont.)				
4	4.50	Vertebra	Retarded Ossification (cen th11)	VR
5	4.45		NAD	
6	4.91	Skull	Retarded Ossification (6 rt)	VR
		Vertebra	Retarded Ossification (cen th12)	VR
7	4.42	Vertebra	Retarded Ossification (cen th11)	VR
8	4.07		NAD	
9	4.68		NAD	
10	4.14	Vertebra	Retarded Ossification (arches ce4 rt)	VR
11	4.05		NAD	
12	3.90	Skull	Retarded Ossification (7 bil)	VR
		Vertebra	Retarded Ossification (cen th11)	VR
13	4.27		NAD	
14	3.97	Sternebra	Retarded Ossification (4)	VR
15	3.92		NAD	
646283				
1	5.90	Vertebra	Retarded Ossification (cen th11)	VR
2	5.87		NAD	
3	6.16		NAD	
4	6.19	Vertebra	Retarded Ossification (cen th9,11)	VR
5	6.36	Kidney	Small Papilla - Size 2 (rt)	VR
6	6.04	Vertebra	Retarded Ossification (cen th11)	VR
7	6.03		NAD	
8	5.86		NAD	
9	6.43	Vertebra	Retarded Ossification (cen th11)	VR
10	6.27		NAD	
11	6.56	Kidney	Papilla - Size 3 (right)	VR

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INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP IV: 500 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646283 (Cont.)				
		Vertebra	Retarded Ossification (cen th12)	VR
12	6.11	Vertebra	Retarded Ossification (cen th11)	VR
646287				
1	5.19	Rib	Supernumerary (th site 14bil)	DV
2	5.47	Rib	Supernumerary (th site 14lt)	DV
		Skull	Retarded Ossification (6bil)	VR
3	5.65	Rib	Supernumerary (th site 14rt)	DV
4	5.77	Rib	Supernumerary (th site 14bil)	DV
5	5.55		NAD	
6	5.38	Skull	Retarded Ossification (6bil)	VR
7	5.21		NAD	
8	5.54	Subcutis	Hemorrhage (right, limb*)	N
9	5.09		NAD	
10	5.14	Rib	Supernumerary (th site 14lt)	DV
		Skull	Retarded Ossification (6lt)	VR
		Vertebra	Retarded Ossification (cen th12)	VR
11	5.72	Rib	Supernumerary (th site 14lt)	DV
12	5.29	Skull	Retarded Ossification (6lt)	VR
13	5.50		NAD	
14	5.43	Rib	Supernumerary (th short 14rt; site 14lt)	DV
		Skull	Retarded Ossification (6bil)	VR
646289				
1	6.10		NAD	
2 ^a	5.26		NAD	
3	5.89		NAD	
4	5.75		NAD	
5	5.98		NAD	
6	5.94		NAD	
7	6.30		NAD	
8	5.04		NAD	
9	5.50		NAD	
10	5.55		NAD	

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INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP IV: 500 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646289 (Cont.)				
11	5.65		NAD	
12	5.87		NAD	
13	5.58		NAD	
14 ^a	5.30		NAD	
15	5.55		NAD	
16	5.78		NAD	
646293				
1	6.04	Vertebra	Retarded Ossification (cen th11)	VR
2	5.66	Skull	Retarded Ossification (6 rt)	VR
3	5.53		NAD	
4	5.61		NAD	
5	5.07		NAD	
6	5.54	Skull	Retarded Ossification (6 lt)	VR
7	5.79		NAD	
8	5.11	Skull	Retarded Ossification (6 bil)	VR
9	4.80		NAD	
10	5.70		NAD	
11	5.70		NAD	
12	5.98		NAD	
13	5.75	Kidney	Papilla - Size 3 (bil)	VR
14	5.86		NAD	
15	5.25		NAD	
16	5.56	Skull	Retarded Ossification (6 lt)	VR
17	5.66		NAD	
646295				
1	5.88		NAD	
2	5.92		NAD	
3	5.80		NAD	
4	5.37		NAD	
5	5.38	Rib	Supernumerary (th site 14lt)	DV
6	5.47		NAD	
7	5.25	Rib	Supernumerary (th site 14bil)	DV
8	5.59	Skull	Retarded Ossification (12)	VR
9	5.94		NAD	
10	5.40		NAD	

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INDIVIDUAL FETAL WEIGHTS (grams) AND ALTERATIONS

GROUP IV: 500 MG/KG/DAY

DAM NO./ FETUS NO.	FETUS WT.	STRUCTURE	FINDING(S)	CLASSIFICATION
646295 (Cont.)				
11	5.42		NAD	
12	5.52	Skull	Retarded Ossification (6lt)	VR
13	5.66		NAD	
14 ^a	5.69		NAD	
646301				
1	5.49		NAD	
2	5.50	Vertebra	Retarded Ossification (cen th12)	VR
3	5.44		NAD	
4	5.74		NAD	
5	5.35		NAD	
6	5.00	Vertebra	Retarded Ossification (cen th10)	VR
7	5.06		NAD	
8	5.63	Vertebra	Retarded Ossification (cen th13)	VR
9	5.30		NAD	
10	5.50	Vertebra	Retarded Ossification (cen th12)	VR
11	4.91		NAD	
12	5.30		NAD	
646304				
1	5.38		NAD	
2	6.05	Skull	Retarded Ossification (6bil)	VR
3	5.60	Kidney	Papilla - Size 3 (bil)	VR
4	5.83	Skull	Retarded Ossification (6bil)	VR
5	4.84		NAD	
6	5.06	Vertebra	Retarded Ossification (cen th10)	VR
7	5.05		NAD	
8	5.14	Skull	Retarded Ossification (6lt)	VR
9	5.17		NAD	
10	4.85		NAD	
11	4.66		NAD	
12	5.45	Skull	Retarded Ossification (6bil)	VR

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APPENDIX H
Analytical Report

Temporarily Sanitized. Does not contain TSCA CFS

A. SAMPLE SUBMITTAL

Samples containing H-24516 at the concentrations of 0, 5.0, 20.0 and 50.0 mg/mL were collected on March 2, 2001. These samples were analyzed to verify homogeneity, concentration, and 5-hour room temperature stability. Samples from the same preparation at the concentrations of 5.0 mg/mL were collected on March 5, 2001 to verify the mixing homogeneity for this level. The refrigerated stability for the levels in this study had been established in a previous Subchronic Toxicity 90 Day Gavage Study [REDACTED]

[REDACTED] with H-24516. [REDACTED]

Samples containing H-24516 at the concentrations of 0, 5.0, 20.0 and 50.0 mg/mL were collected on March 9, 2001 and March 20, 2001. The samples were analyzed to verify concentration.

All dosing suspension samples were collected on the same day the suspensions were prepared. They were analyzed when received or were frozen until analyzed.

The suspension vehicle was 0.5% aqueous methylcellulose.

B. METHODS

1. Analytical Methods

a. Dosing Suspension Treatment

Each dosing sample was diluted to 100 mL with methanol and sonicated to dissolve the H-24516 in the suspension. The dosing samples were further diluted with the 0 mg/mL sample (initial dilution) to an expected concentration of approximately 0.09 mg/mL (active ingredient [a.i.]) prior to analysis. An internal standard (refer to Calibration and Quantitation Section) at an equivalent amount was added to each sample before the final analysis dilution.

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b. Chromatographic Conditions

Instrument:	Hewlett-Packard Model 6890 GC
Column:	J & W, DB-1701, 30 m, 0.32 mm ID, 1 um film thickness
Injector:	Split, 250°C
Detector:	FID; 250°C
Carrier Gas:	Helium (2.1 mL/min)
Split vent:	22.3 mL/min
Injection Volume:	2 microliter
Oven Program:	Gradient
Initial Temperature:	100°C
Initial Time	1.00 min.
Level 1 Rate:	20.0°C/min.
Level 1 Temperature:	260°C
Level 1 Time:	0.00 min.
Total run time:	9.00 min.

c. Calibration and Quantitation

A separate sample of H-24516 (-3) was obtained for use as the analytical reference standard

[REDACTED] A stock solution was prepared in methanol. This stock solution was sonicated to assure that all material was in solution. Before analysis, appropriate aliquots of the stock were diluted with methanol to make calibration standards that bracketed the target concentration of the diluted dosing samples. A stock solution of an internal standard [REDACTED]

[REDACTED] was prepared in methanol and added to each calibration standard and test sample to give an equivalent final concentration in all dilutions. The ratio of the peak heights for internal standard and H-24516 at three retention times (3.5, 4.17, and 4.77 minutes) from replicate GC analysis of these solutions were used to construct a calibration curves by least squares regression (see Figure 1a, 1b, and 1c for a representative curves). Measured concentrations for the dosing samples were determined by applying the peak height ratios from replicate injections of each sample to the respective calibration curve.

Test substance homogeneity in the dosing suspensions was evaluated by calculating the coefficient of variation ($C.V. = \text{standard deviation}/\text{mean} \times 100$) of the measured concentrations in the top, middle, and bottom (T, M, and B) samples or the mean of duplicate samples for each concentration. A coefficient of variation of less than 10% is considered indicative of acceptable distribution of the test substance throughout the dosing suspension. The mean result of the top, middle, and bottom homogeneity samples or of the duplicate concentration verification samples for each dosing level was used to determine the concentration of the test substance for the respective dosing levels.

Stability was evaluated by using the mean of the top, middle, and bottom homogeneity samples or of the duplicate concentration verification samples (0-day room temperature) as the baseline for comparing the corresponding room temperature and refrigerated results.

C. ANALYTICAL RESULTS

1. Chromatography

H-24516 eluted from the GC column as resolved peaks with retention times from 2.9 minutes to approximately 6.0 minutes. For the purpose of quantitation, resolved peaks at the retention times of approximately 3.5, 4.17, and 4.77 minutes were used. The internal standard [REDACTED] eluted as a resolved peak at approximately 3.99 minutes. Representative GC chromatograms are shown in Figures 2(a - c). Test substance was not detected in the 0 mg/mL control.

2. Homogeneity, Concentration, and Stability Verification

Analytical results from dosing suspensions collected on March 2, 2001 and March 5, 2001 (5.0 mg/mL level) and analyzed for homogeneity, concentration, and stability verification are shown in Analytical Table I and Analytical Summary Table 1.

The following table summarizes the results for homogeneity, concentration, and stability verification.

Preparation Date	Nominal mg/mL	Measured T,M,B ^a mg/mL	Mean (T,M,B) % Nominal	C.V. (%)	Stability ^b % Nominal
2-Mar-2001	0	ND ^c	---	---	---
	5.0	7.96, 4.41, 3.99	107.6	41	74.7
	20.0	17.7, 20.6, 20.9	98.7	9	99.5
	50.0	43.6, 44.7, 44.1	88.3	1	87.2
5-Mar-2001	5.0	4.96, 5.06, 5.07	100.7	1	--- ^d

a Mean results for the analysis of the top (T), middle (M) and bottom (B) samples.

b Samples held 5 hours at room temperature.

c Denotes none detected.

d 5-hour room temperature sample not collected.

The data for samples collected on March 3, 2001 indicates that the test substance was homogeneously mixed in the vehicle except for the 5.0 mg/mL level (C.V. = 41). The test substance was at the targeted concentration in the samples ($\pm 11.7\%$ of nominal) and was stable in the vehicle when held 5 hours at room temperature. The 5 mg/mL level was insufficiently mixed before the initial sampling. This was not considered to have adversely affected the study because the samples were collected after formulation preparation. Then, the formulations are used for dosing. The formulations are stirred continuously during dosing so it is reasonable to conclude that the suspension was adequately homogeneous during use. This finding was substantiated by the results from the samples collected March 5, 2001 from the same preparation indicating that the test substance was homogeneously mixed in the vehicle (C.V. = 1). The stability results for the initial sampling (74.7% of nominal) reflect the mixing irregularity of the sampling and not the stability of the test substance. This conclusion is supported by the results of

the stability samples for the other levels in the study and by the data from the referenced stability study done for the Subchronic Toxicity 90 Day Gavage Study [REDACTED] Test substance was not found in the 0 mg/mL samples.

3. Stability Study

The following table is included for a reference in this study to the refrigerated stability for the concentration range. It summarizes the results for Subchronic Toxicity 90 Day Gavage Study [REDACTED] homogeneity/concentration verification (January 8, 2001 and January 15, 2001) and the 4-day refrigerated stability analyses followed by 5 hours room temperature.

Preparation Date Sample Type	Nominal mg/mL	Measured mg/mL	Mean % Nominal	C.V. (%)	Stability % Nominal
<u>8-Jan-2001</u>					
Homogeneity ^a	0	ND ^b	---	---	---
	5.0	4.53, 4.25, 4.39	87.8	3	92.0 ^c
	20	19.9, 17.7, 18.6	93.5	6	86.0 ^c
	50	53.4, 52.6, 54.0	106.8	1	96.6 ^c
Stability					
4-Day Refrigerated ^d	5.0	4.81	96.1	---	97.1
4-Day Refrigerated ^d	20	19.6	97.8	---	88.2
4-Day Refrigerated ^d	50	48.9	97.8	---	95.7

a Mean results for the analysis of the top (T), middle (M) and bottom (B) samples.

b Denotes none detected.

c Samples held 5 hours at room temperature.

d Mean result of single sample for 4-day refrigerated/concentration verification and a single sample for 4-day refrigerated/5 hour room temperature stability.

The data from [REDACTED] samples is included with this study to show that the test substance was stable in the vehicle when held 4 days refrigerated and followed by 5 hours at room temperature for the concentration range of the study. This data supports the mixing and storage conditions of the testing system during this study.

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4. Concentration Verification

Analytical results from dosing suspensions collected on March 9, 2001 and March 20, 2001 and analyzed for concentration verification are shown in Table III and Summary Table 1.

The following table summarizes the results for concentration verification analyses.

Preparation Date	Nominal mg/mL	Measured ^a mg/mL	Mean % Nominal	C.V. ^b (%)
9-Mar-2001	0	ND ^c	---	---
	5.0	4.44, 4.48	89.2	1
	20.0	18.0 ^d , 18.5	91.3	2
	50.0	44.6, 46.0	90.7	2
20-Mar-2001	0	ND ^c	---	---
	5.0	4.33, 4.38	87.0	1
	20.0	17.6, 17.7	88.3	1
	50.0	46.7, 46.1	92.8	1

a Mean results for the analysis of the duplicate samples.

b C.V. for the duplicate samples used to confirm uniformity of mixture.

c Denotes none detected.

d Mean result of duplicate re-sampling from the original sample. Original analysis was lower than expected and will not be reported.

The data for samples collected on March 9, 2001 indicate that the test substance was uniformly mixed in the vehicle at all levels. The test substance was at the targeted concentration in the samples ($\pm 10.8\%$ of nominal). The data for samples collected on March 20, 2001 indicate that the test substance was uniformly mixed in the vehicle at all levels. The test substance was at the targeted concentration in the samples ($\pm 13.0\%$ of nominal).

Test substance was not found in the 0 mg/mL samples.

5. Conclusions

Data from the analysis of the samples during the study indicate that the test substance was homogeneously mixed, at the targeted levels and was stable under all conditions used in the study. Test substance was not found in the 0 mg/mL samples.

ANALYTICAL SUMMARY TABLE 1

SUMMARY OF DOSING ANALYSES

		Dosing Concentration of H-24516 (mg/mL)		
Nominal:		<u>5.0</u>	<u>20.0</u>	<u>50.0</u>
Homogeneity Samples				
3-Mar-2001				
Top		7.96 (159.3) ^a	17.7 (88.5)	43.6 (87.3)
Middle		4.41 (88.1)	20.6 (103.2)	44.7 (89.3)
Bottom		3.99 (79.7)	20.9 (104.3)	44.1 (88.2)
Average Measured Conc. ^b		5.38	19.7	44.1
Average Percent Nominal		(107.6)	(98.7)	(88.3)
Standard Deviation ^b		± 2.2	± 1.8	± 0.5
Coefficient of Variation ^b		41%	9%	1%
Stability Samples				
5-Hour Room Temperature				
		3.73 (74.7)	19.9 (99.5)	43.6 (87.2)
5-Mar-2001				
Homogeneity Samples				
Top		4.96 (99.3)	--- ^c	--- ^c
Middle		5.06 (101.3)	--- ^c	--- ^c
Bottom		5.07 (101.5)	--- ^c	--- ^c
Average Measured Conc. ^b		5.03		
Average Percent Nominal		(100.7)		
Standard Deviation ^b		± 0.06		
Coefficient of Variation ^b		1%		

a Numbers in parentheses are the respective percent of nominal values.

b Statistics based on the average measured concentration (ppm) of the top, middle, and bottom of each dosing level.

c Samples not required for study.

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ANALYTICAL SUMMARY TABLE 1 (Continued)

SUMMARY OF DOSING ANALYSES

		Dosing Concentration of H-24516 (mg/mL)		
Nominal:		<u>5.0</u>	<u>20.0</u>	<u>50.0</u>
Concentration Verification^c				
9-Mar-2001				
#1		4.44 (88.7) ^a	18.0 ^b (90.0)	44.6 (89.3)
#2		4.48 (89.6)	18.5 (92.5)	46.0 (92.1)
Average Measured Conc.^c		4.46	18.3	45.3
Average Percent Nominal		(89.2)	(91.3)	(90.7)
Standard Deviation^c		± 0.03	± 0.4	± 1.0
Coefficient of Variation^c		1%	2%	2%
20-Mar-2001				
#1		4.33 (86.5)	17.6 (87.8)	46.7 (93.4)
#2		4.38 (87.5)	17.7 (88.7)	46.1 (92.3)
Average Measured Conc.^c		4.35	17.7	46.4
Average Percent Nominal		(87.0)	(88.3)	(92.8)
Standard Deviation^c		± 0.04	± 0.1	± 0.4
Coefficient of Variation^c		1%	1%	1%

a Numbers in parentheses are the respective percent of nominal values.

b Mean result of duplicate re-sampling of the original sample. Original analysis was lower than expected and will not be reported.

c Statistics based on the average measured concentration (ppm) of duplicate samples.

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ANALYTICAL SUMMARY TABLE 1 (Continued)

SUMMARY OF DOSING ANALYSES

<u>Stability Study</u> ^a	<u>Dosing Concentration of H-24516 (mg/mL)</u>			
	Nominal:	<u>5.0</u>	<u>20.0</u>	<u>50.0</u>
Homogeneity Samples				
Top		4.53 (90.6) ^b	19.9 (99.5)	53.4 (106.8)
Middle		4.25 (85.0)	17.7 (88.5)	52.6 (105.2)
Bottom		4.39 (87.8)	18.6 (93.0)	54.0 (108.0)
Average Measured Conc. ^c		4.39	18.7	53.4
Average Percent Nominal		(87.8)	(93.5)	(106.8)
Standard Deviation ^c		± 0.14	± 1.1	± 0.7
Coefficient of Variation ^c		3%	6%	1%
Stability Samples				
0-Day Room Temperature ^d		4.39 (87.8)	18.7 (93.5)	53.4 (106.8)
4-Day Refrigerated		4.81 (96.1)	19.6 (97.8)	48.9 (97.8)
4-Day Refrigerated/5 hr.		4.85 (97.1)	17.6 (88.2)	47.9 (95.7)

a Samples prepared January 8, 2001 for Subchronic Toxicity 90 Day Gavage Study

b Numbers in parentheses are the respective percent of nominal values.

c Statistics based on the average measured concentration (ppm) of the top, middle, and bottom of each dosing level.

d The mean measured values from analysis of homogeneity samples (considered fresh/0-day room temperature samples) were used as baselines for comparison with the respective stability samples.

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Analytical Table I. Homogeneity and Stability of H-24516 in Dosing Suspensions

Sample Type	mg/mL H-24516		Percent
	Nominal	Measured	Nominal
2-Mar-2001			
<u>Homogeneity</u>			
CONTROL	0.00	ND(A)	---
TOP	5.0	7.96	159.3
MIDDLE	5.0	4.41	88.1
BOTTOM	5.0	<u>3.99</u>	79.7
		<i>Mean(B): 5.38±2.2</i>	<i>(107.6%)</i>
		<i>C.V. 41%</i>	
TOP	20.0	17.7	88.5
MIDDLE	20.0	20.6	103.2
BOTTOM	20.0	<u>20.9</u>	104.3
		<i>Mean(B): 19.7±1.8</i>	<i>(98.7%)</i>
		<i>C.V. 9%</i>	
TOP	50.0	43.6	87.3
MIDDLE	50.0	44.7	89.3
BOTTOM	50.0	<u>44.1</u>	88.2
		<i>Mean(B): 44.1±0.5</i>	<i>(88.3%)</i>
		<i>C.V. 1%</i>	
<u>Stability(C)</u>			
	5.0	3.73	74.7
	20.0	19.9	99.5
	50.0	43.6	87.2
5-Mar-2001			
TOP	5.0	4.96	99.3
MIDDLE	5.0	5.06	101.3
BOTTOM	5.0	<u>5.07</u>	101.5
		<i>Mean(B): 5.03±0.06</i>	<i>(100.7%)</i>
		<i>C.V. 1%</i>	

(A) Denotes not detected.

(B) The average measured concentration, average percent of nominal (in parentheses), standard deviation, and coefficient of variation of top, middle, and bottom are based on measured concentration for each level.

(C) Stability samples held 5 hours at room temperature.

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Analytical Table II. Stability Study of H-24516 in Dosing Suspensions

Preparation Date	mg/mL H-24516		Percent
Sample Type	Nominal	Measured	Nominal
<u>8-Jan-2001(A)</u>			
0-DAY ROOM	5.0	4.39	87.8
TEMPERATURE(B)			
4-DAY REFRIGERATED	5.0	4.81	96.1
4-DAY REFRIGERATED/5	5.0	4.85	97.1
HOUR RT			
0-DAY ROOM	20.0	18.7	93.5
TEMPERATURE(B)			
4-DAY REFRIGERATED	20.0	19.6	97.8
4-DAY REFRIGERATED/5	20.0	17.6	88.2
HOUR RT			
0-DAY ROOM	50.0	53.4	106.8
TEMPERATURE(B)			
4-DAY REFRIGERATED	50.0	48.9	97.8
4-DAY REFRIGERATED/5	50.0	47.9	95.7
HOUR RT			

(A) Samples from Subchronic Toxicity 90 Day Gavage Study [REDACTED]

(B) The average measured concentration of top, middle, and bottom for the homogeneity samples (0-Day Room Temperature) used as baseline for stability comparison.

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Analytical Table III. Concentration Verification of H-24516 in Dosing Suspensions

Sample Type	mg/mL H-24516		Percent
	Nominal	Measured	Nominal
9-Mar-2001			
CONTROL	0.00	ND(A)	----
#1	5.0	4.44	88.7
#2	5.0	<u>4.48</u>	89.6
		<i>Mean(B): 4.46±0.03</i>	<i>(89.2%)</i>
		<i>C.V. 1 %</i>	
#1	20.0	18.0(C)	90.0
#2	20.0	<u>18.5</u>	92.5
		<i>Mean(B): 18.3±0.4</i>	<i>(91.3%)</i>
		<i>C.V. 2%</i>	
#1	50.0	44.6	89.3
#2	50.0	<u>46.0</u>	92.1
		<i>Mean(B): 45.3±1.0</i>	<i>(90.7%)</i>
		<i>C.V. 2%</i>	
20-Mar-2001			
CONTROL	0.00	ND(A)	----
#1	5.0	4.33	86.5
#2	5.0	<u>4.38</u>	87.5
		<i>Mean(B): 4.35±0.04</i>	<i>(87.0%)</i>
		<i>C.V. 1 %</i>	
#1	20.0	17.6	87.8
#2	20.0	<u>17.7</u>	88.7
		<i>Mean(B): 17.7±0.1</i>	<i>(88.3%)</i>
		<i>C.V. 1%</i>	
#1	50.0	46.7	93.4
#2	50.0	<u>46.1</u>	92.3
		<i>Mean(B): 46.4±0.4</i>	<i>(92.8%)</i>
		<i>C.V. 1%</i>	

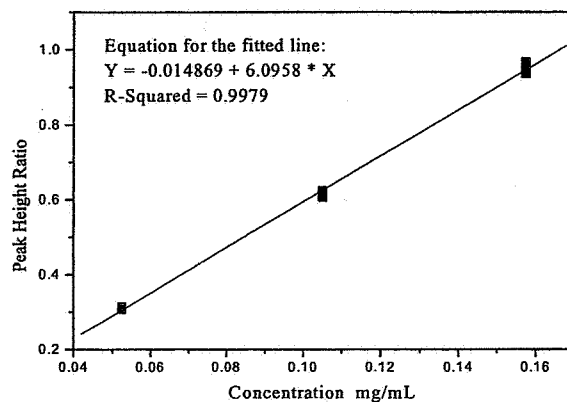
(A) Denotes not detected.

(B) The average measured concentration, average percent of nominal (in parentheses), standard deviation, and coefficient of variation of duplicate samples are based on measured concentration for each level and reported to verify uniformity of mixing.

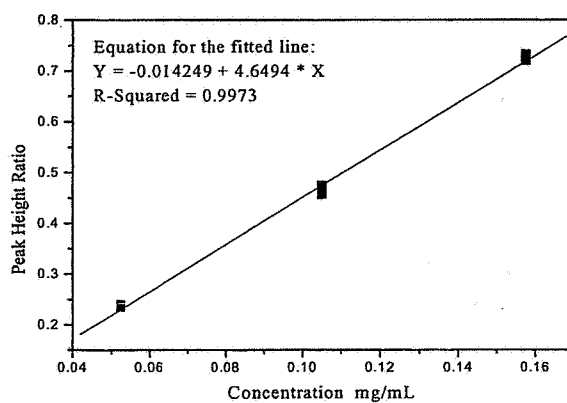
(C) Mean result of duplicate re-sampling from the original sample. Original analysis was lower than expected and will not be reported.

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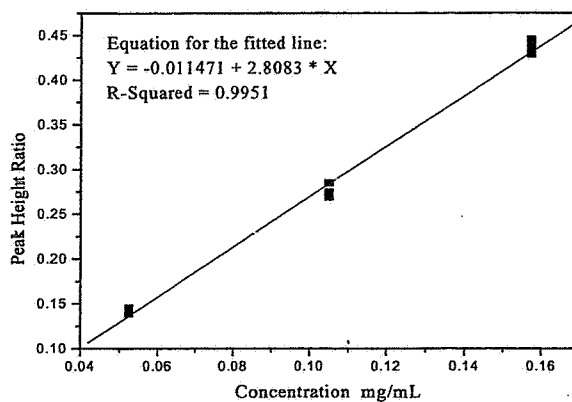
Figure 1
Representative Analytical Calibration Curve



(a)



(b)



(c)

Figure 1: Calibration curve showing linear fit (line) to replicate peak height ratio measurements (squares) for calibration solutions of H-24516 diluted over a concentration range of 0.0525 to 0.1576 mg/mL. [(a) Retention time = 3.5 minutes, (b) Retention = 4.17 minutes, (c) Retention time = 4.77 minutes.]

Figure 2
Representative High Performance Liquid Chromatography Chromatograms

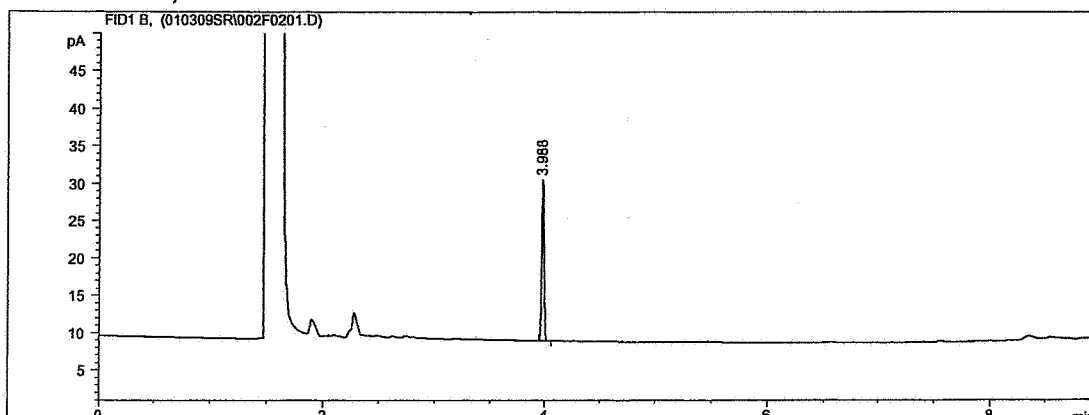


Figure 2a: Representative GC chromatogram of 0 mg/mL (control) sample with internal standard added. Retention time for H-24516 is approximately 3.5, 4.1, 4.7 minutes. Retention time for internal standard is approximately 3.9 minutes.

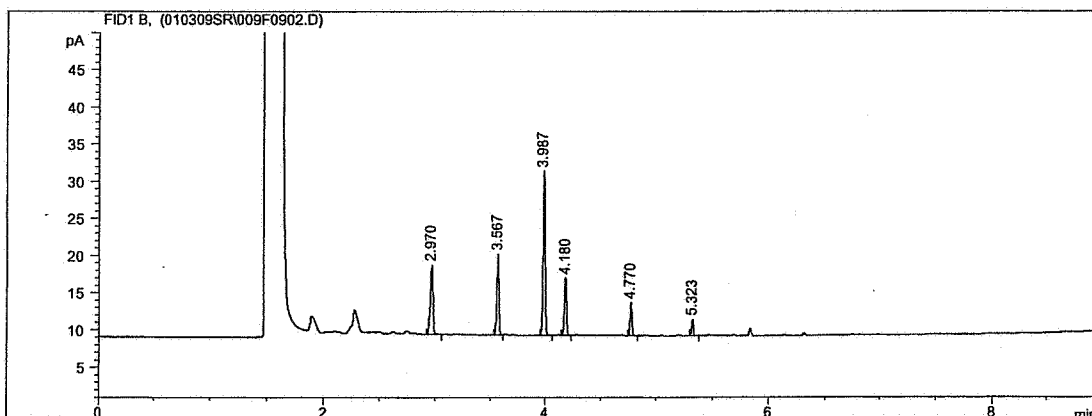


Figure 2b: Representative GC chromatogram of 5.0 mg/mL H-24516 dosing solution diluted to a nominal concentration of 0.09 mg/mL. The average measured concentration of the representative solution is 4.48 mg/mL.

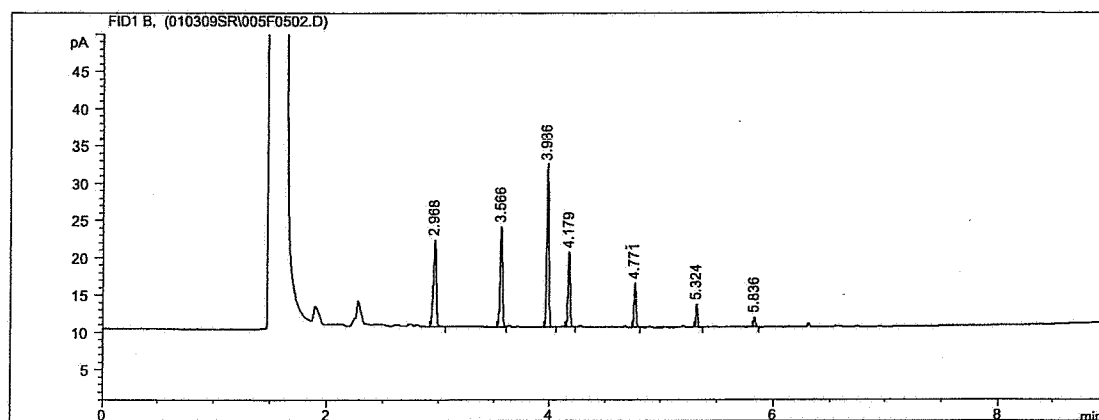


Figure 2c: Representative GC chromatogram of 0.1051 mg/mL H-24516 analytical reference solution.