

FINAL REPORT

Volume 1 of 2
(Text, Summary Tables, and Appendices A-C)

STUDY TITLE

A DERMAL PRENATAL DEVELOPMENTAL
TOXICITY STUDY OF SOLVENT DEWAXED HEAVY PARAFFINIC
DISTILLATES (PETROLEUM) (CAS# 64742-65-0) IN RATS

STUDY NUMBER

WIL-402008

DATA REQUIREMENT

U.S. EPA OPPTS 870.3700
OECD Guideline 414

STUDY DIRECTOR



STUDY INITIATION DATE

21 September 2009

STUDY COMPLETION DATE

19 October 2010

PERFORMING LABORATORY

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WIL-402008
American Petroleum Institute

SDHP (CAS# 64742-65-0)

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study.

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Signature

Date

COMPLIANCE STATEMENT

This study, designated WIL-402008, was conducted in compliance with the United States Environmental Protection Agency (EPA) Good Laboratory Practice Standards (40 CFR Parts 160 and 792), 16 October 1989 and 18 September 1989, respectively; the Organisation for Economic Cooperation and Development (OECD) Principles of Good Laboratory Practice [C(97) 186/Final], 26 November 1997; the standard operating procedures of WIL Research Laboratories, LLC; and the protocol as approved by the Sponsor. The characterization of the test substance was conducted by the Sponsor under non-GLP conditions.

The protocol was designed to be in general accordance with the United States Environmental Protection Agency (EPA) Health Effects Test Guidelines OPPTS 870.3700, Prenatal Developmental Toxicity Study, August, 1998 and the Organization of Economic Co-Operation and Development Guidelines (OECD) for Testing of Chemicals Guideline 414, Prenatal Developmental Toxicity Study, 22 January 2001.


Staff Toxicologist, Developmental and
Reproductive Toxicology
Study Director

19 OCT 2010
Date


Sponsor Representative

22 Nov 2010
Date

Applicant/Submitter

Date

FLAGGING STATEMENT

I have applied the criteria of 40 CFR 158.34 for flagging studies for potential adverse effects to the results of the attached study. This study neither meets nor exceeds any of the applicable criteria.

Sponsor Representative

Date

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1. SUMMARY

1.1. OBJECTIVE

The objective of the study was to determine the potential of dermal exposure to a highly refined, solvent-dewaxed heavy paraffinic distillate (petroleum; SDHP) (CAS#64742-65-0) to induce developmental toxicity after maternal exposure during the critical period of organogenesis; to characterize maternal toxicity at the exposure levels tested; and to determine a no-observed-adverse-effect level (NOAEL) for maternal and developmental toxicity. In addition, this study aimed to provide data to verify/expand the domain of the polycyclic aromatic compound (PAC) prenatal models for predicting toxicity of high-boiling petroleum substances from their PAC content.

1.2. STUDY DESIGN

The test substance, SDHP, was administered by dermal application to 1 group of 25 bred female Crl:CD(SD) rats once daily from gestation days 0 through 19. The dosage level was 1000 mg/kg/day administered at a dosage volume of 1.14 mL/kg. The test substance was applied neat to the clipped dorsal scapular area (over a target of approximately 10% of body surface). Rats were fitted with Elizabethan-style collars to prevent oral ingestion. A concurrent sham (control) group composed of 25 bred females was subjected to the same procedures (i.e. shaving and collaring) as the test substance-treated group; however, no vehicle was applied to these animals. The females were approximately 12 weeks of age at the initiation of dose administration.

All animals were observed twice daily for mortality and moribundity. Clinical observations, dermal observations, body weights, and food consumption were recorded at appropriate intervals. On gestation day 20, a laparohysterectomy was performed on each female. The uteri, placentae, and ovaries were examined, and the numbers of fetuses, early and late resorptions, total implantations, and corpora lutea were recorded. Gravid uterine, adrenal gland, and thymus weights were recorded, and net body weights and net body weight changes were calculated. The fetuses were weighed, sexed, and examined for external, visceral, and skeletal malformations and developmental variations.

Microscopic examinations were performed on untreated skin (shaved) from the sham (control) group animals and treated and untreated skin from the test substance-treated animals.

1.3. RESULTS

All females in the sham (control) and test substance-treated groups survived to the scheduled necropsy on gestation day 20. No test substance-related clinical findings were noted at the daily examinations, at the time of dose administration, or 1-2 hours following dose administration in the 1000 mg/kg/day group. A clinical finding of unkempt appearance was noted in all females in the 1000 mg/kg/day group during gestation days 2-20. This finding was attributed to the impaired grooming behavior of the females following the placement of Elizabethan collars to prevent ingestion of the test substance and distribution of the test substance, a lubricant, to the body surface following application.

Mean maternal body weight, body weight gain, net body weight, net body weight gain, gravid uterine weight, and food consumption in the 1000 mg/kg/day group were unaffected by test substance administration.

There were no test substance-related internal findings noted in the 1000 mg/kg/day group at the scheduled necropsy. A significant ($p < 0.05$) increase in the mean weight of adrenal glands was observed in the 1000 mg/kg/day group compared to the sham (control) group. In addition, a lower thymus weight was observed in this group compared to the sham (control) group, but this difference did not reach statistical significance. In the absence of other signs of maternal toxicity, these organ weight effects were considered to be non-adverse effects of test substance administration.

Histopathological evaluation of routine H&E-stained sections of treated and untreated skin revealed an increased incidence of minimal, multifocal mononuclear infiltrate in the superficial dermis of the treated skin in the 1000 mg/kg/day group compared to the

untreated skin. Although the presence of this infiltrate was considered to be test substance-related, the infiltrate was minimal and therefore considered non-adverse.

Intrauterine growth and survival, as well as fetal morphology, in the 1000 mg/kg/day group were unaffected by maternal test substance administration.

1.4. CONCLUSIONS

Based on the lack of maternal or developmental toxicity observed in the test substance-treated group, the no-observed-adverse-effect level (NOAEL) for maternal toxicity and embryo/fetal development was considered to be greater than or equal to a dosage of 1000 mg/kg/day when SDHP was administered by dermal application to pregnant CrI:CD(SD) rats.

2. INTRODUCTION

2.1. GENERAL STUDY INFORMATION

This report presents the data from “A Dermal Prenatal Developmental Toxicity Study of Solvent Dewaxed Heavy Paraffinic Distillate (Petroleum) (CAS#64742-65-0) in Rats.” Due to software spacing constraints, the study title is presented as “Rat Dermal Prenatal Developmental Tox Study of SDHP” on the report tables.

The following computer protocol was used for data collection during the study:

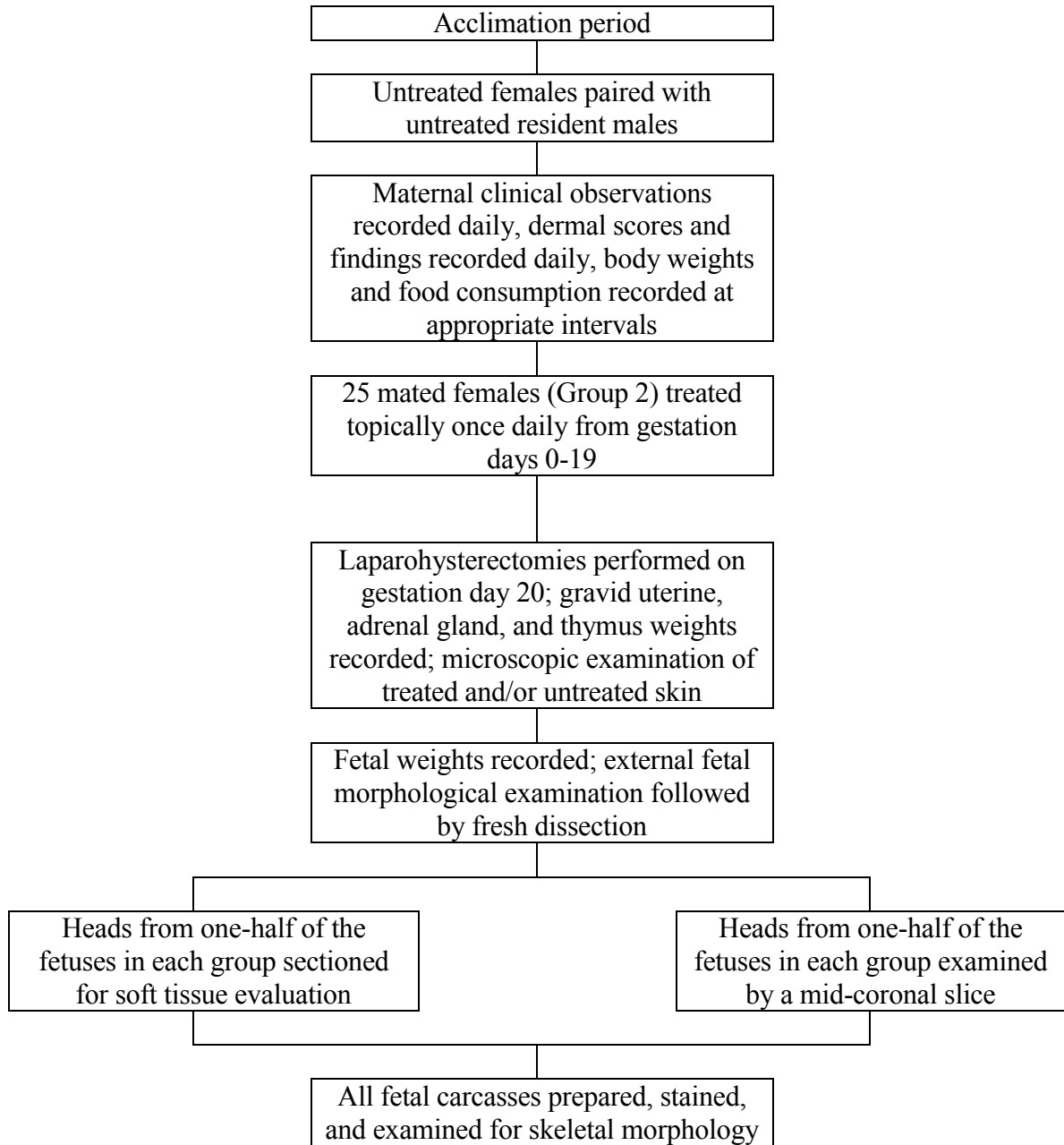
<u>Computer Protocol</u>	<u>Type of Data Collected</u>
WIL-402008	Main study data

2.2. KEY STUDY DATES¹

<u>Date(s)</u>	<u>Event(s)</u>
22 September 2009	Experimental starting date (animal receipt)
6 October 2009	Experimental start date (initiation of test substance administration; first gestation day 0)
6 - 28 October 2009	Test substance administration period
29 October 2009	Last laparohysterectomy
30 November 2009	Experimental termination (completion) date (last fetal skeletal examination)

¹ Date ranges represent the first and last dates of evaluation.

3. STUDY DESIGN



4. EXPERIMENTAL PROCEDURES - MATERIALS AND METHODS

4.1. TEST SUBSTANCE

4.1.1. TEST SUBSTANCE IDENTIFICATION

The test substance, SDHP, was received from EPL Archives, Inc., Sterling, VA, on 3 September 2009 as follows:

Identification	Physical Description
CAS# 64742-65-0 Distillates (petroleum), solvent-dewaxed heavy paraffinic (Site #23, Sample #7) Batch no. TA-125503 Exp. date: 3 September 2014 [WIL ID no. 0900E6]	Yellow, clear, slightly viscous liquid

Documentation regarding the purity and stability of the test substance is on file with the Sponsor and WIL Research Laboratories, LLC. The test substance is considered to be highly refined on the basis of analytical test results showing zero measurable PAC. These test results and other ASTM characterizations are included in Appendix B. The purity of the test substance was 100%. The test substance was stored at room temperature, protected from light, and was considered stable under these conditions. A reserve sample of the test substance was collected and stored in the Archives of WIL Research Laboratories, LLC.

4.1.2. PREPARATION

The test substance was applied neat; therefore, no preparation was required. The test substance was dispensed at the concentration indicated in the following table:

Group Number	Treatment	Dosage Level (mg/kg/day)	Test Substance Concentration (mg/mL)
2	SDHP ^a	1000	Neat

^a = Density of the test substance was 0.875 g/mL

The appropriate amount of test substance was transferred to the appropriate container for each day of dose application, weights were recorded, and was stored at room temperature, protected from light until use. The total amount of test substance that remained in the container was weighed daily and compared to the theoretical amount used.

4.1.3. SAMPLING AND ANALYSES

Because the test substance was applied neat, no formulations were prepared and no analyses were performed.

4.2. TEST SYSTEM

Sexually mature, virgin female Crl:CD(SD) rats from Charles River Laboratories, Inc., Raleigh, NC, were used as the test system on this study.

This species and strain of animal is recognized as appropriate for developmental toxicity studies. WIL Research Laboratories, LLC has historical control data on the background incidence of fetal malformations and developmental variations in the Crl:CD(SD) rat. This animal model has been proven to be susceptible to the effects of developmental toxicants.

4.3. ORGANIZATION OF TEST GROUPS, DOSAGE LEVELS, AND TREATMENT REGIMEN

Prior to the initiation of dose administration, and as often as needed thereafter (prior to daily dose administration or at least 2 to 4 hours following dose administration), the hair

was clipped from the dorsal scapular area (covering approximately 10% of the body surface); a different set of clippers was used for the sham (control) and test substance-treated animals to avoid potential cross-contamination. The test substance was applied evenly over the clipped, unabraded area of skin and distributed using a stainless steel microspatula (to ensure contact with the skin) once daily during gestation days 0-19. No substance was applied to the skin of females in the sham (control) group. Individual dosages were based on the most recently recorded body weights to provide the correct mg/kg/day dose. The dosage volume for the test substance-treated group was 1.14 mL/kg. The area of test substance application was measured daily and recorded for 2 representative animals after application of the test substance. The actual surface area of coverage was calculated for these 2 rats as follows:

$$\frac{\text{Sum of Coverage Area (Length x Width)}}{\text{Total body surface area (cm}^2\text{)}} \times 100$$

Where:

$$\text{Total body surface area (cm}^2\text{)} = K \cdot \text{body weight (grams)}^{(2/3)}$$

K = 9 for rats (Hawk and Leary, 1999).

The mean area of coverage was 10.1% for the test substance-treated group. Elizabethan collars were placed on all animals during the exposure period to prevent ingestion of the test substance. All animals were dosed at approximately the same time each day.

The following table presents the study group assignment:

Group Number	Treatment	Dosage Level (mg/kg/day)	Dosage Volume (mL/kg)	Number of Females
1	Sham	0	0	25
2	SDHP ^a	1000	1.14	25

^a = density = 0.875 g/mL

Dosage levels were selected based on previous studies and were provided by the Sponsor Representative after consultation with the Study Director.

The selected route of administration for this study was dermal because this is a potential exposure for humans. The number of animals selected for this study was based on the following guidelines: the U.S. EPA Health Effects Test Guidelines OPPTS 870.3700, Prenatal Developmental Toxicity Study, August 1998 and the OECD Guidelines for Testing of Chemicals Guideline 414, Prenatal Developmental Toxicity Study, January 2001.

4.4. ANIMAL RECEIPT AND ACCLIMATION

Sixty sexually mature, virgin female Crl:CD(SD) rats were received in good health from Charles River Laboratories, Inc., Raleigh, NC, on 22 September 2009. The animals were approximately 70 days old upon receipt. Each female was examined by a qualified biologist on the day of receipt. The day following receipt, all animals were weighed and clinical observations were recorded. Each rat was uniquely identified by a Monel[®] metal ear tag displaying the animal number and housed for 14 days for acclimation purposes. During the acclimation period, the rats were observed twice daily for mortality and changes in general appearance and behavior. Body weights were recorded prior to the initiation of breeding.

Approximately 1 week prior to randomization, the animals were acclimated to wearing Elizabethan collars. The collars were affixed to each female beginning on 29 September 2009 for approximately 1 hour. On days 2, 3, and 4, the collars were affixed to the females for approximately 2, 4, and 8 hours, respectively. Thereafter, except during cohabitation and collection of body weights, the females were fitted continuously with the collars.

4.5. ANIMAL HOUSING

Upon arrival and until pairing, all rats were individually housed in clean, stainless steel wire-mesh cages suspended above cage-board. The cage-board was changed at least

3 times per week. The rats were paired for mating in the home cage of the male. Following positive evidence of mating, the females were returned to individual suspended wire-mesh cages; nesting material was not required as the females were euthanized prior to the date of expected parturition. Animals were maintained in accordance with the *Guide for the Care and Use of Laboratory Animals* (National Research Council, 1996). The animal facilities at WIL Research Laboratories, LLC are fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

4.6. DIET, DRINKING WATER, AND MAINTENANCE

The basal diet used in this study, PMI Nutrition International, LLC Certified Rodent LabDiet® 5002 (meal and pellets), is a certified feed with appropriate analyses performed by the manufacturer and provided to WIL Research Laboratories, LLC. Rodent meal was provided from receipt through the Elizabethan collar acclimation period; continuing thereafter (i.e., when rats wore Elizabethan collars) rats were provided food pellets to ensure access to food. Feed lots used during the study are documented in the study records. The feeders were changed and sanitized once per week. Municipal water supplying the facility is regularly sampled for contaminants according to standard operating procedures. The results of the diet and water analyses are maintained at WIL Research Laboratories, LLC. No contaminants were present in animal feed or water at concentrations sufficient to interfere with the objectives of this study. Reverse osmosis-purified (on-site) drinking water, delivered by an automatic watering system, and the basal diet were provided ad libitum throughout the acclimation period and during the study.

4.7. ENVIRONMENTAL CONDITIONS

All rats were housed throughout the acclimation period and during the study in an environmentally controlled room. The room temperature and humidity controls were set to maintain environmental conditions of 71°F ± 5°F (22°C ± 3°C) and 50% ± 20% relative humidity. Room temperature and relative humidity were controlled and

monitored using the Metasys[®] DDC Electronic Environmental control system. These data were recorded approximately hourly and are summarized in Appendix C. Actual mean daily temperature ranged from 67.1°F to 73.7°F (19.5°C to 23.2°C) and mean daily relative humidity ranged from 35.5% to 57.5% during the study. Light timers were calibrated to provide a 12-hour light (0600 hours to 1800 hours)/12-hour dark photoperiod. Air handling units were set to provide a minimum of 10 fresh air changes per hour.

4.8. ASSIGNMENT OF ANIMALS TO TREATMENT GROUPS AND BREEDING PROCEDURES

At the conclusion of the acclimation period, all available females were weighed and examined in detail for physical abnormalities. At the discretion of the Study Director, each animal judged to be in good health and meeting acceptable body weight requirements (a minimum of 210 g) was placed in a suspended wire-mesh cage with a resident male from the same strain and source for breeding. Resident males were untreated, sexually mature rats utilized exclusively for breeding. These rats were maintained under similar laboratory conditions as the females. Animals were paired each afternoon, remained cohabitated overnight, and separated each morning until evidence of mating was observed. Collars were removed from females prior to cohabitation and replaced each morning after separation from the male. A breeding record containing the male and female identification numbers and the dates of cohabitation was prepared. The selected females were approximately 12 weeks old when paired for breeding.

Positive evidence of mating was confirmed by the presence of a vaginal copulatory plug or the presence of sperm in a vaginal lavage and verified by a second biologist. Each mating pair was examined daily. The day on which evidence of mating was identified was termed gestation day 0 and the animals were separated.

The experimental design for this study consisted of 1 test substance-treated group and 1 sham (control) group, composed of 25 rats per group. The bred females were assigned to groups using a WIL Toxicology Data Management System (WTDMS™) computer

program which randomized the animals based on stratification of the gestation day 0 body weights in a block design. Body weight values ranged from 220 g to 283 g on gestation day 0.

5. PARAMETERS EVALUATED

5.1. MATERNAL OBSERVATIONS DURING GESTATION

5.1.1. CLINICAL OBSERVATIONS AND SURVIVAL

All rats were observed twice daily, once in the morning and once in the afternoon, for moribundity and mortality. Individual clinical observations were recorded from gestation days 0 through 20 (prior to dose administration during the treatment period). Animals were also observed for signs of toxicity at the time of dose administration and approximately 1-2 hours following dose administration. The absence or presence of findings was recorded for individual animals.

5.1.2. DERMAL OBSERVATIONS

The application site was scored daily (prior to dose administration during the treatment period) for erythema and edema in accordance with a 4-step grading system (Draize, 1965) presented in Appendix D. Other remarkable dermal findings, if present, were recorded.

5.1.3. BODY WEIGHTS AND GRAVID UTERINE WEIGHTS

Individual maternal body weights were recorded on gestation days 0, 3, 6, 9, 12, 15, 18, and 20. Group mean body weights were calculated for each of these days. Mean body weight changes were calculated for each corresponding interval and also for gestation days 0-20. Collars were removed prior to collection of body weights.

Gravid uterine weight was collected and net body weight (the gestation day 20 body weight exclusive of the weight of the uterus and contents) and net body weight change (the gestation day 0-20 body weight change exclusive of the weight of the uterus and contents) were calculated and presented for each gravid female at the scheduled laparohysterectomy.

5.1.4. FOOD CONSUMPTION

Individual food consumption was recorded on gestation days 0, 3, 6, 9, 12, 15, 18, and 20. Food intake was reported as g/animal/day and g/kg/day for the corresponding body

weight change intervals. When food consumption could not be determined for an animal during a given interval (due to a weighing error, food spillage, obvious erroneous value, etc.), group mean values were calculated for that interval using the available data. The time periods when food consumption values were unavailable for a given animal were designated as "NA" (Not Applicable) on the individual report tables.

5.1.5. GESTATION DAY 20 LAPAROHYSTERECTOMY

Laparohysterectomies and macroscopic examinations were performed blind to treatment group. All females were euthanized on gestation day 20 by carbon dioxide inhalation. The thoracic, abdominal, and pelvic cavities were opened by a ventral mid-line incision, and the contents were examined. In all instances, the postmortem findings were correlated with the antemortem comments, and any abnormalities were recorded. The uterus and ovaries were then exposed and excised. The number of corpora lutea on each ovary was recorded. The trimmed uterus was weighed and opened, and the number and location of all fetuses, early and late resorptions, and the total number of implantation sites were recorded. The placentae were also examined. The individual uterine distribution of implantation sites was documented using the following procedure. All implantation sites, including resorptions, were numbered in consecutive order beginning with the left distal to the left proximal uterine horn, noting the position of the cervix, and continuing from the right proximal to the right distal uterine horn.

Samples of dorsal skin were collected from the application site and adjacent untreated area of the test substance-treated females and placed in 10% neutral-buffered formalin for histopathological evaluation. For the sham (control) group, samples of dorsal skin from the shaved and unshaved areas were collected and placed in 10% neutral-buffered formalin; only the samples from the shaved areas were examined microscopically. The carcass of each female was then discarded.

Uteri with no macroscopic evidence of implantation were opened and subsequently placed in 10% ammonium sulfide solution for detection of early implantation loss (Salewski, 1964).

Intrauterine data were summarized using 2 methods of calculation. An example of each method of calculation follows:

1. Group Mean Litter Basis:

$$\text{Postimplantation Loss/Litter} = \frac{\text{No. Dead Fetuses, Resorptions (Early/Late)/Group}}{\text{No. Gravid Females/Group}}$$

2. Proportional Litter Basis:

$$\text{Summation Per Group (\%)} = \frac{\text{Sum of Postimplantation Loss/Litter (\%)}}{\text{No. Litters/Group}}$$

Where:

$$\text{Postimplantation Loss/Litter (\%)} = \frac{\text{No. Dead Fetuses, Resorptions (Early/Late)/Litter}}{\text{No. Implantation Sites/Litter}} \times 100$$

5.1.6. ORGAN WEIGHTS

At the scheduled necropsy, the adrenal glands and thymus were weighed from all animals, a PAC model parameter and a general measure of maternal stress, respectively. Paired organs were weighed together.

5.1.7. MICROSCOPIC EXAMINATION

After fixation, the skin samples from all groups were trimmed according to WIL standard operating procedures. The trimmed samples were processed into paraffin blocks, sectioned at 4-8 microns, mounted on glass microscope slides, stained with hematoxylin and eosin, and examined microscopically. The pathology report is presented in Appendix E.

5.2. FETAL MORPHOLOGICAL EXAMINATION

Fetal examinations were performed blind to treatment group. Each viable fetus was examined externally, individually sexed, weighed, euthanized by hypothermia followed by an intrathoracic injection of sodium pentobarbital (if necessary), and tagged for identification. Fetal tags contained the WIL study number, the female number, and the fetus number. The detailed external examination of each fetus included, but was not limited to, an examination of the eyes, palate, and external orifices, and each finding was recorded. Crown-rump measurements and degrees of autolysis were recorded for late resorptions, a gross external examination was performed (if possible), and the tissues were discarded.

Each viable fetus was subjected to a visceral examination using a modification of the Stuckhardt and Poppe fresh dissection technique to include the heart and major blood vessels (Stuckhardt and Poppe, 1984). The sex of each fetus was confirmed by internal examination. Fetal kidneys were examined and graded for renal papillae development (Woo and Hoar, 1972). Heads from approximately one-half of the fetuses in each litter were placed in Bouin's fixative for subsequent soft-tissue examination by the Wilson sectioning technique (Wilson, 1965). The heads from the remaining one-half of the fetuses were examined by a mid-coronal slice. All carcasses were eviscerated and fixed in 100% ethyl alcohol.

Following fixation in alcohol, each fetus was macerated in potassium hydroxide and stained with Alizarin Red S (Dawson, 1926) and Alcian Blue (Inouye, 1976). External, visceral, and skeletal findings were recorded as developmental variations (alterations in anatomic structure that are considered to have no significant biological effect on animal health or body conformity and/or occur at high incidence, representing slight deviations from normal) or malformations (those structural anomalies that alter general body conformity, disrupt or interfere with normal body function, or may be incompatible with life).

The fetal developmental findings were summarized by: 1) presenting the incidence of a given finding both as the number of fetuses and the number of litters available for examination in the group; and 2) considering the litter as the basic unit for comparison and calculating the number of affected fetuses in a litter on a proportional basis as follows:

$$\text{Summation per Group (\%)} = \frac{\text{Sum of Viable Fetuses Affected/Litter (\%)}}{\text{No. Litters/Group}}$$

Where:

$$\text{Viable Fetuses Affected/Litter (\%)} = \frac{\text{No. Viable Fetuses Affected/Litter}}{\text{No. Viable Fetuses/Litter}} \times 100$$

5.3. STATISTICAL ANALYSES

All statistical tests were performed using appropriate computing devices or programs. Analyses were conducted using two-tailed tests (except as noted otherwise) for minimum significance levels of 1% and 5%, comparing the test substance-treated group to the sham (control) group. Each mean was presented with the standard deviation (S.D.), standard error (S.E.), and the number of animals (N) used to calculate the mean. Data obtained from nongravid animals were excluded from statistical analyses. Due to the different rounding conventions inherent in the types of software used, the means, standard deviations, and standard errors on the summary and individual tables may differ by ± 1 in the last significant figure. Where applicable, the litter was used as the experimental unit.

Mean maternal body weights (absolute and net), body weight changes (absolute and net), and food consumption, gravid uterine weights, organ weights, numbers of corpora lutea, implantation sites, and viable fetuses, and fetal body weights (separately by sex and combined) were subjected to a two sample t-test (Snedecor and Cochran, 1980) to determine intergroup differences between the sham (control) and test substance-treated group. Mean litter proportions (percent per litter) of prenatal data (viable and nonviable fetuses, early and late resorptions, total resorptions, pre- and postimplantation loss, and fetal

sex distribution), total fetal malformations and developmental variations (external, visceral, skeletal, and combined) and each particular external, visceral, and skeletal malformation or variation were subjected to Dunn's test (Dunn, 1964) to determine intergroup differences between the sham (control) and test substance-treated group.

5.4. DATA RETENTION

The Sponsor has title to all documentation records, raw data, specimens, or other work product generated during the performance of the study. All work product generated by WIL Research Laboratories, LLC, including raw paper data and specimens, are retained in the Archives at WIL Research Laboratories, LLC as specified in the study protocol.

A reserve sample of the test substance, pertinent electronic storage media, and the original final report are retained in the Archives at WIL Research Laboratories, LLC in compliance with regulatory requirements.

6. RESULTS AND DISCUSSION

6.1. MATERNAL CLINICAL OBSERVATIONS AND SURVIVAL

Summary Data: Table 1, Table 2, Table 3

Individual Data: Table A1, Table A2, Table A3

All females in the sham (control) and test substance-treated groups survived to the scheduled necropsy on gestation day 20. No test substance-related clinical findings were noted at the daily examinations, at the time of dose administration, or 1-2 hours following dose administration in the 1000 mg/kg/day group. A clinical finding of unkempt appearance was noted in all females in the 1000 mg/kg group during gestation days 2-20. This finding was attributed to the impaired grooming behavior of the females following the placement of Elizabethan collars to prevent ingestion of the test substance and distribution of the test substance, a lubricant, to the body surface following application. Other clinical findings noted in the 1000 mg/kg/day group, including hair loss on various body surfaces and yellow, clear, and/or red material on various body surfaces, occurred infrequently or at similar frequencies in the sham (control) group.

6.2. MATERNAL DERMAL OBSERVATIONS

Summary Data: Table 4

Individual Data: Table A4

Scoring Criteria For Dermal Reactions: Appendix D

No dermal findings were noted for females in the test substance-treated group.

6.3. MATERNAL BODY WEIGHTS AND GRAVID UTERINE WEIGHTS

Summary Data: Table 5, Table 6, Table 7

Individual Data: Table A5, Table A6, Table A7

Mean maternal body weight, body weight gain, net body weight, net body weight gain, and gravid uterine weight in the 1000 mg/kg/day group were unaffected by test substance

administration. Differences from the sham (control) group were slight and not statistically significant.

6.4. MATERNAL FOOD CONSUMPTION

Summary Data: Table 8, Table 9

Individual Data: Table A8, Table A9

Maternal food consumption, evaluated as g/animal/day and g/kg/day, in the 1000 mg/kg/day group was unaffected by test substance administration. Significantly ($p < 0.05$ or < 0.01) higher food consumption values were noted in the 1000 mg/kg/day group compared to the sham (control) group during gestation days 15-20 for the g/animal/day values and during gestation days 6-20 and 0-20 for the g/kg/day values. There were no corresponding effects on mean body weight or body weight gain during these intervals and the magnitude of change was slight (3-4 g/animal/day), therefore, the effects on mean food consumption noted in the 1000 mg/kg/day group were not considered to be test substance-related.

6.5. MATERNAL NECROPSY DATA

Summary Data: Table 10

Individual Data: Table A10

At the scheduled necropsy on gestation day 20, no test substance-related internal findings were observed for females in the 1000 mg/kg/day group. Macroscopic findings observed in the test substance-treated group were limited to yellow matting of the skin which was due to the physical nature of the test substance and not considered adverse. All females were gravid with the exception of 1 female each in the sham (control) and 1000 mg/kg/day groups.

6.6. MICROSCOPIC EXAMINATION

Summary Data: Table 11

Individual Data: Table A11

Pathology Report: Appendix E

A test substance-related finding of minimal, multifocal mononuclear infiltrate was observed in the superficial dermis of the 1000 mg/kg/day group rats. The infiltrate was composed of lymphocytes with occasional macrophages and partially degranulated mast cells. In 2 females (nos. 56136 and 56131), there were very low numbers of neutrophils observed focally in the dermal capillaries (female no. 56136) or associated with the mononuclear infiltrate in the dermis (female no. 56131). The mononuclear infiltrate was also observed in the untreated application site of 3 females in the 1000 mg/kg/day group, but the incidence in the treated application site was much higher, indicating a test substance-related effect. The infiltrate was minimal and was considered a non-adverse finding.

6.7. ORGAN WEIGHTS

Summary Data: Table 12

Individual Data: Table A12

Pathology Report: Appendix E

A significant increase ($p < 0.05$) in the mean absolute weight of the adrenal glands was observed in the 1000 mg/kg/day group compared to the sham (control) group value. The mean absolute weight of the thymus was lower (12.5%) than the sham (control) group mean; the difference was not statistically significant. These organ weight changes were considered to be test substance-related. The adrenal weight change in the treated animals may be a sign of stress in the animals due to the presence of the liquid that sham (control) animals did not experience. In a parallel subchronic study (Crittenden, Draft, WIL-402009), the residual presence of the test substance was significant enough to warrant protocol amendments to include daily pat-downs and weekly baths to remove

excess test material on the animals and in the cages. The effects noted in the current study are consistent with reports in which chronic stress is associated with adrenal enlargement (Gamallo *et al.*, 1986; Ulrich-Lai *et al.*, 2006). Due to the small magnitude of change from the sham (control) group and the absence of signs of maternal toxicity, the organ weight changes were considered to be non-adverse.

6.8. GESTATION DAY 20 LAPAROHYSTERECTOMY DATA

Summary Data: Table 13, Table 14

Individual Data: Table A13, Table A14, Table A15

Historical Control Data: Appendix F

Intrauterine growth and survival were unaffected by test substance administration. Parameters evaluated included postimplantation loss, live litter size, mean fetal body weights, and fetal sex ratios. Mean numbers of corpora lutea and implantation sites and the mean litter proportions of preimplantation loss were similar across both groups. Differences from the sham (control) group were slight and not statistically significant.

6.9. FETAL MORPHOLOGICAL DATA

Summary Data: Table 15, Table 16, Table 17, Table 18

Individual Data: Table A16

Historical Control Data: Appendix F

The numbers of fetuses (litters) available for morphological evaluation were 346(24) and 346(24) in the sham (control) and 1000 mg/kg/day groups, respectively. Malformations were observed in 2(2) and 2(2) fetuses (litters) in these same respective dose groups and were considered spontaneous in origin.

6.9.1. EXTERNAL MALFORMATIONS AND VARIATIONS

External malformations were noted in 2(2) and 1(1) fetuses (litters) in the sham (control) and 1000 mg/kg/day groups, respectively. Unilateral microphthalmia was noted in fetus no. 56158-13 in the sham (control) group and fetus no. 56152-05 in the 1000 mg/kg/day

group; the sham (control) group fetus had a skeletal confirmation of orbit smaller than normal. Because this finding was also noted in the sham (control) group it was not considered to be test substance-related. In addition, fetus no. 56137-01 in the sham (control) group was noted with vertebral agenesis (curly tail). All vertebrae posterior to sacral vertebra no. 3 were absent in this fetus at the skeletal examination.

No external developmental variations were noted for any fetuses in this study.

6.9.2. VISCERAL MALFORMATIONS AND VARIATIONS

No test substance-related visceral malformations were noted for any fetuses in this study. A visceral finding of situs inversus (trachea, esophagus, lungs, liver, stomach, spleen, pancreas, kidneys, adrenal glands, and intestine laterally transposed) was noted for fetus no. 56145-02 in the 1000 mg/kg/day group. This finding was not considered to be test substance-related because it occurred in a single fetus, the mean litter proportion (0.3% per litter) was not statistically significant from the concurrent sham (control) group, and the value was within the WIL developmental historical control range (0.0-0.4% per litter) for this finding (see Appendix F).

Soft tissue developmental variations noted in the 1000 mg/kg/day group included hemorrhagic ring around the iris for fetus nos. 56155-06 and 56155-10 and distended ureters for fetus no. 56109-07. These developmental variations occurred in a single fetus or litter, the mean litter proportions of these findings were not statistically significant from the sham (control) group, and/or were within the WIL developmental historical control data ranges. Therefore, these developmental variations were not considered test substance-related.

A dark red area on the left adrenal gland was observed in fetus no. 56107-11 in the sham (control) group. This finding was not classified as either a malformation or developmental variation and was not included in any tabulation.

6.9.3. SKELETAL MALFORMATIONS AND VARIATIONS

No skeletal malformations were noted in the 1000 mg/kg/day group.

Skeletal developmental variations observed in the 1000 mg/kg/day group, including, unossified sternebra(e) nos. 5 and/or 6 and/or nos. 1, 2, 3, and or 4; ossified cervical centrum no. 1; sternebra(e) malaligned (slight or moderate); 14th rudimentary rib(s); 7th cervical rib(s); reduced ossification of the 13th rib(s), skull, and/or vertebral arches; and bent rib(s), were noted in single fetuses, were noted similarly in the concurrent sham (control) group, and/or the mean litter proportions were within the range of the WIL developmental historical control data. Additionally, there were no statistically significant differences from the concurrent sham (control) group. Therefore, these skeletal developmental variations were not considered test substance-related.

6.9.4. SUMMARY OF EXTERNAL, VISCERAL AND SKELETAL EXAMINATIONS

The numbers of fetuses (litters) available for morphological evaluation were 346(24) and 346(24) in the sham (control) and 1000 mg/kg/day groups, respectively. Malformations were observed in 2(2) and 2(2) fetuses (litters) in the same respective groups, and were considered to be spontaneous in origin. When the total malformations and developmental variations were evaluated on a proportional basis, no statistically significant differences from the sham (control) group were noted. Fetal malformations and developmental variations, when observed in the test substance-treated group, occurred infrequently or at a frequency similar to that in the sham (control) group, and/or were within the WIL historical control data ranges. Based on these data, no fetal malformations or developmental variations were attributed to the test substance.

7. CONCLUSIONS

Based on the lack of maternal or developmental toxicity observed in the test substance-treated group, the no-observed-adverse-effect level (NOAEL) for maternal toxicity and embryo/fetal development was considered to be greater than or equal to a dosage of 1000 mg/kg/day when SDHP was administered by dermal application to pregnant CrI:CD(SD) rats.

8. KEY STUDY PERSONNEL AND REPORT SUBMISSION

Report Submitted By:

[REDACTED]

[Signature]

Staff Toxicologist, Developmental and
Reproductive Toxicology
Study Director

19 OCT 2010

Date

Report Prepared By:

[REDACTED]

[REDACTED]

Study Analyst

19 October 2010

Date

Report Reviewed By:

[REDACTED]

Director, Developmental and
Reproductive Toxicology

19 Oct 2010

Date

[REDACTED]

[REDACTED]

Group Supervisor, Study Analysis and Reports

19 Oct 2010

Date

KEY STUDY PERSONNEL AND REPORT SUBMISSION (CONTINUED)

Study Personnel:

[REDACTED]

Operations Manager, Pathology
Senior Operations Manager, Vivarium
Manager, Gross Pathology and

[REDACTED]

Developmental Toxicology Laboratory
Group Manager, Formulations Laboratory
Manager, Histology

[REDACTED]

Operations Manager, Developmental and
Reproductive Toxicology and the
Formulations Laboratory
Manager, Reporting and Regulatory
Technical Services

9. QUALITY ASSURANCE UNIT STATEMENT

9.1. PHASES INSPECTED

<u>Date(s) of Inspection(s)</u>	<u>Phase Inspected</u>	<u>Date(s) Findings Reported to Study Director</u>	<u>Date(s) Findings Reported to Management</u>	<u>Auditor(s)</u>
6-Oct-2009	Dermal Dispense	6-Oct-2009	20-Nov-2009	L. Weinstock
9-Oct-2009	Dermal Administration	9-Oct-2009	20-Nov-2009	R. Siburt
15-Oct-2009	Gestational Body and Food Weights	15-Oct-2009	20-Nov-2009	R. Rohr
26-Oct-2009	Laparohysterectomy and Fetal Exam	26-Oct-2009	20-Nov-2009	J. Adams, R. Siburt
4-Nov-2009	Study Records (N-1)	4-Nov-2009	21-Dec-2009	J. Adams
4-Nov-2009, 12-Nov-2009, 13-Nov-2009, 18-Nov-2009	Study Records (I-1)	18-Nov-2009	21-Dec-2009	J. Adams
5-Nov-2009, 6-Nov-2009, 12-Nov-2009, 18-Nov-2009	Study Records (I-2 Excluding Final Body Weights)	18-Nov-2009	21-Dec-2009	J. Adams
6-Nov-2009	Study Records (N-2 External Fetal Data Only)	6-Nov-2009	21-Dec-2009	J. Adams
6-Nov-2009	Study Records (I-2 Final Body Weights Only)	6-Nov-2009	21-Dec-2009	J. Adams
13-Nov-2009, 19-Nov-2009	Study Records (Rx-1)	19-Nov-2009	21-Dec-2009	K. Mentzer, J. Adams
9-Dec-2009, 10-Dec-2009	Study Records (H-1)	10-Dec-2009	25-Jan-2010	K. Mentzer, J. Adams
9-Dec-2009, 10-Dec-2009	Study Records (P-1)	10-Dec-2009	25-Jan-2010	K. Mentzer, J. Adams

<u>Date(s) of Inspection(s)</u>	<u>Phase Inspected</u>	<u>Date(s) Findings Reported to Study Director</u>	<u>Date(s) Findings Reported to Management</u>	<u>Auditor(s)</u>
11-Dec-2009, 4-Jan-2010, 5-Jan-2010, 6-Jan-2010	Draft Report (Pathology Appendix)	6-Jan-2010	22-Feb-2010	K. Mentzer, J. Adams
14-Dec-2009, 15-Dec-2009	Study Records (N-2 Excluding External Fetal Exams)	15-Dec-2009	25-Jan-2010	J. Adams
23-Dec-2009, 28-Dec-2009, 29-Dec-2009, 4-Jan-2010, 5-Jan-2010, 6-Jan-2010	Draft Report (Excluding Pathology Appendix)	6-Jan-2010	22-Feb-2010	K. Mentzer, J. Adams

This study was inspected in accordance with the U.S. EPA TSCA Good Laboratory Practice Standards (40 CFR Part 792), the U.S. EPA FIFRA Good Laboratory Practice Standards (40 CFR Part 160), the OECD Principles of Good Laboratory Practice, the standard operating procedures of WIL Research Laboratories, LLC, and the Sponsor's protocol and protocol amendment. Quality Assurance findings, derived from the inspections during the conduct of the study and from the inspections of the raw data and draft report, are documented and have been reported to the Study Director. Review of the protocol and protocol amendment as well as a yearly internal facility inspection are conducted by the WIL Quality Assurance Unit. A status report is submitted to management monthly.

This report accurately reflects the data generated during the study. The methods and procedures used in the study were those specified in the protocol, its amendments, and the standard operating procedures of WIL Research Laboratories, LLC.

WIL-402008
American Petroleum Institute

SDHP (CAS# 64742-65-0)

The raw data, the retention sample, and the final report will be stored in the Archives at WIL Research Laboratories, LLC or another location specified by the Sponsor.

9.2. APPROVAL

This study was inspected according to the criteria discussed in Section 9.1.

Report Audited By:



Compliance Specialist

19 Oct. 2010

Date



for: Group Supervisor, Quality Assurance

19 Oct. 2010

Date

Report Released By:



Manager, Quality Assurance

19 Oct 2010

Date

10. REFERENCES

Crittenden, P.L. A 90-Day Repeat-Dose Dermal Toxicity Study of Solvent Dewaxed Heavy Paraffinic Distillates (Petroleum) (CAS# 64742-65-0) in Sprague Dawley Rats (Study No. WIL-402009). WIL Research Laboratories, LLC, Ashland, OH, **Draft**.

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11. DEVIATIONS FROM THE PROTOCOL

This study was conducted in accordance with the protocol and protocol amendments, except for the following.

- **Protocol Section 5.5** states that the minimum body weight at the initiation of breeding would be 220 g. The actual body weight range prior to breeding was 214 g to 277 g; the observed lower body weights were due to reduced food consumption during the acclimation period to Elizabethan collars. A protocol amendment was generated to lower the minimum body weight based on the Study Director Notification written on the day breeding was initiated.
- **Protocol Section 7.1** states that at the conclusion of the quarantine period, female rats judged to be suitable test subjects and meeting the acceptable body weight requirements would be cohabitated with an untreated male (1:1) of the same source and strain and that after confirmation of mating, the female would be returned to an individual suspended wire-mesh cage. During the cohabitation period, any female that did not show evidence of mating in the morning was unpaired and placed in an individual wire-mesh cage so that the female could have a collar affixed. The collars were left on the animal until cohabitation was resumed each afternoon.
- **Protocol Section 7.4** states that all animals would be clipped in the dorsal scapular area (covering approximately 10% of the body surface) prior to the start of dose administration and, as needed, thereafter during the administration period (repeated clippings would be performed prior to or at least 2-4 hours after dose administration). On gestation day 0, additional clipping of the dorsal scapular area hair was required for 15 and 11 females in the sham (control) and 1000 mg/kg/day groups, respectively, in order to acquire the necessary dosing dimensions due to changes in body weight. Additional clipping of the dorsal scapular area was also necessary for 2 females in the 1000 mg/kg/day group on gestation day 1. In addition, 8 females each in the sham (control) and 1000 mg/kg/day groups on gestation day 3 and 1 female each in the sham (control) and 1000 mg/kg/day groups on gestation day 6 required additional clipping of the hair to acquire the needed daily dosing dimensions based on the changes in body weights. Documentation of these procedures was not recorded.
- **Protocol Section 7.4** states that all animals would be clipped in the dorsal scapular area (covering approximately 10% of the body surface) prior to the start of dose administration and, as needed, thereafter during the administration period (repeated clippings would be performed prior to or at least 2-4 hours after dose administration). On gestation day 6, 10 and 9 females in the sham (control) and 1000 mg/kg/day groups, respectively, and on gestation day 18, 7 females in the sham (control) group required additional clipping of the dorsal scapular area to ensure the appropriate dosing dimensions based on body weights. The time that the procedure was

performed was not documented therefore it cannot be determined whether the procedure was performed prior to or at least 2-4 hours following dose administration.

- **Protocol Section 7.5.3** states that the test substance would be administered as a single daily dose, applied over as much of the clipped dorsal scapular area (approximately 10% of total body surface) as possible and distributed to avoid running. On gestation day 0, the dose site dimensions for female no. 56142 in the 1000 mg/kg/day group were 4.5 cm x 7.8 cm based on body weight. The test substance was applied to a 4.5 cm x 7.6 cm dorsal scapular area. Therefore, the dose volume was not applied to approximately 10% of this female's total body surface area.

These deviations did not negatively impact the quality or integrity of the data or the outcome of the study.

TABLES 1 - 18

PROJECT NO.:WIL-402008
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TABLE 1
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF MATERNAL SURVIVAL AND PREGNANCY STATUS

PAGE 1

DOSE GROUP :	1		2	
	NO.	%	NO.	%
FEMALES ON STUDY	25		25	
FEMALES THAT ABORTED OR DELIVERED	0	0.0	0	0.0
FEMALES THAT DIED	0	0.0	0	0.0
FEMALES THAT ABORTED	0	0.0	0	0.0
NONGRAVID	0	0.0	0	0.0
GRAVID	0	0.0	0	0.0
FEMALES THAT WERE EUTHANIZED	0	0.0	0	0.0
NONGRAVID	0	0.0	0	0.0
GRAVID	0	0.0	0	0.0
FEMALES EXAMINED AT SCHEDULED NECROPSY	25	100.0	25	100.0
NONGRAVID	1	4.0	1	4.0
GRAVID	24	96.0	24	96.0
WITH RESORPTIONS ONLY	0	0.0	0	0.0
WITH VIABLE FETUSES	24	100.0	24	100.0
TOTAL FEMALES GRAVID	24	96.0	24	96.0

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

PSPSv4.01
11/11/2009
R:04/15/2010

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE 2 (DAILY EXAMINATIONS)
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

PAGE 1

----- F E M A L E -----

TABLE RANGE:	10-06-09 TO 10-29-09		
GROUP:		1	2

NORMAL			
-NO SIGNIFICANT CLINICAL OBSERVATIONS		78/23	42/23
DISPOSITION			
-SCHEDULED EUTHANASIA; GESTATION DAY 20		25/25	25/25
BODY/INTEGUMENT			
-HAIR LOSS RIGHT FORELIMB		27/ 5	51/14
-HAIR LOSS LEFT FORELIMB		33/ 4	25/ 5
-DRIED YELLOW MATERIAL UROGENITAL AREA		3/ 1	11/ 6
-DRIED YELLOW MATERIAL VENTRAL ABDOMINAL AREA		6/ 3	1/ 1
-UNKEMPT APPEARANCE		0/ 0	262/25
-SCABBING DORSAL THORACIC AREA		0/ 0	3/ 1
-HAIR LOSS DORSAL HEAD		10/ 2	0/ 0
-DRIED RED MATERIAL UROGENITAL AREA		0/ 0	5/ 5
EYES/EARS/NOSE			
-DRIED RED MATERIAL AROUND NOSE		409/25	400/25
-DRIED RED MATERIAL AROUND RIGHT EYE		123/22	154/22
-DRIED RED MATERIAL AROUND LEFT EYE		107/23	122/21
-WET CLEAR MATERIAL AROUND RIGHT EYE		52/22	154/25

1- 0 MG/KG/DAY	2- 1000 MG/KG/DAY		

PROJECT NO.:WIL-402008
 SPONSOR:AMERICAN PETROLEUM

TABLE 2 (DAILY EXAMINATIONS)
 RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
 SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

PAGE 2

----- F E M A L E -----

TABLE RANGE:	10-06-09 TO 10-29-09		
GROUP:		1	2
EYES/EARS/NOSE			
-WET CLEAR MATERIAL AROUND LEFT EYE	42/18		161/25
-WET RED MATERIAL AROUND RIGHT EYE	0/ 0		2/ 2
-WET RED MATERIAL AROUND LEFT EYE	0/ 0		1/ 1
-WET RED MATERIAL AROUND NOSE	0/ 0		4/ 3
-HAIR LOSS AROUND LEFT EYE	2/ 2		0/ 0
-WET CLEAR MATERIAL AROUND NOSE	5/ 3		17/10
-LACRIMATION RIGHT EYE	0/ 0		1/ 1
-LACRIMATION LEFT EYE	0/ 0		1/ 1

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

PCSUv4.07
 11/11/2009
 R:04/15/2010

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE 3
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF POST-DOSE FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

PAGE 1

----- F E M A L E -----

TABLE RANGE: 10-06-09 TO 10-28-09
GROUP: 1 2

NORMAL

TIME OF DOSE		
-NO SIGNIFICANT CLINICAL OBSERVATIONS	500/25	500/25
1-2 HOURS POST-DOSING		
-NO SIGNIFICANT CLINICAL OBSERVATIONS	499/25	497/25

EYES/EARS/NOSE

1-2 HOURS POST-DOSING		
-LACRIMATION RIGHT EYE	0/0	2/2
-LACRIMATION LEFT EYE	0/0	2/2

EXCRETA

1-2 HOURS POST-DOSING		
-WET RED VAGINAL DISCHARGE	1/1	1/1

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

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11/11/2009
R:04/15/2010

PROJECT NO.:WIL-402008
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TABLE 4
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF DERMAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

PAGE 1

----- F E M A L E -----

TABLE RANGE:	10-06-09 TO 10-29-09		
GROUP:		1	2

DERMAL OBS			
-SCORED, NOT REMARKABLE	523/25		525/25
-NO ERYTHEMA	2/ 1		0/ 0
-NO EDEMA	2/ 1		0/ 0
-DESQUAMATION	2/ 1		0/ 0

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

PCSUv4.07
11/11/2009
R:04/15/2010

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE 5
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF BODY WEIGHTS DURING GESTATION [G]

PAGE 1

GROUP:		0 MG/KG/DAY	1000 MG/KG/DAY
DAY	0		
	MEAN	247.	250.
	% DIFFERENCE		1.2
	S.D.	11.6	14.6
	S.E.	2.4	3.0
	N	24	24
DAY	3		
	MEAN	257.	256.
	% DIFFERENCE		-0.4
	S.D.	12.1	17.1
	S.E.	2.5	3.5
	N	24	24
DAY	6		
	MEAN	269.	267.
	% DIFFERENCE		-0.7
	S.D.	13.7	17.9
	S.E.	2.8	3.7
	N	24	24
DAY	9		
	MEAN	280.	278.
	% DIFFERENCE		-0.7
	S.D.	13.2	18.3
	S.E.	2.7	3.7
	N	24	24
DAY	12		
	MEAN	294.	294.
	% DIFFERENCE		0.0
	S.D.	15.0	19.6
	S.E.	3.1	4.0
	N	24	24

MODIFIED STATISTICS USED.
None significantly different from control group
NONGRAVID WEIGHT(S) NOT INCLUDED IN CALCULATION OF MEAN

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE 5
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF BODY WEIGHTS DURING GESTATION [G]

PAGE 2

GROUP:		0 MG/KG/DAY	1000 MG/KG/DAY
DAY 15	MEAN	313.	311.
	% DIFFERENCE		-0.6
	S.D.	16.7	21.2
	S.E.	3.4	4.3
	N	24	24
DAY 18	MEAN	355.	352.
	% DIFFERENCE		-0.8
	S.D.	20.9	24.3
	S.E.	4.3	5.0
	N	24	24
DAY 20	MEAN	388.	387.
	% DIFFERENCE		-0.3
	S.D.	23.8	25.4
	S.E.	4.9	5.2
	N	24	24

MODIFIED STATISTICS USED.
None significantly different from control group
NONGRAVID WEIGHT(S) NOT INCLUDED IN CALCULATION OF MEAN

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PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE 6
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF BODY WEIGHT CHANGES DURING GESTATION [G]

PAGE 1

GROUP:			0 MG/KG/DAY	1000 MG/KG/DAY
DAY	0-	3		
		MEAN	9.	7.
		S.D.	5.7	7.0
		S.E.	1.2	1.4
		N	24	24
DAY	3-	6		
		MEAN	13.	10.
		S.D.	4.0	6.6
		S.E.	0.8	1.4
		N	24	24
DAY	6-	9		
		MEAN	11.	11.
		S.D.	6.4	5.1
		S.E.	1.3	1.0
		N	24	24
DAY	9-	12		
		MEAN	14.	16.
		S.D.	5.1	4.9
		S.E.	1.0	1.0
		N	24	24
DAY	12-	15		
		MEAN	19.	17.
		S.D.	5.5	5.7
		S.E.	1.1	1.2
		N	24	24

MODIFIED STATISTICS USED.
None significantly different from control group
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES
NONGRAVID WEIGHT(S) NOT INCLUDED IN CALCULATION OF MEAN

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE 6
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF BODY WEIGHT CHANGES DURING GESTATION [G]

PAGE 2

GROUP:			0 MG/KG/DAY	1000 MG/KG/DAY
DAY	15-	18		
		MEAN	42.	42.
		S.D.	7.0	7.2
		S.E.	1.4	1.5
		N	24	24
DAY	18-	20		
		MEAN	33.	34.
		S.D.	5.9	6.4
		S.E.	1.2	1.3
		N	24	24
DAY	0-	20		
		MEAN	141.	137.
		S.D.	18.2	16.8
		S.E.	3.7	3.4
		N	24	24

MODIFIED STATISTICS USED.
None significantly different from control group
MEAN DIFFERENCES CALCULATED FROM INDIVIDUAL DIFFERENCES
NONGRAVID WEIGHT(S) NOT INCLUDED IN CALCULATION OF MEAN

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11/11/2009
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PROJECT NO.:WIL-402008
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TABLE 7
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF GRAVID UTERINE WTS. AND NET BODY WT. CHANGES [G]

PAGE 1

GROUP:	0 MG/KG/DAY	1000 MG/KG/DAY
INITIAL BODY WT.		
MEAN	247.	250.
S.D.	11.6	14.6
S.E.	2.4	3.0
N	24	24
TERMINAL BODY WT.		
MEAN	388.	387.
S.D.	23.8	25.4
S.E.	4.9	5.2
N	24	24
GRAVID UTERINE WT.		
MEAN	84.3	83.5
S.D.	10.84	9.13
S.E.	2.21	1.86
N	24	24
NET BODY WT.		
MEAN	303.8	303.2
S.D.	18.22	19.67
S.E.	3.72	4.02
N	24	24
NET BODY WT. CHANGE		
MEAN	56.6	53.5
S.D.	14.38	12.19
S.E.	2.94	2.49
N	24	24

MODIFIED STATISTICS USED.
None significantly different from control group

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PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE 8
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF FOOD CONSUMPTION DURING GESTATION [G/ANIMAL/DAY]

PAGE 1

GROUP:			0 MG/KG/DAY	1000 MG/KG/DAY
DAY	0-	3		
		MEAN	26.	26.
		S.D.	3.3	3.9
		S.E.	0.7	0.8
		N	24	24
DAY	3-	6		
		MEAN	29.	30.
		S.D.	3.2	3.6
		S.E.	0.7	0.7
		N	24	24
DAY	6-	9		
		MEAN	29.	31.
		S.D.	3.3	3.6
		S.E.	0.7	0.7
		N	24	23
DAY	9-	12		
		MEAN	30.	31.
		S.D.	3.0	3.7
		S.E.	0.6	0.8
		N	24	24
DAY	12-	15		
		MEAN	30.	32.
		S.D.	3.1	4.3
		S.E.	0.6	0.9
		N	24	24

MODIFIED STATISTICS USED.
None significantly different from control group
NONGRAVID WEIGHT(S) NOT INCLUDED IN CALCULATION OF MEAN

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE 8
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF FOOD CONSUMPTION DURING GESTATION [G/ANIMAL/DAY]

PAGE 2

GROUP:			0 MG/KG/DAY	1000 MG/KG/DAY
DAY	15-	18		
		MEAN	33.	36.*
		S.D.	3.5	4.7
		S.E.	0.7	1.0
		N	24	24
DAY	18-	20		
		MEAN	33.	37.**
		S.D.	4.8	3.5
		S.E.	1.0	0.7
		N	23	24
DAY	0-	20		
		MEAN	30.	31.
		S.D.	2.8	3.2
		S.E.	0.6	0.7
		N	23	24

MODIFIED STATISTICS USED.

* = Significantly different from the control group at 0.05 using two-sample t-test

** = Significantly different from the control group at 0.01 using two-sample t-test

NONGRAVID WEIGHT(S) NOT INCLUDED IN CALCULATION OF MEAN

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TABLE 9
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF FOOD CONSUMPTION DURING GESTATION [G/KG/DAY]

PAGE 1

GROUP:			0 MG/KG/DAY	1000 MG/KG/DAY
DAY	0-	3		
		MEAN	103.	103.
		S.D.	13.1	12.8
		S.E.	2.7	2.6
		N	24	24
DAY	3-	6		
		MEAN	110.	113.
		S.D.	11.3	10.7
		S.E.	2.3	2.2
		N	24	24
DAY	6-	9		
		MEAN	107.	114.*
		S.D.	11.8	10.1
		S.E.	2.4	2.1
		N	24	23
DAY	9-	12		
		MEAN	103.	110.*
		S.D.	8.5	10.6
		S.E.	1.7	2.2
		N	24	24
DAY	12-	15		
		MEAN	100.	106.*
		S.D.	7.8	11.9
		S.E.	1.6	2.4
		N	24	24

MODIFIED STATISTICS USED.

* = Significantly different from the control group at 0.05 using two-sample t-test
NONGRAVID WEIGHT(S) NOT INCLUDED IN CALCULATION OF MEAN

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE 9
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF FOOD CONSUMPTION DURING GESTATION [G/KG/DAY]

PAGE 2

GROUP:		0 MG/KG/DAY	1000 MG/KG/DAY
DAY	15- 18		
	MEAN	99.	107.**
	S.D.	8.1	10.6
	S.E.	1.7	2.2
	N	24	24
DAY	18- 20		
	MEAN	89.	100.**
	S.D.	11.0	7.6
	S.E.	2.3	1.6
	N	23	24
DAY	0- 20		
	MEAN	99.	105.*
	S.D.	7.8	7.0
	S.E.	1.6	1.4
	N	23	24

MODIFIED STATISTICS USED.

* = Significantly different from the control group at 0.05 using two-sample t-test

** = Significantly different from the control group at 0.01 using two-sample t-test

NONGRAVID WEIGHT(S) NOT INCLUDED IN CALCULATION OF MEAN

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11/11/2009
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TABLE 10
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF MATERNAL MACROSCOPIC FINDINGS

PAGE 1

	GROUP :	1 2

NUMBER EXAMINED		25 25
NO SIGNIFICANT CHANGES OBSERVED		24 15
NONGRAVID -- AMMONIUM SULFIDE NEGATIVE		1 1
SKIN: MATTING, YELLOW		0 9

1- 0 MG/KG/DAY	2- 1000 MG/KG/DAY	

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11/11/2009
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TABLE 11
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF MICROSCOPIC FINDINGS

PAGE 1

----- FEMALE -----		
GROUP:	1	2
NUMBER OF ANIMALS IN DOSE GROUP	30	30
NUMBER OF ANIMALS EXAMINED	25	25
APPL SITE-TREAT		
TOTAL NUMBER EXAMINED	NA	25
EXAMINED, UNREMARKABLE	NA	5
-APOPTOSIS	NA	6
MINIMAL	NA	6
-INFILTRATE, MONONUCLEAR	NA	16
MINIMAL	NA	16
APPL SITE-UNTREA		
TOTAL NUMBER EXAMINED	25	25
EXAMINED, UNREMARKABLE	16	13
-APOPTOSIS	9	8
MINIMAL	9	7
MILD	NONE	1
-FIBROPLASIA	0	1
MINIMAL	NONE	1
-INFILTRATE, HISTIOCYTE	0	1
MINIMAL	NONE	1
-INFILTRATE, MONONUCLEAR	0	3
MINIMAL	NONE	3
1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY		
NA = NOT APPLICABLE		

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R:04/15/2010

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TABLE 12
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF ORGAN WEIGHTS [G]

PAGE 1

----- F E M A L E -----			
GROUP:	0 MG/KG/DAY	1000 MG/KG/DAY	
THYMUS			
MEAN	0.2440	0.2136	
% DIFFERENCE		-12.5	
S.D.	0.06517	0.05033	
S.E.	0.01330	0.01027	
N	24	24	
ADRENAL GLANDS			
MEAN	0.0781	0.0855*	
% DIFFERENCE		9.5	
S.D.	0.00859	0.01137	
S.E.	0.00175	0.00232	
N	24	24	

MODIFIED STATISTICS USED.

* = Significantly different from the control group at 0.05 using two-sample t-test
NONGRAVID WEIGHT(S) NOT INCLUDED IN CALCULATION OF MEAN

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11/11/2009
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PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE 13
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF FETAL DATA AT SCHEDULED NECROPSY

PAGE 1

GROUP		SEX		VIABLE FETUSES	DEAD FETUSES	RESORPTIONS		POST	IMPLANTATION SITES	CORPORA LUTEA	PRE	FETAL WEIGHTS IN GRAMS	NO. OF GRAVID FEMALES
		M	F			EARLY	LATE	LOSS			LOSS		
1	TOTAL	161	185	346	0	17	0	17	363	385	22	NA	24
	MEAN	6.7	7.7	14.4	0.0	0.7	0.0	0.7	15.1	16.0	0.9	3.8	
	S.D.	1.81	1.85	1.79	0.00	0.86	0.00	0.86	1.75	1.90	1.28	0.21	
	S.E.	0.37	0.38	0.37	0.00	0.18	0.00	0.18	0.36	0.39	0.26	0.04	
2	TOTAL	172	174	346	0	22	1	23	369	390	21	NA	24
	MEAN	7.2	7.3	14.4	0.0	0.9	0.0	1.0	15.4	16.3	0.9	3.7	
	S.D.	2.41	2.29	1.74	0.00	1.14	0.20	1.16	1.86	1.85	1.19	0.26	
	S.E.	0.49	0.47	0.36	0.00	0.23	0.04	0.24	0.38	0.38	0.24	0.05	

MODIFIED STATISTICS USED.

None significantly different from control group

NA = NOT APPLICABLE

MEAN NUMBER OF VIABLE FETUSES, MEAN NUMBER OF IMPLANTATION SITES, MEAN NUMBER OF CORPORA LUTEA,
FETAL WEIGHTS COMPARED USING TWO-SAMPLE T-TEST

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

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11/11/2009
R:04/15/2010

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE 14
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF FETAL DATA AT SCHEDULED NECROPSY [% PER LITTER]

PAGE 1

GROUP:	0 MG/KG/DAY	1000 MG/KG/DAY
CORPORA LUTEA		
MEAN	16.0	16.3
S.D.	1.90	1.85
S.E.	0.39	0.38
N	24	24
IMPLANTATION SITES		
MEAN	15.1	15.4
S.D.	1.75	1.86
S.E.	0.36	0.38
N	24	24
VIABLE FETUSES (%)		
MEAN	95.4	94.0
S.D.	5.59	7.17
S.E.	1.14	1.46
N	24	24
DEAD FETUSES (%)		
MEAN	0.0	0.0
S.D.	0.00	0.00
S.E.	0.00	0.00
N	24	24
EARLY RESORPTIONS (%)		
MEAN	4.6	5.7
S.D.	5.59	7.00
S.E.	1.14	1.43
N	24	24

PROPORTIONAL (%) DATA COMPARED USING DUNN'S TEST
CORPORA LUTEA AND IMPLANTATION SITES COMPARED USING TWO-SAMPLE T-TEST
MODIFIED STATISTICS USED. * INDICATES PARAMETRIC ANALYSIS AND + INDICATES NON-PARAMETRIC ANALYSIS.
None significantly different from control group

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE 14
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF FETAL DATA AT SCHEDULED NECROPSY [% PER LITTER]

PAGE 2

GROUP:	0 MG/KG/DAY	1000 MG/KG/DAY
LATE RESORPTIONS (%)		
MEAN	0.0	0.3
S.D.	0.00	1.37
S.E.	0.00	0.28
N	24	24
TOTAL RESORPTIONS (%)		
MEAN	4.6	6.0
S.D.	5.59	7.17
S.E.	1.14	1.46
N	24	24
PRE-IMPLANTATION LOSS (%)		
MEAN	5.4	5.2
S.D.	7.15	6.89
S.E.	1.46	1.41
N	24	24
POST-IMPLANTATION LOSS (%)		
MEAN	4.6	6.0
S.D.	5.59	7.17
S.E.	1.14	1.46
N	24	24
MALES (%)		
MEAN	46.5	49.5
S.D.	11.82	15.67
S.E.	2.41	3.20
N	24	24

PROPORTIONAL (%) DATA COMPARED USING DUNN'S TEST
MODIFIED STATISTICS USED. * INDICATES PARAMETRIC ANALYSIS AND + INDICATES NON-PARAMETRIC ANALYSIS.
None significantly different from control group

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE 14
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF FETAL DATA AT SCHEDULED NECROPSY [% PER LITTER]

PAGE 3

GROUP:	0 MG/KG/DAY	1000 MG/KG/DAY
FEMALES (%)		
MEAN	53.5	50.5
S.D.	11.82	15.67
S.E.	2.41	3.20
N	24	24
MALE FETAL WEIGHTS (g)		
MEAN	3.9	3.8
% DIFFERENCE		-2.6
S.D.	0.24	0.29
S.E.	0.05	0.06
N	24	24
FEMALE FETAL WEIGHTS (g)		
MEAN	3.7	3.6
% DIFFERENCE		-2.7
S.D.	0.20	0.24
S.E.	0.04	0.05
N	24	24
COMBINED FETAL WEIGHTS (g)		
MEAN	3.8	3.7
% DIFFERENCE		-2.6
S.D.	0.21	0.26
S.E.	0.04	0.05
N	24	24

PROPORTIONAL (%) DATA COMPARED USING DUNN'S TEST
FETAL WEIGHTS COMPARED USING TWO-SAMPLE T-TEST
MODIFIED STATISTICS USED. * INDICATES PARAMETRIC ANALYSIS AND + INDICATES NON-PARAMETRIC ANALYSIS.
None significantly different from control group

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11/11/2009
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SPONSOR:AMERICAN PETROLEUM

TABLE 15
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF FETUSES AND LITTERS WITH MALFORMATIONS [ABSOLUTE NO.]

PAGE 1

DAY 20

DOSE GROUP:	F E T U S E S		L I T T E R S	
	1	2	1	2
NUMBER EXAMINED EXTERNALLY	346	346	24	24
MICROPHTHALMIA AND/OR ANOPHTHALMIA	1	1	1	1
VERTEBRAL AGENESIS	1	0	1	0
NUMBER EXAMINED VISCERALLY	346	346	24	24
SITUS INVERSUS	0	1	0	1
NUMBER EXAMINED SKELETALLY	346	346	24	24
NUMBER WITH FINDINGS	0	0	0	0
TOTAL NUMBER WITH MALFORMATIONS				
EXTERNAL :	2	1	2	1
SOFT TISSUE :	0	1	0	1
SKELETAL :	0	0	0	0
COMBINED :	2	2	2	2
1- 0 MG/KG/DAY	2- 1000 MG/KG/DAY			

PMALv5.08
12/16/2009
R:04/15/2010

PROJECT NO.:WIL-402008	TABLE 16	PAGE 1
SPONSOR:AMERICAN PETROLEUM	RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP	
	SUMMARY OF LITTER PROPORTIONS OF MALFORMATIONS	
	% PER LITTER	DAY 20

DOSE GROUP:		1	2
NUMBER OF LITTERS EXAMINED EXTERNALLY		24	24
MICROPTHALMIA AND/OR ANOPHTHALMIA	MEAN	0.3	0.3
	S.D.	1.70	1.57
	S.E.	0.35	0.32
VERTEBRAL AGENESIS	MEAN	0.3	0.0
	S.D.	1.57	0.00
	S.E.	0.32	0.00

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY
MODIFIED STATISTICS USED.
None significantly different from control group

PROJECT NO.:WIL-402008	TABLE 16	PAGE 2
SPONSOR:AMERICAN PETROLEUM	RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP	
	SUMMARY OF LITTER PROPORTIONS OF MALFORMATIONS	
	% PER LITTER	DAY 20

DOSE GROUP:		1	2
NUMBER OF LITTERS EXAMINED VISCERALLY		24	24
SITUS INVERSUS	MEAN	0.0	0.3
	S.D.	0.00	1.57
	S.E.	0.00	0.32

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY
MODIFIED STATISTICS USED.
None significantly different from control group

PROJECT NO.:WIL-402008		TABLE 16	PAGE 3
SPONSOR:AMERICAN PETROLEUM		RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP	
		SUMMARY OF LITTER PROPORTIONS OF MALFORMATIONS	
		% PER LITTER	DAY 20
DOSE GROUP:		1	2
NUMBER OF LITTERS EXAMINED SKELETALLY		24	24
NUMBER OF LITTERS WITH FINDINGS		0	0
1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY			
MODIFIED STATISTICS USED.			
None significantly different from control group			

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE 16
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF LITTER PROPORTIONS OF MALFORMATIONS
% PER LITTER

PAGE 4

DAY 20

DOSE GROUP:		1	2
NUMBER OF LITTERS EXAMINED		24	24
TOTAL MALFORMATIONS			
PERCENT PER LITTER WITH EXTERNAL MALFORMATIONS	MEAN	0.7	0.3
	S.D.	2.26	1.57
	S.E.	0.46	0.32
PERCENT PER LITTER WITH SOFT TISSUE MALFORMATIONS	MEAN	0.0	0.3
	S.D.	0.00	1.57
	S.E.	0.00	0.32
PERCENT PER LITTER WITH SKELETAL MALFORMATIONS	MEAN	0.0	0.0
	S.D.	0.00	0.00
	S.E.	0.00	0.00
TOTAL PERCENT PER LITTER WITH MALFORMATIONS	MEAN	0.7	0.6
	S.D.	2.26	2.17
	S.E.	0.46	0.44

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

MODIFIED STATISTICS USED.

None significantly different from control group

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12/16/2009
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PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE 17
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF FETUSES AND LITTERS WITH VARIATIONS [ABSOLUTE NO.]

PAGE 1

DAY 20

DOSE GROUP:	F E T U S E S		L I T T E R S	
	1	2	1	2
NUMBER EXAMINED EXTERNALLY	346	346	24	24
NUMBER WITH FINDINGS	0	0	0	0
NUMBER EXAMINED VISCERALLY	346	346	24	24
HEMORRHAGIC RING AROUND THE IRIS	0	2	0	1
RENAL PAPILLA(E) NOT DEVELOPED AND/OR DISTENDED URETER(S)	0	1	0	1
NUMBER EXAMINED SKELETALLY	346	346	24	24
STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	51	64	19	18
CERVICAL CENTRUM #1 OSSIFIED	50	47	18	16
14TH RUDIMENTARY RIB(S)	25	22	9	10
REDUCED OSSIFICATION OF THE VERTEBRAL ARCHES	2	1	2	1
STERNEBRA(E) MALALIGNED(SLIGHT OR MODERATE)	2	1	2	1
STERNEBRA(E) #1,#2,#3 AND/OR #4 UNOSSIFIED	2	2	2	2
REDUCED OSSIFICATION OF THE 13TH RIB(S)	1	3	1	3
REDUCED OSSIFICATION OF THE SKULL	1	1	1	1
BENT RIB(S)	1	2	1	2
7TH CERVICAL RIB(S)	1	2	1	2
HYOID UNOSSIFIED	2	0	1	0
UNCO-OSSIFIED VERTEBRAL CENTRA	1	0	1	0
PUBIS UNOSSIFIED	1	0	1	0
27 PRESACRAL VERTEBRAE	1	0	1	0
1- 0 MG/KG/DAY	2- 1000 MG/KG/DAY			

PMALv5.08
12/16/2009
R:04/15/2010

PROJECT NO.:WIL-402008		TABLE 18	PAGE 1
SPONSOR:AMERICAN PETROLEUM		RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP	
		SUMMARY OF LITTER PROPORTIONS OF VARIATIONS	
		% PER LITTER	DAY 20
DOSE GROUP:		1	2
NUMBER OF LITTERS EXAMINED EXTERNALLY		24	24
NUMBER OF LITTERS WITH FINDINGS		0	0
1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY			
MODIFIED STATISTICS USED.			
None significantly different from control group			

PROJECT NO.:WIL-402008	TABLE 18	PAGE 2
SPONSOR:AMERICAN PETROLEUM	RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP	
	SUMMARY OF LITTER PROPORTIONS OF VARIATIONS	
	% PER LITTER	DAY 20

DOSE GROUP:		1	2
NUMBER OF LITTERS EXAMINED VISCERALLY		24	24
HEMORRHAGIC RING AROUND THE IRIS	MEAN	0.0	0.6
	S.D.	0.00	3.14
	S.E.	0.00	0.64
RENAL PAPILLA(E) NOT DEVELOPED AND/OR DISTENDED URETER(S)	MEAN	0.0	0.3
	S.D.	0.00	1.28
	S.E.	0.00	0.26

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY
 MODIFIED STATISTICS USED.
 None significantly different from control group

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE 18
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF LITTER PROPORTIONS OF VARIATIONS
% PER LITTER

PAGE 3

DAY 20

DOSE GROUP:		1	2
NUMBER OF LITTERS EXAMINED SKELETALLY		24	24
STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	MEAN	15.0	18.2
	S.D.	13.41	19.48
	S.E.	2.74	3.98
CERVICAL CENTRUM #1 OSSIFIED	MEAN	15.2	14.3
	S.D.	16.02	17.04
	S.E.	3.27	3.48
14TH RUDIMENTARY RIB(S)	MEAN	7.5	6.0
	S.D.	13.99	8.97
	S.E.	2.86	1.83
REDUCED OSSIFICATION OF THE VERTEBRAL ARCHES	MEAN	0.6	0.3
	S.D.	2.08	1.28
	S.E.	0.42	0.26
STERNEBRA(E) MALALIGNED(SLIGHT OR MODERATE)	MEAN	0.6	0.3
	S.D.	2.19	1.28
	S.E.	0.45	0.26
STERNEBRA(E) #1,#2,#3 AND/OR #4 UNOSSIFIED	MEAN	0.6	0.6
	S.D.	1.98	2.03
	S.E.	0.40	0.41
REDUCED OSSIFICATION OF THE 13TH RIB(S)	MEAN	0.3	0.9
	S.D.	1.70	2.47
	S.E.	0.35	0.50
REDUCED OSSIFICATION OF THE SKULL	MEAN	0.3	0.3
	S.D.	1.46	1.70
	S.E.	0.30	0.35

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

MODIFIED STATISTICS USED.

None significantly different from control group

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE 18
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF LITTER PROPORTIONS OF VARIATIONS
% PER LITTER

PAGE 4

DAY 20

DOSE GROUP:		1	2
NUMBER OF LITTERS EXAMINED SKELETALLY		24	24
BENT RIB(S)	MEAN	0.3	0.6
	S.D.	1.36	2.13
	S.E.	0.28	0.44
7TH CERVICAL RIB(S)	MEAN	0.3	0.6
	S.D.	1.28	1.90
	S.E.	0.26	0.39
HYOID UNOSSIFIED	MEAN	0.6	0.0
	S.D.	2.92	0.00
	S.E.	0.60	0.00
UNCO-OSSIFIED VERTEBRAL CENTRA	MEAN	0.3	0.0
	S.D.	1.28	0.00
	S.E.	0.26	0.00
PUBIS UNOSSIFIED	MEAN	0.3	0.0
	S.D.	1.28	0.00
	S.E.	0.26	0.00
27 PRESACRAL VERTEBRAE	MEAN	0.3	0.0
	S.D.	1.28	0.00
	S.E.	0.26	0.00

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

MODIFIED STATISTICS USED.

None significantly different from control group

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE 18
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
SUMMARY OF LITTER PROPORTIONS OF VARIATIONS
% PER LITTER

PAGE 5

DAY 20

DOSE GROUP:		1	2
NUMBER OF LITTERS EXAMINED		24	24
TOTAL VARIATIONS			
PERCENT PER LITTER WITH EXTERNAL VARIATIONS	MEAN	0.0	0.0
	S.D.	0.00	0.00
	S.E.	0.00	0.00
PERCENT PER LITTER WITH SOFT TISSUE VARIATIONS	MEAN	0.0	0.9
	S.D.	0.00	3.34
	S.E.	0.00	0.68
PERCENT PER LITTER WITH SKELETAL VARIATIONS	MEAN	35.4	36.8
	S.D.	19.19	21.66
	S.E.	3.92	4.42
TOTAL PERCENT PER LITTER WITH VARIATIONS	MEAN	35.4	37.7
	S.D.	19.19	21.42
	S.E.	3.92	4.37

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY
MODIFIED STATISTICS USED.
None significantly different from control group

PMALKv5.07
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R:04/15/2010

APPENDIX A

Individual Animal Data

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A1 (DAILY EXAMINATIONS)
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL CLINICAL OBSERVATIONS

PAGE 1

OBSERVATION	ANIMAL	GROUP	GESTATIONAL DAY																				
			0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
NO SIGNIFICANT CLINICAL OBSERVATIONS	56130	1	P																				
	56138	1	P							P							P	P		P	P		
	56137	1	P														P						
	56154	1	P																				
	56133	1	P			P	P	P	P				P	P			P						
	56129	1	P				P							P			P	P				P	
	56132	1						P															
	56112	1	P																				
	56106	1	P			P			P												P	P	
	56121	1	P																				
	56156	1	P														P						P
	56107	1												P	P		P						
	56134	1	P	P										P	P								
	56158	1	P															P	P				
	56119	1	P											P									
	56151	1	P											P			P		P		P		
	56126	1					P																
	56117	1	P																				
	56160	1	P				P										P	P			P		
	56123	1	P																				
	56162	1		P										P	P		P	P	P	P	P	P	P
	56122	1															P		P				P
	56165	1	P			P					P							P	P				
	56142	2	P																				
	56161	2	P				P																
	56113	2	P																P				
	56143	2	P					P															

GRADE CODE: P = PRESENT 1 = SLIGHT 2 = MODERATE 3 = SEVERE

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A1 (DAILY EXAMINATIONS)
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL CLINICAL OBSERVATIONS

PAGE 2

OBSERVATION	ANIMAL	GROUP	GESTATIONAL DAY														1	1	1	1	1	1	1	1	2
			0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0		
NO SIGNIFICANT CLINICAL OBSERVATIONS	56136	2	P																						
	56159	2	P			P																			
	56155	2	P																						
	56141	2	P																						
	56164	2	P															P							
	56131	2	P																						
	56157	2	P																P						
	56128	2	P																						
	56140	2	P			P																			
	56114	2	P																						
	56118	2	P			P																			
	56147	2	P																						
	56152	2	P	P																					
	56145	2	P																						
	56120	2	P																						
	56108	2	P	P	P	P	P																		
	56150	2	P	P	P	P									P										
	56116	2	P	P																					
	56125	2	P			P																			
SCHEDULED EUTHANASIA; GESTATION DAY 20	56130	1																				P			
	56138	1																				P			
	56137	1																				P			
	56154	1																				P			
	56133	1																				P			
	56129	1																				P			
	56132	1																				P			

GRADE CODE: P = PRESENT 1 = SLIGHT 2 = MODERATE 3 = SEVERE

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A1 (DAILY EXAMINATIONS)
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL CLINICAL OBSERVATIONS

PAGE 3

OBSERVATION	ANIMAL	GROUP	GESTATIONAL DAY																					
			0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	
SCHEDULED EUTHANASIA; GESTATION DAY 20	56112	1																						P
	56106	1																						P
	56121	1																						P
	56156	1																						P
	56107	1																						P
	56134	1																						P
	56158	1																						P
	56119	1																						P
	56151	1																						P
	56126	1																						P
	56117	1																						P
	56160	1																						P
	56123	1																						P
	56115	1																						P
	56162	1																						P
	56122	1																						P
	56111	1																						P
	56165	1																						P
	56142	2																						P
	56161	2																						P
56113	2																						P	
56143	2																						P	
56136	2																						P	
56159	2																						P	
56155	2																						P	
56141	2																						P	
56164	2																						P	

GRADE CODE: P = PRESENT 1 = SLIGHT 2 = MODERATE 3 = SEVERE

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A1 (DAILY EXAMINATIONS)
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL CLINICAL OBSERVATIONS

PAGE 4

OBSERVATION	ANIMAL	GROUP	GESTATIONAL DAY																							
			0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0			
SCHEDULED EUTHANASIA; GESTATION DAY 20	56131	2																						P		
	56157	2																						P		
	56128	2																						P		
	56140	2																						P		
	56114	2																						P		
	56118	2																						P		
	56147	2																						P		
	56152	2																						P		
	56145	2																						P		
	56120	2																						P		
	56109	2																						P		
	56108	2																						P		
	56139	2																						P		
	56150	2																						P		
	56116	2																						P		
56125	2																						P			
HAIR LOSS RIGHT FORELIMB	56132	1	1	1		1	1		1	1	1		1	1	1	1	1		1	1	1					
	56106	1									1															
	56151	1																		1						
	56117	1													1											
	56115	1	1	1	1	1	1		1									1	1							
	56142	2																			1	1				
	56161	2																			1	1				
	56159	2											1								1					
	56155	2																1		1						
	56141	2											1				1	1		1	1					
GRADE CODE: P = PRESENT 1 = SLIGHT 2 = MODERATE 3 = SEVERE																										
1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY																										

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A1 (DAILY EXAMINATIONS)
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL CLINICAL OBSERVATIONS

PAGE 5

OBSERVATION	ANIMAL	GROUP	GESTATIONAL DAY																				
			0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
HAIR LOSS RIGHT FORELIMB	56164	2																				1	
	56128	2								1							1						1
	56140	2																				1	1
	56114	2																		1			1
	56152	2										1											
	56109	2	1	1	1		1		1	1		1	1	1	1	1	1	1	1	1	1	1	1
	56139	2							1		1	1		1	1	1					1		
	56150	2																	1	1			
	56125	2																					1
HAIR LOSS LEFT FORELIMB	56132	1	1	1			1	1		1	1	1		1	1	1	1	1		1	1	1	
	56158	1								1													
	56117	1														1							
	56115	1	1	1	1	1		1	1	1	1				1	1	1	1	1	1	1	1	
	56159	2											1				1	1					
	56141	2																				1	
	56109	2	1	1	1		1		1	1		1	1	1	1	1	1	1	1	1	1	1	
	56139	2										1	1										
	56150	2																	1	1			
DRIED YELLOW MATERIAL UROGENITAL AREA	56126	1		1								1	1										
	56159	2			1														1	1	1		
	56164	2				1	1																
	56128	2				1	1																
	56118	2						1															
	56150	2							1														
	56125	2									1												

GRADE CODE: P = PRESENT 1 = SLIGHT 2 = MODERATE 3 = SEVERE

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A1 (DAILY EXAMINATIONS)
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL CLINICAL OBSERVATIONS

PAGE 6

OBSERVATION	ANIMAL	GROUP	GESTATIONAL DAY																							
			0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0			
DRIED YELLOW MATERIAL VENTRAL ABDOMINAL AREA	56112	1												1	1											
	56158	1			1																					
	56126	1									1	1	1													
	56118	2		1																						
UNKEMPT APPEARANCE	56142	2				P				P										P	P					
	56161	2				P				P	P	P	P		P					P	P	P				
	56113	2				P				P	P	P	P		P	P				P	P	P				
	56143	2				P				P	P	P	P	P	P	P				P	P	P				
	56136	2					P			P		P	P	P	P	P				P	P	P	P			
	56159	2								P	P	P	P	P	P	P	P	P	P	P	P	P	P			
	56155	2					P			P	P	P	P	P	P	P				P	P	P	P			
	56141	2			P	P	P			P	P	P	P	P	P	P	P	P	P	P	P	P	P			
	56164	2				P				P		P	P		P		P			P		P				
	56131	2				P				P	P	P	P	P	P	P	P	P	P	P	P	P	P			
	56157	2					P							P	P		P			P	P					
	56128	2					P			P		P								P	P	P	P			
	56140	2								P	P	P	P	P	P	P	P	P	P	P	P	P	P			
	56114	2					P				P	P		P	P	P	P	P	P	P	P		P			
	56118	2					P							P	P					P	P					
	56147	2								P	P	P	P	P	P	P	P	P	P	P	P	P	P			
	56152	2					P			P	P	P	P		P	P	P	P	P	P	P	P	P			
	56145	2								P	P	P	P	P	P	P	P	P	P	P		P				
	56120	2					P			P	P		P	P	P	P	P	P	P	P		P				
	56109	2								P		P	P		P				P	P	P		P	P		
	56108	2								P					P				P	P	P					
	56139	2					P			P	P	P	P	P	P	P	P	P	P	P	P	P	P			
GRADE CODE: P = PRESENT 1 = SLIGHT 2 = MODERATE 3 = SEVERE																										
1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY																										

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A1 (DAILY EXAMINATIONS)
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL CLINICAL OBSERVATIONS

PAGE 7

OBSERVATION	ANIMAL	GROUP	GESTATIONAL DAY																				
			0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
UNKEMPT APPEARANCE	56150	2							P					P					P	P			P
	56116	2							P					P	P				P	P		P	P
	56125	2							P		P		P	P	P	P	P	P	P	P	P	P	P
SCABBING DORSAL THORACIC AREA	56152	2			P	P													P				
HAIR LOSS DORSAL HEAD	56106	1											1	1	1	1	1						
	56123	1									1	1	1	1	1								
DRIED RED MATERIAL UROGENITAL AREA	56159	2																	1				
	56155	2																	1				
	56131	2																	1				
	56140	2																	1				
	56147	2															1						
DRIED RED MATERIAL AROUND NOSE	56130	1		1	1	1		1	1	1	1	1	1	1	1	1	1	1	1	1	2	2	1
	56138	1		1	1	1	2	2	1	1		1	1	1	1	1			1			1	1
	56137	1		1	1	1	2	2	1	1	1	1	1	1	1	1		1	1	1	1	1	1
	56154	1		1	1	1	1	1	1	1	1	1	1	2	1	1	1	1	2	2	1	1	
	56133	1		1	1	1				1		1	1				1	1		1	1	1	
	56129	1		1	1	2	2		1	1	1	1	1	1			1	1			1	1	
	56132	1			1	1	1	1		1	1	1	1	1			1	1	1	1	1	1	
	56112	1		1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
	56106	1		1	1	1		1	1		1		1	1			1	1					
	56121	1		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		1	1	
	56156	1		1	1	2	2	1	1	1	1	1	1	1			1		1	1	1	1	
	56107	1		1	1	2		1	1	1	1		1								1	1	

GRADE CODE: P = PRESENT 1 = SLIGHT 2 = MODERATE 3 = SEVERE

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A1 (DAILY EXAMINATIONS)
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL CLINICAL OBSERVATIONS

PAGE 8

OBSERVATION	ANIMAL	GROUP	GESTATIONAL DAY																				
			0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
DRIED RED MATERIAL AROUND NOSE	56134	1		1	2	2	2	1	1	1	1	1	1				1						
	56158	1		1	2	2	2	1	1	1	1	1	1	1	1	1			2	1	1	1	
	56119	1		1	2	2	1	1	1	1	1	1	1		1	1	1	1	1	1	1	1	
	56151	1		1	1	1	1	1	1	1	1	1	1		1	1		1				1	
	56126	1		1	2	2	2		1	1	1	2	2	2	2	1	1	1	2	2		1	1
	56117	1		1	2	2	1	1	1	1	1	1	2	1	1	1	1	2	2	1	1	1	1
	56160	1		1	1	1	1		1	1	1	1	1	1	1			1	1		1	1	
	56123	1		1	1	1	1	1	1	1	1	1	1	2	2	2	2	2	3	2	2	2	
	56115	1		1	1		1	1	1		1	1	1	1	1	1	1		1		1		
	56162	1	1		1	1	1	1	1	1	1	1	1			1							
	56122	1		1	2	2	1	1	1	1	1	1	1		1	1		1	1		1	1	
	56111	1	1	2	2	1	1	1	1	1	1	1	1	1	1	1	2	1	1	1	1	1	1
	56165	1		1	1	1		1	1	1	1	1		1	1	1	1		1	1	1	1	
	56142	2		1	1	1		1	1	1	1	1	1	1		1	1	1	1	1	1	1	
	56161	2		1	1	1	1		1	1	1	1	1	1	1		1	1	1	2	2	1	
	56113	2		1	1	1	1	1		1	1	1	1	1									
	56143	2		1	1	1	1		1	1	1	1				1							
	56136	2		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		1	1
	56159	2		1	1	2		1	1	1	1	1	1	1	1	1	1	1	2	1	1	1	1
	56155	2			1	1	1	1	1		1	1	1	1	1	1	1				1	1	1
	56141	2		1	1	1	1	1	1	1	1	1	1	1		1	1	1	1	2	2		
	56164	2		1	1	2	2	2	1	1	1	1	1			1	1		1	1	1	1	1
	56131	2		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	56157	2		1	1	1		1	1	1			1	1		1	1	1			1	1	1
56128	2		1	1	2	1	1	1	1	1	1	1	1		1	1	1	2	3	2	2		
56140	2			1	1		1	1	1	1		1	1	2	2	1	1	1	3	2		2	
56114	2		1	1	1	1	1	1	1	1		1	1	1		1	1	1	1	1	1	1	

GRADE CODE: P = PRESENT 1 = SLIGHT 2 = MODERATE 3 = SEVERE

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A1 (DAILY EXAMINATIONS)
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL CLINICAL OBSERVATIONS

PAGE 9

OBSERVATION	ANIMAL	GROUP	GESTATIONAL DAY																				
			0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
DRIED RED MATERIAL AROUND NOSE	56118	2	1	1		1		1	1	1	1	1	1	1	1	1	1	1		1	1	1	
	56147	2	1	2	1	1	1	1	1	1	2	2	2	2	1	1	1	2	2	1		2	
	56152	2		2	1	1	1	1	1	1	1	1			1	1	1		2	1			
	56145	2	1	2	1	1	1	1	1	1	1	1	1	1	1			1				1	
	56120	2	1	2	2	1	1	1	1	1	1	1			1	1				1	1	1	
	56109	2		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
	56108	2				1	1	1	1	1	1	1			1	1	1	1			1	1	
	56139	2	1	1	1	1	1	1	1	1	2	2	2	1	1	1	1	1	2			1	
	56150	2				1	1	1	1	1	1	1	1			1	1	1	1	1	1	1	
	56116	2		1	1	1	1	1	1	1	1	1				1						1	
56125	2	1	1	1		1	1	1	1	1	1	1		1	1	1	2	1	1	1	1		
DRIED RED MATERIAL AROUND RIGHT EYE	56130	1		1		1	1	1	1	1	1	1											
	56138	1	1		1			1															
	56137	1		1	1	1	1	1		1													
	56154	1	1	1	1	1	1		1	1	1	1											
	56133	1	1	1												1	1			1			
	56129	1		1	1																		
	56132	1	1		1					1	1												
	56112	1	1	1	2	2	1	1	1	1		1	1							1	1		
	56121	1		1	1		1	1	1		1												
	56107	1	1	1	2	1	1	1					1					1	1	1	1		
	56134	1		1	1	1																	
	56158	1								1													
	56119	1		1	1	1	1	1	1	1	1		1					1					
	56151	1													1			1					
	56126	1		1		1	1		1	1	1								1				

GRADE CODE: P = PRESENT 1 = SLIGHT 2 = MODERATE 3 = SEVERE

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A1 (DAILY EXAMINATIONS)
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL CLINICAL OBSERVATIONS

PAGE 10

OBSERVATION	ANIMAL	GROUP	GESTATIONAL DAY																					
			0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	
DRIED RED MATERIAL AROUND RIGHT EYE	56117	1			1		1		1	1		1											1	
	56160	1			1	1																		
	56123	1						1	1			1												
	56115	1						1			1	1			1					1		1	1	
	56122	1		1	1	1	1				1													
	56111	1		1		1			1	1		1				1	1	1					1	
	56165	1		1																				
	56142	2				1																	1	
	56143	2									1			1										
	56136	2		1	1	1	1						1	1										
	56159	2		1	1	1		1	1	1	1	1	1	1	1		1	1	1	1	1	1	1	1
	56155	2					1	1			1	1	1	1	1							1	1	
	56141	2									1	1								1	1	1		
	56164	2				1	1	1	1		1	1	1									1	1	1
	56131	2			1	1	1	1	1	1	1	1	1	1			1			1				
	56157	2		1	1	1		1	1	1			1	1										
	56128	2		1	1			1			1	1	1						1	1	1	1		
	56140	2		1			1					1		1								1	1	
	56114	2						1			1	1										1	1	
	56118	2		1	1			1			1	1										1		
	56147	2					1			1	1	1	1	1								1		
	56152	2							1	1		1					1	1			1	1		
	56145	2						1	1	1	1	1	1							1				
	56109	2					1		1	1				1										
	56108	2							1															
56139	2		1	1	1	1	1	1	1	1	1	1	1			1	1	1	1	1	1	1	1	
56150	2						1	1								1	1							

GRADE CODE: P = PRESENT 1 = SLIGHT 2 = MODERATE 3 = SEVERE

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A1 (DAILY EXAMINATIONS)
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL CLINICAL OBSERVATIONS

PAGE 11

OBSERVATION	ANIMAL	GROUP	GESTATIONAL DAY																			
			0	1	2	3	4	5	6	7	8	9	0	1	1	1	1	1	1	1	1	2
DRIED RED MATERIAL AROUND RIGHT EYE	56116	2										1	1									
	56125	2				1		1	1	1	1	1										
DRIED RED MATERIAL AROUND LEFT EYE	56130	1			1		1	1	1	1	1	1										
	56138	1		1	1	1			1													
	56154	1		1	1	1						1										
	56133	1		1																		
	56129	1			1	1					1	1										
	56132	1				1																
	56112	1		1	1	1		1	1	1	1		1									
	56106	1		1	1	1		1						1			1	1	1	1	1	
	56121	1			1	1		1	1	1		1	1	1								
	56156	1		1																		
	56107	1		1	1	2	2	1	1	1										1	1	1
	56134	1																			1	
	56158	1									1											
	56119	1		1	1	1	1		1	1	1	1	1						1	1		
	56151	1							1	1	1	1	1	1								
	56126	1		1			1		1	1	1	1	1									
	56117	1					1									1					1	1
	56160	1			1																	
	56123	1											1	1								
	56162	1												1								
	56122	1		1	1	1	1			1	1							1				
	56111	1							1	1			1			1	1	1	1			1
	56165	1			1																	
	56142	2				1																

GRADE CODE: P = PRESENT 1 = SLIGHT 2 = MODERATE 3 = SEVERE

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A1 (DAILY EXAMINATIONS)
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL CLINICAL OBSERVATIONS

PAGE 12

OBSERVATION	ANIMAL	GROUP	GESTATIONAL DAY																				
			0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
DRIED RED MATERIAL AROUND LEFT EYE	56136	2	1	1	1	1																	
	56159	2	1	1	1		1	1	1	1	1	1	1	1		1	1	1	2	1	1		
	56155	2		1							1	1	1	1									
	56141	2																	1	1	1		
	56164	2			1	1	1	1		1	1	1									1		1
	56131	2		1			1		1	1	1								1				
	56157	2	1	1	1	1	1	1	1				1								1	1	
	56128	2		1							1												
	56140	2	1				1		1	1	1		1							1	1		
	56114	2			1		1		1	1										1	1		
	56118	2	1			1			1														
	56147	2				1		1	1	1	1	1											
	56152	2						1	1		1						1	1		1	1		
	56145	2					1	1	1	1	1												
	56120	2							1														
	56109	2				1			1														
	56108	2						1								1	1		1	1			
	56139	2	1	1	1	1	1				1						1	1	1	1	1	1	1
	56150	2					1	1	1	1		1											
	56125	2				1		1		1						1							
WET CLEAR MATERIAL AROUND RIGHT EYE	56130	1		1		1							1								1	1	
	56138	1										1											
	56137	1		1							1	1										1	
	56154	1											1			1	1		1	1			
	56133	1									1												
	56129	1										1											

GRADE CODE: P = PRESENT 1 = SLIGHT 2 = MODERATE 3 = SEVERE

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A1 (DAILY EXAMINATIONS)
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL CLINICAL OBSERVATIONS

PAGE 13

OBSERVATION	ANIMAL	GROUP	GESTATIONAL DAY																				
			0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
WET CLEAR MATERIAL AROUND RIGHT EYE	56132	1										1											
	56112	1										1											
	56121	1										1	1						1	1			
	56107	1							1	1	1	1				1							
	56134	1														1		1	1	1			
	56158	1																	1				
	56119	1																	1			1	
	56151	1						1															
	56126	1										1	1										
	56117	1																	1				1
	56123	1										1					1		1	1			
	56115	1										1											
	56162	1															1						
	56122	1							1	1													
	56111	1										1					1						
	56165	1										1											
	56142	2		1	1				1			1		1	1	1	1						1
	56161	2			1				1			1					1	1	1	1			
	56113	2		1					1				1	1	1	1				1			1
	56143	2											1							1			1
	56136	2						1		1				1	1				1	1			1
	56159	2															1			2			1
	56155	2		1													1	1	1	1			
	56141	2										1		1	1	1			1			1	1
	56164	2		1										1	1	1	1	1					
	56131	2													1	1	1		1			1	1
	56157	2										1	1				1						

GRADE CODE: P = PRESENT 1 = SLIGHT 2 = MODERATE 3 = SEVERE

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A1 (DAILY EXAMINATIONS)
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL CLINICAL OBSERVATIONS

PAGE 14

OBSERVATION	ANIMAL	GROUP	GESTATIONAL DAY																		
			0	1	2	3	4	5	6	7	8	9	0	1	1	1	1	1	1	1	2
WET CLEAR MATERIAL AROUND RIGHT EYE	56128	2											1	1	1						1
	56140	2						1	1	1		1		1	1	1	1	2		1	
	56114	2										1		1	1	1	1	2			
	56118	2					1	1			1	1	1	1	1				1	1	
	56147	2						1					1	1	1		1		1	1	1
	56152	2				1	1			1			1	1							
	56145	2											1	1	1	1	1		1		1
	56120	2						1						1	1	1	1	1		1	
	56109	2									1		1	1	1	1	1			1	
	56108	2									1		1			1	1				
	56139	2											1	1	1			1			
	56150	2								1	1	1		1	1					1	
	56116	2				1		1	1	1		1	1	1	1	1	2		1	1	1
	56125	2											1								
WET CLEAR MATERIAL AROUND LEFT EYE	56130	1			1	1							1	1						1	
	56138	1											1								
	56137	1			1								1								
	56154	1											1	1	1				1		
	56133	1											1								
	56129	1											1								
	56132	1											1	1							
	56112	1											1		1						
	56106	1										1	1								
	56121	1															1		1		
	56107	1		1								1	1	1	1		1		1		
	56134	1																1	1		

GRADE CODE: P = PRESENT 1 = SLIGHT 2 = MODERATE 3 = SEVERE

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A1 (DAILY EXAMINATIONS)
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL CLINICAL OBSERVATIONS

PAGE 15

OBSERVATION	ANIMAL	GROUP	GESTATIONAL DAY																				
			0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
WET CLEAR MATERIAL AROUND LEFT EYE	56126	1	1																		1		
	56117	1																		1			
	56123	1						1								1			1	1			
	56162	1										1											
	56122	1	1																				
	56165	1					1																
	56142	2		1	1			1		1	1	1	1	1	1				1			1	
	56161	2					1			1						1							
	56113	2					1	1		1	1	1	1	1	1								
	56143	2																1					
	56136	2										1	1	1	1	1			1				
	56159	2														1			2			1	
	56155	2						1								1	1	1					
	56141	2								1		1	1	1	1	1							1
	56164	2		1									1	1	1	1	1					1	
	56131	2										1	1	1	1	1	1	1					1
	56157	2								1	1	1				1							
	56128	2					1				1	1			1	1						1	
	56140	2					1					1			1	1	1	1	2		1		
	56114	2									1	1	1	1	1	1	1	1	2				
	56118	2					1	1					1	1		1	3						
	56147	2												1	1	1	1	1	1		1		1
	56152	2				1	1			1		1	1	1									
	56145	2										1	1	1	1	1	1	1		1		1	
	56120	2										1											
56109	2					1		1	1	1	1	1	1	1	1	1			1	1	1		
56108	2										1	1	1				1		1				

GRADE CODE: P = PRESENT 1 = SLIGHT 2 = MODERATE 3 = SEVERE

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A1 (DAILY EXAMINATIONS)
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL CLINICAL OBSERVATIONS

PAGE 16

OBSERVATION	ANIMAL	GROUP	GESTATIONAL DAY																				
			0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
WET CLEAR MATERIAL AROUND LEFT EYE	56139	2							1		1	1	1	1		1							
	56150	2								1		1	1	1		1							
	56116	2			1			1	1	1	1	1	1	1	1	2	1	1	1	1	1	1	
	56125	2										1											
WET RED MATERIAL AROUND RIGHT EYE	56113	2			1																		
	56116	2																1					
WET RED MATERIAL AROUND LEFT EYE	56136	2						1															
WET RED MATERIAL AROUND NOSE	56143	2					1																
	56140	2		1							1												
	56114	2									1												
HAIR LOSS AROUND LEFT EYE	56121	1																	1				
	56122	1											1										
WET CLEAR MATERIAL AROUND NOSE	56134	1													1						1	1	
	56126	1																		1			
	56123	1																	1				
	56142	2																			1		
	56143	2														1	1				1		
	56155	2														1	1						
	56141	2																		1	1		
	56128	2																		1			
	56140	2																		1	1		
	56147	2																			2		

GRADE CODE: P = PRESENT 1 = SLIGHT 2 = MODERATE 3 = SEVERE

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A1 (DAILY EXAMINATIONS)
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL CLINICAL OBSERVATIONS

PAGE 17

OBSERVATION	ANIMAL	GROUP	GESTATIONAL DAY																							
			0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0			
WET CLEAR MATERIAL AROUND NOSE	56145	2																					1	1		
	56139	2																					1	1		
	56116	2																					1			
LACRIMATION RIGHT EYE	56164	2																					1			
LACRIMATION LEFT EYE	56164	2																					1			
GRADE CODE: P = PRESENT 1 = SLIGHT 2 = MODERATE 3 = SEVERE																										
1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY																										

PCov3.13
11/11/2009
R:04/15/2010

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A2 (AT TIME OF DOSING)
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL POST-DOSE OBSERVATIONS

PAGE 1

- - - F E M A L E S - - -

OBSERVATION: TIME OF DOSE	ANIMAL	GD GP																	1	1	1	1	1	1	1	1	1	1
			0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9						

NORMAL																												
NO SIGNIFICANT CLINICAL OBSERVATIONS		56130	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56138	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56137	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56154	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56133	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56129	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56132	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56112	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56106	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56121	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56156	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56107	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56134	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56158	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56119	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56151	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56126	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56117	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56160	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56123	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56115	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56162	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56122	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56111	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56165	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56142	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56161	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56113	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56143	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			
		56136	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P			

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

GRADE CODE: P = PRESENT 1 = SLIGHT 2 = MODERATE 3 = SEVERE

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A2 (AT TIME OF DOSING)
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL POST-DOSE OBSERVATIONS

PAGE 2

- - - F E M A L E S - - -

OBSERVATION: TIME OF DOSE	ANIMAL	GD GP	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1																			
			0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
NO SIGNIFICANT CLINICAL OBSERVATIONS	56159	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56155	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56141	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56164	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56131	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56157	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56128	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56140	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56114	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56118	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56147	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56152	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56145	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56120	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56109	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56108	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56139	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56150	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56116	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56125	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

GRADE CODE: P = PRESENT 1 = SLIGHT 2 = MODERATE 3 = SEVERE

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PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A3 (1-2 HOURS POST-DOSING)
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL POST-DOSE OBSERVATIONS

PAGE 1

- - - F E M A L E S - - -

OBSERVATION: 1-2 HOURS POST-DOSING	ANIMAL	GD GP																	1	1	1	1	1	1	1	1	1
			0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9					

NORMAL																											
NO SIGNIFICANT CLINICAL OBSERVATIONS	56130	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56138	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56137	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56154	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56133	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56129	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56132	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56112	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56106	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56121	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56156	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56107	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56134	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56158	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56119	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56151	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56126	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56117	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56160	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56123	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56115	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56162	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56122	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56111	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56165	1	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56142	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56161	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56113	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56143	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		
	56136	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		

1- 0 MG/KG/DAY	2- 1000 MG/KG/DAY																										

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

GRADE CODE: P = PRESENT 1 = SLIGHT 2 = MODERATE 3 = SEVERE

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A3 (1-2 HOURS POST-DOSING)
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL POST-DOSE OBSERVATIONS

PAGE 2

- - - F E M A L E S - - -

OBSERVATION: 1-2 HOURS POST-DOSING	ANIMAL	GD GP	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1																			
			0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
NO SIGNIFICANT CLINICAL OBSERVATIONS	56159	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56155	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56141	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56164	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56131	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56157	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56128	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56140	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56114	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56118	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56147	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56152	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56145	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56120	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56109	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56108	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56139	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56150	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56116	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	56125	2	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
EYES/EARS/NOSE																						
LACRIMATION RIGHT EYE	56128	2																		1		
	56109	2																		1		
LACRIMATION LEFT EYE	56128	2																			1	
	56109	2																			1	
EXCRETA																						
WET RED VAGINAL DISCHARGE	56121	1																	P			
	56140	2																	P			

1- 0 MG/KG/DAY 2- 1000 MG/KG/DAY

GRADE CODE: P = PRESENT 1 = SLIGHT 2 = MODERATE 3 = SEVERE

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PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A4
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL DERMAL OBSERVATIONS

PAGE 1

GROUP : 0 MG/KG/DAY		ANIMAL NO. / SEX								
56130/F		56138/F	56137/F	56154/F	56133/F	56129/F	56132/F	56112/F	56106/F	56121/F
GESTATION DAY	ERYTHEMA+/EDEMA+/OTHER FINDINGS									
0	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
1	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
2	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
3	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
4	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
5	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
6	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
7	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
8	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
9	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
10	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
11	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
12	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
13	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
14	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
15	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
16	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
17	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
18	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
19	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
20	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR

+ = REFER TO DRAIZE SCALE FOR DERMAL SCORING CRITERIA
SEX CODE: M = MALE F = FEMALE
SNR = SCORED, NOT REMARKABLE

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A4
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL DERMAL OBSERVATIONS

PAGE 2

GROUP : 0 MG/KG/DAY		ANIMAL NO. / SEX								
56156/F		56107/F	56134/F	56158/F	56119/F	56151/F	56126/F	56117/F	56160/F	56123/F
GESTATION DAY	ERYTHEMA+/EDEMA+/OTHER FINDINGS									
0	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
1	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
2	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
3	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
4	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
5	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
6	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
7	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
8	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
9	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
10	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
11	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
12	SNR	SNR	SNR	SNR	0/0/d	SNR	SNR	SNR	SNR	SNR
13	SNR	SNR	SNR	SNR	0/0/d	SNR	SNR	SNR	SNR	SNR
14	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
15	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
16	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
17	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
18	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
19	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
20	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR

+ = REFER TO DRAIZE SCALE FOR DERMAL SCORING CRITERIA
SEX CODE: M = MALE F = FEMALE
d = DESQUAMATION, SNR = SCORED, NOT REMARKABLE

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A4
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL DERMAL OBSERVATIONS

PAGE 3

GROUP : 0 MG/KG/DAY						ANIMAL NO. / SEX					
56115/F						56162/F					
56122/F						56111/F					
56165/F											
GESTATION DAY						ERYTHEMA+/EDEMA+/OTHER FINDINGS					
0	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
1	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
2	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
3	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
4	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
5	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
6	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
7	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
8	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
9	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
10	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
11	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
12	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
13	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
14	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
15	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
16	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
17	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
18	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
19	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
20	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR

+ = REFER TO DRAIZE SCALE FOR DERMAL SCORING CRITERIA
SEX CODE: M = MALE F = FEMALE
d = DESQUAMATION, SNR = SCORED, NOT REMARKABLE

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A4
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL DERMAL OBSERVATIONS

PAGE 4

GROUP : 1000 MG/KG/DAY		ANIMAL NO. / SEX								
56142/F		56161/F	56113/F	56143/F	56136/F	56159/F	56155/F	56141/F	56164/F	56131/F
GESTATION DAY	ERYTHEMA+/EDEMA+/OTHER FINDINGS									
0	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
1	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
2	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
3	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
4	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
5	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
6	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
7	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
8	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
9	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
10	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
11	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
12	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
13	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
14	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
15	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
16	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
17	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
18	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
19	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
20	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR

+ = REFER TO DRAIZE SCALE FOR DERMAL SCORING CRITERIA
SEX CODE: M = MALE F = FEMALE
d = DESQUAMATION, SNR = SCORED, NOT REMARKABLE

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A4
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL DERMAL OBSERVATIONS

PAGE 5

GROUP : 1000 MG/KG/DAY				ANIMAL NO. / SEX															
56157/F		56128/F		56140/F		56114/F		56118/F		56147/F		56152/F		56145/F		56120/F		56109/F	
GESTATION DAY		ERYTHEMA+/EDEMA+/OTHER FINDINGS																	
0	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
1	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
2	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
3	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
4	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
5	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
6	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
7	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
8	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
9	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
10	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
11	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
12	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
13	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
14	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
15	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
16	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
17	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
18	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
19	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR
20	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR	SNR

+ = REFER TO DRAIZE SCALE FOR DERMAL SCORING CRITERIA
SEX CODE: M = MALE F = FEMALE
d = DESQUAMATION, SNR = SCORED, NOT REMARKABLE

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A4
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL DERMAL OBSERVATIONS

PAGE 6

GROUP : 1000 MG/KG/DAY					
ANIMAL NO. / SEX					
56108/F 56139/F 56150/F 56116/F 56125/F					
GESTATION DAY	ERYTHEMA+/EDEMA+/OTHER FINDINGS				
0	SNR	SNR	SNR	SNR	SNR
1	SNR	SNR	SNR	SNR	SNR
2	SNR	SNR	SNR	SNR	SNR
3	SNR	SNR	SNR	SNR	SNR
4	SNR	SNR	SNR	SNR	SNR
5	SNR	SNR	SNR	SNR	SNR
6	SNR	SNR	SNR	SNR	SNR
7	SNR	SNR	SNR	SNR	SNR
8	SNR	SNR	SNR	SNR	SNR
9	SNR	SNR	SNR	SNR	SNR
10	SNR	SNR	SNR	SNR	SNR
11	SNR	SNR	SNR	SNR	SNR
12	SNR	SNR	SNR	SNR	SNR
13	SNR	SNR	SNR	SNR	SNR
14	SNR	SNR	SNR	SNR	SNR
15	SNR	SNR	SNR	SNR	SNR
16	SNR	SNR	SNR	SNR	SNR
17	SNR	SNR	SNR	SNR	SNR
18	SNR	SNR	SNR	SNR	SNR
19	SNR	SNR	SNR	SNR	SNR
20	SNR	SNR	SNR	SNR	SNR

+ = REFER TO DRAIZE SCALE FOR DERMAL SCORING CRITERIA
SEX CODE: M = MALE F = FEMALE
d = DESQUAMATION, SNR = SCORED, NOT REMARKABLE

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PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A5
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL BODY WEIGHTS DURING GESTATION [G]

PAGE 1

PREGNANCY STATUS		DAY 0	3	6	9	12	15	18	20				
DAMS	FROM GROUP 1:	0 MG/KG/DAY											
56106	G	247.	251.	259.	268.	280.	297.	330.	358.	SCHEDULED	NECROPSY	DAY 20	
56107	G	237.	243.	252.	261.	272.	290.	321.	342.	SCHEDULED	NECROPSY	DAY 20	
56111	G	242.	247.	257.	268.	273.	293.	329.	359.	SCHEDULED	NECROPSY	DAY 20	
56112	G	248.	265.	272.	291.	311.	321.	365.	387.	SCHEDULED	NECROPSY	DAY 20	
56115	G	259.	270.	287.	293.	309.	325.	369.	412.	SCHEDULED	NECROPSY	DAY 20	
56117	G	248.	265.	280.	284.	291.	311.	355.	390.	SCHEDULED	NECROPSY	DAY 20	
56119	G	225.	234.	249.	249.	266.	289.	329.	362.	SCHEDULED	NECROPSY	DAY 20	
56121	G	246.	254.	266.	277.	294.	305.	353.	385.	SCHEDULED	NECROPSY	DAY 20	
56122	G	271.	273.	294.	297.	318.	342.	383.	422.	SCHEDULED	NECROPSY	DAY 20	
56123	G	255.	272.	287.	294.	303.	321.	355.	382.	SCHEDULED	NECROPSY	DAY 20	
56126	G	245.	243.	253.	267.	288.	300.	346.	380.	SCHEDULED	NECROPSY	DAY 20	
56129	G	254.	261.	274.	282.	300.	322.	378.	416.	SCHEDULED	NECROPSY	DAY 20	
56130	G	237.	246.	259.	275.	281.	306.	347.	384.	SCHEDULED	NECROPSY	DAY 20	
56132	G	251.	268.	286.	294.	315.	337.	383.	423.	SCHEDULED	NECROPSY	DAY 20	
56133	NG	267.	275.	289.	296.	309.	298.	292.	299.	SCHEDULED	NECROPSY	DAY 20	
56134	G	235.	241.	256.	275.	283.	300.	342.	369.	SCHEDULED	NECROPSY	DAY 20	
56137	G	256.	263.	277.	291.	305.	324.	351.	386.	SCHEDULED	NECROPSY	DAY 20	
56138	G	250.	261.	274.	283.	299.	314.	359.	395.	SCHEDULED	NECROPSY	DAY 20	
56151	G	229.	241.	246.	266.	277.	290.	328.	366.	SCHEDULED	NECROPSY	DAY 20	
56154	G	270.	270.	283.	287.	298.	329.	377.	410.	SCHEDULED	NECROPSY	DAY 20	
56156	G	243.	248.	259.	272.	286.	297.	331.	362.	SCHEDULED	NECROPSY	DAY 20	
56158	G	233.	250.	268.	288.	308.	337.	383.	410.	SCHEDULED	NECROPSY	DAY 20	
56160	G	248.	264.	277.	281.	300.	316.	358.	392.	SCHEDULED	NECROPSY	DAY 20	
56162	G	262.	275.	280.	305.	317.	339.	394.	433.	SCHEDULED	NECROPSY	DAY 20	
56165	G	242.	252.	265.	273.	293.	308.	348.	390.	SCHEDULED	NECROPSY	DAY 20	
MEAN		247.	257.	269.	280.	294.	313.	355.	388.				
S.D.		11.6	12.1	13.7	13.2	15.0	16.7	20.9	23.8				
S.E.		2.4	2.5	2.8	2.7	3.1	3.4	4.3	4.9				
N		24	24	24	24	24	24	24	24				

G = GRAVID NG = NONGRAVID - WEIGHT(S) NOT INCLUDED IN CALCULATION OF MEAN

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A5
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL BODY WEIGHTS DURING GESTATION [G]

PAGE 2

PREGNANCY STATUS		DAY 0	3	6	9	12	15	18	20			
DAMS FROM GROUP 2:		1000 MG/KG/DAY										
56108	G	260.	264.	275.	292.	304.	330.	367.	408.	SCHEDULED	NECROPSY	DAY 20
56109	G	253.	261.	271.	283.	296.	318.	363.	403.	SCHEDULED	NECROPSY	DAY 20
56113	G	275.	278.	294.	300.	317.	342.	384.	406.	SCHEDULED	NECROPSY	DAY 20
56114	G	229.	226.	239.	248.	263.	279.	315.	344.	SCHEDULED	NECROPSY	DAY 20
56116	G	265.	270.	289.	302.	321.	338.	387.	417.	SCHEDULED	NECROPSY	DAY 20
56118	G	220.	231.	243.	257.	266.	292.	330.	362.	SCHEDULED	NECROPSY	DAY 20
56120	G	251.	259.	273.	285.	304.	324.	364.	405.	SCHEDULED	NECROPSY	DAY 20
56125	G	243.	257.	269.	285.	303.	319.	366.	413.	SCHEDULED	NECROPSY	DAY 20
56128	G	240.	242.	255.	257.	268.	280.	320.	349.	SCHEDULED	NECROPSY	DAY 20
56131	G	247.	256.	268.	277.	298.	312.	349.	386.	SCHEDULED	NECROPSY	DAY 20
56136	G	260.	277.	296.	299.	319.	339.	389.	416.	SCHEDULED	NECROPSY	DAY 20
56139	G	262.	282.	282.	299.	306.	320.	355.	404.	SCHEDULED	NECROPSY	DAY 20
56140	G	236.	229.	230.	241.	260.	273.	310.	345.	SCHEDULED	NECROPSY	DAY 20
56141	G	249.	255.	270.	280.	290.	302.	327.	358.	SCHEDULED	NECROPSY	DAY 20
56142	NG	235.	239.	250.	261.	271.	261.	258.	263.	SCHEDULED	NECROPSY	DAY 20
56143	G	283.	282.	296.	304.	322.	342.	393.	430.	SCHEDULED	NECROPSY	DAY 20
56145	G	248.	259.	271.	295.	310.	331.	361.	399.	SCHEDULED	NECROPSY	DAY 20
56147	G	231.	239.	249.	261.	269.	290.	335.	366.	SCHEDULED	NECROPSY	DAY 20
56150	G	266.	286.	277.	286.	311.	328.	379.	407.	SCHEDULED	NECROPSY	DAY 20
56152	G	240.	248.	252.	260.	277.	297.	336.	371.	SCHEDULED	NECROPSY	DAY 20
56155	G	249.	254.	266.	285.	298.	299.	354.	386.	SCHEDULED	NECROPSY	DAY 20
56157	G	242.	240.	246.	259.	275.	289.	333.	369.	SCHEDULED	NECROPSY	DAY 20
56159	G	256.	255.	258.	271.	281.	298.	337.	373.	SCHEDULED	NECROPSY	DAY 20
56161	G	242.	243.	261.	266.	288.	298.	338.	365.	SCHEDULED	NECROPSY	DAY 20
56164	G	247.	257.	271.	280.	302.	315.	365.	400.	SCHEDULED	NECROPSY	DAY 20
MEAN		250.	256.	267.	278.	294.	311.	352.	387.			
S.D.		14.6	17.1	17.9	18.3	19.6	21.2	24.3	25.4			
S.E.		3.0	3.5	3.7	3.7	4.0	4.3	5.0	5.2			
N		24	24	24	24	24	24	24	24			

G = GRAVID NG = NONGRAVID - WEIGHT(S) NOT INCLUDED IN CALCULATION OF MEAN

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R:04/15/2010

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A6
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL BODY WEIGHT CHANGES DURING GESTATION [G]

PAGE 1

PREGNANCY STATUS		DAY 0- 3	3- 6	6- 9	9-12	12-15	15-18	18-20	0-20		
DAMS FROM GROUP 1:		0 MG/KG/DAY									
56106	G	4.	8.	9.	12.	17.	33.	28.	111.	SCHEDULED NECROPSY	DAY 20
56107	G	6.	9.	9.	11.	18.	31.	21.	105.	SCHEDULED NECROPSY	DAY 20
56111	G	5.	10.	11.	5.	20.	36.	30.	117.	SCHEDULED NECROPSY	DAY 20
56112	G	17.	7.	19.	20.	10.	44.	22.	139.	SCHEDULED NECROPSY	DAY 20
56115	G	11.	17.	6.	16.	16.	44.	43.	153.	SCHEDULED NECROPSY	DAY 20
56117	G	17.	15.	4.	7.	20.	44.	35.	142.	SCHEDULED NECROPSY	DAY 20
56119	G	9.	15.	0.	17.	23.	40.	33.	137.	SCHEDULED NECROPSY	DAY 20
56121	G	8.	12.	11.	17.	11.	48.	32.	139.	SCHEDULED NECROPSY	DAY 20
56122	G	2.	21.	3.	21.	24.	41.	39.	151.	SCHEDULED NECROPSY	DAY 20
56123	G	17.	15.	7.	9.	18.	34.	27.	127.	SCHEDULED NECROPSY	DAY 20
56126	G	-2.	10.	14.	21.	12.	46.	34.	135.	SCHEDULED NECROPSY	DAY 20
56129	G	7.	13.	8.	18.	22.	56.	38.	162.	SCHEDULED NECROPSY	DAY 20
56130	G	9.	13.	16.	6.	25.	41.	37.	147.	SCHEDULED NECROPSY	DAY 20
56132	G	17.	18.	8.	21.	22.	46.	40.	172.	SCHEDULED NECROPSY	DAY 20
56133	NG	8.	14.	7.	13.	-11.	-6.	7.	32.	SCHEDULED NECROPSY	DAY 20
56134	G	6.	15.	19.	8.	17.	42.	27.	134.	SCHEDULED NECROPSY	DAY 20
56137	G	7.	14.	14.	14.	19.	27.	35.	130.	SCHEDULED NECROPSY	DAY 20
56138	G	11.	13.	9.	16.	15.	45.	36.	145.	SCHEDULED NECROPSY	DAY 20
56151	G	12.	5.	20.	11.	13.	38.	38.	137.	SCHEDULED NECROPSY	DAY 20
56154	G	0.	13.	4.	11.	31.	48.	33.	140.	SCHEDULED NECROPSY	DAY 20
56156	G	5.	11.	13.	14.	11.	34.	31.	119.	SCHEDULED NECROPSY	DAY 20
56158	G	17.	18.	20.	20.	29.	46.	27.	177.	SCHEDULED NECROPSY	DAY 20
56160	G	16.	13.	4.	19.	16.	42.	34.	144.	SCHEDULED NECROPSY	DAY 20
56162	G	13.	5.	25.	12.	22.	55.	39.	171.	SCHEDULED NECROPSY	DAY 20
56165	G	10.	13.	8.	20.	15.	40.	42.	148.	SCHEDULED NECROPSY	DAY 20
MEAN		9.	13.	11.	14.	19.	42.	33.	141.		
S.D.		5.7	4.0	6.4	5.1	5.5	7.0	5.9	18.2		
S.E.		1.2	0.8	1.3	1.0	1.1	1.4	1.2	3.7		
N		24	24	24	24	24	24	24	24		

G = GRAVID NG = NONGRAVID - WEIGHT(S) NOT INCLUDED IN CALCULATION OF MEAN

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A6
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL BODY WEIGHT CHANGES DURING GESTATION [G]

PAGE 2

PREGNANCY STATUS		DAY 0- 3	3- 6	6- 9	9-12	12-15	15-18	18-20	0-20		
DAMS FROM GROUP 2: 1000 MG/KG/DAY											
56108	G	4.	11.	17.	12.	26.	37.	41.	148.	SCHEDULED	NECROPSY DAY 20
56109	G	8.	10.	12.	13.	22.	45.	40.	150.	SCHEDULED	NECROPSY DAY 20
56113	G	3.	16.	6.	17.	25.	42.	22.	131.	SCHEDULED	NECROPSY DAY 20
56114	G	-3.	13.	9.	15.	16.	36.	29.	115.	SCHEDULED	NECROPSY DAY 20
56116	G	5.	19.	13.	19.	17.	49.	30.	152.	SCHEDULED	NECROPSY DAY 20
56118	G	11.	12.	14.	9.	26.	38.	32.	142.	SCHEDULED	NECROPSY DAY 20
56120	G	8.	14.	12.	19.	20.	40.	41.	154.	SCHEDULED	NECROPSY DAY 20
56125	G	14.	12.	16.	18.	16.	47.	47.	170.	SCHEDULED	NECROPSY DAY 20
56128	G	2.	13.	2.	11.	12.	40.	29.	109.	SCHEDULED	NECROPSY DAY 20
56131	G	9.	12.	9.	21.	14.	37.	37.	139.	SCHEDULED	NECROPSY DAY 20
56136	G	17.	19.	3.	20.	20.	50.	27.	156.	SCHEDULED	NECROPSY DAY 20
56139	G	20.	0.	17.	7.	14.	35.	49.	142.	SCHEDULED	NECROPSY DAY 20
56140	G	-7.	1.	11.	19.	13.	37.	35.	109.	SCHEDULED	NECROPSY DAY 20
56141	G	6.	15.	10.	10.	12.	25.	31.	109.	SCHEDULED	NECROPSY DAY 20
56142	NG	4.	11.	11.	10.	-10.	-3.	5.	28.	SCHEDULED	NECROPSY DAY 20
56143	G	-1.	14.	8.	18.	20.	51.	37.	147.	SCHEDULED	NECROPSY DAY 20
56145	G	11.	12.	24.	15.	21.	30.	38.	151.	SCHEDULED	NECROPSY DAY 20
56147	G	8.	10.	12.	8.	21.	45.	31.	135.	SCHEDULED	NECROPSY DAY 20
56150	G	20.	-9.	9.	25.	17.	51.	28.	141.	SCHEDULED	NECROPSY DAY 20
56152	G	8.	4.	8.	17.	20.	39.	35.	131.	SCHEDULED	NECROPSY DAY 20
56155	G	5.	12.	19.	13.	1.	55.	32.	137.	SCHEDULED	NECROPSY DAY 20
56157	G	-2.	6.	13.	16.	14.	44.	36.	127.	SCHEDULED	NECROPSY DAY 20
56159	G	-1.	3.	13.	10.	17.	39.	36.	117.	SCHEDULED	NECROPSY DAY 20
56161	G	1.	18.	5.	22.	10.	40.	27.	123.	SCHEDULED	NECROPSY DAY 20
56164	G	10.	14.	9.	22.	13.	50.	35.	153.	SCHEDULED	NECROPSY DAY 20
MEAN		7.	10.	11.	16.	17.	42.	34.	137.		
S.D.		7.0	6.6	5.1	4.9	5.7	7.2	6.4	16.8		
S.E.		1.4	1.4	1.0	1.0	1.2	1.5	1.3	3.4		
N		24	24	24	24	24	24	24	24		

G = GRAVID NG = NONGRAVID - WEIGHT(S) NOT INCLUDED IN CALCULATION OF MEAN

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SPONSOR:AMERICAN PETROLEUM

TABLE A7
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL GRAVID UTERINE WTS. AND NET BODY WT. CHANGES [G]

PAGE 1

PREGNANCY STATUS		INITIAL BODY WT.	TERMINAL BODY WT.	GRAVID UTERINE WT.	NET BODY WT.	NET BODY WT. CHANGE
DAM #	GROUP	1:	0 MG/KG/DAY			
56106	G	247.	358.	63.9	294.1	47.1
56107	G	237.	342.	66.3	275.7	38.7
56111	G	242.	359.	75.7	283.3	41.3
56112	G	248.	387.	76.2	310.8	62.8
56115	G	259.	412.	90.1	321.9	62.9
56117	G	248.	390.	76.6	313.4	65.4
56119	G	225.	362.	85.3	276.7	51.7
56121	G	246.	385.	86.4	298.6	52.6
56122	G	271.	422.	94.1	327.9	56.9
56123	G	255.	382.	73.0	309.0	54.0
56126	G	245.	380.	90.6	289.4	44.4
56129	G	254.	416.	101.8	314.2	60.2
56130	G	237.	384.	88.0	296.0	59.0
56132	G	251.	423.	93.0	330.0	79.0
56133	NG	267.	299.	NA	NA	NA
56134	G	235.	369.	88.7	280.3	45.3
56137	G	256.	386.	77.4	308.6	52.6
56138	G	250.	395.	85.4	309.6	59.6
56151	G	229.	366.	86.5	279.5	50.5
56154	G	270.	410.	102.8	307.2	37.2
56156	G	243.	362.	70.9	291.1	48.1
56158	G	233.	410.	71.6	338.4	105.4
56160	G	248.	392.	90.5	301.5	53.5
56162	G	262.	433.	100.1	332.9	70.9
56165	G	242.	390.	89.0	301.0	59.0
MEAN		247.	388.	84.3	303.8	56.6
S.D.		11.6	23.8	10.84	18.22	14.38
S.E.		2.4	4.9	2.21	3.72	2.94
N		24	24	24	24	24

G = GRAVID, NG = NONGRAVID, NOT INCLUDED IN CALCULATION OF THE MEAN
NA = NOT APPLICABLE

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A7
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL GRAVID UTERINE WTS. AND NET BODY WT. CHANGES [G]

PAGE 2

PREGNANCY STATUS		INITIAL BODY WT.	TERMINAL BODY WT.	GRAVID UTERINE WT.	NET BODY WT.	NET BODY WT. CHANGE
DAM #	GROUP	2: 1000 MG/KG/DAY				
56108	G	260.	408.	89.1	318.9	58.9
56109	G	253.	403.	91.4	311.6	58.6
56113	G	275.	406.	80.9	325.1	50.1
56114	G	229.	344.	70.1	273.9	44.9
56116	G	265.	417.	84.2	332.8	67.8
56118	G	220.	362.	78.2	283.8	63.8
56120	G	251.	405.	83.6	321.4	70.4
56125	G	243.	413.	95.4	317.6	74.6
56128	G	240.	349.	70.1	278.9	38.9
56131	G	247.	386.	83.9	302.1	55.1
56136	G	260.	416.	99.1	316.9	56.9
56139	G	262.	404.	90.0	314.0	52.0
56140	G	236.	345.	77.4	267.6	31.6
56141	G	249.	358.	64.5	293.5	44.5
56142	NG	235.	263.	NA	NA	NA
56143	G	283.	430.	95.4	334.6	51.6
56145	G	248.	399.	76.3	322.7	74.7
56147	G	231.	366.	82.5	283.5	52.5
56150	G	266.	407.	85.0	322.0	56.0
56152	G	240.	371.	76.3	294.7	54.7
56155	G	249.	386.	88.1	297.9	48.9
56157	G	242.	369.	87.0	282.0	40.0
56159	G	256.	373.	90.9	282.1	26.1
56161	G	242.	365.	71.1	293.9	51.9
56164	G	247.	400.	94.2	305.8	58.8
MEAN		250.	387.	83.5	303.2	53.5
S.D.		14.6	25.4	9.13	19.67	12.19
S.E.		3.0	5.2	1.86	4.02	2.49
N		24	24	24	24	24

G = GRAVID, NG = NONGRAVID, NOT INCLUDED IN CALCULATION OF THE MEAN
NA = NOT APPLICABLE

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SPONSOR:AMERICAN PETROLEUM

TABLE A8
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL FOOD CONSUMPTION DURING GESTATION [G/ANIMAL/DAY]

PAGE 1

PREGNANCY STATUS		DAY	0- 3	3- 6	6- 9	9-12	12-15	15-18	18-20	0-20		
DAMS FROM GROUP 1: 0 MG/KG/DAY												
56106	G		21.	26.	28.	27.	30.	31.	31.	28.	SCHEDULED NECROPSY	DAY 20
56107	G		23.	29.	31.	27.	27.	30.	27.	28.	SCHEDULED NECROPSY	DAY 20
56111	G		26.	27.	27.	27.	31.	35.	33.	29.	SCHEDULED NECROPSY	DAY 20
56112	G		26.	28.	31.	30.	26.	33.	30.	29.	SCHEDULED NECROPSY	DAY 20
56115	G		27.	29.	30.	30.	32.	34.	36.	31.	SCHEDULED NECROPSY	DAY 20
56117	G		25.	28.	28.	26.	29.	35.	38.	29.	SCHEDULED NECROPSY	DAY 20
56119	G		24.	25.	25.	27.	27.	31.	31.	27.	SCHEDULED NECROPSY	DAY 20
56121	G		32.	37.	31.	33.	29.	35.	36.	33.	SCHEDULED NECROPSY	DAY 20
56122	G		28.	31.	27.	32.	35.	33.	32.	31.	SCHEDULED NECROPSY	DAY 20
56123	G		28.	30.	31.	33.	31.	35.	NA	NA	SCHEDULED NECROPSY	DAY 20
56126	G		21.	26.	24.	30.	29.	30.	32.	27.	SCHEDULED NECROPSY	DAY 20
56129	G		26.	27.	30.	29.	32.	35.	39.	31.	SCHEDULED NECROPSY	DAY 20
56130	G		25.	32.	32.	27.	29.	30.	32.	30.	SCHEDULED NECROPSY	DAY 20
56132	G		31.	31.	30.	33.	32.	36.	37.	32.	SCHEDULED NECROPSY	DAY 20
56133	NG		30.	31.	30.	30.	23.	20.	28.	27.	SCHEDULED NECROPSY	DAY 20
56134	G		22.	28.	29.	28.	29.	30.	31.	28.	SCHEDULED NECROPSY	DAY 20
56137	G		26.	29.	32.	30.	31.	29.	35.	30.	SCHEDULED NECROPSY	DAY 20
56138	G		26.	29.	29.	31.	31.	33.	34.	30.	SCHEDULED NECROPSY	DAY 20
56151	G		23.	25.	26.	28.	27.	28.	17.	25.	SCHEDULED NECROPSY	DAY 20
56154	G		24.	32.	25.	28.	32.	35.	33.	30.	SCHEDULED NECROPSY	DAY 20
56156	G		24.	29.	29.	29.	27.	29.	33.	28.	SCHEDULED NECROPSY	DAY 20
56158	G		35.	35.	40.	40.	41.	45.	42.	40.	SCHEDULED NECROPSY	DAY 20
56160	G		25.	30.	27.	29.	32.	32.	33.	30.	SCHEDULED NECROPSY	DAY 20
56162	G		25.	32.	29.	29.	31.	34.	35.	30.	SCHEDULED NECROPSY	DAY 20
56165	G		27.	23.	32.	28.	30.	32.	34.	29.	SCHEDULED NECROPSY	DAY 20
MEAN			26.	29.	29.	30.	30.	33.	33.	30.		
S.D.			3.3	3.2	3.3	3.0	3.1	3.5	4.8	2.8		
S.E.			0.7	0.7	0.7	0.6	0.6	0.7	1.0	0.6		
N			24	24	24	24	24	24	23	23		

G = GRAVID NG = NONGRAVID - WEIGHT(S) NOT INCLUDED IN CALCULATION OF MEAN
NA = NOT APPLICABLE

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A8
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL FOOD CONSUMPTION DURING GESTATION [G/ANIMAL/DAY]

PAGE 2

PREGNANCY STATUS		DAY	0- 3	3- 6	6- 9	9-12	12-15	15-18	18-20	0-20		
DAMS FROM GROUP 2:		1000		MG/KG/DAY								
56108	G		24.	36.	36.	41.	41.	43.	42.	37.	SCHEDULED	NECROPSY DAY 20
56109	G		24.	32.	32.	27.	35.	38.	40.	32.	SCHEDULED	NECROPSY DAY 20
56113	G		36.	34.	30.	30.	35.	37.	39.	34.	SCHEDULED	NECROPSY DAY 20
56114	G		23.	29.	28.	28.	34.	35.	35.	30.	SCHEDULED	NECROPSY DAY 20
56116	G		36.	35.	39.	40.	41.	47.	40.	40.	SCHEDULED	NECROPSY DAY 20
56118	G		23.	26.	23.	29.	31.	29.	32.	27.	SCHEDULED	NECROPSY DAY 20
56120	G		27.	29.	29.	31.	33.	35.	40.	31.	SCHEDULED	NECROPSY DAY 20
56125	G		29.	30.	32.	32.	36.	41.	40.	34.	SCHEDULED	NECROPSY DAY 20
56128	G		26.	32.	27.	27.	28.	33.	36.	29.	SCHEDULED	NECROPSY DAY 20
56131	G		27.	29.	36.	33.	32.	37.	40.	33.	SCHEDULED	NECROPSY DAY 20
56136	G		28.	32.	33.	33.	32.	34.	34.	32.	SCHEDULED	NECROPSY DAY 20
56139	G		27.	33.	35.	31.	34.	35.	43.	33.	SCHEDULED	NECROPSY DAY 20
56140	G		24.	20.	30.	30.	27.	27.	32.	27.	SCHEDULED	NECROPSY DAY 20
56141	G		23.	31.	32.	32.	31.	29.	34.	30.	SCHEDULED	NECROPSY DAY 20
56142	NG		22.	27.	30.	27.	25.	23.	26.	26.	SCHEDULED	NECROPSY DAY 20
56143	G		26.	32.	33.	33.	33.	37.	38.	33.	SCHEDULED	NECROPSY DAY 20
56145	G		26.	31.	33.	34.	34.	38.	37.	33.	SCHEDULED	NECROPSY DAY 20
56147	G		23.	28.	28.	31.	33.	37.	35.	30.	SCHEDULED	NECROPSY DAY 20
56150	G		28.	27.	30.	36.	33.	41.	40.	33.	SCHEDULED	NECROPSY DAY 20
56152	G		22.	24.	26.	24.	22.	29.	30.	25.	SCHEDULED	NECROPSY DAY 20
56155	G		21.	32.	29.	30.	26.	36.	35.	30.	SCHEDULED	NECROPSY DAY 20
56157	G		28.	27.	30.	31.	32.	35.	39.	31.	SCHEDULED	NECROPSY DAY 20
56159	G		21.	27.	31.	31.	28.	32.	34.	29.	SCHEDULED	NECROPSY DAY 20
56161	G		25.	27.	30.	30.	27.	32.	33.	29.	SCHEDULED	NECROPSY DAY 20
56164	G		29.	28.	NA	31.	32.	36.	35.	32.	SCHEDULED	NECROPSY DAY 20
MEAN			26.	30.	31.	31.	32.	36.	37.	31.		
S.D.			3.9	3.6	3.6	3.7	4.3	4.7	3.5	3.2		
S.E.			0.8	0.7	0.7	0.8	0.9	1.0	0.7	0.7		
N			24	24	23	24	24	24	24	24		

G = GRAVID NG = NONGRAVID - WEIGHT(S) NOT INCLUDED IN CALCULATION OF MEAN
NA = NOT APPLICABLE

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SPONSOR:AMERICAN PETROLEUM

TABLE A9
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL FOOD CONSUMPTION DURING GESTATION [G/KG/DAY]

PAGE 1

PREGNANCY		DAY	0- 3	3- 6	6- 9	9-12	12-15	15-18	18-20	0-20		
STATUS												
DAMS FROM GROUP 1:			0 MG/KG/DAY									
56106	G		84.	102.	106.	99.	104.	99.	90.	98.	SCHEDULED	NECROPSY DAY 20
56107	G		96.	117.	121.	101.	96.	98.	81.	101.	SCHEDULED	NECROPSY DAY 20
56111	G		106.	107.	103.	100.	110.	113.	96.	102.	SCHEDULED	NECROPSY DAY 20
56112	G		101.	104.	110.	100.	82.	96.	80.	94.	SCHEDULED	NECROPSY DAY 20
56115	G		102.	104.	103.	100.	101.	98.	92.	98.	SCHEDULED	NECROPSY DAY 20
56117	G		97.	103.	99.	90.	96.	105.	102.	96.	SCHEDULED	NECROPSY DAY 20
56119	G		104.	103.	100.	105.	97.	100.	90.	98.	SCHEDULED	NECROPSY DAY 20
56121	G		128.	142.	114.	115.	97.	106.	98.	111.	SCHEDULED	NECROPSY DAY 20
56122	G		103.	109.	91.	104.	106.	91.	79.	95.	SCHEDULED	NECROPSY DAY 20
56123	G		106.	107.	107.	110.	99.	104.	NA	NA	SCHEDULED	NECROPSY DAY 20
56126	G		86.	105.	92.	108.	99.	93.	88.	93.	SCHEDULED	NECROPSY DAY 20
56129	G		101.	101.	108.	100.	103.	100.	98.	100.	SCHEDULED	NECROPSY DAY 20
56130	G		103.	126.	120.	97.	99.	92.	87.	103.	SCHEDULED	NECROPSY DAY 20
56132	G		119.	112.	103.	108.	98.	100.	92.	100.	SCHEDULED	NECROPSY DAY 20
56133	NG		111.	110.	102.	99.	76.	68.	95.	93.	SCHEDULED	NECROPSY DAY 20
56134	G		92.	112.	109.	100.	99.	93.	87.	97.	SCHEDULED	NECROPSY DAY 20
56137	G		100.	107.	113.	101.	98.	86.	95.	98.	SCHEDULED	NECROPSY DAY 20
56138	G		102.	108.	104.	107.	101.	98.	90.	99.	SCHEDULED	NECROPSY DAY 20
56151	G		98.	102.	102.	103.	95.	91.	49.	89.	SCHEDULED	NECROPSY DAY 20
56154	G		89.	116.	88.	96.	102.	99.	84.	95.	SCHEDULED	NECROPSY DAY 20
56156	G		98.	114.	109.	104.	92.	92.	95.	98.	SCHEDULED	NECROPSY DAY 20
56158	G		145.	135.	144.	134.	127.	125.	106.	129.	SCHEDULED	NECROPSY DAY 20
56160	G		98.	111.	97.	100.	104.	95.	88.	98.	SCHEDULED	NECROPSY DAY 20
56162	G		93.	115.	99.	93.	95.	93.	85.	92.	SCHEDULED	NECROPSY DAY 20
56165	G		109.	89.	119.	99.	100.	98.	92.	98.	SCHEDULED	NECROPSY DAY 20
MEAN			103.	110.	107.	103.	100.	99.	89.	99.		
S.D.			13.1	11.3	11.8	8.5	7.8	8.1	11.0	7.8		
S.E.			2.7	2.3	2.4	1.7	1.6	1.7	2.3	1.6		
N			24	24	24	24	24	24	23	23		

G = GRAVID NG = NONGRAVID - WEIGHT(S) NOT INCLUDED IN CALCULATION OF MEAN
NA = NOT APPLICABLE

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A9
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL FOOD CONSUMPTION DURING GESTATION [G/KG/DAY]

PAGE 2

PREGNANCY STATUS		DAY	0- 3	3- 6	6- 9	9-12	12-15	15-18	18-20	0-20			
DAMS FROM GROUP 2:			1000 MG/KG/DAY										
56108	G		92.	133.	127.	138.	129.	123.	108.	118.	SCHEDULED	NECROPSY DAY 20	
56109	G		93.	120.	116.	93.	114.	111.	104.	105.	SCHEDULED	NECROPSY DAY 20	
56113	G		130.	119.	101.	97.	106.	102.	99.	105.	SCHEDULED	NECROPSY DAY 20	
56114	G		101.	124.	115.	109.	125.	118.	106.	112.	SCHEDULED	NECROPSY DAY 20	
56116	G		134.	125.	132.	128.	124.	129.	100.	123.	SCHEDULED	NECROPSY DAY 20	
56118	G		102.	110.	92.	111.	111.	93.	92.	98.	SCHEDULED	NECROPSY DAY 20	
56120	G		106.	109.	104.	105.	105.	102.	104.	101.	SCHEDULED	NECROPSY DAY 20	
56125	G		116.	114.	116.	109.	116.	120.	103.	111.	SCHEDULED	NECROPSY DAY 20	
56128	G		108.	129.	105.	103.	102.	110.	107.	105.	SCHEDULED	NECROPSY DAY 20	
56131	G		107.	111.	132.	115.	105.	112.	109.	110.	SCHEDULED	NECROPSY DAY 20	
56136	G		104.	111.	111.	107.	97.	93.	84.	99.	SCHEDULED	NECROPSY DAY 20	
56139	G		99.	117.	120.	102.	109.	104.	113.	105.	SCHEDULED	NECROPSY DAY 20	
56140	G		103.	87.	127.	120.	101.	92.	98.	102.	SCHEDULED	NECROPSY DAY 20	
56141	G		91.	118.	116.	112.	105.	92.	99.	103.	SCHEDULED	NECROPSY DAY 20	
56142	NG		93.	110.	117.	102.	94.	88.	100.	102.	SCHEDULED	NECROPSY DAY 20	
56143	G		92.	111.	110.	105.	99.	101.	92.	99.	SCHEDULED	NECROPSY DAY 20	
56145	G		102.	117.	117.	112.	106.	110.	97.	107.	SCHEDULED	NECROPSY DAY 20	
56147	G		98.	115.	110.	117.	118.	118.	100.	107.	SCHEDULED	NECROPSY DAY 20	
56150	G		101.	96.	106.	120.	103.	116.	102.	104.	SCHEDULED	NECROPSY DAY 20	
56152	G		90.	96.	102.	89.	77.	91.	85.	88.	SCHEDULED	NECROPSY DAY 20	
56155	G		83.	123.	105.	103.	87.	110.	95.	100.	SCHEDULED	NECROPSY DAY 20	
56157	G		116.	111.	119.	116.	113.	113.	111.	110.	SCHEDULED	NECROPSY DAY 20	
56159	G		82.	105.	117.	112.	97.	101.	96.	100.	SCHEDULED	NECROPSY DAY 20	
56161	G		103.	107.	114.	108.	92.	101.	94.	101.	SCHEDULED	NECROPSY DAY 20	
56164	G		115.	106.	NA	107.	104.	106.	91.	105.	SCHEDULED	NECROPSY DAY 20	
MEAN			103.	113.	114.	110.	106.	107.	100.	105.			
S.D.			12.8	10.7	10.1	10.6	11.9	10.6	7.6	7.0			
S.E.			2.6	2.2	2.1	2.2	2.4	2.2	1.6	1.4			
N			24	24	23	24	24	24	24	24			

G = GRAVID NG = NONGRAVID - WEIGHT(S) NOT INCLUDED IN CALCULATION OF MEAN
NA = NOT APPLICABLE

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SPONSOR:AMERICAN PETROLEUM

TABLE A10
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MATERNAL MACROSCOPIC FINDINGS

PAGE 1

DAMS FROM GROUP 1: 0 MG/KG/DAY		MATERNAL GROSS OBSERVATION
56106		NO SIGNIFICANT CHANGES OBSERVED
56107		NO SIGNIFICANT CHANGES OBSERVED
56111		NO SIGNIFICANT CHANGES OBSERVED
56112		NO SIGNIFICANT CHANGES OBSERVED
56115		NO SIGNIFICANT CHANGES OBSERVED
56117		NO SIGNIFICANT CHANGES OBSERVED
56119		NO SIGNIFICANT CHANGES OBSERVED
56121		NO SIGNIFICANT CHANGES OBSERVED
56122		NO SIGNIFICANT CHANGES OBSERVED
56123		NO SIGNIFICANT CHANGES OBSERVED
56126		NO SIGNIFICANT CHANGES OBSERVED
56129		NO SIGNIFICANT CHANGES OBSERVED
56130		NO SIGNIFICANT CHANGES OBSERVED
56132		NO SIGNIFICANT CHANGES OBSERVED
56133		NONGRAVID -- AMMONIUM SULFIDE NEGATIVE
56134		NO SIGNIFICANT CHANGES OBSERVED
56137		NO SIGNIFICANT CHANGES OBSERVED
56138		NO SIGNIFICANT CHANGES OBSERVED
56151		NO SIGNIFICANT CHANGES OBSERVED
56154		NO SIGNIFICANT CHANGES OBSERVED
56156		NO SIGNIFICANT CHANGES OBSERVED
56158		NO SIGNIFICANT CHANGES OBSERVED
56160		NO SIGNIFICANT CHANGES OBSERVED
56162		NO SIGNIFICANT CHANGES OBSERVED
56165		NO SIGNIFICANT CHANGES OBSERVED

DAMS FROM GROUP 2: 1000 MG/KG/DAY	MATERNAL GROSS OBSERVATION
56108	NO SIGNIFICANT CHANGES OBSERVED
56109	NO SIGNIFICANT CHANGES OBSERVED
56113	NO SIGNIFICANT CHANGES OBSERVED
56114	SKIN: MATTING, YELLOW UROGENITAL; LATERAL ABDOMINAL, BILATERAL
56116	SKIN: MATTING, YELLOW ALL EXTERNAL SURFACES
56118	NO SIGNIFICANT CHANGES OBSERVED
56120	NO SIGNIFICANT CHANGES OBSERVED
56125	NO SIGNIFICANT CHANGES OBSERVED
56128	SKIN: MATTING, YELLOW UROGENITAL; LATERAL ABDOMINAL, BILATERAL
56131	SKIN: MATTING, YELLOW ALL EXTERNAL SURFACES
56136	SKIN: MATTING, YELLOW ALL EXTERNAL SURFACES
56139	NO SIGNIFICANT CHANGES OBSERVED
56140	SKIN: MATTING, YELLOW UROGENITAL; ANOGENITAL; LEFT LATERAL THORACIC
56141	SKIN: MATTING, YELLOW ALL EXTERNAL SURFACES
56142	NONGRAVID -- AMMONIUM SULFIDE NEGATIVE
56143	NO SIGNIFICANT CHANGES OBSERVED
56145	NO SIGNIFICANT CHANGES OBSERVED
56147	NO SIGNIFICANT CHANGES OBSERVED
56150	NO SIGNIFICANT CHANGES OBSERVED
56152	SKIN: MATTING, YELLOW UROGENITAL
56155	SKIN: MATTING, YELLOW ALL EXTERNAL SURFACES
56157	NO SIGNIFICANT CHANGES OBSERVED
56159	NO SIGNIFICANT CHANGES OBSERVED
56161	NO SIGNIFICANT CHANGES OBSERVED

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TABLE A10
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MATERNAL MACROSCOPIC FINDINGS

PAGE 3

DAMS FROM GROUP 2: 1000 MG/KG/DAY	MATERNAL GROSS OBSERVATION
56164	NO SIGNIFICANT CHANGES OBSERVED

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TABLE A11
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

PAGE 1

ANIMAL NO.	56130	GROUP	1:	0 MG/KG/DAY	FEMALE	SCHEDULED EUTH	10/26/09	DATE OF DEATH: 10/26/09	GRADE
ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-UNTREA	MICRO: APOPTOSIS					((1))
THYMUS	0.3154	0.082	NO SIGNIFICANT						
ADRENAL GLANDS	0.0693	0.018	CHANGES OBSERVED	GROSS:APPL SITE-UNTREA					
FINAL BODY WT(G)	384.								

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT
()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

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TABLE A11
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

PAGE 2

ANIMAL NO. 56138 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/26/09 DATE OF DEATH: 10/26/09

GRADE
ORGAN WEIGHT ABS.(G) REL. NO SIGNIFICANT
THYMUS 0.3182 0.081 CHANGES OBSERVED GROSS:APPL SITE-UNTREA
ADRENAL GLANDS 0.0794 0.020 MICRO:APPL SITE-UNTREA
FINAL BODY WT(G) 395.

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

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TABLE A11
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO.	56137	GROUP	1:	0 MG/KG/DAY	FEMALE	SCHEDULED EUTH	10/26/09	DATE OF DEATH: 10/26/09	GRADE
ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-UNTREA	MICRO: APOPTOSIS					((1))
THYMUS	0.2792	0.072	NO SIGNIFICANT						
ADRENAL GLANDS	0.0608	0.016	CHANGES OBSERVED	GROSS:APPL SITE-UNTREA					
FINAL BODY WT(G)	386.								

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT
()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

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TABLE A11
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO. 56154 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/27/09 DATE OF DEATH: 10/27/09

GRADE
ORGAN WEIGHT ABS.(G) REL. NO SIGNIFICANT
THYMUS 0.2347 0.057 CHANGES OBSERVED GROSS:APPL SITE-UNTREA
ADRENAL GLANDS 0.0813 0.020 MICRO:APPL SITE-UNTREA
FINAL BODY WT(G) 410.

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

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TABLE A11
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO.	56133	GROUP	1:	0 MG/KG/DAY	FEMALE	SCHEDULED EUTH	10/27/09	DATE OF DEATH: 10/27/09	GRADE
ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-UNTREA	MICRO: APOPTOSIS					((1))
THYMUS	0.3707	0.124	NO SIGNIFICANT						
ADRENAL GLANDS	0.0725	0.024	CHANGES OBSERVED	GROSS:APPL SITE-UNTREA					
FINAL BODY WT(G)	299.								

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT
()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

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TABLE A11
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO. 56129 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/27/09 DATE OF DEATH: 10/27/09

GRADE
ORGAN WEIGHT ABS.(G) REL. NO SIGNIFICANT
THYMUS 0.3183 0.077 CHANGES OBSERVED GROSS:APPL SITE-UNTREA
ADRENAL GLANDS 0.0670 0.016 MICRO:APPL SITE-UNTREA
FINAL BODY WT(G) 416.

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

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TABLE A11
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO. 56132 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/27/09 DATE OF DEATH: 10/27/09

GRADE
ORGAN WEIGHT ABS.(G) REL. NO SIGNIFICANT
THYMUS 0.2208 0.052 CHANGES OBSERVED GROSS:APPL SITE-UNTREA
ADRENAL GLANDS 0.0720 0.017 MICRO:APPL SITE-UNTREA
FINAL BODY WT(G) 423.

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

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TABLE A11
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO.	56112	GROUP	1:	0 MG/KG/DAY	FEMALE	SCHEDULED EUTH	10/27/09	DATE OF DEATH: 10/27/09	GRADE
ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-UNTREA	MICRO: APOPTOSIS					((1))
THYMUS	0.2978	0.077	NO SIGNIFICANT						
ADRENAL GLANDS	0.0784	0.020	CHANGES OBSERVED	GROSS:APPL SITE-UNTREA					
FINAL BODY WT(G)	387.								

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT
()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

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TABLE A11
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO.	56106	GROUP	1:	0 MG/KG/DAY	FEMALE	SCHEDULED EUTH	10/27/09	DATE OF DEATH: 10/27/09	GRADE
ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-UNTREA	MICRO: APOPTOSIS					((1))
THYMUS	0.2288	0.064	NO SIGNIFICANT						
ADRENAL GLANDS	0.0787	0.022	CHANGES OBSERVED	GROSS:APPL SITE-UNTREA					
FINAL BODY WT(G)	358.								

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT
()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

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TABLE A11
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO.	56121	GROUP	1:	0 MG/KG/DAY	FEMALE	SCHEDULED EUTH	10/27/09	DATE OF DEATH: 10/27/09	GRADE
ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-UNTREA	MICRO: APOPTOSIS					((1))
THYMUS	0.2861	0.074	NO SIGNIFICANT						
ADRENAL GLANDS	0.0914	0.024	CHANGES OBSERVED	GROSS:APPL SITE-UNTREA					
FINAL BODY WT(G)	385.								

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT
()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

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TABLE A11
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO. 56156 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/27/09 DATE OF DEATH: 10/27/09

GRADE
ORGAN WEIGHT ABS.(G) REL. NO SIGNIFICANT
THYMUS 0.1839 0.051 CHANGES OBSERVED GROSS:APPL SITE-UNTREA
ADRENAL GLANDS 0.0672 0.019 MICRO:APPL SITE-UNTREA
FINAL BODY WT(G) 362.

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

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TABLE A11
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO. 56107 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/27/09 DATE OF DEATH: 10/27/09
GRADE

ORGAN WEIGHT ABS.(G) REL. NO SIGNIFICANT
THYMUS 0.1912 0.056 CHANGES OBSERVED GROSS:APPL SITE-UNTREA
ADRENAL GLANDS 0.0855 0.025 MICRO:APPL SITE-UNTREA
FINAL BODY WT(G) 342.

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

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TABLE A11
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO. 56134 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/27/09 DATE OF DEATH: 10/27/09
GRADE

ORGAN WEIGHT ABS.(G) REL. NO SIGNIFICANT
THYMUS 0.2477 0.067 CHANGES OBSERVED GROSS:APPL SITE-UNTREA
ADRENAL GLANDS 0.0956 0.026 MICRO:APPL SITE-UNTREA
FINAL BODY WT(G) 369.

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

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TABLE A11
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO. 56158 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/27/09 DATE OF DEATH: 10/27/09
GRADE

ORGAN WEIGHT ABS.(G) REL. NO SIGNIFICANT
THYMUS 0.2802 0.068 CHANGES OBSERVED GROSS:APPL SITE-UNTREA
ADRENAL GLANDS 0.0704 0.017 MICRO:APPL SITE-UNTREA
FINAL BODY WT(G) 410.

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

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TABLE A11
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO. 56119 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/28/09 DATE OF DEATH: 10/28/09
GRADE

ORGAN WEIGHT ABS.(G) REL. NO SIGNIFICANT
THYMUS 0.2139 0.059 CHANGES OBSERVED GROSS:APPL SITE-UNTREA
ADRENAL GLANDS 0.0673 0.019 MICRO:APPL SITE-UNTREA
FINAL BODY WT(G) 362.

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

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RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO.	56151	GROUP	1:	0 MG/KG/DAY	FEMALE	SCHEDULED EUTH	10/28/09	DATE OF DEATH: 10/28/09	GRADE
ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-UNTREA	MICRO: APOPTOSIS					((1))
THYMUS	0.1380	0.038	NO SIGNIFICANT						
ADRENAL GLANDS	0.0747	0.020	CHANGES OBSERVED	GROSS:APPL SITE-UNTREA					
FINAL BODY WT(G)	366.								

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT
()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

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RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO. 56126 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/28/09 DATE OF DEATH: 10/28/09
GRADE

ORGAN WEIGHT	ABS. (G)	REL.	NO SIGNIFICANT	
THYMUS	0.1678	0.044	CHANGES OBSERVED	GROSS:APPL SITE-UNTREA
ADRENAL GLANDS	0.0811	0.021		MICRO:APPL SITE-UNTREA
FINAL BODY WT (G)	380.			

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

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RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO. 56117 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/28/09 DATE OF DEATH: 10/28/09
GRADE

ORGAN WEIGHT	ABS. (G)	REL.	NO SIGNIFICANT
THYMUS	0.3397	0.087	CHANGES OBSERVED
ADRENAL GLANDS	0.0783	0.020	GROSS:APPL SITE-UNTREA
FINAL BODY WT (G)	390.		MICRO:APPL SITE-UNTREA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

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RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO. 56160 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/28/09 DATE OF DEATH: 10/28/09

GRADE

ORGAN WEIGHT ABS.(G) REL. NO SIGNIFICANT
THYMUS 0.2214 0.056 CHANGES OBSERVED GROSS:APPL SITE-UNTREA
ADRENAL GLANDS 0.0828 0.021 MICRO:APPL SITE-UNTREA
FINAL BODY WT(G) 392.

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

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TABLE A11
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO. 56123 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/28/09 DATE OF DEATH: 10/28/09

GRADE
ORGAN WEIGHT ABS.(G) REL. NO SIGNIFICANT
THYMUS 0.1949 0.051 CHANGES OBSERVED GROSS:APPL SITE-UNTREA
ADRENAL GLANDS 0.0835 0.022 MICRO:APPL SITE-UNTREA
FINAL BODY WT(G) 382.

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

PROJECT NO.:WIL-402008
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TABLE A11
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO.	56115	GROUP	1:	0 MG/KG/DAY	FEMALE	SCHEDULED EUTH	10/28/09	DATE OF DEATH: 10/28/09	GRADE
ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-UNTREA	MICRO: APOPTOSIS					
THYMUS	0.2693	0.065	NO SIGNIFICANT						
ADRENAL GLANDS	0.0884	0.021	CHANGES OBSERVED	GROSS:APPL SITE-UNTREA					
FINAL BODY WT(G)	412.								

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT
()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

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RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO.	56162	GROUP	1:	0 MG/KG/DAY	FEMALE	SCHEDULED EUTH	10/28/09	DATE OF DEATH: 10/28/09	GRADE
ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-UNTREA	MICRO: APOPTOSIS					((1))
THYMUS	0.2515	0.058	NO SIGNIFICANT						
ADRENAL GLANDS	0.0780	0.018	CHANGES OBSERVED	GROSS:APPL SITE-UNTREA					
FINAL BODY WT(G)	433.								

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT
()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

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TABLE A11
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO. 56122 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/28/09 DATE OF DEATH: 10/28/09
GRADE

ORGAN WEIGHT ABS.(G) REL. NO SIGNIFICANT
THYMUS 0.3704 0.088 CHANGES OBSERVED GROSS:APPL SITE-UNTREA
ADRENAL GLANDS 0.0884 0.021 MICRO:APPL SITE-UNTREA
FINAL BODY WT(G) 422.

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

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RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO. 56111 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/29/09 DATE OF DEATH: 10/29/09

GRADE
ORGAN WEIGHT ABS.(G) REL. NO SIGNIFICANT
THYMUS 0.1362 0.038 CHANGES OBSERVED GROSS:APPL SITE-UNTREA
ADRENAL GLANDS 0.0739 0.021 MICRO:APPL SITE-UNTREA
FINAL BODY WT(G) 359.

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

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ANIMAL NO. 56165 GROUP 1: 0 MG/KG/DAY FEMALE SCHEDULED EUTH 10/29/09 DATE OF DEATH: 10/29/09

GRADE

ORGAN WEIGHT ABS.(G) REL. NO SIGNIFICANT
THYMUS 0.1504 0.039 CHANGES OBSERVED GROSS:APPL SITE-UNTREA
ADRENAL GLANDS 0.0819 0.021 MICRO:APPL SITE-UNTREA
FINAL BODY WT(G) 390.

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

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ANIMAL NO.	56142	GROUP	2: 1000 MG/KG/DAY	FEMALE	SCHEDULED EUTH	10/26/09	DATE OF DEATH: 10/26/09	GRADE
ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-TREAT	MICRO: INFILTRATE, MONONUCLEAR				((1))
THYMUS	0.2083	0.079	APPL SITE-UNTREA	MICRO: APOPTOSIS				((1))
ADRENAL GLANDS	0.0709	0.027	NO SIGNIFICANT					
FINAL BODY WT(G)	263.		CHANGES OBSERVED	GROSS:APPL SITE-TREAT APPL SITE-UNTREA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT
()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

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ANIMAL NO. 56161 GROUP 2: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 10/26/09 DATE OF DEATH: 10/26/09

ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-TREAT	MICRO: APOPTOSIS	GRADE
THYMUS	0.2393	0.066	APPL SITE-UNTREA	MICRO: APOPTOSIS	((1))
ADRENAL GLANDS	0.0601	0.016	NO SIGNIFICANT		((2))
FINAL BODY WT(G)	365.		CHANGES OBSERVED	GROSS:APPL SITE-TREAT APPL SITE-UNTREA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT
()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

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ANIMAL NO. 56113 GROUP 2: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 10/26/09 DATE OF DEATH: 10/26/09

ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-TREAT	MICRO: INFILTRATE, MONONUCLEAR	GRADE
THYMUS	0.3450	0.085	NO SIGNIFICANT		((1))
ADRENAL GLANDS	0.1009	0.025	CHANGES OBSERVED	GROSS:APPL SITE-TREAT APPL SITE-UNTREA	
FINAL BODY WT(G)	406.			MICRO:APPL SITE-UNTREA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

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ANIMAL NO. 56143 GROUP 2: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 10/27/09 DATE OF DEATH: 10/27/09

				GRADE
ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-TREAT MICRO: INFILTRATE, MONONUCLEAR	((1))
THYMUS	0.1923	0.045	APPL SITE-UNTREA MICRO: APOPTOSIS	((1))
ADRENAL GLANDS	0.0896	0.021	NO SIGNIFICANT	
FINAL BODY WT(G)	430.		CHANGES OBSERVED GROSS:APPL SITE-TREAT APPL SITE-UNTREA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT
()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

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ANIMAL NO.	56136	GROUP	2: 1000 MG/KG/DAY	FEMALE	SCHEDULED EUTH	10/27/09	DATE OF DEATH: 10/27/09	GRADE
ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-TREAT	MICRO: INFILTRATE, MONONUCLEAR				((1))
THYMUS	0.2939	0.071		WITH VERY LOW NUMBERS OF NEUTROPHILS FOCALLY IN DERMAL				
ADRENAL GLANDS	0.0774	0.019		CAPILLARIES.				
FINAL BODY WT(G)	416.		APPL SITE-UNTREA	MICRO: INFILTRATE, HISTIOCYTE				((1))
			NO SIGNIFICANT					
			CHANGES OBSERVED	GROSS:APPL SITE-TREAT APPL SITE-UNTREA				
				GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT				
				MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT				
				()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED				

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ANIMAL NO. 56159 GROUP 2: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 10/27/09 DATE OF DEATH: 10/27/09

ORGAN WEIGHT ABS.(G) REL. APPL SITE-UNTREA MICRO: APOPTOSIS GRADE
THYMUS 0.1898 0.051 NO SIGNIFICANT ((1))
ADRENAL GLANDS 0.0831 0.022 CHANGES OBSERVED GROSS:APPL SITE-TREAT APPL SITE-UNTREA
FINAL BODY WT(G) 373. MICRO:APPL SITE-TREAT

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT
()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

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ANIMAL NO. 56155 GROUP 2: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 10/27/09 DATE OF DEATH: 10/27/09

ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-TREAT	MICRO: INFILTRATE, MONONUCLEAR	GRADE
THYMUS	0.1576	0.041		APOPTOSIS	((1))
ADRENAL GLANDS	0.0979	0.025	APPL SITE-UNTREA	MICRO: INFILTRATE, MONONUCLEAR	((1))
FINAL BODY WT(G)	386.		NO SIGNIFICANT		((1))
			CHANGES OBSERVED	GROSS:APPL SITE-TREAT APPL SITE-UNTREA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

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ANIMAL NO. 56141 GROUP 2: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 10/27/09 DATE OF DEATH: 10/27/09

ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-TREAT	MICRO: INFILTRATE, MONONUCLEAR	GRADE
THYMUS	0.1598	0.045	NO SIGNIFICANT		((1))
ADRENAL GLANDS	0.0838	0.023	CHANGES OBSERVED	GROSS:APPL SITE-TREAT APPL SITE-UNTREA	
FINAL BODY WT(G)	358.			MICRO:APPL SITE-UNTREA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

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ANIMAL NO.	56164	GROUP	2: 1000 MG/KG/DAY	FEMALE	SCHEDULED EUTH	10/27/09	DATE OF DEATH: 10/27/09	GRADE
ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-TREAT	MICRO: INFILTRATE, MONONUCLEAR				((1))
THYMUS	0.2721	0.068	NO SIGNIFICANT					
ADRENAL GLANDS	0.0882	0.022	CHANGES OBSERVED	GROSS:APPL SITE-TREAT	APPL SITE-UNTREA			
FINAL BODY WT(G)	400.			MICRO:APPL SITE-UNTREA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT
()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

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ANIMAL NO.	56131	GROUP	2: 1000 MG/KG/DAY	FEMALE	SCHEDULED EUTH	10/27/09	DATE OF DEATH: 10/27/09	GRADE
ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-TREAT	MICRO: INFILTRATE, MONONUCLEAR				((1))
THYMUS	0.2173	0.056		WITH RARE NEUTROPHILS				
ADRENAL GLANDS	0.0813	0.021	APPL SITE-UNTREA	MICRO: APOPTOSIS				((1))
FINAL BODY WT(G)	386.		NO SIGNIFICANT					
			CHANGES OBSERVED	GROSS:APPL SITE-TREAT APPL SITE-UNTREA				
GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT								
MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT								
()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED								

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ANIMAL NO.	56157	GROUP	2: 1000 MG/KG/DAY	FEMALE	SCHEDULED EUTH	10/27/09	DATE OF DEATH: 10/27/09	GRADE

ORGAN WEIGHT	ABS. (G)	REL.	NO SIGNIFICANT					
THYMUS	0.2202	0.060	CHANGES OBSERVED	GROSS:APPL SITE-TREAT APPL SITE-UNTREA				
ADRENAL GLANDS	0.0805	0.022		MICRO:APPL SITE-TREAT APPL SITE-UNTREA				
FINAL BODY WT (G)	369.							

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

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ANIMAL NO.	56128	GROUP	2: 1000 MG/KG/DAY	FEMALE	SCHEDULED EUTH	10/27/09	DATE OF DEATH: 10/27/09	GRADE
ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-TREAT	MICRO: INFILTRATE, MONONUCLEAR				((1))
THYMUS	0.2649	0.076	NO SIGNIFICANT					
ADRENAL GLANDS	0.0766	0.022	CHANGES OBSERVED	GROSS:APPL SITE-TREAT	APPL SITE-UNTREA			
FINAL BODY WT(G)	349.			MICRO:APPL SITE-UNTREA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

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ANIMAL NO.	56140	GROUP	2: 1000 MG/KG/DAY	FEMALE	SCHEDULED EUTH	10/27/09	DATE OF DEATH: 10/27/09	GRADE
ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-UNTREA	MICRO: APOPTOSIS				((1))
THYMUS	0.1936	0.056		FIBROPLASIA				1
ADRENAL GLANDS	0.0781	0.023		FOCALLY EXTENSIVE, IN SUPERFICIAL DERMIS WITH MINIMAL				
FINAL BODY WT(G)	345.			MONONUCLEAR INFILTRATE				
			NO SIGNIFICANT					
			CHANGES OBSERVED	GROSS:APPL SITE-TREAT	APPL SITE-UNTREA			
				MICRO:APPL SITE-TREAT				
				GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT				
				MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT				
				()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED				

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ANIMAL NO. 56114 GROUP 2: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 10/27/09 DATE OF DEATH: 10/27/09

ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-TREAT	MICRO: INFILTRATE, MONONUCLEAR	GRADE
THYMUS	0.1779	0.052	NO SIGNIFICANT		((1))
ADRENAL GLANDS	0.1083	0.031	CHANGES OBSERVED	GROSS:APPL SITE-TREAT APPL SITE-UNTREA	
FINAL BODY WT(G)	344.			MICRO:APPL SITE-UNTREA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

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ANIMAL NO. 56118 GROUP 2: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 10/28/09 DATE OF DEATH: 10/28/09

ORGAN WEIGHT ABS.(G) REL. APPL SITE-TREAT MICRO: APOPTOSIS GRADE
THYMUS 0.2189 0.060 NO SIGNIFICANT ((1))
ADRENAL GLANDS 0.0864 0.024 CHANGES OBSERVED GROSS:APPL SITE-TREAT APPL SITE-UNTREA
FINAL BODY WT(G) 362. MICRO:APPL SITE-UNTREA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT
()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

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ANIMAL NO. 56147 GROUP 2: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 10/28/09 DATE OF DEATH: 10/28/09
GRADE

ORGAN WEIGHT ABS.(G) REL. NO SIGNIFICANT
THYMUS 0.1271 0.035 CHANGES OBSERVED GROSS:APPL SITE-TREAT APPL SITE-UNTREA
ADRENAL GLANDS 0.0614 0.017 MICRO:APPL SITE-TREAT APPL SITE-UNTREA
FINAL BODY WT(G) 366.

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

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ANIMAL NO. 56152 GROUP 2: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 10/28/09 DATE OF DEATH: 10/28/09

						GRADE
ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-TREAT	MICRO: INFILTRATE, MONONUCLEAR		((1))
THYMUS	0.2134	0.058		APOPTOSIS		((1))
ADRENAL GLANDS	0.0839	0.023	APPL SITE-UNTREA	MICRO: INFILTRATE, MONONUCLEAR		((1))
FINAL BODY WT(G)	371.		NO SIGNIFICANT			
			CHANGES OBSERVED	GROSS:APPL SITE-TREAT APPL SITE-UNTREA		
				GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT		
				MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT		
				()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED		

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ANIMAL NO. 56145 GROUP 2: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 10/28/09 DATE OF DEATH: 10/28/09

GRADE
ORGAN WEIGHT ABS.(G) REL. APPL SITE-TREAT MICRO: APOPTOSIS ((1))
THYMUS 0.2153 0.054 APPL SITE-UNTREA MICRO: APOPTOSIS ((1))
ADRENAL GLANDS 0.0842 0.021 NO SIGNIFICANT
FINAL BODY WT(G) 399. CHANGES OBSERVED GROSS:APPL SITE-TREAT APPL SITE-UNTREA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT
()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

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ANIMAL NO. 56120 GROUP 2: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 10/28/09 DATE OF DEATH: 10/28/09

ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-TREAT	MICRO: INFILTRATE, MONONUCLEAR	GRADE
THYMUS	0.1779	0.044	NO SIGNIFICANT		((1))
ADRENAL GLANDS	0.0921	0.023	CHANGES OBSERVED	GROSS:APPL SITE-TREAT APPL SITE-UNTREA	
FINAL BODY WT(G)	405.			MICRO:APPL SITE-UNTREA	

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

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ANIMAL NO.	56109	GROUP	2: 1000 MG/KG/DAY	FEMALE	SCHEDULED EUTH	10/28/09	DATE OF DEATH: 10/28/09	GRADE
ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-TREAT	MICRO: INFILTRATE, MONONUCLEAR				((1))
THYMUS	0.1884	0.047	NO SIGNIFICANT					
ADRENAL GLANDS	0.0921	0.023	CHANGES OBSERVED	GROSS:APPL SITE-TREAT	APPL SITE-UNTREA			
FINAL BODY WT(G)	403.			MICRO:APPL SITE-UNTREA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT

()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

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ANIMAL NO.	56108	GROUP	2: 1000 MG/KG/DAY	FEMALE	SCHEDULED EUTH	10/28/09	DATE OF DEATH: 10/28/09	GRADE
ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-TREAT	MICRO: INFILTRATE, MONONUCLEAR				((1))
THYMUS	0.1933	0.047	NO SIGNIFICANT					
ADRENAL GLANDS	0.0917	0.022	CHANGES OBSERVED	GROSS:APPL SITE-TREAT	APPL SITE-UNTREA			
FINAL BODY WT(G)	408.			MICRO:APPL SITE-UNTREA				

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT
()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

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INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO. 56139 GROUP 2: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 10/28/09 DATE OF DEATH: 10/28/09

ORGAN WEIGHT ABS.(G) REL. APPL SITE-UNTREA MICRO: APOPTOSIS GRADE
THYMUS 0.2894 0.072 NO SIGNIFICANT ((1))
ADRENAL GLANDS 0.0932 0.023 CHANGES OBSERVED GROSS:APPL SITE-TREAT APPL SITE-UNTREA
FINAL BODY WT(G) 404. MICRO:APPL SITE-TREAT

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT
()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A11
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

PAGE 48

ANIMAL NO.	56150	GROUP	2: 1000 MG/KG/DAY	FEMALE	SCHEDULED EUTH	10/28/09	DATE OF DEATH: 10/28/09	GRADE
ORGAN WEIGHT	ABS.(G)	REL.	APPL SITE-TREAT	MICRO: INFILTRATE, MONONUCLEAR				((1))
THYMUS	0.1588	0.039	NO SIGNIFICANT					
ADRENAL GLANDS	0.0712	0.017	CHANGES OBSERVED	GROSS:APPL SITE-TREAT	APPL SITE-UNTREA			
FINAL BODY WT(G)	407.			MICRO:APPL SITE-UNTREA				
GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT								
MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT								
()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED								

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A11
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO. 56116 GROUP 2: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 10/29/09 DATE OF DEATH: 10/29/09

GRADE
ORGAN WEIGHT ABS.(G) REL. APPL SITE-TREAT MICRO: APOPTOSIS ((1))
THYMUS 0.1949 0.047 APPL SITE-UNTREA MICRO: INFILTRATE, MONONUCLEAR ((1))
ADRENAL GLANDS 0.0937 0.022 NO SIGNIFICANT
FINAL BODY WT(G) 417. CHANGES OBSERVED GROSS:APPL SITE-TREAT APPL SITE-UNTREA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT
()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A11
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL MACROSCOPIC AND MICROSCOPIC FINDINGS

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ANIMAL NO. 56125 GROUP 2: 1000 MG/KG/DAY FEMALE SCHEDULED EUTH 10/29/09 DATE OF DEATH: 10/29/09

ORGAN WEIGHT ABS.(G) REL. APPL SITE-TREAT MICRO: INFILTRATE, MONONUCLEAR GRADE
THYMUS 0.2244 0.054 NO SIGNIFICANT ((1))
ADRENAL GLANDS 0.0954 0.023 CHANGES OBSERVED GROSS:APPL SITE-TREAT APPL SITE-UNTREA
FINAL BODY WT(G) 413. MICRO:APPL SITE-UNTREA

GROSS GRADE CODE: 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT

MICRO GRADE CODE: 1-MINIMAL; 2-MILD; 3-MODERATE; 4-SEVERE; P-PRESENT
()-FOCAL/SOLITARY, (())-MULTIFOCAL/MULTIPLE, NO PARENTHESES-NOT SPECIFIED

PGRHv4.64
01/12/2010
R:04/15/2010

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A12
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL ORGAN WEIGHTS [G]

PAGE 1

FEMALE GROUP: 0 MG/KG/DAY

ANIMAL	PREGNANCY STATUS	THYMUS	ADRENAL GLANDS
56106	G	0.2288	0.0787
56107	G	0.1912	0.0855
56111	G	0.1362	0.0739
56112	G	0.2978	0.0784
56115	G	0.2693	0.0884
56117	G	0.3397	0.0783
56119	G	0.2139	0.0673
56121	G	0.2861	0.0914
56122	G	0.3704	0.0884
56123	G	0.1949	0.0835
56126	G	0.1678	0.0811
56129	G	0.3183	0.0670
56130	G	0.3154	0.0693
56132	G	0.2208	0.0720
56133	NG	0.3707	0.0725
56134	G	0.2477	0.0956
56137	G	0.2792	0.0608
56138	G	0.3182	0.0794
56151	G	0.1380	0.0747
56154	G	0.2347	0.0813
56156	G	0.1839	0.0672
56158	G	0.2802	0.0704
56160	G	0.2214	0.0828
56162	G	0.2515	0.0780
56165	G	0.1504	0.0819
MEAN		0.2440	0.0781
S.D.		0.06517	0.00859
S.E.		0.01330	0.00175
N		24	24

G = GRAVID NG = NONGRAVID - WEIGHTS NOT INCLUDED IN THE CALCULATION OF THE MEAN

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A12
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL ORGAN WEIGHTS [G]

PAGE 2

FEMALE GROUP: 1000 MG/KG/DAY

ANIMAL	PREGNANCY STATUS	THYMUS	ADRENAL GLANDS
56108	G	0.1933	0.0917
56109	G	0.1884	0.0921
56113	G	0.3450	0.1009
56114	G	0.1779	0.1083
56116	G	0.1949	0.0937
56118	G	0.2189	0.0864
56120	G	0.1779	0.0921
56125	G	0.2244	0.0954
56128	G	0.2649	0.0766
56131	G	0.2173	0.0813
56136	G	0.2939	0.0774
56139	G	0.2894	0.0932
56140	G	0.1936	0.0781
56141	G	0.1598	0.0838
56142	NG	0.2083	0.0709
56143	G	0.1923	0.0896
56145	G	0.2153	0.0842
56147	G	0.1271	0.0614
56150	G	0.1588	0.0712
56152	G	0.2134	0.0839
56155	G	0.1576	0.0979
56157	G	0.2202	0.0805
56159	G	0.1898	0.0831
56161	G	0.2393	0.0601
56164	G	0.2721	0.0882
MEAN		0.2136	0.0855
S.D.		0.05033	0.01137
S.E.		0.01027	0.00232
N		24	24

G = GRAVID NG = NONGRAVID - WEIGHTS NOT INCLUDED IN THE CALCULATION OF THE MEAN

POFBWRv4.07
12/10/2009
R:04/15/2010

TABLE A13
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL FETAL DATA AT SCHEDULED NECROPSY

DAMS FROM GROUP 1: 0 MG/KG/DAY

DAM#	SEX		VIABLE FETUSES			DEAD FETUSES			EARLY RESORPTIONS			LATE RESORPTIONS			IMPLANTATION SITES			CORPORA LUTEA		
	M	F	LEFT HORN	RIGHT HORN	TOTAL	LEFT HORN	RIGHT HORN	TOTAL	LEFT HORN	RIGHT HORN	TOTAL	LEFT HORN	RIGHT HORN	TOTAL	LEFT HORN	RIGHT HORN	TOTAL	LEFT OVARY	RIGHT OVARY	TOTAL
56106	7	4	6	5	11	0	0	0	1	0	1	0	0	0	7	5	12	7	6	13
56107	3	9	8	4	12	0	0	0	1	0	1	0	0	0	9	4	13	9	4	13
56111	7	7	7	7	14	0	0	0	0	0	0	0	0	0	7	7	14	8	8	16
56112	7	7	8	6	14	0	0	0	0	1	1	0	0	0	8	7	15	9	8	17
56115	6	9	5	10	15	0	0	0	0	0	0	0	0	0	5	10	15	6	10	16
56117	6	7	8	5	13	0	0	0	0	0	0	0	0	0	8	5	13	8	6	14
56119	6	10	10	6	16	0	0	0	0	0	0	0	0	0	10	6	16	10	6	16
56121	6	7	6	7	13	0	0	0	1	1	2	0	0	0	7	8	15	7	8	15
56122	8	8	5	11	16	0	0	0	1	0	1	0	0	0	6	11	17	6	11	17
56123	6	7	5	8	13	0	0	0	0	2	2	0	0	0	5	10	15	5	10	15
56126	8	8	9	7	16	0	0	0	1	0	1	0	0	0	10	7	17	10	7	17
56129	7	10	10	7	17	0	0	0	0	0	0	0	0	0	10	7	17	10	8	18
56130	7	7	7	7	14	0	0	0	0	0	0	0	0	0	7	7	14	10	9	19
56132	7	8	4	11	15	0	0	0	0	0	0	0	0	0	4	11	15	5	11	16
56133	NONGRAVID																			
56134	11	4	7	8	15	0	0	0	0	0	0	0	0	0	7	8	15	7	8	15
56137	6	7	7	6	13	0	0	0	0	0	0	0	0	0	7	6	13	7	6	13
56138	9	5	9	5	14	0	0	0	0	1	1	0	0	0	9	6	15	9	6	15
56151	8	7	2	13	15	0	0	0	0	0	0	0	0	0	2	13	15	2	13	15
56154	8	10	7	11	18	0	0	0	2	0	2	0	0	0	9	11	20	9	11	20
56156	6	6	3	9	12	0	0	0	1	2	3	0	0	0	4	11	15	4	11	15
56158	2	10	5	7	12	0	0	0	1	0	1	0	0	0	6	7	13	6	10	16
56160	5	11	8	8	16	0	0	0	0	1	1	0	0	0	8	9	17	8	10	18
56162	7	9	8	8	16	0	0	0	0	0	0	0	0	0	8	8	16	9	10	19
56165	8	8	9	7	16	0	0	0	0	0	0	0	0	0	9	7	16	10	7	17
TOTAL	161	185	163	183	346	0	0	0	9	8	17	0	0	0	172	191	363	181	204	385
MEAN	6.7	7.7	6.8	7.6	14.4	0.0	0.0	0.0	0.4	0.3	0.7	0.0	0.0	0.0	7.2	8.0	15.1	7.5	8.5	16.0
S.D.	1.81	1.85	2.11	2.24	1.79	0.00	0.00	0.00	0.58	0.64	0.86	0.00	0.00	0.00	2.08	2.31	1.75	2.15	2.23	1.90
S.E.	0.37	0.38	0.43	0.46	0.37	0.00	0.00	0.00	0.12	0.13	0.18	0.00	0.00	0.00	0.42	0.47	0.36	0.44	0.45	0.39
N =	24																			

DAMS FROM GROUP 2: 1000 MG/KG/DAY

DAM#	SEX		VIABLE FETUSES			DEAD FETUSES			EARLY RESORPTIONS			LATE RESORPTIONS			IMPLANTATION SITES			CORPORA LUTEA		
	M	F	LEFT HORN	RIGHT HORN	TOTAL	LEFT HORN	RIGHT HORN	TOTAL	LEFT HORN	RIGHT HORN	TOTAL	LEFT HORN	RIGHT HORN	TOTAL	LEFT HORN	RIGHT HORN	TOTAL	LEFT OVARY	RIGHT OVARY	TOTAL
56108	4	12	9	7	16	0	0	0	1	0	1	0	0	0	10	7	17	10	8	18
56109	10	6	7	9	16	0	0	0	0	0	0	0	0	0	7	9	16	7	10	17
56113	7	8	7	8	15	0	0	0	0	0	0	0	0	0	7	8	15	9	10	19
56114	6	6	7	5	12	0	0	0	0	0	0	0	0	0	7	5	12	7	6	13
56116	11	3	8	6	14	0	0	0	1	1	2	0	0	0	9	7	16	9	7	16
56118	6	9	6	9	15	0	0	0	0	0	0	0	0	0	6	9	15	6	11	17
56120	11	3	6	8	14	0	0	0	0	0	0	0	0	0	6	8	14	6	9	15
56125	11	5	10	6	16	0	0	0	1	1	2	0	0	0	11	7	18	11	7	18
56128	5	7	8	4	12	0	0	0	0	1	1	0	0	0	8	5	13	9	7	16
56131	6	9	7	8	15	0	0	0	0	1	1	0	0	0	7	9	16	7	9	16
56136	9	8	10	7	17	0	0	0	0	0	0	0	0	0	10	7	17	10	7	17
56139	10	7	7	10	17	0	0	0	1	0	1	0	0	0	8	10	18	8	10	18
56140	6	8	6	8	14	0	0	0	0	3	3	0	0	0	6	11	17	6	11	17
56141	2	9	7	4	11	0	0	0	3	1	4	0	0	0	10	5	15	10	5	15
56142	NONGRAVID																			
56143	6	10	8	8	16	0	0	0	2	1	3	0	0	0	10	9	19	10	9	19
56145	6	7	8	5	13	0	0	0	1	0	1	0	1	1	9	6	15	9	9	18
56147	6	8	10	4	14	0	0	0	0	0	0	0	0	0	10	4	14	10	4	14
56150	8	6	8	6	14	0	0	0	0	1	1	0	0	0	8	7	15	8	7	15
56152	9	4	4	9	13	0	0	0	0	0	0	0	0	0	4	9	13	4	9	13
56155	9	4	3	10	13	0	0	0	1	0	1	0	0	0	4	10	14	4	10	14
56157	6	8	7	7	14	0	0	0	1	0	1	0	0	0	8	7	15	8	7	15
56159	7	10	8	9	17	0	0	0	0	0	0	0	0	0	8	9	17	8	10	18
56161	4	8	5	7	12	0	0	0	0	0	0	0	0	0	5	7	12	6	8	14
56164	7	9	9	7	16	0	0	0	0	0	0	0	0	0	9	7	16	10	8	18
TOTAL	172	174	175	171	346	0	0	0	12	10	22	0	1	1	187	182	369	192	198	390
MEAN	7.2	7.3	7.3	7.1	14.4	0.0	0.0	0.0	0.5	0.4	0.9	0.0	0.0	0.0	7.8	7.6	15.4	8.0	8.3	16.3
S.D.	2.41	2.29	1.76	1.83	1.74	0.00	0.00	0.00	0.78	0.72	1.14	0.00	0.20	0.20	1.96	1.79	1.86	1.96	1.82	1.85
S.E.	0.49	0.47	0.36	0.37	0.36	0.00	0.00	0.00	0.16	0.15	0.23	0.00	0.04	0.04	0.40	0.37	0.38	0.40	0.37	0.38
N =	24																			

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A14
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL FETAL DATA AT SCHEDULED NECROPSY [% PER LITTER]

PAGE 1

DAMS FROM GROUP 1: 0 MG/KG/DAY

DAM #	CORPORA LUTEA	IMPLANTATION SITES	FETUSES		RESORPTIONS			PRE- IMPLANTATION LOSS	POST- IMPLANTATION LOSS	MALES	FEMALES
	#	#	VIABLE	DEAD	EARLY	LATE	TOTAL				
			%	%	%	%	%	%	%	%	%
56106	13.0	12.0	91.7	0.0	8.3	0.0	8.3	7.7	8.3	63.6	36.4
56107	13.0	13.0	92.3	0.0	7.7	0.0	7.7	0.0	7.7	25.0	75.0
56111	16.0	14.0	100.0	0.0	0.0	0.0	0.0	12.5	0.0	50.0	50.0
56112	17.0	15.0	93.3	0.0	6.7	0.0	6.7	11.8	6.7	50.0	50.0
56115	16.0	15.0	100.0	0.0	0.0	0.0	0.0	6.3	0.0	40.0	60.0
56117	14.0	13.0	100.0	0.0	0.0	0.0	0.0	7.1	0.0	46.2	53.8
56119	16.0	16.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	37.5	62.5
56121	15.0	15.0	86.7	0.0	13.3	0.0	13.3	0.0	13.3	46.2	53.8
56122	17.0	17.0	94.1	0.0	5.9	0.0	5.9	0.0	5.9	50.0	50.0
56123	15.0	15.0	86.7	0.0	13.3	0.0	13.3	0.0	13.3	46.2	53.8
56126	17.0	17.0	94.1	0.0	5.9	0.0	5.9	0.0	5.9	50.0	50.0
56129	18.0	17.0	100.0	0.0	0.0	0.0	0.0	5.6	0.0	41.2	58.8
56130	19.0	14.0	100.0	0.0	0.0	0.0	0.0	26.3	0.0	50.0	50.0
56132	16.0	15.0	100.0	0.0	0.0	0.0	0.0	6.3	0.0	46.7	53.3
56134	15.0	15.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	73.3	26.7
56137	13.0	13.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	46.2	53.8
56138	15.0	15.0	93.3	0.0	6.7	0.0	6.7	0.0	6.7	64.3	35.7
56151	15.0	15.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	53.3	46.7
56154	20.0	20.0	90.0	0.0	10.0	0.0	10.0	0.0	10.0	44.4	55.6
56156	15.0	15.0	80.0	0.0	20.0	0.0	20.0	0.0	20.0	50.0	50.0
56158	16.0	13.0	92.3	0.0	7.7	0.0	7.7	18.8	7.7	16.7	83.3
56160	18.0	17.0	94.1	0.0	5.9	0.0	5.9	5.6	5.9	31.3	68.8
56162	19.0	16.0	100.0	0.0	0.0	0.0	0.0	15.8	0.0	43.8	56.3
56165	17.0	16.0	100.0	0.0	0.0	0.0	0.0	5.9	0.0	50.0	50.0
MEAN	16.0	15.1	95.4	0.0	4.6	0.0	4.6	5.4	4.6	46.5	53.5
S.D.	1.90	1.75	5.59	0.00	5.59	0.00	5.59	7.15	5.59	11.82	11.82
S.E.	0.39	0.36	1.14	0.00	1.14	0.00	1.14	1.46	1.14	2.41	2.41
N	24	24	24	24	24	24	24	24	24	24	24

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A14
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL FETAL DATA AT SCHEDULED NECROPSY [% PER LITTER]

PAGE 2

DAMS FROM GROUP 2: 1000 MG/KG/DAY

DAM #	CORPORA LUTEA	IMPLANTATION SITES	FETUSES		RESORPTIONS			PRE- IMPLANTATION LOSS	POST- IMPLANTATION LOSS	MALES	FEMALES
	#	#	VIABLE	DEAD	EARLY	LATE	TOTAL				
			%	%	%	%	%	%	%	%	%
56108	18.0	17.0	94.1	0.0	5.9	0.0	5.9	5.6	5.9	25.0	75.0
56109	17.0	16.0	100.0	0.0	0.0	0.0	0.0	5.9	0.0	62.5	37.5
56113	19.0	15.0	100.0	0.0	0.0	0.0	0.0	21.1	0.0	46.7	53.3
56114	13.0	12.0	100.0	0.0	0.0	0.0	0.0	7.7	0.0	50.0	50.0
56116	16.0	16.0	87.5	0.0	12.5	0.0	12.5	0.0	12.5	78.6	21.4
56118	17.0	15.0	100.0	0.0	0.0	0.0	0.0	11.8	0.0	40.0	60.0
56120	15.0	14.0	100.0	0.0	0.0	0.0	0.0	6.7	0.0	78.6	21.4
56125	18.0	18.0	88.9	0.0	11.1	0.0	11.1	0.0	11.1	68.8	31.3
56128	16.0	13.0	92.3	0.0	7.7	0.0	7.7	18.8	7.7	41.7	58.3
56131	16.0	16.0	93.8	0.0	6.3	0.0	6.3	0.0	6.3	40.0	60.0
56136	17.0	17.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	52.9	47.1
56139	18.0	18.0	94.4	0.0	5.6	0.0	5.6	0.0	5.6	58.8	41.2
56140	17.0	17.0	82.4	0.0	17.6	0.0	17.6	0.0	17.6	42.9	57.1
56141	15.0	15.0	73.3	0.0	26.7	0.0	26.7	0.0	26.7	18.2	81.8
56143	19.0	19.0	84.2	0.0	15.8	0.0	15.8	0.0	15.8	37.5	62.5
56145	18.0	15.0	86.7	0.0	6.7	6.7	13.3	16.7	13.3	46.2	53.8
56147	14.0	14.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	42.9	57.1
56150	15.0	15.0	93.3	0.0	6.7	0.0	6.7	0.0	6.7	57.1	42.9
56152	13.0	13.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	69.2	30.8
56155	14.0	14.0	92.9	0.0	7.1	0.0	7.1	0.0	7.1	69.2	30.8
56157	15.0	15.0	93.3	0.0	6.7	0.0	6.7	0.0	6.7	42.9	57.1
56159	18.0	17.0	100.0	0.0	0.0	0.0	0.0	5.6	0.0	41.2	58.8
56161	14.0	12.0	100.0	0.0	0.0	0.0	0.0	14.3	0.0	33.3	66.7
56164	18.0	16.0	100.0	0.0	0.0	0.0	0.0	11.1	0.0	43.8	56.3
MEAN	16.3	15.4	94.0	0.0	5.7	0.3	6.0	5.2	6.0	49.5	50.5
S.D.	1.85	1.86	7.17	0.00	7.00	1.37	7.17	6.89	7.17	15.67	15.67
S.E.	0.38	0.38	1.46	0.00	1.43	0.28	1.46	1.41	1.46	3.20	3.20
N	24	24	24	24	24	24	24	24	24	24	24

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SPONSOR:AMERICAN PETROLEUM

TABLE A15
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL FETAL WEIGHTS [G]

PAGE 1

FETUS #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
DAM # MEAN	GROUP 1:	0 MG/KG/DAY																					
56106	3.7	3.6	3.7	3.7	3.8	3.7	3.8	E /	3.7	3.9	3.7	3.5	3.6										
56107	3.6	3.7	E	3.4	3.3	3.4	3.8	3.8	3.5	3.1/	4.2	3.3	3.8	3.7									
56111	3.5	3.8	3.6	3.6	4.2	4.0	3.5	3.3/	2.6	3.5	3.7	3.6	3.7	3.1	3.2								
56112	3.3	2.9	3.1	3.4	3.6	3.2	3.5	3.1	3.4/	3.4	3.5	3.4	3.6	3.4	3.2	E							
56115	4.0	3.5	4.4	4.2	4.4	4.4/	3.9	3.6	3.9	3.8	3.9	4.0	4.1	4.0	4.5	3.4							
56117	3.8	3.6	3.7	3.8	3.7	3.6	3.6	3.8	4.0/	4.1	3.8	4.0	3.6	3.7									
56119	3.5	3.4	3.4	3.5	3.5	3.3	3.2	3.5	3.5	3.7	3.8/	3.6	3.4	3.5	3.4	3.6	3.5						
56121	4.0	3.6	4.0	4.1	E	3.6	4.0	4.2/	3.6	4.0	E	3.8	4.4	4.2	4.3	4.0							
56122	3.8	3.3	4.1	4.1	3.8	E	3.7/	4.0	3.8	3.9	4.3	4.1	4.2	4.1	3.5	3.5	3.2	3.0					
56123	3.6	3.3	3.3	3.9	4.0	3.8/	4.0	E	3.6	3.6	3.5	3.5	3.4	3.1	3.4	E							
56126	3.8	3.8	3.5	3.4	3.4	4.1	3.8	3.3	E	3.8	3.8/	3.8	3.9	3.9	4.0	4.0	3.8	4.2					
56129	3.9	3.6	4.1	4.0	3.9	4.0	3.8	4.1	3.5	3.6	3.8/	4.1	4.1	3.9	3.9	4.0	3.9	4.1					
56130	4.2	4.1	4.3	4.1	4.2	4.2	4.2	4.3/	4.4	4.2	4.4	4.4	4.1	4.4	3.9								
56132	4.1	4.3	4.4	4.3	4.5/	4.3	4.1	3.7	4.8	4.2	3.9	4.1	3.9	3.7	3.7	3.6							
56134	3.8	3.4	3.4	3.6	3.7	4.1	3.7	4.2/	4.0	3.9	3.8	3.9	4.1	3.9	3.9	3.7							
56137	3.8	1.9	3.7	3.8	4.1	3.7	3.7	4.0/	4.0	4.1	4.4	4.3	4.1	4.0									
56138	4.0	3.6	3.9	4.1	3.8	2.9	4.1	4.5	4.2	4.6/	E	4.2	4.3	4.0	3.7	4.0							
56151	3.8	3.8	3.6/	3.6	3.6	4.2	3.8	4.0	3.9	3.8	3.9	4.0	3.9	3.9	3.6	3.3							
56154	3.9	3.5	E	3.7	E	4.0	3.9	4.3	4.0	4.0/	4.4	3.8	4.1	3.7	3.5	3.7	4.0	4.0	3.0	3.9	3.8		
56156	3.9	E	3.8	3.9	3.6/	3.7	E	3.9	3.8	4.1	E	3.7	3.9	4.4	3.6	4.0							
56158	3.7	3.6	E	3.8	3.9	4.0	4.0/	3.3	4.1	4.0	3.8	3.6	3.7	2.6									
56160	3.6	3.2	3.1	4.2	3.9	3.8	3.6	3.0	3.3/	3.2	3.9	4.1	4.0	3.8	E	3.7	3.9	3.6					
56162	3.8	3.5	3.7	3.7	3.4	3.7	4.1	4.1	4.3/	4.1	4.2	3.7	3.9	3.7	3.8	3.4	3.6						
56165	3.6	3.3	3.7	3.9	4.0	3.6	3.3	3.5	3.6	4.1/	3.5	3.5	3.6	3.7	3.3	3.5	3.7						
MEAN	3.8																						
S.D.	0.21																						
S.E.	0.04																						
N	24																						

E = EARLY RESORPTION L = LATE RESORPTION D = DEAD FETUS '/' DENOTES POSITION OF CERVIX

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A15
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL FETAL WEIGHTS [G]

PAGE 2

FETUS #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
DAM # MEAN	GROUP 2: 1000 MG/KG/DAY																						
56108	3.6	3.3	3.6	3.4	E	3.7	3.9	3.9	3.8	3.6	4.0/	3.7	3.8	3.8	3.3	3.4	3.2	3.0					
56109	3.6	3.5	4.0	3.9	3.5	3.8	3.7	3.9/	3.9	3.5	3.6	3.8	3.8	3.7	3.3	3.1	3.3						
56113	3.4	3.5	3.3	3.5	3.5	3.7	2.7	3.8/	3.5	3.5	3.5	3.4	3.3	3.4	3.4	3.0							
56114	3.6	3.5	3.7	3.6	3.7	3.6	3.6	3.2/	3.8	3.6	3.6	3.6	3.7	3.4									
56116	4.0	3.7	4.1	3.8	3.7	E	3.8	4.5	4.2	4.1/	3.7	4.3	3.9	3.8	4.0	3.8	E						
56118	3.3	3.4	3.6	3.5	3.1	2.6	3.7/	3.4	3.3	3.3	2.8	3.5	3.6	3.6	3.5	3.1							
56120	3.9	3.7	3.8	3.9	3.9	4.1	4.5/	4.0	3.8	4.4	4.0	3.8	3.9	3.5	3.6								
56125	3.8	3.7	3.9	3.6	3.8	3.8	3.9	3.8	3.9	3.5	4.2	E /	4.1	3.7	3.7	3.9	E	3.2	3.5				
56128	3.8	3.3	3.7	4.3	3.8	3.6	3.7	4.0	4.0/	3.7	3.7	3.9	E	3.3									
56131	3.6	3.3	3.7	3.9	3.6	3.6	3.6	3.9/	3.7	3.6	3.6	3.7	3.5	3.8	3.7	E	3.1						
56136	3.7	3.5	3.7	3.8	3.9	3.8	3.9	3.7	3.8	3.7	3.7/	4.1	3.7	3.5	3.7	3.6	3.5	3.3					
56139	3.6	3.2	3.8	E	3.7	3.8	3.6	3.9	3.8/	4.0	3.5	3.5	3.6	3.5	3.6	3.6	3.6	3.4	2.9				
56140	3.7	3.8	3.6	3.9	3.7	2.9	3.9/	3.7	E	3.1	4.4	4.1	3.7	3.9	3.6	4.1	E	E					
56141	3.9	3.7	4.2	3.7	4.1	E	E	3.6	4.2	E	4.2/	4.4	3.9	E	3.7	3.3							
56143	3.6	3.3	3.4	3.6	3.5	E	E	3.8	4.0	3.6	4.1/	E	3.9	3.7	3.3	3.9	3.8	3.2	3.4	3.1			
56145	3.4	3.2	3.1	3.0	3.2	3.5	E	3.1	3.3	3.9/	3.7	3.4	3.7	3.3	3.3	L							
56147	3.7	3.4	3.3	3.7	3.6	3.6	3.8	3.7	3.6	3.2	4.1/	3.6	3.7	4.1	3.8								
56150	3.9	3.6	3.9	3.8	4.4	4.3	4.1	3.7	4.0/	4.2	4.1	4.2	E	3.9	3.3	3.0							
56152	3.7	3.2	3.6	4.4	3.8/	3.9	3.5	3.7	3.8	3.6	3.6	4.1	3.4	3.2									
56155	4.5	4.1	E	4.5	4.6/	4.9	4.4	4.8	4.3	5.1	4.9	4.5	4.0	4.4	4.2								
56157	4.2	3.9	3.8	E	4.0	4.1	4.0	4.4	4.2/	4.5	4.2	4.3	4.3	4.4	4.2	4.3							
56159	3.5	3.2	3.4	3.2	3.7	4.0	3.8	3.7	4.1/	3.5	3.1	3.6	3.6	3.2	3.8	3.3	3.5	3.3					
56161	3.7	3.6	3.8	3.9	4.2	3.7/	3.7	3.7	3.7	3.6	3.8	3.4	2.8										
56164	3.6	3.3	3.8	3.7	3.9	4.1	3.3	3.2	3.6	3.4/	3.9	3.6	3.8	3.8	3.7	3.8	3.4						
MEAN	3.7																						
S.D.	0.26																						
S.E.	0.05																						
N	24																						

E = EARLY RESORPTION L = LATE RESORPTION D = DEAD FETUS '/' DENOTES POSITION OF CERVIX

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PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A16
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL FETAL EXTERNAL, VISCERAL AND SKELETAL FINDINGS

PAGE 1

DAMS FROM GROUP 1: 0 MG/KG/DAY		FETUS #	GRADE
56106		1 2 3 4 5 6 7 8 9 10 11 12 A A A A A A E/ A A A A A SEX: F M M F M F - F M M M M CEPHALIC: 1,3,5,8,10,12	
	SKELETAL	6 V CERVICAL CENTRUM #1 OSSIFIED	P
	EXTERNAL	7 EARLY RESORPTION	
	SKELETAL	9 V CERVICAL CENTRUM #1 OSSIFIED	P
		NO REMARKABLE OBSERVATIONS	
	EXTERNAL	1,2,3,4,5,6,8,9,10,11,12	
	VISCERAL	1,2,3,4,5,6,8,9,10,11,12	
	SKELETAL	1,2,3,4,5,8,10,11,12	
56107		1 2 3 4 5 6 7 8 9 10 11 12 13 A E A A A A A A A/ A A A A SEX: F - F F M M F F F M F F F CEPHALIC: 3,5,7,9,11,13	
	EXTERNAL	2 EARLY RESORPTION	
	SKELETAL	3 V 14TH RUDIMENTARY RIB(S) BILATERAL	P
	SKELETAL	4 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	SKELETAL	5 V 14TH RUDIMENTARY RIB(S) BILATERAL	P
	SKELETAL	6 V 14TH RUDIMENTARY RIB(S) LEFT	P
	SKELETAL	8 V 14TH RUDIMENTARY RIB(S) BILATERAL	P

A = VIABLE FETUS, E = EARLY RESORPTION, L = LATE RESORPTION, D = DEAD FETUS, "/" DENOTES CERVIX POSITION
OBSERVATION CODE: M = MALFORMATION, V = VARIATION GRADE CODE: 1 = SLIGHT, 2 = MODERATE, 3 = MARKED, P = PRESENT
SEX CODE: M = MALE, F = FEMALE, - = NOT APPLICABLE

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A16
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL FETAL EXTERNAL, VISCERAL AND SKELETAL FINDINGS

PAGE 2

DAMS FROM GROUP 1: 0 MG/KG/DAY		FETUS #		GRADE
56107	(CONTINUED)			
	SKELETAL	9	V 14TH RUDIMENTARY RIB(S) BILATERAL	P
	VISCERAL	11	ADRENAL GLAND(S)- AREA(S), DARK RED ONE, IRREGULARLY SHAPED, LEFT	P
	SKELETAL		V 14TH RUDIMENTARY RIB(S) LEFT	P
			V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	SKELETAL	13	V 14TH RUDIMENTARY RIB(S) LEFT	P
			NO REMARKABLE OBSERVATIONS	
	EXTERNAL		1,3,4,5,6,7,8,9,10,11,12,13	
	VISCERAL		1,3,4,5,6,7,8,9,10,12,13	
	SKELETAL		1,7,10,12	
56111			1 2 3 4 5 6 7 8 9 10 11 12 13 14 A A A A A A A/ A A A A A A SEX: M M F M F F M F M M F M F F CEPHALIC: 2,4,6,8,10,12,14	
	SKELETAL	3	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	4	V CERVICAL CENTRUM #1 OSSIFIED V 14TH RUDIMENTARY RIB(S) BILATERAL	P P
	SKELETAL	5	V HYOID UNOSSIFIED V CERVICAL CENTRUM #1 OSSIFIED	P P
	SKELETAL	6	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	7	V 14TH RUDIMENTARY RIB(S) BILATERAL	P
	SKELETAL	9	V HYOID UNOSSIFIED	P

A = VIABLE FETUS, E = EARLY RESORPTION, L = LATE RESORPTION, D = DEAD FETUS, "/" DENOTES CERVIX POSITION
OBSERVATION CODE: M = MALFORMATION, V = VARIATION GRADE CODE: 1 = SLIGHT, 2 = MODERATE, 3 = MARKED, P = PRESENT
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PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A16
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL FETAL EXTERNAL, VISCERAL AND SKELETAL FINDINGS

PAGE 3

DAMS FROM GROUP 1: 0 MG/KG/DAY		FETUS #		GRADE
56111	(CONTINUED)			
	SKELETAL	10	V 14TH RUDIMENTARY RIB(S) LEFT	P
	SKELETAL	11	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	SKELETAL	13	V CERVICAL CENTRUM #1 OSSIFIED V 14TH RUDIMENTARY RIB(S) LEFT	P P
	SKELETAL	14	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	EXTERNAL	NO REMARKABLE OBSERVATIONS		
	VISCERAL	1,2,3,4,5,6,7,8,9,10,11,12,13,14		
	SKELETAL	1,2,3,4,5,6,7,8,9,10,11,12,13,14 1,2,8,12		
56112		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15		
		A A A A A A A A/ A A A A A A E		
	SEX:	F M M M F M F F F M M M F F -		
	CEPHALIC:	1,3,5,7,9,11,13		
	SKELETAL	1	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5 AND #6	P
	SKELETAL	5	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	SKELETAL	7	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	SKELETAL	8	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	EXTERNAL	15	EARLY RESORPTION	

A = VIABLE FETUS, E = EARLY RESORPTION, L = LATE RESORPTION, D = DEAD FETUS, "/" DENOTES CERVIX POSITION
OBSERVATION CODE: M = MALFORMATION, V = VARIATION GRADE CODE: 1 = SLIGHT, 2 = MODERATE, 3 = MARKED, P = PRESENT
SEX CODE: M = MALE, F = FEMALE, - = NOT APPLICABLE

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A16
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL FETAL EXTERNAL, VISCERAL AND SKELETAL FINDINGS

PAGE 4

DAMS FROM GROUP 1: 0 MG/KG/DAY		FETUS #	GRADE
56112	(CONTINUED)		
		NO REMARKABLE OBSERVATIONS	
	EXTERNAL	1,2,3,4,5,6,7,8,9,10,11,12,13,14	
	VISCERAL	1,2,3,4,5,6,7,8,9,10,11,12,13,14	
	SKELETAL	2,3,4,6,9,10,11,12,13,14	
56115		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15	
		A A A A A/ A A A A A A A A A A	
	SEX:	F M F M M F F F M F F F M M F	
	CEPHALIC:	2,4,6,8,10,12,14	
	SKELETAL	1 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	SKELETAL	3 V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	6 V CERVICAL CENTRUM #1 OSSIFIED	P
		V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	SKELETAL	7 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	SKELETAL	10 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
		V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	15 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
		NO REMARKABLE OBSERVATIONS	
	EXTERNAL	1,2,3,4,5,6,7,8,9,10,11,12,13,14,15	
	VISCERAL	1,2,3,4,5,6,7,8,9,10,11,12,13,14,15	
	SKELETAL	2,4,5,8,9,11,12,13,14	
56117		1 2 3 4 5 6 7 8 9 10 11 12 13	
		A A A A A A A A/ A A A A A	
	SEX:	M F F M F F M F M F M M F	
	CEPHALIC:	2,4,6,8,10,12	
A = VIABLE FETUS, E = EARLY RESORPTION, L = LATE RESORPTION, D = DEAD FETUS, "/" DENOTES CERVIX POSITION OBSERVATION CODE: M = MALFORMATION, V = VARIATION GRADE CODE: 1 = SLIGHT, 2 = MODERATE, 3 = MARKED, P = PRESENT SEX CODE: M = MALE, F = FEMALE, - = NOT APPLICABLE			

PROJECT NO.:WIL-402008
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TABLE A16
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL FETAL EXTERNAL, VISCERAL AND SKELETAL FINDINGS

PAGE 5

DAMS FROM GROUP 1: 0 MG/KG/DAY		FETUS #		GRADE
56117	(CONTINUED)			
	SKELETAL	1	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	3	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	6	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	8	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	13	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
			#5	
			V CERVICAL CENTRUM #1 OSSIFIED	P
			NO REMARKABLE OBSERVATIONS	
	EXTERNAL		1,2,3,4,5,6,7,8,9,10,11,12,13	
	VISCERAL		1,2,3,4,5,6,7,8,9,10,11,12,13	
	SKELETAL		2,4,5,7,9,10,11,12	
56119		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16		
		A A A A A A A A A A/ A A A A A A		
	SEX:	M F F F F F M F M M F F M F F M		
	CEPHALIC:	2,4,6,8,10,12,14,16		
			NO REMARKABLE OBSERVATIONS	
	EXTERNAL		1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16	
	VISCERAL		1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16	
	SKELETAL		1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16	
56121		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15		
		A A A E A A A/ A A E A A A A A		
	SEX:	F F M - F F M F M - F M F M M		
	CEPHALIC:	2,5,7,9,12,14		
	SKELETAL	1	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
			#5	
	SKELETAL	2	V CERVICAL CENTRUM #1 OSSIFIED	P

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TABLE A16
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL FETAL EXTERNAL, VISCERAL AND SKELETAL FINDINGS

PAGE 6

DAMS FROM GROUP 1: 0 MG/KG/DAY		FETUS #		GRADE
56121	(CONTINUED)			
	EXTERNAL	4	EARLY RESORPTION	
	SKELETAL	6	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	8	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	9	V CERVICAL CENTRUM #1 OSSIFIED	P
	EXTERNAL	10	EARLY RESORPTION	
	SKELETAL	11	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	12	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	13	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	14	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	15	V CERVICAL CENTRUM #1 OSSIFIED	P
		NO REMARKABLE OBSERVATIONS		
	EXTERNAL	1,2,3,5,6,7,8,9,11,12,13,14,15		
	VISCERAL	1,2,3,5,6,7,8,9,11,12,13,14,15		
	SKELETAL	3,5,7		
56122		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17		
		A A A A E A/ A A A A A A A A A A		
	SEX:	F M M F - F M F F M F M M F M F M		
	CEPHALIC:	1,3,6,8,10,12,14,16		
	SKELETAL	1	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
		#5		
	EXTERNAL	5	EARLY RESORPTION	
	SKELETAL	8	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	14	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	17	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
		#5		

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PAGE 7

DAMS FROM GROUP 1: 0 MG/KG/DAY		FETUS #	GRADE
56122	(CONTINUED)	NO REMARKABLE OBSERVATIONS	
	EXTERNAL	1,2,3,4,6,7,8,9,10,11,12,13,14,15,16,17	
	VISCERAL	1,2,3,4,6,7,8,9,10,11,12,13,14,15,16,17	
	SKELETAL	2,3,4,6,7,9,10,11,12,13,15,16	
56123		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15	
		A A A A A/ A E A A A A A A E	
	SEX:	F M F M M M - F F M M F F F -	
	CEPHALIC:	2,4,6,9,11,13	
	SKELETAL	4 V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	6 V CERVICAL CENTRUM #1 OSSIFIED	P
	EXTERNAL	7 EARLY RESORPTION	
	SKELETAL	9 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
		#5	
	EXTERNAL	15 EARLY RESORPTION	
		NO REMARKABLE OBSERVATIONS	
	EXTERNAL	1,2,3,4,5,6,8,9,10,11,12,13,14	
	VISCERAL	1,2,3,4,5,6,8,9,10,11,12,13,14	
	SKELETAL	1,2,3,5,8,10,11,12,13,14	
56126		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	
		A A A A A A A E A A/ A A A A A A	
	SEX:	M M F M M F F - M F F M M F F F M	
	CEPHALIC:	1,3,5,7,10,12,14,16	
	SKELETAL	5 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
		#5	
	SKELETAL	7 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
		#5	

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PAGE 8

DAMS FROM GROUP 1:	0 MG/KG/DAY	FETUS #																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																													</
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PAGE 9

DAMS FROM GROUP 1: 0 MG/KG/DAY		FETUS #		GRADE
56130	(CONTINUED)			
	SKELETAL	1	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	5	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	SKELETAL	11	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	SKELETAL	13	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	14	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
			NO REMARKABLE OBSERVATIONS	
	EXTERNAL		1,2,3,4,5,6,7,8,9,10,11,12,13,14	
	VISCERAL		1,2,3,4,5,6,7,8,9,10,11,12,13,14	
	SKELETAL		2,3,4,6,7,8,9,10,12	
56132		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15		
		A A A A/ A A A A A A A A A A A		
	SEX:	M M F M F M F M F F M F F F F M		
	CEPHALIC:	1,3,5,7,9,11,13,15		
	SKELETAL	1	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	6	V BENT RIB(S) #6 THROUGH #8 AND #11, RIGHT	1
	SKELETAL	7	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	8	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	11	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	SKELETAL	12	V CERVICAL CENTRUM #1 OSSIFIED	P
			NO REMARKABLE OBSERVATIONS	
	EXTERNAL		1,2,3,4,5,6,7,8,9,10,11,12,13,14,15	
	VISCERAL		1,2,3,4,5,6,7,8,9,10,11,12,13,14,15	
	SKELETAL		2,3,4,5,9,10,13,14,15	

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PAGE 10

DAMS FROM GROUP	1:	0 MG/KG/DAY	FETUS #	GRADE
56134			1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 A A A A A A A/ A A A A A A A SEX: M M F M M F M M F M F M M M M CEPHALIC: 1,3,5,7,9,11,13,15 SKELETAL 3 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED P #5 NO REMARKABLE OBSERVATIONS EXTERNAL 1,2,3,4,5,6,7,8,9,10,11,12,13,14,15 VISCERAL 1,2,3,4,5,6,7,8,9,10,11,12,13,14,15 SKELETAL 1,2,4,5,6,7,8,9,10,11,12,13,14,15	
56137			1 2 3 4 5 6 7 8 9 10 11 12 13 A A A A A A A/ A A A A A A SEX: F F F M F F M M F F M M M CEPHALIC: 2,4,6,8,10,12 EXTERNAL 1 M VERTEBRAL AGENESIS CURLY TAIL VISCERAL CONFIRMATION OF VERTEBRAL AGENESIS P SKELETAL V STERNEBRA(E) #1,#2,#3 AND/OR #4 UNOSSIFIED P #4 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED P #5 AND #6 CONFIRMATION OF VERTEBRAL AGENESIS P ALL VERTEBRAE POSTERIOR TO SACRAL VERTEBRA #3 ABSENT SKELETAL 5 V 14TH RUDIMENTARY RIB(S) P LEFT V CERVICAL CENTRUM #1 OSSIFIED P	
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PAGE 11

DAMS FROM GROUP 1: 0 MG/KG/DAY		FETUS #		GRADE
56137	(CONTINUED)			
	SKELETAL	10	V 14TH RUDIMENTARY RIB(S) LEFT NO REMARKABLE OBSERVATIONS	P
	EXTERNAL		2,3,4,5,6,7,8,9,10,11,12,13	
	VISCERAL		2,3,4,5,6,7,8,9,10,11,12,13	
	SKELETAL		2,3,4,6,7,8,9,11,12,13	
56138		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15		
		A A A A A A A A A/ E A A A A A		
	SEX:	F F M F F M M M M - M M M F M		
	CEPHALIC:	1,3,5,7,9,12,14		
	SKELETAL	1	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	2	V REDUCED OSSIFICATION OF THE SKULL PARIETAL, BILATERAL	1
	SKELETAL	5	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	SKELETAL	6	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	7	V STERNEBRA(E) MALALIGNED(SLIGHT OR MODERATE) #4	1
			V CERVICAL CENTRUM #1 OSSIFIED	P
	EXTERNAL	10	EARLY RESORPTION	
	SKELETAL	11	V 14TH RUDIMENTARY RIB(S) RIGHT NO REMARKABLE OBSERVATIONS	P
	EXTERNAL		1,2,3,4,5,6,7,8,9,11,12,13,14,15	
	VISCERAL		1,2,3,4,5,6,7,8,9,11,12,13,14,15	
	SKELETAL		3,4,8,9,12,13,14,15	
56151		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15		
		A A/ A A A A A A A A A A A A A		
	SEX:	F M F F M F F M M M M F M M F		
	CEPHALIC:	2,4,6,8,10,12,14		

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PAGE 12

DAMS FROM GROUP	1: 0 MG/KG/DAY	FETUS #		GRADE
56151	(CONTINUED)			
	SKELETAL	1	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
			#5	
	SKELETAL	6	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	12	V CERVICAL CENTRUM #1 OSSIFIED	P
			V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
			#5	
	SKELETAL	13	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
			#5	
	SKELETAL	14	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
			#5	
			V 14TH RUDIMENTARY RIB(S)	P
			LEFT	
	SKELETAL	15	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
			#5	
			NO REMARKABLE OBSERVATIONS	
	EXTERNAL		1,2,3,4,5,6,7,8,9,10,11,12,13,14,15	
	VISCERAL		1,2,3,4,5,6,7,8,9,10,11,12,13,14,15	
	SKELETAL		2,3,4,5,7,8,9,10,11	
56154				
		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20		
		A E A E A A A A A/ A A A A A A A A A A		
	SEX:	M - F - M M M M F M F M F F F F M F F F		
	CEPHALIC:	1,5,7,9,11,13,15,17,19		
	EXTERNAL	2	EARLY RESORPTION	
	EXTERNAL	4	EARLY RESORPTION	
	SKELETAL	10	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	16	V CERVICAL CENTRUM #1 OSSIFIED	P

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TABLE A16
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL FETAL EXTERNAL, VISCERAL AND SKELETAL FINDINGS

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DAMS FROM GROUP 1: 0 MG/KG/DAY		FETUS #	GRADE
56154	(CONTINUED)	NO REMARKABLE OBSERVATIONS	
	EXTERNAL	1,3,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20	
	VISCERAL	1,3,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20	
	SKELETAL	1,3,5,6,7,8,9,11,12,13,14,15,17,18,19,20	
56156		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15	
		E A A A/ A E A A A E A A A A A	
	SEX:	- F M F F - M F M - F M M F M	
	CEPHALIC:	2,4,7,9,12,14	
	EXTERNAL	1 EARLY RESORPTION	
	SKELETAL	2 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
		#5	
		V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	3 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
		#5	
	EXTERNAL	6 EARLY RESORPTION	
	SKELETAL	7 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
		#5	
	EXTERNAL	10 EARLY RESORPTION	
	SKELETAL	11 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
		#5	
	SKELETAL	12 V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	14 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
		#5 AND #6	
		V REDUCED OSSIFICATION OF THE 13TH RIB(S)	1
		RIGHT	
	SKELETAL	15 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
		#5	

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DAMS FROM GROUP 1: 0 MG/KG/DAY		FETUS #	GRADE
56156	(CONTINUED)	NO REMARKABLE OBSERVATIONS	
	EXTERNAL	2,3,4,5,7,8,9,11,12,13,14,15	
	VISCERAL	2,3,4,5,7,8,9,11,12,13,14,15	
	SKELETAL	4,5,8,9,13	
56158		1 2 3 4 5 6 7 8 9 10 11 12 13	
		A E A A A A/ A A A A A A A	
	SEX:	F - F F F F F F M F M F F F	
	CEPHALIC:	1,4,6,8,10,12	
	EXTERNAL	2	EARLY RESORPTION
	SKELETAL	5	V CERVICAL CENTRUM #1 OSSIFIED
	SKELETAL	6	V CERVICAL CENTRUM #1 OSSIFIED
	SKELETAL	7	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED
		#5	
	SKELETAL	8	V CERVICAL CENTRUM #1 OSSIFIED
	SKELETAL	10	V STERNEBRA(E) MALALIGNED(SLIGHT OR MODERATE)
		#3 AND #4	
	EXTERNAL	13	M MICROPTHALMIA AND/OR ANOPHTHALMIA
			MICROPTHALMIA, RIGHT
	VISCERAL		CONFIRMATION OF MICROPTHALMIA
	SKELETAL		V REDUCED OSSIFICATION OF THE VERTEBRAL ARCHES
			CERVICAL #3 THROUGH #7, BILATERAL
			V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED
			#5 AND #6
			CONFIRMATION OF MICROPTHALMIA
			ORBIT SMALLER THAN NORMAL, RIGHT
			V 14TH RUDIMENTARY RIB(S)
			LEFT

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INDIVIDUAL FETAL EXTERNAL, VISCERAL AND SKELETAL FINDINGS

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DAMS FROM GROUP 1: 0 MG/KG/DAY		FETUS #	GRADE
56158	(CONTINUED)	NO REMARKABLE OBSERVATIONS	
	EXTERNAL	1,3,4,5,6,7,8,9,10,11,12	
	VISCERAL	1,3,4,5,6,7,8,9,10,11,12	
	SKELETAL	1,3,4,9,11,12	
56160		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	
		A A A A A A A A/ A A A A A E A A A	
	SEX:	M F M F F F F M F F M F F - M F F	
	CEPHALIC:	1,3,5,7,9,11,13,16	
	SKELETAL	1 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	SKELETAL	2 V UNCO-OSSIFIED VERTEBRAL CENTRA THORACIC #10 THROUGH LUMBAR #1 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	SKELETAL	3 V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	7 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
		V STERNEBRA(E) #1,#2,#3 AND/OR #4 UNOSSIFIED #2 AND #4	P
		V PUBIS UNOSSIFIED BILATERAL	P
		V 27 PRESACRAL VERTEBRAE	P
		V REDUCED OSSIFICATION OF THE VERTEBRAL ARCHES SACRAL #2 THROUGH #4, BILATERAL	1
	SKELETAL	8 V 14TH RUDIMENTARY RIB(S) RIGHT	P
		V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P

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DAMS FROM GROUP 1: 0 MG/KG/DAY		FETUS #		GRADE
56160	(CONTINUED)			
	SKELETAL	9	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	EXTERNAL	14	EARLY RESORPTION	
	EXTERNAL		NO REMARKABLE OBSERVATIONS	
	VISCERAL		1,2,3,4,5,6,7,8,9,10,11,12,13,15,16,17	
	SKELETAL		1,2,3,4,5,6,7,8,9,10,11,12,13,15,16,17	
			4,5,6,10,11,12,13,15,16,17	
56162		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16		
		A A A A A A A A/ A A A A A A A A		
	SEX:	M F F F F M M M M M F F F M F F		
	CEPHALIC:	1,3,5,7,9,11,13,15		
	SKELETAL	1	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	SKELETAL	6	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	10	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	SKELETAL	11	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	SKELETAL	16	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
			NO REMARKABLE OBSERVATIONS	
	EXTERNAL		1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16	
	VISCERAL		1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16	
	SKELETAL		2,3,4,5,7,8,9,12,13,14,15	
56165		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16		
		A A A A A A A A/ A A A A A A A A		
	SEX:	F M M M M F F M M M F F M F F F		
	CEPHALIC:	2,4,6,8,10,12,14,16		

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DAMS FROM GROUP 1: 0 MG/KG/DAY		FETUS #		GRADE
56165	(CONTINUED)			
	SKELETAL	9	V 14TH RUDIMENTARY RIB(S) BILATERAL	P
	SKELETAL	10	V 14TH RUDIMENTARY RIB(S) LEFT	P
	SKELETAL	11	V 14TH RUDIMENTARY RIB(S) BILATERAL	P
	SKELETAL	12	V 14TH RUDIMENTARY RIB(S) BILATERAL	P
	SKELETAL	15	V 7TH CERVICAL RIB(S) PINPOINT, BILATERAL	P
			NO REMARKABLE OBSERVATIONS	
	EXTERNAL		1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16	
	VISCERAL		1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16	
	SKELETAL		1,2,3,4,5,6,7,8,13,14,16	

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RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
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DAMS FROM GROUP 2: 1000 MG/KG/DAY		FETUS #																	GRADE
56108		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	
		A	A	A	E	A	A	A	A	A	A/	A	A	A	A	A	A	A	
SEX:		F	M	M	-	F	M	F	M	F	F	F	F	F	F	F	F	F	
CEPHALIC:		1,3,6,8,10,12,14,16																	
SKELETAL		1	V CERVICAL CENTRUM #1 OSSIFIED																P
EXTERNAL		4	EARLY RESORPTION																
SKELETAL		6	V CERVICAL CENTRUM #1 OSSIFIED																P
SKELETAL		8	V CERVICAL CENTRUM #1 OSSIFIED																P
SKELETAL		9	V CERVICAL CENTRUM #1 OSSIFIED																P
SKELETAL		10	V CERVICAL CENTRUM #1 OSSIFIED																P
SKELETAL		12	V CERVICAL CENTRUM #1 OSSIFIED																P
			V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED																P
			#5																
SKELETAL		14	V CERVICAL CENTRUM #1 OSSIFIED																P
SKELETAL		17	V 7TH CERVICAL RIB(S)																P
			PINPOINT, LEFT																
			V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED																P
			#5																
			NO REMARKABLE OBSERVATIONS																
EXTERNAL			1,2,3,5,6,7,8,9,10,11,12,13,14,15,16,17																
VISCERAL			1,2,3,5,6,7,8,9,10,11,12,13,14,15,16,17																
SKELETAL			2,3,5,7,11,13,15,16																
56109		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16		
		A	A	A	A	A	A	A/	A	A	A	A	A	A	A	A	A		
SEX:		M	F	M	F	M	M	F	M	F	F	M	F	M	M	M	M		
CEPHALIC:		2,4,6,8,10,12,14,16																	

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DAMS FROM GROUP 2: 1000 MG/KG/DAY		FETUS #		GRADE
56109	(CONTINUED)			
	SKELETAL	2	V REDUCED OSSIFICATION OF THE VERTEBRAL ARCHES CERVICAL #4 THROUGH #6, BILATERAL	1
	SKELETAL	4	V 14TH RUDIMENTARY RIB(S) LEFT	P
	VISCERAL	7	V RENAL PAPILLA(E) NOT DEVELOPED AND/OR DISTENDED URETER(S) URETER, BILATERAL	1
	SKELETAL	8	V STERNEBRA(E) MALALIGNED(SLIGHT OR MODERATE) #3 AND #4	1
	SKELETAL	9	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	SKELETAL	10	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
			V 14TH RUDIMENTARY RIB(S) RIGHT	P
	SKELETAL	11	V 14TH RUDIMENTARY RIB(S) RIGHT	P
	SKELETAL	15	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5 AND #6	P
	SKELETAL	16	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5 AND #6	P
			NO REMARKABLE OBSERVATIONS	
	EXTERNAL		1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16	
	VISCERAL		1,2,3,4,5,6,8,9,10,11,12,13,14,15,16	
	SKELETAL		1,3,5,6,7,12,13,14	
56113		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15		
		A A A A A A A/ A A A A A A A A		
	SEX:	M F M F F F F F F M M F M M M		
	CEPHALIC:	2,4,6,8,10,12,14		

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DAMS FROM GROUP	2: 1000 MG/KG/DAY	FETUS #		GRADE
56113	(CONTINUED)			
	SKELETAL	4	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	6	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
			#5 AND #6	
			V STERNEBRA(E) #1,#2,#3 AND/OR #4 UNOSSIFIED	P
			#2	
			V 14TH RUDIMENTARY RIB(S)	P
			BILATERAL	
	SKELETAL	7	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	8	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
			#5	
	SKELETAL	9	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
			#5	
	SKELETAL	13	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	14	V CERVICAL CENTRUM #1 OSSIFIED	P
			NO REMARKABLE OBSERVATIONS	
	EXTERNAL		1,2,3,4,5,6,7,8,9,10,11,12,13,14,15	
	VISCERAL		1,2,3,4,5,6,7,8,9,10,11,12,13,14,15	
	SKELETAL		1,2,3,5,10,11,12,15	
56114		1 2 3 4 5 6 7 8 9 10 11 12		
		A A A A A A A A/ A A A A A		
	SEX:	F M M M F F F M F M M F		
	CEPHALIC:	1,3,5,7,9,11		
	SKELETAL	5	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	9	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
			#5	
	SKELETAL	12	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
			#5	

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DAMS FROM GROUP 2: 1000 MG/KG/DAY		FETUS #	GRADE
56114	(CONTINUED)	NO REMARKABLE OBSERVATIONS	
	EXTERNAL	1,2,3,4,5,6,7,8,9,10,11,12	
	VISCERAL	1,2,3,4,5,6,7,8,9,10,11,12	
	SKELETAL	1,2,3,4,6,7,8,10,11	
56116		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	
		A A A A E A A A A/ A A A A A A E	
	SEX:	M M M M - F M F M F M M M M -	
	CEPHALIC:	1,3,6,8,10,12,14	
	SKELETAL	1 V CERVICAL CENTRUM #1 OSSIFIED	P
	EXTERNAL	5 EARLY RESORPTION	
	SKELETAL	8 V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	10 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
		#5	
	SKELETAL	13 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
		#5	
	EXTERNAL	16 EARLY RESORPTION	
		NO REMARKABLE OBSERVATIONS	
	EXTERNAL	1,2,3,4,6,7,8,9,10,11,12,13,14,15	
	VISCERAL	1,2,3,4,6,7,8,9,10,11,12,13,14,15	
	SKELETAL	2,3,4,6,7,9,11,12,14,15	
56118		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15	
		A A A A A A/ A A A A A A A A	
	SEX:	F M F F F M F F F F M M F M M	
	CEPHALIC:	1,3,5,7,9,11,13,15	

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DAMS FROM GROUP 2: 1000 MG/KG/DAY		FETUS #	GRADE
56118	(CONTINUED)		
		NO REMARKABLE OBSERVATIONS	
	EXTERNAL	1,2,3,4,5,6,7,8,9,10,11,12,13,14,15	
	VISCERAL	1,2,3,4,5,6,7,8,9,10,11,12,13,14,15	
	SKELETAL	1,2,3,4,5,6,7,8,9,10,11,12,13,14,15	
56120		1 2 3 4 5 6 7 8 9 10 11 12 13 14	
		A A A A A A/ A A A A A A A	
	SEX:	M M M M M M F F M M M M F M	
	CEPHALIC:	1,3,5,7,9,11,13	
	SKELETAL	3 V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	7 V CERVICAL CENTRUM #1 OSSIFIED	P
		NO REMARKABLE OBSERVATIONS	
	EXTERNAL	1,2,3,4,5,6,7,8,9,10,11,12,13,14	
	VISCERAL	1,2,3,4,5,6,7,8,9,10,11,12,13,14	
	SKELETAL	1,2,4,5,6,8,9,10,11,12,13,14	
56125		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	
		A A A A A A A A A A E/ A A A A E A A	
	SEX:	M M M M F M M M F M - M F M M - F F	
	CEPHALIC:	2,4,6,8,10,13,15,18	
	SKELETAL	4 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
		#5	
	SKELETAL	7 V 14TH RUDIMENTARY RIB(S)	P
		LEFT	
	SKELETAL	8 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
		#5	
	SKELETAL	9 V 14TH RUDIMENTARY RIB(S)	P
		LEFT	

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DAMS FROM GROUP 2: 1000 MG/KG/DAY		FETUS #		GRADE
56125	(CONTINUED)			
	SKELETAL	9	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	EXTERNAL	11	EARLY RESORPTION	
	SKELETAL	12	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	15	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	EXTERNAL	16	EARLY RESORPTION	
	SKELETAL	17	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	SKELETAL	18	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
			V CERVICAL CENTRUM #1 OSSIFIED	P
			NO REMARKABLE OBSERVATIONS	
	EXTERNAL		1,2,3,4,5,6,7,8,9,10,12,13,14,15,17,18	
	VISCERAL		1,2,3,4,5,6,7,8,9,10,12,13,14,15,17,18	
	SKELETAL		1,2,3,5,6,10,13,14	
56128				
			1 2 3 4 5 6 7 8 9 10 11 12 13	
			A A A A A A A A/ A A A E A	
	SEX:		F F M M F F F F M M M - F	
	CEPHALIC:		1,3,5,7,9,11	
	SKELETAL	2	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
			V REDUCED OSSIFICATION OF THE 13TH RIB(S) BILATERAL	1
	SKELETAL	5	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	6	V CERVICAL CENTRUM #1 OSSIFIED	P
	EXTERNAL	12	EARLY RESORPTION	

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RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL FETAL EXTERNAL, VISCERAL AND SKELETAL FINDINGS

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DAMS FROM GROUP 2: 1000 MG/KG/DAY		FETUS #	GRADE
56128	(CONTINUED)	NO REMARKABLE OBSERVATIONS	
	EXTERNAL	1,2,3,4,5,6,7,8,9,10,11,13	
	VISCERAL	1,2,3,4,5,6,7,8,9,10,11,13	
	SKELETAL	1,3,4,7,8,9,10,11,13	
56131		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	
		A A A A A A A/ A A A A A A A E A	
	SEX:	F M F F F F F F M F F M M M - M	
	CEPHALIC:	2,4,6,8,10,12,14	
	SKELETAL	9 V BENT RIB(S)	1
		#5 THROUGH #8 AND #11, RIGHT	
	SKELETAL	10 V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	12 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
		#5	
	EXTERNAL	15 EARLY RESORPTION	
		NO REMARKABLE OBSERVATIONS	
	EXTERNAL	1,2,3,4,5,6,7,8,9,10,11,12,13,14,16	
	VISCERAL	1,2,3,4,5,6,7,8,9,10,11,12,13,14,16	
	SKELETAL	1,2,3,4,5,6,7,8,11,13,14,16	
56136		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	
		A A A A A A A A A/ A A A A A A A	
	SEX:	M M M M F M F M F F M F F M M F F	
	CEPHALIC:	1,3,5,7,9,11,13,15,17	
	SKELETAL	1 V 14TH RUDIMENTARY RIB(S)	P
		LEFT	
	SKELETAL	3 V 14TH RUDIMENTARY RIB(S)	P
		BILATERAL	

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DAMS FROM GROUP	2: 1000 MG/KG/DAY	FETUS #	GRADE
56136	(CONTINUED)		
	SKELETAL	5 V 14TH RUDIMENTARY RIB(S) LEFT	P
	SKELETAL	7 V 14TH RUDIMENTARY RIB(S) BILATERAL	P
	SKELETAL	11 V 14TH RUDIMENTARY RIB(S) BILATERAL	P
	SKELETAL	15 V 14TH RUDIMENTARY RIB(S) BILATERAL	P
		NO REMARKABLE OBSERVATIONS	
	EXTERNAL	1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17	
	VISCERAL	1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17	
	SKELETAL	2,4,6,8,9,10,12,13,14,16,17	
56139		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 A A E A A A A A/ A A A A A A A A A SEX: F M - M M F M F M F M M F M M F M F CEPHALIC: 2,5,7,9,11,13,15,17	
	EXTERNAL	3 EARLY RESORPTION	
	SKELETAL	13 V 14TH RUDIMENTARY RIB(S) BILATERAL	P
	SKELETAL	18 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
		V 14TH RUDIMENTARY RIB(S) LEFT	P
		NO REMARKABLE OBSERVATIONS	
	EXTERNAL	1,2,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18	
	VISCERAL	1,2,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18	
	SKELETAL	1,2,4,5,6,7,8,9,10,11,12,14,15,16,17	
56140		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 A A A A A A/ A E A A A A A A A E E SEX: M F F F F M F - M M M F M F F - - CEPHALIC: 1,3,5,7,10,12,14	

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DAMS FROM GROUP 2: 1000 MG/KG/DAY		FETUS #		GRADE
56140	(CONTINUED)			
	SKELETAL	3	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
			#5	
	SKELETAL	5	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
			#5	
	EXTERNAL	8	EARLY RESORPTION	
	EXTERNAL	16	EARLY RESORPTION	
	EXTERNAL	17	EARLY RESORPTION	
		NO REMARKABLE OBSERVATIONS		
	EXTERNAL	1,2,3,4,5,6,7,9,10,11,12,13,14,15		
	VISCERAL	1,2,3,4,5,6,7,9,10,11,12,13,14,15		
	SKELETAL	1,2,4,6,7,9,10,11,12,13,14,15		
56141		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15		
		A A A A E E A A E A/ A A E A A		
	SEX:	F F F F - - F M - F M F - F F		
	CEPHALIC:	2,4,7,8,11,14		
	SKELETAL	1	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	4	V CERVICAL CENTRUM #1 OSSIFIED	P
	EXTERNAL	5	EARLY RESORPTION	
	EXTERNAL	6	EARLY RESORPTION	
	SKELETAL	8	V CERVICAL CENTRUM #1 OSSIFIED	P
	EXTERNAL	9	EARLY RESORPTION	
	SKELETAL	10	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	12	V CERVICAL CENTRUM #1 OSSIFIED	P
	EXTERNAL	13	EARLY RESORPTION	
		NO REMARKABLE OBSERVATIONS		
	EXTERNAL	1,2,3,4,7,8,10,11,12,14,15		
	VISCERAL	1,2,3,4,7,8,10,11,12,14,15		
	SKELETAL	2,3,7,11,14,15		

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DAMS FROM GROUP 2: 1000 MG/KG/DAY		FETUS #																			GRADE
56143		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	
		A	A	A	A	E	E	A	A	A/	E	A	A	A	A	A	A	A	A	A	
SEX:		M	M	F	M	-	-	F	F	F	M	-	F	F	F	F	M	M	F	F	
CEPHALIC:		2,4,8,10,13,15,17,19																			
SKELETAL		1		V STERNEBRA (E) #5 AND/OR #6 UNOSSIFIED																	P
				V REDUCED OSSIFICATION OF THE 13TH RIB(S) RIGHT																	1
SKELETAL		2		V 14TH RUDIMENTARY RIB(S) LEFT																	P
SKELETAL		3		V 14TH RUDIMENTARY RIB(S) LEFT																	P
SKELETAL		4		V STERNEBRA (E) #5 AND/OR #6 UNOSSIFIED																	P
EXTERNAL		5		EARLY RESORPTION																	
EXTERNAL		6		EARLY RESORPTION																	
SKELETAL		7		V STERNEBRA (E) #5 AND/OR #6 UNOSSIFIED																	P
SKELETAL		9		V STERNEBRA (E) #5 AND/OR #6 UNOSSIFIED																	P
EXTERNAL		11		EARLY RESORPTION																	
SKELETAL		12		V STERNEBRA (E) #5 AND/OR #6 UNOSSIFIED																	P
SKELETAL		14		V STERNEBRA (E) #5 AND/OR #6 UNOSSIFIED																	P
SKELETAL		15		V STERNEBRA (E) #5 AND/OR #6 UNOSSIFIED																	P
SKELETAL		19		V STERNEBRA (E) #5 AND/OR #6 UNOSSIFIED																	P

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DAMS FROM GROUP 2: 1000 MG/KG/DAY		FETUS #	GRADE
56143	(CONTINUED)		
		#5	
		NO REMARKABLE OBSERVATIONS	
	EXTERNAL	1,2,3,4,7,8,9,10,12,13,14,15,16,17,18,19	
	VISCERAL	1,2,3,4,7,8,9,10,12,13,14,15,16,17,18,19	
	SKELETAL	8,10,13,16,17,18	
56145			
		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15	
		A A A A A E A A A/ A A A A A L	
	SEX:	M M M F F - F F M F M M F F -	
	CEPHALIC:	2,4,7,9,11,13	
	SKELETAL	1 V 14TH RUDIMENTARY RIB(S) LEFT	P
	VISCERAL	2 M SITUS INVERSUS TRACHEA, ESOPHAGUS, LUNGS, LIVER, STOMACH, SPLEEN, PANCREAS, KIDNEYS, ADRENAL GLANDS, AND INTESTINE Laterally transposed	P
	SKELETAL	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5 AND #6	P
		V STERNEBRA(E) #1,#2,#3 AND/OR #4 UNOSSIFIED #2	P
	SKELETAL	3 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	SKELETAL	5 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	EXTERNAL	6 EARLY RESORPTION	
	SKELETAL	7 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED #5	P
	SKELETAL	8 V 14TH RUDIMENTARY RIB(S) LEFT	P
		V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P

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DAMS FROM GROUP 2: 1000 MG/KG/DAY		FETUS #		GRADE
56145	(CONTINUED)			
			#5	
	SKELETAL	9	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	10	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
			#5	
	SKELETAL	11	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
			#5	
	SKELETAL	13	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
			#5	
	SKELETAL	14	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
			#5	
	EXTERNAL	15	LATE RESORPTION	
			CROWN-RUMP LENGTH: 3.0 CM, MUMMIFIED	
			NO REMARKABLE OBSERVATIONS	
	EXTERNAL		1,2,3,4,5,7,8,9,10,11,12,13,14	
	VISCERAL		1,3,4,5,7,8,9,10,11,12,13,14	
	SKELETAL		4,12	
56147				
		1 2 3 4 5 6 7 8 9 10 11 12 13 14		
		A A A A A A A A A A/ A A A A		
	SEX:	F F F F M M M M F M F F M F		
	CEPHALIC:	2,4,6,8,10,12,14		
	SKELETAL	5	V 7TH CERVICAL RIB(S)	P
			PINPOINT, LEFT	
	SKELETAL	13	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	14	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
			#5	

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DAMS FROM GROUP 2: 1000 MG/KG/DAY		FETUS #															GRADE	
56147	(CONTINUED)																	
		NO REMARKABLE OBSERVATIONS																
	EXTERNAL	1,2,3,4,5,6,7,8,9,10,11,12,13,14																
	VISCERAL	1,2,3,4,5,6,7,8,9,10,11,12,13,14																
	SKELETAL	1,2,3,4,6,7,8,9,10,11,12																
56150		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15		
		A	A	A	A	A	A	A	A/	A	A	A	E	A	A	A		
	SEX:	M	M	F	M	M	M	F	F	M	F	M	-	M	F	F		
	CEPHALIC:	1,3,5,7,9,11,14																
	SKELETAL		2	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED													P	
				#5														
	SKELETAL		3	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED													P	
				#5														
				V 14TH RUDIMENTARY RIB(S)													P	
				RIGHT														
	SKELETAL		4	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED													P	
				#5														
				V CERVICAL CENTRUM #1 OSSIFIED													P	
	SKELETAL		5	V CERVICAL CENTRUM #1 OSSIFIED													P	
	SKELETAL		6	V CERVICAL CENTRUM #1 OSSIFIED													P	
	SKELETAL		7	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED													P	
				#5														
	SKELETAL		8	V CERVICAL CENTRUM #1 OSSIFIED													P	
				V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED													P	
				#5														
	SKELETAL		9	V CERVICAL CENTRUM #1 OSSIFIED													P	
	SKELETAL		10	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED													P	
				#5														
				V CERVICAL CENTRUM #1 OSSIFIED													P	

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DAMS FROM GROUP	2: 1000 MG/KG/DAY	FETUS #	GRADE
56150	(CONTINUED)		
	EXTERNAL	12	EARLY RESORPTION
	SKELETAL	14	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED
		#5	
		NO REMARKABLE OBSERVATIONS	
	EXTERNAL	1,2,3,4,5,6,7,8,9,10,11,13,14,15	
	VISCERAL	1,2,3,4,5,6,7,8,9,10,11,13,14,15	
	SKELETAL	1,11,13,15	
56152		1 2 3 4 5 6 7 8 9 10 11 12 13	
		A A A A/ A A A A A A A A	
	SEX:	M M M F M M M M M F M F F	
	CEPHALIC:	1,3,5,7,9,11,13	
	SKELETAL	1	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED
		#5 AND #6	
	EXTERNAL	5	M MICROPHthalmia AND/OR ANOPHTHALMIA
		MICROPHthalmia, LEFT	
	VISCERAL		CONFIRMATION OF MICROPHthalmia
	SKELETAL	8	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED
		#5	
	SKELETAL	9	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED
		#5	
	SKELETAL	11	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED
		#5	
	SKELETAL	13	V CERVICAL CENTRUM #1 OSSIFIED
		NO REMARKABLE OBSERVATIONS	
	EXTERNAL	1,2,3,4,6,7,8,9,10,11,12,13	
	VISCERAL	1,2,3,4,6,7,8,9,10,11,12,13	
	SKELETAL	2,3,4,5,6,7,10,12	
56155		1 2 3 4 5 6 7 8 9 10 11 12 13 14	
		A E A A/ A A A A A A A A	
	SEX:	M - M F M F M F M M M F M M	
	CEPHALIC:	3,5,7,9,11,13	

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* = CEPHALIC FINDING

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DAMS FROM GROUP 2: 1000 MG/KG/DAY		FETUS #		GRADE
56155	(CONTINUED)			
	EXTERNAL	2	EARLY RESORPTION	
	SKELETAL	4	V 14TH RUDIMENTARY RIB(S) LEFT	P
	VISCERAL	6	V HEMORRHAGIC RING AROUND THE IRIS RIGHT	P
	SKELETAL	9	V CERVICAL CENTRUM #1 OSSIFIED	P
	VISCERAL	10	V HEMORRHAGIC RING AROUND THE IRIS BILATERAL	P
			NO REMARKABLE OBSERVATIONS	
	EXTERNAL		1,3,4,5,6,7,8,9,10,11,12,13,14	
	VISCERAL		1,3,4,5,7,8,9,11,12,13,14	
	SKELETAL		1,3,5,6,7,8,10,11,12,13,14	
56157		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15		
		A A E A A A A A/ A A A A A A A		
	SEX:	M F - F F F M F M F M F M F M		
	CEPHALIC:	2,5,7,9,11,13,15		
	SKELETAL	1	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	2	V CERVICAL CENTRUM #1 OSSIFIED	P
	EXTERNAL	3	EARLY RESORPTION	
	SKELETAL	4	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	5	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	6	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	8	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	10	V REDUCED OSSIFICATION OF THE 13TH RIB(S) LEFT	1
	SKELETAL	12	V CERVICAL CENTRUM #1 OSSIFIED	P
	SKELETAL	14	V CERVICAL CENTRUM #1 OSSIFIED	P

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INDIVIDUAL FETAL EXTERNAL, VISCERAL AND SKELETAL FINDINGS

PAGE 33

DAMS FROM GROUP	2: 1000 MG/KG/DAY	FETUS #	GRADE
56157	(CONTINUED)	NO REMARKABLE OBSERVATIONS	
	EXTERNAL	1,2,4,5,6,7,8,9,10,11,12,13,14,15	
	VISCERAL	1,2,4,5,6,7,8,9,10,11,12,13,14,15	
	SKELETAL	7,9,11,13,15	
56159		1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	
	SEX:	A A A A A A A A/ A A A A A A A A	
	CEPHALIC:	F M F F M F F M M F M F F M F M F	
		2,4,6,8,10,12,14,16	
	SKELETAL	1 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
	SKELETAL	6 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
	SKELETAL	9 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
	SKELETAL	10 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
	SKELETAL	11 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
	SKELETAL	14 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
	SKELETAL	15 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
	SKELETAL	17 V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
		NO REMARKABLE OBSERVATIONS	
	EXTERNAL	1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17	
	VISCERAL	1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17	
	SKELETAL	2,3,4,5,7,8,12,13,16	

A = VIABLE FETUS, E = EARLY RESORPTION, L = LATE RESORPTION, D = DEAD FETUS, "/" DENOTES CERVIX POSITION
OBSERVATION CODE: M = MALFORMATION, V = VARIATION GRADE CODE: 1 = SLIGHT, 2 = MODERATE, 3 = MARKED, P = PRESENT
SEX CODE: M = MALE, F = FEMALE, - = NOT APPLICABLE

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A16
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL FETAL EXTERNAL, VISCERAL AND SKELETAL FINDINGS

PAGE 34

DAMS FROM GROUP 2: 1000 MG/KG/DAY		FETUS #												GRADE																
56161		1	2	3	4	5	6	7	8	9	10	11	12																	
		A	A	A	A	A/	A	A	A	A	A	A	A																	
SEX:		F	F	M	M	F	F	M	F	F	M	F	F																	
CEPHALIC:		2,4,6,8,10,12																												
SKELETAL		1	V REDUCED OSSIFICATION OF THE SKULL											1																
			PARIETAL, BILATERAL																											
SKELETAL		3	V CERVICAL CENTRUM #1 OSSIFIED											P																
			V BENT RIB(S)											P																
			#5 THROUGH #11, MODERATE, RIGHT; #5 THROUGH #7 AND																											
			#10 THROUGH #12, MODERATE, LEFT; #12, SLIGHT, RIGHT;																											
			#8 AND #9, SLIGHT, LEFT; REDUCED OSSIFICATION OF #10 AND #11,																											
			SLIGHT, RIGHT; REDUCED OSSIFICATION OF #8 AND #11, SLIGHT,																											
			LEFT																											
SKELETAL		9	V 14TH RUDIMENTARY RIB(S)											P																
			BILATERAL																											
SKELETAL		10	V CERVICAL CENTRUM #1 OSSIFIED											P																
			V 14TH RUDIMENTARY RIB(S)											P																
			BILATERAL																											
SKELETAL		11	V CERVICAL CENTRUM #1 OSSIFIED											P																
SKELETAL		12	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED											P																
			#5																											
		NO REMARKABLE OBSERVATIONS																												
EXTERNAL		1,2,3,4,5,6,7,8,9,10,11,12																												
VISCERAL		1,2,3,4,5,6,7,8,9,10,11,12																												
SKELETAL		2,4,5,6,7,8																												
56164		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16													
		A	A	A	A	A	A	A	A	A/	A	A	A	A	A	A	A													
SEX:		M	F	M	F	M	M	F	M	F	M	F	M	F	F	F	F													
CEPHALIC:		1,3,5,7,9,11,13,15																												

A = VIABLE FETUS, E = EARLY RESORPTION, L = LATE RESORPTION, D = DEAD FETUS, "/" DENOTES CERVIX POSITION
OBSERVATION CODE: M = MALFORMATION, V = VARIATION GRADE CODE: 1 = SLIGHT, 2 = MODERATE, 3 = MARKED, P = PRESENT
SEX CODE: M = MALE, F = FEMALE, - = NOT APPLICABLE

PROJECT NO.:WIL-402008
SPONSOR:AMERICAN PETROLEUM

TABLE A16
RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP
INDIVIDUAL FETAL EXTERNAL, VISCERAL AND SKELETAL FINDINGS

PAGE 35

DAMS FROM GROUP 2: 1000 MG/KG/DAY		FETUS #		GRADE
56164	(CONTINUED)			
	SKELETAL	1	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
			#5	
	SKELETAL	15	V STERNEBRA(E) #5 AND/OR #6 UNOSSIFIED	P
			#5	
			NO REMARKABLE OBSERVATIONS	
	EXTERNAL		1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16	
	VISCERAL		1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16	
	SKELETAL		2,3,4,5,6,7,8,9,10,11,12,13,14,16	

A = VIABLE FETUS, E = EARLY RESORPTION, L = LATE RESORPTION, D = DEAD FETUS, "/" DENOTES CERVIX POSITION
OBSERVATION CODE: M = MALFORMATION, V = VARIATION GRADE CODE: 1 = SLIGHT, 2 = MODERATE, 3 = MARKED, P = PRESENT
SEX CODE: M = MALE, F = FEMALE, - = NOT APPLICABLE

PFETv4.14
12/16/2009
R:04/15/2010

APPENDIX B

Characterization Reports (Sponsor-Provided Data)



Deer Park Technical Center Laboratory
1114 Seaco Avenue
Deer Park, Texas 77536
USA
Tel: (713) 844-3200

Report of Analysis

Job Reference: US785-0017157
Job Location: Deer Park, TX, USA
Vessel: API

Date Job Created: 01-Apr-2009
Job Description: Analysis only of VARIOUS CRUDE OIL SAMPLES at
Deer Park, TX, USA on April 1, 2009

Client: American Petroleum Institute (API)
Contact: Paula Podhasky

Customer Reference:
PO# 2008-103518
APIREG10374601
VARIOUS CRUDE OIL SAMPLES



Report of Analysis

Sample Summary

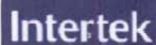
Sample Number	Date Completed	Description
2009-DRPK-003707-001	20-Apr-2009	Site #4, Sx. #3 (As Received)
2009-DRPK-003707-002	16-Apr-2009	Site #16, Sx. #6 (As Received)
2009-DRPK-003707-003	16-Apr-2009	Site #23, Sx. #12 (As Received)
2009-DRPK-003707-004	16-Apr-2009	Site #26, Sx. #8 (As Received)
2009-DRPK-003707-005	16-Apr-2009	Site #41, Sx. #1 (As Received)
2009-DRPK-003707-006	16-Apr-2009	Site #16, Sx. #8 (As Received)
2009-DRPK-003707-007	16-Apr-2009	Site #25, Sx. #3 (As Received)
2009-DRPK-003707-008	16-Apr-2009	Site #32, Sx. #5 (As Received)
2009-DRPK-003707-009	16-Apr-2009	Site #7, Sx. #3 (As Received)
2009-DRPK-003707-010	16-Apr-2009	Site #25, Sx. #5 (As Received)
2009-DRPK-003707-011	16-Apr-2009	Site #25, Sx. #6 (As Received)
2009-DRPK-003707-012	16-Apr-2009	Site #31, Sx. #7 (As Received)
2009-DRPK-003707-013	20-Apr-2009	Site #34, Sx. #2 (As Received)
2009-DRPK-003707-014	08-Apr-2009	Site #26, Sx. #20 (As Received)
2009-DRPK-003707-015	08-Apr-2009	Site #31, Sx. #2 (As Received)
2009-DRPK-003707-017	08-Apr-2009	Site #11, Sx. #1 (As Received)
2009-DRPK-003707-018	08-Apr-2009	Site #17, Sx. #11 (As Received)
2009-DRPK-003707-019	08-Apr-2009	Site #26, Sx. #7 (As Received)
2009-DRPK-003707-020	08-Apr-2009	Site #31, Sx. #5 (As Received)
2009-DRPK-003707-021	08-Apr-2009	Site #12, Sx. #15 (As Received)
2009-DRPK-003707-022	08-Apr-2009	Site #11, Sx. #3 (As Received)
2009-DRPK-003707-023	08-Apr-2009	Site #20, Sx. #2 (As Received)
2009-DRPK-003707-024	08-Apr-2009	Site #26, Sx. #13 (As Received)
2009-DRPK-003707-025	08-Apr-2009	Site #26, Sx. #14 (As Received)
2009-DRPK-003707-026	08-Apr-2009	Site #23, Sx. #11 (As Received)
2009-DRPK-003707-027	08-Apr-2009	Site #7, Sx. #1 (As Received)
2009-DRPK-003707-028	08-Apr-2009	Site #12, Sx. #10 (As Received)
2009-DRPK-003707-029	08-Apr-2009	Site #9, Sx. #1 (As Received)
2009-DRPK-003707-030	08-Apr-2009	Site #33, Sx. #3 (As Received)
2009-DRPK-003707-031	08-Apr-2009	Site #7, Sx. #4 (As Received)
2009-DRPK-003707-032	08-Apr-2009	Site #33, Sx. #2 (As Received)
2009-DRPK-003707-033	08-Apr-2009	Site #6, Sx. #2 (As Received)
2009-DRPK-003707-034	08-Apr-2009	Site #25, Sx. #13 (As Received)
2009-DRPK-003707-035	08-Apr-2009	Site #7, Sx. #5 (As Received)
2009-DRPK-003707-036	08-Apr-2009	Site #23, Sx. #1 (As Received)
2009-DRPK-003707-037	08-Apr-2009	Site #25, Sx. #8 (As Received)
2009-DRPK-003707-038	08-Apr-2009	Site #12, Sx. #17 (As Received)
2009-DRPK-003707-039	13-Apr-2009	Site #34, Sx. #6 (As Received)
2009-DRPK-003707-040	08-Apr-2009	Site #12, Sx. #16 (As Received)
2009-DRPK-003707-041	08-Apr-2009	Site #23, Sx. #2 (As Received)
2009-DRPK-003707-042	08-Apr-2009	Site #12, Sx. #4 (As Received)
2009-DRPK-003707-043	08-Apr-2009	Site #33, Sx. #1 (As Received)
2009-DRPK-003707-044	08-Apr-2009	Site #33, Sx. #4 (As Received)
2009-DRPK-003707-045	08-Apr-2009	Site #9, Sx. #2 (As Received)
2009-DRPK-003707-046	08-Apr-2009	Site #12, Sx. #7 (As Received)
2009-DRPK-003707-047	08-Apr-2009	Site #23, Sx. #10 (As Received)
2009-DRPK-003707-048	08-Apr-2009	Site #23, Sx. #7 (As Received)



Report of Analysis

Sample Summary

Sample Number	Date Completed	Description
2009-DRPK-003707-049	08-Apr-2009	Site #25, Sx. #4 (As Received)
2009-DRPK-003707-050	13-Apr-2009	Site #23, Sx. #8 (As Received)
2009-DRPK-003707-051	13-Apr-2009	Site #25, Sx. #2 (As Received)
2009-DRPK-003707-052	08-Apr-2009	Site #12, Sx. #13 (As Received)
2009-DRPK-003707-053	08-Apr-2009	Site #23, Sx. #3 (As Received)
2009-DRPK-003707-054	08-Apr-2009	Site #37, Sx. #5 (As Received)
2009-DRPK-003707-055	13-Apr-2009	Site #25, Sx. #18 (As Received)
2009-DRPK-003707-056	13-Apr-2009	Site #37, Sx. #6 (As Received)



Report of Analysis

Sample ID: 2009-DRPK-003707-043		Date Taken: 01-April-2009	
Drawn By: Client		Date Submitted: 01-April-2009	
Sample Designated As: Various		Date Tested: 08-April-2009	
Representing: Site #33, Sx. #1 (As Received)			
Method	Test	Result	Units
ASTM D2887	Boiling Range Distribution of Petroleum Fractions by GC (Simulated Distillation)		
	Boiling Point Distribution	See Attached Report	

Sample ID: 2009-DRPK-003707-044		Date Taken: 01-April-2009	
Drawn By: Client		Date Submitted: 01-April-2009	
Sample Designated As: Various		Date Tested: 08-April-2009	
Representing: Site #33, Sx. #4 (As Received)			
Method	Test	Result	Units
ASTM D2887	Boiling Range Distribution of Petroleum Fractions by GC (Simulated Distillation)		
	Boiling Point Distribution	See Attached Report	

Sample ID: 2009-DRPK-003707-045		Date Taken: 01-April-2009	
Drawn By: Client		Date Submitted: 01-April-2009	
Sample Designated As: Various		Date Tested: 08-April-2009	
Representing: Site #9, Sx. #2 (As Received)			
Method	Test	Result	Units
ASTM D2887	Boiling Range Distribution of Petroleum Fractions by GC (Simulated Distillation)		
	Boiling Point Distribution	See Attached Report	

Sample ID: 2009-DRPK-003707-046		Date Taken: 01-April-2009	
Drawn By: Client		Date Submitted: 01-April-2009	
Sample Designated As: Various		Date Tested: 08-April-2009	
Representing: Site #12, Sx. #7 (As Received)			
Method	Test	Result	Units
ASTM D2887	Boiling Range Distribution of Petroleum Fractions by GC (Simulated Distillation)		
	Boiling Point Distribution	See Attached Report	

Sample ID: 2009-DRPK-003707-047		Date Taken: 01-April-2009	
Drawn By: Client		Date Submitted: 01-April-2009	
Sample Designated As: Various		Date Tested: 08-April-2009	
Representing: Site #23, Sx. #10 (As Received)			
Method	Test	Result	Units
ASTM D7169	Boiling Point Distribution of Samples with Residues by High Temperature GC		
	Boiling Point Distribution	See Attached Report	

Sample ID: 2009-DRPK-003707-048		Date Taken: 01-April-2009	
Drawn By: Client		Date Submitted: 01-April-2009	
Sample Designated As: Various		Date Tested: 08-April-2009	
Representing: Site #23, Sx. #7 (As Received)			
Method	Test	Result	Units
ASTM D2887	Boiling Range Distribution of Petroleum Fractions by GC (Simulated Distillation)		
	Boiling Point Distribution	See Attached Report	



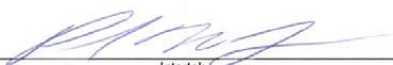
Report of Analysis

Sample ID:	2009-DRPK-003707-055	Date Taken:	01-April-2009
Drawn By:	Client	Date Submitted:	01-April-2009
Sample Designated As:	Various	Date Tested:	13-April-2009
Representing:	Site #25, Sx. #18 (As Received)		

Method	Test	Result	Units
ASTM D7169	Boiling Point Distribution of Samples with Residues by High Temperature GC		
	Boiling Point Distribution	See Attached Report	

Sample ID:	2009-DRPK-003707-056	Date Taken:	01-April-2009
Drawn By:	Client	Date Submitted:	01-April-2009
Sample Designated As:	Various	Date Tested:	13-April-2009
Representing:	Site #37, Sx. #6 (As Received)		

Method	Test	Result	Units
ASTM D7169	Boiling Point Distribution of Samples with Residues by High Temperature GC		
	Boiling Point Distribution	See Attached Report	

Signed:  Date: 5/7/09

Intertek

Simdist-2000
ITS Caleb Brett - Houston

SAMPLE:	09-3707-48 (Site #23 Sx. #7)	Injection Date:	0090406174632-0600
FILE:	C:\CP32 Instruments\ID2887 & D3710\Data\2009\APR-09\09-3707-48.0002.CDF	Report Date:	4/8/09 11:40
PROCEDURE:	C:\CP32 Instruments\ID2887 & D3710\PROCEDURES\ID2887-031709.prc		
EXCEL FILE:	C:\CP32 Instruments\ID2887 & D3710\Reports\2009\APR-09\09-3707-48_0002_CDF.xls		

Boiling Point Distribution Report
ASTM D2887 Simulated Distillation

%Off	BP °F	BP °C	%Off	BP °F	BP °C	%Off	BP °F	BP °C
IBP	715.3	379.6	40%	918.8	492.7	80%	985.9	529.9
1%	746.0	396.7	41%	920.5	493.6	81%	988.0	531.1
2%	774.5	412.5	42%	922.2	494.5	82%	990.1	532.3
3%	790.6	421.4	43%	923.9	495.5	83%	992.4	533.5
4%	801.8	427.7	44%	925.5	496.4	84%	994.7	534.8
5%	811.1	432.8	45%	927.1	497.3	85%	997.1	536.2
6%	818.7	437.0	46%	928.7	498.2	86%	999.6	537.6
7%	825.5	440.8	47%	930.2	499.0	87%	1002.3	539.0
8%	831.2	444.0	48%	931.7	499.9	88%	1005.0	540.6
9%	836.6	447.0	49%	933.3	500.7	89%	1007.9	542.2
10%	841.5	449.7	50%	934.9	501.6	90%	1011.1	543.9
11%	846.1	452.3	51%	936.4	502.5	91%	1014.5	545.8
12%	850.3	454.6	52%	938.0	503.3	92%	1018.4	548.0
13%	854.3	456.8	53%	939.5	504.2	93%	1022.7	550.4
14%	858.2	459.0	54%	941.1	505.1	94%	1027.4	553.0
15%	861.8	461.0	55%	942.6	505.9	95%	1033.0	556.1
16%	865.2	462.9	56%	944.2	506.8	96%	1039.2	559.5
17%	868.3	464.6	57%	945.7	507.6	97%	1046.9	563.8
18%	871.5	466.4	58%	947.2	508.5	98%	1057.2	569.5
19%	874.4	468.0	59%	948.9	509.4	99%	1074.8	579.3
20%	877.2	469.6	60%	950.4	510.2	FBP	1093.5	589.7
21%	879.8	471.0	61%	952.0	511.1			
22%	882.4	472.4	62%	953.7	512.0			
23%	884.9	473.8	63%	955.3	512.9			
24%	887.3	475.2	64%	956.9	513.8			
25%	889.7	476.5	65%	958.6	514.8			
26%	892.0	477.8	66%	960.3	515.7			
27%	894.1	479.0	67%	961.9	516.6			
28%	896.3	480.2	68%	963.7	517.6			
29%	898.4	481.3	69%	965.4	518.6			
30%	900.4	482.5	70%	967.1	519.5			
31%	902.4	483.6	71%	968.9	520.5			
32%	904.4	484.7	72%	970.8	521.5			
33%	906.3	485.7	73%	972.5	522.5			
34%	908.2	486.8	74%	974.3	523.5			
35%	910.1	487.8	75%	976.2	524.5			
36%	911.9	488.8	76%	978.0	525.6			
37%	913.7	489.8	77%	979.9	526.6			
38%	915.4	490.8	78%	981.9	527.7			
39%	917.1	491.7	79%	983.9	528.8			

Start Elution Time (mins):	3.033	Sample Wt:	0 g
End Elution Time (mins):	24.252	Solvent Wt:	0 g
		Material Balance:	100.0 wt%
Blank File:	C:\CP32 Instruments\ID2887 & D3710\Data\2009\APR-09\BLANK-2-040609.0002.CDF		
Calib File:	D:\CP32 Instruments\ID2887 & D3710\DATA\RTMIX-060905.0006.CDF		
Resp Factor:	1.000E+00		



Deer Park Technical Center Laboratory
1114 Seaco Avenue
Deer Park, Texas 77536
USA
Tel: (713) 844-3200

Report of Analysis

Job Reference: US785-0017916 Job Location: Deer Park, TX, USA Vessel: API	Date Job Created: 04-Jun-2009 Job Description: Analysis only of VARIOUS CRUDE OIL SAMPLES submitted at Deer Park, TX, USA in JUNE 2009
Client: American Petroleum Institute (API) Contact: Paula Podhasky	Customer Reference: PO# 2008-193518 CONT# APIREG10374601 VARIOUS CRUDE OIL SAMPLES

Sample Summary

Sample Number	Date Completed	Description
2009-DRPK-006524-001	11-Jun-2009	Site #23 Sx. #7 (As Received)
2009-DRPK-006524-002	11-Jun-2009	Site #25 Sx. #19 (As Received)
2009-DRPK-006524-003	11-Jun-2009	Site #37 Sx. #2 (As Received)



Report of Analysis

Description	Method	Test	Result	Units
Site #23 Sx. #7 (As Received)				
	ASTM D2887	Boiling Point Distribution	See Attached Report	
	ASTM D4052	Relative Density @ 60/60°F	0.8750	
		API Gravity @ 60°F	30.2	°API
	ASTM D445	Kinematic Viscosity @ 104 °F/ 40 °C	106.9	mm²/s
	ASTM D445	Kinematic Viscosity @ 212 °F/ 100 °C	11.38	mm²/s
Site #25 Sx. #19 (As Received)				
	ASTM D2887	Boiling Point Distribution	See Attached Report	
	ASTM D4052	Relative Density @ 60/60°F	0.8860	
		API Gravity @ 60°F	28.2	°API
	ASTM D445	Kinematic Viscosity @ 104 °F/ 40 °C	112.4	mm²/s
	ASTM D445	Kinematic Viscosity @ 212 °F/ 100 °C	12.14	mm²/s
Site #37 Sx. #2 (As Received)				
	ASTM D2887	Boiling Point Distribution	See Attached Report	
	ASTM D4052	Relative Density @ 60/60°F	0.8577	
		API Gravity @ 60°F	33.5	°API
	ASTM D445	Kinematic Viscosity @ 104 °F/ 40 °C	26.20	mm²/s
	ASTM D445	Kinematic Viscosity @ 212 °F/ 100 °C	4.252	mm²/s

Signed:


Intertek

Date:

7/20/09

Simdist-2000
ITS Caleb Brett - Houston

SAMPLE:	09-6524-1 (Site #23 Sx. #7)	Injection Date:	0090604132704-0600
FILE:	C:\CP32 Instruments\ID2887 & D3710\Data\2009\JUN-09\09-6524-1.0004.CDF	Report Date:	6/9/09 16:46
PROCEDURE:	C:\CP32 Instruments\ID2887 & D3710\PROCEDURES\ID2887-050409.prc		
EXCEL FILE:	C:\CP32 Instruments\ID2887 & D3710\Reports\2009\JUN-09\09-6524-1_0004_CDF.xls		

Boiling Point Distribution Report
ASTM D2887 Simulated Distillation

%Off	BP °F	BP °C	%Off	BP °F	BP °C	%Off	BP °F	BP °C
IBP	722.7	383.7	40%	920.0	493.4	80%	987.0	530.5
1%	750.3	399.0	41%	921.8	494.3	81%	989.0	531.7
2%	777.3	414.0	42%	923.4	495.2	82%	991.2	532.9
3%	792.8	422.7	43%	925.1	496.2	83%	993.5	534.1
4%	803.8	428.8	44%	926.8	497.1	84%	995.7	535.4
5%	812.9	433.8	45%	928.3	498.0	85%	998.1	536.7
6%	820.3	438.0	46%	929.9	498.8	86%	1000.6	538.1
7%	827.1	441.7	47%	931.4	499.7	87%	1003.3	539.6
8%	832.6	444.8	48%	933.0	500.5	88%	1006.0	541.1
9%	837.9	447.7	49%	934.5	501.4	89%	1009.0	542.8
10%	842.8	450.5	50%	936.1	502.3	90%	1012.1	544.5
11%	847.3	452.9	51%	937.6	503.1	91%	1015.6	546.4
12%	851.5	455.3	52%	939.2	504.0	92%	1019.5	548.6
13%	855.5	457.5	53%	940.8	504.9	93%	1023.8	551.0
14%	859.3	459.6	54%	942.3	505.7	94%	1028.6	553.7
15%	862.9	461.6	55%	943.8	506.6	95%	1034.0	556.7
16%	866.3	463.5	56%	945.4	507.4	96%	1040.1	560.0
17%	869.4	465.2	57%	946.9	508.3	97%	1047.7	564.3
18%	872.4	466.9	58%	948.5	509.2	98%	1058.2	570.1
19%	875.4	468.6	59%	950.0	510.0	99%	1077.0	580.5
20%	878.2	470.1	60%	951.6	510.9	FBP	1097.3	591.8
21%	880.8	471.6	61%	953.2	511.8			
22%	883.4	473.0	62%	954.8	512.7			
23%	885.9	474.4	63%	956.5	513.6			
24%	888.4	475.8	64%	958.1	514.5			
25%	890.8	477.1	65%	959.8	515.4			
26%	893.1	478.4	66%	961.5	516.4			
27%	895.3	479.6	67%	963.1	517.3			
28%	897.4	480.8	68%	964.8	518.2			
29%	899.6	482.0	69%	966.5	519.2			
30%	901.6	483.1	70%	968.3	520.2			
31%	903.6	484.2	71%	970.1	521.1			
32%	905.5	485.3	72%	971.9	522.1			
33%	907.5	486.4	73%	973.6	523.1			
34%	909.4	487.4	74%	975.4	524.1			
35%	911.3	488.5	75%	977.3	525.1			
36%	913.2	489.5	76%	979.1	526.2			
37%	914.9	490.5	77%	981.0	527.2			
38%	916.6	491.5	78%	982.9	528.3			
39%	918.3	492.4	79%	984.9	529.4			

Start Elution Time (mins):	2.374	Sample Wt:	0 g
End Elution Time (mins):	26.606	Solvent Wt:	0 g
		Material Balance:	100.0 wt%
Blank File:	C:\CP32 Instruments\ID2887 & D3710\Data\2009\JUN-09\CS2-BLK2-060409.0002.CDF		
Calib File:	D:\CP32 Instruments\ID2887 & D3710\DATA\RTMIX-060905.0006.CDF		
Resp Factor:	1.000E+00		

Simdist-2000
ITS Caleb Brett - Houston

SAMPLE:	09-6524-2 (Site #25 Sx. #19)	Injection Date:	0090604140741-0600
FILE:	C:\CP32 Instruments\ID2887 & D3710\Data\2009\JUN-09\09-6524-2_0005.CDF	Report Date:	6/9/09 16:48
PROCEDURE:	C:\CP32 Instruments\ID2887 & D3710\PROCEDURES\ID2887-050409.prc		
EXCEL FILE:	C:\CP32 Instruments\ID2887 & D3710\Reports\2009\JUN-09\09-6524-2_0005_CDF.xls		

Boiling Point Distribution Report
ASTM D2887 Simulated Distillation

%Off	BP °F	BP °C	%Off	BP °F	BP °C	%Off	BP °F	BP °C
IBP	713.9	378.8	40%	932.4	500.2	80%	995.4	535.2
1%	749.4	398.6	41%	933.9	501.1	81%	997.4	536.3
2%	785.5	418.6	42%	935.4	501.9	82%	999.4	537.4
3%	805.1	429.5	43%	936.9	502.7	83%	1001.4	538.6
4%	818.5	436.9	44%	938.5	503.6	84%	1003.6	539.8
5%	829.2	442.9	45%	940.0	504.4	85%	1005.8	541.0
6%	837.0	447.2	46%	941.5	505.3	86%	1008.1	542.3
7%	844.3	451.3	47%	943.0	506.1	87%	1010.4	543.6
8%	850.5	454.7	48%	944.5	506.9	88%	1012.9	544.9
9%	856.3	458.0	49%	945.9	507.7	89%	1015.6	546.4
10%	861.4	460.8	50%	947.4	508.5	90%	1018.4	548.0
11%	865.7	463.2	51%	948.9	509.4	91%	1021.4	549.7
12%	869.9	465.5	52%	950.3	510.2	92%	1024.6	551.4
13%	873.8	467.7	53%	951.8	511.0	93%	1028.1	553.4
14%	877.3	469.6	54%	953.3	511.8	94%	1031.9	555.5
15%	880.6	471.4	55%	954.8	512.7	95%	1035.8	557.7
16%	883.8	473.2	56%	956.2	513.5	96%	1040.2	560.1
17%	886.8	474.9	57%	957.8	514.3	97%	1045.5	563.0
18%	889.6	476.4	58%	959.2	515.1	98%	1052.2	566.8
19%	892.2	477.9	59%	960.8	516.0	99%	1062.4	572.4
20%	894.7	479.3	60%	962.3	516.8	FBP	1072.0	577.8
21%	897.2	480.6	61%	963.8	517.7			
22%	899.5	482.0	62%	965.4	518.6			
23%	901.8	483.2	63%	966.9	519.4			
24%	904.0	484.4	64%	968.4	520.2			
25%	906.1	485.6	65%	970.1	521.1			
26%	908.1	486.7	66%	971.7	522.0			
27%	910.1	487.9	67%	973.2	522.9			
28%	912.1	488.9	68%	974.8	523.8			
29%	914.0	490.0	69%	976.4	524.7			
30%	915.8	491.0	70%	978.0	525.5			
31%	917.6	492.0	71%	979.6	526.4			
32%	919.3	493.0	72%	981.3	527.4			
33%	921.0	493.9	73%	982.9	528.3			
34%	922.8	494.9	74%	984.6	529.2			
35%	924.4	495.8	75%	986.3	530.2			
36%	926.1	496.7	76%	988.1	531.2			
37%	927.7	497.6	77%	989.8	532.1			
38%	929.2	498.5	78%	991.7	533.1			
39%	930.8	499.3	79%	993.6	534.2			

Start Elution Time (mins):	2.07	Sample Wt:	0 g
End Elution Time (mins):	26.25	Solvent Wt:	0 g
		Material Balance:	100.0 wt%
Blank File:	C:\CP32 Instruments\ID2887 & D3710\Data\2009\JUN-09\CS2-BLK2-060409.0002.CDF		
Calib File:	D:\CP32 Instruments\ID2887 & D3710\DATA\RTMIX-060905.0006.CDF		
Resp Factor:	1.000E+00		

Simdist-2000
ITS Caleb Brett - Houston

SAMPLE:	09-6524-3 (Site #37 Sx. #2)	Injection Date:	0090604144817-0600
FILE:	C:\CP32 Instruments\ID2887 & D3710\Data\2009\JUN-09\09-6524-3.0006.CDF	Report Date:	6/9/09 16:49
PROCEDURE:	C:\CP32 Instruments\ID2887 & D3710\PROCEDURES\ID2887-050409.prc		
EXCEL FILE:	C:\CP32 Instruments\ID2887 & D3710\Reports\2009\JUN-09\09-6524-3_0006_CDF.xls		

Boiling Point Distribution Report
ASTM D2887 Simulated Distillation

%Off	BP °F	BP °C	%Off	BP °F	BP °C	%Off	BP °F	BP °C
IBP	572.4	300.2	40%	761.9	405.5	80%	868.5	464.7
1%	598.8	314.9	41%	764.1	406.7	81%	872.0	466.7
2%	629.4	331.9	42%	766.3	407.9	82%	875.5	468.6
3%	648.1	342.3	43%	768.5	409.2	83%	878.9	470.5
4%	660.1	348.9	44%	770.8	410.5	84%	882.5	472.5
5%	668.4	353.5	45%	773.2	411.8	85%	886.2	474.6
6%	675.0	357.2	46%	775.5	413.1	86%	890.0	476.7
7%	680.2	360.1	47%	778.0	414.4	87%	893.8	478.8
8%	685.0	362.8	48%	780.4	415.8	88%	897.8	481.0
9%	688.8	364.9	49%	782.6	417.0	89%	901.9	483.3
10%	692.2	366.8	50%	784.8	418.2	90%	906.2	485.7
11%	695.7	368.7	51%	787.2	419.6	91%	910.7	488.2
12%	698.6	370.4	52%	789.7	420.9	92%	915.3	490.7
13%	701.3	371.8	53%	792.2	422.3	93%	920.2	493.4
14%	703.9	373.3	54%	794.7	423.7	94%	925.5	496.4
15%	706.4	374.7	55%	797.2	425.1	95%	931.1	499.5
16%	708.7	375.9	56%	799.6	426.4	96%	937.4	503.0
17%	710.8	377.1	57%	802.0	427.8	97%	944.6	507.0
18%	713.0	378.3	58%	804.5	429.2	98%	953.7	512.0
19%	715.3	379.6	59%	807.1	430.6	99%	967.2	519.6
20%	717.7	380.9	60%	809.8	432.1	FBP	979.5	526.4
21%	720.0	382.2	61%	812.4	433.6			
22%	722.2	383.4	62%	815.1	435.0			
23%	724.3	384.6	63%	817.6	436.4			
24%	726.5	385.8	64%	820.3	438.0			
25%	728.5	386.9	65%	823.1	439.5			
26%	730.6	388.1	66%	826.0	441.1			
27%	732.6	389.2	67%	828.8	442.7			
28%	734.8	390.4	68%	831.5	444.2			
29%	737.2	391.8	69%	834.3	445.7			
30%	739.4	393.0	70%	837.2	447.3			
31%	741.7	394.3	71%	840.2	449.0			
32%	743.9	395.5	72%	843.2	450.7			
33%	746.0	396.7	73%	846.2	452.3			
34%	748.2	397.9	74%	849.2	454.0			
35%	750.4	399.1	75%	852.2	455.7			
36%	752.7	400.4	76%	855.4	457.4			
37%	755.1	401.7	77%	858.7	459.3			
38%	757.3	403.0	78%	861.9	461.1			
39%	759.6	404.2	79%	865.2	462.9			

Start Elution Time (mins):	3.088	Sample Wt:	0 g
End Elution Time (mins):	27.817	Solvent Wt:	0 g
		Material Balance:	100.0 wt%
Blank File:	C:\CP32 Instruments\ID2887 & D3710\Data\2009\JUN-09\CS2-BLK2-060409.0002.CDF		
Calib File:	D:\CP32 Instruments\ID2887 & D3710\DATA\RTMIX-060905.0006.CDF		
Resp Factor:	1.000E+00		

PORT ROYAL RESEARCH, LLC

Final Report
PTI Study No. 2009-0602
June 8, 2009

CHARACTERIZATION AND QUANTITATION OF
POLYNUCLEAR AROMATIC COMPOUNDS (PAC) IN THREE
HPV SOLVENT DEWAXED HEAVY PARAFFINIC
DISTILLATES BY PRR ("MOBIL" METHOD 2) PAC

Sponsor: American Petroleum Institute

CHARACTERIZATION AND QUANTITATION OF POLYNUCLEAR AROMATIC
COMPOUNDS (PAC) IN THREE HPV SOLVENT DEWAXED HEAVY PARAFFINIC
DISTILLATES BY PRR ("MOBIL" METHOD 2) PAC

STUDY NO.: 2009-0602

MATERIALS TESTED: 3-HPV solvent dewaxed heavy paraffinic
distillates

CRU SAMPLE NOS.: 060901 - 060903

REQUESTER: American Petroleum Institute
1220 L Street, NW
Washington, DC 2005-4070

LIAISON:



STUDY PERFORMED BY: Port Royal Research, LLC
61 S. Port Royal Drive
Hilton Head, SC 29928

EXPERIMENTAL START DATE: June 3, 2009

EXPERIMENTAL TERMINATION DATE: June 5, 2009

PORT ROYAL RESEARCH

STUDY NO. 2009-0602


Study Director  6/8/09
Date

DISTRIBUTION

Study Director
API Liaison (original)

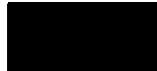


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Results	1
Discussion	2
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Appendix

Sample Description and Identification Sheets

PRR Test Article Receipt Log

Study Worksheets PRR ("Mobil" Method 2) PAC

Test Material GC/MS Chromatograms

RESULTS**PRR ("MOBIL" METHOD 2) PAC**

The polynuclear aromatics (PAC) in the solvent-dewaxed heavy paraffinic distillate samples were isolated by following PRR Standard Operating Procedure No. A.3.1.. The total weight percent PAC and the group percentages of the total Wt.% are as follows:

TABLE I

Sample Identification		total Wt.%	Group Percentages of total Wt. % ^a						
			I	II	III	IV	V	VI	≥VII
SITE# 23	SAMPLE# 7	0.0	0	0	0	0	0	0	0
SITE# 25	SAMPLE# 19	0.0	0	0	0	0	0	0	0
SITE# 37	SAMPLE# 2	0.0	0	0	0	0	0	0	0

^apercentages are reported to one significant figure where groups I through VII represent benzenes and two-through seven-fused ring aromatics, respectively.

Table II below reports these same results as the weight percent of the total in each ring group:

TABLE II

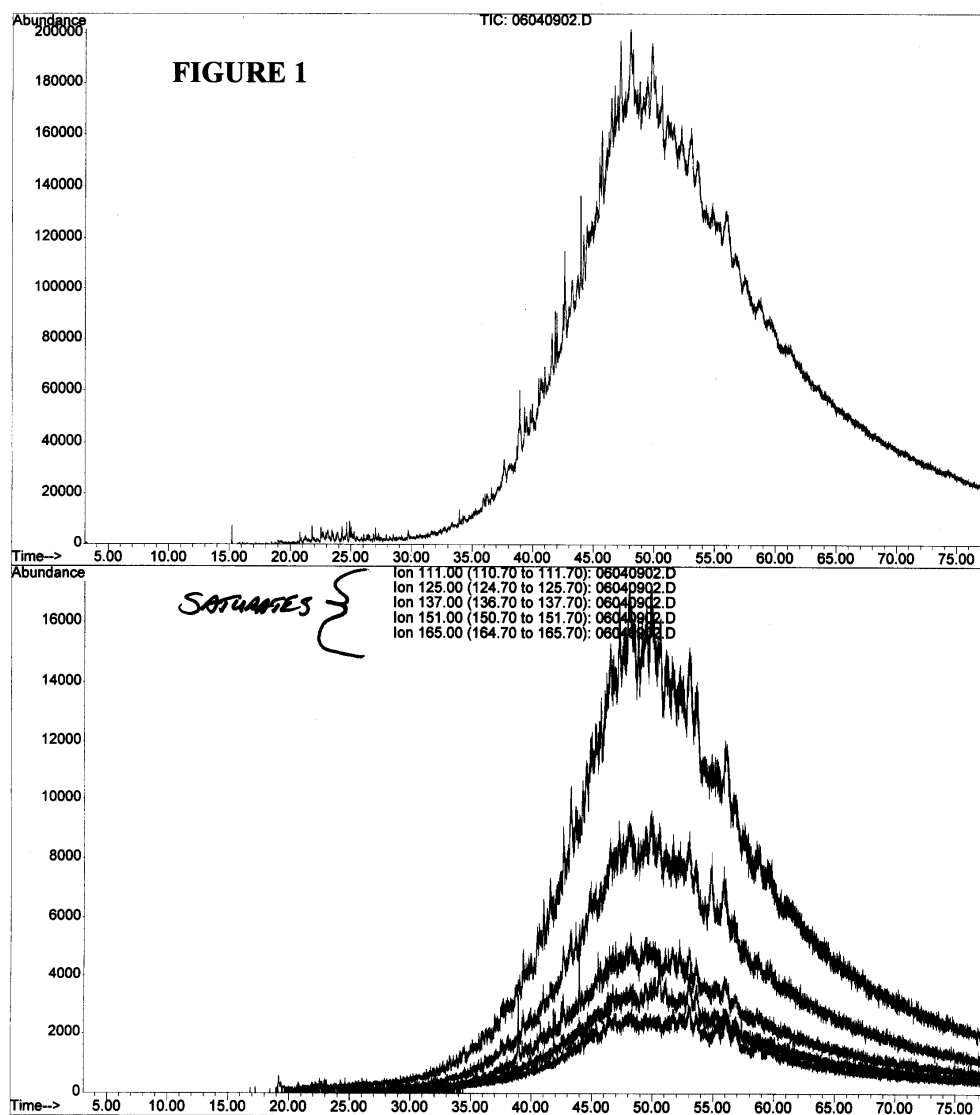
Sample Identification		total Wt.%	Group Wt%						
			I	II	III	IV	V	VI	≥VII
SITE# 23	SAMPLE# 7	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.00
SITE# 25	SAMPLE# 19	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.00
SITE# 37	SAMPLE# 2	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.00

DISCUSSION

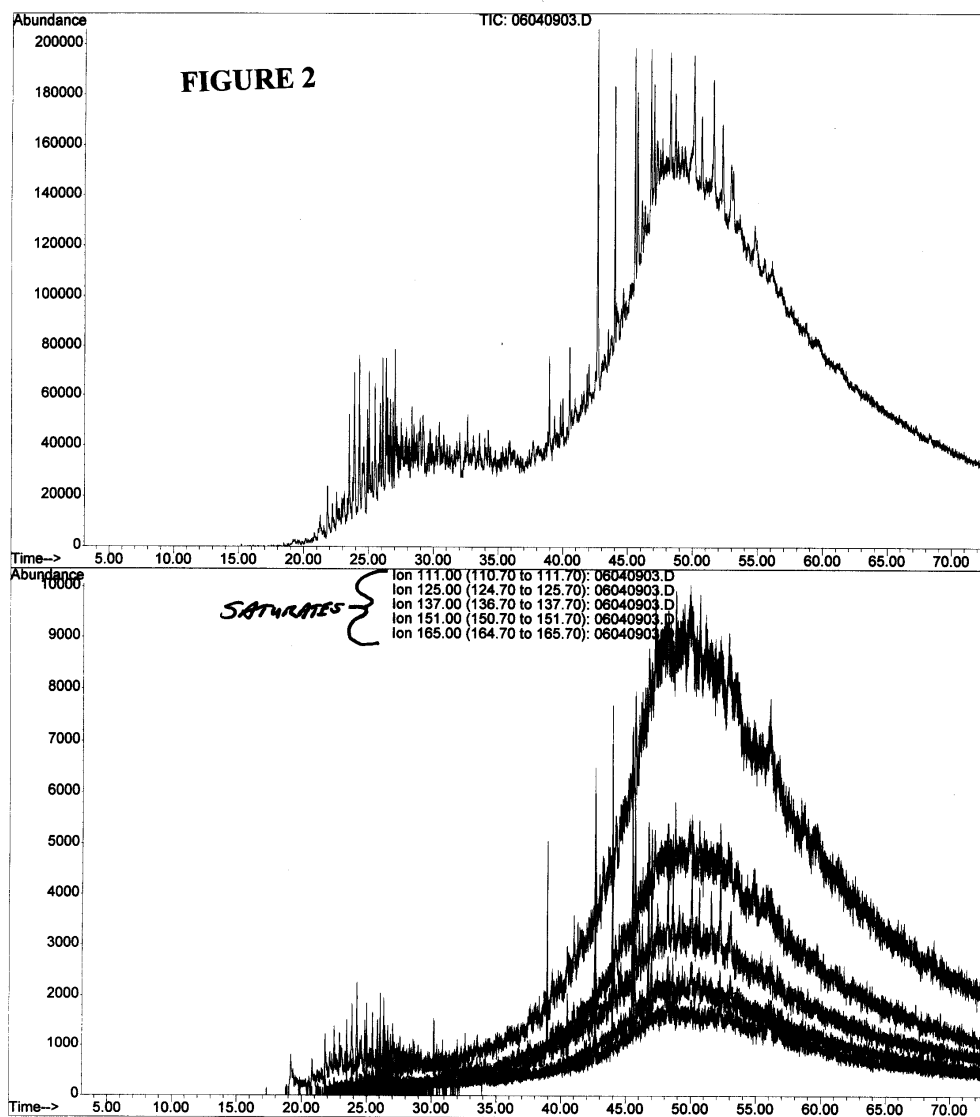
All three sample extracts contained approximately 10 milligrams of residue which, if composed entirely of aromatic compounds, would result in total Wt% values of ~0.25%. The extracts were subjected to GC-MS analysis and the vast majority of the residue in all was determined to be aliphatic in nature. Figures 1 and 2 each show two mass chromatograms, the upper being the total ion current and the lower the merged selected ion chromatogram for ions typified by aliphatic hydrocarbons for sample extracts 23:7 (figure 1) and 25:19 (figure 2), respectively. The aliphatics clearly define the shape and bulk of components in the chromatograms. A closer investigation of the chromatograms did not find any presence of aromatics.

Figure 3 follow the same format as figures 1-2 and again shows that the extract for sample 37:2 to be predominantly aliphatic in character. Closer investigation of this mass chromatogram does reveal the presence of trace amounts of aromatics as seen in figure 4 which shows the selected ion chromatograms for masses 216 (C1-pyrenes), 230 (C2-pyrenes), 242 (C1-benzanthracenes) and 256 (C2-benzanthracenes). However, the total amount of these materials are estimated to be just a few part-per-million (or <0.0005%) which is well below the nominal detection limit of the assay (~0.01). As a consequence of these GC-MS analyses of the extracts, the residues are deemed to be 'contaminants' in nature and the Total Wt% for all samples assigned zero percent (see appendix for calculations).

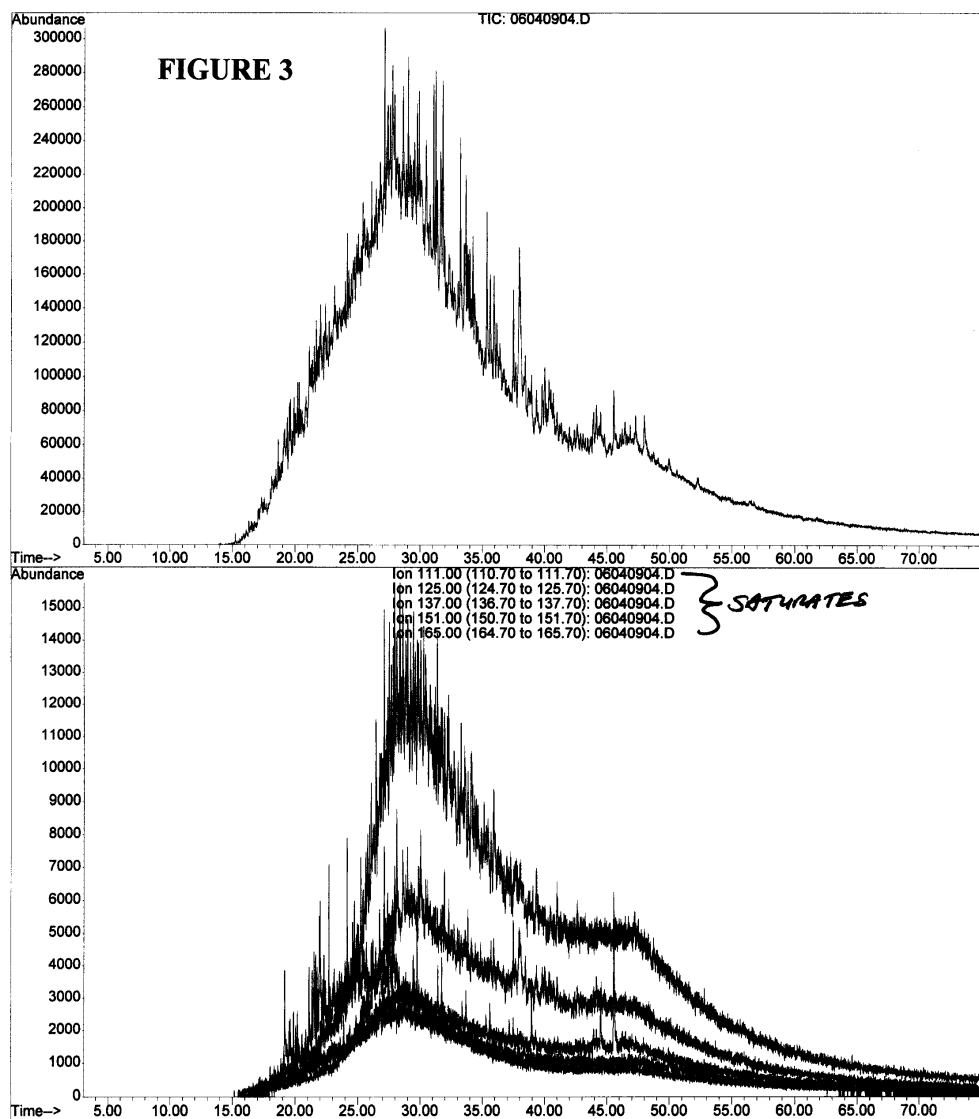
File : C:\HPCHEM\1\DATA\06040902.D
Operator : TAR
Acquired : 4 Jun 2009 11:54 using AcqMethod TAR1
Instrument : GC/MS Ins
Sample Name: API HPV SITE# 23 : SAMPLE#7 PAC2 EXTRACT
Ac Info : STUDY NO. 2009-0602
Vial Number: 1



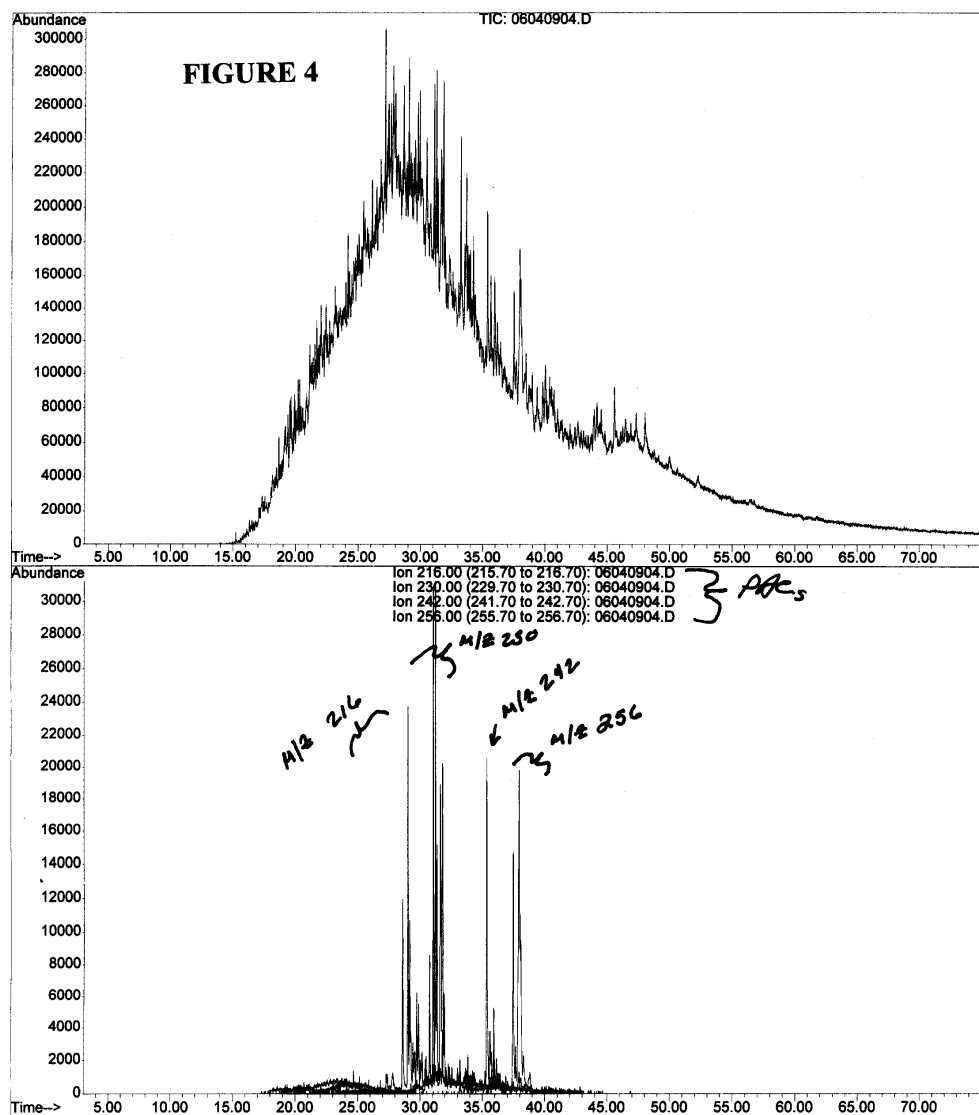
File : C:\HPCHEM\1\DATA\06040903.D
Operator : TAR
Acquired : 4 Jun 2009 13:52 using AcqMethod TAR1
Instrument : GC/MS Ins
Sample Name: API HPV SITE# 25 : SAMPLE#19 PAC2 EXTRACT
Sc Info : STUDY NO. 2009-0602
Vial Number: 1



File : C:\HPCHEM\1\DATA\06040904.D
Operator : TAR
Acquired : 4 Jun 2009 15:11 using AcqMethod TAR1
Instrument : GC/MS Ins
Sample Name: API HPV SITE# 37 : SAMPLE#2 PAC2 EXTRACT
Sc Info : STUDY NO. 2009-0602
Vial Number: 1



File : C:\HPCHEM\1\DATA\06040904.D
Operator : TAR
Acquired : 4 Jun 2009 15:11 using AcqMethod TAR1
Instrument : GC/MS Ins
Sample Name: API HPV SITE# 37 : SAMPLE#2 PAC2 EXTRACT
C Info : STUDY NO. 2009-0602
Vial Number: 1



APPENDIX

Sample Description and Identification Sheets

PRR Test Article Receipt Log

Study Worksheets PRR ("Mobil" Method 2) PAC

Test Material GC/MS Chromatograms

SAMPLE DESCRIPTION AND IDENTIFICATION SHEETS

EPL®

EPL ARCHIVES, INC.
P.O. Box 1253
Sterling, Virginia 20167

Shipping:
45610 Terminal Drive
Sterling, Virginia 20166

Telephone: (703) 435-8780
Fax: (703) 435-1330
E-mail: info@EPLarchives.com

June 2, 2009

University of South Carolina - Beaufort
South Campus, Business Office
One University Blvd.
Bluffton, SC 29909-6085

STUDY NUMBER

20090602

Dear [REDACTED]:

At the request of [REDACTED] of the American Petroleum Institute, enclosed are three samples (approx. 25 ml each) of HPV Oils (Lubricating Basestocks) intended for analysis at your laboratory. Your laboratory is to analyze these samples without the knowledge of the sample source or product name, therefore EPL Archives has blinded this information in the sample ID's. **Please note that MSDS's have been provided for shipping requirements only. All samples are to be identified by the blinded sample ID only in all reports and correspondence to API**

Also enclosed are two delivery slips for this shipment. Please sign one original and return to EPL Archives in the envelope provided.

Sincerely,

[REDACTED]
Archives Supervisor

[REDACTED]/saa

Material Delivery Slip



4010001000100151

Transport FEDEX
Requestor [REDACTED]
Requestor Phone
Remarks
Transaction Date 06/02/2009

STUDY NUMBER

20090602

CLIENT HPV OILS
[REDACTED]
1220 L STREET, NW
WASHINGTON, DC 20005

SHIP TO UNIVERSITY OF SOUTH CAROLINA - BEAUFORT
[REDACTED]
ONE UNIVERSITY BLVD.
SOUTH CAMPUS, BUSINESS OFFICE
BUFFTON, SC 29909
843-290-2559

Shipment verified by:

[REDACTED]
EPL Representative

6/1/09

Date

With my signature below, I certify that all items on the attached 1-page inventory were received in good condition.

Shipment received by:

[REDACTED]
Signature

6/3/09
Date

Material Delivery Slip Shipping By Study

Client HPV OILS (1637)
Request Date 06/01/2009



ITEMS SHIPPED (PERMANENTLY RETURNED)				
Client Study No. HPV OILS	Title of Study SITE# 23, SAMPLE# 7	Compounds LUBRICATING BASESTOCKS	Species	
Type (Subtype)	Description	Cross References	Box	Client Box ID
CUBIC FOOT ITEM (TEST ARTICLE)	ONE 25ML SAMPLE OF DISTILLATES (PETROLEUM), SOLVENT-DEWAXED HEAVY PARAFFINIC	CAS# 64742-65-0	TA-125503	
Client Study No. HPV OILS	Title of Study SITE# 25, SAMPLE# 19	Compounds LUBRICATING BASESTOCKS	Species	
Type (Subtype)	Description	Cross References	Box	Client Box ID
CUBIC FOOT ITEM (TEST ARTICLE)	ONE 25ML SAMPLE OF DISTILLATES (PETROLEUM), SOLVENT-DEWAXED HEAVY PARAFFINIC	CAS# 64742-65-0	TA-125512	
Client Study No. HPV OILS	Title of Study SITE# 37, SAMPLE# 2	Compounds LUBRICATING BASESTOCKS	Species	
Type (Subtype)	Description	Cross References	Box	Client Box ID
CUBIC FOOT ITEM (TEST ARTICLE)	ONE 25ML SAMPLE OF DISTILLATES (PETROLEUM), SOLVENT-DEWAXED HEAVY PARAFFINIC	CAS# 64742-65-0	TA-127217	

STUDY NUMBER
20090602

PRR TEST ARTICLE RECEIPT LOG

PORT ROYAL RESEARCH TEST ARTICLE RECEIPT LOG

Date Received: 6/3/09

Origin: EPL Archives

Test Article Name (lot #)	CRU Number	Estimated Amount	Gross Weight (g)	Color/State	Container/Size	Storage Location
Site 23/sample 7	060901	25me	~140	lt. straw clean/l	amber 20cc jar	PRR/usc-B/S&T reg/room 31 at 12T
Site 25/sample 19	060902	"	"	lt. straw " / "	"	"
Site 37/sample 2	060903	"	"	clean " / "	"	"

COMMENTS: _____

SIGNATURE/DATE: _____


J

6/3/09

STUDY NUMBER
20090602

**STUDY WORKSHEETS: PRR
("MOBIL" METHOD 2) PAC**

Isolation of Polynuclear Aromatic Compounds - PRR ("Mobil") PAC 2 METHOD

Study No:

2009-0602

CRU Nos.:

060901-060903

The following steps were performed for the above samples:

- Prepared equilibrated DMSO by combining approximately 1L DMSO with 100 mL cyclohexane, shaking, and draining out the DMSO layer into an amber bottle.
- Prepared approximately 4% NaCl solution by dissolving 40 g of crystal in approximately 1000 mL distilled H₂O.
- Weighed out sample into a 60 mL separatory funnel.
- Added 10 mL of cyclohexane and 10 mL pre-equilibrated DMSO and extracted for one minute and collected (lower) DMSO layer in a 125 mL separatory funnel. Repeated extraction with another 10 mL DMSO and collected lower DMSO layer in the same 125 mL separatory funnel.
- Diluted with 40 mL of a 4% sodium chloride solution and back extracted for one minute into 20 mL and 10 mL of cyclohexane. Collected the lower layers from the two back extractions in a clean 60 mL separatory funnel.
- Washed the combined cyclohexane layers for approximately one minute with 5 mL of sodium chloride solution. Removed the aqueous layer. Repeated with an additional 5 mL sodium chloride solution.
- Filtered the cyclohexane solution through a funnel containing folded filter paper and approximately 2g anhydrous sodium sulfate. Washed the filter with 2x2 mL cyclohexane. Collected extract and rinsings in a 50 mL flask.
- Evaporated sample on a rotary vacuum evaporator at 35- 50°C to near dryness and then at 80°C for an additional 30 minutes.
- Allowed sample to cool at ambient temperature ($\geq$ 1-hr) and weighed.

STUDY NO.: 2009-0602

PORT ROYAL RESEARCH

SITE: SAMAE

[illegible]

TEST MATERIAL GC/MS CHROMATOGRAMS

TIC: 06040904.D

API HPV SITE# 37 : SAMPLE#2 PAC2 EXTRACT

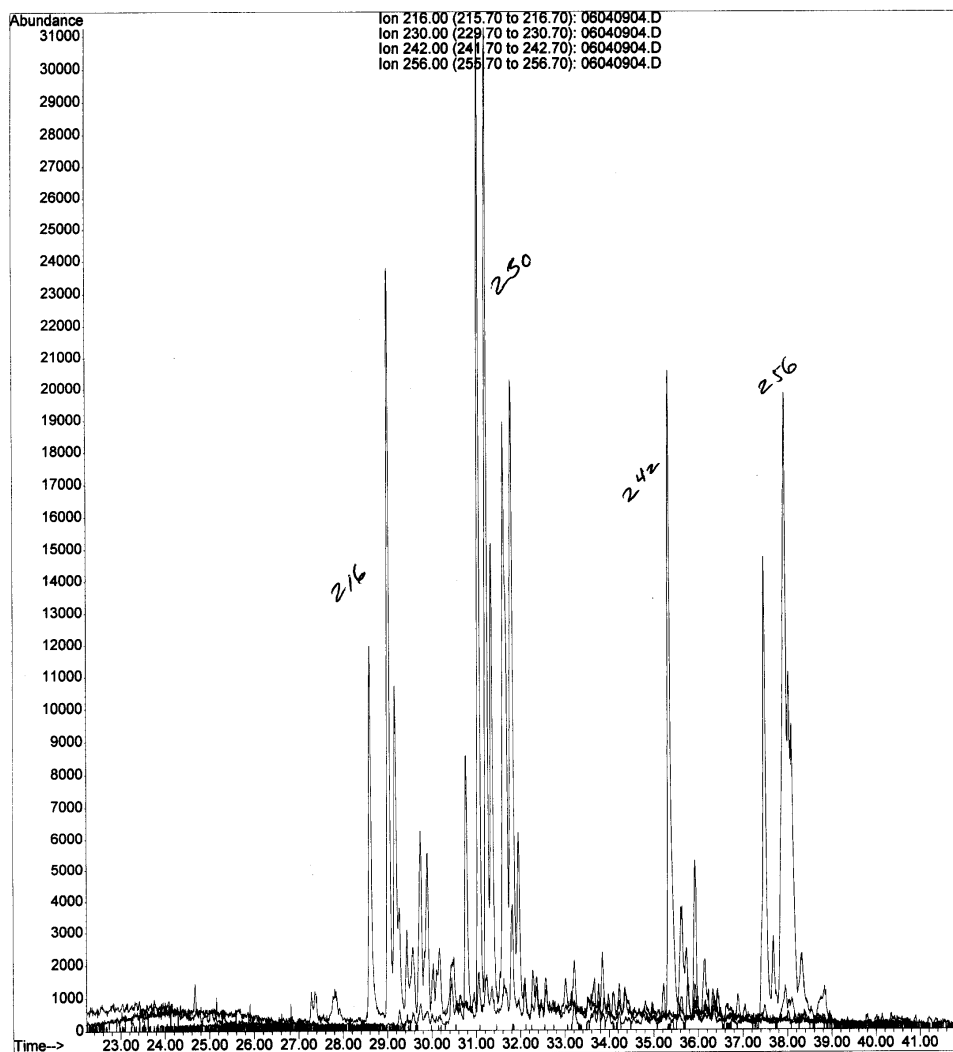
Peak#	Ret Time	Type	Width	Area	Start Time	End Time
1	27.132	M	12.783	234817601	14.337	64.769

$$\Sigma AUC = 2348 \times 10^6$$

6/5/09
D.Hoy

STUDY NUMBER
20090602

File : C:\HPCHEM\1\DATA\06040904.D
Operator : TAR
Acquired : 4 Jun 2009 15:11 using AcqMethod TAR1
Instrument : GC/MS Ins
Sample Name: API HPV SITE# 37 : SAMPLE#2 PAC2 EXTRACT
Misc Info : STUDY NO. 2009-0602
Vial Number: 1



Ion 216.00 (215.70 to 216.70): 06040904.D

API HPV SITE# 37 : SAMPLE#2 PAC2 EXTRACT

M/2

Peak#	Ret Time	Type	Width	Area	Start Time	End Time	
1	29.021	M	0.229	3272743	28.300	30.313	216
2	31.814	M	0.365	844571	30.624	32.180	230
3	35.608	M	0.238	95462	35.168	35.624	242
4	36.365	M	1.219	475965	35.936	38.716	256

$$\Sigma = 4.685 \times 10^6$$

3+4-mg PAC

6/5/09
DARoy

$$PAC/TIC =$$

$$= 4.685 / 2348 = 2 \times 10^{-3}$$

$$2 \times 10^{-3} \times 0.24\% = 4.8 \times 10^{-4} =$$

$$.00048 \sim .0005\% PAC \equiv 5 \mu\text{g/g}$$

DARoy
6/5/09

STUDY NUMBER

20090602



Deer Park Technical Center Laboratory
1114 Seaco Avenue
Deer Park, Texas 77536
USA
Tel: (713) 844-3200

Report of Analysis

Job Reference: US785-0018281
Job Location: Deer Park, TX, USA

Date Job Created: 01-Jul-2009
Job Description: Analysis only of Lubrication Oil, Submitted, July 1, 2009 at Deer Park, TX, USA

Client: American Petroleum Institute (API)
Contact: Paula Podhasky
Address: 1220 L. Street NW
Washington, DC 20005-4070
United States of America

Customer Reference:
CONTRACT# 2008103518-0
Quote # 500164134
SCHDLR: RUSSELL WHITE

Sample Summary

Sample Number	Date Completed	Description
2009-DRPK-007763-001	14-Jul-2009	CAS# 8042-47-5 P15 OIL
2009-DRPK-007763-002	14-Jul-2009	SITE# 23 SAMPLE# 7
2009-DRPK-007763-003	14-Jul-2009	SITE# 25 SAMPLE# 19
2009-DRPK-007763-004	14-Jul-2009	SITE# 37 SAMPLE# 2
2009-DRPK-007763-005	14-Jul-2009	SITE# 45 SAMPLE# 3



Report of Analysis

Sample ID: 2009-DRPK-007763-001		Date Taken: 01-July-2009	
Sample Designated As: Lubrication Oil		Date Submitted: 01-July-2009	
Vessel/Location: Deer Park		Date Tested: 14-July-2009	
Representing: CAS# 8042-47-5 P15 OIL		Drawn By: Client	
Method	Test	Result	Units
ASTM D2008	Absorbance by UV		
	Absorbance	9.71	A/nm
AD HOC	Various Methodology		
	Method Name	ASTM D2669	
	Absorption	0.109	mg/L
ASTM D5453	Sulfur Content by UV Fluorescence		
	Sulfur Content	< 1.0	mg/kg
AD HOC	Various Methodology		
	Method Name	ASTM D565	
	Carbonizable substances	Pass	

Sample ID: 2009-DRPK-007763-002		Date Taken: 01-July-2009	
Sample Designated As: Lubrication Oil		Date Submitted: 01-July-2009	
Vessel/Location: Deer Park		Date Tested: 14-July-2009	
Representing: SITE# 23 SAMPLE# 7		Drawn By: Client	
Method	Test	Result	Units
ASTM D2008	Absorbance by UV		
	Absorbance	474.683	A/nm
AD HOC	Various Methodology		
	Method Name	ASTM D2669	
	Absorption	3.316	mg/L
ASTM D5453	Sulfur Content by UV Fluorescence		
	Sulfur Content	438	mg/kg
AD HOC	Various Methodology		
	Method Name	ASTM D565	
	Carbonizable substances	Fail	

Sample ID: 2009-DRPK-007763-003		Date Taken: 01-July-2009	
Sample Designated As: Lubrication Oil		Date Submitted: 01-July-2009	
Vessel/Location: Deer Park		Date Tested: 14-July-2009	
Representing: SITE# 25 SAMPLE# 19		Drawn By: Client	
Method	Test	Result	Units
ASTM D2008	Absorbance by UV		
	Absorbance	688.608	A/nm
AD HOC	Various Methodology		
	Method Name	ASTM D2269	
	Absorption	3.367	mg/L
ASTM D5453	Sulfur Content by UV Fluorescence		
	Sulfur Content	3840	mg/kg
AD HOC	Various Methodology		
	Method Name	ASTM D565	
	Carbonizable substances	Fail	



Report of Analysis

Sample ID: 2009-DRPK-007763-004	Date Taken: 01-July-2009
Sample Designated As: Lubrication Oil	Date Submitted: 01-July-2009
Vessel/Location: Deer Park	Date Tested: 14-July-2009
Representing: SITE# 37 SAMPLE# 2	Drawn By: Client

Method	Test	Result	Units
ASTM D2008	Absorbance by UV		
	Absorbance	573.867	A/nm
AD HOC	Various Methodology		
	Method Name	ASTM D2269	
	Absorption	3.739	mg/L
ASTM D5453	Sulfur Content by UV Fluorescence		
	Sulfur Content	1.7	mg/kg
AD HOC	Various Methodology		
	Method Name	ASTM D565	
	Carbonizable substances	Fail	

Sample ID: 2009-DRPK-007763-005	Date Taken: 01-July-2009
Sample Designated As: Lubrication Oil	Date Submitted: 01-July-2009
Vessel/Location: Deer Park	Date Tested: 14-July-2009
Representing: SITE# 45 SAMPLE# 3	Drawn By: Client

Method	Test	Result	Units
ASTM D2008	Absorbance by UV		
	Absorbance	67.008	A/nm
AD HOC	Various Methodology		
	Method Name	ASTM D2269	
	Absorption	0.131	mg/L
ASTM D5453	Sulfur Content by UV Fluorescence		
	Sulfur Content	< 1.0	mg/kg
AD HOC	Various Methodology		
	Method Name	ASTM D565	
	Carbonizable substances	Pass	

Signed: Bernard F. Holly
Intertek

Date: 8/6

APPENDIX C

Animal Room Environmental Conditions

RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP

PROJECT NO.:WIL- 402008

TEMPERATURE/HUMIDITY - STUDY SUMMARY REPORT

SPONSOR: 402 - AMERICAN PETROLEUM

Page 1 of 5

STUDY SPECIFICATIONS: 402008

DATE IN 09/22/09 TIME IN 10:00

DATE OUT 10/29/09 TIME OUT 10:00

ROOM SPECIFICATIONS: B ROOM 09

LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY %RH: 30.0

TEST SYSTEM: Rat

LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY %RH: 70.0

DATE	PRIMARY TEMP		SECONDARY TEMP		PRIMARY HUM	SECONDARY HUM
	MEAN (°F)	MEAN (°C)	MEAN (°F)	MEAN (°C)	MEAN (%RH)	MEAN (%RH)
09/22/09	70.9	21.6	70.7	21.5	56.3	55.9
09/23/09	70.3	21.3	70.2	21.2	57.5	57.1
09/24/09	69.3	20.7	69.2	20.7	54.1	53.7
09/25/09	68.1	20.1	68.0	20.0	52.1	51.7
09/26/09	68.0	20.0	67.9	19.9	53.0	52.7
09/27/09	68.2	20.1	68.1	20.1	52.1	51.8
09/28/09	67.1	19.5	67.0	19.4	48.2	47.9
09/29/09	68.6	20.3	68.6	20.3	47.6	47.2
09/30/09	70.7	21.5	70.7	21.5	44.1	43.8
10/01/09	70.3	21.3	70.3	21.3	41.2	41.0
10/02/09	70.9	21.6	70.8	21.6	53.2	52.8
10/03/09	70.2	21.2	70.2	21.2	47.3	47.0
10/04/09	70.5	21.4	70.5	21.4	47.0	46.8
10/05/09	71.0	21.7	71.0	21.7	44.3	44.0
10/06/09	70.8	21.6	70.8	21.6	48.2	47.9
10/07/09	70.1	21.2	70.1	21.2	46.1	45.9
10/08/09	70.4	21.3	70.4	21.3	46.9	46.5
10/09/09	70.4	21.3	70.4	21.3	53.8	53.4
10/10/09	71.8	22.1	71.7	22.1	44.6	44.3

RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP

PROJECT NO.:WIL- 402008

TEMPERATURE/HUMIDITY - STUDY SUMMARY REPORT

SPONSOR: 402 - AMERICAN PETROLEUM

Page 2 of 5

DATE	PRIMARY TEMP		SECONDARY TEMP		PRIMARY HUM	SECONDARY HUM
	MEAN (°F)	MEAN (°C)	MEAN (°F)	MEAN (°C)	MEAN (%RH)	MEAN (%RH)
10/11/09	70.4	21.3	70.4	21.3	37.6	37.4
10/12/09	71.1	21.7	71.1	21.7	39.7	39.4
10/13/09	71.9	22.2	71.9	22.2	40.7	40.2
10/14/09	71.5	21.9	71.5	21.9	38.2	38.0
10/15/09	71.9	22.2	71.9	22.2	38.7	38.5
10/16/09	71.8	22.1	71.8	22.1	37.6	37.3
10/17/09	71.2	21.8	71.3	21.8	37.7	37.4
10/18/09	71.0	21.7	71.0	21.7	35.5	35.4
10/19/09	70.7	21.5	70.8	21.6	36.3	36.1
10/20/09	70.6	21.4	70.6	21.4	42.5	42.0
10/21/09	69.5	20.8	69.6	20.9	46.5	45.9
10/22/09	69.3	20.7	69.3	20.7	50.1	49.5
10/23/09	68.6	20.3	68.7	20.4	52.6	52.0
10/24/09	70.4	21.3	70.5	21.4	45.8	45.3
10/25/09	70.4	21.3	70.5	21.4	38.6	38.4
10/26/09	70.8	21.6	70.8	21.6	37.9	37.5
10/27/09	69.9	21.1	70.0	21.1	44.2	43.6
10/28/09	70.8	21.6	70.9	21.6	50.6	50.2
10/29/09	73.7	23.2	73.7	23.2	47.0	47.0

RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP

PROJECT NO.:WIL- 402008

TEMPERATURE/HUMIDITY - STUDY SUMMARY REPORT

SPONSOR: 402 - AMERICAN PETROLEUM

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DATE	PRIMARY TEMP			SECONDARY TEMP		PRIMARY HUM	SECONDARY HUM
	MEAN (°F)	MEAN (°C)		MEAN (°F)	MEAN (°C)	MEAN (%RH)	MEAN (%RH)
SUMMARY OF DAILY MEANS	MEAN	MIN	MAX				
PRIMARY TEMP °F:	70.3	67.1	73.7				
PRIMARY TEMP °C:	21.3	19.5	23.2				
SECONDARY TEMP °F:	70.3	67.0	73.7				
SECONDARY TEMP °C:	21.3	19.4	23.2				
PRIMARY HUM %RH:	45.5	35.5	57.5				
SECONDARY HUM %RH:	45.2	35.4	57.1				
N DAYS	38						

RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP

PROJECT NO.:WIL- 402008

TEMPERATURE/HUMIDITY - STUDY SUMMARY REPORT

SPONSOR: 402 - AMERICAN PETROLEUM

Page 4 of 5

B ROOM 09 SUMMARY OF HOURLY VALUES

	PRIMARY TEMP				SECONDARY TEMP				PRIMARY HUM		SECONDARY HUM	
MEAN	70.3	°F	21.3	°C	70.3	°F	21.3	°C	45.5	%RH	45.2	%RH
MIN	65.8	°F	18.8	°C	65.7	°F	18.7	°C	33.1	%RH	33.8	%RH
MAX	75.1	°F	23.9	°C	75.1	°F	23.9	°C	68.4	%RH	67.8	%RH
SD	1.94		1.08		1.95		1.08		6.91		6.80	
SE	0.07		0.04		0.07		0.04		0.23		0.23	
N SAMPLES	888				888				888		888	
FIRST DAY	09/22/09											
LAST DAY	10/29/09											
N DAYS	38											

RAT DERMAL PRENATAL DEVELOPMENTAL TOX STUDY OF SDHP

PROJECT NO.:WIL- 402008

TEMPERATURE/HUMIDITY - STUDY SUMMARY REPORT

SPONSOR: 402 - AMERICAN PETROLEUM

Page 5 of 5

STUDY 402008 SUMMARY OF HOURLY VALUES

	PRIMARY TEMP				SECONDARY TEMP				PRIMARY HUM		SECONDARY HUM	
MEAN	70.3	°F	21.3	°C	70.3	°F	21.3	°C	45.5	%RH	45.2	%RH
MIN	65.8	°F	18.8	°C	65.7	°F	18.7	°C	33.1	%RH	33.8	%RH
MAX	75.1	°F	23.9	°C	75.1	°F	23.9	°C	68.4	%RH	67.8	%RH
SD	1.94		1.08		1.95		1.08		6.91		6.80	
SE	0.07		0.04		0.07		0.04		0.23		0.23	
N SAMPLES	888				888				888		888	
FIRST DAY	09/22/09											
LAST DAY	10/29/09											
N DAYS	38											

FINAL REPORT

Volume 2 of 2
(Appendices D-G)

STUDY TITLE

A DERMAL PRENATAL DEVELOPMENTAL
TOXICITY STUDY OF SOLVENT DEWAXED HEAVY PARAFFINIC
DISTILLATES (PETROLEUM) (CAS# 64742-65-0) IN RATS

STUDY NUMBER

WIL-402008

DATA REQUIREMENT

U.S. EPA OPPTS 870.3700
OECD Guideline 414

STUDY DIRECTOR

[REDACTED]

STUDY INITIATION DATE

21 September 2009

STUDY COMPLETION DATE

19 October 2010

PERFORMING LABORATORY

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-8946

SPONSOR

American Petroleum Institute
1220 L Street, NW
Washington, DC 20005

APPENDIX D

Scoring Criteria For Dermal Reactions

SCORING CRITERIA FOR DERMAL REACTIONS

Evaluation of Dermal Reactions*

<u>Value</u>	<u>Erythema and Eschar Formation</u>	<u>Computer Designation</u>
0	No erythema	No erythema
1	Very slight erythema (barely perceptible, edges of area not well defined)	Very slight erythema
2	Slight erythema (pale red in color and edges definable)	Slight erythema
3	Moderate to severe erythema (definite red in color and area well defined)	Moderate erythema
4	Severe erythema (beet or crimson red) to slight eschar formation (injuries in depth)	Severe erythema

<u>Value</u>	<u>Edema Formation</u>	<u>Computer Designation</u>
0	No edema	No edema
1	Very slight edema (barely perceptible, edges of area not well defined)	Very slight edema
2	Slight edema (edges of area well defined by definite raising)	Slight edema
3	Moderate edema (raised approximately 1 mm)	Moderate edema
4	Severe edema (raised more than 1 mm and extending beyond area of exposure)	Severe edema

* Draize, J.H. The appraisal of the safety of chemicals in foods, drugs and cosmetics. *Dermal Toxicity* **1965**, 46-59. Assoc. of Food and Drug Officials of the U.S., Topeka, Kansas and the EPA-OPPTS Health Effects Test Guidelines **1998**.

APPENDIX E

Pathology Report (WIL Research Laboratories, LLC)

WIL-402008
American Petroleum Institute

SDHP (CAS# 64742-65-0)

A DERMAL PRENATAL DEVELOPMENTAL
TOXICITY STUDY OF SOLVENT DEWAXED HEAVY PARAFFINIC
DISTILLATES (PETROLEUM) (CAS# 64742-65-0) IN RATS

PATHOLOGY REPORT

Pathology Department

WIL Research Laboratories, LLC

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1. INTRODUCTION

The objective of this study was to determine the potential of dermal exposure to a highly refined, solvent-dewaxed heavy paraffinic distillate (petroleum; SDHP) (CAS# 64742-65-0) to induce developmental toxicity after maternal exposure during the critical period of organogenesis, to characterize maternal toxicity at the exposure levels tested and to determine a NOAEL (no-observed-adverse-effect level) for maternal toxicity and developmental toxicity. Additionally, this study aimed to provide data to verify/expand the domain of the polycyclic aromatic compounds (PAC) prenatal models for predicting the toxicity of high-boiling petroleum substances from their PAC content and to further test the hypothesis that developmental toxicity endpoints are more sensitive to effects of high-boiling petroleum substances than other reproductive endpoints, such as fertility or reproductive organ weight and histopathology.

2. STUDY DESIGN

Female Sprague-Dawley Crl:CD(SD) rats, approximately 12 weeks of age at the initiation of breeding, were administered SDHP dermally as a single daily dose as indicated in the following table. SDHP was applied over as much of the clipped dorsal scapular area (approximately 10% of total body surface area) as possible during the period of major organogenesis, gestation days 0 through 19.

<u>Group Number</u>	<u>Treatment</u>	<u>Dosage Level (mg/kg/day)</u>	<u>Dosage Concentration (mg/mL)</u>	<u>Number of Animals</u>
1	Sham ^a	0	0	25
2	SDHP	1000	Neat	25

^a - The Group 1 sham control animals were subject to the same procedures (i.e., shaving and collaring) as the Group 2 animals. However, no vehicle or carrier was applied to the sham control animals.

3. METHODS

3.1. ANATOMIC PATHOLOGY

3.1.1. MACROSCOPIC EXAMINATION

Laparohysterectomy and complete postmortem examinations were performed on all females at the gestation day 20 scheduled necropsy. Females were euthanized by carbon dioxide inhalation and exsanguinated. At the time of necropsy, samples of dorsal skin from shaved and unshaved areas of the sham (control) group females and treated and adjacent untreated skin from the test substance-treated females were preserved in 10% neutral-buffered formalin for histopathologic examination.

3.1.2. ORGAN WEIGHTS

The following organs were weighed from all animals at the scheduled necropsy:

Adrenal glands
Thymus

Gravid uteri with cervix

3.1.3. MICROSCOPIC EXAMINATION

Microscopic examination of routinely prepared hematoxylin-eosin stained paraffin sections was performed on untreated skin for the control group animals, treated and untreated skin for the test article group animals. Stained histologic sections were examined by light microscopy and observations were entered in the WIL Toxicology Data Management System (WTDMS™) by the pathologist. All gross necropsy observations were addressed. Histologic sections were of adequate size and quality for detailed evaluation. The number of tissues examined from each dosage group may not necessarily equal the number of animals included in the group due to sectioning difficulties. The number of missing tissues was negligible and did not interfere with detection of test substance-related histologic alterations in the study. Histopathologic lesions were classified using standard published terminology to the extent possible. The WTDMS™ histopathology tables contain all of the recorded data and serve as the basis for this narrative report.

3.2. ABBREVIATIONS

The following abbreviations may apply to this report:

- Interval - point in the study at which event occurred (specimen collection, necropsy, etc.)
- GD - gestation day
- SN - scheduled necropsy

3.3. DATA INTERPRETATION

In the discussion of organ weight differences, the indication of higher or lower mean organ weights refers to a statistically significant ($p < 0.05$ using a two-sample t-test) difference between test substance-treated versus control group animals in the present study. In addition, historical control values for this laboratory were consulted to refine data interpretation.

4. RESULTS

4.1. SURVIVAL

All rats survived to the scheduled necropsy.

4.2. GROSS OBSERVATIONS

Review of the gross necropsy observations revealed no observations that were considered to be associated with administration of the test substance.

Descriptions of test substance-related histologic alterations are discussed in Section 4.4. (Histologic Changes).

4.3. ORGAN WEIGHTS

Organ weight differences presented in Text Table 1 were considered to be associated with administration of the test substance.

Text Table 1. Toxicologically Relevant Organ Weight Differences

<u>Parameter</u>	<u>Direction and magnitude of change</u>	<u>Dosage level (mg/kg/day)</u>
Adrenal Glands		
Absolute	↑ 9.5%*	1000
Thymus		
Absolute	↓ 12.5%	1000

* = Significantly different from the control group at 0.05 using a two-sample t-test

The mean absolute weight of the adrenal gland was higher than the control group mean, and this difference was statistically significant ($p < 0.05$). The mean absolute weight of the thymus was lower than the control group mean; the difference was not statistically significant. These organ weight changes were considered to be test substance-related. Microscopic analysis of the adrenal gland and thymus was not performed. There were no test substance-related changes in gravid uterine weights.

4.4. HISTOLOGIC CHANGES

4.4.1. CHANGES ASSOCIATED WITH TEST SUBSTANCE ADMINISTRATION

The only test substance-related finding was minimal, multifocal mononuclear infiltrate that was observed in the superficial dermis of the 1000 mg/kg/day group rats. The infiltrate was composed of lymphocytes with occasional macrophages and partially degranulated mast cells. In 2 rats (nos. 56136 and 56131), there were very low numbers of neutrophils observed focally in the dermal capillaries (no. 56136) or associated with the mononuclear infiltrate in the dermis (no. 56131). The mononuclear infiltrate was also observed in the untreated application site of three rats in the 1000 mg/kg/day group, but the incidence in the treated application site was much higher, indicating a test substance-related effect. The infiltrate was minimal and was considered a non-adverse finding.

**Text Table 2. Incidence Of Selected Histopathologic Findings,
Gestation Day 20 Scheduled Necropsy**

Dosage (mg/kg/day):	Group 1 0	Group 2 1000
Application site - treated ^{a, b}	N/A	25
Infiltrate, mononuclear, minimal	N/A	16
Application site - untreated ^a	25	25
Infiltrate, mononuclear, minimal	0	3

^a = Number of tissues examined from each group.

^b = Three sections of treated application site examined, the section with the most severe grade was recorded.

4.4.2. CHANGES UNRELATED TO TEST SUBSTANCE ADMINISTRATION

Remaining histologic changes were considered to be incidental findings or related to some aspect of experimental manipulation other than administration of the test substance. There was no test substance-related alteration in the prevalence, severity, or histologic character of those incidental tissue alterations.

5. DISCUSSION

The presence of minimal mononuclear infiltration after application of SDHP to the shaved dorsal scapular area of pregnant female rats indicated a minimal inflammatory response that was not associated with any other test substance-related changes in the skin and was considered a non-adverse finding.

6. CONCLUSIONS

Application of SHDP once daily to the dorsal scapular area of pregnant Sprague-Dawley Crl:CD(SD) rats at a dosage level of 0 (sham rats) or 1000 mg/kg/day from gestation days 0 to 19 was associated with minimal mononuclear infiltration in the superficial dermis of the treated application site in the 1000 mg/kg/day group rats. This infiltrate was considered to be a non-adverse finding.

The application of SDHP also resulted in higher absolute weight of the adrenal glands and lower absolute weight of the thymus in the 1000 mg/kg/day group rats. Histopathologic examination was not performed on the adrenal glands or thymus.

7. REPORT SUBMISSION

Report Submitted By:

[REDACTED]

Study Pathologist

13 October 2010
Date

Report Reviewed By:

[REDACTED]

Reviewing Pathologist

15 Oct 2010
Date

APPENDIX F

WIL Developmental Historical Control Data Version 3.9 [CrI:CD(SD) Rats]

Study Key

Study Number	Date of First Gestation Day 0 (GD 0)	Date of Study Laparohysterectomy (GD 20)	Route	Vehicle
1	4/21/1998	5/15/1998	Gavage	0.5% methylcellulose
2	5/6/1998	5/29/1998	Gavage	Sponsor- Supplied Placebo
3	5/20/1998	6/12/1998	Subcutaneous	Sponsor-SuppliedPlacebo
4	6/16/1998	7/9/1998	Gavage	0.2% hydroxypropyl methylcellulose
5	6/2/1998	6/26/1998	Gavage	0.5% methylcellulose/0.1% Tween 80
6	7/28/1998	8/20/1998	Gavage	Deionized H2O
7	9/8/1998	10/14/1998	Dermal	0.5% methylcellulose
8	8/19/1998	9/11/1998	Subcutaneous	Sponsor-Supplied Placebo
9	11/24/1998	12/18/1998	Gavage	Corn Oil
10	1/12/1999	2/5/1999	Gavage	Deionized H2O
11	3/2/1999	3/25/1999	Gavage	0.5% methylcellulose
12	3/2/1999	3/25/1999	Gavage	0.5% methylcellulose
13	4/27/1999	5/22/1999	Surgical Implant	Surgical Sham
14	4/27/1999	5/21/1999	Gavage	Phosphate Buffer
15	5/12/1999	6/5/1999	Gavage	0.5% methylcellulose
16	6/1/1999	6/24/1999	Gavage	0.5% methylcellulose
17	8/18/1999	9/11/1999	Gavage	Deionized H2O

Study Key

Study Number	Date of First Gestation Day 0 (GD 0)	Date of Study Laparohysterectomy (GD 20)	Route	Vehicle
18	6/22/1999	7/16/1999	Gavage	Deionized H2O
19	12/7/1999	12/30/1999	Gavage	Corn Oil
20	12/28/1999	1/21/2000	Gavage	Sponsor-Supplied Vehicle
21	2/22/2000	3/18/2000	Gavage	0.5% carboxymethylcellulose
22	8/24/1999	9/19/1999	Gavage	0.5% carboxymethylcellulose
23	10/5/1999	10/30/1999	Gavage	0.4% methylcellulose
24	11/16/1999	12/10/1999	Gavage	Deionized H2O
25	11/9/1999	12/2/1999	Gavage	0.5% methylcellulose/0.1% Tween 80
26	1/19/1999	2/11/1999	Gavage	0.5% methylcellulose
27	2/27/2001	3/22/2001	Subcutaneous	10 mM Na2HPO4.7H2O/150 mM NaCl
28	11/27/2001	12/21/2001	Gavage	Olive Oil
29	1/17/2001	2/10/2001	Gavage	50 mM Sodium Acetate Trihydrate
30	6/27/2000	7/21/2000	Gavage	Placebo Formulation
31	5/16/2000	6/8/2000	Dietary	Basal Diet
32	8/22/2000	9/15/2000	Gavage	Citric Acid Solution
33	12/29/1998	1/23/1999	Gavage	0.5% carboxymethylcellulose
34	7/13/1999	8/5/1999	Intranasal	Methylcellulose Matrix

Study Key

Study Number	Date of First Gestation Day 0 (GD 0)	Date of Study Laparohysterectomy (GD 20)	Route	Vehicle
35	1/11/2000	2/3/2000	Inhalation	Clean Filtered Air
36	7/20/1999	8/13/1999	Gavage	PEG 400
37	8/26/1999	9/19/1999	Intravenous	Sodium Phosphate Dibasic Heptahydrate in 0.9% NaCl
38	2/2/1999	2/27/1999	Gavage	10% Aqueous Acacia
39	1/23/2001	2/16/2001	Gavage	Deionized H2O
40	5/15/2001	6/8/2001	Gavage	30% Aqueous 1,3-Butylene Glycol
41	9/5/2001	9/29/2001	Gavage	Sponsor-Supplied Vehicle
42	7/20/1999	8/12/1999	Intravenous	Sponsor-Supplied Placebo
43	5/1/2001	5/25/2001	Inhalation	Clean Filtered Air
44	5/15/2001	6/8/2001	Gavage	2% Cremophor EL/0.15% Benzoic Acid/150 mM NaCl
45	7/14/1998	8/7/1998	Gavage	0.5% hydroxypropyl methylcellulose
46	7/3/2001	7/26/2001	Dietary	Basal Diet
47	3/6/2001	3/29/2001	Gavage	Deionized H2O
48	7/17/2001	8/10/2001	Gavage	0.5% methylcellulose/0.1% Polysorbate 80/1% Sodium Dodecyl Sulfate
49	11/13/2001	12/8/2001	Gavage	2.5% hydroxypropyl methylcellulose in 50 mM Sodium Acetate
50	2/5/2002	3/2/2002	Gavage	0.5% Aqueous methylcellulose
51	2/5/2002	2/28/2002	Gavage	0.125 M Citrate Buffer Solution (pH 3.0)

Study Key

Study Number	Date of First Gestation Day 0 (GD 0)	Date of Study Laparohysterectomy (GD 20)	Route	Vehicle
52	2/19/2002	3/15/2002	Gavage	20 mM Phosphate Buffer
53	4/9/2002	5/3/2002	Gavage	Deionized H2O
54	8/20/2002	9/14/2002	Gavage	Reverse Osmosis-Purified H2O
55	11/13/2002	12/8/2002	Gavage	Deionized H2O
56	1/7/2003	1/31/2003	Gavage	Deionized H2O
57	4/8/2003	5/1/2003	Gavage	Arachis Oil
58	10/9/2001	11/1/2001	Gavage	Deionized H2O
59	1/15/2002	2/8/2002	Gavage	Corn Oil
60	5/27/2003	6/20/2003	Gavage	10% Acacia/0.05% Dow Corning Antifoam US-1510
61	6/3/2003	6/26/2003	Gavage	Olive Oil
62	10/3/2001	10/29/2001	Gavage	Polyethylene Glycol
63	10/3/2001	10/29/2001	Gavage	Deionized H2O
64	9/9/2003	10/3/2003	Gavage	Corn Oil
65	9/9/2003	10/3/2003	Gavage	Deionized H2O
66	8/19/2003	9/11/2003	Gavage	0.5% carboxymethylcellulose
67	6/17/2003	7/10/2003	Gavage	0.5% methylcellulose
68	3/23/2004	4/17/2004	Gavage	Deionized H2O

Study Key

Study Number	Date of First Gestation Day 0 (GD 0)	Date of Study Laparohysterectomy (GD 20)	Route	Vehicle
69	1/27/2004	2/21/2004	Gavage	Deionized H2O
70	9/2/2003	9/25/2003	Intravenous	Sterile 0.9% NaCl
71	9/14/2004	10/9/2004	Gavage	Sponsor-Supplied Vehicle
72	10/26/2004	11/19/2004	Intravenous	26mM Sodium Bicarbonate Buffer/0.9% NaCl
73	1/18/2005	2/12/2005	Gavage	0.5% carboxymethylcellulose in Reverse Osmosis-Treated H2O
74	1/4/2005	1/27/2005	Gavage	Deionized H2O
75	10/19/2004	11/12/2004	Drinking Water	Reverse Osmosis-Purified H2O
76	9/7/2004	9/30/2004	Gavage	Deionized H2O
77	6/29/2005	7/24/2005	Gavage	Deionized H2O
78	7/12/2005	8/4/2005	Gavage	Deionized H2O
79	7/19/2005	8/11/2005	Gavage	0.5% methylcellulose/0.1% Tween 80
80	7/5/2005	7/28/2005	Gavage	100 mM Sodium Acetate Buffer
81	5/17/2005	6/11/2005	Gavage	1% carboxymethylcellulose sodium/0.25% Tween 80/0.05% Dow Corning Antifoam US-1510
82	6/7/2005	6/30/2005	Gavage	Deionized H2O
83	11/23/2004	12/18/2004	Intravenous	PBS
84	2/22/2005	3/18/2005	Intravenous	0.9% NaCl

Study Key

Study Number	Date of First Gestation Day 0 (GD 0)	Date of Study Laparohysterectomy (GD 20)	Route	Vehicle
85	9/27/2005	10/20/2005	Gavage	0.25% carboxymethylcellulose in 0.1 M SodiumAcetate TrihydrateBuffer
86	11/22/2005	12/16/2005	Dermal	Propylene Glycol:Absolute EtOH
87	11/29/2005	12/22/2005	Gavage	0.5 % carboxymethylcellulose Sodium
88	11/8/2005	12/1/2005	Gavage	10% Acacia/0.05% Dow Corning Antifoam 1510-US
89	12/20/2005	1/12/2006	Gavage	0.5% Sodium carboxymethylcellulose
90	1/17/2006	2/12/2006	Subcutaneous	Dulbecco's PBS
91	1/31/2006	2/24/2006	Subcutaneous	Dulbecco's PBS
92	1/31/2006	2/24/2006	Subcutaneous	Dulbecco's PBS
93	2/7/2006	3/4/2006	Gavage	20% Hydroxypropyl- β -Cyclodextrin in 10 mM Citric Acid
94	2/14/2006	3/9/2006	Gavage	Deionized H2O
95	2/28/2006	3/22/2006	Gavage	Deionized H2O
96	2/28/2006	3/24/2006	Gavage	Deionized H2O
97	3/14/2006	4/6/2006	Dermal	16% EtOH in Acetone
98	4/12/2006	5/6/2006	Gavage	Deionized H2O
99	5/10/2006	6/2/2006	Gavage	Deionized H2O
100	4/11/2006	5/14/2006	Gavage	Deionized H2O
101	5/30/2006	6/22/2006	Gavage	0.5% carboxymethylcellulose

Study Key

Study Number	Date of First Gestation Day 0 (GD 0)	Date of Study Laparohysterectomy (GD 20)	Route	Vehicle
102	7/11/2006	8/4/2006	Inhalation	Clean Filtered Air
103	7/25/2006	8/19/2006	Gavage	50% Capryol 90/25% Soybean Oil,16.7% Labrasol and 8.3% Tween 80
104	9/12/2006	10/7/2006	Subcutaneous	10 mM Citrate Buffer/0.02% Tween 80/150 mM NaCl
105	10/3/2006	10/26/2007	Gavage	0.5% hydroxypropyl methylcellulose/0.2% Polysorbate 80
106	2/13/2007	3/14/2007	Gavage	3.0% (w/v) poloxamer 407/ 1.0% (w/v) citric acid monohydrate/ 0.5% (w/v) sodium metabisulfite and purified water
107	12/13/2006	1/5/2007	Gavage	Deionized Water
108	3/20/2007	4/27/2007	Gavage	1% (w/v) hydroxypropyl methylcellulose/25% Polysorbate 80/0.05% Dow Corning Antifoam 1510-US in reverse osmosis water
109	9/27/2006	11/14/2006	IV	5% glucose solution (pH adjusted to 4.5 with lactic acid)
110	9/27/2006	10/31/2006	Gavage	1% methylcellulose
111	5/9/2007	6/1/2007	Gavage	pH adjusted to 5.0 using 0.2 N NaOH and/or 0.1 N to 10.0 N HCl
112	4/10/2007	4/30/2007	Gavage	0.5% (w/v) methylcellulose/deionized water
113	1/9/2007	2/3/2007	Gavage	0.1 M citrate buffer, pH 2.7 ± 0.1
114	1/30/2007	2/23/2007	Gavage	corn oil
115	11/12/2007	11/29/2007	Gavage	DI WATER
116	3/11/2008	3/29/2008	Gavage	KLUCEL LF
119	2/5/2008	2/22/2008	IV	SALINE

Study Key

Study Number	Date of First Gestation Day 0 (GD 0)	Date of Study Laparohysterectomy (GD 20)	Route	Vehicle
122	1/14/2008	2/2/2008	GAVAGE	DI WATER
123	10/2/2006	10/20/2006	GAVAGE	DI WATER
124	3/19/2008	3/22/2008	GAVAGE	ACETATE BUFFER
125	2/18/2008	3/3/2008	GAVAGE	ACETATE BUFFER
126	10/22/2007	11/8/2007	GAVAGE	METHYLCELLULOSE, TWEEN 80
127	9/11/2007	10/5/2007	Subcutaneous	CITRIC ACID, SODIUM CITRATE, NACL
128	9/4/2007	12/4/2007	GAVAGE	CMC SODIUM, POLYSORBATE 80, DOW CORNING ANTIFOAM
129	9/18/2007	10/24/2007	GAVAGE	CMC SODIUM, POLYSORBATE 80, DOW CORNING ANTIFOAM
130	3/31/2008	4/17/2008	Surgical Implant	STERILE SALINE
131	11/26/2007	12/13/2007	DERMAL	ACETONE
132	2/18/2008	3/8/2008	GAVAGE	EN3285 PLACEBO
133	2/25/2008	4/12/2008	IV	SALINE, HCL, SODIUM CITRATE
134	1/7/2008	1/25/2008	GAVAGE	METHYLCELLULOSE
135	2/25/2008	3/15/2008	GAVAGE	METHYLCELLULOSE, DI WATER
136	10/15/2007	11/1/2007	GAVAGE	METHYLCELLULOSE, SODIUM LAURYL SULFATE
137	3/19/2007	4/6/2007	GAVAGE	METHYLCELLULOSE
138	5/21/2007	6/8/2007	GAVAGE	DI WATER

Study Key

Study Number	Date of First Gestation Day 0 (GD 0)	Date of Study Laparohysterectomy (GD 20)	Route	Vehicle
139	10/1/2007	10/19/2007	GAVAGE	GELUCINE, PEG 400
140	10/26/2007	11/12/2007	GAVAGE	CORN OIL
141	10/11/2007	10/29/2007	GAVAGE	CMC, NACL, POLYSORBATE 80, DI WATER
142	11/10/2007	11/27/2007	DERMAL	DI WATER
143	1/28/2008	2/16/2008	GAVAGE	CMC, DI WATER
144	10/5/2007	11/15/2007	GAVAGE	ACACIA, POLYSORBATE 80, DOW CORNING ANTIFOAM
145	9/22/2008	10/9/2008	GAVAGE	CORN OIL
146	2/9/2009	2/27/2009	GAVAGE	DI WATER
148	6/9/2008	6/28/2008	GAVAGE	50 MMOL ACETATE BUFFER
149	5/19/2008	6/5/2008	GAVAGE	50 MMOL PHOSPHATE BUFFER
150	7/9/2008	8/2/2008	INTRANEOUS INJEC	10 MMOL SODIUM CITRATE BUFFER (150 MMOL SODIUM CHLORIDE, 0.02% POLYSORBATE 80, STERILE WATER)
151	12/1/2008	12/19/2008	INTRANEOUS INJEC	STERILE PHYSIOLOGICAL SALINE
152	7/7/2008	7/26/2008	GAVAGE	0.5% METHYLCELLULOSE
157	6/30/2008	7/19/2008	INTRANEOUS INJEC	DI WATER
158	4/14/2008	5/1/2008	GAVAGE	STERILE WATER
159	8/25/2008	9/11/2008	GAVAGE	0.5% METHYLCELLULOSE

Study Key

Study Number	Date of First	Date of Study	Route	Vehicle
	Gestation Day 0 (GD 0)	Laparohysterectomy (GD 20)		
160	7/7/2008	7/26/2008	GAVAGE	0.5% METHYLCELLULOSE
161	11/24/2008	12/11/2008	RAVENOUS INFUS	SALINE

Study Date Range: 21 Apr 1998 - 27 Feb 2009

Mean of Study Means

Endpoint	Total	Mean	S.D.	SEM	Median	Min	Max	25th Quartile	75th Quartile
NO. OF DATASETS	152								
Total No. of Animals in the Control Group	3767								
No. of Animals That Died	6								
No. of Animals That Aborted	0								
No. of Animals That Delivered	0								
Percent Pregnant		96.3	5.16	0.42	98.0	69.2	100.0	95.9	100.0
No. Gravid	3631								
No. With Only Resorptions	5								
No. of Dams With Live Fetuses	3621								
No. Nongravid	136								
No. of Animals Examined at Laparohysterectomy	3761								
Mean Gravid Uterine Weight (g)		85.4	3.70	0.30	85.7	72.2	95.4	82.8	88.1
Mean No. Viable Fetuses/Dam		15.2	0.67	0.05	15.2	12.2	17.1	14.8	15.6
Total No. Viable Fetuses	54997								
Viable Fetuses (%/Litter)		95.2	1.54	0.13	95.5	90.1	98.0	94.1	96.2
Mean No. Postimplantation Loss/Dam		0.7	0.22	0.02	0.7	0.3	1.4	0.6	0.9
Total No. of Postimplantation Losses	2703								
Postimplantation Loss (%/Litter)		4.8	1.54	0.13	4.5	2.0	9.9	3.8	5.9
Early Resorptions (%/Litter)		4.7	1.56	0.13	4.5	1.5	9.9	3.6	5.8
Late Resorptions (%/Litter)		0.1	0.19	0.02	0.0	0.0	0.8	0.0	0.2
Dead Fetuses (%/Litter)		0.0	0.05	0.00	0.0	0.0	0.5	0.0	0.0
Mean No. Implantations/Dam		15.9	0.67	0.05	15.9	13.0	17.6	15.5	16.3
Mean No. Corpora Lutea/Dam		17.3	0.82	0.07	17.3	14.5	19.4	16.7	17.8
Mean No. Preimplantation Loss/Dam		1.4	0.60	0.05	1.3	0.3	3.1	0.9	1.7
Total No. Preimplantation Losses	4967								
Preimplantation Loss (%/Litter)		7.4	3.04	0.25	7.3	1.5	15.7	5.3	9.2
Total No. Male Fetuses	27427								
Total No. Female Fetuses	27570								
% Males/Litter		49.8	2.72	0.22	49.7	43.1	56.7	47.9	51.7
% Females/Litter		50.2	2.72	0.22	50.3	43.3	56.9	48.3	52.1
Mean Fetal Body Weight (g)		3.7	0.11	0.01	3.6	3.4	3.9	3.6	3.7
Mean Male Body Weight (g)		3.7	0.12	0.01	3.7	3.5	4.0	3.7	3.8
Mean Female Body Weight (g)		3.6	0.11	0.01	3.5	3.4	3.8	3.5	3.6

		Mean of Study Means							
NO. OF DATASETS		149							
Total No. of Fetuses/Litters Examined Externally		53902	3548						
Total No. of Fetuses/Litters Examined Viscerally		53708	3548						
Total No. of Fetuses/Litters Examined Skeletally		53695	3547						
MALFORMATIONS (% Per Litter)		Mean	S.D.	SEM	Median	Min	Max	25th Quartile	75th Quartile
TOTAL EXTERNAL MALFORMATIONS		0.1	0.21	0.02	0.0	0.0	1.3	0.0	0.2
TOTAL VISCERAL MALFORMATIONS		0.1	0.17	0.01	0.0	0.0	0.9	0.0	0.0
TOTAL SKELETAL MALFORMATIONS		0.1	0.24	0.02	0.0	0.0	1.1	0.0	0.2
TOTAL MALFORMATIONS		0.3	0.36	0.03	0.3	0.0	1.6	0.0	0.5
EXTERNAL									
Aglossia		0.0	0.03	0.00	0.0	0.0	0.3	0.0	0.0
Anal Atresia		0.0	0.05	0.00	0.0	0.0	0.3	0.0	0.0
Apodia		0.0	0.02	0.00	0.0	0.0	0.3	0.0	0.0
Astomia		0.0	0.03	0.00	0.0	0.0	0.3	0.0	0.0
Carpal and/or Tarsal Flexure		0.0	0.03	0.00	0.0	0.0	0.3	0.0	0.0
Cleft Face		0.0	0.02	0.00	0.0	0.0	0.3	0.0	0.0
Cleft Lip		0.0	0.02	0.00	0.0	0.0	0.3	0.0	0.0
Cleft Palate		0.0	0.04	0.00	0.0	0.0	0.3	0.0	0.0
Craniorachischisis		0.0	0.02	0.00	0.0	0.0	0.3	0.0	0.0
Cyclopia		0.0	0.04	0.00	0.0	0.0	0.3	0.0	0.0
Ectromelia		0.0	0.02	0.00	0.0	0.0	0.3	0.0	0.0
Exencephaly with or without Open Eyelid(s)		0.0	0.03	0.00	0.0	0.0	0.3	0.0	0.0
Fetal Anasarca		0.0	0.12	0.01	0.0	0.0	1.3	0.0	0.0
Filamentous Tail		0.0	0.05	0.00	0.0	0.0	0.3	0.0	0.0
Gastroschisis		0.0	0.02	0.00	0.0	0.0	0.3	0.0	0.0
Hydrocephaly with or without Dome Head		0.0	0.02	0.00	0.0	0.0	0.2	0.0	0.0
Mandibular Agnathia		0.0	0.03	0.00	0.0	0.0	0.3	0.0	0.0
Mandibular Micrognathia		0.0	0.05	0.00	0.0	0.0	0.3	0.0	0.0
Maxillary Agnathia		0.0	0.02	0.00	0.0	0.0	0.2	0.0	0.0
Meningoencephalocele		0.0	0.02	0.00	0.0	0.0	0.2	0.0	0.0

		Mean of Study Means						
NO. OF DATASETS	149							
Total No. of Fetuses/Litters Examined Externally	53902	3548						
Total No. of Fetuses/Litters Examined Viscerally	53708	3548						
Total No. of Fetuses/Litters Examined Skeletally	53695	3547						
MALFORMATIONS (% Per Litter)	Mean	S.D.	SEM	Median	Min	Max	25th Quartile	75th Quartile
EXTERNAL								
Micromelia	0.0	0.02	0.00	0.0	0.0	0.2	0.0	0.0
Microphthalmia and/or Anophthalmia	0.0	0.09	0.01	0.0	0.0	0.5	0.0	0.0
Omphalocele	0.0	0.05	0.00	0.0	0.0	0.3	0.0	0.0
Open Eyelid(s)	0.0	0.02	0.00	0.0	0.0	0.2	0.0	0.0
Proboscis-Like Nose	0.0	0.02	0.00	0.0	0.0	0.2	0.0	0.0
Tail- Short	0.0	0.04	0.00	0.0	0.0	0.3	0.0	0.0
Umbilical Herniation of the Intestine	0.0	0.05	0.00	0.0	0.0	0.3	0.0	0.0
VISCERAL								
Aorta- Narrowed	0.0	0.03	0.00	0.0	0.0	0.3	0.0	0.0
Epididymis- Absent	0.0	0.02	0.00	0.0	0.0	0.3	0.0	0.0
Heart and/or Great Vessel Anomaly	0.0	0.02	0.00	0.0	0.0	0.2	0.0	0.0
Hydrocephaly	0.0	0.08	0.01	0.0	0.0	0.8	0.0	0.0
Interrupted Aortic Arch	0.0	0.03	0.00	0.0	0.0	0.3	0.0	0.0
Kidney(s)- Absent	0.0	0.03	0.00	0.0	0.0	0.4	0.0	0.0
Kidney(s) and/or Ureter(s) Absent	0.0	0.04	0.00	0.0	0.0	0.3	0.0	0.0
Lung(s)- Lobular Agenesis	0.0	0.05	0.00	0.0	0.0	0.6	0.0	0.0
Lung(s)- Lobular Dysgenesis	0.0	0.05	0.00	0.0	0.0	0.3	0.0	0.0
Retroesophageal Aortic Arch	0.0	0.05	0.00	0.0	0.0	0.3	0.0	0.0
Situs Inversus	0.0	0.09	0.01	0.0	0.0	0.4	0.0	0.0
Testis- Absent	0.0	0.02	0.00	0.0	0.0	0.3	0.0	0.0
Thyroid Gland(s)- Absent	0.0	0.03	0.00	0.0	0.0	0.3	0.0	0.0
Transposition of the Great Vessels	0.0	0.03	0.00	0.0	0.0	0.3	0.0	0.0
Vessel(s)- Malpositioned	0.0	0.03	0.00	0.0	0.0	0.3	0.0	0.0

		Mean of Study Means							
NO. OF DATASETS		149							
Total No. of Fetuses/Litters Examined Externally		53902	3548						
Total No. of Fetuses/Litters Examined Viscerally		53708	3548						
Total No. of Fetuses/Litters Examined Skeletally		53695	3547						
MALFORMATIONS (% Per Litter)		Mean	S.D.	SEM	Median	Min	Max	25th Quartile	75th Quartile
SKELETAL									
Bent Limb Bone(s)		0.0	0.09	0.01	0.0	0.0	1.0	0.0	0.0
Costal Cartilage Anomaly		0.0	0.05	0.00	0.0	0.0	0.3	0.0	0.0
Rib Anomaly		0.0	0.08	0.01	0.0	0.0	0.4	0.0	0.0
Rib(s)- Only 11 Pairs Present		0.0	0.02	0.00	0.0	0.0	0.2	0.0	0.0
Rib(s)- Only 12 Pairs Present		0.0	0.06	0.01	0.0	0.0	0.5	0.0	0.0
Skull Anomaly		0.0	0.04	0.00	0.0	0.0	0.4	0.0	0.0
Sternebra(e)- Fused		0.0	0.08	0.01	0.0	0.0	1.0	0.0	0.0
Sternebra(e)- Malaligned (Severe)		0.0	0.06	0.00	0.0	0.0	0.4	0.0	0.0
Sternoschisis		0.0	0.07	0.01	0.0	0.0	0.6	0.0	0.0
Vertebral Agenesis		0.0	0.07	0.01	0.0	0.0	0.3	0.0	0.0
Vertebral Anomaly with or without Associated Rib Anomaly		0.0	0.11	0.01	0.0	0.0	0.7	0.0	0.0
Vertebral Centra Anomaly		0.0	0.06	0.00	0.0	0.0	0.5	0.0	0.0

		Mean of Study Means							
NO. OF DATASETS		149							
Total No. of Fetuses/Litters Examined Externally		53902	3548						
Total No. of Fetuses/Litters Examined Viscerally		53708	3548						
Total No. of Fetuses/Litters Examined Skeletally		53695	3547						
VARIATIONS (% Per Litter)		Mean	S.D.	SEM	Median	Min	Max	25th Quartile	75th Quartile
TOTAL EXTERNAL VARIATIONS		0.0	0.02	0.00	0.0	0.0	0.3	0.0	0.0
TOTAL VISCERAL VARIATIONS		0.4	0.70	0.06	0.2	0.0	4.0	0.0	0.6
TOTAL SKELETAL VARIATIONS		33.6	6.79	0.56	33.4	18.0	50.4	29.6	37.2
TOTAL VARIATIONS		33.9	6.77	0.55	33.6	18.0	51.1	30.0	37.8
EXTERNAL									
Twinning		0.0	0.02	0.00	0.0	0.0	0.3	0.0	0.0
VISCERAL									
Adrenal Gland(s)- Enlarged		0.0	0.12	0.01	0.0	0.0	1.4	0.0	0.0
Adrenal Gland(s)- Pale		0.0	0.02	0.00	0.0	0.0	0.2	0.0	0.0
Diaphragm- Thin		0.0	0.02	0.00	0.0	0.0	0.3	0.0	0.0
Hemorrhagic Iris		0.0	0.03	0.00	0.0	0.0	0.3	0.0	0.0
Hemorrhagic Ring Around the Iris		0.0	0.07	0.01	0.0	0.0	0.3	0.0	0.0
Kidney(s)- Small		0.0	0.03	0.00	0.0	0.0	0.3	0.0	0.0
Liver- Accessory Lobule(s)		0.0	0.09	0.01	0.0	0.0	0.8	0.0	0.0
Liver- Pale		0.0	0.03	0.00	0.0	0.0	0.3	0.0	0.0
Liver- Swollen		0.0	0.02	0.00	0.0	0.0	0.3	0.0	0.0
Major Blood Vessel Variation		0.1	0.15	0.01	0.0	0.0	0.8	0.0	0.0
Renal Papilla(e) not Developed and/or Distended Ureter(s)		0.2	0.62	0.05	0.0	0.0	4.0	0.0	0.3
Spleen- Accessory		0.0	0.09	0.01	0.0	0.0	1.0	0.0	0.0
Spleen- Pale		0.0	0.07	0.01	0.0	0.0	0.3	0.0	0.0
Spleen- Small		0.0	0.13	0.01	0.0	0.0	1.4	0.0	0.0
Testis- Small		0.0	0.03	0.00	0.0	0.0	0.2	0.0	0.0
SKELETAL									
14th Full Rib(s)		0.1	0.17	0.01	0.0	0.0	0.9	0.0	0.0

		Mean of Study Means						
NO. OF DATASETS	149							
Total No. of Fetuses/Litters Examined Externally	53902	3548						
Total No. of Fetuses/Litters Examined Viscerally	53708	3548						
Total No. of Fetuses/Litters Examined Skeletally	53695	3547						
VARIATIONS (% Per Litter)	Mean	S.D.	SEM	Median	Min	Max	25th Quartile	75th Quartile
SKELETAL								
14th Rudimentary Rib(s)	6.8	2.84	0.23	6.5	0.0	15.1	4.8	8.6
25 Presacral Vertebrae	0.1	0.31	0.03	0.0	0.0	2.0	0.0	0.0
27 Presacral Vertebrae	0.2	0.28	0.02	0.0	0.0	1.8	0.0	0.3
7th Cervical Rib(s)	0.8	0.78	0.06	0.7	0.0	3.5	0.3	1.1
7th Sternebra	0.0	0.25	0.02	0.0	0.0	2.5	0.0	0.0
Bent Rib(s)	0.2	0.48	0.04	0.0	0.0	4.0	0.0	0.3
Cervical Centrum #1 Ossified	20.2	5.87	0.48	19.7	6.6	35.8	16.3	24.2
Entire Sternum Unossified	0.0	0.06	0.01	0.0	0.0	0.4	0.0	0.0
Extra Site of Ossification Anterior to Cervical Centrum #2	0.0	0.02	0.00	0.0	0.0	0.3	0.0	0.0
Extra Site of Ossification Anterior to Rib #5	0.0	0.02	0.00	0.0	0.0	0.2	0.0	0.0
Extra Site of Ossification Anterior to Sternebra #1	0.0	0.04	0.00	0.0	0.0	0.4	0.0	0.0
Extra Site of Ossification Ventral to Cervical Centrum #2	0.0	0.02	0.00	0.0	0.0	0.3	0.0	0.0
Hyoid Unossified	1.3	0.98	0.08	1.2	0.0	4.4	0.5	2.0
Ischium Unossified	0.0	0.06	0.01	0.0	0.0	0.6	0.0	0.0
Pubis Unossified	0.1	0.22	0.02	0.0	0.0	2.3	0.0	0.0
Reduced Ossification of the 13th Rib(s)	0.6	0.69	0.06	0.5	0.0	3.6	0.2	0.8
Reduced Ossification of the Limb Bone(s)	0.0	0.03	0.00	0.0	0.0	0.2	0.0	0.0
Reduced Ossification of the Rib(s)	0.0	0.13	0.01	0.0	0.0	1.2	0.0	0.0
Reduced Ossification of the Skull	0.1	0.20	0.02	0.0	0.0	1.0	0.0	0.0
Reduced Ossification of the Vertebral Arches	0.1	0.20	0.02	0.0	0.0	1.1	0.0	0.2
Skull Bone(s)- Accessory	0.0	0.08	0.01	0.0	0.0	0.7	0.0	0.0
Sternebra(e) #1, #2, #3 and/or #4 Unossified	0.2	0.27	0.02	0.0	0.0	1.3	0.0	0.3
Sternebra(e) #5 and/or #6 Unossified	6.6	6.03	0.49	4.0	0.0	26.1	2.5	9.3
Sternebra(e)- Malaligned (Slight or Moderate)	0.4	0.49	0.04	0.3	0.0	3.0	0.0	0.6
Sternebrae with Thread-Like Attachment	0.0	0.05	0.00	0.0	0.0	0.6	0.0	0.0

		Mean of Study Means							
NO. OF DATASETS		149							
Total No. of Fetuses/Litters Examined Externally		53902	3548						
Total No. of Fetuses/Litters Examined Viscerally		53708	3548						
Total No. of Fetuses/Litters Examined Skeletally		53695	3547						
VARIATIONS (% Per Litter)		Mean	S.D.	SEM	Median	Min	Max	25th Quartile	75th Quartile
SKELETAL									
Unco-Ossified Vertebral Centra		0.0	0.06	0.00	0.0	0.0	0.5	0.0	0.0
Vertebral Centra Unossified		0.0	0.05	0.00	0.0	0.0	0.4	0.0	0.0

Modal Distribution of Fetal Body Weights

No. of Datasets in Historical Control

152

Range of Study Dates

4/21/1998 - 2/27/2009

No. of Dams in Historical Control

3767

No. of Dams with Live Fetuses

3621

Mean Fetal Body Weight Range (g)

3.4 - 3.9

Mean Fetal Body Weight (g)	3.4	3.5	3.6	3.7	3.8	3.9
Total No. Datasets	2	27	52	43	20	8
Mean Litter Size	15.1	15.4	15.2	15.2	14.7	14.6
Litter Size Range	15.0 - 15.1	14.4 - 17.1	13.7 - 16.7	13.7 - 16.6	12.2 - 15.8	13.8 - 15.3

Summary Incidence Malformations and Variations

(Total Number Fetuses/Litters Affected)

Ranked Uppermost to Nethermost

NO. OF DATASETS	149	
Total No. of Fetuses/Litters Examined Externally	53902	3548
Total No. of Fetuses/Litters Examined Viscerally	53708	3548
Total No. of Fetuses/Litters Examined Skeletally	53695	3547

MALFORMATIONS	Number	
	Fetuses	Litters
EXTERNAL		
Microphthalmia and/or Anophthalmia	18	18
Fetal Anasarca	7	5
Mandibular Micrognathia	6	6
Omphalocele	6	6
Anal Atresia	5	5
Filamentous Tail	5	5
Cleft Palate	4	4
Umbilical Herniation of the Intestine	4	4
Tail- Short	3	3
Aglossia	2	2
Carpal and/or Tarsal Flexure	2	2
Cyclopia	2	2
Exencephaly with or without Open Eyelid(s)	2	2
Mandibular Agnathia	2	2
Apodia	1	1
Astomia	1	1
Cleft Face	1	1
Cleft Lip	1	1
Craniorachischisis	1	1
Ectromelia	1	1
Gastroschisis	1	1
Hydrocephaly with or without Dome Head	1	1
Maxillary Agnathia	1	1

Summary Incidence Malformations and Variations

(Total Number Fetuses/Litters Affected)

Ranked Uppermost to Nethermost

NO. OF DATASETS	149	
Total No. of Fetuses/Litters Examined Externally	53902	3548
Total No. of Fetuses/Litters Examined Viscerally	53708	3548
Total No. of Fetuses/Litters Examined Skeletally	53695	3547

MALFORMATIONS	Number	
	Fetuses	Litters
EXTERNAL		
Meningoencephalocele	1	1
Micromelia	1	1
Open Eyelid(s)	1	1
Proboscis-Like Nose	1	1
VISCERAL		
Situs Inversus	13	13
Hydrocephaly	8	8
Lung(s)- Lobular Dysgenesis	5	5
Retroesophageal Aortic Arch	5	5
Kidney(s) and/or Ureter(s) Absent	4	4
Interrupted Aortic Arch	2	2
Thyroid Gland(s)- Absent	2	2
Transposition of the Great Vessels	2	2
Aorta- Narrowed	1	1
Epididymis- Absent	1	1
Heart and/or Great Vessel Anomaly	1	1
Kidney(s)- Absent	1	1
Lung(s)- Lobular Agenesis	1	1
Testis- Absent	1	1
Vessel(s)- Malpositioned	1	1
SKELETAL		
Vertebral Anomaly with or without Associated Rib Anomaly	20	17
Rib Anomaly	11	11

Summary Incidence Malformations and Variations

(Total Number Fetuses/Litters Affected)

Ranked Uppermost to Nethermost

NO. OF DATASETS	149	
Total No. of Fetuses/Litters Examined Externally	53902	3548
Total No. of Fetuses/Litters Examined Viscerally	53708	3548
Total No. of Fetuses/Litters Examined Skeletally	53695	3547

MALFORMATIONS	Number	
	Fetuses	Litters
SKELETAL		
Vertebral Agenesis	10	10
Sternoschisis	10	9
Vertebral Centra Anomaly	6	6
Bent Limb Bone(s)	6	4
Costal Cartilage Anomaly	5	5
Rib(s)- Only 12 Pairs Present	5	5
Sternebra(e)- Malaligned (Severe)	5	5
Sternebra(e)- Fused	2	2
Rib(s)- Only 11 Pairs Present	1	1
Skull Anomaly	1	1

Summary Incidence Malformations and Variations

(Total Number Fetuses/Litters Affected)

Ranked Uppermost to Nethermost

NO. OF DATASETS	149	
Total No. of Fetuses/Litters Examined Externally	53902	3548
Total No. of Fetuses/Litters Examined Viscerally	53708	3548
Total No. of Fetuses/Litters Examined Skeletally	53695	3547

VARIATIONS	Number	
	Fetuses	Litters
EXTERNAL		
Twinning	1	1
VISCERAL		
Renal Papilla(e) not Developed and/or Distended Ureter(s)	121	75
Major Blood Vessel Variation	42	41
Hemorrhagic Ring Around the Iris	11	11
Spleen- Pale	8	8
Spleen- Accessory	8	5
Liver- Accessory Lobule(s)	7	5
Spleen- Small	6	6
Adrenal Gland(s)- Enlarged	5	1
Hemorrhagic Iris	2	2
Kidney(s)- Small	2	2
Liver- Pale	2	2
Testis- Small	2	2
Adrenal Gland(s)- Pale	1	1
Diaphragm- Thin	1	1
Liver- Swollen	1	1
SKELETAL		
Cervical Centrum #1 Ossified	10707	2698
14th Rudimentary Rib(s)	3655	1519
Sternebra(e) #5 and/or #6 Unossified	3593	1287
Hyoid Unossified	705	448
7th Cervical Rib(s)	433	335

Summary Incidence Malformations and Variations

(Total Number Fetuses/Litters Affected)

Ranked Uppermost to Nethermost

NO. OF DATASETS	149	
Total No. of Fetuses/Litters Examined Externally	53902	3548
Total No. of Fetuses/Litters Examined Viscerally	53708	3548
Total No. of Fetuses/Litters Examined Skeletally	53695	3547

VARIATIONS	Number	
	Fetuses	Litters
SKELETAL		
Reduced Ossification of the 13th Rib(s)	328	220
Sternebra(e)- Malaligned (Slight or Moderate)	201	180
Sternebra(e) #1, #2, #3 and/or #4 Unossified	103	95
Bent Rib(s)	88	67
27 Presacral Vertebrae	82	64
Reduced Ossification of the Vertebral Arches	59	54
25 Presacral Vertebrae	57	34
Reduced Ossification of the Skull	47	40
14th Full Rib(s)	40	34
Pubis Unossified	37	31
7th Sternebra	24	10
Reduced Ossification of the Rib(s)	19	16
Entire Sternum Unossified	8	8
Skull Bone(s)- Accessory	8	8
Vertebral Centra Unossified	5	5
Unco-Ossified Vertebral Centra	4	4
Ischium Unossified	4	3
Extra Site of Ossification Anterior to Sternebra #1	3	3
Reduced Ossification of the Limb Bone(s)	2	2
Sternebrae with Thread-Like Attachment	2	1
Extra Site of Ossification Anterior to Cervical Centrum #2	1	1
Extra Site of Ossification Anterior to Rib #5	1	1
Extra Site of Ossification Ventral to Cervical Centrum #2	1	1

Endpoint	Study No.	1	2	3	4	5	6	7	8	9	10
Total No. of Animals in the Control Group		25	25	22	25	25	22	25	25	25	25
No. of Animals That Died		0	1	0	0	0	0	0	0	0	0
No. of Animals That Aborted		0	0	0	0	0	0	0	0	0	0
No. of Animals That Delivered		0	0	0	0	0	0	0	0	0	0
Percent Pregnant		88.0	76.0	95.5	100.0	100.0	100.0	88.0	88.0	88.0	96.0
No. Gravid		22	19	21	25	25	22	22	22	22	24
No. With Only Resorptions		0	0	0	0	0	0	0	0	0	0
No. of Dams With Live Fetuses		22	19	21	25	25	22	22	22	22	24
No. Nongravid		3	6	1	0	0	0	3	3	3	1
No. of Animals Examined at Laparohysterectomy		25	24	22	25	25	22	25	25	25	25
Mean Gravid Uterine Weight (g)		82.0	79.6	80.6	78.7	84.0	89.8	78.1	83.8	80.0	89.8
Mean No. Viable Fetuses/Dam		14.0	14.1	15.0	14.3	14.9	15.7	14.4	15.2	14.6	16.5
Total No. Viable Fetuses		309	267	315	357	373	346	316	334	322	397
Viable Fetuses (%/Litter)		95.9	95.9	94.9	94.1	95.0	96.2	93.3	95.7	95.4	94.3
Mean No. Postimplantation Loss/Dam		0.6	0.6	0.8	0.9	0.7	0.6	1.1	0.7	0.7	1.0
Total No. of Implantation Sites Lost		13	11	17	22	17	14	24	15	15	24
Postimplantation Loss (%/Litter)		4.1	4.1	5.1	5.9	5.0	3.8	6.7	4.3	4.6	5.7
Early Resorptions (%/Litter)		3.8	4.1	5.1	5.6	5.0	3.5	6.7	4.3	4.6	5.7
Late Resorptions (%/Litter)		0.3	0.0	0.0	0.3	0.0	0.3	0.0	0.0	0.0	0.0
Dead Fetuses (%/Litter)		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Mean No. Implantations/Dam		14.6	14.6	15.8	15.2	15.6	16.4	15.5	15.9	15.3	17.5
Mean No. Corpora Lutea/Dam		16.7	16.5	17.9	16.6	17.3	18.1	17.2	17.6	17.5	19.3
Mean No. Preimplantation Loss/Dam		2.1	1.8	2.2	1.5	1.7	1.8	1.8	1.7	2.2	1.7
Total No. Preimplantation Losses		46	35	44	37	43	39	39	38	48	41
Preimplantation Loss (%/Litter)		11.3	10.7	11.6	7.9	8.9	9.0	9.9	8.7	12.0	8.8
Total No. Male Fetuses		158	135	155	187	204	170	157	166	144	205
Total No. Female Fetuses		151	132	160	170	169	176	159	168	178	192
% Males/Litter		50.7	50.3	48.5	52.8	55.2	48.6	49.6	49.0	44.5	52.0
% Females/Litter		49.3	49.7	51.5	47.2	44.8	51.4	50.4	51.0	55.5	48.0
Mean Fetal Body Weight (g)		3.82	3.72	3.43	3.64	3.60	3.70	3.53	3.57	3.56	3.47
Mean Male Body Weight (g)		3.93	3.81	3.50	3.73	3.69	3.79	3.62	3.66	3.64	3.57
Mean Female Body Weight (g)		3.72	3.62	3.37	3.52	3.50	3.61	3.44	3.48	3.49	3.36

Endpoint	Study No.	11	12	13	14	15	16	17	18	19	20
Total No. of Animals in the Control Group		25	25	25	25	25	22	25	25	25	25
No. of Animals That Died		0	0	0	0	0	0	0	0	0	0
No. of Animals That Aborted		0	0	0	0	0	0	0	0	0	0
No. of Animals That Delivered		0	0	0	0	0	0	0	0	0	0
Percent Pregnant		100.0	96.0	96.0	100.0	100.0	95.5	100.0	100.0	92.0	96.0
No. Gravid		25	24	24	25	25	21	25	25	23	24
No. With Only Resorptions		0	0	0	0	0	0	0	0	0	0
No. of Dams With Live Fetuses		25	24	24	25	25	21	25	25	23	24
No. Nongravid		0	1	1	0	0	1	0	0	2	1
No. of Animals Examined at Laparohysterectomy		25	25	25	25	25	22	25	25	25	25
Mean Gravid Uterine Weight (g)		85.7	88.0	81.9	89.7	87.4	87.4	79.1	87.4	86.9	86.6
Mean No. Viable Fetuses/Dam		15.7	15.7	14.5	16.3	15.2	15.4	15.1	15.5	15.4	15.8
Total No. Viable Fetuses		393	377	349	407	380	323	378	388	355	379
Viable Fetuses (%/Litter)		96.2	96.5	95.3	96.3	96.2	96.8	95.7	94.9	97.6	97.8
Mean No. Postimplantation Loss/Dam		0.6	0.5	0.8	0.6	0.6	0.5	0.8	0.8	0.4	0.4
Total No. of Implantation Sites Lost		15	13	18	15	15	11	19	21	9	9
Postimplantation Loss (%/Litter)		3.8	3.5	4.7	3.7	3.8	3.2	4.3	5.1	2.4	2.2
Early Resorptions (%/Litter)		3.8	3.5	4.7	3.7	3.5	2.9	4.3	4.8	2.4	2.2
Late Resorptions (%/Litter)		0.0	0.0	0.0	0.0	0.3	0.3	0.0	0.3	0.0	0.0
Dead Fetuses (%/Litter)		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Mean No. Implantations/Dam		16.3	16.3	15.3	16.9	15.8	15.9	15.9	16.4	15.8	16.2
Mean No. Corpora Lutea/Dam		18.2	18.1	17.2	18.8	18.9	17.7	18.7	18.4	17.5	18.6
Mean No. Preimplantation Loss/Dam		1.9	1.9	1.9	1.9	3.1	1.8	2.8	2.0	1.7	2.4
Total No. Preimplantation Losses		47	45	45	47	77	37	71	50	39	58
Preimplantation Loss (%/Litter)		9.4	9.7	10.5	8.9	14.3	9.6	13.4	10.1	9.3	12.1
Total No. Male Fetuses		178	197	160	220	189	159	184	179	175	191
Total No. Female Fetuses		215	180	189	187	191	164	194	209	180	188
% Males/Litter		45.5	52.4	45.2	53.8	49.3	49.2	48.7	45.8	50.1	50.3
% Females/Litter		54.5	47.6	54.8	46.2	50.7	50.8	51.3	54.2	49.9	49.7
Mean Fetal Body Weight (g)		3.53	3.67	3.64	3.56	3.74	3.77	3.41	3.70	3.68	3.53
Mean Male Body Weight (g)		3.65	3.74	3.77	3.63	3.81	3.84	3.47	3.81	3.74	3.60
Mean Female Body Weight (g)		3.44	3.58	3.52	3.47	3.65	3.70	3.35	3.62	3.62	3.45

Endpoint	Study No.	21	22	23	24	25	26	27	28	29	30
Total No. of Animals in the Control Group		25	25	25	25	25	25	25	25	25	25
No. of Animals That Died		0	0	0	0	0	0	0	0	0	0
No. of Animals That Aborted		0	0	0	0	0	0	0	0	0	0
No. of Animals That Delivered		0	0	0	0	0	0	0	0	0	0
Percent Pregnant		88.0	100.0	100.0	92.0	100.0	100.0	100.0	96.0	100.0	96.0
No. Gravid		22	25	25	23	25	25	25	24	25	24
No. With Only Resorptions		0	0	0	0	0	0	0	0	0	0
No. of Dams With Live Fetuses		22	25	25	23	25	25	25	24	25	24
No. Nongravid		3	0	0	2	0	0	0	1	0	1
No. of Animals Examined at Laparohysterectomy		25	25	25	25	25	25	25	25	25	25
Mean Gravid Uterine Weight (g)		83.5	87.4	87.3	83.4	81.3	86.0	83.6	87.1	86.7	90.0
Mean No. Viable Fetuses/Dam		15.5	15.3	15.6	14.3	14.8	15.4	15.1	15.8	15.0	16.1
Total No. Viable Fetuses		342	383	391	328	370	386	378	379	376	386
Viable Fetuses (%/Litter)		97.2	94.7	96.1	93.4	95.6	98.0	91.9	93.7	95.4	97.0
Mean No. Postimplantation Loss/Dam		0.5	0.9	0.6	1.0	0.7	0.3	1.0	1.0	0.7	0.5
Total No. of Implantation Sites Lost		10	23	15	24	17	8	26	25	18	12
Postimplantation Loss (%/Litter)		2.8	5.3	3.9	6.6	4.4	2.0	8.1	6.3	4.6	3.0
Early Resorptions (%/Litter)		2.8	5.3	3.1	6.6	4.2	2.0	8.1	6.0	4.6	3.0
Late Resorptions (%/Litter)		0.0	0.0	0.8	0.0	0.3	0.0	0.0	0.3	0.0	0.0
Dead Fetuses (%/Litter)		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Mean No. Implantations/Dam		16.0	16.2	16.2	15.3	15.5	15.8	16.2	16.8	15.8	16.6
Mean No. Corpora Lutea/Dam		18.0	18.5	18.1	16.9	16.9	17.3	19.0	18.2	16.6	19.0
Mean No. Preimplantation Loss/Dam		2.0	2.2	1.9	1.6	1.4	1.6	2.9	1.3	0.9	2.4
Total No. Preimplantation Losses		44	56	47	36	35	39	72	32	22	57
Preimplantation Loss (%/Litter)		10.7	11.8	9.4	8.9	7.8	9.1	15.7	6.0	5.3	11.7
Total No. Male Fetuses		153	180	195	151	186	185	192	193	187	181
Total No. Female Fetuses		189	203	196	177	184	201	186	186	189	205
% Males/Litter		44.5	46.8	49.7	45.4	49.6	47.9	47.8	51.3	50.0	46.6
% Females/Litter		55.5	53.2	50.3	54.6	50.4	52.1	52.2	48.7	50.0	53.4
Mean Fetal Body Weight (g)		3.49	3.68	3.57	3.76	3.58	3.62	3.60	3.48	3.71	3.66
Mean Male Body Weight (g)		3.58	3.78	3.67	3.86	3.68	3.72	3.65	3.58	3.82	3.77
Mean Female Body Weight (g)		3.43	3.58	3.46	3.67	3.48	3.53	3.51	3.40	3.61	3.58

Endpoint	Study No.	31	32	33	34	35	36	37	38	39	40
Total No. of Animals in the Control Group		25	22	25	25	25	25	25	25	25	25
No. of Animals That Died		0	0	0	0	0	0	0	1	0	0
No. of Animals That Aborted		0	0	0	0	0	0	0	0	0	0
No. of Animals That Delivered		0	0	0	0	0	0	0	0	0	0
Percent Pregnant		100.0	100.0	100.0	100.0	92.0	100.0	100.0	92.0	92.0	100.0
No. Gravid		25	22	25	25	23	25	25	23	23	25
No. With Only Resorptions		0	0	0	0	1	0	0	0	1	0
No. of Dams With Live Fetuses		25	22	25	25	22	25	25	22	22	25
No. Nongravid		0	0	0	0	2	0	0	2	2	0
No. of Animals Examined at Laparohysterectomy		25	22	25	25	25	25	25	24	25	25
Mean Gravid Uterine Weight (g)		81.5	87.0	82.1	83.7	77.8	87.5	81.2	83.6	88.2	82.0
Mean No. Viable Fetuses/Dam		14.4	14.9	14.8	15.0	14.5	15.3	15.1	14.7	15.3	15.0
Total No. Viable Fetuses		361	328	369	375	334	382	378	324	352	376
Viable Fetuses (%/Litter)		95.7	97.6	96.2	96.4	92.3	95.9	95.8	95.8	92.6	97.7
Mean No. Postimplantation Loss/Dam		0.7	0.4	0.6	0.6	0.6	0.7	0.7	0.7	0.6	0.3
Total No. of Implantation Sites Lost		17	9	15	14	14	17	17	15	13	8
Postimplantation Loss (%/Litter)		4.3	2.4	3.8	3.6	7.7	4.1	4.2	4.2	7.4	2.3
Early Resorptions (%/Litter)		4.3	2.4	3.8	3.6	7.7	4.1	3.9	4.2	7.4	2.3
Late Resorptions (%/Litter)		0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0
Dead Fetuses (%/Litter)		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Mean No. Implantations/Dam		15.1	15.3	15.4	15.6	15.1	16.0	15.8	15.4	15.9	15.4
Mean No. Corpora Lutea/Dam		18.1	17.2	17.3	17.9	17.2	18.4	17.0	17.3	17.4	17.0
Mean No. Preimplantation Loss/Dam		3.0	1.9	2.0	2.3	2.0	2.4	1.2	1.9	1.6	1.6
Total No. Preimplantation Losses		74	42	49	58	47	60	30	42	36	40
Preimplantation Loss (%/Litter)		15.0	11.2	10.2	11.1	12.5	12.1	6.4	8.9	7.8	9.2
Total No. Male Fetuses		173	173	191	206	154	183	200	165	185	180
Total No. Female Fetuses		188	155	178	169	180	199	178	159	167	196
% Males/Litter		47.7	52.9	51.2	54.8	46.2	47.6	53.1	51.4	52.1	48.7
% Females/Litter		52.3	47.1	48.8	45.2	53.8	52.4	46.9	48.6	47.9	51.3
Mean Fetal Body Weight (g)		3.63	3.80	3.58	3.68	3.47	3.72	3.50	3.73	3.78	3.49
Mean Male Body Weight (g)		3.71	3.88	3.67	3.77	3.55	3.82	3.59	3.81	3.87	3.60
Mean Female Body Weight (g)		3.56	3.71	3.46	3.60	3.39	3.61	3.40	3.65	3.68	3.39

Endpoint	Study No.	41	42	43	44	45	46	47	48	49	50
Total No. of Animals in the Control Group		25	25	24	25	25	25	25	25	25	25
No. of Animals That Died		0	0	0	0	0	0	0	0	0	0
No. of Animals That Aborted		0	0	0	0	0	0	0	0	0	0
No. of Animals That Delivered		0	0	0	0	0	0	0	0	0	0
Percent Pregnant		100.0	100.0	100.0	88.0	100.0	96.0	100.0	92.0	96.0	96.0
No. Gravid		25	25	24	22	25	24	25	23	24	24
No. With Only Resorptions		0	0	0	0	0	0	0	0	0	0
No. of Dams With Live Fetuses		25	25	24	22	25	24	25	23	24	24
No. Nongravid		0	0	0	3	0	1	0	2	1	1
No. of Animals Examined at Laparohysterectomy		25	25	24	25	25	25	25	25	25	25
Mean Gravid Uterine Weight (g)		84.2	85.3	87.4	90.1	81.6	90.2	95.4	80.7	91.3	78.2
Mean No. Viable Fetuses/Dam		15.5	15.6	15.3	15.1	14.8	16.3	16.6	14.7	15.8	14.4
Total No. Viable Fetuses		388	391	367	332	369	392	416	339	380	346
Viable Fetuses (%/Litter)		95.5	95.9	95.5	95.5	95.3	95.0	95.5	94.5	95.1	97.1
Mean No. Postimplantation Loss/Dam		0.7	0.7	0.7	0.7	0.7	0.9	0.8	0.9	0.8	0.4
Total No. of Implantation Sites Lost		18	17	17	15	18	21	20	21	20	10
Postimplantation Loss (%/Litter)		4.5	4.1	4.5	4.5	4.7	5.0	4.5	5.5	4.9	2.9
Early Resorptions (%/Litter)		4.5	4.1	4.5	4.5	4.7	5.0	4.3	5.5	4.9	2.9
Late Resorptions (%/Litter)		0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0
Dead Fetuses (%/Litter)		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Mean No. Implantations/Dam		16.2	16.3	16.0	15.8	15.5	17.2	17.4	15.7	16.7	14.8
Mean No. Corpora Lutea/Dam		17.5	19.4	16.7	16.7	17.9	18.5	18.9	17.0	18.0	16.0
Mean No. Preimplantation Loss/Dam		1.1	3.1	0.7	1.0	2.4	1.3	1.4	1.3	1.3	1.2
Total No. Preimplantation Losses		26	78	17	21	60	32	36	30	32	29
Preimplantation Loss (%/Litter)		5.5	15.5	4.0	5.8	12.0	6.7	7.3	7.4	5.7	7.0
Total No. Male Fetuses		181	194	182	160	182	202	215	166	178	174
Total No. Female Fetuses		207	197	185	172	187	190	201	173	202	172
% Males/Litter		47.2	47.5	49.4	48.9	49.7	51.5	52.0	48.8	47.1	50.7
% Females/Litter		52.8	52.5	50.6	51.1	50.3	48.5	48.0	51.2	52.9	49.3
Mean Fetal Body Weight (g)		3.50	3.57	3.73	3.76	3.56	3.53	3.70	3.58	3.71	3.50
Mean Male Body Weight (g)		3.62	3.62	3.84	3.87	3.66	3.61	3.78	3.66	3.82	3.59
Mean Female Body Weight (g)		3.38	3.48	3.61	3.66	3.47	3.46	3.62	3.50	3.61	3.42

Endpoint	Study No.	51	52	53	54	55	56	57	58	59	60
Total No. of Animals in the Control Group		25	25	25	25	25	25	25	25	25	25
No. of Animals That Died		1	0	0	0	0	0	0	0	0	0
No. of Animals That Aborted		0	0	0	0	0	0	0	0	0	0
No. of Animals That Delivered		0	0	0	0	0	0	0	0	0	0
Percent Pregnant		96.0	76.0	96.0	100.0	88.0	100.0	96.0	100.0	100.0	100.0
No. Gravid		24	19	24	25	22	25	24	25	25	25
No. With Only Resorptions		0	0	0	0	0	0	0	0	1	0
No. of Dams With Live Fetuses		23	19	24	25	22	25	24	25	24	25
No. Nongravid		1	6	1	0	3	0	1	0	0	0
No. of Animals Examined at Laparohysterectomy		24	25	25	25	25	25	25	25	25	25
Mean Gravid Uterine Weight (g)		83.8	78.3	86.2	80.0	88.1	81.2	90.9	90.1	85.5	84.2
Mean No. Viable Fetuses/Dam		14.7	14.4	15.2	14.2	15.7	15.0	15.8	16.3	15.0	15.6
Total No. Viable Fetuses		339	274	364	356	346	374	379	407	374	389
Viable Fetuses (%/Litter)		94.2	96.8	96.4	93.1	97.7	96.7	97.6	95.7	91.4	96.5
Mean No. Postimplantation Loss/Dam		0.9	0.5	0.6	1.1	0.4	0.5	0.4	0.7	0.8	0.6
Total No. of Implantation Sites Lost		20	9	14	27	8	12	9	18	21	14
Postimplantation Loss (%/Litter)		5.8	3.2	3.6	6.9	2.3	3.3	2.4	4.3	8.6	3.5
Early Resorptions (%/Litter)		5.8	3.2	3.3	6.6	1.5	3.3	2.4	4.1	8.6	3.2
Late Resorptions (%/Litter)		0.0	0.0	0.3	0.3	0.8	0.0	0.0	0.2	0.0	0.3
Dead Fetuses (%/Litter)		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Mean No. Implantations/Dam		15.6	14.9	15.8	15.3	16.1	15.4	16.2	17.0	15.8	16.1
Mean No. Corpora Lutea/Dam		16.6	16.0	17.2	17.8	17.3	16.4	17.4	19.4	17.9	17.8
Mean No. Preimplantation Loss/Dam		1.0	1.1	1.5	2.5	1.2	1.0	1.3	2.4	2.1	1.6
Total No. Preimplantation Losses		23	21	35	62	27	25	30	61	52	41
Preimplantation Loss (%/Litter)		6.0	6.5	8.0	12.9	7.4	5.8	6.9	11.1	11.3	8.7
Total No. Male Fetuses		184	135	196	176	160	212	195	187	180	190
Total No. Female Fetuses		155	139	168	180	186	162	184	220	194	199
% Males/Litter		54.9	49.2	54.2	49.6	47.1	56.0	51.5	46.1	48.2	48.5
% Females/Litter		45.1	50.8	45.8	50.4	52.9	44.0	48.5	53.9	51.8	51.5
Mean Fetal Body Weight (g)		3.69	3.50	3.62	3.64	3.66	3.54	3.76	3.61	3.64	3.51
Mean Male Body Weight (g)		3.75	3.61	3.70	3.74	3.77	3.62	3.87	3.70	3.74	3.58
Mean Female Body Weight (g)		3.60	3.40	3.52	3.54	3.55	3.44	3.64	3.53	3.55	3.43

Endpoint	Study No.	61	62	63	64	65	66	67	68	69	70
Total No. of Animals in the Control Group		25	25	25	25	25	25	25	25	25	25
No. of Animals That Died		0	0	0	0	0	0	0	0	0	0
No. of Animals That Aborted		0	0	0	0	0	0	0	0	0	0
No. of Animals That Delivered		0	0	0	0	0	0	0	0	0	0
Percent Pregnant		96.0	96.0	96.0	96.0	96.0	88.0	92.0	100.0	92.0	92.0
No. Gravid		24	24	24	24	24	22	23	25	23	23
No. With Only Resorptions		0	0	0	0	0	0	0	0	0	0
No. of Dams With Live Fetuses		24	24	24	24	24	22	23	25	23	23
No. Nongravid		1	1	1	1	1	3	2	0	2	2
No. of Animals Examined at Laparohysterectomy		25	25	25	25	25	25	25	25	25	25
Mean Gravid Uterine Weight (g)		86.9	84.9	82.7	82.8	84.5	82.6	78.5	85.3	81.7	85.0
Mean No. Viable Fetuses/Dam		15.1	15.4	15.2	15.4	14.6	15.4	13.9	15.4	14.1	15.0
Total No. Viable Fetuses		362	369	364	369	350	338	320	384	324	344
Viable Fetuses (%/Litter)		94.5	96.0	96.8	95.8	92.8	97.0	95.8	95.4	95.5	94.7
Mean No. Postimplantation Loss/Dam		0.8	0.6	0.5	0.7	1.0	0.4	0.6	0.8	0.7	0.8
Total No. of Implantation Sites Lost		20	15	12	17	25	8	13	19	16	19
Postimplantation Loss (%/Litter)		5.5	4.0	3.2	4.2	7.2	3.0	4.2	4.6	4.5	5.3
Early Resorptions (%/Litter)		5.5	3.4	3.2	3.9	7.2	3.0	4.2	4.6	4.3	5.3
Late Resorptions (%/Litter)		0.0	0.5	0.0	0.3	0.0	0.0	0.0	0.0	0.2	0.0
Dead Fetuses (%/Litter)		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Mean No. Implantations/Dam		15.9	16.0	15.7	16.1	15.6	15.7	14.5	16.1	14.8	15.8
Mean No. Corpora Lutea/Dam		17.7	18.5	17.4	17.5	17.1	17.7	17.0	16.7	16.1	16.6
Mean No. Preimplantation Loss/Dam		1.8	2.5	1.7	1.5	1.5	2.0	2.5	0.6	1.3	0.8
Total No. Preimplantation Losses		42	60	41	35	36	44	58	14	31	19
Preimplantation Loss (%/Litter)		9.2	12.3	9.4	7.6	8.8	11.3	14.2	3.2	7.6	4.8
Total No. Male Fetuses		180	195	182	180	168	171	156	193	159	178
Total No. Female Fetuses		182	174	182	189	182	167	164	191	165	166
% Males/Litter		49.4	53.4	49.9	48.9	47.9	50.7	46.7	50.3	49.3	51.8
% Females/Litter		50.6	46.6	50.1	51.1	52.1	49.3	53.3	49.7	50.7	48.2
Mean Fetal Body Weight (g)		3.64	3.51	3.46	3.47	3.81	3.56	3.79	3.55	3.79	3.84
Mean Male Body Weight (g)		3.72	3.58	3.56	3.57	3.96	3.65	3.90	3.62	3.89	3.93
Mean Female Body Weight (g)		3.57	3.43	3.37	3.38	3.68	3.46	3.68	3.47	3.70	3.74

Endpoint	Study No.	71	72	73	74	75	76	77	78	79	80
Total No. of Animals in the Control Group		25	25	25	25	25	25	25	25	25	25
No. of Animals That Died		0	0	0	0	0	0	0	0	0	0
No. of Animals That Aborted		0	0	0	0	0	0	0	0	0	0
No. of Animals That Delivered		0	0	0	0	0	0	0	0	0	0
Percent Pregnant		100.0	100.0	100.0	96.0	88.0	100.0	84.0	96.0	88.0	100.0
No. Gravid		25	25	25	24	22	25	21	24	22	25
No. With Only Resorptions		0	0	0	0	0	0	0	0	0	0
No. of Dams With Live Fetuses		25	25	25	24	22	25	21	24	22	25
No. Nongravid		0	0	0	1	3	0	4	1	3	0
No. of Animals Examined at Laparohysterectomy		25	25	25	25	25	25	25	25	25	25
Mean Gravid Uterine Weight (g)		89.7	81.1	90.4	86.3	85.7	87.4	83.5	89.4	89.2	83.6
Mean No. Viable Fetuses/Dam		16.0	14.6	15.8	15.0	15.4	15.5	14.6	15.7	15.7	14.8
Total No. Viable Fetuses		400	364	396	359	338	387	306	376	346	369
Viable Fetuses (%/Litter)		97.1	94.8	96.5	95.4	97.1	93.1	94.1	96.7	93.7	94.3
Mean No. Postimplantation Loss/Dam		0.5	0.8	0.6	0.8	0.5	1.2	0.7	0.5	1.0	0.8
Total No. of Implantation Sites Lost		12	19	14	18	10	31	15	13	23	21
Postimplantation Loss (%/Litter)		2.9	5.2	3.5	4.6	2.9	6.9	5.9	3.3	6.3	5.7
Early Resorptions (%/Litter)		2.9	4.7	3.5	4.6	2.9	6.9	5.4	3.0	6.3	5.7
Late Resorptions (%/Litter)		0.0	0.5	0.0	0.0	0.0	0.0	0.4	0.3	0.0	0.0
Dead Fetuses (%/Litter)		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Mean No. Implantations/Dam		16.5	15.3	16.4	15.7	15.8	16.7	15.3	16.2	16.8	15.6
Mean No. Corpora Lutea/Dam		17.8	16.2	17.3	17.1	16.7	17.8	16.9	17.4	17.7	16.5
Mean No. Preimplantation Loss/Dam		1.4	0.8	0.9	1.4	0.9	1.1	1.6	1.2	1.0	0.9
Total No. Preimplantation Losses		34	21	23	33	20	28	33	29	21	22
Preimplantation Loss (%/Litter)		7.2	5.2	4.9	8.2	5.4	6.6	8.5	6.0	5.1	4.5
Total No. Male Fetuses		193	195	209	190	153	193	150	173	166	182
Total No. Female Fetuses		207	169	187	169	185	194	156	203	180	187
% Males/Litter		48.2	53.0	52.1	53.0	44.8	50.7	47.1	45.7	48.0	49.1
% Females/Litter		51.8	47.0	47.9	47.0	55.2	49.3	52.9	54.3	52.0	50.9
Mean Fetal Body Weight (g)		3.68	3.67	3.69	3.72	3.64	3.65	3.71	3.66	3.68	3.57
Mean Male Body Weight (g)		3.78	3.75	3.78	3.80	3.75	3.75	3.82	3.75	3.78	3.66
Mean Female Body Weight (g)		3.59	3.56	3.60	3.62	3.56	3.57	3.63	3.58	3.58	3.47

Endpoint	Study No.	81	82	83	84	85	86	87	88	89	90
Total No. of Animals in the Control Group		25	24	25	25	25	20	25	25	25	25
No. of Animals That Died		0	0	0	0	0	0	0	0	0	0
No. of Animals That Aborted		0	0	0	0	0	0	0	0	0	0
No. of Animals That Delivered		0	0	0	0	0	0	0	0	0	0
Percent Pregnant		100.0	100.0	88.0	100.0	100.0	95.0	100.0	100.0	100.0	92.0
No. Gravid		25	24	22	25	25	19	25	25	25	23
No. With Only Resorptions		0	0	0	0	0	0	0	0	0	0
No. of Dams With Live Fetuses		25	24	22	25	25	19	25	25	25	23
No. Nongravid		0	0	3	0	0	1	0	0	0	2
No. of Animals Examined at Laparohysterectomy		25	24	25	25	25	20	25	25	25	25
Mean Gravid Uterine Weight (g)		84.9	88.1	83.6	91.5	85.0	86.4	85.0	88.0	89.1	82.6
Mean No. Viable Fetuses/Dam		15.0	15.7	15.3	16.4	15.4	15.6	15.4	15.7	15.7	15.0
Total No. Viable Fetuses		376	377	336	410	386	297	384	392	392	344
Viable Fetuses (%/Litter)		95.0	93.9	96.1	95.8	94.9	97.3	96.4	95.7	95.4	96.0
Mean No. Postimplantation Loss/Dam		0.8	1.0	0.6	0.7	0.8	0.4	0.6	0.7	0.8	0.6
Total No. of Implantation Sites Lost		20	24	14	18	20	8	14	17	19	14
Postimplantation Loss (%/Litter)		5.0	6.1	3.9	4.2	5.1	2.7	3.6	4.3	4.6	4.0
Early Resorptions (%/Litter)		5.0	6.1	3.9	4.0	4.9	2.7	3.6	4.3	4.6	4.0
Late Resorptions (%/Litter)		0.0	0.0	0.0	0.2	0.2	0.0	0.0	0.0	0.0	0.0
Dead Fetuses (%/Litter)		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Mean No. Implantations/Dam		15.8	16.7	15.9	17.1	16.2	16.1	15.9	16.4	16.4	15.6
Mean No. Corpora Lutea/Dam		16.5	17.8	17.0	17.8	17.6	17.1	17.3	17.2	17.0	16.2
Mean No. Preimplantation Loss/Dam		0.7	1.1	1.1	0.6	1.4	1.1	1.4	0.8	0.6	0.6
Total No. Preimplantation Losses		17	26	24	16	35	20	35	20	15	14
Preimplantation Loss (%/Litter)		3.9	5.5	6.4	3.3	7.6	5.5	7.6	4.2	3.2	3.4
Total No. Male Fetuses		196	185	169	219	192	137	194	189	198	164
Total No. Female Fetuses		180	192	167	191	194	160	190	203	194	180
% Males/Litter		52.2	48.5	49.3	53.5	50.0	46.1	51.2	48.8	51.2	47.9
% Females/Litter		47.8	51.5	50.7	46.5	50.0	53.9	48.8	51.2	48.8	52.1
Mean Fetal Body Weight (g)		3.69	3.60	3.62	3.62	3.53	3.69	3.61	3.64	3.70	3.64
Mean Male Body Weight (g)		3.80	3.72	3.72	3.73	3.63	3.79	3.69	3.74	3.81	3.76
Mean Female Body Weight (g)		3.57	3.50	3.52	3.49	3.43	3.60	3.52	3.55	3.58	3.53

Endpoint	Study No.	91	92	93	94	95	96	97	98	99	100
Total No. of Animals in the Control Group		25	25	25	25	25	25	25	25	25	24
No. of Animals That Died		0	0	0	0	0	0	0	0	0	0
No. of Animals That Aborted		0	0	0	0	0	0	0	0	0	0
No. of Animals That Delivered		0	0	0	0	0	0	0	0	0	0
Percent Pregnant		96.0	100.0	92.0	100.0	100.0	100.0	96.0	92.0	96.0	91.7
No. Gravid		24	25	23	25	25	25	24	23	24	22
No. With Only Resorptions		0	0	0	0	0	0	0	0	0	0
No. of Dams With Live Fetuses		24	25	23	25	25	25	24	23	24	22
No. Nongravid		1	0	2	0	0	0	1	2	1	2
No. of Animals Examined at Laparohysterectomy		25	25	25	25	25	25	25	25	25	24
Mean Gravid Uterine Weight (g)		84.6	83.7	85.9	89.1	86.8	88.9	90.4	84.3	92.8	84.0
Mean No. Viable Fetuses/Dam		15.4	14.7	15.6	15.6	15.4	15.0	15.3	15.0	16.7	15.3
Total No. Viable Fetuses		369	368	358	389	385	376	367	344	401	336
Viable Fetuses (%/Litter)		95.9	96.1	92.4	95.3	94.1	96.2	95.9	91.7	96.0	95.3
Mean No. Postimplantation Loss/Dam		0.7	0.6	1.3	0.8	1.0	0.6	0.6	1.4	0.7	0.8
Total No. of Implantation Sites Lost		16	15	29	19	26	16	15	32	17	18
Postimplantation Loss (%/Litter)		4.1	3.9	7.6	4.7	5.9	3.8	4.1	8.3	4.0	4.7
Early Resorptions (%/Litter)		4.1	3.9	7.6	4.4	5.9	3.3	3.9	8.3	4.0	4.7
Late Resorptions (%/Litter)		0.0	0.0	0.0	0.2	0.0	0.4	0.3	0.0	0.0	0.0
Dead Fetuses (%/Litter)		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Mean No. Implantations/Dam		16.0	15.3	16.8	16.3	16.4	15.7	15.9	16.3	17.4	16.1
Mean No. Corpora Lutea/Dam		16.5	15.8	17.7	16.8	17.0	16.3	16.3	17.3	18.0	17.2
Mean No. Preimplantation Loss/Dam		0.4	0.5	0.9	0.5	0.6	0.6	0.3	0.9	0.7	1.1
Total No. Preimplantation Losses		10	12	21	12	15	15	8	21	15	24
Preimplantation Loss (%/Litter)		2.5	2.9	4.8	2.6	2.7	5.3	1.5	4.8	3.1	6.5
Total No. Male Fetuses		175	187	166	192	202	189	179	168	207	164
Total No. Female Fetuses		194	181	192	197	183	187	188	176	194	172
% Males/Litter		47.6	51.1	46.1	49.4	52.7	52.2	48.8	48.3	51.6	48.6
% Females/Litter		52.4	48.9	53.9	50.6	47.3	47.8	51.2	51.7	48.4	51.4
Mean Fetal Body Weight (g)		3.64	3.71	3.57	3.63	3.70	3.85	3.77	3.59	3.61	3.53
Mean Male Body Weight (g)		3.76	3.82	3.68	3.74	3.79	3.94	3.91	3.69	3.69	3.64
Mean Female Body Weight (g)		3.53	3.60	3.48	3.53	3.60	3.70	3.65	3.50	3.53	3.43

Endpoint	Study No.	101	102	103	104	105	106	107	108	109	110
Total No. of Animals in the Control Group		25	27	25	25	25	25	25	25	25	25
No. of Animals That Died		0	0	0	0	0	0	0	0	0	0
No. of Animals That Aborted		0	0	0	0	0	0	0	0	0	0
No. of Animals That Delivered		0	0	0	0	0	0	0	0	0	0
Percent Pregnant		100.0	100.0	100.0	100.0	100.0	100.0	92.0	100.0	100.0	100.0
No. Gravid		25	27	25	25	25	25	23	25	25	25
No. With Only Resorptions		0	0	0	0	1	0	0	0	0	0
No. of Dams With Live Fetuses		25	27	25	25	24	25	23	25	25	25
No. Nongravid		0	0	0	0	0	0	2	0	0	0
No. of Animals Examined at Laparohysterectomy		25	27	25	25	25	25	25	25	25	25
Mean Gravid Uterine Weight (g)		89.8	84.8	85.9	89.7	86.0	81.8	86.0	83.6	89.2	90.5
Mean No. Viable Fetuses/Dam		15.3	15.0	15.4	15.4	15.1	14.4	14.8	14.6	15.8	16.0
Total No. Viable Fetuses		383	405	384	386	377	361	340	365	394	400
Viable Fetuses (%/Litter)		94.0	92.2	93.9	96.2	91.8	94.2	94.6	92.7	96.6	97.2
Mean No. Postimplantation Loss/Dam		1.0	1.2	1.0	0.6	0.7	0.9	0.8	1.2	0.6	0.5
Total No. of Implantation Sites Lost		24	33	24	16	18	23	19	29	14	12
Postimplantation Loss (%/Litter)		6.0	7.8	6.1	3.8	8.2	5.8	5.4	7.3	3.4	2.8
Early Resorptions (%/Litter)		6.0	7.8	6.1	3.8	8.2	5.8	5.4	7.0	3.4	2.8
Late Resorptions (%/Litter)		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.0
Dead Fetuses (%/Litter)		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Mean No. Implantations/Dam		16.3	16.2	16.3	16.1	15.8	15.4	15.6	15.8	16.3	16.5
Mean No. Corpora Lutea/Dam		16.6	16.7	17.0	16.4	17.3	16.0	17.1	17.3	16.8	17.5
Mean No. Preimplantation Loss/Dam		0.3	0.5	0.7	0.4	1.5	0.6	1.5	1.5	0.5	1.0
Total No. Preimplantation Losses		8	13	17	9	38	15	34	38	12	25
Preimplantation Loss (%/Litter)		1.9	3.0	3.6	2.1	9.9	3.8	8.4	7.5	2.6	5.3
Total No. Male Fetuses		189	202	195	180	188	196	179	202	186	206
Total No. Female Fetuses		194	203	189	206	189	165	161	163	208	194
% Males/Litter		49.5	49.3	51.3	46.6	49.8	54.0	51.7	55.6	47.1	51.6
% Females/Litter		50.5	50.7	48.7	53.4	50.2	46.0	48.3	44.4	52.9	48.4
Mean Fetal Body Weight (g)		3.75	3.66	3.59	3.78	3.58	3.70	3.65	3.73	3.73	3.72
Mean Male Body Weight (g)		3.84	3.74	3.69	3.90	3.68	3.83	3.74	3.84	3.82	3.83
Mean Female Body Weight (g)		3.66	3.58	3.50	3.67	3.48	3.56	3.57	3.61	3.64	3.61

Endpoint	Study No.	111	112	113	114	115	116	119	122	123	124
Total No. of Animals in the Control Group		25	25	25	25	25	25	13	25	25	25
No. of Animals That Died		0	0	0	0	0	0	0	0	0	1
No. of Animals That Aborted		0	0	0	0	0	0	0	0	0	0
No. of Animals That Delivered		0	0	0	0	0	0	0	0	0	0
Percent Pregnant		100.0	96.0	96.0	100.0	100.0	100.0	69.2	100.0	92.0	100.0
No. Gravid		25	24	24	25	25	25	9	25	23	25
No. With Only Resorptions		0	0	0	0	0	0	0	0	0	0
No. of Dams With Live Fetuses		25	24	24	25	25	25	9	25	23	24
No. Nongravid		0	1	1	0	0	0	4	0	2	0
No. of Animals Examined at Laparohysterectomy		25	25	25	25	25	25	13	25	25	24
Mean Gravid Uterine Weight (g)		89.1	87.9	87.3	84.0	82.5	88.4	78.3	88.9	83.3	89.2
Mean No. Viable Fetuses/Dam		15.1	14.8	14.6	15.0	14.8	15.6	14.4	15.6	14.6	15.2
Total No. Viable Fetuses		377	355	351	375	370	389	130	391	336	365
Viable Fetuses (%/Litter)		97.2	96.9	95.1	93.5	96.4	95.7	94.7	92.6	94.7	95.2
Mean No. Postimplantation Loss/Dam		0.4	0.5	0.8	1.0	0.6	0.7	0.9	1.2	0.7	0.8
Total No. of Implantation Sites Lost		11	11	19	26	14	18	8	29	17	18
Postimplantation Loss (%/Litter)		2.8	3.1	4.9	6.5	3.6	4.3	5.3	7.4	5.3	4.8
Early Resorptions (%/Litter)		2.8	3.1	3.7	6.5	3.6	3.9	4.7	6.9	5.3	4.0
Late Resorptions (%/Litter)		0.0	0.0	0.7	0.0	0.0	0.2	0.6	0.5	0.0	0.8
Dead Fetuses (%/Litter)		0.0	0.0	0.5	0.0	0.0	0.2	0.0	0.0	0.0	0.0
Mean No. Implantations/Dam		15.5	15.3	15.4	16.0	15.4	16.3	15.3	16.8	15.3	16.0
Mean No. Corpora Lutea/Dam		16.6	16.5	16.2	17.3	15.8	17.4	16.6	17.6	16.4	17.5
Mean No. Preimplantation Loss/Dam		1.0	1.3	0.8	1.3	0.5	1.2	1.2	0.8	1.0	1.5
Total No. Preimplantation Losses		26	30	18	32	12	29	11	20	24	36
Preimplantation Loss (%/Litter)		6.0	7.7	4.3	6.7	3.0	6.2	8.5	4.1	6.1	7.9
Total No. Male Fetuses		172	175	176	200	187	202	71	179	175	187
Total No. Female Fetuses		205	180	175	175	183	187	59	212	161	178
% Males/Litter		45.6	49.4	50.0	53.2	50.7	52.2	51.3	45.9	52.4	51.5
% Females/Litter		54.4	50.6	50.0	46.8	49.3	47.8	48.7	54.1	47.6	48.5
Mean Fetal Body Weight (g)		3.88	3.93	3.83	3.66	3.63	3.63	3.51	3.71	3.66	3.76
Mean Male Body Weight (g)		4.01	4.01	3.95	3.75	3.72	3.72	3.60	3.82	3.76	3.87
Mean Female Body Weight (g)		3.77	3.85	3.73	3.54	3.53	3.53	3.38	3.61	3.55	3.65

Endpoint	Study No.	125	126	127	128	129	130	131	132	133	134
Total No. of Animals in the Control Group		25	25	25	25	25	25	25	25	25	25
No. of Animals That Died		0	0	0	0	0	0	0	0	0	0
No. of Animals That Aborted		0	0	0	0	0	0	0	0	0	0
No. of Animals That Delivered		0	0	0	0	0	0	0	0	0	0
Percent Pregnant		100.0	92.0	96.0	96.0	100.0	100.0	100.0	100.0	100.0	100.0
No. Gravid		25	23	24	24	25	25	25	25	25	25
No. With Only Resorptions		0	0	1	0	0	0	0	0	0	0
No. of Dams With Live Fetuses		25	23	23	24	25	25	25	25	25	25
No. Nongravid		0	2	1	1	0	0	0	0	0	0
No. of Animals Examined at Laparohysterectomy		25	25	25	25	25	25	25	25	25	25
Mean Gravid Uterine Weight (g)		85.7	91.8	82.2	89.4	82.7	84.7	86.5	89.3	80.1	78.6
Mean No. Viable Fetuses/Dam		15.0	16.7	14.0	16.0	14.9	14.8	15.5	15.4	14.2	13.7
Total No. Viable Fetuses		376	383	336	383	372	371	388	384	356	343
Viable Fetuses (%/Litter)		96.0	95.8	91.7	94.0	92.9	94.1	92.8	96.6	90.1	92.4
Mean No. Postimplantation Loss/Dam		0.6	0.7	0.7	1.0	1.1	0.9	1.2	0.5	1.2	1.2
Total No. of Implantation Sites Lost		16	16	17	25	27	23	30	13	30	30
Postimplantation Loss (%/Litter)		4.0	4.2	8.3	6.0	7.1	5.9	7.2	3.4	9.9	7.6
Early Resorptions (%/Litter)		4.0	3.9	8.3	5.8	7.1	5.4	7.2	3.2	9.9	7.0
Late Resorptions (%/Litter)		0.0	0.3	0.0	0.2	0.0	0.5	0.0	0.2	0.0	0.6
Dead Fetuses (%/Litter)		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Mean No. Implantations/Dam		15.7	17.3	14.7	17.0	16.0	15.8	16.7	15.9	15.4	14.9
Mean No. Corpora Lutea/Dam		16.4	18.4	16.0	18.2	17.2	17.2	17.6	16.7	16.8	16.3
Mean No. Preimplantation Loss/Dam		0.7	1.1	1.3	1.2	1.3	1.4	0.9	0.8	1.4	1.4
Total No. Preimplantation Losses		18	25	30	29	32	35	22	21	35	34
Preimplantation Loss (%/Litter)		4.1	5.2	5.6	6.1	7.3	7.3	4.4	4.9	8.0	9.1
Total No. Male Fetuses		189	178	159	197	201	173	184	187	184	164
Total No. Female Fetuses		187	205	177	186	171	198	204	197	172	179
% Males/Litter		50.0	46.8	47.2	51.7	53.1	47.0	46.9	49.3	53.5	48.2
% Females/Litter		50.0	53.2	52.8	48.3	46.9	53.0	53.1	50.7	46.5	51.8
Mean Fetal Body Weight (g)		3.64	3.57	3.88	3.62	3.55	3.62	3.53	3.78	3.66	3.73
Mean Male Body Weight (g)		3.74	3.66	3.98	3.72	3.63	3.74	3.61	3.89	3.74	3.85
Mean Female Body Weight (g)		3.56	3.47	3.78	3.52	3.47	3.51	3.46	3.69	3.54	3.64

Endpoint	Study No.	135	136	137	138	139	140	141	142	143	144
Total No. of Animals in the Control Group		25	25	25	22	25	25	25	25	25	25
No. of Animals That Died		0	0	0	0	0	1	0	0	0	0
No. of Animals That Aborted		0	0	0	0	0	0	0	0	0	0
No. of Animals That Delivered		0	0	0	0	0	0	0	0	0	0
Percent Pregnant		96.0	96.0	96.0	100.0	100.0	96.0	84.0	100.0	100.0	96.0
No. Gravid		24	24	24	22	25	24	21	25	25	24
No. With Only Resorptions		0	0	0	0	0	0	0	0	0	0
No. of Dams With Live Fetuses		24	24	24	22	25	23	21	25	25	24
No. Nongravid		1	1	1	0	0	1	4	0	0	1
No. of Animals Examined at Laparohysterectomy		25	25	25	22	25	24	25	25	25	25
Mean Gravid Uterine Weight (g)		86.3	85.4	NA	87.7	82.7	82.7	82.6	72.2	86.3	86.5
Mean No. Viable Fetuses/Dam		15.4	15.3	13.7	16.0	14.8	14.5	14.9	12.2	15.5	15.7
Total No. Viable Fetuses		370	366	328	351	369	333	313	305	388	377
Viable Fetuses (%/Litter)		95.3	93.9	92.8	96.4	94.3	96.4	93.9	94.0	93.5	96.5
Mean No. Postimplantation Loss/Dam		0.8	1.0	0.8	0.6	0.9	0.5	1.0	0.8	1.1	0.6
Total No. of Implantation Sites Lost		18	25	18	14	22	11	21	21	27	14
Postimplantation Loss (%/Litter)		4.7	6.1	7.2	3.6	5.7	3.6	6.1	6.0	6.5	3.5
Early Resorptions (%/Litter)		4.7	6.1	6.9	3.6	5.7	3.6	5.5	6.0	6.5	3.5
Late Resorptions (%/Litter)		0.0	0.0	0.0	0.0	0.0	0.0	0.6	0.0	0.0	0.0
Dead Fetuses (%/Litter)		0.0	0.0	0.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Mean No. Implantations/Dam		16.2	16.3	14.4	16.6	15.6	15.0	15.9	13.0	16.6	16.3
Mean No. Corpora Lutea/Dam		17.0	17.4	16.2	17.6	16.4	16.3	17.0	14.5	17.6	17.8
Mean No. Preimplantation Loss/Dam		0.9	1.1	1.8	1.0	0.8	1.3	1.1	1.4	1.0	1.5
Total No. Preimplantation Losses		21	27	42	22	19	30	24	36	26	37
Preimplantation Loss (%/Litter)		5.0	6.1	12.2	4.5	4.4	7.3	6.0	9.7	5.4	7.8
Total No. Male Fetuses		177	181	149	187	192	174	154	151	179	192
Total No. Female Fetuses		193	185	179	164	177	159	159	154	209	185
% Males/Litter		47.2	49.7	43.1	53.3	52.7	53.0	49.8	50.1	45.7	50.6
% Females/Litter		52.8	50.3	56.9	46.7	47.3	47.0	50.2	49.9	54.3	49.4
Mean Fetal Body Weight (g)		3.55	3.60	3.62	3.51	3.61	3.84	3.58	3.83	3.58	3.60
Mean Male Body Weight (g)		3.64	3.69	3.71	3.60	3.69	3.94	3.73	3.93	3.71	3.70
Mean Female Body Weight (g)		3.47	3.50	3.56	3.40	3.53	3.74	3.45	3.72	3.48	3.50

Endpoint	Study No.	145	146	148	149	150	151	152	157	158	159
Total No. of Animals in the Control Group		25	25	25	25	25	25	25	25	25	25
No. of Animals That Died		1	0	0	0	0	0	0	0	0	0
No. of Animals That Aborted		0	0	0	0	0	0	0	0	0	0
No. of Animals That Delivered		0	0	0	0	0	0	0	0	0	0
Percent Pregnant		96.0	96.0	96.0	92.0	100.0	96.0	96.0	96.0	100.0	92.0
No. Gravid		24	24	24	23	25	24	24	24	25	23
No. With Only Resorptions		0	0	0	0	0	0	0	0	0	0
No. of Dams With Live Fetuses		23	24	24	23	25	24	24	24	25	23
No. Nongravid		1	1	1	2	0	1	1	1	0	2
No. of Animals Examined at Laparohysterectomy		24	25	25	25	25	25	25	25	25	25
Mean Gravid Uterine Weight (g)		86.0	86.0	83.7	85.7	81.6	88.2	88.6	89.6	85.0	89.5
Mean No. Viable Fetuses/Dam		15.0	14.5	14.2	15.0	13.8	15.4	15.2	15.3	14.5	16.4
Total No. Viable Fetuses		346	348	341	345	345	370	364	368	363	378
Viable Fetuses (%/Litter)		93.6	93.2	93.9	96.0	93.9	95.3	95.7	97.0	94.4	95.1
Mean No. Postimplantation Loss/Dam		1.0	1.0	0.9	0.7	0.9	0.8	0.7	0.5	0.9	0.8
Total No. of Implantation Sites Lost		24	23	22	15	22	19	17	11	22	19
Postimplantation Loss (%/Litter)		6.4	6.8	6.1	4.0	6.1	4.7	4.3	3.0	5.6	4.9
Early Resorptions (%/Litter)		6.1	6.8	6.1	4.0	6.1	4.7	4.3	3.0	5.4	4.9
Late Resorptions (%/Litter)		0.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.0
Dead Fetuses (%/Litter)		0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Mean No. Implantations/Dam		16.1	15.5	15.1	15.7	14.7	16.2	15.9	15.8	15.4	17.3
Mean No. Corpora Lutea/Dam		17.6	16.7	16.4	17.3	16.3	17.0	17.0	16.8	16.4	18.4
Mean No. Preimplantation Loss/Dam		1.5	1.2	1.3	1.6	1.6	0.8	1.2	1.0	1.0	1.2
Total No. Preimplantation Losses		34	29	31	37	40	19	28	25	25	27
Preimplantation Loss (%/Litter)		8.2	7.3	7.6	8.7	9.5	4.7	6.5	6.4	5.3	5.3
Total No. Male Fetuses		163	177	182	160	195	167	200	191	178	205
Total No. Female Fetuses		183	171	159	185	150	203	164	177	185	173
% Males/Litter		47.3	50.4	54.3	47.1	56.7	45.2	54.8	51.7	49.1	54.2
% Females/Litter		52.7	49.6	45.7	52.9	43.3	54.8	45.2	48.3	50.9	45.8
Mean Fetal Body Weight (g)		3.64	3.86	3.89	3.63	3.89	3.69	3.80	3.91	3.79	3.50
Mean Male Body Weight (g)		3.74	3.97	3.99	3.73	4.00	3.79	3.90	4.03	3.89	3.58
Mean Female Body Weight (g)		3.54	3.76	3.78	3.55	3.76	3.60	3.71	3.77	3.69	3.41

Endpoint	Study No.	160	161
Total No. of Animals in the Control Group		25	25
No. of Animals That Died		0	0
No. of Animals That Aborted		0	0
No. of Animals That Delivered		0	0
Percent Pregnant		96.0	92.0
No. Gravid		24	23
No. With Only Resorptions		0	0
No. of Dams With Live Fetuses		24	23
No. Nongravid		1	2
No. of Animals Examined at Laparohysterectomy		25	25
Mean Gravid Uterine Weight (g)		91.9	86.1
Mean No. Viable Fetuses/Dam		17.1	15.5
Total No. Viable Fetuses		410	356
Viable Fetuses (%/Litter)		97.1	94.0
Mean No. Postimplantation Loss/Dam		0.5	1.0
Total No. of Implantation Sites Lost		12	22
Postimplantation Loss (%/Litter)		2.9	6.0
Early Resorptions (%/Litter)		2.6	6.0
Late Resorptions (%/Litter)		0.2	0.0
Dead Fetuses (%/Litter)		0.0	0.0
Mean No. Implantations/Dam		17.6	16.4
Mean No. Corpora Lutea/Dam		19.2	17.3
Mean No. Preimplantation Loss/Dam		1.6	0.9
Total No. Preimplantation Losses		39	20
Preimplantation Loss (%/Litter)		8.2	4.8
Total No. Male Fetuses		216	181
Total No. Female Fetuses		194	175
% Males/Litter		52.5	51.1
% Females/Litter		47.5	48.9
Mean Fetal Body Weight (g)		3.47	3.59
Mean Male Body Weight (g)		3.55	3.68
Mean Female Body Weight (g)		3.37	3.48

EXAMINATION TYPE Finding	Individual Study Counts and Incidence MALFORMATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL EXTERNAL MALFORMATIONS					
	1	0	0.0	309	22
	2	0	0.0	267	19
	3	0	0.0	315	21
	4	1	0.3	357	25
	5	0	0.0	373	25
	6	1	0.3	346	22
	7	1	0.3	316	22
	8	0	0.0	334	22
	9	0	0.0	322	22
	10	1	0.3	397	24
	11	3	0.8	393	25
	12	1	0.2	377	24
	13	0	0.0	349	24
	14	1	0.2	407	25
	15	2	0.6	380	25
	16	0	0.0	323	21
	17	0	0.0	378	25
	18	2	0.6	388	25
	19	1	0.2	355	23
	20	0	0.0	379	24
	21	0	0.0	342	22
	22	0	0.0	383	25
	23	0	0.0	391	25
	24	1	0.3	328	23
	25	0	0.0	370	25
	26	0	0.0	386	25
	27	3	1.3	378	25

EXAMINATION TYPE Finding	Individual Study Counts and Incidence MALFORMATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL EXTERNAL MALFORMATIONS					
	28	0	0.0	379	24
	29	1	0.3	376	25
	30	1	0.3	386	24
	31	0	0.0	361	25
	32	0	0.0	328	22
	33	1	0.3	369	25
	34	0	0.0	375	25
	35	0	0.0	334	22
	36	0	0.0	382	25
	37	0	0.0	378	25
	38	0	0.0	324	22
	39	0	0.0	352	22
	40	0	0.0	376	25
	41	0	0.0	388	25
	42	1	0.2	391	25
	43	0	0.0	367	24
	44	0	0.0	332	22
	45	0	0.0	369	25
	46	0	0.0	392	24
	47	2	0.5	416	25
	48	0	0.0	339	23
	49	0	0.0	380	24
	50	1	0.3	346	24
	51	0	0.0	339	23
	52	0	0.0	274	19
	53	0	0.0	364	24
	54	0	0.0	356	25

EXAMINATION TYPE Finding	Individual Study Counts and Incidence MALFORMATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL EXTERNAL MALFORMATIONS					
	55	0	0.0	346	22
	56	0	0.0	374	25
	57	0	0.0	379	24
	58	1	0.2	407	25
	59	0	0.0	374	24
	60	0	0.0	389	25
	61	0	0.0	362	24
	62	1	0.3	369	24
	63	0	0.0	364	24
	64	0	0.0	369	24
	65	0	0.0	350	24
	66	1	0.3	338	22
	67	0	0.0	320	23
	68	0	0.0	384	25
	69	0	0.0	324	23
	70	0	0.0	344	23
	71	1	0.3	400	25
	72	0	0.0	364	25
	73	3	1.0	396	25
	74	0	0.0	359	24
	75	0	0.0	338	22
	76	0	0.0	387	25
	77	0	0.0	306	21
	78	0	0.0	376	24
	79	0	0.0	346	22
	80	2	0.5	369	25
	81	0	0.0	376	25

EXAMINATION TYPE Finding	Individual Study Counts and Incidence MALFORMATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL EXTERNAL MALFORMATIONS					
	82	0	0.0	377	24
	83	1	0.3	336	22
	84	0	0.0	410	25
	85	0	0.0	386	25
	86	2	0.6	297	19
	87	1	0.3	384	25
	88	1	0.3	392	25
	89	0	0.0	392	25
	90	0	0.0	344	23
	91	0	0.0	369	24
	92	0	0.0	368	25
	93	0	0.0	358	23
	94	2	0.6	389	25
	95	1	0.2	385	25
	96	0	0.0	376	25
	97	0	0.0	367	24
	98	0	0.0	344	23
	99	0	0.0	401	24
	100	1	0.3	336	22
	101	0	0.0	383	25
	102	1	0.2	405	27
	103	1	0.2	384	25
	104	0	0.0	386	25
	105	1	0.3	377	24
	106	0	0.0	361	25
	107	0	0.0	340	23
	108	0	0.0	365	25

EXAMINATION TYPE Finding	Individual Study Counts and Incidence MALFORMATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL EXTERNAL MALFORMATIONS					
	109	0	0.0	394	25
	110	1	0.2	400	25
	111	1	0.3	377	25
	112	0	0.0	355	24
	113	0	0.0	351	24
	114	1	0.2	375	25
	115	2	0.5	370	25
	116	0	0.0	389	25
	119	0	0.0	130	9
	122	2	0.5	391	25
	123	1	0.4	336	23
	124	0	0.0	365	24
	125	1	0.2	376	25
	126	0	0.0	383	23
	127	0	0.0	336	23
	128	0	0.0	383	24
	129	0	0.0	372	25
	130	0	0.0	371	25
	132	1	0.3	384	25
	133	0	0.0	356	25
	134	1	0.3	343	25
	135	0	0.0	370	24
	137	1	0.3	328	24
	138	0	0.0	351	22
	139	0	0.0	369	25
	140	1	0.3	333	23
	141	0	0.0	313	21

Individual Study Counts and Incidence						
EXAMINATION TYPE	MALFORMATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
TOTAL EXTERNAL MALFORMATIONS						
		142	0	0.0	305	25
		143	0	0.0	388	25
		144	1	0.3	377	24
		145	0	0.0	346	23
		146	0	0.0	348	24
		149	0	0.0	345	23
		150	0	0.0	345	25
		151	0	0.0	370	24
		152	0	0.0	364	24
		157	0	0.0	368	24
		158	1	0.2	363	25
		159	1	0.3	378	23
		160	0	0.0	410	24
		161	1	0.3	356	23
TOTAL VISCERAL MALFORMATIONS						
		1	0	0.0	309	22
		2	0	0.0	267	19
		3	0	0.0	315	21
		4	0	0.0	357	25
		5	0	0.0	373	25
		6	1	0.3	346	22
		7	0	0.0	315	22
		8	0	0.0	334	22
		9	0	0.0	322	22
		10	0	0.0	397	24
		11	0	0.0	393	25
		12	0	0.0	377	24

EXAMINATION TYPE Finding	Individual Study Counts and Incidence MALFORMATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL VISCERAL MALFORMATIONS					
	13	0	0.0	349	24
	14	0	0.0	407	25
	15	0	0.0	380	25
	16	1	0.3	323	21
	17	0	0.0	378	25
	18	3	0.9	388	25
	19	0	0.0	355	23
	20	0	0.0	379	24
	21	0	0.0	342	22
	22	0	0.0	383	25
	23	2	0.7	391	25
	24	0	0.0	328	23
	25	0	0.0	370	25
	26	0	0.0	386	25
	27	0	0.0	378	25
	28	0	0.0	379	24
	29	0	0.0	376	25
	30	1	0.3	386	24
	31	0	0.0	361	25
	32	0	0.0	328	22
	33	0	0.0	369	25
	34	0	0.0	375	25
	35	0	0.0	334	22
	36	1	0.6	189	25
	37	0	0.0	378	25
	38	0	0.0	324	22
	39	0	0.0	352	22

EXAMINATION TYPE Finding	Individual Study Counts and Incidence MALFORMATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL VISCERAL MALFORMATIONS					
	40	0	0.0	376	25
	41	0	0.0	388	25
	42	0	0.0	391	25
	43	0	0.0	367	24
	44	0	0.0	332	22
	45	0	0.0	369	25
	46	0	0.0	392	24
	47	0	0.0	416	25
	48	0	0.0	339	23
	49	0	0.0	380	24
	50	0	0.0	346	24
	51	1	0.3	339	23
	52	0	0.0	274	19
	53	0	0.0	364	24
	54	1	0.3	356	25
	55	0	0.0	346	22
	56	2	0.6	374	25
	57	0	0.0	379	24
	58	0	0.0	407	25
	59	0	0.0	374	24
	60	1	0.3	389	25
	61	0	0.0	362	24
	62	0	0.0	369	24
	63	1	0.2	364	24
	64	1	0.2	369	24
	65	0	0.0	350	24
	66	1	0.3	338	22

EXAMINATION TYPE Finding	Individual Study Counts and Incidence MALFORMATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL VISCERAL MALFORMATIONS					
	67	0	0.0	320	23
	68	0	0.0	384	25
	69	1	0.3	324	23
	70	0	0.0	344	23
	71	0	0.0	400	25
	72	0	0.0	364	25
	73	2	0.8	396	25
	74	0	0.0	359	24
	75	1	0.3	338	22
	76	0	0.0	387	25
	77	1	0.3	306	21
	78	0	0.0	376	24
	79	0	0.0	346	22
	80	1	0.2	369	25
	81	1	0.2	376	25
	82	0	0.0	377	24
	83	0	0.0	336	22
	84	1	0.3	410	25
	85	0	0.0	386	25
	86	0	0.0	297	19
	87	0	0.0	384	25
	88	0	0.0	392	25
	89	0	0.0	392	25
	90	0	0.0	344	23
	91	0	0.0	369	24
	92	0	0.0	368	25
	93	1	0.3	358	23

Individual Study Counts and Incidence					
EXAMINATION TYPE	MALFORMATIONS			Total Fetuses Examined	Total Litters Examined
	Finding	Study Number	Number		
TOTAL VISCERAL MALFORMATIONS					
	94	0	0.0	389	25
	95	0	0.0	385	25
	96	0	0.0	376	25
	97	0	0.0	367	24
	98	0	0.0	344	23
	99	0	0.0	401	24
	100	0	0.0	336	22
	101	2	0.5	383	25
	102	1	0.2	405	27
	103	0	0.0	384	25
	104	0	0.0	386	25
	105	0	0.0	377	24
	106	0	0.0	361	25
	107	0	0.0	340	23
	108	0	0.0	365	25
	109	0	0.0	394	25
	110	0	0.0	400	25
	111	0	0.0	377	25
	112	0	0.0	355	24
	113	0	0.0	351	24
	114	0	0.0	375	25
	115	0	0.0	370	25
	116	0	0.0	389	25
	119	0	0.0	130	9
	122	1	0.2	391	25
	123	0	0.0	336	23
	124	0	0.0	365	24

EXAMINATION TYPE Finding	Individual Study Counts and Incidence MALFORMATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL VISCERAL MALFORMATIONS					
	125	0	0.0	376	25
	126	0	0.0	383	23
	127	0	0.0	336	23
	128	1	0.3	383	24
	129	0	0.0	372	25
	130	0	0.0	371	25
	132	1	0.2	384	25
	133	0	0.0	356	25
	134	0	0.0	343	25
	135	0	0.0	370	24
	137	0	0.0	328	24
	138	0	0.0	351	22
	139	0	0.0	369	25
	140	0	0.0	333	23
	141	0	0.0	313	21
	142	2	0.6	305	25
	143	1	0.4	388	25
	144	0	0.0	377	24
	145	0	0.0	346	23
	146	0	0.0	348	24
	149	1	0.3	345	23
	150	0	0.0	345	25
	151	1	0.2	370	24
	152	0	0.0	364	24
	157	0	0.0	368	24
	158	0	0.0	363	25
	159	2	0.5	378	23

EXAMINATION TYPE Finding	Individual Study Counts and Incidence MALFORMATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL VISCERAL MALFORMATIONS					
	160	1	0.3	410	24
	161	1	0.3	356	23
TOTAL SKELETAL MALFORMATIONS					
	1	0	0.0	309	22
	2	0	0.0	267	19
	3	0	0.0	315	21
	4	1	0.3	357	25
	5	0	0.0	373	25
	6	0	0.0	346	22
	7	0	0.0	316	22
	8	0	0.0	334	22
	9	0	0.0	322	22
	10	1	0.2	397	24
	11	0	0.0	393	25
	12	0	0.0	377	24
	13	0	0.0	349	24
	14	0	0.0	407	25
	15	2	0.5	380	25
	16	0	0.0	323	21
	17	0	0.0	378	25
	18	1	0.3	388	25
	19	0	0.0	355	23
	20	0	0.0	379	24
	21	0	0.0	342	22
	22	0	0.0	383	25
	23	0	0.0	391	25
	24	1	0.3	328	23

EXAMINATION TYPE Finding	Individual Study Counts and Incidence MALFORMATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL SKELETAL MALFORMATIONS					
	25	0	0.0	370	25
	26	0	0.0	386	25
	27	3	1.1	378	25
	28	4	0.9	379	24
	29	0	0.0	376	25
	30	1	0.3	386	24
	31	1	0.3	361	25
	32	0	0.0	328	22
	33	0	0.0	369	25
	34	0	0.0	375	25
	35	0	0.0	334	22
	36	1	1.0	193	25
	37	1	0.2	378	25
	38	0	0.0	324	22
	39	0	0.0	352	22
	40	4	0.9	376	25
	41	0	0.0	388	25
	42	0	0.0	391	25
	43	0	0.0	367	24
	44	0	0.0	332	22
	45	0	0.0	355	25
	46	1	0.3	392	24
	47	0	0.0	416	25
	48	0	0.0	339	23
	49	0	0.0	380	24
	50	0	0.0	346	24
	51	0	0.0	339	23

EXAMINATION TYPE Finding	Individual Study Counts and Incidence MALFORMATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL SKELETAL MALFORMATIONS					
	52	0	0.0	274	19
	53	0	0.0	364	24
	54	1	0.2	355	25
	55	0	0.0	346	22
	56	1	0.4	374	25
	57	0	0.0	379	24
	58	0	0.0	407	25
	59	0	0.0	374	24
	60	0	0.0	389	25
	61	0	0.0	362	24
	62	1	0.3	368	24
	63	1	0.3	363	24
	64	0	0.0	369	24
	65	0	0.0	350	24
	66	1	0.3	338	22
	67	0	0.0	320	23
	68	0	0.0	384	25
	69	0	0.0	323	23
	70	0	0.0	344	23
	71	0	0.0	400	25
	72	1	0.2	364	25
	73	1	0.3	396	25
	74	0	0.0	359	24
	75	1	0.3	338	22
	76	0	0.0	387	25
	77	1	0.2	306	21
	78	0	0.0	376	24

EXAMINATION TYPE Finding	Individual Study Counts and Incidence MALFORMATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL SKELETAL MALFORMATIONS					
	79	2	0.6	346	22
	80	0	0.0	369	25
	81	1	0.3	376	25
	82	0	0.0	377	24
	83	0	0.0	336	22
	84	0	0.0	410	25
	85	0	0.0	386	25
	86	3	0.9	297	19
	87	1	0.2	384	25
	88	0	0.0	392	25
	89	1	0.3	392	25
	90	0	0.0	344	23
	91	0	0.0	369	24
	92	1	0.3	368	25
	93	2	0.5	358	23
	94	1	0.2	389	25
	95	0	0.0	385	25
	96	0	0.0	376	25
	97	0	0.0	367	24
	98	0	0.0	344	23
	99	2	0.5	401	24
	100	0	0.0	336	22
	101	1	0.2	383	25
	102	0	0.0	405	27
	103	0	0.0	384	25
	104	0	0.0	386	25
	105	0	0.0	377	24

EXAMINATION TYPE Finding	Individual Study Counts and Incidence MALFORMATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL SKELETAL MALFORMATIONS					
	106	0	0.0	361	25
	107	3	0.8	340	23
	108	1	0.3	365	25
	109	0	0.0	394	25
	110	0	0.0	400	25
	111	0	0.0	377	25
	112	1	0.3	355	24
	113	0	0.0	351	24
	114	0	0.0	375	25
	115	0	0.0	370	25
	116	0	0.0	389	25
	119	0	0.0	130	9
	122	0	0.0	391	25
	123	0	0.0	336	23
	124	1	0.3	365	24
	125	1	0.3	376	25
	126	0	0.0	383	23
	127	0	0.0	336	23
	128	0	0.0	383	24
	129	0	0.0	372	25
	130	2	0.6	371	25
	132	1	0.2	384	25
	133	1	0.3	356	25
	134	0	0.0	343	25
	135	1	0.3	370	24
	137	1	0.3	328	24
	138	0	0.0	351	22

EXAMINATION TYPE Finding	Individual Study Counts and Incidence MALFORMATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL SKELETAL MALFORMATIONS					
	139	0	0.0	369	25
	140	0	0.0	333	23
	141	0	0.0	313	21
	142	3	1.0	305	25
	143	0	0.0	388	25
	144	0	0.0	377	24
	145	0	0.0	346	23
	146	0	0.0	348	24
	149	0	0.0	345	23
	150	0	0.0	345	25
	151	1	0.2	370	24
	152	0	0.0	364	24
	157	0	0.0	368	24
	158	2	0.5	363	25
	159	2	0.5	378	23
	160	0	0.0	410	24
	161	1	0.3	356	23
TOTAL MALFORMATIONS					
	1	0	0.0		22
	2	0	0.0		19
	3	0	0.0		21
	4	2	0.6		25
	5	0	0.0		25
	6	2	0.6		22
	7	1	0.3		22
	8	0	0.0		22
	9	0	0.0		22

EXAMINATION TYPE Finding	Individual Study Counts and Incidence MALFORMATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL MALFORMATIONS					
	10	2	0.5		24
	11	3	0.8		25
	12	1	0.2		24
	13	0	0.0		24
	14	1	0.2		25
	15	3	0.8		25
	16	1	0.3		21
	17	0	0.0		25
	18	4	1.2		25
	19	1	0.2		23
	20	0	0.0		24
	21	0	0.0		22
	22	0	0.0		25
	23	2	0.7		25
	24	2	0.6		23
	25	0	0.0		25
	26	0	0.0		25
	27	4	1.6		25
	28	4	0.9		24
	29	1	0.3		25
	30	2	0.6		24
	31	1	0.3		25
	32	0	0.0		22
	33	1	0.3		25
	34	0	0.0		25
	35	0	0.0		22
	36	2	1.6		25

EXAMINATION TYPE Finding	Individual Study Counts and Incidence MALFORMATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL MALFORMATIONS					
	37	1	0.2		25
	38	0	0.0		22
	39	0	0.0		22
	40	4	0.9		25
	41	0	0.0		25
	42	1	0.2		25
	43	0	0.0		24
	44	0	0.0		22
	45	0	0.0		25
	46	1	0.3		24
	47	2	0.5		25
	48	0	0.0		23
	49	0	0.0		24
	50	1	0.3		24
	51	1	0.3		23
	52	0	0.0		19
	53	0	0.0		24
	54	2	0.5		25
	55	0	0.0		22
	56	3	1.0		25
	57	0	0.0		24
	58	1	0.2		25
	59	0	0.0		24
	60	1	0.3		25
	61	0	0.0		24
	62	2	0.6		24
	63	2	0.5		24

EXAMINATION TYPE Finding	Individual Study Counts and Incidence MALFORMATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL MALFORMATIONS					
	64	1	0.2		24
	65	0	0.0		24
	66	3	0.9		22
	67	0	0.0		23
	68	0	0.0		25
	69	1	0.3		23
	70	0	0.0		23
	71	1	0.3		25
	72	1	0.2		25
	73	4	1.3		25
	74	0	0.0		24
	75	2	0.6		22
	76	0	0.0		25
	77	2	0.5		21
	78	0	0.0		24
	79	2	0.6		22
	80	3	0.7		25
	81	2	0.5		25
	82	0	0.0		24
	83	1	0.3		22
	84	1	0.3		25
	85	0	0.0		25
	86	4	1.2		19
	87	2	0.5		25
	88	1	0.3		25
	89	1	0.3		25
	90	0	0.0		23

EXAMINATION TYPE Finding	Individual Study Counts and Incidence MALFORMATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL MALFORMATIONS					
	91	0	0.0		24
	92	1	0.3		25
	93	3	0.8		23
	94	3	0.8		25
	95	1	0.2		25
	96	0	0.0		25
	97	0	0.0		24
	98	0	0.0		23
	99	2	0.5		24
	100	1	0.3		22
	101	2	0.5		25
	102	2	0.5		27
	103	1	0.2		25
	104	0	0.0		25
	105	1	0.3		24
	106	0	0.0		25
	107	3	0.8		23
	108	1	0.3		25
	109	0	0.0		25
	110	1	0.2		25
	111	1	0.3		25
	112	1	0.3		24
	113	0	0.0		24
	114	1	0.2		25
	115	2	0.5		25
	116	0	0.0		25
	119	0	0.0		9

EXAMINATION TYPE Finding	Individual Study Counts and Incidence MALFORMATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL MALFORMATIONS					
	122	3	0.7		25
	123	1	0.4		23
	124	1	0.3		24
	125	2	0.5		25
	126	0	0.0		23
	127	0	0.0		23
	128	1	0.3		24
	129	0	0.0		25
	130	2	0.6		25
	132	2	0.5		25
	133	1	0.3		25
	134	1	0.3		25
	135	1	0.3		24
	137	2	0.6		24
	138	0	0.0		22
	139	0	0.0		25
	140	1	0.3		23
	141	0	0.0		21
	142	5	1.6		25
	143	1	0.4		25
	144	1	0.3		24
	145	0	0.0		23
	146	0	0.0		24
	149	1	0.3		23
	150	0	0.0		25
	151	2	0.5		24
	152	0	0.0		24

EXAMINATION TYPE Finding	Individual Study Counts and Incidence MALFORMATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL MALFORMATIONS					
	157	0	0.0		24
	158	2	0.5		25
	159	4	1.0		23
	160	1	0.3		24
	161	3	0.9		23

EXAMINATION TYPE	Individual Study Counts and Incidence			Total Fetuses Examined	Total Litters Examined
	MALFORMATIONS				
Finding	Study Number	Number	% Per Litter		
EXTERNAL					
Aglossia	66	1	0.3	338	22
	103	1	0.2	384	25
Anal Atresia	80	1	0.3	369	25
	83	1	0.3	336	22
	86	1	0.3	297	19
	87	1	0.3	384	25
	115	1	0.3	370	25
Apodia	11	1	0.3	393	25
Astomia	18	1	0.3	388	25
Carpal and/or Tarsal Flexure	73	1	0.3	396	25
	86	1	0.3	297	19
Cleft Face	30	1	0.3	386	24
Cleft Lip	137	1	0.3	328	24
Cleft Palate	15	1	0.3	380	25
	19	1	0.2	355	23
	30	1	0.3	386	24
	73	1	0.3	396	25
Craniorachischisis	140	1	0.3	333	23
Cyclopia					

Individual Study Counts and Incidence						
EXAMINATION TYPE	MALFORMATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
EXTERNAL						
Cyclopia		18	1	0.3	388	25
		105	1	0.3	377	24
Ectromelia		11	1	0.3	393	25
Exencephaly with or without Open Eyelid(s)		80	1	0.2	369	25
		137	1	0.3	328	24
Fetal Anasarca		15	1	0.3	380	25
		27	3	1.3	378	25
		42	1	0.2	391	25
		47	1	0.2	416	25
		73	1	0.5	396	25
Filamentous Tail		11	1	0.3	393	25
		18	1	0.3	388	25
		33	1	0.3	369	25
		58	1	0.2	407	25
		87	1	0.3	384	25
Gastroschisis		11	1	0.3	393	25
Hydrocephaly with or without Dome Head		14	1	0.2	407	25
Mandibular Agnathia		4	1	0.3	357	25
		114	1	0.2	375	25
Mandibular Micrognathia						

Individual Study Counts and Incidence						
EXAMINATION TYPE	MALFORMATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
EXTERNAL						
Mandibular Micrognathia						
		18	1	0.3	388	25
		66	1	0.3	338	22
		94	1	0.3	389	25
		103	1	0.2	384	25
		111	1	0.3	377	25
		144	1	0.3	377	24
Maxillary Agnathia						
		114	1	0.2	375	25
Meningoencephalocele						
		95	1	0.2	385	25
Micromelia						
		159	1	0.2	378	23
Microphthalmia and/or Anophthalmia						
		4	1	0.3	357	25
		11	1	0.3	393	25
		30	1	0.3	386	24
		71	1	0.3	400	25
		73	1	0.5	396	25
		94	1	0.3	389	25
		102	1	0.2	405	27
		110	1	0.2	400	25
		111	1	0.3	377	25
		114	1	0.2	375	25
		115	1	0.3	370	25
		122	1	0.2	391	25
		123	1	0.4	336	23
		125	1	0.2	376	25

Individual Study Counts and Incidence					
MALFORMATIONS				Total Fetuses Examined	Total Litters Examined
EXAMINATION TYPE	Study Number	Number	% Per Litter		
Finding					
EXTERNAL					
Microphthalmia and/or Anophthalmia	132	1	0.3	384	25
	137	1	0.3	328	24
	158	1	0.2	363	25
	159	1	0.3	378	23
Omphalocele	6	1	0.3	346	22
	12	1	0.2	377	24
	15	1	0.3	380	25
	29	1	0.3	376	25
	47	1	0.2	416	25
	161	1	0.3	356	23
Open Eyelid(s)	114	1	0.2	375	25
Proboscis-Like Nose	114	1	0.2	375	25
Tail- Short	11	1	0.3	393	25
	100	1	0.3	336	22
	134	1	0.3	343	25
Umbilical Herniation of the Intestine	30	1	0.3	386	24
	50	1	0.3	346	24
	62	1	0.3	369	24
	122	1	0.3	391	25

Individual Study Counts and Incidence					
EXAMINATION TYPE	MALFORMATIONS			Total Fetuses Examined	Total Litters Examined
	Finding	Study Number	Number		
VISCERAL					
Aorta- Narrowed	18	1	0.3	388	25
Epididymis- Absent	56	1	0.3	374	25
Heart and/or Great Vessel Anomaly	63	1	0.2	364	24
Hydrocephaly	6	1	0.3	346	22
	18	1	0.3	388	25
	73	2	0.8	396	25
	80	1	0.2	369	25
	81	1	0.2	376	25
	102	1	0.2	405	27
	132	1	0.2	384	25
Interrupted Aortic Arch	56	1	0.3	374	25
	159	1	0.2	378	23
Kidney(s)- Absent	143	1	0.4	388	25
Kidney(s) and/or Ureter(s) Absent	18	1	0.3	388	25
	64	1	0.2	369	24
	66	1	0.3	338	22
	132	1	0.2	384	25
Lung(s)- Lobular Agenesis	36	1	0.6	189	25
Lung(s)- Lobular Dysgenesis	93	1	0.3	358	23

Individual Study Counts and Incidence					
MALFORMATIONS				Total Fetuses Examined	Total Litters Examined
EXAMINATION TYPE	Study Number	Number	% Per Litter		
Finding					
VISCERAL					
Lung(s)- Lobular Dysgenesis	122	1	0.2	391	25
	142	1	0.3	305	25
	159	1	0.2	378	23
	161	1	0.3	356	23
Retrosophageal Aortic Arch	16	1	0.3	323	21
	23	1	0.3	391	25
	51	1	0.3	339	23
	101	1	0.2	383	25
	160	1	0.3	410	24
Situs Inversus	23	1	0.4	391	25
	30	1	0.3	386	24
	54	1	0.3	356	25
	60	1	0.3	389	25
	69	1	0.3	324	23
	75	1	0.3	338	22
	77	1	0.3	306	21
	84	1	0.3	410	25
	93	1	0.3	358	23
	128	1	0.3	383	24
	142	1	0.3	305	25
	151	1	0.2	370	24
	161	1	0.3	356	23
Testis- Absent	56	1	0.3	374	25
Thyroid Gland(s)- Absent					

Individual Study Counts and Incidence						
EXAMINATION TYPE	MALFORMATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
VISCERAL						
Thyroid Gland(s)- Absent		101	1	0.2	383	25
		149	1	0.3	345	23
Transposition of the Great Vessels		142	1	0.3	305	25
		161	1	0.3	356	23
Vessel(s)- Malpositioned		161	1	0.3	356	23

Individual Study Counts and Incidence						
EXAMINATION TYPE	MALFORMATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
SKELETAL						
Bent Limb Bone(s)		10	1	0.2	397	24
		15	1	0.3	380	25
		142	3	1.0	305	25
		158	1	0.3	363	25
Costal Cartilage Anomaly		46	1	0.3	392	24
		81	1	0.3	376	25
		89	1	0.3	392	25
		92	1	0.3	368	25
		107	1	0.2	340	23
Rib Anomaly		4	1	0.3	357	25
		56	1	0.4	374	25
		63	1	0.3	363	24
		79	1	0.3	346	22
		86	1	0.3	297	19
		93	1	0.2	358	23
		101	1	0.2	383	25
		108	1	0.3	365	25
		130	1	0.3	371	25
		132	1	0.2	384	25
		161	1	0.3	356	23
Rib(s)- Only 11 Pairs Present		40	1	0.2	376	25
Rib(s)- Only 12 Pairs Present		27	1	0.4	378	25
		87	1	0.2	384	25

Individual Study Counts and Incidence						
EXAMINATION TYPE	MALFORMATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
SKELETAL						
Rib(s)- Only 12 Pairs Present		137	1	0.3	328	24
		159	2	0.5	378	23
	Skull Anomaly	27	1	0.4	378	25
Sternebra(e)- Fused		36	1	1.0	193	25
		77	1	0.2	306	21
	Sternebra(e)- Malaligned (Severe)	27	1	0.4	378	25
		31	1	0.3	361	25
		75	1	0.3	338	22
		89	1	0.3	392	25
		135	1	0.3	370	24
	Sternoschisis	24	1	0.3	328	23
		28	1	0.2	379	24
		54	1	0.2	355	25
		62	1	0.3	368	24
		93	1	0.2	358	23
		99	1	0.3	401	24
		101	1	0.2	383	25
		107	2	0.6	340	23
		130	1	0.3	371	25
	Vertebral Agenesis	7	1	0.3	316	22
	10	1	0.3	397	24	
	24	1	0.3	328	23	

Individual Study Counts and Incidence						
EXAMINATION TYPE	MALFORMATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
SKELETAL						
Vertebral Agenesis		37	1	0.2	378	25
		80	1	0.3	369	25
		83	1	0.3	336	22
		86	1	0.3	297	19
		88	1	0.3	392	25
		94	1	0.3	389	25
		115	1	0.3	370	25
Vertebral Anomaly with or without Associated Rib Anomaly		15	1	0.2	380	25
		18	1	0.3	388	25
		27	1	0.2	378	25
		28	3	0.7	379	24
		30	1	0.3	386	24
		40	2	0.5	376	25
		66	1	0.3	338	22
		72	1	0.2	364	25
		73	1	0.3	396	25
		79	1	0.3	346	22
		86	2	0.6	297	19
		99	1	0.2	401	24
		112	1	0.3	355	24
		124	1	0.3	365	24
		151	1	0.2	370	24
		158	1	0.2	363	25
	Vertebral Centra Anomaly		40	1	0.2	376
		94	1	0.2	389	25

EXAMINATION TYPE	Individual Study Counts and Incidence			Total Fetuses Examined	Total Litters Examined
	MALFORMATIONS				
	Study Number	Number	% Per Litter		
Finding					
SKELETAL					
Vertebral Centra Anomaly					
	125	1	0.3	376	25
	133	1	0.3	356	25
	159	2	0.5	378	23

EXAMINATION TYPE Finding	Individual Study Counts and Incidence VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL EXTERNAL VARIATIONS					
	1	0	0.0	309	22
	2	0	0.0	267	19
	3	0	0.0	315	21
	4	0	0.0	357	25
	5	0	0.0	373	25
	6	0	0.0	346	22
	7	0	0.0	316	22
	8	0	0.0	334	22
	9	0	0.0	322	22
	10	0	0.0	397	24
	11	0	0.0	393	25
	12	0	0.0	377	24
	13	0	0.0	349	24
	14	0	0.0	407	25
	15	0	0.0	380	25
	16	0	0.0	323	21
	17	0	0.0	378	25
	18	0	0.0	388	25
	19	0	0.0	355	23
	20	0	0.0	379	24
	21	0	0.0	342	22
	22	0	0.0	383	25
	23	0	0.0	391	25
	24	0	0.0	328	23
	25	0	0.0	370	25
	26	0	0.0	386	25
	27	0	0.0	378	25

EXAMINATION TYPE Finding	Individual Study Counts and Incidence VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL EXTERNAL VARIATIONS					
	28	0	0.0	379	24
	29	0	0.0	376	25
	30	0	0.0	386	24
	31	0	0.0	361	25
	32	0	0.0	328	22
	33	0	0.0	369	25
	34	0	0.0	375	25
	35	0	0.0	334	22
	36	0	0.0	382	25
	37	0	0.0	378	25
	38	0	0.0	324	22
	39	0	0.0	352	22
	40	0	0.0	376	25
	41	0	0.0	388	25
	42	0	0.0	391	25
	43	0	0.0	367	24
	44	0	0.0	332	22
	45	0	0.0	369	25
	46	0	0.0	392	24
	47	0	0.0	416	25
	48	0	0.0	339	23
	49	0	0.0	380	24
	50	0	0.0	346	24
	51	0	0.0	339	23
	52	0	0.0	274	19
	53	0	0.0	364	24
	54	0	0.0	356	25

EXAMINATION TYPE Finding	Individual Study Counts and Incidence VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL EXTERNAL VARIATIONS					
	55	0	0.0	346	22
	56	0	0.0	374	25
	57	0	0.0	379	24
	58	0	0.0	407	25
	59	0	0.0	374	24
	60	0	0.0	389	25
	61	0	0.0	362	24
	62	0	0.0	369	24
	63	0	0.0	364	24
	64	0	0.0	369	24
	65	0	0.0	350	24
	66	0	0.0	338	22
	67	0	0.0	320	23
	68	0	0.0	384	25
	69	0	0.0	324	23
	70	0	0.0	344	23
	71	0	0.0	400	25
	72	0	0.0	364	25
	73	0	0.0	396	25
	74	0	0.0	359	24
	75	0	0.0	338	22
	76	0	0.0	387	25
	77	0	0.0	306	21
	78	0	0.0	376	24
	79	0	0.0	346	22
	80	0	0.0	369	25
	81	0	0.0	376	25

EXAMINATION TYPE Finding	Individual Study Counts and Incidence VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL EXTERNAL VARIATIONS					
	82	0	0.0	377	24
	83	0	0.0	336	22
	84	0	0.0	410	25
	85	0	0.0	386	25
	86	0	0.0	297	19
	87	0	0.0	384	25
	88	0	0.0	392	25
	89	0	0.0	392	25
	90	0	0.0	344	23
	91	0	0.0	369	24
	92	0	0.0	368	25
	93	0	0.0	358	23
	94	0	0.0	389	25
	95	0	0.0	385	25
	96	1	0.3	376	25
	97	0	0.0	367	24
	98	0	0.0	344	23
	99	0	0.0	401	24
	100	0	0.0	336	22
	101	0	0.0	383	25
	102	0	0.0	405	27
	103	0	0.0	384	25
	104	0	0.0	386	25
	105	0	0.0	377	24
	106	0	0.0	361	25
	107	0	0.0	340	23
	108	0	0.0	365	25

Individual Study Counts and Incidence					
EXAMINATION TYPE Finding	VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL EXTERNAL VARIATIONS					
	109	0	0.0	394	25
	110	0	0.0	400	25
	111	0	0.0	377	25
	112	0	0.0	355	24
	113	0	0.0	351	24
	114	0	0.0	375	25
	115	0	0.0	370	25
	116	0	0.0	389	25
	119	0	0.0	130	9
	122	0	0.0	391	25
	123	0	0.0	336	23
	124	0	0.0	365	24
	125	0	0.0	376	25
	126	0	0.0	383	23
	127	0	0.0	336	23
	128	0	0.0	383	24
	129	0	0.0	372	25
	130	0	0.0	371	25
	132	0	0.0	384	25
	133	0	0.0	356	25
	134	0	0.0	343	25
	135	0	0.0	370	24
	137	0	0.0	328	24
	138	0	0.0	351	22
	139	0	0.0	369	25
	140	0	0.0	333	23
	141	0	0.0	313	21

EXAMINATION TYPE Finding	Individual Study Counts and Incidence VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL EXTERNAL VARIATIONS	142	0	0.0	305	25
	143	0	0.0	388	25
	144	0	0.0	377	24
	145	0	0.0	346	23
	146	0	0.0	348	24
	149	0	0.0	345	23
	150	0	0.0	345	25
	151	0	0.0	370	24
	152	0	0.0	364	24
	157	0	0.0	368	24
	158	0	0.0	363	25
	159	0	0.0	378	23
	160	0	0.0	410	24
	161	0	0.0	356	23
TOTAL VISCERAL VARIATIONS	1	1	0.4	309	22
	2	0	0.0	267	19
	3	0	0.0	315	21
	4	1	0.2	357	25
	5	0	0.0	373	25
	6	0	0.0	346	22
	7	0	0.0	315	22
	8	0	0.0	334	22
	9	0	0.0	322	22
	10	0	0.0	397	24
	11	0	0.0	393	25
	12	1	0.2	377	24

EXAMINATION TYPE Finding	Individual Study Counts and Incidence VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL VISCERAL VARIATIONS					
	13	0	0.0	349	24
	14	0	0.0	407	25
	15	0	0.0	380	25
	16	0	0.0	323	21
	17	1	0.2	378	25
	18	0	0.0	388	25
	19	0	0.0	355	23
	20	0	0.0	379	24
	21	1	0.2	342	22
	22	0	0.0	383	25
	23	0	0.0	391	25
	24	1	0.3	328	23
	25	3	0.8	370	25
	26	0	0.0	386	25
	27	0	0.0	378	25
	28	0	0.0	379	24
	29	1	0.3	376	25
	30	1	0.3	386	24
	31	0	0.0	361	25
	32	0	0.0	328	22
	33	1	0.3	369	25
	34	0	0.0	375	25
	35	1	0.3	334	22
	36	0	0.0	189	25
	37	0	0.0	378	25
	38	0	0.0	324	22
	39	1	0.2	352	22

EXAMINATION TYPE Finding	Individual Study Counts and Incidence VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL VISCERAL VARIATIONS					
	40	0	0.0	376	25
	41	1	0.3	388	25
	42	0	0.0	391	25
	43	1	0.3	367	24
	44	0	0.0	332	22
	45	0	0.0	369	25
	46	1	0.2	392	24
	47	0	0.0	416	25
	48	1	0.3	339	23
	49	0	0.0	380	24
	50	1	0.3	346	24
	51	1	0.2	339	23
	52	1	0.4	274	19
	53	0	0.0	364	24
	54	0	0.0	356	25
	55	2	0.6	346	22
	56	1	0.2	374	25
	57	0	0.0	379	24
	58	0	0.0	407	25
	59	1	0.3	374	24
	60	0	0.0	389	25
	61	0	0.0	362	24
	62	0	0.0	369	24
	63	2	0.8	364	24
	64	1	0.3	369	24
	65	2	0.5	350	24
	66	0	0.0	338	22

Individual Study Counts and Incidence						
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
TOTAL VISCERAL VARIATIONS						
		67	0	0.0	320	23
		68	0	0.0	384	25
		69	0	0.0	324	23
		70	0	0.0	344	23
		71	1	0.2	400	25
		72	1	0.3	364	25
		73	1	0.5	396	25
		74	0	0.0	359	24
		75	1	0.3	338	22
		76	1	0.2	387	25
		77	0	0.0	306	21
		78	4	1.2	376	24
		79	0	0.0	346	22
		80	5	1.2	369	25
		81	0	0.0	376	25
		82	3	0.8	377	24
		83	0	0.0	336	22
		84	0	0.0	410	25
		85	1	0.2	386	25
		86	1	0.3	297	19
		87	4	1.0	384	25
		88	0	0.0	392	25
		89	1	0.3	392	25
		90	5	1.4	344	23
		91	4	1.0	369	24
		92	3	0.7	368	25
		93	3	0.8	358	23

EXAMINATION TYPE Finding	Individual Study Counts and Incidence VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL VISCERAL VARIATIONS					
	94	0	0.0	389	25
	95	2	0.5	385	25
	96	0	0.0	376	25
	97	2	0.5	367	24
	98	0	0.0	344	23
	99	0	0.0	401	24
	100	1	0.3	336	22
	101	0	0.0	383	25
	102	1	0.4	405	27
	103	2	0.8	384	25
	104	11	2.7	386	25
	105	4	1.0	377	24
	106	4	1.1	361	25
	107	0	0.0	340	23
	108	0	0.0	365	25
	109	5	1.2	394	25
	110	3	0.7	400	25
	111	1	0.3	377	25
	112	0	0.0	355	24
	113	0	0.0	351	24
	114	6	1.6	375	25
	115	1	0.2	370	25
	116	5	1.3	389	25
	119	0	0.0	130	9
	122	0	0.0	391	25
	123	3	0.8	336	23
	124	2	0.5	365	24

EXAMINATION TYPE Finding	Individual Study Counts and Incidence VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL VISCERAL VARIATIONS					
	125	1	0.3	376	25
	126	0	0.0	383	23
	127	2	0.6	336	23
	128	2	0.5	383	24
	129	2	0.5	372	25
	130	8	2.6	371	25
	132	2	0.5	384	25
	133	1	4.0	356	25
	134	3	0.9	343	25
	135	8	2.1	370	24
	137	2	0.5	328	24
	138	1	0.2	351	22
	139	0	0.0	369	25
	140	2	0.6	333	23
	141	2	0.6	313	21
	142	2	0.8	305	25
	143	1	0.3	388	25
	144	15	3.9	377	24
	145	3	0.8	346	23
	146	2	0.6	348	24
	149	8	3.5	345	23
	150	6	1.8	345	25
	151	2	0.5	370	24
	152	3	0.8	364	24
	157	5	1.2	368	24
	158	5	1.6	363	25
	159	2	0.6	378	23

EXAMINATION TYPE Finding	Individual Study Counts and Incidence VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL VISCERAL VARIATIONS					
	160	2	0.7	410	24
	161	1	0.3	356	23
TOTAL SKELETAL VARIATIONS					
	1	117	37.6	309	22
	2	85	31.1	267	19
	3	97	31.5	315	21
	4	88	24.6	357	25
	5	139	37.1	373	25
	6	119	34.1	346	22
	7	135	43.5	316	22
	8	119	36.1	334	22
	9	105	31.6	322	22
	10	116	29.1	397	24
	11	163	41.8	393	25
	12	136	35.3	377	24
	13	69	21.3	349	24
	14	75	18.0	407	25
	15	103	27.6	380	25
	16	105	32.5	323	21
	17	169	44.1	378	25
	18	120	29.5	388	25
	19	115	32.1	355	23
	20	127	33.8	379	24
	21	122	34.4	342	22
	22	106	27.9	383	25
	23	135	33.6	391	25
	24	107	33.4	328	23

EXAMINATION TYPE Finding	Individual Study Counts and Incidence VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL SKELETAL VARIATIONS					
	25	132	37.1	370	25
	26	72	19.7	386	25
	27	106	31.1	378	25
	28	102	26.7	379	24
	29	143	38.8	376	25
	30	113	28.8	386	24
	31	98	26.3	361	25
	32	123	37.2	328	22
	33	84	22.7	369	25
	34	117	31.1	375	25
	35	123	36.5	334	22
	36	63	33.4	193	25
	37	129	35.0	378	25
	38	63	19.6	324	22
	39	161	45.7	352	22
	40	132	34.1	376	25
	41	117	30.1	388	25
	42	123	32.5	391	25
	43	121	33.0	367	24
	44	123	36.6	332	22
	45	79	21.3	355	25
	46	140	35.3	392	24
	47	106	25.6	416	25
	48	103	29.9	339	23
	49	80	21.2	380	24
	50	130	38.2	346	24
	51	78	23.1	339	23

EXAMINATION TYPE Finding	Individual Study Counts and Incidence VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL SKELETAL VARIATIONS					
	52	92	34.1	274	19
	53	127	35.7	364	24
	54	136	39.3	355	25
	55	111	31.3	346	22
	56	188	50.3	374	25
	57	176	47.3	379	24
	58	131	32.0	407	25
	59	161	43.3	374	24
	60	100	26.3	389	25
	61	155	42.3	362	24
	62	120	33.1	368	24
	63	143	40.9	363	24
	64	140	37.0	369	24
	65	137	40.3	350	24
	66	108	33.5	338	22
	67	98	29.6	320	23
	68	108	27.9	384	25
	69	94	29.8	323	23
	70	123	35.4	344	23
	71	132	33.0	400	25
	72	126	35.0	364	25
	73	128	32.8	396	25
	74	137	39.2	359	24
	75	117	34.5	338	22
	76	149	37.6	387	25
	77	107	33.7	306	21
	78	109	29.0	376	24

EXAMINATION TYPE Finding	Individual Study Counts and Incidence VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL SKELETAL VARIATIONS					
	79	154	44.8	346	22
	80	102	27.9	369	25
	81	117	31.8	376	25
	82	144	38.0	377	24
	83	63	19.7	336	22
	84	138	34.1	410	25
	85	170	44.3	386	25
	86	91	30.4	297	19
	87	199	50.4	384	25
	88	103	25.9	392	25
	89	120	30.6	392	25
	90	166	49.4	344	23
	91	120	32.3	369	24
	92	120	32.8	368	25
	93	115	32.4	358	23
	94	125	31.8	389	25
	95	117	31.9	385	25
	96	138	39.5	376	25
	97	147	41.5	367	24
	98	85	24.5	344	23
	99	116	29.5	401	24
	100	92	28.0	336	22
	101	188	49.7	383	25
	102	199	49.0	405	27
	103	141	36.6	384	25
	104	154	40.2	386	25
	105	113	30.4	377	24

EXAMINATION TYPE Finding	Individual Study Counts and Incidence VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL SKELETAL VARIATIONS					
	106	126	34.7	361	25
	107	90	26.4	340	23
	108	136	37.8	365	25
	109	89	22.5	394	25
	110	143	35.7	400	25
	111	120	31.8	377	25
	112	167	46.9	355	24
	113	135	38.8	351	24
	114	128	34.1	375	25
	115	108	28.9	370	25
	116	97	24.5	389	25
	119	31	26.0	130	9
	122	147	38.2	391	25
	123	125	37.1	336	23
	124	112	31.3	365	24
	125	86	22.7	376	25
	126	182	46.0	383	23
	127	125	37.3	336	23
	128	126	32.8	383	24
	129	132	35.0	372	25
	130	127	34.0	371	25
	132	92	24.6	384	25
	133	122	33.5	356	25
	134	136	40.9	343	25
	135	79	21.1	370	24
	137	96	33.1	328	24
	138	137	38.9	351	22

EXAMINATION TYPE Finding	Individual Study Counts and Incidence VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL SKELETAL VARIATIONS					
	139	129	35.8	369	25
	140	121	37.0	333	23
	141	110	35.2	313	21
	142	138	45.4	305	25
	143	87	22.9	388	25
	144	144	39.0	377	24
	145	132	37.8	346	23
	146	114	32.8	348	24
	149	107	29.7	345	23
	150	120	34.6	345	25
	151	121	32.9	370	24
	152	107	29.1	364	24
	157	110	30.8	368	24
	158	115	31.2	363	25
	159	138	36.5	378	23
	160	117	28.2	410	24
	161	111	31.4	356	23
TOTAL VARIATIONS					
	1	118	38.0		22
	2	85	31.1		19
	3	97	31.5		21
	4	89	24.9		25
	5	139	37.1		25
	6	119	34.1		22
	7	135	43.5		22
	8	119	36.1		22
	9	105	31.6		22

EXAMINATION TYPE Finding	Individual Study Counts and Incidence VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL VARIATIONS					
	10	116	29.1		24
	11	163	41.8		25
	12	136	35.3		24
	13	69	21.3		24
	14	75	18.0		25
	15	103	27.6		25
	16	105	32.5		21
	17	170	44.3		25
	18	120	29.5		25
	19	115	32.1		23
	20	127	33.8		24
	21	123	34.6		22
	22	106	27.9		25
	23	135	33.6		25
	24	108	33.7		23
	25	135	37.9		25
	26	72	19.7		25
	27	106	31.1		25
	28	102	26.7		24
	29	143	38.8		25
	30	113	28.8		24
	31	98	26.3		25
	32	123	37.2		22
	33	84	22.7		25
	34	117	31.1		25
	35	124	36.8		22
	36	63	33.4		25

EXAMINATION TYPE Finding	Individual Study Counts and Incidence VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL VARIATIONS					
	37	129	35.0		25
	38	63	19.6		22
	39	162	45.9		22
	40	132	34.1		25
	41	117	30.1		25
	42	123	32.5		25
	43	121	33.0		24
	44	123	36.6		22
	45	79	20.4		25
	46	141	35.6		24
	47	106	25.6		25
	48	104	30.2		23
	49	80	21.2		24
	50	131	38.5		24
	51	78	23.1		23
	52	93	34.4		19
	53	127	35.7		24
	54	136	39.2		25
	55	112	31.6		22
	56	188	50.3		25
	57	176	47.3		24
	58	131	32.0		25
	59	161	43.3		24
	60	100	26.3		25
	61	155	42.3		24
	62	120	33.0		24
	63	144	41.2		24

EXAMINATION TYPE Finding	Individual Study Counts and Incidence VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL VARIATIONS					
	64	141	37.3		24
	65	138	40.6		24
	66	108	33.5		22
	67	98	29.6		23
	68	108	27.9		25
	69	94	29.8		23
	70	123	35.4		23
	71	133	33.2		25
	72	127	35.2		25
	73	128	32.8		25
	74	137	39.2		24
	75	118	34.8		22
	76	149	37.6		25
	77	107	33.7		21
	78	113	30.2		24
	79	154	44.8		22
	80	107	29.1		25
	81	117	31.8		25
	82	145	38.3		24
	83	63	19.7		22
	84	138	34.2		25
	85	171	44.6		25
	86	91	30.4		19
	87	202	51.1		25
	88	103	25.9		25
	89	121	30.8		25
	90	170	50.6		23

EXAMINATION TYPE Finding	Individual Study Counts and Incidence VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL VARIATIONS					
	91	122	32.8		24
	92	121	33.1		25
	93	117	32.9		23
	94	125	31.8		25
	95	119	32.4		25
	96	138	39.5		25
	97	147	41.5		24
	98	85	24.5		23
	99	116	29.5		24
	100	93	28.3		22
	101	188	49.7		25
	102	199	49.0		27
	103	141	36.6		25
	104	163	42.5		25
	105	115	30.9		24
	106	128	35.1		25
	107	90	26.4		23
	108	136	37.8		25
	109	93	23.6		25
	110	145	36.2		25
	111	121	32.1		25
	112	167	46.9		24
	113	135	38.8		24
	114	132	35.2		25
	115	109	29.1		25
	116	101	25.6		25
	119	31	26.0		9

EXAMINATION TYPE Finding	Individual Study Counts and Incidence VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL VARIATIONS					
	122	147	38.2		25
	123	128	37.9		23
	124	114	31.8		24
	125	87	23.0		25
	126	182	46.0		23
	127	127	37.9		23
	128	128	33.3		24
	129	134	35.5		25
	130	134	36.3		25
	132	94	25.1		25
	133	123	37.5		25
	134	138	41.5		25
	135	87	23.2		24
	137	98	33.6		24
	138	138	39.1		22
	139	129	35.8		25
	140	121	37.0		23
	141	111	35.5		21
	142	139	45.7		25
	143	88	23.2		25
	144	151	40.8		24
	145	132	37.8		23
	146	116	33.4		24
	149	113	32.6		23
	150	126	36.4		25
	151	121	32.9		24
	152	109	29.7		24

EXAMINATION TYPE Finding	Individual Study Counts and Incidence VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Study Number	Number	% Per Litter		
TOTAL VARIATIONS					
	157	114	31.8		24
	158	119	32.6		25
	159	139	36.7		23
	160	119	28.9		24
	161	111	31.4		23

EXAMINATION TYPE	Individual Study Counts and Incidence			Total Fetuses Examined	Total Litters Examined
	VARIATIONS				
	Finding	Study Number	Number		
EXTERNAL					
Twining					
	96	1	0.3	376	25

Individual Study Counts and Incidence					
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Finding	Study Number	Number		
VISCERAL					
Adrenal Gland(s)- Enlarged	90	5	1.4	344	23
Adrenal Gland(s)- Pale	129	1	0.2	372	25
Diaphragm- Thin	125	1	0.3	376	25
Hemorrhagic Iris	30	1	0.3	386	24
	89	1	0.3	392	25
Hemorrhagic Ring Around the Iris	35	1	0.3	334	22
	46	1	0.2	392	24
	55	1	0.3	346	22
	65	1	0.2	350	24
	72	1	0.3	364	25
	82	1	0.3	377	24
	106	1	0.2	361	25
	129	1	0.3	372	25
	134	1	0.3	343	25
	149	1	0.3	345	23
	152	1	0.3	364	24
Kidney(s)- Small	55	1	0.3	346	22
	106	1	0.2	361	25
Liver- Accessory Lobule(s)	110	2	0.5	400	25
	114	3	0.8	375	25
	142	1	0.5	305	25

Individual Study Counts and Incidence						
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
VISCERAL						
Liver- Accessory Lobule(s)		145	1	0.3	346	23
Liver- Pale		109	1	0.3	394	25
		152	1	0.3	364	24
Liver- Swollen		109	1	0.3	394	25
Major Blood Vessel Variation		4	1	0.2	357	25
		12	1	0.2	377	24
		17	1	0.2	378	25
		21	1	0.2	342	22
		24	1	0.3	328	23
		29	1	0.3	376	25
		33	1	0.3	369	25
		41	1	0.3	388	25
		43	1	0.3	367	24
		48	1	0.3	339	23
		50	1	0.3	346	24
		51	1	0.2	339	23
		52	1	0.4	274	19
		56	1	0.2	374	25
		59	1	0.3	374	24
		63	2	0.8	364	24
		64	1	0.3	369	24
		65	1	0.3	350	24
		76	1	0.2	387	25
		85	1	0.2	386	25

Individual Study Counts and Incidence					
		VARIATIONS			
EXAMINATION TYPE				Total Fetuses	Total Litters
Finding	Study Number	Number	% Per Litter	Examined	Examined
VISCERAL					
Major Blood Vessel Variation					
	87	1	0.2	384	25
	102	1	0.4	405	27
	103	1	0.6	384	25
	106	1	0.3	361	25
	109	2	0.4	394	25
	114	3	0.8	375	25
	116	1	0.2	389	25
	124	1	0.3	365	24
	127	1	0.3	336	23
	134	1	0.3	343	25
	135	2	0.6	370	24
	137	1	0.3	328	24
	142	1	0.3	305	25
	143	1	0.3	388	25
	145	1	0.3	346	23
	149	1	0.3	345	23
	151	1	0.2	370	24
Renal Papilla(e) not Developed and/or Distended Ureter(s)					
	1	1	0.4	309	22
	25	3	0.8	370	25
	39	1	0.2	352	22
	75	1	0.3	338	22
	78	4	1.2	376	24
	80	1	0.2	369	25
	82	1	0.2	377	24
	86	1	0.3	297	19
	87	3	0.8	384	25

Individual Study Counts and Incidence					
EXAMINATION TYPE		VARIATIONS		Total Fetuses Examined	Total Litters Examined
Finding	Study Number	Number	% Per Litter		
VISCERAL					
Renal Papilla(e) not Developed and/or Distended Ureter(s)					
	90	1	0.3	344	23
	91	4	1.0	369	24
	92	2	0.5	368	25
	93	3	0.8	358	23
	95	2	0.5	385	25
	97	1	0.3	367	24
	100	1	0.3	336	22
	104	11	2.7	386	25
	105	4	1.0	377	24
	106	1	0.4	361	25
	109	1	0.2	394	25
	110	1	0.3	400	25
	115	1	0.2	370	25
	116	4	1.1	389	25
	123	1	0.3	336	23
	124	1	0.3	365	24
	127	1	0.3	336	23
	128	2	0.5	383	24
	130	8	2.6	371	25
	132	2	0.5	384	25
	133	1	4.0	356	25
	134	1	0.4	343	25
	135	5	1.3	370	24
	137	1	0.2	328	24
	138	1	0.2	351	22
	140	1	0.3	333	23
	141	2	0.6	313	21

Individual Study Counts and Incidence					
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Finding	Study Number	Number		
VISCERAL					
Renal Papilla(e) not Developed and/or Distended Ureter(s)					
	144	15	3.9	377	24
	145	1	0.3	346	23
	146	2	0.6	348	24
	149	4	1.2	345	23
	150	6	1.8	345	25
	151	1	0.2	370	24
	152	1	0.3	364	24
	157	4	1.0	368	24
	158	4	1.3	363	25
	159	2	0.6	378	23
	161	1	0.3	356	23
Spleen- Accessory					
	80	4	1.0	369	25
	103	1	0.3	384	25
	123	2	0.5	336	23
	135	1	0.2	370	24
Spleen- Pale					
	71	1	0.2	400	25
	109	1	0.3	394	25
	111	1	0.3	377	25
	135	1	0.3	370	24
	140	1	0.3	333	23
	149	1	0.3	345	23
	158	1	0.3	363	25
	160	1	0.2	410	24
Spleen- Small					
	73	1	0.5	396	25

Individual Study Counts and Incidence					
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Finding	Study Number	Number	% Per Litter	
VISCERAL					
Spleen- Small					
		82	1	0.3	377
		92	1	0.2	368
		111	1	0.3	377
		149	1	1.4	345
		160	1	0.4	410
Testis- Small					
		97	1	0.2	367
		157	1	0.2	368

Individual Study Counts and Incidence						
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
SKELETAL						
14th Full Rib(s)						
		2	1	0.4	267	19
		4	1	0.2	357	25
		14	1	0.2	407	25
		15	3	0.9	380	25
		17	1	0.3	378	25
		21	3	0.7	342	22
		27	1	0.4	378	25
		39	1	0.3	352	22
		42	1	0.2	391	25
		44	1	0.3	332	22
		45	1	0.3	355	25
		46	1	0.3	392	24
		48	1	0.3	339	23
		57	1	0.3	379	24
		63	2	0.6	363	24
		71	1	0.2	400	25
		73	1	0.3	396	25
		85	1	0.3	386	25
		86	1	0.3	297	19
		88	1	0.3	392	25
		89	1	0.3	392	25
		90	1	0.3	344	23
		94	1	0.2	389	25
		111	2	0.6	377	25
		113	1	0.3	351	24
		123	1	0.4	336	23
		128	1	0.3	383	24

Individual Study Counts and Incidence					
EXAMINATION TYPE		VARIATIONS		Total Fetuses Examined	Total Litters Examined
Finding	Study Number	Number	% Per Litter		
SKELETAL					
14th Full Rib(s)	129	1	0.3	372	25
	141	1	0.3	313	21
	143	1	0.2	388	25
	146	2	0.6	348	24
	161	2	0.6	356	23
14th Rudimentary Rib(s)	1	31	9.7	309	22
	2	32	12.0	267	19
	3	15	5.1	315	21
	4	19	4.8	357	25
	5	34	9.2	373	25
	6	18	4.8	346	22
	7	26	8.1	316	22
	8	18	5.9	334	22
	9	11	3.6	322	22
	10	17	4.5	397	24
	11	10	2.5	393	25
	12	18	4.8	377	24
	13	14	4.2	349	24
	14	19	4.5	407	25
	15	27	7.0	380	25
	16	21	6.5	323	21
	17	28	7.3	378	25
	18	10	2.6	388	25
	19	24	6.4	355	23
	20	40	10.9	379	24
	21	39	10.9	342	22

Individual Study Counts and Incidence						
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
SKELETAL						
14th Rudimentary Rib(s)		22	18	4.9	383	25
		23	21	5.2	391	25
		24	22	6.6	328	23
		25	30	8.6	370	25
		26	7	2.1	386	25
		27	27	6.7	378	25
		28	18	4.9	379	24
		29	32	9.3	376	25
		30	19	4.8	386	24
		31	18	5.0	361	25
		32	9	2.6	328	22
		33	10	2.7	369	25
		34	28	7.9	375	25
		35	10	2.8	334	22
		36	12	6.2	193	25
		37	21	5.6	378	25
		38	10	3.2	324	22
		39	37	11.3	352	22
		40	18	4.5	376	25
		41	21	5.7	388	25
		42	26	6.6	391	25
		43	16	4.3	367	24
		44	45	13.1	332	22
		45	17	4.4	355	25
		46	19	5.1	392	24
		47	6	1.4	416	25
		48	14	3.6	339	23

Individual Study Counts and Incidence						
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
SKELETAL						
14th Rudimentary Rib(s)						
		49	16	4.1	380	24
		50	21	6.0	346	24
		51	20	6.1	339	23
		52	15	5.4	274	19
		53	26	7.2	364	24
		54	21	5.8	355	25
		55	50	15.1	346	22
		56	25	6.4	374	25
		57	35	9.1	379	24
		58	29	7.0	407	25
		59	40	11.0	374	24
		60	16	4.3	389	25
		61	12	3.1	362	24
		62	17	5.0	368	24
		63	30	8.2	363	24
		64	23	6.1	369	24
		65	32	8.6	350	24
		66	11	3.2	338	22
		67	10	2.8	320	23
		68	20	5.3	384	25
		69	13	3.9	323	23
		70	34	9.7	344	23
		71	21	4.9	400	25
		72	24	6.4	364	25
		73	24	5.8	396	25
		74	39	10.5	359	24
		75	24	7.2	338	22

Individual Study Counts and Incidence						
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
SKELETAL						
14th Rudimentary Rib(s)						
		76	15	3.5	387	25
		77	34	11.1	306	21
		78	15	4.0	376	24
		79	22	6.6	346	22
		80	13	3.8	369	25
		81	32	5.1	376	25
		82	46	12.3	377	24
		83	9	2.8	336	22
		84	26	6.7	410	25
		85	33	9.1	386	25
		86	11	3.6	297	19
		87	38	9.8	384	25
		88	25	6.6	392	25
		89	31	7.8	392	25
		90	51	15.0	344	23
		91	49	12.9	369	24
		92	40	11.0	368	25
		93	28	8.0	358	23
		94	41	10.2	389	25
		95	38	9.4	385	25
		96	17	4.4	376	25
		97	34	9.4	367	24
		98	13	3.7	344	23
		99	24	6.1	401	24
		100	18	5.4	336	22
		101	43	11.1	383	25
		102	23	5.6	405	27

Individual Study Counts and Incidence						
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
SKELETAL						
14th Rudimentary Rib(s)		103	20	5.0	384	25
		104	42	11.3	386	25
		105	34	9.5	377	24
		106	16	4.9	361	25
		107	5	1.4	340	23
		108	31	8.5	365	25
		109	23	5.7	394	25
		110	48	12.0	400	25
		111	30	8.0	377	25
		112	30	8.2	355	24
		113	32	9.5	351	24
		114	26	7.4	375	25
		115	41	11.1	370	25
		116	36	8.8	389	25
		119	8	5.6	130	9
		122	32	8.4	391	25
		123	23	6.4	336	23
		124	27	7.5	365	24
		125	17	4.4	376	25
		127	23	6.6	336	23
		128	39	10.4	383	24
		129	24	6.3	372	25
		130	25	7.0	371	25
		132	15	4.3	384	25
		133	29	7.5	356	25
		134	24	8.4	343	25
		135	28	7.1	370	24

Individual Study Counts and Incidence						
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
SKELETAL						
14th Rudimentary Rib(s)		137	20	5.6	328	24
		138	29	8.6	351	22
		139	26	8.0	369	25
		140	23	6.8	333	23
		141	25	7.9	313	21
		142	36	11.1	305	25
		143	22	6.0	388	25
		144	31	8.3	377	24
		145	22	6.9	346	23
		146	37	10.7	348	24
		149	11	3.2	345	23
		150	36	9.6	345	25
		151	28	7.8	370	24
		152	33	8.8	364	24
		157	19	4.8	368	24
		158	30	8.3	363	25
		159	26	7.0	378	23
		160	20	4.6	410	24
		161	34	9.9	356	23
25 Presacral Vertebrae		1	1	0.4	309	22
		3	2	0.7	315	21
		6	1	0.3	346	22
		10	1	0.3	397	24
		12	4	1.0	377	24
		14	1	0.2	407	25
		16	3	0.9	323	21

Individual Study Counts and Incidence						
EXAMINATION TYPE		VARIATIONS		Total Fetuses Examined	Total Litters Examined	
Finding	Study Number	Number	% Per Litter			
SKELETAL						
25 Presacral Vertebrae		19	2	0.5	355	23
		20	1	0.2	379	24
		21	1	0.3	342	22
		32	2	0.6	328	22
		36	2	2.0	193	25
		40	1	0.2	376	25
		46	1	0.3	392	24
		47	1	0.3	416	25
		56	4	1.6	374	25
		57	2	0.6	379	24
		64	1	0.3	369	24
		68	2	0.5	384	25
		70	6	1.6	344	23
		75	1	0.3	338	22
		81	1	0.3	376	25
		84	1	0.2	410	25
		86	1	0.4	297	19
		100	3	0.9	336	22
		132	3	0.7	384	25
		137	1	0.3	328	24
		143	2	0.4	388	25
		145	1	0.3	346	23
		159	1	0.3	378	23
		161	3	0.9	356	23
27 Presacral Vertebrae		2	1	0.4	267	19
		3	1	0.3	315	21

Individual Study Counts and Incidence						
		VARIATIONS		Total Fetuses Examined	Total Litters Examined	
EXAMINATION TYPE	Finding	Study Number	Number			% Per Litter
SKELETAL						
27 Presacral Vertebrae						
		5	1	0.3	373	25
		13	1	0.3	349	24
		14	2	0.5	407	25
		15	6	1.8	380	25
		17	2	0.6	378	25
		21	3	0.7	342	22
		27	1	0.4	378	25
		29	1	0.4	376	25
		37	2	0.5	378	25
		38	1	0.3	324	22
		42	2	0.6	391	25
		45	2	0.6	355	25
		48	1	0.2	339	23
		49	1	0.2	380	24
		51	1	0.2	339	23
		63	2	0.6	363	24
		71	2	0.4	400	25
		72	2	0.4	364	25
		73	2	0.5	396	25
		79	1	0.3	346	22
		80	1	0.2	369	25
		82	2	0.5	377	24
		83	1	0.3	336	22
		85	1	0.3	386	25
		86	1	0.3	297	19
		88	2	0.6	392	25
		89	1	0.3	392	25

Individual Study Counts and Incidence						
EXAMINATION TYPE		VARIATIONS		Total Fetuses Examined	Total Litters Examined	
Finding	Study Number	Number	% Per Litter			
SKELETAL						
27 Presacral Vertebrae		90	1	0.3	344	23
		94	1	0.3	389	25
		95	2	0.5	385	25
		103	3	0.8	384	25
		107	1	0.3	340	23
		113	2	0.5	351	24
		119	2	1.2	130	9
		122	1	0.2	391	25
		123	1	0.4	336	23
		124	1	0.3	365	24
		126	1	0.2	383	23
		127	1	0.3	336	23
		134	1	0.3	343	25
		135	1	0.3	370	24
		143	3	0.8	388	25
		144	2	0.5	377	24
		146	3	0.8	348	24
		151	3	1.0	370	24
		157	2	0.7	368	24
		160	1	0.2	410	24
		161	2	0.6	356	23
7th Cervical Rib(s)		2	1	0.3	267	19
		3	2	0.7	315	21
		4	1	0.2	357	25
		6	1	0.3	346	22
		7	2	0.6	316	22

Individual Study Counts and Incidence						
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
SKELETAL						
7th Cervical Rib(s)		8	1	0.3	334	22
		14	1	0.3	407	25
		17	5	1.2	378	25
		20	3	0.8	379	24
		21	2	0.7	342	22
		22	6	1.4	383	25
		23	5	1.3	391	25
		25	2	0.6	370	25
		26	1	0.3	386	25
		27	2	0.5	378	25
		28	3	0.7	379	24
		29	2	0.5	376	25
		30	1	0.3	386	24
		31	3	0.8	361	25
		32	1	0.3	328	22
		34	1	0.2	375	25
		35	4	1.1	334	22
		40	1	0.3	376	25
		41	2	0.5	388	25
		43	6	1.6	367	24
		45	2	0.6	355	25
		46	4	1.0	392	24
		47	1	0.2	416	25
		48	4	1.4	339	23
		49	4	1.1	380	24
		50	5	1.4	346	24
		51	5	1.6	339	23

Individual Study Counts and Incidence						
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
SKELETAL						
7th Cervical Rib(s)						
		52	7	2.7	274	19
		53	1	0.2	364	24
		54	4	1.0	355	25
		55	3	0.8	346	22
		56	8	2.5	374	25
		57	3	0.8	379	24
		58	1	0.2	407	25
		59	3	0.8	374	24
		60	6	1.5	389	25
		61	1	0.3	362	24
		62	8	1.9	368	24
		63	2	0.5	363	24
		64	5	1.5	369	24
		65	2	1.2	350	24
		67	4	1.2	320	23
		68	2	0.5	384	25
		70	1	0.3	344	23
		71	4	0.9	400	25
		72	8	2.3	364	25
		73	1	0.3	396	25
		74	2	0.6	359	24
		75	5	1.4	338	22
		77	2	0.7	306	21
		78	2	0.6	376	24
		80	3	0.8	369	25
		81	7	1.7	376	25
		82	3	0.7	377	24

Individual Study Counts and Incidence						
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
SKELETAL						
7th Cervical Rib(s)						
		83	6	2.1	336	22
		85	13	3.3	386	25
		86	1	0.3	297	19
		87	3	0.7	384	25
		88	2	0.4	392	25
		89	4	1.1	392	25
		90	9	2.6	344	23
		91	3	0.9	369	24
		92	8	2.2	368	25
		93	2	0.5	358	23
		95	1	0.2	385	25
		96	2	0.6	376	25
		97	10	2.9	367	24
		98	3	0.8	344	23
		99	3	0.8	401	24
		101	6	1.5	383	25
		102	9	2.4	405	27
		103	4	1.0	384	25
		104	5	1.2	386	25
		105	4	1.0	377	24
		106	7	2.2	361	25
		107	5	1.2	340	23
		108	2	0.6	365	25
		109	1	0.3	394	25
		110	7	1.7	400	25
		111	4	1.0	377	25
		112	9	2.3	355	24

Individual Study Counts and Incidence						
		VARIATIONS		Total Fetuses Examined	Total Litters Examined	
EXAMINATION TYPE	Finding	Study Number	Number			% Per Litter
SKELETAL						
	7th Cervical Rib(s)					
		113	3	1.0	351	24
		114	11	3.0	375	25
		115	2	0.5	370	25
		119	1	0.7	130	9
		122	2	0.4	391	25
		123	3	0.9	336	23
		124	4	1.1	365	24
		125	3	0.8	376	25
		126	1	0.2	383	23
		127	12	3.5	336	23
		128	3	0.9	383	24
		129	3	0.9	372	25
		132	5	1.2	384	25
		133	1	0.3	356	25
		134	3	0.8	343	25
		135	1	0.3	370	24
		137	3	0.8	328	24
		138	9	2.5	351	22
		139	1	0.3	369	25
		140	1	0.3	333	23
		141	3	1.0	313	21
		142	6	1.9	305	25
		143	3	0.7	388	25
		144	3	1.0	377	24
		145	2	0.5	346	23
		146	1	0.3	348	24
		151	2	0.6	370	24

Individual Study Counts and Incidence						
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
SKELETAL						
7th Cervical Rib(s)		152	3	0.8	364	24
		157	1	0.3	368	24
		158	4	1.1	363	25
		159	11	2.9	378	23
		160	4	1.0	410	24
		161	3	0.8	356	23
7th Sternebra		27	7	1.8	378	25
		39	1	0.3	352	22
		47	10	2.5	416	25
		49	1	0.3	380	24
		77	1	0.3	306	21
		90	1	0.3	344	23
		103	1	0.2	384	25
		106	1	0.4	361	25
		145	1	0.3	346	23
Bent Rib(s)		1	2	0.6	309	22
		6	1	0.3	346	22
		7	1	0.5	316	22
		10	1	0.2	397	24
		12	1	0.3	377	24
		14	1	0.2	407	25
		16	1	0.3	323	21
		20	1	0.2	379	24
		27	1	4.0	378	25
		29	1	0.3	376	25

Individual Study Counts and Incidence						
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
SKELETAL						
Bent Rib(s)						
		30	1	0.3	386	24
		32	1	0.8	328	22
		42	1	0.2	391	25
		46	1	0.3	392	24
		50	1	0.3	346	24
		51	1	0.4	339	23
		55	1	0.3	346	22
		62	2	0.7	368	24
		66	2	0.6	338	22
		68	2	0.5	384	25
		69	1	0.5	323	23
		74	1	0.3	359	24
		78	1	0.2	376	24
		79	1	0.3	346	22
		80	1	0.3	369	25
		81	3	0.8	376	25
		85	1	0.3	386	25
		86	2	0.6	297	19
		87	4	1.0	384	25
		89	2	0.5	392	25
		90	4	1.3	344	23
		92	2	0.6	368	25
		93	4	1.2	358	23
		95	2	0.4	385	25
		96	1	0.3	376	25
		97	7	2.1	367	24
		98	1	0.3	344	23

Individual Study Counts and Incidence						
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
SKELETAL						
Bent Rib(s)		99	1	0.2	401	24
		103	3	0.8	384	25
		104	1	0.3	386	25
		105	1	0.3	377	24
		106	1	0.2	361	25
		107	1	0.3	340	23
		111	1	0.3	377	25
		116	1	0.3	389	25
		122	1	0.3	391	25
		123	3	0.8	336	23
		129	1	0.3	372	25
		142	8	2.7	305	25
		144	1	0.3	377	24
		158	2	0.5	363	25
	Cervical Centrum #1 Ossified		1	52	17.2	309
		2	33	12.2	267	19
		3	51	16.1	315	21
		4	57	16.5	357	25
		5	88	23.0	373	25
		6	53	15.4	346	22
		7	52	16.4	316	22
		8	92	27.6	334	22
		9	71	21.6	322	22
		10	25	6.6	397	24
		11	75	19.7	393	25
		12	52	13.7	377	24

Individual Study Counts and Incidence					
		VARIATIONS			
EXAMINATION TYPE				Total Fetuses	Total Litters
Finding	Study Number	Number	% Per Litter	Examined	Examined
SKELETAL					
Cervical Centrum #1 Ossified					
	13	43	13.7	349	24
	14	30	7.3	407	25
	15	37	10.2	380	25
	16	54	17.1	323	21
	17	92	24.6	378	25
	18	69	16.1	388	25
	19	35	10.8	355	23
	20	75	20.8	379	24
	21	54	15.4	342	22
	22	51	14.0	383	25
	23	86	21.3	391	25
	24	62	18.7	328	23
	25	73	20.7	370	25
	26	35	10.3	386	25
	27	55	14.2	378	25
	28	45	11.2	379	24
	29	116	31.2	376	25
	30	70	17.9	386	24
	31	61	16.3	361	25
	32	80	23.9	328	22
	33	60	15.2	369	25
	34	64	17.0	375	25
	35	43	12.7	334	22
	36	40	21.6	193	25
	37	67	18.2	378	25
	38	37	11.3	324	22
	39	72	19.6	352	22

Individual Study Counts and Incidence						
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
SKELETAL						
Cervical Centrum #1 Ossified		40	51	12.7	376	25
		41	94	24.1	388	25
		42	61	16.5	391	25
		43	69	19.6	367	24
		44	75	22.9	332	22
		45	35	9.5	355	25
		46	71	17.7	392	24
		47	61	14.8	416	25
		48	83	23.8	339	23
		49	50	13.4	380	24
		50	102	29.7	346	24
		51	46	13.3	339	23
		52	71	26.3	274	19
		53	60	17.8	364	24
		54	110	32.1	355	25
		55	52	14.2	346	22
		56	91	24.6	374	25
		57	108	29.9	379	24
		58	105	25.6	407	25
		59	98	25.7	374	24
		60	55	14.8	389	25
		61	64	17.3	362	24
		62	47	13.4	368	24
		63	70	19.3	363	24
		64	101	26.4	369	24
		65	107	31.3	350	24
		66	86	26.4	338	22

Individual Study Counts and Incidence						
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
SKELETAL						
Cervical Centrum #1 Ossified						
		67	70	21.6	320	23
		68	72	18.4	384	25
		69	70	22.1	323	23
		70	82	23.6	344	23
		71	72	18.1	400	25
		72	88	24.9	364	25
		73	81	20.8	396	25
		74	85	22.7	359	24
		75	85	25.1	338	22
		76	69	17.4	387	25
		77	49	15.6	306	21
		78	85	22.3	376	24
		79	69	19.7	346	22
		80	62	16.7	369	25
		81	74	21.2	376	25
		82	111	29.0	377	24
		83	33	10.5	336	22
		84	85	20.8	410	25
		85	122	32.0	386	25
		86	75	25.1	297	19
		87	91	22.8	384	25
		88	67	16.8	392	25
		89	78	19.6	392	25
		90	115	34.4	344	23
		91	65	17.7	369	24
		92	68	18.6	368	25
		93	74	21.1	358	23

Individual Study Counts and Incidence						
EXAMINATION TYPE		VARIATIONS			Total Fetuses Examined	Total Litters Examined
Finding	Study Number	Number	% Per Litter			
SKELETAL						
Cervical Centrum #1 Ossified	94	79	20.4	389	25	
	95	72	20.9	385	25	
	96	97	29.0	376	25	
	97	73	20.2	367	24	
	98	62	17.8	344	23	
	99	75	19.0	401	24	
	100	57	17.3	336	22	
	101	91	24.9	383	25	
	102	106	26.5	405	27	
	103	99	25.7	384	25	
	104	115	29.8	386	25	
	105	65	17.4	377	24	
	106	88	23.8	361	25	
	107	53	17.2	340	23	
	108	107	29.9	365	25	
	109	62	15.9	394	25	
	110	105	26.3	400	25	
	111	81	21.6	377	25	
	112	127	35.8	355	24	
	113	99	28.6	351	24	
	114	73	19.0	375	25	
	115	63	16.5	370	25	
	116	55	14.1	389	25	
	119	24	20.5	130	9	
	122	101	26.5	391	25	
	123	95	28.5	336	23	
	124	68	19.3	365	24	

Individual Study Counts and Incidence						
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
SKELETAL						
Cervical Centrum #1 Ossified		125	60	16.0	376	25
		126	76	19.7	383	23
		127	74	22.5	336	23
		128	63	16.1	383	24
		129	52	13.8	372	25
		130	72	19.1	371	25
		132	63	17.2	384	25
		133	71	20.4	356	25
		134	96	27.9	343	25
		135	43	11.5	370	24
		137	62	23.8	328	24
		138	87	24.8	351	22
		139	75	20.9	369	25
		140	96	29.2	333	23
		141	77	24.9	313	21
		142	100	33.3	305	25
		143	42	11.6	388	25
		144	103	28.5	377	24
		145	44	13.3	346	23
		146	68	19.8	348	24
		149	88	24.2	345	23
		150	84	24.8	345	25
		151	87	23.3	370	24
		152	61	16.6	364	24
		157	70	20.3	368	24
		158	72	19.6	363	25
		159	90	23.7	378	23

Individual Study Counts and Incidence					
		VARIATIONS			
EXAMINATION TYPE				Total Fetuses	Total Litters
Finding	Study Number	Number	% Per Litter	Examined	Examined
SKELETAL					
Cervical Centrum #1 Ossified	160	48	11.8	410	24
	161	64	18.1	356	23
Entire Sternum Unossified	11	1	0.2	393	25
	76	1	0.3	387	25
	89	1	0.3	392	25
	105	1	0.2	377	24
	107	1	0.3	340	23
	141	1	0.4	313	21
	142	1	0.3	305	25
	144	1	0.2	377	24
	Extra Site of Ossification Anterior to Cervical Centrum #2	86	1	0.3	297
Extra Site of Ossification Anterior to Rib #5	105	1	0.2	377	24
Extra Site of Ossification Anterior to Sternebra #1	63	1	0.4	363	24
	81	1	0.3	376	25
	92	1	0.3	368	25
Extra Site of Ossification Ventral to Cervical Centrum #2	58	1	0.3	407	25
Hyoid Unossified	1	6	2.0	309	22
	2	6	2.3	267	19
	3	7	2.2	315	21
	5	8	2.2	373	25
	6	9	2.5	346	22

Individual Study Counts and Incidence						
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
SKELETAL						
Hyoid Unossified						
		7	5	1.4	316	22
		8	4	1.2	334	22
		9	2	0.6	322	22
		10	4	1.0	397	24
		11	11	2.7	393	25
		12	9	2.2	377	24
		13	1	0.2	349	24
		14	1	0.3	407	25
		15	5	1.6	380	25
		16	8	2.6	323	21
		17	6	1.6	378	25
		18	7	1.7	388	25
		19	3	0.8	355	23
		20	6	1.4	379	24
		21	6	1.9	342	22
		22	8	1.9	383	25
		23	7	1.7	391	25
		24	4	1.4	328	23
		25	6	1.7	370	25
		26	9	2.3	386	25
		27	8	2.0	378	25
		28	5	1.2	379	24
		29	5	1.3	376	25
		30	8	2.1	386	24
		31	8	2.1	361	25
		32	2	0.6	328	22
		33	3	0.9	369	25

Individual Study Counts and Incidence						
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
SKELETAL						
Hyoid Unossified						
		34	5	1.3	375	25
		35	3	0.9	334	22
		36	3	1.5	193	25
		37	3	0.8	378	25
		38	6	2.0	324	22
		39	12	3.4	352	22
		40	10	2.4	376	25
		41	1	0.3	388	25
		42	10	2.5	391	25
		43	3	0.9	367	24
		44	10	2.9	332	22
		45	4	1.1	355	25
		46	4	1.0	392	24
		47	8	1.9	416	25
		48	2	0.6	339	23
		49	3	0.8	380	24
		50	1	0.3	346	24
		51	9	2.9	339	23
		52	2	0.8	274	19
		53	4	1.0	364	24
		54	4	1.2	355	25
		55	5	1.4	346	22
		57	2	0.5	379	24
		58	1	0.3	407	25
		59	7	2.1	374	24
		60	5	1.3	389	25
		61	11	3.0	362	24

Individual Study Counts and Incidence						
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
SKELETAL						
Hyoid Unossified		62	2	0.6	368	24
		63	1	0.3	363	24
		64	5	1.5	369	24
		65	3	0.9	350	24
		66	6	2.4	338	22
		67	13	3.9	320	23
		68	7	1.8	384	25
		69	4	1.1	323	23
		70	7	2.1	344	23
		71	9	2.4	400	25
		72	4	1.1	364	25
		73	10	2.4	396	25
		74	11	3.1	359	24
		75	5	1.4	338	22
		76	16	3.8	387	25
		77	13	3.7	306	21
		78	1	0.2	376	24
		79	4	1.2	346	22
		80	9	2.4	369	25
		81	5	1.2	376	25
		82	1	0.3	377	24
		83	2	0.5	336	22
		84	17	4.2	410	25
		85	8	2.1	386	25
		86	1	0.3	297	19
		87	1	0.3	384	25
		88	4	1.0	392	25

Individual Study Counts and Incidence					
EXAMINATION TYPE		VARIATIONS		Total Fetuses Examined	Total Litters Examined
Finding	Study Number	Number	% Per Litter		
SKELETAL					
Hyoid Unossified					
	89	1	0.3	392	25
	90	3	0.9	344	23
	91	8	2.1	369	24
	92	1	0.3	368	25
	93	5	1.4	358	23
	94	3	0.8	389	25
	95	6	1.4	385	25
	96	1	0.2	376	25
	98	5	1.5	344	23
	100	6	1.6	336	22
	101	3	0.8	383	25
	102	1	0.2	405	27
	103	4	1.2	384	25
	106	10	2.6	361	25
	107	4	1.1	340	23
	109	2	0.4	394	25
	110	1	0.3	400	25
	111	3	0.8	377	25
	112	4	1.1	355	24
	113	2	0.5	351	24
	114	7	2.0	375	25
	115	7	1.9	370	25
	116	1	0.2	389	25
	123	1	0.4	336	23
	124	9	2.1	365	24
	125	4	1.0	376	25
	126	6	1.4	383	23

Individual Study Counts and Incidence					
		VARIATIONS			
EXAMINATION TYPE				Total Fetuses	Total Litters
Finding	Study Number	Number	% Per Litter	Examined	Examined
SKELETAL					
Hyoid Unossified	127	6	1.7	336	23
	128	1	0.2	383	24
	129	6	1.4	372	25
	130	16	4.4	371	25
	133	8	2.1	356	25
	134	5	1.3	343	25
	137	3	0.8	328	24
	138	3	0.7	351	22
	139	6	1.6	369	25
	140	1	0.3	333	23
	141	2	0.6	313	21
	143	7	1.9	388	25
	145	10	2.7	346	23
	146	1	0.2	348	24
	149	5	1.4	345	23
	150	4	1.1	345	25
	152	3	0.8	364	24
	157	7	1.6	368	24
	158	3	0.9	363	25
	159	1	0.3	378	23
	160	5	1.2	410	24
Ischium Unossified	64	2	0.6	369	24
	141	1	0.4	313	21
	152	1	0.4	364	24
Pubis Unossified	11	2	0.5	393	25

Individual Study Counts and Incidence					
EXAMINATION TYPE		VARIATIONS		Total Fetuses Examined	Total Litters Examined
Finding	Study Number	Number	% Per Litter		
SKELETAL					
Pubis Unossified					
	15	1	0.3	380	25
	22	1	0.2	383	25
	27	1	0.4	378	25
	34	1	0.2	375	25
	43	1	0.3	367	24
	48	1	0.3	339	23
	61	1	0.3	362	24
	64	8	2.3	369	24
	70	1	0.2	344	23
	74	1	0.6	359	24
	76	1	0.3	387	25
	77	1	0.2	306	21
	84	1	0.2	410	25
	89	1	0.3	392	25
	105	1	0.2	377	24
	107	1	0.3	340	23
	113	1	0.3	351	24
	122	1	0.2	391	25
	123	1	0.4	336	23
	130	1	0.3	371	25
	137	1	0.3	328	24
	139	1	0.3	369	25
	141	1	0.4	313	21
	145	1	0.3	346	23
	152	1	0.4	364	24
	158	1	0.2	363	25
	160	1	0.3	410	24

Individual Study Counts and Incidence					
		VARIATIONS			
EXAMINATION TYPE				Total Fetuses	Total Litters
Finding	Study Number	Number	% Per Litter	Examined	Examined
SKELETAL					
Pubis Unossified	161	1	0.3	356	23
Reduced Ossification of the 13th Rib(s)	1	1	0.4	309	22
	3	4	1.3	315	21
	6	7	2.2	346	22
	8	5	1.5	334	22
	9	3	0.9	322	22
	11	1	0.3	393	25
	12	8	2.1	377	24
	13	1	0.2	349	24
	16	1	0.3	323	21
	17	2	0.6	378	25
	18	1	0.3	388	25
	19	1	0.3	355	23
	20	3	0.7	379	24
	21	3	0.8	342	22
	22	4	0.9	383	25
	23	4	1.1	391	25
	24	2	0.5	328	23
	25	1	0.3	370	25
	26	1	0.3	386	25
	27	4	1.3	378	25
	28	2	0.5	379	24
	29	2	0.5	376	25
	31	3	0.8	361	25
	32	4	1.1	328	22
	33	1	0.3	369	25

Individual Study Counts and Incidence					
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined
	Finding	Study Number	Number		
SKELETAL					
Reduced Ossification of the 13th Rib(s)					
		34	2	0.6	375
		36	3	3.0	193
		37	2	0.6	378
		40	4	1.5	376
		41	6	1.4	388
		46	3	0.8	392
		47	5	1.3	416
		48	4	1.2	339
		50	3	1.0	346
		52	1	0.4	274
		53	1	0.3	364
		54	2	0.6	355
		56	9	2.5	374
		59	2	0.5	374
		61	3	0.7	362
		62	9	2.2	368
		63	3	0.8	363
		64	1	0.2	369
		65	1	0.3	350
		66	2	0.6	338
		68	1	0.3	384
		69	5	2.1	323
		70	2	0.5	344
		71	2	0.5	400
		72	1	0.2	364
		73	4	1.0	396
		75	6	1.8	338

Individual Study Counts and Incidence					
		VARIATIONS			
EXAMINATION TYPE				Total Fetuses	Total Litters
Finding	Study Number	Number	% Per Litter	Examined	Examined
SKELETAL					
Reduced Ossification of the 13th Rib(s)					
	76	1	0.2	387	25
	77	1	0.4	306	21
	79	2	0.6	346	22
	80	1	0.5	369	25
	81	2	0.5	376	25
	82	2	0.5	377	24
	83	7	2.2	336	22
	84	2	0.4	410	25
	86	4	1.3	297	19
	87	10	2.7	384	25
	88	6	1.4	392	25
	89	2	0.5	392	25
	90	1	0.3	344	23
	91	2	0.5	369	24
	92	1	0.3	368	25
	93	2	0.5	358	23
	94	2	0.5	389	25
	95	1	0.3	385	25
	97	1	0.2	367	24
	98	1	0.3	344	23
	99	1	0.2	401	24
	100	8	2.3	336	22
	101	1	0.3	383	25
	102	3	0.7	405	27
	103	4	1.1	384	25
	106	3	0.8	361	25
	107	2	0.6	340	23

Individual Study Counts and Incidence						
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
SKELETAL						
Reduced Ossification of the 13th Rib(s)						
		108	1	0.3	365	25
		109	1	0.3	394	25
		110	2	0.4	400	25
		111	1	0.3	377	25
		112	2	0.7	355	24
		113	1	0.3	351	24
		114	1	0.3	375	25
		115	3	0.9	370	25
		116	1	0.3	389	25
		122	1	0.3	391	25
		127	2	0.6	336	23
		128	3	0.8	383	24
		129	6	1.6	372	25
		130	3	0.8	371	25
		132	6	1.4	384	25
		133	2	0.6	356	25
		134	2	0.7	343	25
		135	2	0.5	370	24
		137	5	1.3	328	24
		139	2	0.5	369	25
		140	2	0.5	333	23
		141	12	3.6	313	21
		142	1	0.4	305	25
		143	8	1.8	388	25
		144	1	0.2	377	24
		149	2	0.5	345	23
		150	3	1.1	345	25

Individual Study Counts and Incidence					
EXAMINATION TYPE		VARIATIONS		Total Fetuses Examined	Total Litters Examined
Finding	Study Number	Number	% Per Litter		
SKELETAL					
Reduced Ossification of the 13th Rib(s)	151	2	0.5	370	24
	152	5	1.3	364	24
	157	1	0.2	368	24
	158	5	1.3	363	25
	159	2	0.5	378	23
	160	1	0.2	410	24
	161	7	2.0	356	23
	Reduced Ossification of the Limb Bone(s)	28	1	0.2	379
40		1	0.2	376	25
Reduced Ossification of the Rib(s)	28	2	0.5	379	24
	56	1	0.2	374	25
	68	1	0.3	384	25
	79	1	0.3	346	22
	87	1	0.3	384	25
	89	1	0.3	392	25
	93	1	0.3	358	23
	95	1	0.3	385	25
	96	1	0.3	376	25
	97	4	1.2	367	24
	99	1	0.2	401	24
	104	1	0.3	386	25
	122	1	0.3	391	25
	128	1	0.3	383	24
	142	1	0.3	305	25
	Reduced Ossification of the Skull				

Individual Study Counts and Incidence					
EXAMINATION TYPE		VARIATIONS		Total Fetuses Examined	Total Litters Examined
Finding	Study Number	Number	% Per Litter		
SKELETAL					
Reduced Ossification of the Skull					
	55	1	0.2	346	22
	68	1	0.3	384	25
	71	1	0.3	400	25
	73	2	1.0	396	25
	79	2	0.6	346	22
	85	4	1.0	386	25
	89	1	0.2	392	25
	90	2	0.6	344	23
	91	1	0.2	369	24
	92	1	0.3	368	25
	93	1	0.3	358	23
	94	3	0.8	389	25
	95	1	0.3	385	25
	96	1	0.3	376	25
	97	2	0.5	367	24
	99	2	0.4	401	24
	100	1	0.3	336	22
	101	1	0.3	383	25
	106	2	0.5	361	25
	109	2	0.5	394	25
	123	2	0.6	336	23
	126	1	0.3	383	23
	130	1	0.3	371	25
	137	2	0.6	328	24
	138	1	0.3	351	22
	139	1	0.3	369	25
	142	1	0.3	305	25

Individual Study Counts and Incidence					
		VARIATIONS			
EXAMINATION TYPE				Total Fetuses	Total Litters
Finding	Study Number	Number	% Per Litter	Examined	Examined
SKELETAL					
Reduced Ossification of the Skull	152	2	0.7	364	24
	157	1	0.2	368	24
	158	1	0.3	363	25
	161	2	0.6	356	23
Reduced Ossification of the Vertebral Arches	11	1	0.3	393	25
	26	1	0.2	386	25
	41	1	0.3	388	25
	48	2	0.8	339	23
	49	1	0.3	380	24
	61	1	0.2	362	24
	62	1	0.3	368	24
	65	1	0.3	350	24
	71	1	0.3	400	25
	76	1	0.3	387	25
	78	2	0.6	376	24
	80	1	0.5	369	25
	82	1	0.3	377	24
	84	4	1.1	410	25
	85	2	0.5	386	25
	89	1	0.2	392	25
	90	1	0.3	344	23
	91	2	0.5	369	24
	93	2	0.6	358	23
	94	3	0.6	389	25
	95	1	0.3	385	25
	96	2	0.5	376	25

Individual Study Counts and Incidence					
EXAMINATION TYPE		VARIATIONS		Total Fetuses Examined	Total Litters Examined
Finding	Study Number	Number	% Per Litter		
SKELETAL					
Reduced Ossification of the Vertebral Arches	97	2	0.5	367	24
	102	1	0.2	405	27
	105	1	0.2	377	24
	106	1	0.2	361	25
	107	2	0.6	340	23
	128	2	0.6	383	24
	129	1	0.2	372	25
	130	1	0.3	371	25
	132	1	0.2	384	25
	134	1	0.3	343	25
	135	1	0.3	370	24
	137	1	0.3	328	24
	138	2	0.6	351	22
	141	1	0.4	313	21
	142	1	0.3	305	25
	144	1	0.2	377	24
	145	1	0.3	346	23
	151	1	0.3	370	24
	157	1	0.2	368	24
	158	1	0.3	363	25
	159	1	0.2	378	23
	161	1	0.3	356	23
Skull Bone(s)- Accessory	46	1	0.2	392	24
	86	1	0.3	297	19
	92	1	0.3	368	25
	116	2	0.5	389	25

Individual Study Counts and Incidence					
		VARIATIONS			
EXAMINATION TYPE				Total Fetuses	Total Litters
Finding	Study Number	Number	% Per Litter	Examined	Examined
SKELETAL					
Skull Bone(s)- Accessory	142	2	0.7	305	25
	143	1	0.2	388	25
Sternebra(e) #1, #2, #3 and/or #4 Unossified	2	1	0.4	267	19
	4	2	0.7	357	25
	5	1	0.3	373	25
	7	2	0.6	316	22
	10	4	1.0	397	24
	11	2	0.5	393	25
	15	3	0.9	380	25
	18	1	0.3	388	25
	19	2	0.5	355	23
	22	3	0.7	383	25
	24	3	1.0	328	23
	25	1	0.3	370	25
	28	1	0.3	379	24
	35	2	0.7	334	22
	36	1	1.0	193	25
	40	2	0.5	376	25
	41	2	0.5	388	25
	42	3	0.7	391	25
	43	1	0.3	367	24
	48	1	0.2	339	23
	49	2	0.5	380	24
	51	2	0.7	339	23
	56	2	0.6	374	25
	59	1	0.3	374	24

Individual Study Counts and Incidence					
EXAMINATION TYPE		VARIATIONS		Total Fetuses Examined	Total Litters Examined
Finding	Study Number	Number	% Per Litter		
SKELETAL					
Sternebra(e) #1, #2, #3 and/or #4 Unossified					
	61	5	1.3	362	24
	63	1	0.3	363	24
	64	1	0.3	369	24
	65	1	0.3	350	24
	68	1	0.3	384	25
	70	1	0.2	344	23
	71	2	0.5	400	25
	74	1	0.6	359	24
	76	1	0.3	387	25
	81	2	0.5	376	25
	84	2	0.5	410	25
	87	2	0.5	384	25
	88	1	0.3	392	25
	94	1	0.2	389	25
	96	2	0.5	376	25
	97	1	0.2	367	24
	100	1	0.6	336	22
	101	1	0.2	383	25
	102	1	0.2	405	27
	103	1	0.2	384	25
	105	1	0.2	377	24
	108	1	0.3	365	25
	113	1	0.3	351	24
	114	1	0.2	375	25
	115	1	0.2	370	25
	116	1	0.2	389	25
	122	1	0.2	391	25

Individual Study Counts and Incidence					
EXAMINATION TYPE		VARIATIONS		Total Fetuses Examined	Total Litters Examined
Finding	Study Number	Number	% Per Litter		
SKELETAL					
Sternebra(e) #1, #2, #3 and/or #4 Unossified	123	1	0.4	336	23
	126	1	0.3	383	23
	127	1	0.3	336	23
	128	1	0.3	383	24
	129	1	0.3	372	25
	130	1	0.3	371	25
	132	1	0.2	384	25
	133	2	0.5	356	25
	135	1	0.3	370	24
	137	1	0.3	328	24
	138	1	0.3	351	22
	139	2	0.5	369	25
	143	1	0.2	388	25
	145	1	0.3	346	23
	151	1	0.2	370	24
	152	2	0.7	364	24
	158	2	0.5	363	25
	160	1	0.3	410	24
Sternebra(e) #5 and/or #6 Unossified	1	42	13.0	309	22
	2	29	10.2	267	19
	3	32	10.8	315	21
	4	15	4.1	357	25
	5	18	5.0	373	25
	6	42	11.9	346	22
	7	58	19.3	316	22
	8	15	4.6	334	22

Individual Study Counts and Incidence					
EXAMINATION TYPE		VARIATIONS		Total Fetuses Examined	Total Litters Examined
Finding	Study Number	Number	% Per Litter		
SKELETAL					
Sternebra(e) #5 and/or #6 Unossified					
	9	30	8.8	322	22
	10	81	19.9	397	24
	11	85	21.4	393	25
	12	66	17.0	377	24
	13	12	3.4	349	24
	14	24	5.7	407	25
	15	43	11.1	380	25
	16	30	8.7	323	21
	17	66	16.6	378	25
	18	41	10.8	388	25
	19	56	15.0	355	23
	20	18	4.4	379	24
	21	23	6.2	342	22
	22	33	8.2	383	25
	23	24	5.9	391	25
	24	34	11.2	328	23
	25	30	8.0	370	25
	26	22	5.5	386	25
	27	8	2.1	378	25
	28	37	10.5	379	24
	29	1	0.3	376	25
	30	17	4.3	386	24
	31	13	3.4	361	25
	32	47	14.0	328	22
	33	12	4.2	369	25
	34	29	7.4	375	25
	35	77	23.1	334	22

Individual Study Counts and Incidence						
EXAMINATION TYPE	VARIATIONS			Total Fetuses Examined	Total Litters Examined	
	Finding	Study Number	Number			% Per Litter
SKELETAL						
Sternebra(e) #5 and/or #6 Unossified		36	11	5.3	193	25
		37	40	10.9	378	25
		38	12	3.7	324	22
		39	54	15.5	352	22
		40	59	16.0	376	25
		41	7	1.8	388	25
		42	32	8.6	391	25
		43	37	9.3	367	24
		44	8	2.1	332	22
		45	28	7.6	355	25
		46	44	11.1	392	24
		47	20	4.6	416	25
		48	4	1.2	339	23
		49	8	2.0	380	24
		50	7	2.5	346	24
		51	9	2.8	339	23
		52	3	1.1	274	19
		53	48	12.7	364	24
		54	8	2.3	355	25
		55	10	2.6	346	22
		56	86	23.1	374	25
		57	37	9.6	379	24
		58	7	1.9	407	25
		59	27	7.6	374	24
		60	26	6.5	389	25
		61	78	21.5	362	24
		62	55	15.2	368	24

Individual Study Counts and Incidence					
		VARIATIONS			
EXAMINATION TYPE				Total Fetuses	Total Litters
Finding	Study Number	Number	% Per Litter	Examined	Examined
SKELETAL					
Sternebra(e) #5 and/or #6 Unossified					
	63	49	15.0	363	24
	64	15	3.8	369	24
	65	8	2.1	350	24
	66	9	2.6	338	22
	67	11	3.0	320	23
	68	12	3.3	384	25
	69	6	1.7	323	23
	70	5	1.5	344	23
	71	39	9.6	400	25
	72	15	4.0	364	25
	73	17	4.4	396	25
	74	7	3.8	359	24
	75	5	1.5	338	22
	76	64	16.4	387	25
	77	12	3.5	306	21
	78	8	2.1	376	24
	79	73	21.3	346	22
	80	18	4.6	369	25
	81	8	1.9	376	25
	82	12	3.3	377	24
	83	15	4.6	336	22
	84	14	3.4	410	25
	85	15	3.9	386	25
	86	1	0.3	297	19
	87	82	20.8	384	25
	88	11	2.8	392	25
	89	13	3.5	392	25

Individual Study Counts and Incidence					
EXAMINATION TYPE		VARIATIONS		Total Fetuses Examined	Total Litters Examined
Finding	Study Number	Number	% Per Litter		
SKELETAL					
Sternebra(e) #5 and/or #6 Unossified	90	4	1.2	344	23
	91	1	0.3	369	24
	92	8	2.1	368	25
	93	6	1.6	358	23
	94	5	1.2	389	25
	95	3	0.7	385	25
	96	32	8.0	376	25
	97	42	12.4	367	24
	98	6	1.8	344	23
	99	12	3.1	401	24
	100	8	2.9	336	22
	101	73	19.2	383	25
	102	92	22.2	405	27
	103	14	3.8	384	25
	104	10	2.8	386	25
	105	14	3.6	377	24
	106	8	2.1	361	25
	107	26	7.5	340	23
	108	5	1.4	365	25
	109	1	0.2	394	25
	110	1	0.3	400	25
	111	9	2.2	377	25
	112	10	2.6	355	24
	113	10	2.8	351	24
	114	19	5.0	375	25
	115	14	3.7	370	25
	116	10	2.5	389	25

Individual Study Counts and Incidence					
EXAMINATION TYPE		VARIATIONS		Total Fetuses Examined	Total Litters Examined
Finding	Study Number	Number	% Per Litter		
SKELETAL					
Sternebra(e) #5 and/or #6 Unossified	119	4	3.5	130	9
	122	19	5.0	391	25
	123	6	1.7	336	23
	124	9	2.5	365	24
	125	6	1.5	376	25
	126	104	26.1	383	23
	127	20	5.8	336	23
	128	22	5.8	383	24
	129	59	15.6	372	25
	130	20	5.4	371	25
	132	13	3.2	384	25
	133	18	4.4	356	25
	134	16	4.4	343	25
	135	15	4.3	370	24
	137	5	1.4	328	24
	138	24	6.4	351	22
	139	32	8.9	369	25
	140	12	3.9	333	23
	141	2	0.7	313	21
	143	10	2.5	388	25
	144	15	3.6	377	24
	145	70	18.8	346	23
	146	11	3.3	348	24
	149	5	1.4	345	23
	150	9	2.6	345	25
	151	8	2.2	370	24
	152	4	1.2	364	24

Individual Study Counts and Incidence					
		VARIATIONS			
EXAMINATION TYPE				Total Fetuses	Total Litters
Finding	Study Number	Number	% Per Litter	Examined	Examined
SKELETAL					
Sternebra(e) #5 and/or #6 Unossified	157	12	3.2	368	24
	158	11	2.9	363	25
	159	14	3.6	378	23
	160	51	12.2	410	24
	161	5	1.3	356	23
Sternebra(e)- Malaligned (Slight or Moderate)	1	1	0.3	309	22
	2	2	0.8	267	19
	4	2	0.6	357	25
	8	1	0.3	334	22
	15	2	0.6	380	25
	19	2	0.6	355	23
	20	1	0.3	379	24
	22	1	0.2	383	25
	24	1	0.3	328	23
	27	1	0.3	378	25
	32	1	0.3	328	22
	34	1	0.3	375	25
	37	2	0.5	378	25
	39	1	0.3	352	22
	41	1	0.3	388	25
	42	1	0.3	391	25
	45	1	0.3	355	25
	46	2	0.5	392	24
	47	1	0.3	416	25
	48	2	0.7	339	23
	49	1	0.2	380	24

APPENDIX G

Study Protocol



Study Number: WIL-402008

PROTOCOL AMENDMENT 2

Sponsor: American Petroleum Institute

Title of Study:

A Dermal Prenatal Developmental Toxicity Study of HPV Lube Oil in Rats

Protocol Modifications:

1) Title:

Per the Sponsor's request, the title is now referred to as the following:

A Dermal Prenatal Developmental Toxicity Study Of Solvent Dewaxed Heavy Paraffinic Distillates (Petroleum) (Cas# 64742-65-0) In Rats

2) Compound Reference:

Per Sponsor's request, the compound will be referred to as the following:

Solvent Dewaxed Heavy Paraffinic Distillates (Petroleum) (Cas# 64742-65-0)

3) 1 Objective:

The second paragraph is changed to the following:

This study is subject to the United States Environmental Protection Agency (EPA) Health Effects Test Guidelines OPPTS 870.3700, Prenatal Developmental Toxicity Study, August, 1998 and the Organisation of Economic Co-operation and Development Guidelines (OECD) for Testing of Chemicals Guideline 414, Prenatal Developmental Toxicity Study, January 2001, and will be conducted in accordance with the EPA (40 CFR Part 792 **and** 40 CFR 160) and OECD Good Laboratory Practice Regulations.

4) 10 Quality Assurance:

The first sentence of this paragraph is changed to the following:

The study will be audited by the WIL Quality Assurance Unit while in progress to assure compliance with the study protocol and protocol amendments, WIL Standard Operating Procedures and the appropriate provisions of the EPA TSCA (40 CFR Part 792) and FIFRA (40 CFR Part 160) Good Laboratory Practice Standards published in the Federal Register and the OECD Principles of Good Laboratory Practice, November 26, 1997 [C(97)186/Final].

Reasons for Protocol Modification:

- 1) Change title
- 2) Edit compound name
- 3-4) This study will also be audited according to FIFRA Good Laboratory Practice.

Approval:

Sponsor's approval was obtained via email on 13 April 2010.

American Petroleum Institute

[Redacted Signature]
[Redacted Name]
Sponsor Representative

19 Apr 2010
Date

WIL Research Laboratories, LLC

[Redacted Signature]
Study Director

14 Apr 2010
Date

[Redacted Signature]
Director, Developmental and
Reproductive Toxicology

14 Apr 2010
Date



Study Number: WIL-402008

PROTOCOL AMENDMENT I

- Sponsor: American Petroleum Institute

A. Title of Study:

A Dermal Prenatal Developmental Toxicity Study of HPV Lube Oil in Rats

B. Protocol Modifications:

1) 5.5 **Body Weight Range:**

In accordance with Study Director Notification form A-186-8 dated October 5, 2009, this section is replaced with the following:

A minimum of 210g at initiation of breeding.

2) 7.7.1 **Appearance and Behavior:**

In accordance with Study Director Notification form A-186-8 dated October 5, 2009, the first sentence is the second paragraph is replaced with the following:

During the treatment period, each animal will be observed at the time of dosing and at approximately 1-2 hours following each sham and dose administration for findings that are potentially related to treatment or that might change before the next scheduled observation.

3) 7.8.4.2 **Visceral (Internal):**

This last sentence is replaced with the following:

All carcasses, including the carcasses without heads, will be eviscerated, "skinned", and fixed in 100% ethyl alcohol for subsequent examination of skeletons.

C. Reason for Protocol Modifications:

- 1) The minimum body weight at the initiation of breeding is reduced by 10g to 210g.
- 2) Both sham and treated animals will be observed at the time of dosing and at 1-2 hours post-dose.

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WIL-402008
Protocol Amendment I
Page 2

- 3) Clarifies that pups will be skinned in preparation of skeletal staining.

Approved By:

American Petroleum Institute

[Redacted Signature]

Sponsor Representative

15 Oct 2009
Date

WIL Research Laboratories, LLC

[Redacted Signature]

Study Director

10/14/09
Date

[Redacted Signature]

Director, Developmental and
Reproductive Toxicology

14 Oct 2009
Date





PROTOCOL

A DERMAL PRENATAL DEVELOPMENTAL TOXICITY STUDY OF HPV LUBE OIL IN RATS

(U.S. EPA OPPTS and OECD Guidelines)

Submitted To:

American Petroleum Institute
1220 L Street, NW
Washington, DC 20005

WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805-8946

WIL RESEARCH LABORATORIES, LLC 1407 GEORGE ROAD ASHLAND, OH 44805-9281 (419) 289-8700 FAX (419) 289-3650

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1 OBJECTIVE:

The objective of this study is to determine the potential of dermal exposure to white mineral oil to induce developmental toxicity after maternal exposure during the critical period of organogenesis, to characterize maternal toxicity at the exposure levels tested and to determine a NOAEL (no-observed-adverse-effect level) for maternal toxicity and developmental toxicity. Additionally, this study aims to provide data to verify/expand the domain of the PAC (polycyclic aromatic compounds) prenatal models for predicting the toxicity of high-boiling petroleum substances from their PAC content and to further test the hypothesis that developmental toxicity endpoints are more sensitive to effects of high-boiling petroleum substances than other reproductive endpoints, such as fertility or reproductive organ weight and histopathology.

This study is subject to the United States Environmental Protection Agency (EPA) Health Effects Test Guidelines OPPTS 870.3700, Prenatal Developmental Toxicity Study, August, 1998 and the Organisation of Economic Co-operation and Development Guidelines (OECD) for Testing of Chemicals Guideline 414, Prenatal Developmental Toxicity Study, January 2001, and will be conducted in accordance with the EPA (40 CFR Part 792) and OECD Good Laboratory Practice Regulations.

2 PERSONNEL INVOLVED IN THE STUDY:

2.1 Sponsor Representative:

[REDACTED]
American Petroleum Institute
1220 L Street, NW
Washington, DC 20005
Tel: (202) 682-8333
Email: [REDACTED]

2.2 WIL Study Director:

[REDACTED]
Staff Toxicologist, Developmental and
Reproductive Toxicology
Tel: (419) 289-8700
Fax: (419) 289-3650
Email: [REDACTED]



2.3 WIL Departmental Responsibilities:

[REDACTED]
Director, Developmental and
Reproductive Toxicology

Emergency Contact

Tel: (419) 289-8700

Fax: (419) 289-3650

Email: [REDACTED]

[REDACTED]
President and Chief Operating Officer

[REDACTED]
Director, Pathology

[REDACTED]
Assistant Director, Neurosciences

[REDACTED]
Director, Metabolism and Analytical Chemistry

[REDACTED]
Clinical Veterinarian,
Head of Surgery and Experimental Medicine

[REDACTED]
Director, Informational Systems

[REDACTED]
Manager, Gross Pathology and
Developmental Toxicology Laboratory

[REDACTED]
Manager, Quality Assurance

[REDACTED]
Operations Manager, Developmental and
Reproductive Toxicology and the Formulations Laboratory

[REDACTED]
Manager, Reporting and Regulatory
Technical Services



3 STUDY SCHEDULE:

Proposed Animal Receipt Date (Experimental Starting Date):	September 22, 2009
Proposed Breeding Start Date:	October 6, 2009
Proposed Experimental Start Date:	October 6, 2009
Proposed Experimental Termination/ Completion Date:	October 30, 2009
Proposed Preliminary Quality Assurance Reviewed Tables and Interpretation:	November 13, 2009
Proposed Audited Draft Report	January, 2010

4 TEST ARTICLE DATA:**4.1 Test Article Shipment:**

Test article and applicable documentation, including a Certificate of Analysis, will be shipped under Sponsor's responsibility to:

Formulations Laboratory (WIL-402008; Adam J. Kuhl, PhD)
Attn. [REDACTED]
WIL Research Laboratories, LLC
1407 George Road
Ashland, Ohio 44805-8946

4.2 Identification:

HPV Lube Oil (Site# 23, Sample# 7)

4.3 Lot Number:

TA-125503

4.4 Expiration/Retest Date:

To be included in the study records.



4.5 Purity:

100%

4.6 Stability:

The test article is considered to be stable under the storage conditions provided by the Sponsor.

4.7 Physical Description:

To be documented by WIL Research Laboratories, LLC.

4.8 Storage Conditions:

Room temperature, protected from light.

4.9 Reserve Samples:

Reserve samples of the test article will be taken in accordance with WIL Standard Operating Procedures and stored in the Archives at WIL Research Laboratories, LLC indefinitely, unless otherwise specified.

4.10 Personnel Safety Data:

Provided by the Sponsor. A Material Safety Data Sheet (MSDS) accompanied the test article upon arrival at the laboratory.

4.11 Test Article Disposition:

With the exception of the reserve sample for each batch of test article, all neat test article remaining at study completion will be returned to the Sponsor (storage conditions, contact, address, fax number and telephone to be provided). Alternatively, the test article can be retained for subsequent studies.

5 TEST SYSTEM:**5.1 Species:**

Rat

5.2 Strain:

Sprague-Dawley Crl:CD(SD)



5.3 Source:

Charles River Laboratories, Inc.
(Raleigh, NC)

5.4 Number of Study:

50 females (maximum of 60 purchased). A sufficient number of sexually mature untreated resident males of the same strain and source will be used to induce pregnancies. Animals not assigned to the study will be transferred to the stock animal colony or will be euthanized by carbon dioxide inhalation and the carcasses discarded.

The number of animals selected for this study is based on the US EPA Health Effects Test Guidelines OPPTS 870.3700, Prenatal Development Toxicity Study, August 1998 and the OECD Guidelines for Testing of Chemicals Guideline 414, Prenatal Developmental Toxicity Study, January 2001.

5.5 Body Weight Range:

A minimum of 220g at initiation of breeding.

5.6 Approximate Age:

80 to 120 days at the initiation of breeding.

5.7 Identification System:

The animals will be uniquely identified by a Monel[®] metal ear tag displaying the animal number. Individual cage cards will be affixed to each cage and will display the animal number, group number, study number, dosage level and sex of the animal.

5.8 Justification for Selection:

This species and strain of rat has been recognized as appropriate for developmental toxicity studies. WIL Research Laboratories, LLC has historical data on the background incidence of fetal malformations and developmental variations in the CrI:CD(SD) rat. This animal model has been proven to be susceptible to the effects of developmental toxicants.



6 SPECIFIC MAINTENANCE SCHEDULE:

6.1 Animal Housing:

The rats will be individually housed (except during mating) in clean suspended wire-mesh cages in an environmentally controlled room during the study. The cages will be elevated above cage-board or other suitable material, which will be changed at least three times each week. Nesting material will not be provided, as euthanasia is scheduled prior to anticipated parturition. The cages will be subjected to routine cleaning at a frequency consistent with maintaining good animal health and WIL Standard Operating Procedures. The facilities at WIL Research Laboratories, LLC are fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

6.2 Acclimation to Collars:

Beginning one week (approximately) prior to randomization, all female animals will be acclimated to wearing collars. On the first day of the training period, the collars will be affixed to each rat for an approximate 1 hour period. On days two, three and four, the collars will be affixed to all animals for approximately 2 hours, 4 hours and 8 hours, respectively. Thereafter (except during cohabitation), the animals will be fitted with the collars continuously throughout dose administration.

6.3 Environmental Conditions:

Controls will be set to maintain temperature at $71 \pm 5^{\circ}\text{F}$ ($22 \pm 3^{\circ}\text{C}$) and relative humidity at $50 \pm 20\%$. Temperature and relative humidity will be monitored continuously. Data for these two parameters will be scheduled for automatic collection on an hourly basis. Fluorescent lighting controlled by light timers will provide illumination for a 12-hour light/dark photoperiod. The ventilation rate will be set at a minimum of 10 room air changes per hour, 100% fresh air.

6.4 Drinking Water:

Reverse osmosis-purified water will be available *ad libitum*. Filters servicing the automatic watering system are changed regularly according to WIL Standard Operating Procedures. The municipal water supplying the laboratory is analyzed according to WIL Standard Operating Procedures on a routine basis to ensure that contaminants are not present in concentrations that would be expected to affect the outcome of the study.



6.5 Basal Diet:

PMI Nutrition International, LLC Certified Rodent LabDiet® 5002 will be offered *ad libitum* during the study. Periodic analyses of the certified feed are performed by the manufacturer to ensure that heavy metals and pesticides are not present at concentrations that would be expected to affect the outcome of the study. Results of the analyses are provided to WIL Research Laboratories, LLC by the manufacturer. Feeders will be changed and sanitized once per week.

7 EXPERIMENTAL DESIGN:

7.1 Animal Receipt and Quarantine:

Each rat will be inspected by a qualified technician upon receipt. Rats judged to be in good health and suitable as test animals will be immediately placed in quarantine for a minimum of 14 days. During this quarantine period, animals will be acclimated to wearing collars as described above in Section 6.2. All rats will be initially weighed, permanently identified with a metal ear tag and receive a clinical observation. During the quarantine period, each rat will be observed twice daily for changes in general appearance and behavior. Body weights may be recorded prior to the initiation of breeding. Prior to the start of the in-life phase, those rats judged to be suitable test subjects will be identified.

7.2 Breeding Procedure:

At the conclusion of the quarantine period, female rats judged to be suitable test subjects and meeting acceptable body weight requirements will be cohabitated with an untreated male (1:1) of the same source and strain. Detection of mating will be confirmed by evidence of a vaginal copulatory plug or by a vaginal lavage for sperm. After confirmation of mating, the female will be returned to an individual suspended wire-mesh cage (assigned to a group), and the day will be designated as day 0 of gestation.

7.3 Randomization:

Mated females will be assigned to groups using a WIL Toxicology Data Management System (WTDMS™) computer program which assigns animals based on stratification of gestation day 0 body weights into a block design to one control group and one test article group of 25 rats each.

Any animal assigned to the study that is found dead, euthanized *in extremis* or exhibits abnormal clinical signs, reduced food consumption or body weight losses prior to the start of dosing may be replaced by an animal of appropriate gestation age when possible. Replacement animals will be arbitrarily assigned



(not computer randomized) to the study based on comparable body weights (if possible) with respect to the animal that was replaced.

7.4 Route and Rationale of Test Article Administration:

The route of administration will be dermal as this is a potential route of exposure for humans.

All animals will be clipped in the dorsal scapular area (covering approximately 10% of the body surface) prior to the start of dose administration and, as needed, thereafter during the administration period (repeated clippings will be performed prior to or at least 2-4 hours after dose administration). A different set of clippers will be used for control and treated animals to avoid potential for cross-contamination. Care will be taken not to abrade the skin. The test article and vehicle will be applied approximately in the center of the clipped area and distributed to avoid running.

Elizabethan-style collars will be used to minimize ingestion of the test material. Collars will be worn continuously during the dosing period. Collars will be fitted on the rats several days prior to the initiation of dosing and replaced as necessary during the dosing period.

7.5 Organization of Test Groups, Dosage Levels and Treatment Regimen:

7.5.1 Organization of Test Groups:

The dosage levels were determined from results of previous studies and were provided by the Sponsor Representative after consultation with the WIL Study Director.

The following table presents the study group arrangement.

Group Number	Test Article	Dosage Level (mg/kg/day)	Dosage Concentration (mg/mL)	Dosage Volume (mL/kg)	Number of Females
1	Sham	0	0	0	25
2	HPV Lube Oil ^a	1000	Neat	1.14	25

a - density = 0.875g/mL

7.5.1 Vehicle Control Article:

The test article will be applied as supplied by sponsor. Therefore, no vehicle will be used.



7.5.2 Sham Control:

The Group 1 sham control animals will be subject to the same procedures (i.e. shaving and collaring) as the Group 2 animals. However, no vehicle or carrier will be applied to the sham control animals.

7.5.3 Treatment Regimen:

The test article will be administered as a single daily dose, applied over as much of the the clipped dorsal scapular area (approximately 10% of total body surface area) as possible and distributed to avoid running, during the period of major organogenesis, gestation days 0 through 19. If the test substance does not cover at least 10% of the total body surface, the actual body surface area covered by the test substance will be documented for 2 representative rats/sex/group. All rats will be dosed at approximately the same time each day.

7.5.4 Adjustment of Doses:

Individual dosages will be calculated on the most recent body weight to provide the proper mg/kg/day dosage.

7.6 Preparation and Analysis of Test Article Formulations:**7.6.1 Method and Frequency of Preparation:**

The test article will be administered as supplied by the Sponsor, therefore, no formulation will be necessary.

7.6.2 Mass Balance:

The total amount left in the container(s) will be weighed daily and compared to the theoretical amount used.

7.6.3 Homogeneity, Stability and Concentration of Test Article Formulations:

The test article will be administered as supplied by the Sponsor, therefore, no additional analysis will be conducted.



7.7 Maternal Observations During Gestation:

7.7.1 Appearance and Behavior:

Each rat will be observed twice daily for moribundity and mortality, once in the morning and once in the afternoon from gestation day 0 until euthanasia. Clinical observations will be recorded daily. Mortality and all signs of overt toxicity will be recorded on the day observed. The observations shall include, but are not limited to, evaluation for changes in appearance of skin and fur, eyes, mucous membranes, respiratory and circulatory system, autonomic and central nervous systems, somatomotor activity and behavior. All animals will also be observed on the day of necropsy and any findings will be recorded.

During the treatment period, each animal will be observed at approximately 1-2 hours following each dose administration for findings that are potentially related to treatment or that might change before the next scheduled observation. Additional post-dosing observation periods may be necessary and will be documented in the study records.

7.7.2 Dermal Observations:

Application sites will be examined for erythema, edema and other dermal findings daily (prior to dose administration) using a four-step grading system in accordance with the method of Draize (Appendix A), and inspected for remarkable changes. Other dermal findings, if present, will be noted.

7.7.3 Body Weights:

Individual body weights will be recorded once prior to breeding and on gestation days 0, 3, 6, 9, 12, 15, 18, and 20. Collars will be removed during collection of body weights.

7.7.4 Food Consumption:

Individual food consumption will be recorded on gestation days 0, 3, 6, 9, 12, 15, 18, and 20. Food intake will be reported as g/animal/day and g/kg/day for each corresponding body weight interval of gestation.

7.7.5 Deaths and Animals Euthanized *in Extremis*:

Females not surviving until the scheduled euthanasia will be necropsied and cause of death recorded, if possible. Rats not expected to survive to the next observation period (moribund) will be euthanized by carbon



dioxide inhalation. The cranial, thoracic, abdominal and pelvic cavities will be opened and the organs examined. The number and location of implantation sites and viable fetuses will be recorded. Corpora lutea will also be counted and recorded. Gross lesions will be preserved in 10% neutral-buffered formalin for possible future histopathologic examination. Sham and treated skin from the application site will be preserved in 10% neutral-buffered formalin for histopathologic examination. Carcasses from adult animals will be discarded. Viable fetuses will be euthanized by hypothermia followed by an intrathoracic injection of sodium pentobarbital, if necessary. Recognizable fetuses will be examined externally and preserved in 10% neutral-buffered formalin.

7.7.6 Premature Deliveries:

Females that deliver prematurely will be euthanized by carbon dioxide inhalation that day. The thoracic, abdominal and pelvic cavities will be opened and the organs examined. The number and location of former implantation sites and viable fetuses will be recorded. Corpora lutea will also be counted and recorded. Gross lesions will be preserved in 10% neutral-buffered formalin for possible future histopathologic examinations. Sham and treated skin from the application site will be preserved in 10% neutral-buffered formalin for histopathologic examination. Carcasses from adult animals will be discarded. Viable fetuses will be euthanized by hypothermia followed by an intrathoracic injection of sodium pentobarbital (if needed). Viable pups will be euthanized by an intraperitoneal injection of sodium pentobarbital. Recognizable fetuses or pups will be examined externally and preserved in 10% neutral buffered formalin. Recognizable fetuses or pups aborted on GD 20 will be examined according to Section 7.8.4, if possible.

7.8 Gestation Day 20 Terminal Procedures:

7.8.1 Laparohysterectomy and Macroscopic Examination:

Laparohysterectomy and macroscopic examinations will be performed blind to treatment group. All surviving rats will be euthanized by carbon dioxide inhalation on gestation day 20. The thoracic, abdominal and pelvic cavities will be opened and the organs examined. The uterus of each dam will be excised and its adnexa trimmed. Corpora lutea will be counted and recorded. Gravid uterine weights will be obtained and recorded. The uterus of each dam will be opened and the number of viable and nonviable fetuses, early and late resorptions and total number of implantation sites will be recorded, and the placentae will be



examined. The individual uterine distribution will be documented using the following procedure: all implantation sites, including early and late resorptions, will be numbered in consecutive fashion beginning with the left distal uterine horn, noting the position of the cervix and continuing from the proximal to the distal right uterine horn. Uteri which appear nongravid by macroscopic examination will be opened and placed in a 10% ammonium sulfide solution as described by Salewski (Salewski, 1964) for detection of early implantation loss. Maternal tissues will be preserved for future histopathologic examination in 10% neutral-buffered formalin only as deemed necessary by the gross findings. Representative sections of corresponding organs from a sufficient number of controls will be retained for comparison, if possible. The carcasses will be discarded. Sham and treated skin from the application site will be preserved in 10% neutral-buffered formalin for histopathologic examination.

7.8.2 Organ Weights:

The following organs will be weighed from all animals euthanized at scheduled termination.

Adrenal glands
Thymus

Gravid Uteri w/
cervix

7.8.3 Microscopic Examinations:

Microscopic examination of hematoxylin-eosin stained paraffin sections will be performed on untreated skin for the control group animals, treated and untreated skin for the test article group animals and all gross lesions from all animals.

7.8.4 Fetal Examination:

Fetal examinations will be conducted without knowledge of treatment group. External, internal and skeletal fetal findings will be recorded as developmental variations or malformations. Representative photographs of all malformations, as appropriate, will be included in the study records. Corresponding low magnification photographs, depicting both the malformed fetus and a comparison control fetus, or normal littermate, will also be included in the study records as needed and as appropriate for comparison, when possible. Prenatal data (viable and nonviable fetuses, early and late resorptions, pre- and post-implantation loss and the fetal sex distribution) will be presented on a group mean basis and additionally as proportional data (% per litter).



7.8.4.1 External:

Each viable fetus will be examined in detail, sexed, weighed, euthanized by hypothermia followed by an intrathoracic injection of sodium pentobarbital (if necessary), and tagged. Nonviable fetuses (the degree of autolysis is minimal or absent) will be examined, crown-rump length measured, weighed, sexed and tagged individually. The crown-rump length of late resorptions (advanced degree of autolysis) will be measured, the degree of autolysis recorded, a gross external examination performed (if possible) and the tissue will be discarded.

7.8.4.2 Visceral (Internal):

Fetuses will be examined for visceral anomalies by dissection in the fresh (non-fixed) state. The thoracic and abdominal cavities will be opened and dissected using a technique described by Stuckhardt and Poppe (Stuckhardt, 1984). Fetal kidneys will be examined and graded for renal papillae development (Woo and Hoar, 1972). This examination will include the heart and major vessels. The sex of all fetuses will be confirmed by internal examination.

The heads will be removed from approximately one-half of the fetuses in each litter and placed in Bouin's solution for subsequent processing and soft-tissue examination using the Wilson sectioning technique (1965).

The heads from the remaining one-half of the fetuses in each litter will be examined by a mid-coronal slice.

All carcasses, including the carcasses without heads, will be eviscerated and fixed in 100% ethyl alcohol for subsequent examination of skeletons.

7.8.4.3 Skeletal:

Each eviscerated viable and non-viable fetus, following fixation in alcohol, will be stained with Alizarin Red S and Alcian Blue by a method similar to that described by Dawson (1926) and Inouye (1976).



8 DURATION OF STUDY:

The quarantine, breeding and gestation phases of the study will require approximately two months. The laparohysterectomy phase of the study and processing and evaluation of the fetal specimens will require approximately four weeks.

9 STATISTICAL METHODS:

All analyses will be two-tailed for significance levels of 5% and 1%. All statistical tests will be performed using a computer with appropriate programming as referenced below. The litter, rather than the fetus, will be considered as the experimental unit.

9.1 Maternal In-Life Data:

Continuous data variables [mean body weights (absolute and net), body weight gains (absolute and net) and food consumption of each interval] will be subjected to a parametric two sample t-test (Dunnett, 1964) to determine intergroup difference.

9.2 Laparohysterectomy Data:

The group mean numbers of corpora lutea, implantation sites, viable fetuses, maternal gravid uterine weights and mean fetal weight (separately by sex, and combined) will be subjected to a parametric two sample t-test (Dunnett, 1964) to determine intergroup difference. The mean litter proportions of prenatal data (% per litter of viable and nonviable fetuses, early and late resorptions, total resorptions, pre- and post-implantation loss and the fetal sex distribution) will be subjected to the Dunn's Test (1964) to determine intergroup difference.

9.3 Fetal Morphology Data:

The mean litter proportion (% per litter) of total fetal malformations and developmental variations (external, visceral, skeletal and combined) and of each particular external, visceral and skeletal malformation or variation will be tabulated. The mean litter proportions of fetal malformations and developmental variations will be subjected to the Dunn's Test (1964) to determine intergroup difference.

9.4 Organ Weight Data:

Organ weights will be subjected to a parametric two sample t-test (Dunnett, 1964) to determine intergroup difference as described above.



10 QUALITY ASSURANCE:

The study will be audited by the WIL Quality Assurance Unit while in progress to assure compliance with the study protocol and protocol amendments, WIL Standard Operating Procedures and the appropriate provisions of the EPA TSCA Good Laboratory Practice Standards published in the Federal Register (40 CFR Part 792) and the OECD Principles of Good Laboratory Practice, November 26, 1997 [C(97)186/Final]. The raw data and draft report will be audited by the WIL Quality Assurance Unit prior to submission to the Sponsor to assure that the final report accurately describes the conduct and the findings of the study.

This study will be included on the WIL master list of regulated studies.

11 RECORDS TO BE MAINTAINED:

All original raw data records, as defined by WIL SOPs and the applicable GLPs, will be stored as described in Section 12 in the Archives at WIL Research Laboratories, LLC.

12 WORK PRODUCT:

The Sponsor will have title to all documentation records, raw data, specimens or other work product generated during the performance of the study. All remaining formulation samples will not be archived, but will be discarded upon issuance of the Final Report. All work product, including raw paper data, pertinent electronic storage media and specimens, will be retained at no charge for six months following issuance of the final report in the Archives at WIL Research Laboratories, LLC. Thereafter, WIL Research Laboratories, LLC will charge a monthly archiving fee for retention of all work product. All work product will be stored in compliance with regulatory requirements.

Any work product, including documents, specimens, and samples, that are required by this protocol, its amendments, or other written instructions of the Sponsor, to be shipped by WIL Research Laboratories, LLC to another location will be appropriately packaged and labeled as defined by WIL's SOPs and delivered to a common carrier for shipment. WIL Research Laboratories, LLC will not be responsible for shipment following delivery to the common carrier.

13 REPORTS:

Within two weeks of necropsy, the following data will be audited by Quality Assurance:

- Terminal maternal body weight
- Maternal absolute thymus weight



- Live fetuses per litter
- Resorptions per litter
- Individual fetal body weights and sex

A brief report including the data with explanation and interpretation will be prepared and sent to the study monitor.

The final report will contain a summary, test article data, methods and procedures, maternal and fetal data, WIL Historical Control Data, and an interpretation and discussion of the study results. The final report will be comprehensive and shall define level(s) inducing toxic effects as well as no effect level(s) under the condition of this investigation. The report will contain all information necessary to conform with current EPA OPPTS and OECD specifications.

WIL Research Laboratories, LLC will submit one copy of an audited draft report in a timely manner upon completion of data collection prior to issuance of the final report. One revision will be permitted as part of the cost of the study, from which the Sponsor's reasonable revisions and suggestions will be incorporated into the final report, as appropriate. Additional changes or revisions may be made, at extra cost. It is expected that the Sponsor will review the draft report and provide comments to WIL Research Laboratories, LLC within a two-month time frame following submission. WIL Research Laboratories, LLC will submit the final report within one month following receipt of comments. If the Sponsor's comments and/or authorization to finalize the report have not been received at WIL Research Laboratories, LLC within one year following submission of the draft report, WIL Research Laboratories, LLC may elect to finalize the report following appropriate written notification to the Sponsor. Two electronic copies (PDF) of the final report on CD-R will be provided. Requests for paper copies of the final report may result in additional charges.

14 ANIMAL WELFARE ACT COMPLIANCE:

This study will comply with all applicable sections of the Final Rules of the Animal Welfare Act (AWA) regulations (9 CFR Parts 1, 2 and 3). The Sponsor should make particular note of the following:

- The Sponsor Representative's signature on this protocol documents for the Study Director the Sponsor's assurance that the study described in this protocol does not unnecessarily duplicate previous experiments.
- Whenever possible, procedures used in this study have been designed to avoid or minimize discomfort, distress or pain to animals. All methods are described in this study protocol or in written laboratory Standard Operating Procedures.



- Animals that experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized as deemed appropriate by the veterinary staff and Study Director. The Sponsor will be advised by the Study Director of all circumstances which could lead to this action in as timely a manner as possible.
- Methods of euthanasia used during this study are in conformance with the above-referenced regulation.
- The Sponsor/Study Director has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and has provided a written narrative description (AWA covered species only) of the methods and sources used to determine that alternatives are not available.

15 PROTOCOL MODIFICATION:

Modification of the protocol may be accomplished during the course of this investigation. However, no changes will be made in the study design without the verbal or written permission of the Sponsor. In the event that the Sponsor verbally requests or approves a change in the protocol, such changes will be made by appropriate documentation in the form of a protocol amendment. All alterations of the protocol and reasons for the modification(s) will be signed by the Study Director and the Sponsor Representative.

16 REFERENCES:

- Dawson, A.B. A note on the staining of the skeleton of cleared specimens with Alizarin Red S. *Stain Technology* **1926**, *1*, 123-124.
- Dunn, O.J. Multiple comparisons using rank sums. *Technometrics* **1964**, *6*(3), 241-252.
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[REDACTED]
Sponsor Representative

22 Sept 2009
Date

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APPENDIX A**SCORING CRITERIA FOR DERMAL REACTIONS****Evaluation of Dermal Reactions***

<u>Value</u>	<u>Erythema and Eschar Formation</u>	<u>Computer Designation</u>
0	No erythema	No erythema
1	Very slight erythema (barely perceptible, edges of area not well defined)	Very slight erythema
2	Slight erythema (pale red in color and edges definable)	Slight erythema
3	Moderate to severe erythema (definite red in color and area well defined)	Moderate erythema
4	Severe erythema (beet or crimson red) to slight eschar formation (injuries in depth)	Severe erythema
	<u>Edema Formation</u>	<u>Computer Designation</u>
0	No edema	No edema
1	Very slight edema (barely perceptible, edges of area not well defined)	Very slight edema
2	Slight edema (edges of area well defined by definite raising)	Slight edema
3	Moderate edema (raised approximately 1 mm)	Moderate edema
4	Severe edema (raised more than 1 mm and extending beyond area of exposure)	Severe edema

*Draize, J. H., 1965. The Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Dermal Toxicity, pp. 46-59. Assoc. of Food and Drug Officials of the U.S., Topeka, Kansas.

