RCC Study Number 851839

raw material No.: 23081

2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE:

Prenatal Developmental Toxicity Study

in the Rat

Report

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Dr. D. Flade

Sponsor:

Study Completion Date: October 14, 2004

RCC

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1 PREFACE

1.1 GENERAL

Title	2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE: Prenatal developmental toxicity study in the rat
Sponsor	
Study Monitor	
Test Facility	(a) RCC Ltd Toxicology Operational Unit: Safety Assessment I Wölferstrasse 4 CH-4414 Füllinsdorf / Switzerland
Test Site	(b) RCC Ltd Environmental Chemistry & Pharmanalytics Zelgliweg 1 CH-4452 Itingen / Switzerland
Lead QA	RCC Ltd Quality Assurance GLP Toxicology CH-4452 Itingen / Switzerland
Test Site QA	RCC Ltd Quality Assurance GLP Environmental Chemistry & Pharmanalytics CH-4452 Itingen / Switzerland (responsible for test site (b))

1.2 RESPONSIBILITIES

Study Director	H. Becker (a)
Deputy Study Director	Dr. A. Marburger (a)
Technical Coordinator	D. Frei (a)
Principal Investigator: Study Phase: Analytical Chemistry	Dr. D. Flade (b)
Head of Lead QA	I. Wüthrich

1.3 SCHEDULE

Delivery of the female rats	12-MAR-2004
Experimental Starting Date (Initiation of pairing)	22-MAR-2004
Day 0 post coitum for the first mated females	23-MAR-2004
First Treatment (day 6 p.c.)	29-MAR-2004
Start Necropsy	13-APR-2004
Last Caesarean sections	16-APR-2004
Experimental Completion Date	10-AUG-2004

1.4 ANIMAL WELFARE

In-life part was performed in an AAALAC-approved laboratory in accordance with the Swiss Animal Protection Law under license no. 23.

1.5 TEST GUIDELINES

This study was conducted in compliance with OECD guidelines (OECD guideline for testing of chemicals proposal for updating guideline 414, prenatal developmental toxicity study. Adopted: 22nd January 2001) and EEC guidelines (Commission Directive 88/302/EEC, Official Journal of the European Communities L 133, dated May 30, 1988) and US-EPA guidelines (Health Effects Test Guidelines, OPPTS 870.3700 'Prenatal Development Toxicity Study', EPA 712-C-98-207, dated August 1998).

1.6 ARCHIVING

RCC Ltd (CH-4452 Itingen/Switzerland) will retain the study plan, raw data, sample of test item(s), specimens (as long as the quality permits evaluation) and the final report of the present study for at least ten years. Wet tissue samples will be archived at RCC Ltd for a minimum of five years. Thereafter, in agreement with the Sponsor, these samples may be further archived at RCC Ltd or transferred to another GLP archive facility for the remainder of the prescribed period. No data will be discarded without the Sponsor's consent.

1.7 SIGNATURES

STUDY DIRECTOR: H. Becker

.....
date: 14-OCT-2004

DEPUTY FOR STUDY DIRECTOR: Dr. A. Marburger

.....
date: 14-OCT-2004

TEST FACILITY MANAGEMENT: for Dr. H. Fankhauser

.....
date: 14. OCT-2004

GOOD LABORATORY PRACTICE

1.8 STATEMENT OF COMPLIANCE

RCC STUDY NUMBER:	851839
TEST ITEM:	2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE
STUDY DIRECTOR:	H. Becker
TITLE:	2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE: Prenatal developmental toxicity study in the rat

This study was conducted in compliance with the Good Laboratory Practice Regulations listed below:

Swiss Ordinance relating to Good Laboratory Practice, adopted February 2nd, 2000 [RS 813.016.5]. This Ordinance is based on the OECD Principles of Good Laboratory Practice, as revised in 1997 and adopted November 26th, 1997 by decision of the OECD Council [C (97)186/Final].

Study Director: H. Becker

.....
date: 14-OCT-2004

1.9 QUALITY ASSURANCE UNIT

RCC Ltd, Toxicology, CH-4452 Itingen / Switzerland

STATEMENT

RCC STUDY NUMBER:	851839
TEST ITEM:	2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE
STUDY DIRECTOR:	H. Becker
TITLE:	2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE: Prenatal developmental toxicity study in the Han Wistar rat

The general facilities and activities are inspected periodically and the results are reported to the responsible person and the management.

Study procedures were periodically inspected. The study plan and this report were audited by the Quality Assurance Unit. The dates are given below.

Dates and Types of QAU Inspections		Dates of Reports to the Study Director and to Management
11-MAR-2004	Study plan	11-MAR-2004
29-MAR-2004	Test item, treatment	29-MAR-2004
31-MAR-2004	Treatment, raw data	31-MAR-2004
13-APR-2004	Necropsy, raw data	13-APR-2004
15-APR-2004	Microdissection	15-APR-2004
01-02-SEP-2004	Report	02-SEP-2004

This statement also confirms that this final report reflects the raw data.

This final report includes a QAU-Statement issued by the Test Site Quality Assurance Unit.

Quality Assurance V. Gros

.....

date: 14-OCT-2004

2 SUMMARY

The purpose of this study was to assess the effects of 2-AMINO-4-HYDROXYETHYL-AMINOANISOLE SULFATE on the pregnant female and on embryonic and fetal development when administered orally, by gavage once daily to mated female rats from day 6 (implantation) through to day 20 post coitum (one day prior to scheduled Caesarean section, inclusive.

Each group consisted of 22 mated female rats. 2-AMINO-4-HYDROXYETHYLAMINO-ANISOLE SULFATE was administered once daily at dose levels of:

Group 1: 0 mg/kg body weight/day (vehicle control)
Group 2: 10 mg/kg body weight/day
Group 3: 30 mg/kg body weight/day
Group 4: 150 mg/kg body weight/day

A standard dose volume of 10 ml/kg body weight with a daily adjustment to the actual body weight was used. Control animals were dosed with the vehicle alone (bi-distilled water).

All surviving females were sacrificed on day 21 post coitum and the fetuses were removed by Caesarean section. Examination of dams and fetuses was performed in accordance with international recommendations.

The following results were obtained:

MATERNAL DATA

General Tolerability

No death occurred and no macroscopic findings were noted which were considered to be test item related.

At 30 and 150 mg/kg/day, dark discoloration of urine and bedding from day 6 post coitum (first day of treatment) onwards were noted. These discolorations were considered to be due to the presence of test item (and/or metabolites) and were considered to be of no adverse character.

Food Consumption and Body Weights

At 150 mg/kg, the mean food consumption was slightly reduced (7.4% vs vehicle control) during the entire treatment period whereas the mean body weight gain was slightly reduced only up to day 16 post coitum. Further, the corrected mean body weight gain (corrected for gravid uterus weight) was slightly lower (+3.4% vs +7.4% in the vehicle control).

Reproduction Data

No differences between groups were considered to be test item related were noted among the relevant reproduction data (post-implantation loss, number of fetuses per dam).

FETAL DATA

Body Weights and Sex Ratios

No test item related effects on fetal body weights or sex ratios were noted.

External Examination

In the vehicle control, one fetus was noted with malformation of the head (including upper and lower jaw).

Visceral Examination

No test item related abnormalities were noted during visceral examination of fetuses.

Skeletal and Cartilage Examinations

No abnormalities, that were considered to be test item related, were noted during examination of fetal skeletals and cartilages.

3 CONCLUSION

In order to detect effects on embryonic and fetal development in pregnant rats, 2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE was administered orally by gavage once daily from day 6 through to day 20 post coitum at dose levels of 0, 10, 30 and 150 mg/kg body weight/day.

Treatment with the test item at 150 mg/kg body weight/day resulted in slightly reduced food consumption, slightly decreased body weight gain and dark discoloration of urine and bedding. At 30 mg/kg body weight/day only discoloration of urine and bedding was observed. These discolorations observed at 30 and 150 mg/kg body weight/day were considered to be due to the presence of test item (and/or metabolites) and was considered to be of no adverse character.

Based on these results the NOAEL (no observed adverse effect level) for maternal organisms was considered to be 30 mg/kg body weight/day.

The NOEL (no observed effect level) for fetal organisms was considered to be 150 mg/kg body weight/day.

Under the conditions described for this study 2-AMINO-4-HYDROXYETHYLAMINO-ANISOLE SULFATE revealed no teratogenic potential up to and including the highest dose level of 150 mg/kg body weight/day.

4 PURPOSE

The purpose of this study was to assess the effects of the test item on the pregnant female and on embryonic and fetal development when administered orally by gavage once daily to mated female rats from day 6 (implantation) through to day 20 post coitum (one day prior to scheduled Caesarean section), inclusive.

4.1 RATIONALE FOR CHOICE OF SPECIES, ROUTE OF ADMINISTRATION AND DOSE LEVELS

The rat is a suitable rodent species for development toxicity studies required by regulatory authorities. The oral route is one possible route for human exposure. Dose levels were selected in conjunction with the Sponsor, based on the results of a previous dose range-finding study in pregnant rats (RCC study number 851838, Wella raw material No. 23081). In this study, animals were treated with 0, 10, 30 and 90 mg/kg from day 6 to 20 of pregnancy. Slightly reduced food consumption and body weight gain were noted. Therefore the highest dosage for the main study was increased to 150 mg/kg body weight/day. There was no teratogenic effect.

5 MATERIALS AND METHODS

5.1 TEST SYSTEM

Species	Rat HanBrl:WIST (SPF)
Rationale	Specified by the international guidelines as a recommended test system
Source	RCC Ltd Laboratory Animals Services Wölferstrasse 4 CH-4414 Füllinsdorf / Switzerland
Acclimatization	Ten days prior to mating with an evaluation of the health status.
Number of animals	88 mated females, 22 per group
Age at delivery	10 weeks minimum
Body weights (day 0 post coitum)	189 - 257 grams
Identification (day 0 post coitum)	Individual animal number tattooed on the pinnae

5.2 HUSBANDRY

Room number	015.B
Conditions	Animals were housed under standard laboratory conditions: air-conditioned with 10-15 air changes per hour; the environment monitored continuously with recordings of temperature (target range 22 ± 3°C) and relative humidity (target range 30-70%), 12 hours artificial fluorescent light / 12 hours dark with background music played at a centrally defined low volume for at least 8 hours during the light period.
Accommodation	Individually (except during mating) in Makrolon cages (type-3) with wire mesh tops and standardized granulated softwood bedding (Lignocel, Schill AG, CH-4132 Muttenz/Switzerland).
Diet	Pelleted standard Kliba-Nafag 3433 rat/mouse maintenance diet (Provimi Kliba AG, CH-4303 Kaiseraugst/ Switzerland) was available *ad libitum* (Batch No. 78/03). The results of analysis for contaminants are presented in Attachment II (pp. 121, 122).
Water	Community tap water from Füllinsdorf in bottles was available *ad libitum*. The results of the bacteriological, chemical and contaminant analyses scheduled to be conducted at least once yearly by RCC (contaminant analyses only) and by the Official Chemist of the Kanton Basel-Landschaft (bacteriological and chemical analyses) are presented in Attachment I (pp. 117 - 119).

5.3 TEST ITEM

The test item and the information concerning the test item were provided by the Sponsor (see analytical certificate pp. 124, 125).

raw material No.	23081
Identity	2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE
Batch number	Ch. 57/01 (R96000195; R96000196)
Cas-No.	83763-48-8
Description	Pale grey powder
Purity	93.5 weight %; determined by NMR
Storage	Keep tightly closed in a dry, cool and well-ventilated place. Protect from humid air and water as well as from heat and direct sunlight.
Expiry date	July, 2005
Stability in the vehicle (water)	See Certificate of Analysis (p. 125)
Safety precautions	Dust mask, gloves and goggles were applied to ensure personnel security.

5.4 VEHICLE AND CONTROL ITEM

Bi-distilled water was used as the vehicle for the test item in the dose groups and was administered as the control item to the females of the control group.

5.5 DOSE FORMULATION

Dose formulations were prepared in terms of test item as supplied by the Sponsor.

Frequency of dose formulation Daily

The test item was weighed into a glass beaker on a tared precision balance and the vehicle added (w/v). The mixtures were prepared using a homogenizer. During the daily administration period, homogeneity was maintained using a magnetic stirrer.

5.5.1 ANALYSIS OF DOSE FORMULATIONS

During the first and last week of the administration period samples for determination of concentration, homogeneity and stability (first week only) were taken. The samples of approximately 2 g were transferred into flat bottomed flasks and frozen (-25°C to -15°C) pending analyses.

For determination of homogeneity, samples were taken from the top, middle and bottom of each formulation. The mean values from these analyses also represent the concentration and stability immediately after preparation.

Further samples for determination of stability were taken after 4 hours storage at room temperature (22 ± 3°C).

Samples were sent with dry ice to Dr. D. Flade, RCC Ltd, Environmental Chemistry & Pharmanalytics, CH-4452 Itingen / Switzerland. Analysis was performed using an external standard method provided by the Sponsor (HPLC). The Analytical Phase report is presented in Attachment IV (pp. 127 - 140).

5.6 STUDY SCHEDULE (SCHEMATIC DIAGRAM)

Days of study		
Acclimatization		
:		
:		
:		
:	Pairing	
:		
:		
:		
–	Day 0 post coitum	
:		
:		
:		
:		
:		
–	Day 6 post coitum	(first treatment)
:		
:		
:		
:		
:		
:		
:		
:		
:		
:		
:		
:		
–	Day 20 post coitum	(last treatment)
–	Day 21 post coitum	(Cesarean section, necropsy)

5.7 PROCEDURES, OBSERVATIONS, DATA RECORDING AND COMPILATION

5.7.1 PROCEDURES

Mating

After acclimatization, the females were housed with the males (one male : one female) in special automatic mating cages, i.e. with synchronized timing to initiate the night mating period, until evidence of copulation was observed. This system reduced the variation in the copulation times of the different females. The females were removed and housed individually if:

a) the daily vaginal smear was sperm-positive, or

b) a copulation plug was observed.

This day was designated day 0 post coitum.

The male rats used for mating were in the possession of RCC. The fertility of these males was proved and continuously controlled.

Allocation of mated females to the test groups

Group	Female Numbers	Dose* mg/kg body weight/day
1	1 - 22	0 (vehicle control)
2	23 - 44	10
3	45 - 66	30
4	67 - 88	150

* = Dose levels were in terms of material as supplied by the Sponsor.

Method of allocation

Mated rats were assigned to the different groups using a computer-generated random algorithm.

Administration

The test item was administered orally, by gavage, once daily from day 6 (first treatment) through to day 20 post coitum (last treatment). All animals received a dose volume of 10 ml/kg body weight with a daily adjustment of the individual volume to the actual body weight. Control animals were similarly dosed with the vehicle (bi-distilled water) alone.

5.7.2 OBSERVATIONS

Mortality rate

Animals were checked at least twice daily for mortalities, morbidity or signs of abortion. Animals found dead were necropsied.

Signs and/or symptoms

Animals were observed at least twice daily for clinical signs.

5.7.3 DATA RECORDING

Food consumption

Food consumption was recorded on 3-day intervals: days 0-3, 3-6, 6-9, 9-12, 12-15, 15-18 and 18-21 post coitum (see 5.7.4: Data Compilation and 5.8: Data Processing).

Body weight

Body weights were recorded daily from day 0 until day 21 post coitum (see 5.7.4: Data Compilation and 5.8: Data Processing).

Termination of the study

On day 21 post coitum, just prior to expected delivery, females were killed by CO_2 and the fetuses were removed by Cesarean section.

Cesarean section and post mortem examination

At necropsy, the main organs of the thoracic and abdominal cavities, in particular the genitals were examined. Number of corpora lutea in each ovary and the weight of uterus including contents were recorded.

Uterine contents:

1. In dams at scheduled necropsy:

- number and location of live and dead fetuses
- number and location of early and late (embryonic/ fetal) losses
- uteri that appeared non-gravid were further examined (e.g. by ammonium sulfide staining) to confirm the non-pregnant status

2. In dams sacrificed or dying before scheduled necropsy:

- number and location of implantation sites
- uteri that appeared non-gravid were further examined (e.g. by ammonium sulfide staining) to confirm the non-pregnant status

Live fetuses were removed from the uterus, sexed, weighed individually, examined for gross external abnormalities, killed by subcutaneous injection of sodium pentobarbital (Vetanarcol®) in the scruff and allocated to either visceral or skeletal evaluation (using a computer-generated random program) at an approximate 1:1 ratio within each litter, independent of sex. In the case of gross external malformation, fetuses were allocated to the alternate technique depending on the type of finding.

1) Fetal visceral examination / microdissection technique: approximately one half of the fetuses per litter were fixed in Bouin's solution (one fetus per container) for at least two weeks and were micro-dissected. Serial sections of the head, microdissection of the thorax and abdomen and detailed examination of the major blood vessels were done. After examination, organs and sections were preserved in a solution of glycerin/ethanol (one fetus per container). Observations of visceral abnormalities and variations were recorded.

2) The remaining fetuses were eviscerated and with the exception of the paws, the skin was removed and discarded. Carcasses were processed through solutions of ethanol, glacial acetic acid with Alcian blue (for cartilage staining), potassium hydroxide with Alizarin red S (for clearing and staining ossified bone) and aqueous glycerin for preservation and storage*.

The skeletons were examined and all abnormal findings and variations recorded. The specimens were preserved individually.

Fetuses with abnormalities were photographed where applicable.

* = Modification of Inouye, M., (1976) Congenital Abnormalities, 16, pp. 171-173.

5.7.4 DATA COMPILATION

Food consumption, body weight and Caesarean section data were recorded on-line and compiled by computer (LIMS). Individual skeletal examination of fetuses data were recorded on data sheets, transferred to and compiled by computer.

All other data were recorded on data sheets and compiled manually.

5.8 DATA PROCESSING

The mean body weight gain (%), the mean corrected body weight gain (corrected for uterus weight) and the mean daily food consumption were calculated by a computer program based on on-line recorded data.

The calculations for evaluation of the reproduction data were performed by a computer program based on on-line recorded data. The following data were calculated: Pre- and post-implantation losses, embryonic and fetal deaths, live and dead fetuses, abnormal fetuses, sex ratios of fetuses and fetal body weights.

For reproduction data, group mean values were calculated both on a litter basis and on a percentage per group basis. Mean fetal weights were calculated from the individual weights both on a per group and on a per litter basis.

Computer-generated values in the tables represent the rounded-off results of calculations which used the exact raw data values.

5.9 TERMINOLOGY USED IN THE ASSESSMENT OF THE DATA

Empty implantation site	very early resorption or aborted implantation
Embryonic resorption	amorphous mass being resorbed
Fetal resorption	clearly defined fetal body being resorbed
Dead fetus	appearance of live fetus but without induced respiration or movement
Live fetus	breathing and/or moving fetus responding to touch
Abnormality	A structural change in a fetus that would probably impair its health or development. Serious abnormalities, i.e. clearly deleterious abnormalities, will also be distinguished.
Variation	A fetal change that occurs within the normal population under investigation and is unlikely to adversely affect survival or health. This includes a delay in growth or morphogenesis that has otherwise followed a normal pattern of development.
Skeletal variant	Variations in the number and shape of ribs and degree of ossification of phalangeal nuclei and/or sternebrae. Variations in the shape of the vertebral, intercostal and sternebral cartilage.

5.10 STATISTICAL METHODS

The following statistical methods were used to analyse body weights, food consumption, reproduction and skeletal examination data:

- Means and standard deviations of various data were calculated and included in the report.
- If the variables could be assumed to follow a normal distribution, the Dunnett many-one t-test, based on a pooled variance estimate, was used for intergroup comparisons (i.e. single treatment groups against the control group).
- The Steel test (many-one rank test) was applied when the data could not be assumed to follow a normal distribution.
- Fisher's Exact test for 2x2 tables was applied if the variables could be dichotomized without loss of information.

All methods of analysis and the results are included in the report.

References:

- C.W. Dunnett A Multiple Comparison Procedure for Comparing Several Treatments with a Control, J. Amer. Statist. Assoc. 50, 1096-1121 (1955).
- R.G. Miller Simultaneous Statistical Inference, Springer Verlag, New York (1981).
- R.A. Fisher Statistical Methods for Research Workers, Oliver and Boyd, Edinburgh (1950).

6 RESULTS

6.1 SUMMARY OF PERFORMANCE OF MATED FEMALES

Group Dose (mg/kg)	1 (0)	2 (10)	3 (30)	4 (150)
Number of mated females	22	22	22	22
Female numbers	1 - 22	23 - 44	45 - 66	67 - 88
Non pregnant (A)	1	0	1	2
Found dead (B)	0	0	0	1
Number of females with live fetuses at termination*	21	22	21	19

* = Only dams with at least one live fetus at Caesarean section were used for the calculations of food consumption, body weight gain, corrected body weight gain and reproduction data in the following tables.

(A) = Female Nos. 1, 49, 76 and 80 were not pregnant.

(B) = Female No. 81 was found dead on day 10 post coitum.

6.2 MATERNAL DATA

6.2.1 MORTALITIES AND/OR SIGNS OF REACTION TO TREATMENT

(p. 110)

In group 4, ruffled fur, incrusted nose and poor condition were noted for one female (No. 81) on days 7 to 9 post coitum. This female was found dead in the morning of day 10 post coitum. In all probability the death of this female was the consequence of an injury caused by intubation on the first day of test item administration (day 6 post coitum). All other females survived until scheduled necropsy.

In groups 3 and 4, dark discoloration of urine and bedding were observed for all females from day 6 post coitum onwards. These discolorations were considered to be due to the presence of test item (and/or metabolites) and was considered to be of no adverse character.

In group 2, localized alopecia was transiently noted for one female. This isolated and common finding was considered to be incidental.

In group 1, no clinical signs or observations were noted.

6.2.2 FOOD CONSUMPTION

(pp. 31 - 37)

In group 4, reduced mean food consumption was noted during the entire treatment period (7.4%). In comparison with that of the vehicle control, the differences were statistically significant during the first (days 6 to 9 post coitum), the second (days 9 to 12 post coitum) and the third (days 12 to 15 post coitum) recording period.

Mean food consumption in groups 3 and 2 was similar to that of the vehicle control.

6.2.3 BODY WEIGHTS

(pp. 38 - 56)

In group 4, mean body weight gain was slightly reduced during the first ten days of the treatment period, after day 16 post coitum, mean body weight gain was no longer affected by treatment with the test item. Corrected mean body weight gain (corrected for gravid uterus weight) in group 4, was slightly, although not statistically significantly lower than that of the vehicle control (+3.4% compared with +7.4% in the vehicle control).

Body weight gain and corrected body weight gain in groups 3 and 2 was similar to that of the vehicle control and gave no indication of test item related effects.

6.2.4 REPRODUCTION DATA

(pp. 57 - 62, 90 - 109)

The relevant reproduction data (post-implantation loss and number of fetuses per dam), were no affected by treatment with the test item.

The incidence of pre-implantation loss was statistically significantly lower in groups 3 and 4 than in the vehicle control resulting in a slightly higher number of implantations in this group. Since pre-implantation loss is mainly happening before onset of treatment these differences are considered to be incidental.

Statistically significant differences noted for post-implantation loss, embryonic and fetal resorptions in group 2 are due to a lower incidence of post-implantation loss and result in a statistically significantly higher value of fetuses as a percentage of implantation sites. The same applies for the statistically significant lower incidence of fetal resorptions noted in group 3.

In group 4, the incidence of embryonic resorptions was slightly although statistically significantly increased, which was considered to be probably due to the high number of implantation sites per dam (13.7 compared with 12.3 in the vehicle control) and therefore not attributable to treatment with the test item. This opinion is supported by the overall value for post-implantation loss, which was not increased, as well as by the number of fetuses per dam, which was even higher in group 4 than in the vehicle control (11.8 compared with 10.8 in the vehicle control).

6.2.5 NECROPSY FINDINGS

(pp. 111 - 114)

During macroscopic examination no test item-related findings were noted.

In group 3, the non-gravid uterus of one female (No. 49) contained fluid, which is a common finding in non-pregnant rats of this strain.

No abnormal findings were noted in females of groups 4, 2 or vehicle controls.

6.3 FETAL DATA

6.3.1 BODY WEIGHTS

(Group mean p. 58; Litter mean pp. 86 - 89; Individual pp. 94 - 109)

No test item-related effects on fetal weights were noted.

Fetal weights were marginally higher in all groups treated with the test item than in the vehicle control (4.8 g compared with 4.6 g in the vehicle control, combined data for male and female fetuses, calculated on a litter basis). Since this increase did not show any dose dependency over the wide range of dosages applied, it was considered to be incidental.

6.3.2 SEX RATIOS

(p. 58)

No test item-related effects on the sex ratio of fetuses were noted in any group.

6.3.3 EXTERNAL EXAMINATION

(p. 63)

No abnormalities were noted during external examination of fetuses of groups 2, 3 or 4.

In group1, malformation of the head (including upper and lower jaw) and bilateral anophthalmia were noted for one fetus (No. 42, dam 5). All other fetuses were without abnormal findings.

6.3.4 VISCERAL EXAMINATION (MICRODISSECTION TECHNIQUE)

(pp. 64 - 77)

During visceral examination of fixed fetuses findings were noted in:

67 of 121 examined fetuses (20 of 21 litters) of group 1
61 of 137 examined fetuses (22 of 22 litters) of group 2
63 of 128 examined fetuses (21 of 21 litters) of group 3
52 of 118 examined fetuses (19 of 19 litters) of group 4

The noted findings (mainly thymus cranially elongated, liver additional lobe(s) of cleft, renal pelvis dilated, testis displaced and umbilical artery left-sided) are common findings for fetuses of this rat strain. Neither the types nor the frequencies of these findings gave any indication for test item related effects.

6.3.5 SKELETAL EXAMINATION OF FETUSES (ABNORMALITIES AND VARIANTS)

(pp. 78, 79)

There were 8 fetuses with abnormal skeletal findings as follows:

One in group 1, two in group 2, two in group 3 and three in group 4.

The findings noted were confined to common sternebral or vertebral abnormalities (offset sternebrae or bipartite sternebra, dumbbell shaped thoracic vertebral body, unilateral fused zygomatic arch). The low frequencies in this study were considered to be incidental

6.3.6 SKELETAL EXAMINATION OF FETUSES (STAGE OF DEVELOPMENT)

(pp. 80 - 83, 142 - 181)

Occasional statistically significant differences that did occur between groups treated with the test item and vehicle controls showed no dosage dependency and were caused by higher as well as lower stages of development and therefore considered not to be test item-related.

6.3.7 CARTILAGE EXAMINATION OF FETUSES (ABNORMAL FINDINGS AND VARIANTS)

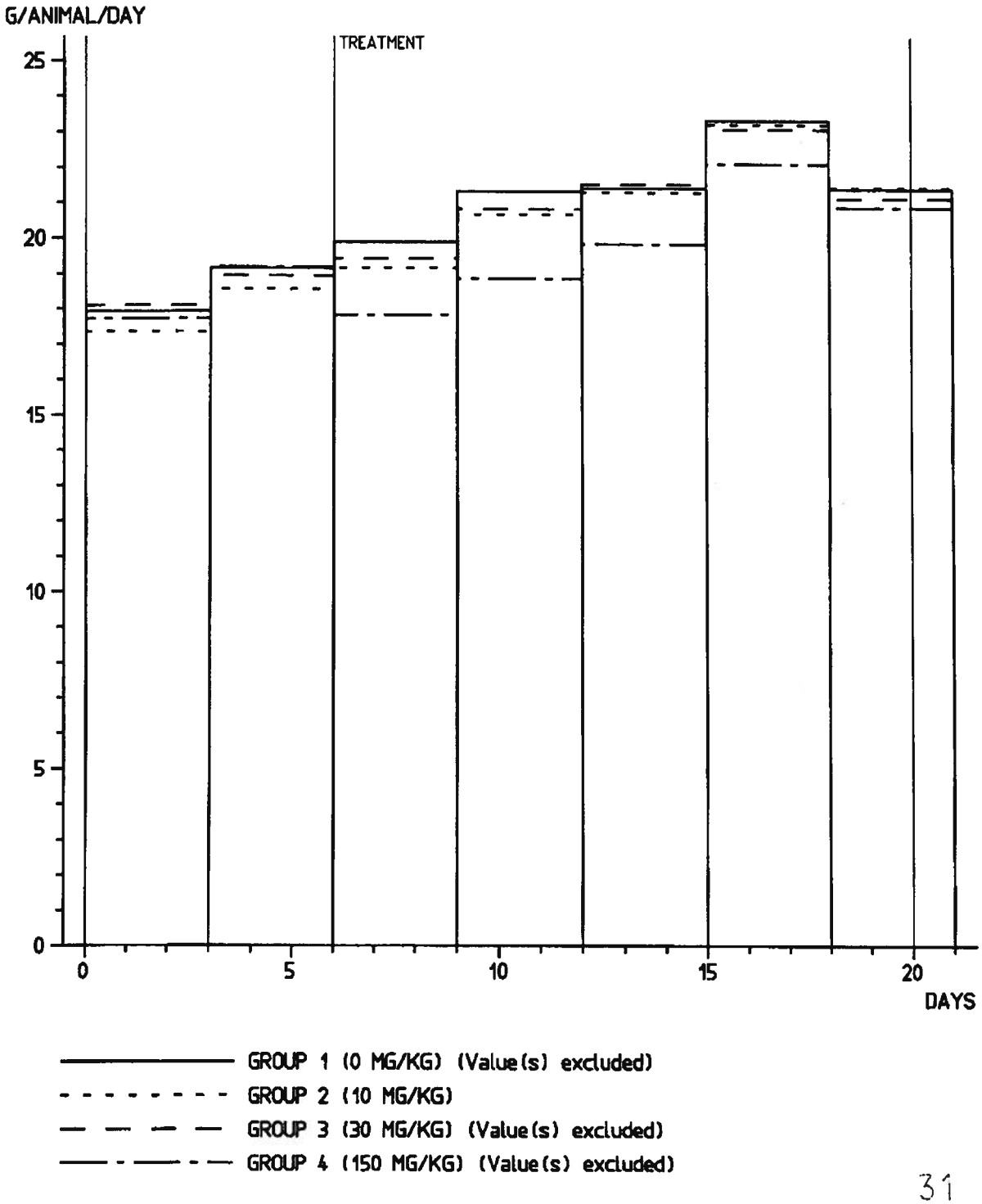
(pp. 78, 79, 84, 85, 183 - 204)

During cartilage examination only 1 fetus with common abnormal cartilage findings was noted (cartelaginous sternebrae 2-5 offset) in group 4.

No abnormal findings or variants were noted in the fetuses of groups 1, 2 or 3.

7 FIGURES AND TABLES

FOOD CONSUMPTION OF DAMS
POST COITUM



FOOD CONSUMPTION (G/ANIMAL/DAY) OF DAMS SUMMARY POST COITUM

		GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 30 MG/KG	GROUP 4 150 MG/KG
DAYS 0-3	MEAN	17.9	17.3	18.1	17.7
	ST.DEV.	1.7	1.8	1.8	2.1
	N	21	22	21	19
DAYS 3-6	MEAN	19.1	18.6	18.9	19.2
	ST.DEV.	1.4	2.0	1.7	1.8
	N	21	22	21	19
DAYS 6-9	MEAN	19.9	19.2	19.4	17.8 **
	ST.DEV.	1.8	2.2	1.3	1.3
	N	21	22	21	19
DAYS 9-12	MEAN	21.3	20.7	20.8	18.9 **
	ST.DEV.	2.1	1.8	1.8	1.6
	N	21	22	21	19
DAYS 12-15	MEAN	21.4	21.3	21.5	19.8 *
	ST.DEV.	2.1	2.3	1.3	1.7
	N	21	22	21	19
DAYS 15-18	MEAN	23.3	23.2	23.1	22.1
	ST.DEV.	1.9	2.6	1.7	1.7
	N	21	22	21	19
DAYS 18-21	MEAN	21.4	21.4	21.1	20.9
	ST.DEV.	1.8	2.9	2.1	1.8
	N	21	22	21	19
MEAN OF MEANS		20.6	20.2	20.4	19.5

Explanations for excluded data are listed in the tables of individual values
* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

FOOD CONSUMPTION (G/ANIMAL/DAY) OF DAMS POST COITUM

GROUP 1 (0 MG/KG)

DAYS ANIMAL	0-3	3-6	6-9	9-12	12-15	15-18	18-21
1 (A)	17.9	18.9	19.3	20.7	14.5	15.9	16.4
2	17.5	19.2	20.9	23.0	24.0	25.7	23.4
3	17.2	18.7	19.7	20.7	20.0	22.1	21.1
4	22.2	21.7	22.3	23.0	24.2	25.0	22.7
5	16.0	17.4	17.4	18.3	18.7	20.4	17.4
6	20.9	19.2	19.8	22.8	22.6	24.7	21.2
7	18.3	20.3	20.0	19.0	22.0	23.4	21.9
8	18.9	19.1	19.9	19.6	20.3	23.9	20.1
9	15.2	17.2	18.2	17.5	19.4	20.9	19.4
10	19.0	21.0	22.5	22.8	24.0	26.0	24.1
11	16.8	18.8	21.1	22.8	23.8	24.3	22.3
12	17.7	19.0	21.2	23.4	22.4	25.0	21.3
13	18.4	20.0	19.9	21.5	21.3	22.3	21.8
14	15.6	17.1	16.5	20.2	18.8	20.6	17.8
15	17.1	17.5	17.8	19.8	17.8	21.7	21.8
16	18.4	19.4	19.7	21.1	20.5	23.4	22.5
17	19.1	20.4	22.3	24.9	21.9	23.3	21.8
18	18.4	22.3	22.0	25.1	24.5	26.4	25.1
19	15.2	17.3	16.3	19.0	18.0	20.6	20.3
20	18.9	19.2	20.0	21.6	21.2	21.8	20.8
21	17.7	19.1	21.3	20.5	22.7	24.9	20.4
22	17.9	18.3	19.0	21.1	21.7	23.6	22.1

(A) Non-pregnant

FOOD CONSUMPTION (G/ANIMAL/DAY) OF DAMS POST COITUM

GROUP 2 (10 MG/KG)

DAYS ANIMAL	0-3	3-6	6-9	9-12	12-15	15-18	18-21
23	17.8	16.7	17.0	18.8	18.2	18.8	18.7
24	17.8	17.6	17.3	20.2	20.2	23.1	22.3
25	18.3	18.8	20.5	22.4	23.6	27.2	25.9
26	17.2	18.1	17.6	20.1	20.6	23.1	22.6
27	18.5	20.1	20.2	21.8	21.7	22.1	22.3
28	19.5	17.5	18.5	21.0	23.0	25.1	23.2
29	17.2	17.1	19.0	21.9	21.9	23.8	22.5
30	16.8	17.7	17.6	18.7	20.8	23.6	20.1
31	17.0	18.7	19.5	20.2	21.3	21.8	20.7
32	21.3	23.2	23.5	22.5	25.3	26.2	23.8
33	21.7	24.6	25.8	25.3	28.0	31.3	29.8
34	18.1	18.5	20.1	22.1	20.9	23.1	22.7
35	15.6	17.9	17.4	20.5	19.2	20.4	17.7
36	15.7	18.3	17.9	21.2	19.8	21.7	17.3
37	15.2	17.3	17.8	21.1	20.3	22.8	20.9
38	17.5	18.6	19.1	20.7	19.9	21.7	20.3
39	14.5	17.0	16.6	17.7	18.4	19.6	19.7
40	16.9	18.2	17.9	20.6	20.3	23.0	22.2
41	14.9	17.0	17.1	17.7	19.6	23.0	18.8
42	18.1	19.7	21.2	20.6	22.3	23.5	22.0
43	15.7	16.9	18.8	18.0	20.6	23.2	17.4
44	16.6	19.1	20.8	21.6	22.5	22.9	20.9

FOOD CONSUMPTION (G/ANIMAL/DAY) OF DAMS POST COITUM

GROUP 3 (30 MG/KG)

DAYS ANIMAL	0-3	3-6	6-9	9-12	12-15	15-18	18-21
45	20.4	19.0	20.4	21.0	22.0	22.7	20.7
46	21.0	22.2	22.5	24.5	25.0	26.4	25.2
47	17.5	16.8	20.1	20.2	21.2	22.2	20.8
48	18.5	17.7	17.7	18.8	20.4	19.0	18.2
49 (A)	18.1	16.3	19.0	18.9	19.7	13.5	14.4
50	16.5	17.2	18.2	19.8	21.4	23.4	21.3
51	21.5	19.4	20.3	21.3	23.1	24.6	21.5
52	16.1	16.6	17.4	19.1	20.1	20.4	17.8
53	19.8	18.5	18.0	19.6	20.5	22.2	19.9
54	16.3	18.7	19.3	22.8	20.9	23.9	21.8
55	18.1	18.7	18.5	19.5	21.1	23.1	19.9
56	16.5	17.2	18.3	18.2	20.2	23.0	21.0
57	20.6	19.5	20.7	21.5	23.4	23.1	22.1
58	18.4	19.3	18.7	19.7	21.9	24.9	22.1
59	17.3	18.6	18.9	18.5	19.6	21.4	19.8
60	16.1	18.2	18.4	21.4	19.9	22.5	22.4
61	15.2	18.2	19.6	21.2	21.0	22.0	21.5
62	18.0	18.0	18.9	22.2	22.3	24.4	23.3
63	18.3	20.8	20.3	23.4	21.4	25.1	23.6
64	17.8	23.4	22.0	24.1	22.5	24.5	24.9
65	16.4	19.1	20.4	20.6	22.0	22.1	17.3
66	20.0	20.8	19.4	20.1	21.8	23.7	18.9

(A) Non-pregnant

FOOD CONSUMPTION (G/ANIMAL/DAY) OF DAMS POST COITUM

GROUP 4 (150 MG/KG)

DAYS ANIMAL	0-3	3-6	6-9	9-12	12-15	15-18	18-21
67	20.4	21.4	19.9	19.8	21.2	23.4	23.0
68	19.5	17.5	17.0	18.3	19.8	23.1	22.7
69	19.2	18.4	17.5	18.1	18.8	20.0	19.2
70	20.6	21.8	20.2	23.9	23.8	24.8	23.7
71	17.0	16.8	17.4	17.3	17.0	19.8	18.6
72	19.8	17.9	17.3	19.2	19.8	21.9	21.1
73	19.1	20.8	18.9	20.8	21.5	24.9	22.6
74	19.7	21.5	17.9	18.1	20.9	23.7	22.8
75	17.8	20.5	17.3	17.7	20.4	21.4	21.1
76 (A)	18.5	19.9	20.6	16.8	14.0	14.7	14.7
77	16.4	17.2	17.5	17.6	19.1	22.2	20.9
78	16.5	20.6	18.0	19.1	20.2	23.9	23.2
79	20.6	22.2	19.2	19.0	21.3	22.8	21.2
80 (A)	16.3	18.1	17.5	16.9	14.1	13.5	14.3
81 (B)	13.9	17.1	3.2	---	---	---	---
82	17.6	19.6	18.0	20.2	18.9	20.1	17.8
83	14.9	18.1	14.1	18.2	17.6	19.2	19.1
84	14.2	18.0	17.0	19.4	18.2	21.7	19.6
85	15.4	17.9	17.1	18.0	17.9	21.2	19.1
86	16.2	19.3	18.6	18.0	22.1	23.9	21.6
87	17.4	17.9	18.5	19.4	19.2	20.9	19.4
88	14.4	17.1	17.3	16.3	19.2	21.0	19.9

(A) Non-pregnant (B) Death prior sch. nec

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

DIFFERENCES IN MEAN FOOD CONSUMPTION OF DAMS (G/ANIMAL/DAY) POST COITUM

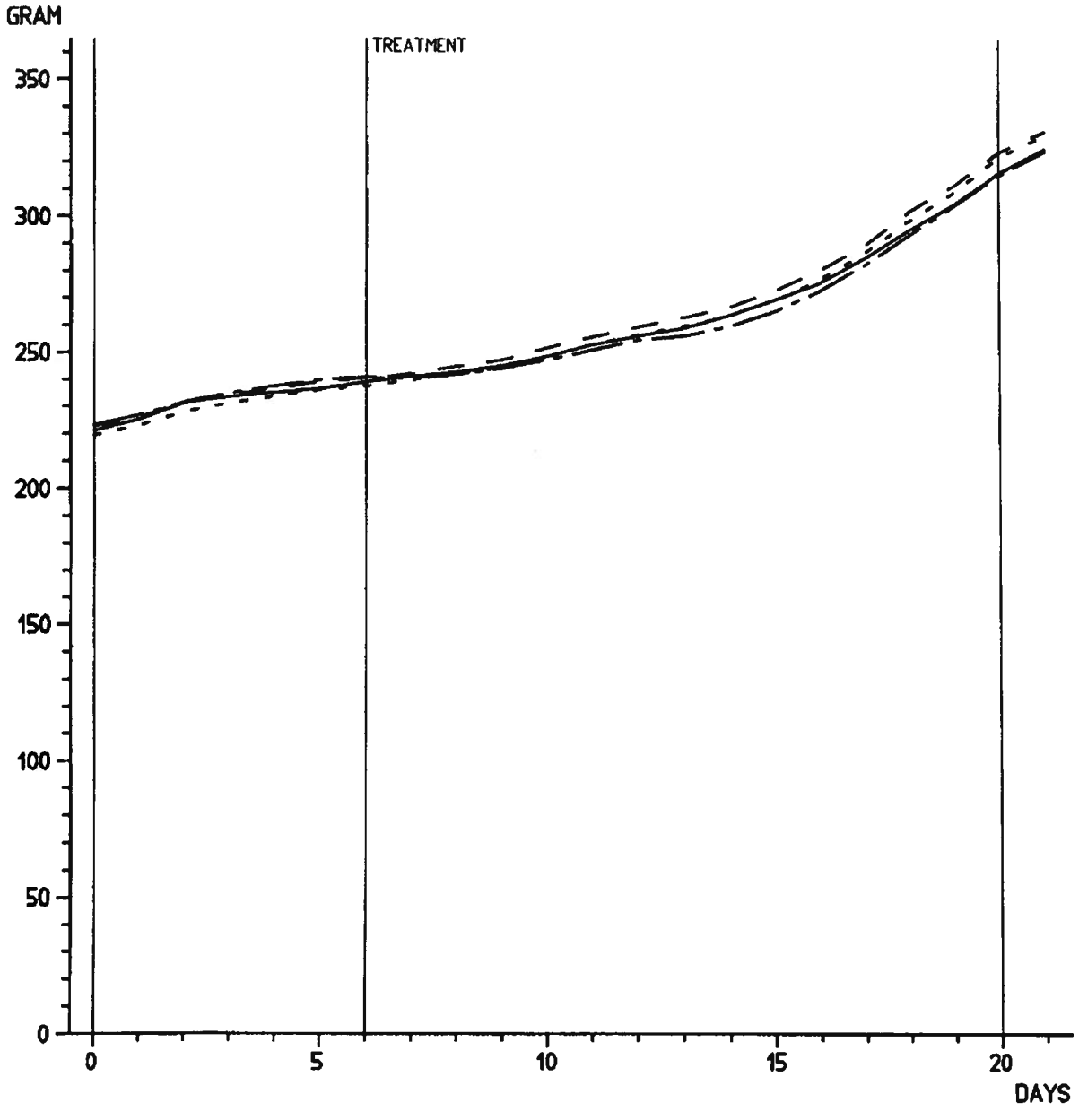
Group	Days post coitum							
	0 - 3		3 - 6		6 - 9		9 - 12	
(mg/kg)	g	(%)	g	(%)	g	(%)	g	(%)
1 (0)	17.9		19.1		19.9		21.3	
2 (10)	17.3	(-3.4)	18.6	(-2.6)	19.2	(-3.5)	20.7	(-2.8)
3 (30)	18.1	(+1.1)	18.9	(-1.0)	19.4	(-2.5)	20.8	(-2.3)
4 (150)	17.7	(-1.1)	19.2	(+0.5)	17.8	(-10.6)	18.9	(-11.3)

Group	Days post coitum							
	12 - 15		15 - 18		18 - 21		6 - 21	
(mg/kg)	g	(%)	g	(%)	g	(%)	g	(%)
1 (0)	21.4		23.3		21.4		21.5	
2 (10)	21.3	(-0.5)	23.2	(-0.4)	21.4	(±0.0)	21.2	(-1.4)
3 (30)	21.5	(+0.5)	23.1	(-0.9)	21.1	(-1.4)	21.2	(-1.4)
4 (150)	19.8	(-7.5)	22.1	(-5.2)	20.9	(-2.3)	19.9	(-7.4)

(%) = Percentages relative to the values of group 1

The calculations of food consumption during the treatment period started on day 6 post coitum (immediately prior to the first administration) and ended on day 21 post coitum (approximately 24 hours after the last administration).

BODY WEIGHTS OF DAMS
POST COITUM



BODY WEIGHTS (GRAM) OF DAMS SUMMARY
POST COITUM

			GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 30 MG/KG	GROUP 4 150 MG/KG
DAY	0	MEAN	221	219	223	223
		ST.DEV.	13.0	17.9	16.1	15.6
		N	21	22	21	19
DAY	1	MEAN	225	223	226	227
		ST.DEV.	12.6	17.7	16.0	16.8
		N	21	22	21	19
DAY	2	MEAN	231	228	231	232
		ST.DEV.	13.1	18.6	16.8	16.3
		N	21	22	21	19
DAY	3	MEAN	233	231	234	235
		ST.DEV.	13.2	19.6	16.2	16.3
		N	21	22	21	19
DAY	4	MEAN	235	234	237	237
		ST.DEV.	13.6	20.5	16.6	17.7
		N	21	22	21	19
DAY	5	MEAN	236	236	239	240
		ST.DEV.	13.1	20.3	15.2	18.4
		N	21	22	21	19
DAY	6	MEAN	239	237	240	241
		ST.DEV.	12.6	20.3	14.8	16.6
		N	21	22	21	19
DAY	7	MEAN	241	240	242	240
		ST.DEV.	12.4	20.1	15.0	16.9
		N	21	22	21	19
DAY	8	MEAN	243	242	245	242
		ST.DEV.	13.2	20.8	15.4	17.1
		N	21	22	21	19
DAY	9	MEAN	245	244	247	244
		ST.DEV.	12.5	20.4	15.0	17.2
		N	21	22	21	19
DAY	10	MEAN	248	248	251	247
		ST.DEV.	12.6	21.5	15.2	16.3
		N	21	22	21	19
DAY	11	MEAN	253	253	256	251
		ST.DEV.	12.3	21.4	15.4	16.4
		N	21	22	21	19
DAY	12	MEAN	256	256	259	255
		ST.DEV.	12.7	22.3	15.1	17.0
		N	21	22	21	19
DAY	13	MEAN	259	260	263	256
		ST.DEV.	11.9	22.0	15.7	16.3
		N	21	22	21	19
DAY	14	MEAN	264	263	267	260
		ST.DEV.	11.2	22.7	15.2	16.8
		N	21	22	21	19
DAY	15	MEAN	269	269	273	265
		ST.DEV.	11.4	22.8	16.5	17.8
		N	21	22	21	19
DAY	16	MEAN	276	277	281	273
		ST.DEV.	11.8	24.0	16.7	17.7
		N	21	22	21	19

Explanations for excluded data are listed in the tables of individual values
* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

BODY WEIGHTS (GRAM) OF DAMS SUMMARY
POST COITUM

			GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 30 MG/KG	GROUP 4 150 MG/KG
DAY	17	MEAN	285	287	290	283
		ST.DEV.	12.3	25.4	18.2	19.1
		N	21	22	21	19
DAY	18	MEAN	295	299	302	294
		ST.DEV.	13.3	26.3	19.2	19.4
		N	21	22	21	19
DAY	19	MEAN	305	309	312	304
		ST.DEV.	15.0	27.1	19.6	20.4
		N	21	22	21	19
DAY	20	MEAN	316	322	324	315
		ST.DEV.	17.1	28.4	21.6	20.8
		N	21	22	21	19
DAY	21	MEAN	325	330	331	324
		ST.DEV.	17.0	29.5	23.3	23.5
		N	21	22	21	19

Explanations for excluded data are listed in the tables of individual values
* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

BODY WEIGHTS (GRAM) OF DAMS POST COITUM

GROUP 1 (0 MG/KG)

DAYS / ANIMAL	0	1	2	3	4	5	6	7
1 (A)	234	240	245	252	257	259	257	257
2	220	226	232	230	237	244	244	244
3	221	226	231	235	240	243	240	241
4	225	231	236	238	243	250	249	247
5	198	204	205	203	211	216	214	217
6	202	208	214	214	217	222	223	222
7	253	255	258	261	271	267	268	268
8	230	232	238	239	243	244	245	246
9	231	235	239	239	244	243	245	243
10	223	225	231	237	238	222	237	243
11	233	233	241	246	244	245	248	252
12	230	234	242	245	242	244	250	254
13	228	235	243	245	244	245	248	249
14	220	224	228	229	226	231	236	240
15	220	223	227	229	234	234	238	239
16	216	219	228	229	228	227	230	231
17	215	222	227	236	235	235	241	245
18	199	203	210	215	217	220	224	228
19	204	205	209	214	212	214	215	219
20	223	229	240	237	239	243	245	249
21	233	236	246	245	241	245	246	251
22	222	224	229	232	229	233	233	237

DAYS / ANIMAL	8	9	10	11	12	13	14	15
1 (A)	259	263	263	264	265	257	251	253
2	245	248	249	253	260	267	266	273
3	246	250	251	255	257	260	263	269
4	249	253	256	258	263	262	267	273
5	219	224	224	229	231	235	243	245
6	223	226	231	236	241	245	248	258
7	272	273	274	273	275	281	280	285
8	250	247	256	258	266	264	270	274
9	247	251	253	258	264	261	266	275
10	242	244	244	253	250	258	263	265
11	257	256	263	268	270	271	276	281
12	253	255	261	270	268	272	281	283
13	252	252	253	257	260	260	265	272
14	235	240	242	246	248	251	258	262
15	240	242	244	253	255	254	262	268
16	232	238	238	241	242	249	252	262
17	249	250	257	261	264	268	276	280
18	231	233	238	246	248	255	258	267
19	216	219	223	226	227	232	240	242
20	250	251	256	261	266	267	271	277
21	250	254	256	258	264	265	272	281
22	237	236	246	245	257	258	261	266

(A) Non-pregnant

BODY WEIGHTS (GRAM) OF DAMS POST COITUM

GROUP 1 (0 MG/KG)

DAYS / ANIMAL	16	17	18	19	20	21
1 (A)	257	252	249	254	256	256
2	276	282	289	299	303	310
3	276	286	298	311	329	336
4	279	286	299	306	320	326
5	251	259	267	275	287	296
6	263	270	281	289	301	313
7	289	291	298	301	305	308
8	279	292	306	318	331	338
9	278	286	291	291	297	307
10	270	281	283	300	308	315
11	294	307	320	339	356	359
12	293	303	315	325	333	348
13	275	281	287	292	302	312
14	272	282	293	299	316	323
15	280	287	301	318	332	345
16	269	279	290	301	312	322
17	285	297	305	311	326	335
18	275	284	302	308	325	335
19	248	258	269	277	285	297
20	284	292	304	315	326	340
21	287	300	307	313	322	329
22	272	282	294	310	323	334

(A) Non-pregnant

BODY WEIGHTS (GRAM) OF DAMS POST COITUM

GROUP 2 (10 MG/KG)

DAYS ANIMAL	0	1	2	3	4	5	6	7
23	198	200	206	206	210	215	215	215
24	216	220	224	226	231	235	238	238
25	228	236	240	244	249	260	257	259
26	217	221	224	228	233	238	235	233
27	236	239	245	246	251	253	254	256
28	201	207	211	214	218	224	226	225
29	201	207	209	209	216	221	219	224
30	225	230	236	240	245	247	248	252
31	200	205	210	211	217	219	219	222
32	256	258	264	271	277	275	276	278
33	257	262	270	277	284	285	287	290
34	227	234	237	244	242	241	245	245
35	224	226	234	239	237	237	239	242
36	208	212	216	220	224	225	228	228
37	225	227	228	232	233	235	240	243
38	224	225	233	235	236	236	241	243
39	190	194	195	202	200	199	202	206
40	201	207	211	216	216	214	215	220
41	217	220	226	224	223	225	226	230
42	238	240	246	248	247	251	253	256
43	230	231	236	238	236	241	241	243
44	207	206	213	215	215	217	220	225

DAYS ANIMAL	8	9	10	11	12	13	14	15
23	220	223	226	231	231	236	236	239
24	240	240	244	250	259	253	258	264
25	263	271	275	280	285	286	294	300
26	237	239	241	246	249	252	253	258
27	256	260	263	265	268	271	275	277
28	228	232	234	240	244	250	253	259
29	227	233	236	243	249	252	250	263
30	253	257	263	265	268	271	277	285
31	225	227	228	238	246	243	249	256
32	283	283	291	296	302	302	306	316
33	294	295	298	306	312	316	322	325
34	252	253	255	265	265	268	275	279
35	240	248	251	254	252	259	265	268
36	231	232	240	245	247	251	253	259
37	246	244	252	259	261	263	269	275
38	244	245	249	256	253	259	262	268
39	204	211	209	214	213	219	224	230
40	221	221	224	228	229	232	239	243
41	231	233	234	239	243	246	254	256
42	256	259	261	261	264	274	273	279
43	245	245	250	254	257	263	264	273
44	225	228	232	234	242	245	245	252

BODY WEIGHTS (GRAM) OF DAMS POST COITUM

GROUP 2 (10 MG/KG)

DAYS ANIMAL	16	17	18	19	20	21
23	247	251	259	270	279	290
24	273	283	297	309	325	333
25	308	326	338	353	370	379
26	268	271	278	289	295	305
27	285	291	296	307	317	325
28	268	271	287	295	305	316
29	271	277	292	303	314	322
30	293	306	316	332	335	340
31	261	271	283	292	304	310
32	326	334	351	359	376	392
33	337	351	363	375	389	396
34	287	295	306	315	329	341
35	277	290	306	310	329	334
36	265	276	287	297	310	308
37	283	296	313	320	340	350
38	276	287	300	311	324	339
39	233	243	256	263	278	285
40	250	264	273	282	296	306
41	265	275	286	296	308	307
42	283	294	298	315	326	337
43	280	290	307	314	327	334
44	258	272	283	293	306	314

BODY WEIGHTS (GRAM) OF DAMS POST COITUM

GROUP 3 (30 MG/KG)

DAYS ANIMAL	0	1	2	3	4	5	6	7
45	235	238	242	244	252	251	245	250
46	224	222	229	234	238	242	242	243
47	215	219	224	225	227	232	235	237
48	231	235	234	236	237	242	241	243
49 (A)	223	229	237	237	234	240	242	244
50	221	223	230	231	233	240	239	242
51	222	231	239	240	244	247	249	249
52	225	226	230	231	235	239	243	239
53	199	207	211	211	217	224	225	223
54	216	218	224	227	230	237	238	237
55	213	220	222	224	228	231	227	230
56	244	244	248	248	250	253	250	254
57	252	256	263	267	272	268	269	270
58	220	223	230	234	240	241	243	243
59	195	198	199	203	205	209	211	211
60	205	203	213	217	218	220	224	230
61	238	236	244	246	246	243	247	252
62	206	206	209	218	214	212	217	220
63	231	237	245	250	250	250	252	256
64	205	210	215	219	221	225	229	230
65	251	252	257	260	260	261	266	267
66	235	240	251	250	250	254	255	257

DAYS ANIMAL	8	9	10	11	12	13	14	15
45	253	255	260	263	266	269	272	276
46	248	255	257	261	266	268	272	281
47	236	240	243	245	248	251	254	256
48	244	248	247	250	258	260	262	269
49 (A)	246	249	251	250	255	254	262	259
50	244	250	252	254	262	265	266	276
51	252	254	257	261	267	270	275	281
52	238	242	249	250	256	259	262	265
53	226	230	235	236	241	245	248	253
54	244	248	253	258	263	269	268	276
55	231	235	241	244	247	249	252	259
56	256	258	261	266	273	273	279	285
57	277	276	283	284	286	289	294	302
58	249	249	254	259	260	264	269	281
59	214	217	220	224	227	231	234	237
60	232	232	240	242	244	250	256	261
61	255	251	260	265	264	266	273	277
62	222	221	225	233	235	237	246	250
63	259	258	265	269	272	276	282	290
64	236	238	241	251	251	254	262	265
65	268	272	275	284	285	294	293	302
66	256	261	263	269	271	278	282	286

(A) Non-pregnant

BODY WEIGHTS (GRAM) OF DAMS POST COITUM

GROUP 3 (30 MG/KG)

DAYS / ANIMAL	16	17	18	19	20	21
45	284	295	304	312	324	331
46	285	297	307	313	333	343
47	263	265	271	277	281	284
48	274	277	290	299	307	309
49 (A)	250	246	247	248	245	243
50	284	289	305	314	326	334
51	290	298	307	318	326	333
52	273	281	296	307	319	325
53	262	270	282	290	305	308
54	284	291	302	313	328	332
55	265	277	289	299	307	316
56	296	306	321	329	341	346
57	309	318	329	342	354	366
58	284	296	313	324	332	346
59	244	252	266	275	283	290
60	273	285	296	309	320	326
61	281	290	302	313	323	334
62	258	268	278	284	299	308
63	302	314	332	335	354	368
64	275	286	301	309	330	337
65	308	323	335	346	361	366
66	298	311	323	333	348	356

(A) Non-pregnant

BODY WEIGHTS (GRAM) OF DAMS POST COITUM

GROUP 4 (150 MG/KG)

DAYS ANIMAL	0	1	2	3	4	5	6	7
67	246	245	253	255	259	267	267	263
68	233	234	235	238	243	249	246	245
69	232	237	240	243	246	251	248	248
70	234	237	238	244	245	256	251	253
71	189	191	197	200	202	207	207	205
72	196	199	203	207	209	214	214	213
73	232	242	248	250	256	256	258	259
74	239	248	249	255	262	261	258	261
75	218	222	225	230	237	234	238	233
76 (A)	209	213	219	226	229	236	232	236
77	224	227	233	235	237	237	242	238
78	225	230	240	242	243	250	250	251
79	246	253	257	263	267	267	265	265
80 (A)	232	232	237	245	245	241	244	246
81 (B)	241	245	246	251	250	252	249	241
82	231	230	236	240	241	244	242	242
83	216	217	222	228	231	229	234	235
84	207	204	210	219	219	218	221	223
85	223	226	229	229	229	231	236	234
86	228	230	239	237	238	241	243	242
87	204	208	217	216	213	212	219	219
88	222	228	231	230	232	232	235	236

DAYS ANIMAL	8	9	10	11	12	13	14	15
67	266	269	270	274	278	279	279	289
68	247	251	251	254	257	257	260	266
69	249	248	252	253	258	259	264	270
70	256	259	261	265	272	268	280	283
71	206	211	214	218	219	220	223	229
72	216	213	222	222	228	228	232	236
73	261	264	269	269	275	276	278	290
74	263	264	265	268	276	275	280	288
75	237	236	238	245	244	247	254	256
76 (A)	240	243	242	242	235	229	232	235
77	242	246	247	251	256	259	263	274
78	250	251	254	262	264	267	269	275
79	266	268	269	276	277	277	281	286
80 (A)	248	249	251	252	245	242	242	244
81 (B)	235	223	---	---	---	---	---	---
82	245	244	248	253	255	255	260	262
83	237	238	244	248	251	253	256	259
84	224	229	233	239	241	244	252	255
85	231	237	237	240	246	248	249	258
86	242	247	253	252	258	262	263	267
87	219	220	224	231	235	237	235	242
88	235	238	242	243	247	252	253	258

(A) Non-pregnant (B) Death prior sch. nec

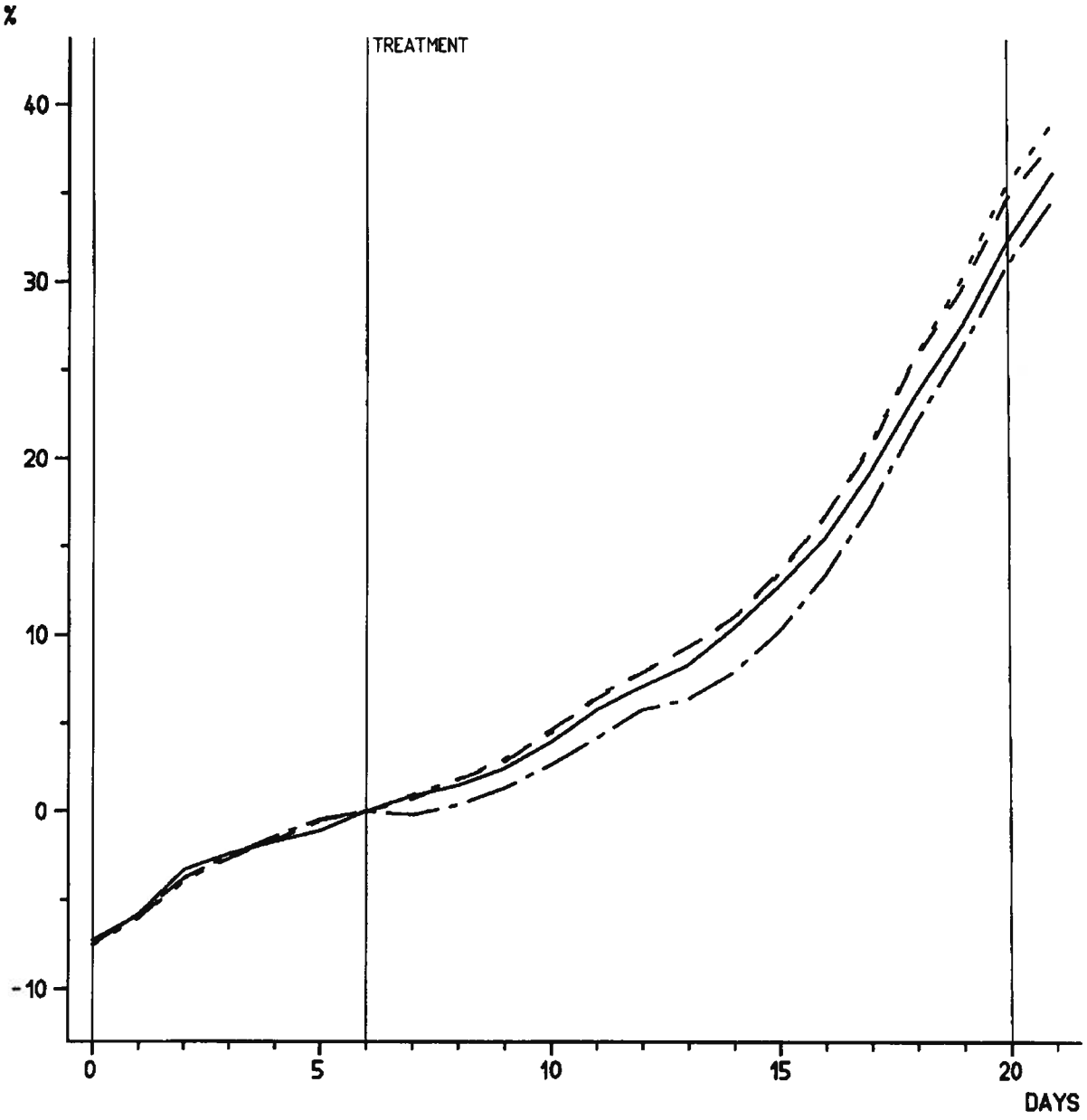
BODY WEIGHTS (GRAM) OF DAMS POST COITUM

GROUP 4 (150 MG/KG)

DAYS ANIMAL	16	17	18	19	20	21
67	297	308	313	325	340	350
68	277	291	303	313	327	337
69	278	288	301	319	330	336
70	291	298	308	319	334	354
71	239	245	255	265	278	280
72	242	247	259	265	272	282
73	298	310	327	334	343	353
74	293	305	311	324	331	342
75	261	276	285	301	305	322
76 (A)	230	225	229	232	231	227
77	278	287	304	316	325	327
78	281	294	309	322	332	341
79	294	301	315	325	333	344
80 (A)	242	242	245	241	243	243
81 (B)	---	---	---	---	---	---
82	272	281	293	299	318	329
83	268	274	286	295	303	298
84	266	280	294	300	318	335
85	266	275	289	300	313	323
86	270	280	281	287	300	302
87	249	256	267	279	286	293
88	264	271	280	290	300	310

(A) Non-pregnant (B) Death prior sch. nec

BODY WEIGHT GAIN OF DAMS
POST COITUM



BODY WEIGHT GAIN (%) OF DAMS SUMMARY
POST COITUM

			GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 30 MG/KG	GROUP 4 150 MG/KG	
DAY	0	MEAN	-7	-8	-7	-7	
		ST.DEV.	1.9	2.0	2.4	1.5	
		N	21	22	21	19	
DAY	1	MEAN	-6	-6	-6	-6	
		ST.DEV.	1.3	1.6	2.1	1.6	
		N	21	22	21	19	
DAY	2	MEAN	-3	-4	-4	-4	
		ST.DEV.	1.5	1.7	1.7	1.4	
		N	21	22	21	19	
DAY	3	MEAN	-2	-3	-3	-3	
		ST.DEV.	1.6	1.8	1.7	1.1	
		N	21	22	21	19	
DAY	4	MEAN	-2	-2	-2	-1	
		ST.DEV.	1.2	1.1	1.6	1.2	
		N	21	22	21	19	
DAY	5	MEAN	-1	-1	-1	0	
		ST.DEV.	1.6	0.9	1.2	1.4	
		N	21	22	21	19	
DAY	6	MEAN	0	0	0	0	
		ST.DEV.	0.0	0.0	0.0	0.0	
		N	21	22	21	19	
DAY	7	MEAN	1	1	1	0	**
		ST.DEV.	1.0	0.9	1.0	0.9	
		N	21	22	21	19	
DAY	8	MEAN	2	2	2	0	**
		ST.DEV.	1.1	0.9	1.3	0.9	
		N	21	22	21	19	
DAY	9	MEAN	2	3	3	1	**
		ST.DEV.	1.1	1.3	1.2	1.1	
		N	21	22	21	19	
DAY	10	MEAN	4	4	5	3	*
		ST.DEV.	1.5	1.3	1.3	1.5	
		N	21	22	21	19	
DAY	11	MEAN	6	7	6	4	*
		ST.DEV.	1.9	1.7	1.6	1.5	
		N	21	22	21	19	
DAY	12	MEAN	7	8	8	6	
		ST.DEV.	2.0	2.3	1.4	1.6	
		N	21	22	21	19	
DAY	13	MEAN	8	9	9	6	**
		ST.DEV.	2.2	1.8	1.5	1.7	
		N	21	22	21	19	
DAY	14	MEAN	10	11	11	8	**
		ST.DEV.	2.6	2.0	1.8	2.2	
		N	21	22	21	19	
DAY	15	MEAN	13	13	14	10	**
		ST.DEV.	2.7	2.6	2.1	2.1	
		N	21	22	21	19	
DAY	16	MEAN	15	17	17	13	*
		ST.DEV.	3.2	2.6	2.5	2.4	
		N	21	22	21	19	

Explanations for excluded data are listed in the tables of individual values
* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

BODY WEIGHT GAIN (%) OF DAMS SUMMARY POST COITUM

			GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 30 MG/KG	GROUP 4 150 MG/KG
DAY	17	MEAN	19	21	21	17
		ST.DEV.	3.9	3.2	3.4	2.8
		N	21	22	21	19
DAY	18	MEAN	24	26	26	22
		ST.DEV.	5.0	4.3	4.0	3.8
		N	21	22	21	19
DAY	19	MEAN	28	30	30	26
		ST.DEV.	6.1	4.1	4.1	3.8
		N	21	22	21	19
DAY	20	MEAN	32	36	35	31
		ST.DEV.	7.5	4.9	5.3	4.4
		N	21	22	21	19
DAY	21	MEAN	36	39	38	35
		ST.DEV.	8.0	4.9	5.9	5.5
		N	21	22	21	19

Explanations for excluded data are listed in the tables of individual values
* / ** : Dunnett-Test based on pooled variance significant at 5% (*) or 1% (**) level

CORRECTED BODY WEIGHT GAIN OF DAMS
GROUP 1 (0 MG/KG)

FEMALE	WEIGHT ON DAY 6 P.C.	WEIGHT ON DAY OF SECTION	WEIGHT OF UTERUS	CORRECTED WEIGHT GAIN GRAM<1>	PERCENT<2>
1 <NP>	257.4	256.4			
2	243.9	309.7	33.1	32.6	13.4
3	239.9	336.5	84.4	12.1	5.1
4	248.8	326.5	65.5	12.2	4.9
5	214.3	295.9	70.3	11.4	5.3
6	223.5	312.6	71.3	17.8	8.0
7	268.3	308.3	16.5	23.6	8.8
8	244.9	338.0	83.1	9.9	4.1
9	245.3	306.6	47.8	13.4	5.5
10	237.3	315.2	57.7	20.3	8.5
11	248.3	359.3	95.9	15.1	6.1
12	249.9	347.6	79.8	17.9	7.2
13	247.9	312.0	40.1	24.0	9.7
14	235.8	322.5	81.7	5.0	2.1
15	238.2	344.7	90.8	15.7	6.6
16	230.2	322.1	75.3	16.6	7.2
17	240.7	335.2	71.9	22.5	9.4
18	223.6	335.1	81.1	30.4	13.6
19	215.3	296.7	62.0	19.5	9.1
20	244.5	339.5	80.9	14.1	5.8
21	245.8	329.0	65.5	17.7	7.2
22	233.3	333.5	82.0	18.3	7.8
		N	21	21	21
		MEAN	68.4	17.6	7.4
		ST.DEV.	19.9	6.6	2.8

<1> : (Weight on Day of Section) - (Weight on Day 6 P.C.) - (Weight Uterus)
<2> : Corrected Weight Gain in Percent of Weight on Day 6 P.C.
Reason for Exclusion from Evaluation :
<NP> Not pregnant

CORRECTED BODY WEIGHT GAIN OF DAMS
GROUP 2 (10 MG/KG)

FEMALE	WEIGHT ON DAY 6 P.C.	WEIGHT ON DAY OF SECTION	WEIGHT OF UTERUS	CORRECTED WEIGHT GAIN GRAM<1>	CORRECTED WEIGHT GAIN PERCENT<2>
23	215.2	289.9	62.0	12.7	5.9
24	238.1	332.9	78.6	16.1	6.8
25	257.5	379.1	95.9	25.8	10.0
26	234.8	305.1	55.3	15.1	6.4
27	254.1	325.4	59.6	11.7	4.6
28	226.4	315.7	63.1	26.2	11.6
29	219.4	321.7	80.8	21.5	9.8
30	248.1	339.9	84.4	7.5	3.0
31	218.9	309.7	69.4	21.5	9.8
32	276.2	391.6	88.4	27.1	9.8
33	287.0	396.3	91.0	18.4	6.4
34	244.7	340.9	74.6	21.6	8.8
35	239.3	334.0	85.2	9.5	4.0
36	227.5	308.2	74.8	6.0	2.6
37	239.7	350.2	95.1	15.4	6.4
38	240.9	338.5	83.6	14.1	5.8
39	201.9	284.8	70.4	12.5	6.2
40	215.1	305.5	69.0	21.4	9.9
41	225.9	307.1	69.1	12.1	5.4
42	253.1	336.8	67.6	16.0	6.3
43	240.7	333.5	86.9	6.0	2.5
44	220.0	314.0	80.7	13.3	6.1
		N	22	22	22
		MEAN	76.6	16.0	6.7
		ST.DEV.	11.6	6.3	2.6

<1> : (Weight on Day of Section) - (Weight on Day 6 P.C.) - (Weight Uterus)
<2> : Corrected Weight Gain in Percent of Weight on Day 6 P.C.

CORRECTED BODY WEIGHT GAIN OF DAMS
GROUP 3 (30 MG/KG)

FEMALE	WEIGHT ON DAY 6 P.C.	WEIGHT ON DAY OF SECTION	WEIGHT OF UTERUS	CORRECTED WEIGHT GAIN GRAM<1>	CORRECTED WEIGHT GAIN PERCENT<2>
45	245.4	331.4	71.5	14.5	5.9
46	242.4	343.4	81.8	19.3	8.0
47	234.6	284.0	29.6	19.9	8.5
48	241.2	309.0	64.0	3.9	1.6
49 <NP>	242.3	243.1			
50	239.4	333.8	72.7	21.7	9.1
51	248.8	333.2	65.2	19.1	7.7
52	242.7	324.5	78.6	3.2	1.3
53	224.7	308.0	73.7	9.6	4.3
54	238.2	332.1	71.3	22.6	9.5
55	227.2	316.1	75.0	14.0	6.2
56	249.7	345.8	80.1	16.0	6.4
57	269.4	366.5	85.6	11.5	4.3
58	242.7	345.6	85.8	17.0	7.0
59	210.8	290.3	69.5	10.0	4.7
60	224.5	325.7	87.6	13.6	6.1
61	246.9	333.5	62.2	24.5	9.9
62	216.6	307.7	68.6	22.5	10.4
63	251.9	368.1	98.9	17.3	6.9
64	228.7	337.3	91.0	17.6	7.7
65	266.0	366.2	107.9	-7.8	-2.9
66	255.4	356.1	91.3	9.4	3.7
		N	21	21	21
		MEAN	76.8	14.3	6.0
		ST.DEV.	16.0	7.7	3.2

<1> : (Weight on Day of Section) - (Weight on Day 6 P.C.) - (Weight Uterus)
<2> : Corrected Weight Gain in Percent of Weight on Day 6 P.C.
Reason for Exclusion from Evaluation :
<NP> Not pregnant

CORRECTED BODY WEIGHT GAIN OF DAMS
GROUP 4 (150 MG/KG)

FEMALE	WEIGHT ON DAY 6 P.C.	WEIGHT ON DAY OF SECTION	WEIGHT OF UTERUS	CORRECTED WEIGHT GAIN GRAM<1>	CORRECTED WEIGHT GAIN PERCENT<2>
67	266.9	349.6	74.8	7.8	2.9
68	246.0	336.7	78.0	12.8	5.2
69	248.4	336.1	93.7	-6.0	-2.4
70	251.2	353.7	86.1	16.4	6.5
71	206.9	279.9	63.4	9.7	4.7
72	213.9	281.7	52.1	15.7	7.3
73	257.5	352.8	81.7	13.5	5.3
74	258.5	342.4	69.8	14.1	5.5
75	238.0	322.4	76.1	8.2	3.5
76 <NP>	232.4	227.3			
77	241.6	327.1	80.9	4.7	1.9
78	250.4	341.3	74.9	16.1	6.4
79	264.7	344.4	76.7	3.0	1.1
80 <NP>	243.9	242.5			
81 <DP>	249.2				
82	242.1	329.4	92.3	-5.0	-2.1
83	233.9	298.1	68.6	-4.4	-1.9
84	221.3	334.7	87.3	26.1	11.8
85	235.9	323.2	79.4	7.9	3.3
86	242.5	302.0	49.9	9.6	3.9
87	218.7	293.0	76.8	-2.5	-1.2
88	235.3	309.6	68.3	5.9	2.5
		N	19	19	19
		MEAN	75.3	8.1	3.4
		ST.DEV.	11.6	8.5	3.6

<1> : (Weight on Day of Section) - (Weight on Day 6 P.C.) - (Weight Uterus)
<2> : Corrected Weight Gain in Percent of Weight on Day 6 P.C.
Reason for Exclusion from Evaluation :
<DP> Death prior sch. necropsy <NP> Not pregnant

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

DIFFERENCES IN MEAN BODY WEIGHT GAIN (G) OF DAMS POST COITUM

Group	Days post coitum									
	0 - 3		3 - 6		6 - 9		9 - 12		12 - 15	
(mg/kg)	g	(%)*	g	(%)*	g	(%)*	g	(%)*	g	(%)*
1 (0)	12	(+5.4)	6	(+2.6)	6	(+2.5)	11	(+4.5)	13	(+5.1)
2 (10)	12	(+5.5)	6	(+2.6)	7	(+3.0)	12	(+4.9)	13	(+5.1)
3 (30)	11	(+4.9)	6	(+2.6)	7	(+2.9)	12	(+4.9)	14	(+5.4)
4 (150)	12	(+5.4)	6	(+2.6)	3	(+1.2)	11	(+4.5)	10	(+3.9)

Group	Days post coitum						Corrected body
	15 - 18		18 - 21		6 - 21**		weight gain %
(mg/kg)	g	(%)*	g	(%)*	g	(%)*	(see pp. 52-55)
1 (0)	26	(+9.7)	30	(+10.2)	86	(+36.0)	7.4
2 (10)	30	(+11.2)	31	(+10.4)	93	(+39.2)	6.7
3 (30)	29	(+10.6)	29	(+9.6)	91	(+37.9)	6.0
4 (150)	29	(+10.9)	30	(+10.2)	83	(+34.4)	3.4

* = Alteration within the recording period.

** = The calculations of body weight gain during the treatment period started on day 6 post coitum (immediately prior to the first administration) and ended on day 21 post coitum (approximately 24 hours after the last administration).

REPRODUCTION DATA SUMMARY

	GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 30 MG/KG	GROUP 4 150 MG/KG
NUMBER OF DAMS	21	22	21	19
CORPORA LUTEA	288	295	281	274
MEAN (+)	13.7	13.4	13.4	14.4
ST.DEV.	2.5	1.9	2.2	1.8
PRE-IMPLANTATION LOSS	30	20	13	14
% OF CORP. LUTEA (#)	10.4	6.8	4.6 ##	5.1 #
MEAN (+)	1.4	0.9	0.6	0.7
ST.DEV.	2.0	0.9	0.6	0.8
NUMBER OF DAMS AFFECTED	12	13	12	10
IMPLANTATION SITES	258	275	268	260
% OF CORP. LUTEA (#)	89.6	93.2	95.4 ##	94.9 #
MEAN (+)	12.3	12.5	12.8	13.7
ST.DEV.	2.8	1.9	2.4	2.1
POST-IMPLANTATION LOSS	31	13	20	35
% OF IMPL. SITES (#)	12.0	4.7 ##	7.5	13.5
MEAN (+)	1.5	0.6	1.0	1.8
ST.DEV.	1.8	0.9	1.1	2.6
NUMBER OF DAMS AFFECTED	14	9	12	16
IMPLANTATION SITE SCARS	0	0	0	0
EMBRYONIC/FETAL DEATHS TOTAL	31	13	20	35
EMBRYONIC RESORPTIONS	20	11	18	35
% OF IMPL. SITES (#)	7.8	4.0 #	6.7	13.5 #
MEAN (+)	1.0	0.5	0.9	1.8
ST.DEV.	1.3	0.9	1.1	2.6
NUMBER OF DAMS AFFECTED	12	7	11	16
FETAL RESORPTIONS	11	2	2	0
% OF IMPL. SITES (#)	4.3	0.7 ##	0.7 ##	
MEAN (+)	0.5	0.1	0.1	
ST.DEV.	1.2	0.3	0.3	
NUMBER OF DAMS AFFECTED	5	2	2	
FETUSES				
TOTAL FETUSES	227	262	248	225
% OF IMPL. SITES (#)	88.0	95.3 ##	92.5	86.5
MEAN (+)	10.8	11.9	11.8	11.8
ST.DEV.	3.4	2.1	2.8	2.1
LIVE FETUSES	227	262	248	225
DEAD FETUSES	0	0	0	0
ABNORMAL FETUSES	1	0	0	0
% OF FETUSES (#)	0.4			
MEAN (+)	0.0			
ST.DEV.	0.2			
NUMBER OF DAMS AFFECTED	1			
ABNORMAL LIVE FETUSES AT EXTERNAL EXAMINATION	1	0	0	0
ABNORMAL DEAD FETUSES AT EXTERNAL EXAMINATION	0	0	0	0

*/** : Dunnett-Test based on pooled variance significant at level 5% (*) or 1% (**)
#/## : Fisher's Exact Test significant at level 5% (#) or 1% (##)
+ : Steel Test significant at level 5%

REPRODUCTION DATA SUMMARY

	GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 30 MG/KG	GROUP 4 150 MG/KG
NUMBER OF DAMS	21	22	21	19
SEX OF FETUSES				
TOTAL MALES	114	133	121	99
% OF FETUSES (#)	50.2	50.8	48.8	44.0
MEAN (+)	5.4	6.0	5.8	5.2
ST.DEV.	2.0	1.7	2.2	1.5
TOTAL FEMALES	113	129	127	126
% OF FETUSES (#)	49.8	49.2	51.2	56.0
MEAN (+)	5.4	5.9	6.0	6.6
ST.DEV.	2.5	2.2	2.1	2.1
LIVE MALES	114	133	121	99
LIVE FEMALES	113	129	127	126
WEIGHTS OF LIVE FETUSES (LITTER BASIS)				
TOTAL FETUSES				
N (LITTERS)	21	22	21	19
MEAN (*)	4.6	4.8	4.8	4.8
ST.DEV.	0.2	0.3	0.3	0.2
MALES				
N (LITTERS)	20	22	21	19
MEAN (*)	4.7	4.9	5.0 *	4.9
ST.DEV.	0.3	0.3	0.3	0.3
FEMALES				
N (LITTERS)	20	22	21	19
MEAN (*)	4.5	4.6	4.7	4.6
ST.DEV.	0.2	0.3	0.3	0.2
WEIGHTS OF LIVE FETUSES (INDIVIDUAL BASIS)				
TOTAL FETUSES				
N (FETUSES)	227	262	248	225
MEAN (*)	4.6	4.8 **	4.8 **	4.8 **
ST.DEV.	0.4	0.4	0.4	0.4
MALES				
N (FETUSES)	114	133	121	99
MEAN (*)	4.7	4.9 **	5.0 **	4.9 **
ST.DEV.	0.4	0.5	0.4	0.4
FEMALES				
N (FETUSES)	113	129	127	126
MEAN (*)	4.5	4.6 *	4.7 **	4.6 **
ST.DEV.	0.3	0.3	0.4	0.3

*/** : Dunnett-Test based on pooled variance significant at level 5% (*) or 1% (**)
#/## : Fisher's Exact Test significant at level 5% (#) or 1% (##)
+ : Steel Test significant at level 5%

REPRODUCTION DATA
GROUP 1 (0 MG/KG)

FEMALE	CORP. LUTEA	IMPL.	-EMBRYONIC DEATHS- TOTAL	EMBR. STAGE	FETAL STAGE	FETUSES TOTAL	LIVE MALE	LIVE FEM.	DEAD MALE	DEAD FEM.	MALF. MALE	MALF. FEM.
1 <NP>												
2	9	6	1	0	1	5	5	0	0	0	0	0
3	15	15	0	0	0	15	5	10	0	0	0	0
4	18	10	0	0	0	10	5	5	0	0	0	0
5	13	13	1	1	0	12	7	5	0	0	1	0
6	17	13	1	1	0	12	5	7	0	0	0	0
7	8	6	4	4	0	2	0	2	0	0	0	0
8	15	14	1	1	0	13	7	6	0	0	0	0
9	12	11	4	1	3	7	5	2	0	0	0	0
10	14	11	2	2	0	9	4	5	0	0	0	0
11	15	15	0	0	0	15	7	8	0	0	0	0
12	14	13	0	0	0	13	9	4	0	0	0	0
13	11	11	5	5	0	6	2	4	0	0	0	0
14	13	13	0	0	0	13	5	8	0	0	0	0
15	15	15	1	0	1	14	6	8	0	0	0	0
16	13	13	1	1	0	12	7	5	0	0	0	0
17	14	11	0	0	0	11	4	7	0	0	0	0
18	15	14	1	1	0	13	5	8	0	0	0	0
19	11	9	0	0	0	9	6	3	0	0	0	0
20	14	14	1	1	0	13	8	5	0	0	0	0
21	17	16	6	1	5	10	7	3	0	0	0	0
22	15	15	2	1	1	13	5	8	0	0	0	0
TOTAL	288	258	31	20	11	227	114	113	0	0	1	0
MEAN	13.7	12.3	1.5	1.0	0.5	10.8	5.4	5.4			0.0	
ST.DEV.	2.5	2.8	1.8	1.3	1.2	3.4	2.0	2.5			0.2	

Reason for Exclusion from Evaluation :
<NP> Not pregnant

REPRODUCTION DATA
GROUP 2 (10 MG/KG)

FEMALE	CORP. LUTEA	IMPL.	-EMBRYONIC DEATHS-- TOTAL	EMBR. STAGE	FETAL STAGE	PETUSES TOTAL	LIVE MALE	LIVE FEM.	DEAD MALE	DEAD FEM.	MALF. MALE	MALF. FEM.
23	12	11	2	2	0	9	6	3	0	0	0	0
24	15	15	2	2	0	13	7	6	0	0	0	0
25	15	15	0	0	0	15	10	5	0	0	0	0
26	11	9	0	0	0	9	7	2	0	0	0	0
27	12	10	1	1	0	9	3	6	0	0	0	0
28	11	9	0	0	0	9	5	4	0	0	0	0
29	13	12	0	0	0	12	7	5	0	0	0	0
30	15	14	0	0	0	14	6	8	0	0	0	0
31	12	12	1	1	0	11	6	5	0	0	0	0
32	17	15	1	0	1	14	6	8	0	0	0	0
33	14	13	0	0	0	13	7	6	0	0	0	0
34	15	12	0	0	0	12	5	7	0	0	0	0
35	13	13	0	0	0	13	7	6	0	0	0	0
36	13	13	1	1	0	12	6	6	0	0	0	0
37	17	16	0	0	0	16	7	9	0	0	0	0
38	13	13	0	0	0	13	9	4	0	0	0	0
39	12	12	1	1	0	11	5	6	0	0	0	0
40	11	11	1	0	1	10	6	4	0	0	0	0
41	11	10	0	0	0	10	4	6	0	0	0	0
42	15	13	3	3	0	10	7	3	0	0	0	0
43	15	14	0	0	0	14	4	10	0	0	0	0
44	13	13	0	0	0	13	3	10	0	0	0	0
TOTAL	295	275	13	11	2	262	133	129	0	0	0	0
MEAN	13.4	12.5	0.6	0.5	0.1	11.9	6.0	5.9				
ST.DEV.	1.9	1.9	0.9	0.9	0.3	2.1	1.7	2.2				

REPRODUCTION DATA
GROUP 3 (30 MG/KG)

FEMALE	CORP. LUTEA	IMPL.	-EMBRYONIC DEATHS-- TOTAL	EMBR. STAGE	FETAL STAGE	FETUSES TOTAL	LIVE MALE	LIVE FEM.	DEAD MALE	DEAD FEM.	MALF. MALE	MALF. FEM.
45	12	12	2	1	1	10	5	5	0	0	0	0
46	14	14	2	2	0	12	7	5	0	0	0	0
47	10	8	4	4	0	4	2	2	0	0	0	0
48	11	10	1	1	0	9	6	3	0	0	0	0
49 <NP>												
50	12	12	0	0	0	12	6	6	0	0	0	0
51	12	11	1	1	0	10	5	5	0	0	0	0
52	14	13	0	0	0	13	5	8	0	0	0	0
53	11	11	0	0	0	11	4	7	0	0	0	0
54	11	10	0	0	0	10	6	4	0	0	0	0
55	15	14	2	2	0	12	7	5	0	0	0	0
56	13	13	1	1	0	12	9	3	0	0	0	0
57	16	15	2	2	0	13	7	6	0	0	0	0
58	14	14	1	0	1	13	6	7	0	0	0	0
59	12	11	0	0	0	11	1	10	0	0	0	0
60	14	14	0	0	0	14	7	7	0	0	0	0
61	13	12	2	2	0	10	2	8	0	0	0	0
62	11	10	0	0	0	10	5	5	0	0	0	0
63	17	16	0	0	0	16	9	7	0	0	0	0
64	16	16	1	1	0	15	6	9	0	0	0	0
65	17	17	0	0	0	17	9	8	0	0	0	0
66	16	15	1	1	0	14	7	7	0	0	0	0
TOTAL	281	268	20	18	2	248	121	127	0	0	0	0
MEAN	13.4	12.8	1.0	0.9	0.1	11.8	5.8	6.0				
ST.DEV.	2.2	2.4	1.1	1.1	0.3	2.8	2.2	2.1				

Reason for Exclusion from Evaluation :
<NP> Not pregnant

REPRODUCTION DATA
GROUP 4 (150 MG/KG)

FEMALE	CORP. LUTEA	IMPL.	-EMBRYONIC DEATHS- TOTAL	EMBR. STAGE	FETAL STAGE	FETUSES TOTAL	LIVE MALE	LIVE FEM.	DEAD MALE	DEAD FEM.	MALF. MALE	MALF. FEM.
67	17	17	6	6	0	11	5	6	0	0	0	0
68	14	13	1	1	0	12	5	7	0	0	0	0
69	16	16	1	1	0	15	5	10	0	0	0	0
70	16	14	1	1	0	13	6	7	0	0	0	0
71	12	10	0	0	0	10	4	6	0	0	0	0
72	13	11	3	3	0	8	4	4	0	0	0	0
73	15	14	2	2	0	12	5	7	0	0	0	0
74	13	13	2	2	0	11	3	8	0	0	0	0
75	13	13	1	1	0	12	5	7	0	0	0	0
76 <NP>												
77	15	14	0	0	0	14	5	9	0	0	0	0
78	12	12	1	1	0	11	7	4	0	0	0	0
79	14	13	1	1	0	12	5	7	0	0	0	0
80 <NP>												
81 <DP>												
82	17	16	1	1	0	15	8	7	0	0	0	0
83	13	12	1	1	0	11	5	6	0	0	0	0
84	16	16	1	1	0	15	8	7	0	0	0	0
85	13	13	0	0	0	13	2	11	0	0	0	0
86	18	18	11	11	0	7	5	2	0	0	0	0
87	13	13	1	1	0	12	5	7	0	0	0	0
88	14	12	1	1	0	11	7	4	0	0	0	0
TOTAL	274	260	35	35	0	225	99	126	0	0	0	0
MEAN	14.4	13.7	1.8	1.8		11.8	5.2	6.6				
ST.DEV.	1.8	2.1	2.6	2.6		2.1	1.5	2.1				

Reason for Exclusion from Evaluation :
<DP> Death prior sch. necropsy <NP> Not pregnant

EXTERNAL EXAMINATION OF FETUSES

Group (mg/kg)	No. of fetuses examined	Type of abnormal finding	Litter No.	Fetus No.
1 (0)	227	Head malformed (including upper and lower jaw), for details see visceral examination p. 65	5	42
2 (10)	262	No abnormal findings noted		
3 (30)	248	No abnormal findings noted		
4 (150)	225	No abnormal findings noted		

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

FINDINGS FROM VISCERAL EXAMINATION OF FETUSES (BY MICRODISSECTION TECHNIQUE) - SUMMARY

	Group 1 0 mg/kg		Group 2 10 mg/kg		Group 3 30 mg/kg		Group 4 150 mg/kg	
Number of litters	21		22		21		19	
Number of fetuses examined	121		137		128		118	
Incidences of fetuses with	N	%	N	%	N	%	N	%
Localized subcutaneous haemorrhage	4	3	4	3	0	0	0	0
Lateral brain ventricles dilated, slight	0	0	1	1	1	1	0	0
Thymus cranially elongated (uni-/bilaterally)	7	6	5	4	11	9	4	3
Lung right caudal and accessory lobes partially fused	0	0	1	1	0	0	1	1
Diaphragm tendineous region locally thinned	0	0	0	0	1	1	2	2
Liver additional lobe(s) within median cleft	28	23	27	20	20	16	22	19
Liver median cleft displaced	0	0	1	1	0	0	0	0
Liver left lateral lobe additional cleft	14	12	11	8	7	5	8	7
Liver left lateral lobe misshapen (folded)	0	0	1	1	0	0	0	0
Liver posterior lobe of papillary process misshapen (folded)	0	0	0	0	1	1	0	0
Renal pelvis dilated (uni-/bilaterally)	5	4	4	3	0	0	1	1
Testis cranial displacement (uni-/bilaterally) – (% of male fetuses)	3	5	6	9	6	9	7	13
Testis medial displacement (right) – (% of male fetuses)	2	4	2	3	2	3	1	2
Umbilical artery left-sided	19	16	12	9	22	17	13	11
Innominate artery short / elongated	0	0	1	1	0	0	1	1
Oesophagus displaced (to right of trachea)	0	0	1	1	0	0	0	0
Urinary bladder distended	1	1	0	0	0	0	0	0
Anophthalmia (uni-/bilaterally)	0	0	1	1	0	0	1	1
Perimeningeal haemorrhage around olfactory lobes, slight	0	0	0	0	1	1	0	0
Azygos vein bilateral	0	0	1	1	0	0	2	2
Small fetus (about 50% of normal size)	0	0	1	1	0	0	0	0
Multiple malformations	1*	1	0	0	0	0	0	0
Litters with any abnormal findings	20	95	22	100	21	100	19	100
Fetuses with any abnormal finding	67	55	61	45	63	49	52	44

* = Litter no. 5, fetus no. 42

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

FINDINGS FROM VISCERAL EXAMINATION OF FETUSES (BY MICRODISSECTION TECHNIQUE) - INDIVIDUAL

Group 1 (0 mg/kg)

Number of fetuses examined: 121

Type of abnormal finding				Litter No.	Fetus No.
K	N	T			
			Renal pelvis dilated (bilaterally) Thymus cranially elongated (bilaterally)	2	1
X	X				5
	X		Subcutaneous haemorrhage head, lower jaw	3	10
	X				12
		X			14
	X				16
	X				18
		X	Thymus cranially elongated (bilaterally)	4	23
			Testis cranial displacement (left)		27
X				5	31
		X			37
X		X			39
X	X				41
X		X	Frontonasal probascis with single naris and fused nasal cavities, eyes close together on midline beneath probascis, mouth reduced and misshapen Lower jaw absent Brain reduced (olfactory lobes absent) and misshapen with no separation of lateral ventricles Aortic arch dilated Pulmonary trunk reduced (shortened) and with displaced origin from heart; over-riding aorta Azygos vein bilateral		42

Fetuses not listed were without findings

K = Liver additional lobe(s) within median cleft
N = Liver left lateral lobe additional cleft
T = Umbilical artery left-sided

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

FINDINGS FROM VISCERAL EXAMINATION OF FETUSES (BY MICRODISSECTION TECHNIQUE) - INDIVIDUAL

Group 1 (0 mg/kg), continued

Type of abnormal finding				Litter No.	Fetus No.
K	N	T			
	X			6	43
	X				47
		X			49
			Testis medial displacement (right)		51
X				8	293
X		X			295
X		X			305
		X		9	306
			Subcutaneous haemorrhage head, lower jaw		308
			Subcutaneous haemorrhage head, lower jaw		310
			Subcutaneous haemorrhage head, lower jaw		312
X				10	498
			Thymus cranially elongated (left side)		500
		X			504
X				11	509
			Renal pelvis dilated (left)		521
			Testis cranial displacement (left)	12	524
		X			526
X					532
X					534
X				13	535
		X			539

Fetuses not listed were without findings

K = Liver additional lobe(s) within median cleft
N = Liver left lateral lobe additional cleft
T = Umbilical artery left-sided

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

FINDINGS FROM VISCERAL EXAMINATION OF FETUSES (BY MICRODISSECTION TECHNIQUE) - INDIVIDUAL

Group 1 (0 mg/kg), continued

Type of abnormal finding				Litter No.	Fetus No.
K	N	T			
X			Urinary bladder distended	14	541
X					545
X					547
X					549
X					553
		X		15	554
X		X		16	568
X					570
X					572
	X				574
			Thymus cranially elongated (right side)	17	582
	X				584
	X			18	591
		X			593
	X				601
	X	X		19	606
		X			610
			Renal pelvis dilated (left)		612
X				20	808
			Thymus cranially elongated (left side)		810
X					814
X		X			816

Fetuses not listed were without findings

K = Liver additional lobe(s) within median cleft
N = Liver left lateral lobe additional cleft
T = Umbilical artery left-sided

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

FINDINGS FROM VISCERAL EXAMINATION OF FETUSES (BY MICRODISSECTION TECHNIQUE) - INDIVIDUAL

Group 1 (0 mg/kg), continued

Type of abnormal finding				Litter No.	Fetus No.
K	N	T			
X			Testis medial displacement (right)	21	819
			Renal pelvis dilated (right)		823
			Renal pelvis dilated (right)		825
	X		Testis cranial displacement (right)		827
			Thymus cranially elongated (left side)	22	829
X			Thymus cranially elongated (left side)		831
X					833
		X			835
X					837

Fetuses not listed were without findings

K = Liver additional lobe(s) within median cleft
N = Liver left lateral lobe additional cleft
T = Umbilical artery left-sided

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

FINDINGS FROM VISCERAL EXAMINATION OF FETUSES (BY MICRODISSECTION TECHNIQUE) - INDIVIDUAL

Group 2 (10 mg/kg)

Number of fetuses examined: 137

Type of abnormal finding				Litter No.	Fetus No.
K	N	T			
			Left lateral liver lobe misshapen (folded)	23	57
X	X			24	64
			Renal pelvis dilated (left)	25	77
			Testis cranial displacement (left)		79
	X		Renal pelvis dilated (right)		81
			Right eye: anophthalmia		85
X					87
	X				91
X		X	Innominate artery short Azygos vein bilateral, oesophagus displaced (to right of trachea) Lateral brain ventricles dilated, slight Fetus small (about 50% of normal size)	26	96
X					100
	X			27	101
X			Renal pelvis dilated (bilaterally)	28	112
X			Renal pelvis dilated (right)		114
		X			118
			Testis cranial displacement (right)	29	123
	X				125
			Testis cranial displacement (right)		129
			Testis medial displacement (right)	30	315
			Lung right caudal and accessory lobes partially fused		319
X			Subcutaneous haemorrhage head, lower jaw		321
X			Liver median cleft displaced		325

Fetuses not listed were without findings

K = Liver additional lobe(s) within median cleft
N = Liver left lateral lobe additional cleft
T = Umbilical artery left-sided

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

FINDINGS FROM VISCERAL EXAMINATION OF FETUSES (BY MICRODISSECTION TECHNIQUE) - INDIVIDUAL

Group 2 (10 mg/kg), continued

Type of abnormal finding				Litter No.	Fetus No.
K	N	T			
			Subcutaneous haemorrhage head, lower jaw	31	329
		X	Subcutaneous haemorrhage head, lower jaw		335
			Subcutaneous haemorrhage head, lower jaw	32	344
			Testis medial displacement (right)		348
X				33	352
			Thymus cranially elongated (left side)		356
X					360
X					364
X				34	615
	X				617
X	X				621
X					623
		X		35	627
	X			36	642
X				37	650
		X			654
	X				658
X			Testis cranial displacement (bilaterally)		660
X				38	666
	X				668
			Thymus cranially elongated (bilaterally)		676
			Testis cranial displacement (right)	39	683
X					687
		X		40	696
			Thymus cranially elongated (left side)		698

Fetuses not listed were without findings

K = Liver additional lobe(s) within median cleft
N = Liver left lateral lobe additional cleft
T = Umbilical artery left-sided

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

FINDINGS FROM VISCERAL EXAMINATION OF FETUSES (BY MICRODISSECTION TECHNIQUE) - INDIVIDUAL

Group 2 (10 mg/kg), continued

Type of abnormal finding				Litter No.	Fetus No.
K	N	T			
X				41	842
X					844
			Testis cranial displacement (right)	42	856
X					858
			Thymus cranially elongated (left side)	43	862
X		X			866
		X			868
X		X			870
		X			872
		X			874
X	X			44	878
X					882
X		X			884
			Thymus cranially elongated (left side)		886
X					888

Fetuses not listed were without findings

K = Liver additional lobe(s) within median cleft
N = Liver left lateral lobe additional cleft
T = Umbilical artery left-sided

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

FINDINGS FROM VISCERAL EXAMINATION OF FETUSES (BY MICRODISSECTION TECHNIQUE) - INDIVIDUAL

Group 3 (30 mg/kg)

Number of fetuses examined: 128

Type of abnormal finding				Litter No.	Fetus No.
K	N	T			
X				45	133
		X			137
X				46	141
			Testis cranial displacement (left)		143
		X			149
X				47	153
	X			48	159
	X				161
			Perimeningeal haemorrhage around olfactory lobes, slight		165
		X		50	170
			Thymus cranially elongated (left side)	51	178
			Thymus cranially elongated (right side)		180
			Thymus cranially elongated (left side)		182
			Thymus cranially elongated (left side)		184
		X			186
		X		52	188
		X			194
X				53	201
		X			205
		X			211
		X		54	216
X			Testis cranial displacement (right)		218

Fetuses not listed were without findings

K = Liver additional lobe(s) within median cleft
N = Liver left lateral lobe additional cleft
T = Umbilical artery left-sided

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

FINDINGS FROM VISCERAL EXAMINATION OF FETUSES (BY MICRODISSECTION TECHNIQUE) - INDIVIDUAL

Group 3 (30 mg/kg), continued

Type of abnormal finding				Litter No.	Fetus No.
K	N	T			
		X		55	365
		X			369
			Testis cranial displacement (right)		373
X	X				375
X				56	377
X		X	Testis cranial displacement (right)		379
		X			381
			Thymus cranially elongated (left side)		385
X					387
		X		57	389
			Testis cranial displacement (left) Liver: posterior lobe of papillary process misshapen (folded)		393
		X			399
			Thymus cranially elongated (left side)	58	406
X					408
			Thymus cranially elongated (left side)		410
X					412
X					414
			Thymus cranially elongated (right side)	59	415
		X			417
	X				419
X		X	Thymus cranially elongated (left side)		423
X			Thymus cranially elongated (left side)		425

Fetuses not listed were without findings

K = Liver additional lobe(s) within median cleft
N = Liver left lateral lobe additional cleft
T = Umbilical artery left-sided

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

FINDINGS FROM VISCERAL EXAMINATION OF FETUSES (BY MICRODISSECTION TECHNIQUE) - INDIVIDUAL

Group 3 (30 mg/kg), continued

Type of abnormal finding				Litter No.	Fetus No.
K	N	T			
	X			60	700
	X				704
			Testis medial displacement (right)		706
		X			712
X				61	714
			Lateral brain ventricles dilated, slight		718
		X			720
			Thymus cranially elongated (right side)	62	726
		X		63	738
X					746
	X				748
			Diaphragm tendineous region locally thinned	64	758
		X			760
X				65	889
X			Testis medial displacement (right)		893
			Testis cranial displacement (left)		903
X				66	908
X					912
		X			916

Fetuses not listed were without findings

K = Liver additional lobe(s) within median cleft
N = Liver left lateral lobe additional cleft
T = Umbilical artery left-sided

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

FINDINGS FROM VISCERAL EXAMINATION OF FETUSES (BY MICRODISSECTION TECHNIQUE) - INDIVIDUAL

Group 4 (150 mg/kg)

Number of fetuses examined: 118

Type of abnormal finding				Litter No.	Fetus No.
K	N	T			
			Lung right caudal and accessory lobes partially fused	67	224
		X			232
X				68	233
X					241
		X			243
	X			69	247
X		X			251
		X			257
	X			70	262
		X		71	277
		X			279
X					281
	X			72	287
	X				289
		X		73	428
X		X			434
X				74	442
X			Thymus cranially elongated (left side) Diaphragm tendineous region locally thinned Renal pelvis dilated (right) Anophthalmia bilateral Innominate artery elongated Azygos vein bilateral	75	449
			Thymus cranially elongated (left side)		451
X					455
X					459

Fetuses not listed were without findings

K = Liver additional lobe(s) within median cleft
N = Liver left lateral lobe additional cleft
T = Umbilical artery left-sided

FINDINGS FROM VISCERAL EXAMINATION OF FETUSES (BY MICRODISSECTION TECHNIQUE) - INDIVIDUAL

Group 4 (150 mg/kg), continued

Type of abnormal finding				Litter No.	Fetus No.
K	N	T			
X				77	465
	X				467
X					469
		X			471
			Testis cranial displacement (right)	78	475
X					481
		X			485
			Testis medial displacement (right)	79	488
		X			490
X					496
X				82	767
			Azygos vein bilateral		771
X					775
X					777
X				83	784
X					786
			Testis cranial displacement (right)		790
			Thymus cranially elongated (left side)	84	793
			Testis cranial displacement (right)		795
X			Testis cranial displacement (bilaterally)		797
	X				801
			Diaphragm tendineous region locally thinned		803
X				85	924
X					928

Fetuses not listed were without findings

K = Liver additional lobe(s) within median cleft
N = Liver left lateral lobe additional cleft
T = Umbilical artery left-sided

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

FINDINGS FROM VISCERAL EXAMINATION OF FETUSES (BY MICRODISSECTION TECHNIQUE) - INDIVIDUAL

Group 4 (150 mg/kg), continued

Type of abnormal finding				Litter No.	Fetus No.
K	N	T			
X	X		Testis cranial displacement (bilaterally)	86	935
			Thymus cranially elongated (right side)	87	942
		X			946
	X				948
			Testis cranial displacement (right)	88	952
			Testis cranial displacement (right)		954
		X			958

Fetuses not listed were without findings

K = Liver additional lobe(s) within median cleft
N = Liver left lateral lobe additional cleft
T = Umbilical artery left-sided

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

ABNORMAL FINDINGS FROM SKELETAL AND CARTILAGE EXAMINATIONS OF FETUSES

Group 1 (0 mg/kg)

Number of fetuses examined: 106

Type of abnormal finding	Litter No.	Fetus No.
(B) Sternebrae 4 and 5 offset	22	830

Group 2 (10 mg/kg)

Number of fetuses examined: 125

Type of abnormal finding	Litter No.	Fetus No.
(B) Thoracic vertebral body 12 dumbbell-shaped	35	630
(B) Zygomatic arch fusion (process of maxilla to jugal), right	43	871

(B) = Observed abnormality of bones; (C) Observed abnormality of cartilages

For percentage incidences of abnormalities and variations see skeletal and cartilage examinations summary, pp. 80, 82.

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

ABNORMAL FINDINGS FROM SKELETAL AND CARTILAGE EXAMINATIONS OF FETUSES

Group 3 (30 mg/kg)

Number of fetuses examined: 120

Type of abnormal finding	Litter No.	Fetus No.
(B) Thoracic vertebral body 11 dumbbell-shaped	52	193
(B) Thoracic vertebral body 11 dumbbell-shaped	53	206

Group 4 (150 mg/kg)

Number of fetuses examined: 107

Type of abnormal finding	Litter No.	Fetus No.
(B) Thoracic vertebral body 13 dumbbell-shaped	72	284
(B) Zygomatic arch fusion (process of maxilla to jugal), right	73	429
(B) Sternebra 2 bipartite Sternebrae 3 and 4 offset (C) Cartilaginous sternebrae 2-5 offset	75	450

(B) = Observed abnormality of bones; (C) Observed abnormality of cartilages

For percentage incidences of abnormalities and variations see skeletal and cartilage examinations summary, pp. 80, 82.

SKELETAL EXAMINATIONS SUMMARY

	GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 30 MG/KG	GROUP 4 150 MG/KG
NUMBER OF LITTERS EXAMINED	21	22	21	19
ABNORMAL FINDING(S) (SHOWN ON PREVIOUS PAGE(S))	1 5%	2 9%	2 10%	3 16%
CRANIUM				
INCOMPLETELY OSSIFIED				
OS OCCIPITALE	0	1 5%	0	0
OS PARIETALE, BILATERAL	1 5%	3 14%	0	1 5%
OS INTERPARIETALE	4 19%	4 18%	2 10%	3 16%
JUGAL, LEFT	0	2 9%	0	0
JUGAL, RIGHT	0	2 9%	0	0
ZYGOMATIC PROCESS OF SQUAMOSAL, LEFT	0	1 5%	0	0
ZYGOMATIC PROCESS OF SQUAMOSAL, RIGH	0	1 5%	0	0
CERVICAL VERTEBRAE				
NON-OSSIFIED				
CERVICAL VERTEBRAL BODY 1	0	1 5%	4 19%	1 5%
CERVICAL VERTEBRAL BODY 2	0	4 18%	3 14%	2 11%
CERVICAL VERTEBRAL BODY 3	0	1 5%	1 5%	1 5%
CERVICAL VERTEBRAL BODY 4	0	0	1 5%	1 5%
CERVICAL VERTEBRAL BODY 5	0	0	1 5%	0
STERNUM				
INCOMPLETELY OSSIFIED				
STERNEBRA 5	2 10%	7 32%	10 48% ##	7 37% #
NON-OSSIFIED				
STERNEBRA 5	0	0	1 5%	0
ABNORMALLY OSSIFIED				
STERNEBRA 4	0	0	1 5%	0
STERNEBRA 5	0	0	0	1 5%
RIB(S), LEFT				
SUPERNUMERARY, ONE				
RIB(S), LEFT	1 5%	1 5%	1 5%	2 11%
SUPERNUMERARY, ONE RUDIMENTARY				
RIB(S), LEFT	8 38%	12 55%	11 52%	15 79% #
RIB(S), RIGHT				
SUPERNUMERARY, ONE				
RIB(S), RIGHT	0	0	1 5%	1 5%
SUPERNUMERARY, ONE RUDIMENTARY				
RIB(S), RIGHT	6 29%	10 45%	11 52%	12 63% #
LEFT FORELIMB				
NON-OSSIFIED				
DIGIT 1 DISTAL PHALANX, LEFT	1 5%	0	1 5%	1 5%
DIGIT 2 PROXIMAL PHALANX, LEFT	10 48%	4 18% #	7 33%	8 42%
DIGIT 2 DISTAL PHALANX, LEFT	0	0	2 10%	0
DIGIT 3 PROXIMAL PHALANX, LEFT	1 5%	0	2 10%	0
DIGIT 4 PROXIMAL PHALANX, LEFT	1 5%	0	2 10%	1 5%
METACARPALIA 5, LEFT	0	0	1 5%	0
DIGIT 5 PROXIMAL PHALANX, LEFT	13 62%	17 77%	17 81%	16 84%
DIGIT 5 DISTAL PHALANX, LEFT	4 19%	8 36%	12 57% #	9 47%
RIGHT FORELIMB				
NON-OSSIFIED				
DIGIT 1 DISTAL PHALANX, RIGHT	1 5%	0	1 5%	1 5%
DIGIT 2 PROXIMAL PHALANX, RIGHT	10 48%	4 18% #	7 33%	8 42%
DIGIT 2 DISTAL PHALANX, RIGHT	0	0	2 10%	0
DIGIT 3 PROXIMAL PHALANX, RIGHT	1 5%	0	1 5%	0

#/## : Fisher's Exact Test significant at level 5% (#) or 1% (##)

SKELETAL EXAMINATIONS SUMMARY

	GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 30 MG/KG	GROUP 4 150 MG/KG
NUMBER OF LITTERS EXAMINED	21	22	21	19
RIGHT FORELIMB				
NON-OSSIFIED				
DIGIT 4 PROXIMAL PHALANX, RIGHT	1 5%	0	2 10%	1 5%
METACARPALIA 5, RIGHT	0	0	1 5%	0
DIGIT 5 PROXIMAL PHALANX, RIGHT	13 62%	17 77%	17 81%	16 84%
DIGIT 5 DISTAL PHALANX, RIGHT	4 19%	9 41%	12 57% #	9 47%
LEFT HIND LIMB				
NON-OSSIFIED				
TALUS LEFT	21 100%	20 91%	18 86%	14 74% #
METATARSALIA 1, LEFT	3 14%	0	3 14%	1 5%
TOE 2 PROXIMAL PHALANX, LEFT	8 38%	7 32%	12 57%	8 42%
TOE 3 PROXIMAL PHALANX, LEFT	4 19%	2 9%	9 43%	5 26%
TOE 4 PROXIMAL PHALANX, LEFT	4 19%	2 9%	8 38%	5 26%
TOE 5 PROXIMAL PHALANX, LEFT	20 95%	20 91%	17 81%	14 74%
RIGHT HIND LIMB				
NON-OSSIFIED				
TALUS RIGHT	21 100%	20 91%	17 81%	13 68% ##
METATARSALIA 1, RIGHT	3 14%	0	3 14%	1 5%
TOE 2 PROXIMAL PHALANX, RIGHT	8 38%	7 32%	12 57%	8 42%
TOE 3 PROXIMAL PHALANX, RIGHT	4 19%	2 9%	9 43%	6 32%
TOE 4 PROXIMAL PHALANX, RIGHT	4 19%	2 9%	8 38%	6 32%
TOE 5 PROXIMAL PHALANX, RIGHT	20 95%	20 91%	17 81%	13 68% #

#/## : Fisher's Exact Test significant at level 5% (#) or 1% (##)

SKELETAL EXAMINATIONS SUMMARY

	GROUP 1 0 MG/KG		GROUP 2 10 MG/KG		GROUP 3 30 MG/KG		GROUP 4 150 MG/KG	
NUMBER OF FETUSES EXAMINED	106		125		120		107	
ABNORMAL FINDING(S)								
(SHOWN ON PREVIOUS PAGE(S))	1	1%	2	2%	2	2%	3	3%
CRANIUM								
INCOMPLETELY OSSIFIED								
OS OCCIPITALE	0		1	1%	0		0	
OS PARIETALE, BILATERAL	1	1%	3	2%	0		1	1%
OS INTERPARIETALE	4	4%	7	6%	2	2%	3	3%
JUGAL, LEFT	0		2	2%	0		0	
JUGAL, RIGHT	0		3	2%	0		0	
ZYGOMATIC PROCESS OF SQUAMOSAL, LEFT	0		1	1%	0		0	
ZYGOMATIC PROCESS OF SQUAMOSAL, RIGH	0		1	1%	0		0	
CERVICAL VERTEBRAE								
NON-OSSIFIED								
CERVICAL VERTEBRAL BODY 1	0		1	1%	5	4% #	2	2%
CERVICAL VERTEBRAL BODY 2	0		6	5% #	4	3%	2	2%
CERVICAL VERTEBRAL BODY 3	0		1	1%	1	1%	1	1%
CERVICAL VERTEBRAL BODY 4	0		0		1	1%	1	1%
CERVICAL VERTEBRAL BODY 5	0		0		1	1%	0	
STERNUM								
INCOMPLETELY OSSIFIED								
STERNEBRA 5	2	2%	8	6%	14	12% ##	9	8% #
NON-OSSIFIED								
STERNEBRA 5	0		0		1	1%	0	
ABNORMALLY OSSIFIED								
STERNEBRA 4	0		0		1	1%	0	
STERNEBRA 5	0		0		0		1	1%
RIB(S), LEFT								
SUPERNUMERARY, ONE								
RIB(S), LEFT	1	1%	1	1%	1	1%	2	2%
SUPERNUMERARY, ONE RUDIMENTARY								
RIB(S), LEFT	14	13%	23	18%	21	18%	27	25% #
RIB(S), RIGHT								
SUPERNUMERARY, ONE								
RIB(S), RIGHT	0		0		1	1%	1	1%
SUPERNUMERARY, ONE RUDIMENTARY								
RIB(S), RIGHT	8	8%	23	18% #	21	18% #	24	22% ##
LEFT FORELIMB								
NON-OSSIFIED								
DIGIT 1 DISTAL PHALANX, LEFT	1	1%	0		1	1%	1	1%
DIGIT 2 PROXIMAL PHALANX, LEFT	20	19%	5	4% ##	11	9% #	9	8% #
DIGIT 2 DISTAL PHALANX, LEFT	0		0		2	2%	0	
DIGIT 3 PROXIMAL PHALANX, LEFT	1	1%	0		2	2%	0	
DIGIT 4 PROXIMAL PHALANX, LEFT	1	1%	0		2	2%	1	1%
METACARPALIA 5, LEFT	0		0		1	1%	0	
DIGIT 5 PROXIMAL PHALANX, LEFT	41	39%	35	28%	48	40%	35	33%
DIGIT 5 DISTAL PHALANX, LEFT	4	4%	12	10%	22	18% ##	10	9%
RIGHT FORELIMB								
NON-OSSIFIED								
DIGIT 1 DISTAL PHALANX, RIGHT	1	1%	0		1	1%	1	1%
DIGIT 2 PROXIMAL PHALANX, RIGHT	20	19%	5	4% ##	11	9% #	9	8% #
DIGIT 2 DISTAL PHALANX, RIGHT	0		0		2	2%	0	
DIGIT 3 PROXIMAL PHALANX, RIGHT	1	1%	0		1	1%	0	

#/## : Fisher's Exact Test significant at level 5% (#) or 1% (##)

SKELETAL EXAMINATIONS SUMMARY

	GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 30 MG/KG	GROUP 4 150 MG/KG
NUMBER OF FETUSES EXAMINED	106	125	120	107
RIGHT FORELIMB				
NON-OSSIFIED				
DIGIT 4 PROXIMAL PHALANX, RIGHT	1 1%	0	2 2%	1 1%
METACARPALIA 5, RIGHT	0	0	1 1%	0
DIGIT 5 PROXIMAL PHALANX, RIGHT	42 40%	35 28% #	46 38%	34 32%
DIGIT 5 DISTAL PHALANX, RIGHT	4 4%	13 10% #	22 18% ##	10 9%
LEFT HIND LIMB				
NON-OSSIFIED				
TALUS LEFT	61 58%	51 41% ##	48 40% ##	42 39% ##
METATARSALIA 1, LEFT	4 4%	0 #	3 3%	1 1%
TOE 2 PROXIMAL PHALANX, LEFT	19 18%	12 10% #	14 12%	12 11%
TOE 3 PROXIMAL PHALANX, LEFT	10 9%	2 2% ##	11 9%	6 6%
TOE 4 PROXIMAL PHALANX, LEFT	9 8%	2 2% #	10 8%	6 6%
TOE 5 PROXIMAL PHALANX, LEFT	54 51%	54 43%	57 48%	46 43%
RIGHT HIND LIMB				
NON-OSSIFIED				
TALUS RIGHT	59 56%	50 40% #	47 39% ##	38 36% ##
METATARSALIA 1, RIGHT	4 4%	0 #	3 3%	1 1%
TOE 2 PROXIMAL PHALANX, RIGHT	19 18%	12 10% #	14 12%	12 11%
TOE 3 PROXIMAL PHALANX, RIGHT	10 9%	2 2% ##	11 9%	7 7%
TOE 4 PROXIMAL PHALANX, RIGHT	10 9%	2 2% ##	10 8%	7 7%
TOE 5 PROXIMAL PHALANX, RIGHT	53 50%	52 42%	55 46%	45 42%

#/## : Fisher's Exact Test significant at level 5% (#) or 1% (##)

CARTILAGE EXAMINATIONS SUMMARY

	GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 30 MG/KG	GROUP 4 150 MG/KG
NUMBER OF LITTERS EXAMINED	21	22	21	19
ABNORMAL FINDING(S)				
(SHOWN ON PREVIOUS PAGE(S))	0	0	0	1 5%
CARTILAGINOUS CERVICAL VERTEBRAE				
LONG				
VENTRAL PLATE, RIGHT	0	1 5%	1 5%	0
CRANIAL SHIFT TO CERVICAL VERTEBRA 5				
VENTRAL PLATE, LEFT	0	1 5%	0	0
VENTRAL PLATE, RIGHT	0	1 5%	1 5%	0
CARTILAGINOUS STERNUM				
ABNORMALLY CHONDRIFIED				
CARTILAGINOUS STERNEBRA 5	1 5%	0	0	0
BRANCHED				
XIPHOID CARTILAGE	13 62%	14 64%	18 86%	13 68%
WITH SMALL HOLE				
XIPHOID CARTILAGE	9 43%	10 45%	11 52%	12 63%
COSTAL CARTILAGES				
LONG				
COSTAL CARTILAGE, 11 LEFT	1 5%	0	2 10%	4 21%
COSTAL CARTILAGE, 11 RIGHT	1 5%	0	2 10%	3 16%
INTERRUPTED				
COSTAL CARTILAGE, 11 LEFT	8 38%	4 18%	7 33%	7 37%
COSTAL CARTILAGE, 13 LEFT	0	0	0	1 5%
COSTAL CARTILAGE, 10 RIGHT	0	1 5%	0	1 5%
COSTAL CARTILAGE, 11 RIGHT	11 52%	4 18% #	5 24%	10 53%
COSTAL CARTILAGE(S), LEFT				
SUPERNUMERARY, ONE				
COSTAL CARTILAGE(S), LEFT	1 5%	1 5%	1 5%	1 5%
COSTAL CARTILAGE(S), RIGHT				
SUPERNUMERARY, ONE				
COSTAL CARTILAGE(S), RIGHT	0	0	1 5%	1 5%

CARTILAGE EXAMINATIONS SUMMARY

	GROUP 1 0 MG/KG	GROUP 2 10 MG/KG	GROUP 3 30 MG/KG	GROUP 4 150 MG/KG
NUMBER OF FETUSES EXANINED	106	125	120	107
ABNORMAL FINDING(S) (SHOWN ON PREVIOUS PAGE(S))	0	0	0	1 1%
CARTILAGINOUS CERVICAL VERTEBRAE				
LONG				
VENTRAL PLATE, RIGHT	0	1 1%	1 1%	0
CRANIAL SHIFT TO CERVICAL VERTEBRA 5				
VENTRAL PLATE, LEFT	0	1 1%	0	0
VENTRAL PLATE, RIGHT	0	1 1%	1 1%	0
CARTILAGINOUS STERNUM				
ABNORMALLY CHONDRIFIED				
CARTILAGINOUS STERNEBRA 5	1 1%	0	0	0
BRANCHED				
XIPHOID CARTILAGE	27 25%	26 21%	29 24%	27 25%
WITH SMALL HOLE				
XIPHOID CARTILAGE	14 13%	22 18%	23 19%	25 23% #
COSTAL CARTILAGES				
LONG				
COSTAL CARTILAGE, 11 LEFT	1 1%	0	2 2%	5 5%
COSTAL CARTILAGE, 11 RIGHT	2 2%	0	2 2%	3 3%
INTERRUPTED				
COSTAL CARTILAGE, 11 LEFT	11 10%	6 5%	8 7%	7 7%
COSTAL CARTILAGE, 13 LEFT	0	0	0	1 1%
COSTAL CARTILAGE, 10 RIGHT	0	1 1%	0	1 1%
COSTAL CARTILAGE, 11 RIGHT	13 12%	4 3% ##	8 7%	13 12%
COSTAL CARTILAGE(S), LEFT				
SUPERNUMERARY, ONE				
COSTAL CARTILAGE(S), LEFT	1 1%	1 1%	1 1%	1 1%
COSTAL CARTILAGE(S), RIGHT				
SUPERNUMERARY, ONE				
COSTAL CARTILAGE(S), RIGHT	0	0	1 1%	1 1%

#/## : Fisher's Exact Test significant at level 5% (#) or 1% (##)

BODY WEIGHTS OF LIVE FETUSES SUMMARY (PER DAM)
GROUP 1 (0 MG/KG)

LITTER	- MALES AND FEMALES - N	MEAN	ST.DEV.	------- MALES ------- N	MEAN	ST.DEV.	------ FEMALES ------ N	MEAN	ST.DEV.
1 <NP>									
2	5	4.6	0.2	5	4.6	0.2	0		
3	15	4.0	0.2	5	4.2	0.2	10	4.0	0.2
4	10	4.5	0.3	5	4.5	0.1	5	4.5	0.4
5	12	4.1	0.4	7	4.2	0.5	5	4.1	0.3
6	12	4.4	0.2	5	4.6	0.1	7	4.3	0.2
7	2	5.1	0.3	0			2	5.1	0.3
8	13	4.8	0.2	7	4.9	0.1	6	4.6	0.2
9	7	4.6	0.2	5	4.7	0.2	2	4.5	0.2
10	9	4.7	0.2	4	4.7	0.3	5	4.6	0.1
11	15	4.8	0.2	7	5.0	0.2	8	4.7	0.2
12	13	4.6	0.3	9	4.7	0.2	4	4.3	0.2
13	6	4.7	0.1	2	4.7	0.1	4	4.7	0.1
14	13	4.8	0.5	5	5.0	0.2	8	4.7	0.5
15	14	4.8	0.3	6	5.0	0.3	8	4.6	0.2
16	12	4.6	0.3	7	4.7	0.2	5	4.5	0.4
17	11	4.9	0.2	4	5.1	0.2	7	4.8	0.2
18	13	4.7	0.4	5	5.0	0.3	8	4.5	0.3
19	9	5.0	0.3	6	5.2	0.2	3	4.8	0.3
20	13	4.6	0.2	8	4.7	0.2	5	4.4	0.2
21	10	4.6	0.2	7	4.5	0.3	3	4.6	0.1
22	13	4.4	0.3	5	4.6	0.3	8	4.3	0.3
N	227	21		114	20		113	20	
MEAN	10.8	4.6		5.4	4.7		5.4	4.5	
ST.DEV.	3.4	0.2		2.0	0.3		2.5	0.2	

Reason for Exclusion from Evaluation :
<NP> Not pregnant

BODY WEIGHTS OF LIVE FETUSES SUMMARY (PER DAM)
GROUP 2 (10 MG/KG)

LITTER	- MALES AND FEMALES - N	MEAN	ST.DEV.	------- MALES ------- N	MEAN	ST.DEV.	------ FEMALES ------ N	MEAN	ST.DEV.
23	9	4.9	0.4	6	5.0	0.1	3	4.5	0.5
24	13	4.5	0.4	7	4.6	0.4	6	4.4	0.5
25	15	4.8	0.3	10	4.9	0.2	5	4.5	0.2
26	9	4.4	1.1	7	4.4	1.2	2	4.3	0.4
27	9	4.9	0.3	3	4.9	0.4	6	4.8	0.3
28	9	5.0	0.2	5	5.1	0.2	4	4.9	0.1
29	12	5.3	0.3	7	5.4	0.2	5	5.1	0.3
30	14	4.5	0.2	6	4.6	0.2	8	4.4	0.1
31	11	4.9	0.2	6	5.0	0.1	5	4.7	0.2
32	14	4.7	0.2	6	4.8	0.2	8	4.6	0.3
33	13	5.3	0.3	7	5.4	0.2	6	5.1	0.2
34	12	4.6	0.3	5	4.7	0.4	7	4.6	0.1
35	13	4.7	0.3	7	4.8	0.3	6	4.6	0.2
36	12	4.6	0.2	6	4.7	0.2	6	4.5	0.1
37	16	4.2	0.2	7	4.2	0.1	9	4.1	0.3
38	13	4.9	0.3	9	5.1	0.2	4	4.7	0.3
39	11	4.8	0.3	5	4.9	0.2	6	4.6	0.4
40	10	5.1	0.3	6	5.3	0.3	4	4.9	0.1
41	10	5.1	0.3	4	5.2	0.4	6	5.0	0.2
42	10	4.9	0.3	7	5.0	0.3	3	4.6	0.2
43	14	4.5	0.3	4	4.8	0.2	10	4.4	0.2
44	13	4.6	0.3	3	4.9	0.2	10	4.5	0.2
N	262	22		133	22		129	22	
MEAN	11.9	4.8		6.0	4.9		5.9	4.6	
ST.DEV.	2.1	0.3		1.7	0.3		2.2	0.3	

BODY WEIGHTS OF LIVE FETUSES SUMMARY (PER DAM)
GROUP 3 (30 MG/KG)

LITTER	- MALES AND FEMALES - N	MEAN	ST.DEV.	------- MALES ------- N	MEAN	ST.DEV.	------ FEMALES ------ N	MEAN	ST.DEV.
45	10	5.2	0.2	5	5.3	0.2	5	5.0	0.1
46	12	5.2	0.2	7	5.3	0.2	5	5.0	0.1
47	4	4.7	0.3	2	4.8	0.1	2	4.6	0.5
48	9	5.1	0.3	6	5.3	0.3	3	4.8	0.3
49 <NP>									
50	12	4.4	0.4	6	4.6	0.3	6	4.3	0.5
51	10	4.8	0.4	5	5.0	0.3	5	4.6	0.3
52	13	4.5	0.3	5	4.7	0.3	8	4.4	0.3
53	11	5.2	0.2	4	5.3	0.2	7	5.1	0.2
54	10	5.3	0.4	6	5.6	0.1	4	4.9	0.2
55	12	4.6	0.3	7	4.8	0.3	5	4.3	0.2
56	12	4.9	0.2	9	4.9	0.2	3	4.9	0.1
57	13	4.8	0.3	7	4.9	0.3	6	4.7	0.3
58	13	4.8	0.2	6	5.0	0.2	7	4.7	0.2
59	11	4.8	0.3	1	4.8		10	4.8	0.3
60	14	4.7	0.2	7	4.9	0.1	7	4.6	0.1
61	10	4.2	0.4	2	4.3	0.3	8	4.2	0.4
62	10	5.2	0.3	5	5.4	0.1	5	4.9	0.2
63	16	4.6	0.5	9	4.8	0.3	7	4.3	0.7
64	15	4.6	0.2	6	4.8	0.1	9	4.6	0.2
65	17	4.8	0.2	9	4.9	0.3	8	4.7	0.2
66	14	4.8	0.3	7	5.0	0.3	7	4.6	0.2
N	248	21		121	21		127	21	
MEAN	11.8	4.8		5.8	5.0		6.0	4.7	
ST.DEV.	2.8	0.3		2.2	0.3		2.1	0.3	

Reason for Exclusion from Evaluation :
<NP> Not pregnant

BODY WEIGHTS OF LIVE FETUSES SUMMARY (PER DAM)
GROUP 4 (150 MG/KG)

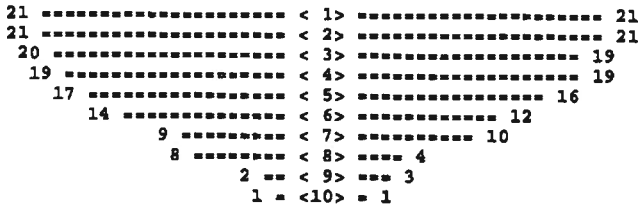
LITTER	- MALES AND FEMALES - N	MEAN	ST.DEV.	------- MALES ------- N	MEAN	ST.DEV.	------ FEMALES ------ N	MEAN	ST.DEV.
67	11	4.7	0.4	5	4.7	0.6	6	4.8	0.4
68	12	4.8	0.2	5	4.9	0.2	7	4.7	0.1
69	15	4.7	0.3	5	5.1	0.2	10	4.5	0.2
70	13	5.0	0.2	6	5.2	0.1	7	4.8	0.1
71	10	4.6	0.4	4	4.9	0.4	6	4.4	0.4
72	8	4.9	0.3	4	5.1	0.1	4	4.6	0.1
73	12	5.2	0.3	5	5.4	0.2	7	5.0	0.2
74	11	4.9	0.2	3	5.1	0.2	8	4.9	0.2
75	12	4.6	0.3	5	4.6	0.3	7	4.6	0.3
76 <NP>									
77	14	4.5	0.3	5	4.6	0.1	9	4.4	0.3
78	11	5.2	0.3	7	5.2	0.2	4	5.0	0.2
79	12	4.9	0.4	5	5.1	0.3	7	4.7	0.3
80 <NP>									
81 <DP>									
82	15	4.7	0.5	8	4.8	0.7	7	4.5	0.3
83	11	4.7	0.3	5	4.9	0.1	6	4.5	0.2
84	15	4.4	0.2	8	4.4	0.2	7	4.4	0.2
85	13	4.5	0.2	2	4.6	0.3	11	4.5	0.2
86	7	4.8	0.5	5	5.1	0.2	2	4.3	0.7
87	12	4.9	0.3	5	5.1	0.3	7	4.7	0.1
88	11	4.7	0.2	7	4.7	0.3	4	4.7	0.2
N	225	19		99	19		126	19	
MEAN	11.8	4.8		5.2	4.9		6.6	4.6	
ST.DEV.	2.1	0.2		1.5	0.3		2.1	0.2	

Reason for Exclusion from Evaluation :
<DP> Death prior sch. necropsy <NP> Not pregnant

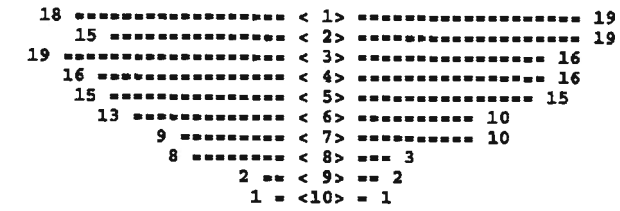
DISTRIBUTION WITHIN UTERUS
GROUP 1 (0 MG/KG)

LEFT HORN						POSITION	RIGHT HORN					
IMPLAN-TATIONS	EMPTY SITES	RESORPTIONS EMBR.	RESORPTIONS FETAL	FETUSES DEAD	FETUSES LIVE	IN UTERUS	FETUSES LIVE	FETUSES DEAD	RESORPTIONS FETAL	RESORPTIONS EMBR.	EMPTY SITES	IMPLAN-TATIONS
21	.	3	.	.	18	< 1>	19	.	.	2	.	21
21	.	5	1	.	15	< 2>	19	.	1	1	.	21
20	.	.	1	.	19	< 3>	16	.	.	3	.	19
19	.	1	2	.	16	< 4>	16	.	1	2	.	19
17	.	.	2	.	15	< 5>	15	.	.	1	.	16
14	.	.	1	.	13	< 6>	10	.	.	2	.	12
9	.	.	.	.	9	< 7>	10	.	.	.	.	10
8	.	.	.	.	8	< 8>	3	.	1	.	.	4
2	.	.	.	.	2	< 9>	2	.	1	.	.	3
1	.	.	.	.	1	<10>	1	.	.	.	.	1

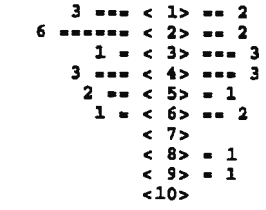
IMPLANTATION SITES



LIVE FETUSES



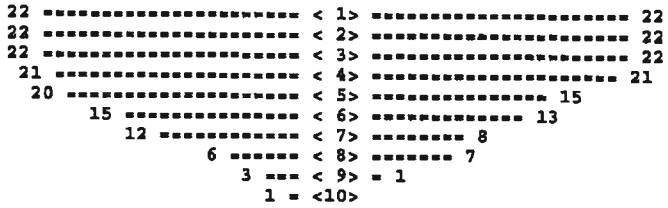
RESORPTIONS



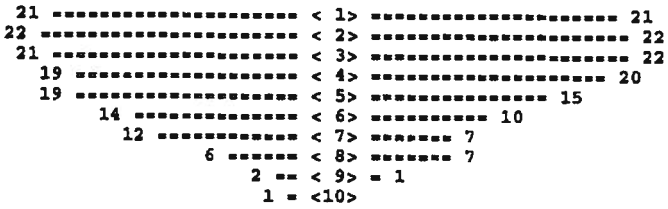
DISTRIBUTION WITHIN UTERUS
GROUP 2 (10 MG/KG)

LEFT HORN						POSITION	RIGHT HORN				
IMPLANTATIONS	EMPTY SITES	RESORPTIONS EMBR.	RESORPTIONS FETAL	FETUSES DEAD	FETUSES LIVE	IN UTERUS	FETUSES LIVE	FETUSES DEAD	RESORPTIONS FETAL	RESORPTIONS EMBR.	EMPTY SITES	IMPLANTATIONS
22	.	1	.	.	21	< 1>	21	.	.	1	.	22
22	.	.	.	.	22	< 2>	22	.	.	.	.	22
22	.	1	.	.	21	< 3>	22	.	.	.	.	22
21	.	2	.	.	19	< 4>	20	.	.	1	.	21
20	.	1	.	.	19	< 5>	15	.	.	.	.	15
15	.	1	.	.	14	< 6>	10	.	1	2	.	13
12	.	.	.	.	12	< 7>	7	.	.	1	.	8
6	.	.	.	.	6	< 8>	7	.	.	.	.	7
3	.	.	1	.	2	< 9>	1	.	.	.	.	1
1	.	.	.	.	1	<10>						

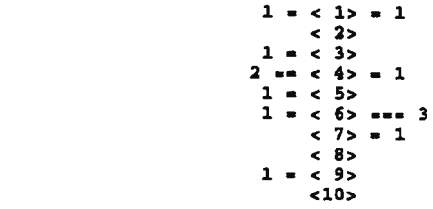
IMPLANTATION SITES



LIVE FETUSES



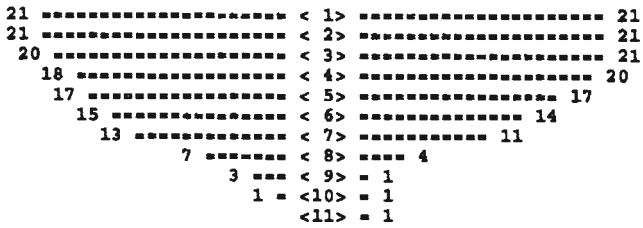
RESORPTIONS



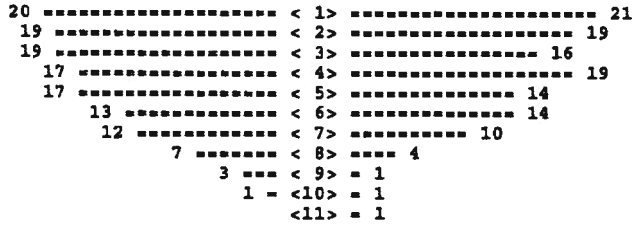
DISTRIBUTION WITHIN UTERUS
GROUP 3 (30 MG/KG)

LEFT HORN						POSITION	RIGHT HORN				
IMPLANTATIONS	EMPTY SITES	RESORPTIONS EMBR.	RESORPTIONS FETAL	FETUSES DEAD	FETUSES LIVE	IN UTERUS	FETUSES LIVE	FETUSES DEAD	RESORPTIONS FETAL	RESORPTIONS EMBR.	EMPTY SITES	IMPLANTATIONS
21	.	.	1	.	20	< 1>	21	.	.	.	.	21
21	.	2	.	.	19	< 2>	19	.	.	2	.	21
20	.	1	.	.	19	< 3>	16	.	.	5	.	21
18	.	.	1	.	17	< 4>	19	.	.	1	.	20
17	.	.	.	.	17	< 5>	14	.	.	3	.	17
15	.	2	.	.	13	< 6>	14	.	.	.	.	14
13	.	1	.	.	12	< 7>	10	.	.	1	.	11
7	.	.	.	.	7	< 8>	4	.	.	.	.	4
3	.	.	.	.	3	< 9>	1	.	.	.	.	1
1	.	.	.	.	1	<10>	1	.	.	.	.	1
						<11>	1	.	.	.	.	1

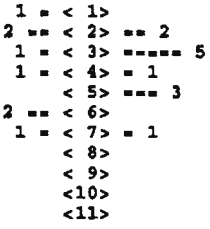
IMPLANTATION SITES



LIVE FETUSES



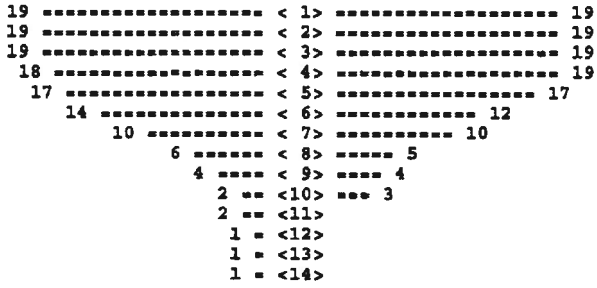
RESORPTIONS



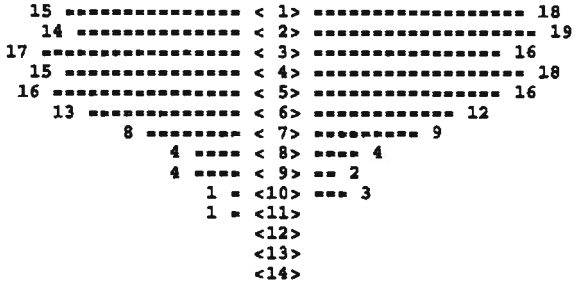
DISTRIBUTION WITHIN UTERUS
GROUP 4 (150 MG/KG)

LEFT HORN					POSITION	RIGHT HORN				
IMPLANTATIONS	EMPTY SITES	RESORPTIONS EMBR.	RESORPTIONS FETAL	FETUSES DEAD	FETUSES LIVE	IN UTERUS	FETUSES LIVE	FETUSES DEAD	RESORPTIONS FETAL	RESORPTIONS EMBR.	EMPTY SITES	IMPLANTATIONS
19	.	4	.	.	15	< 1>	18	.	.	1	.	19
19	.	5	.	.	14	< 2>	19	.	.	.	.	19
19	.	2	.	.	17	< 3>	16	.	.	3	.	19
18	.	3	.	.	15	< 4>	18	.	.	1	.	19
17	.	1	.	.	16	< 5>	16	.	.	1	.	17
14	.	1	.	.	13	< 6>	12	.	.	.	.	12
10	.	2	.	.	8	< 7>	9	.	.	1	.	10
6	.	2	.	.	4	< 8>	4	.	.	1	.	5
4	.	.	.	.	4	< 9>	2	.	.	2	.	4
2	.	1	.	.	1	<10>	3	.	.	.	.	3
2	.	1	.	.	1	<11>						
1	.	1	.	.	.	<12>						
1	.	1	.	.	.	<13>						
1	.	1	.	.	.	<14>						

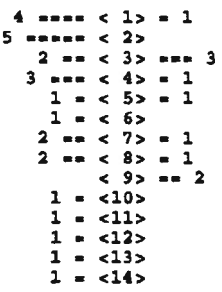
IMPLANTATION SITES



LIVE FETUSES



RESORPTIONS



CONTENTS OF UTERUS (PLAN VIEW)
GROUP 1 (0 MG/KG)

CORPORA LUTEA L/R	---- FETUSES LEFT HORN ----- IDENT	SEX	WEIGHT (GRAM)	ANOM.	A/ V	IMPLANTATION SITES <POS. IN UTERUS>	---- FETUSES RIGHT HORN ---- IDENT	SEX	WEIGHT (GRAM)	ANOM.	A/ V
FEMALE 1	(Not pregnant)										
FEMALE 2											
4/5	1	M	4.5		V	LIVE <1> LIVE	4	M	4.6		A
	2	M	5.0		A	LIVE <2> LIVE	5	M	4.6		V
	3	M	4.4		V	LIVE <3>					
						F.RES <4>					
FEMALE 3											
6/9	6	F	4.3		V	LIVE <1> LIVE	12	F	4.3		V
	7	F	3.9		A	LIVE <2> LIVE	13	M	4.0		A
	8	F	3.9		V	LIVE <3> LIVE	14	F	3.9		V
	9	M	4.3		A	LIVE <4> LIVE	15	F	4.0		A
	10	F	4.1		V	LIVE <5> LIVE	16	M	4.3		V
	11	F	3.9		A	LIVE <6> LIVE	17	M	3.8		A
						<7> LIVE	18	F	4.1		V
						<8> LIVE	19	M	4.4		A
						<9> LIVE	20	F	3.7		V
FEMALE 4											
6/12	21	F	4.7		V	LIVE <1> LIVE	24	F	4.5		A
	22	F	4.7		A	LIVE <2> LIVE	25	F	4.7		V
	23	M	4.3		V	LIVE <3> LIVE	26	M	4.5		A
						<4> LIVE	27	M	4.5		V
						<5> LIVE	28	M	4.6		A
						<6> LIVE	29	M	4.7		V
						<7> LIVE	30	F	3.9		A
FEMALE 5											
6/7	31	F	4.7		V	LIVE <1> LIVE	37	F	4.0		V
	32	M	4.6		A	LIVE <2> LIVE	38	F	4.0		A
	33	F	4.2		V	LIVE <3> LIVE	39	F	3.9		V
	34	M	4.6		A	LIVE <4> LIVE	40	M	4.4		A
	35	M	4.1		V	LIVE <5> LIVE	41	M	4.0		V
	36	M	4.4		A	LIVE <6> E.RES					
						<7> LIVE	42	M	3.1	M	V
FEMALE 6											
8/9						E.RES <1> LIVE	50	F	4.4		A
	43	M	4.7		V	LIVE <2> LIVE	51	M	4.7		V
	44	F	4.4		A	LIVE <3> LIVE	52	M	4.4		A
	45	F	4.2		V	LIVE <4> LIVE	53	F	4.0		V
	46	F	4.5		A	LIVE <5> LIVE	54	F	4.4		A
	47	F	4.2		V	LIVE <6>					
	48	M	4.5		A	LIVE <7>					
	49	M	4.5		V	LIVE <8>					
FEMALE 7											
4/4						E.RES <1> LIVE	291	F	5.3		V
						E.RES <2> LIVE	292	F	4.9		A
						<3> E.RES					
						<4> E.RES					
FEMALE 8											
8/7	293	F	4.7		V	LIVE <1> LIVE	300	M	4.9		A
						E.RES <2> LIVE	301	F	4.7		V
	294	F	4.6		A	LIVE <3> LIVE	302	M	4.6		A
	295	F	4.5		V	LIVE <4> LIVE	303	M	4.9		V
	296	M	4.8		A	LIVE <5> LIVE	304	F	4.9		A
	297	M	5.0		V	LIVE <6> LIVE	305	M	5.0		V
	298	M	4.9		A	LIVE <7>					
	299	F	4.5		V	LIVE <8>					

LIVE - LIVE FETUS E.RES - EMBRYONIC RESORPTION V - VISCERAL EXAMINATION
DEAD - DEAD FETUS F.RES - FETAL RESORPTION A - ALIZARIN RED S SKELETAL STAINING TECHN.

CONTENTS OF UTERUS (PLAN VIEW)
GROUP 1 (0 MG/KG)

CORPORA LUTEA L/R	FETUSES LEFT HORN IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/ V	IMPLANTATION SITES <POS. IN UTERUS>	FETUSES RIGHT HORN IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/ V
FEMALE 9											
7/5	306	M	4.5		V	LIVE <1> LIVE	310	F	4.4		V
	307	F	4.6		A	LIVE <2> E.RES					
						F.RES <3> LIVE	311	M	5.0		A
	308	M	4.6		V	LIVE <4> F.RES					
						F.RES <5> LIVE	312	M	4.5		V
	309	M	4.9		A	LIVE <6>					
FEMALE 10											
8/6	498	M	4.9		V	LIVE <1> E.RES					
	499	F	4.6		A	LIVE <2> LIVE	504	F	4.6		V
	500	F	4.7		V	LIVE <3> E.RES					
	501	F	4.5		A	LIVE <4> LIVE	505	M	4.9		A
	502	F	4.7		V	LIVE <5> LIVE	506	M	4.6		V
	503	M	4.4		A	LIVE <6>					
FEMALE 11											
8/7	507	F	4.8		V	LIVE <1> LIVE	515	F	4.7		V
	508	M	5.0		A	LIVE <2> LIVE	516	M	5.0		A
	509	F	4.5		V	LIVE <3> LIVE	517	M	5.3		V
	510	M	5.0		A	LIVE <4> LIVE	518	M	4.8		A
	511	M	4.8		V	LIVE <5> LIVE	519	F	4.7		V
	512	M	5.0		A	LIVE <6> LIVE	520	F	4.4		A
	513	F	5.0		V	LIVE <7> LIVE	521	F	4.7		V
	514	F	4.7		A	LIVE <8>					
FEMALE 12											
6/8	522	F	4.1		V	LIVE <1> LIVE	528	F	4.2		V
	523	F	4.2		A	LIVE <2> LIVE	529	M	4.6		A
	524	M	4.8		V	LIVE <3> LIVE	530	F	4.5		V
	525	M	4.6		A	LIVE <4> LIVE	531	M	5.0		A
	526	M	4.3		V	LIVE <5> LIVE	532	M	4.8		V
	527	M	4.9		A	LIVE <6> LIVE	533	M	5.0		A
						<7> LIVE	534	M	4.8		V
FEMALE 13											
5/6						E.RES <1> LIVE	537	F	4.6		V
						E.RES <2> LIVE	538	F	4.8		A
	535	F	4.6		V	LIVE <3> LIVE	539	F	4.6		V
						E.RES <4> LIVE	540	M	4.8		A
	536	M	4.7		A	LIVE <5> E.RES					
						<6> E.RES					
FEMALE 14											
8/5	541	F	5.2		V	LIVE <1> LIVE	549	M	5.4		V
	542	M	4.8		A	LIVE <2> LIVE	550	F	4.6		A
	543	F	4.5		V	LIVE <3> LIVE	551	M	5.0		V
	544	F	4.9		A	LIVE <4> LIVE	552	F	4.9		A
	545	M	5.1		V	LIVE <5> LIVE	553	F	5.0		V
	546	M	5.0		A	LIVE <6>					
	547	F	3.6		V	LIVE <7>					
	548	F	4.6		A	LIVE <8>					
FEMALE 15											
8/7	554	F	4.4		V	LIVE <1> LIVE	561	F	4.6		A
						F.RES <2> LIVE	562	F	4.4		V
	555	F	4.9		A	LIVE <3> LIVE	563	M	5.2		A
	556	M	5.3		V	LIVE <4> LIVE	564	M	4.5		V
	557	F	4.8		A	LIVE <5> LIVE	565	M	4.8		A
	558	F	4.7		V	LIVE <6> LIVE	566	F	4.4		V
	559	M	5.3		A	LIVE <7> LIVE	567	F	4.8		A
	560	M	5.0		V	LIVE <8>					

LIVE - LIVE FETUS E.RES - EMBRYONIC RESORPTION V - VISCERAL EXAMINATION
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CONTENTS OF UTERUS (PLAN VIEW)
GROUP 1 (0 MG/KG)

CORPORA LUTEA L/R	---- FETUSES LEFT HORN ----- IDENT	SEX	WEIGHT (GRAM)	ANOM. A/ MALF. V	IMPLANTATION SITES <POS. IN UTERUS>	---- FETUSES RIGHT HORN ---- IDENT	SEX	WEIGHT (GRAM)	ANOM. A/ MALF. V
FEMALE 16									
5/8	568	M	4.5	V	LIVE <1> LIVE	573	M	4.5	A
	569	M	4.9	A	LIVE <2> LIVE	574	F	3.9	V
	570	F	4.4	V	LIVE <3> LIVE	575	F	5.0	A
	571	M	4.6	A	LIVE <4> E.RES				
	572	M	4.7	V	LIVE <5> LIVE	576	F	4.7	V
					<6> LIVE	577	M	5.0	A
					<7> LIVE	578	M	4.7	V
					<8> LIVE	579	F	4.6	A
FEMALE 17									
9/5	580	F	4.9	V	LIVE <1> LIVE	589	F	5.0	A
	581	F	4.9	A	LIVE <2> LIVE	590	M	4.9	V
	582	M	5.3	V	LIVE <3>				
	583	F	4.9	A	LIVE <4>				
	584	F	4.5	V	LIVE <5>				
	585	F	4.7	A	LIVE <6>				
	586	F	4.7	V	LIVE <7>				
	587	M	4.8	A	LIVE <8>				
	588	M	5.2	V	LIVE <9>				
FEMALE 18									
11/4	591	F	4.3	V	LIVE <1> LIVE	601	M	4.8	V
	592	F	4.3	A	LIVE <2> LIVE	602	F	4.5	A
	593	F	5.0	V	LIVE <3> E.RES				
	594	F	4.8	A	LIVE <4> LIVE	603	M	5.3	V
	595	F	4.8	V	LIVE <5>				
	596	M	5.0	A	LIVE <6>				
	597	M	4.6	V	LIVE <7>				
	598	M	5.1	A	LIVE <8>				
	599	F	4.3	V	LIVE <9>				
	600	F	4.1	A	LIVE <10>				
FEMALE 19									
6/5	604	M	5.0	V	LIVE <1> LIVE	609	M	5.2	A
	605	M	5.1	A	LIVE <2> LIVE	610	M	5.4	V
	606	M	5.4	V	LIVE <3> LIVE	611	F	4.9	A
	607	F	4.5	A	LIVE <4> LIVE	612	F	5.1	V
	608	M	5.0	V	LIVE <5>				
FEMALE 20									
4/10	806	F	4.7	V	LIVE <1> E.RES				
	807	M	4.6	A	LIVE <2> LIVE	810	M	4.8	V
	808	M	4.8	V	LIVE <3> LIVE	811	M	4.4	A
	809	M	4.7	A	LIVE <4> LIVE	812	F	4.2	V
					<5> LIVE	813	M	4.8	A
					<6> LIVE	814	M	4.7	V
					<7> LIVE	815	F	4.4	A
					<8> LIVE	816	F	4.1	V
					<9> LIVE	817	F	4.3	A
					<10> LIVE	818	M	4.8	V
FEMALE 21									
7/10	819	M	4.1	V	LIVE <1> LIVE	823	M	4.3	V
					E.RES <2> F.RES				
	820	M	4.8	A	LIVE <3> LIVE	824	F	4.7	A
	821	F	4.6	V	LIVE <4> LIVE	825	M	4.7	V
					F.RES <5> LIVE	826	F	4.4	A
					F.RES <6> LIVE	827	M	4.6	V
	822	M	4.5	A	LIVE <7> LIVE	828	M	4.8	A
					<8> F.RES				
					<9> F.RES				

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CONTENTS OF UTERUS (PLAN VIEW)
GROUP 1 (0 MG/KG)

CORPORA LUTEA L/R	---- FETUSES LEFT HORN ---- IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/ V	IMPLANTATION SITES <POS. IN UTERUS>	---- FETUSES RIGHT HORN ---- IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/ V
FEMALE 22											
8/7	829	F	4.5		V	LIVE <1> LIVE	835	F	4.6		V
						E.RES <2> LIVE	836	M	4.6		A
	830	F	4.3		A	LIVE <3> LIVE	837	F	4.2		V
						F.RES <4> LIVE	838	M	4.2		A
	831	M	4.6		V	LIVE <5> LIVE	839	F	4.3		V
	832	F	3.8		A	LIVE <6> LIVE	840	F	4.5		A
	833	M	4.4		V	LIVE <7> LIVE	841	F	4.7		V
	834	M	5.1		A	LIVE <8>					

LIVE - LIVE FETUS E.RES - EMBRYONIC RESORPTION V - VISCERAL EXAMINATION
DEAD - DEAD FETUS F.RES - FETAL RESORPTION A - ALIZARIN RED S SKELETAL STAINING TECHN.

CONTENTS OF UTERUS (PLAN VIEW)
GROUP 2 (10 MG/KG)

CORPORA LUTEA L/R	---- FETUSES LEFT HORN ----- IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/ V	IMPLANTATION SITES <POS. IN UTERUS>	---- FETUSES RIGHT HORN ---- IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/ V
FEMALE 23											
5/7	55	M	5.0		V	LIVE <1> E.RES					
	56	M	4.9		A	LIVE <2> LIVE	60	F	4.7		A
	57	F	4.9		V	LIVE <3> LIVE	61	M	4.9		V
	58	M	5.0		A	LIVE <4> LIVE	62	M	5.0		A
	59	F	3.9		V	LIVE <5> LIVE	63	M	5.3		V
						<6> E.RES					
FEMALE 24											
7/8	64	M	4.7		V	LIVE <1> LIVE	70	F	4.8		V
	65	M	4.9		A	LIVE <2> LIVE	71	F	4.5		A
	66	M	4.7		V	LIVE <3> LIVE	72	F	4.8		V
						E.RES <4> LIVE	73	F	4.7		A
	67	M	4.8		A	LIVE <5> LIVE	74	F	3.5		V
	68	M	3.8		V	LIVE <6> LIVE	75	M	4.8		A
	69	M	4.8		A	LIVE <7> E.RES					
						<8> LIVE	76	F	4.5		V
FEMALE 25											
7/8	77	F	4.7		V	LIVE <1> LIVE	84	M	5.1		A
	78	F	4.3		A	LIVE <2> LIVE	85	M	4.8		V
	79	M	5.0		V	LIVE <3> LIVE	86	M	5.0		A
	80	F	4.3		A	LIVE <4> LIVE	87	F	4.5		V
	81	M	4.6		V	LIVE <5> LIVE	88	F	4.7		A
	82	M	4.9		A	LIVE <6> LIVE	89	M	5.1		V
	83	M	4.9		V	LIVE <7> LIVE	90	M	5.0		A
						<8> LIVE	91	M	5.1		V
FEMALE 26											
6/5	92	F	4.7		V	LIVE <1> LIVE	97	M	4.8		A
	93	M	5.1		A	LIVE <2> LIVE	98	M	4.9		V
	94	M	4.8		V	LIVE <3> LIVE	99	M	4.7		A
	95	F	4.0		A	LIVE <4> LIVE	100	M	4.8		V
	96	M	1.6		V	LIVE <5>					
FEMALE 27											
7/5	101	F	4.6		V	LIVE <1> LIVE	106	M	5.2		A
	102	F	5.2		A	LIVE <2> LIVE	107	F	4.9		V
	103	M	5.1		V	LIVE <3> LIVE	108	F	5.0		A
	104	F	4.8		A	LIVE <4> LIVE	109	M	4.5		V
	105	F	4.5		V	LIVE <5>					
						E.RES <6>					
FEMALE 28											
6/5	110	M	5.0		V	LIVE <1> LIVE	115	M	5.1		A
	111	F	4.9		A	LIVE <2> LIVE	116	F	4.9		V
	112	F	4.8		V	LIVE <3> LIVE	117	M	5.3		A
	113	F	4.8		A	LIVE <4> LIVE	118	M	5.0		V
	114	M	5.2		V	LIVE <5>					
FEMALE 29											
9/4	119	M	5.4		V	LIVE <1> LIVE	128	F	5.5		A
	120	F	5.0		A	LIVE <2> LIVE	129	M	5.3		V
	121	M	5.1		V	LIVE <3> LIVE	130	F	4.8		A
	122	F	5.2		A	LIVE <4>					
	123	M	5.6		V	LIVE <5>					
	124	M	5.7		A	LIVE <6>					
	125	M	5.2		V	LIVE <7>					
	126	F	4.9		A	LIVE <8>					
	127	M	5.6		V	LIVE <9>					

LIVE - LIVE FETUS E.RES - EMBRYONIC RESORPTION V - VISCERAL EXAMINATION
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CONTENTS OF UTERUS (PLAN VIEW)
GROUP 2 (10 MG/KG)

CORPORA LUTEA L/R	---- FETUSES LEFT HORN ---- IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/ V	IMPLANTATION SITES <POS. IN UTERUS>	---- FETUSES RIGHT HORN ---- IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/ V
FEMALE 30											
6/9	313	M	4.7		V	LIVE <1> LIVE	319	F	4.4		V
	314	F	4.7		A	LIVE <2> LIVE	320	F	4.3		A
	315	M	4.5		V	LIVE <3> LIVE	321	F	4.4		V
	316	M	4.5		A	LIVE <4> LIVE	322	M	4.5		A
	317	F	4.4		V	LIVE <5> LIVE	323	F	4.5		V
	318	M	4.5		A	LIVE <6> LIVE	324	M	4.8		A
						<7> LIVE	325	F	4.2		V
						<8> LIVE	326	F	4.4		A
FEMALE 31											
4/8	327	F	4.8		V	LIVE <1> LIVE	331	F	4.8		V
	328	M	4.9		A	LIVE <2> LIVE	332	M	4.9		A
	329	M	5.1		V	LIVE <3> LIVE	333	M	4.8		V
	330	M	5.1		A	LIVE <4> E.RES					
						<5> LIVE	334	F	4.9		A
						<6> LIVE	335	F	4.8		V
						<7> LIVE	336	M	5.0		A
						<8> LIVE	337	F	4.4		V
FEMALE 32											
10/7	338	F	4.5		V	LIVE <1> LIVE	347	F	4.6		A
	339	F	4.9		A	LIVE <2> LIVE	348	M	4.7		V
	340	M	4.6		V	LIVE <3> LIVE	349	M	4.8		A
	341	F	4.6		A	LIVE <4> LIVE	350	F	4.9		V
	342	F	4.7		V	LIVE <5> LIVE	351	M	4.7		A
	343	M	4.9		A	LIVE <6>					
	344	F	4.2		V	LIVE <7>					
	345	M	5.1		A	LIVE <8>					
						F.RES <9>					
	346	F	4.2		V	LIVE <10>					
FEMALE 33											
7/7	352	M	5.3		V	LIVE <1> LIVE	359	M	5.4		A
	353	M	5.8		A	LIVE <2> LIVE	360	F	4.9		V
	354	M	5.4		V	LIVE <3> LIVE	361	F	5.3		A
	355	M	5.6		A	LIVE <4> LIVE	362	M	5.4		V
	356	F	5.0		V	LIVE <5> LIVE	363	F	4.8		A
	357	M	5.3		A	LIVE <6> LIVE	364	F	5.4		V
	358	F	5.3		V	LIVE <7>					
FEMALE 34											
11/4	613	F	4.7		V	LIVE <1> LIVE	621	M	4.9		V
	614	M	4.7		A	LIVE <2> LIVE	622	F	4.5		A
	615	M	4.0		V	LIVE <3> LIVE	623	F	4.5		V
	616	F	4.6		A	LIVE <4> LIVE	624	F	4.8		A
	617	F	4.7		V	LIVE <5>					
	618	F	4.5		A	LIVE <6>					
	619	M	4.8		V	LIVE <7>					
	620	M	5.0		A	LIVE <8>					
FEMALE 35											
9/4	625	M	4.6		V	LIVE <1> LIVE	634	M	5.1		A
	626	M	4.8		A	LIVE <2> LIVE	635	F	4.2		V
	627	F	4.6		V	LIVE <3> LIVE	636	F	4.7		A
	628	M	4.8		A	LIVE <4> LIVE	637	F	4.5		V
	629	M	4.3		V	LIVE <5>					
	630	F	4.6		A	LIVE <6>					
	631	F	4.8		V	LIVE <7>					
	632	M	4.5		A	LIVE <8>					
	633	M	5.2		V	LIVE <9>					

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CONTENTS OF UTERUS (PLAN VIEW)
GROUP 2 (10 MG/KG)

CORPORA LUTEA L/R	---- FETUSES LEFT HORN ---- IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/ V	IMPLANTATION SITES <POS. IN UTERUS>			---- FETUSES RIGHT HORN ---- IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/ V
FEMALE 36													
8/5						E.RES	<1>	LIVE	645	F	4.5		A
	638	M	4.6		V	LIVE	<2>	LIVE	646	M	4.8		V
	639	M	4.7		A	LIVE	<3>	LIVE	647	F	4.4		A
	640	F	4.3		V	LIVE	<4>	LIVE	648	F	4.5		V
	641	M	4.8		A	LIVE	<5>	LIVE	649	F	4.5		A
	642	M	5.0		V	LIVE	<6>						
	643	F	4.5		A	LIVE	<7>						
	644	M	4.6		V	LIVE	<8>						
FEMALE 37													
7/10	650	M	4.3		V	LIVE	<1>	LIVE	657	F	4.3		A
	651	F	4.0		A	LIVE	<2>	LIVE	658	F	3.9		V
	652	M	4.4		V	LIVE	<3>	LIVE	659	M	4.1		A
	653	M	4.3		A	LIVE	<4>	LIVE	660	M	4.1		V
	654	F	3.6		V	LIVE	<5>	LIVE	661	F	4.1		A
	655	F	4.4		A	LIVE	<6>	LIVE	662	F	4.2		V
	656	F	4.2		V	LIVE	<7>	LIVE	663	M	4.2		A
							<8>	LIVE	664	M	4.4		V
							<9>	LIVE	665	F	4.5		A
FEMALE 38													
7/6	666	M	5.5		V	LIVE	<1>	LIVE	673	M	4.8		A
	667	M	5.1		A	LIVE	<2>	LIVE	674	M	5.0		V
	668	F	4.9		V	LIVE	<3>	LIVE	675	F	4.8		A
	669	F	4.4		A	LIVE	<4>	LIVE	676	M	5.1		V
	670	M	5.3		V	LIVE	<5>	LIVE	677	F	4.5		A
	671	M	5.1		A	LIVE	<6>	LIVE	678	M	4.8		V
	672	M	4.8		V	LIVE	<7>						
FEMALE 39													
8/4	679	F	4.3		V	LIVE	<1>	LIVE	686	F	5.3		A
	680	F	4.5		A	LIVE	<2>	LIVE	687	M	4.8		V
	681	M	5.2		V	LIVE	<3>	LIVE	688	M	5.1		A
						E.RES	<4>	LIVE	689	F	4.7		V
	682	M	4.6		A	LIVE	<5>						
	683	M	5.0		V	LIVE	<6>						
	684	F	4.3		A	LIVE	<7>						
	685	F	4.7		V	LIVE	<8>						
FEMALE 40													
5/6	690	F	4.8		V	LIVE	<1>	LIVE	695	M	5.5		A
	691	M	5.4		A	LIVE	<2>	LIVE	696	F	5.0		V
	692	M	5.7		V	LIVE	<3>	LIVE	697	M	5.1		A
	693	F	4.9		A	LIVE	<4>	LIVE	698	M	5.0		V
	694	M	4.9		V	LIVE	<5>	LIVE	699	F	4.9		A
							<6>	F.RES					
FEMALE 41													
3/8	842	F	5.0		V	LIVE	<1>	LIVE	845	F	5.1		A
	843	M	4.8		A	LIVE	<2>	LIVE	846	F	5.0		V
	844	F	4.9		V	LIVE	<3>	LIVE	847	M	5.2		A
							<4>	LIVE	848	F	5.4		V
							<5>	LIVE	849	M	5.1		A
							<6>	LIVE	850	F	5.0		V
							<7>	LIVE	851	M	5.8		A

LIVE - LIVE FETUS E.RES - EMBRYONIC RESORPTION V - VISCERAL EXAMINATION
DEAD - DEAD FETUS F.RES - FETAL RESORPTION A - ALIZARIN RED S SKELETAL STAINING TECHN.

CONTENTS OF UTERUS (PLAN VIEW)
GROUP 2 (10 MG/KG)

CORPORA LUTEA L/R	FETUSES LEFT HORN IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/V	IMPLANTATION SITES <POS. IN UTERUS>	FETUSES RIGHT HORN IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/V
FEMALE 42											
6/9	852	M	5.1		V	LIVE <1> LIVE	855	M	5.2		A
	853	F	4.6		A	LIVE <2> LIVE	856	M	5.0		V
						E.RES <3> LIVE	857	M	4.9		A
	854	F	4.9		V	LIVE <4> LIVE	858	M	5.1		V
						E.RES <5> LIVE	859	F	4.4		A
						<6> E.RES					
						<7> LIVE	860	M	5.3		V
						<8> LIVE	861	M	4.4		A
FEMALE 43											
7/8	862	M	4.5		V	LIVE <1> LIVE	868	F	4.6		V
	863	M	5.0		A	LIVE <2> LIVE	869	M	4.9		A
	864	F	4.4		V	LIVE <3> LIVE	870	M	4.7		V
	865	F	4.2		A	LIVE <4> LIVE	871	F	4.1		A
	866	F	4.3		V	LIVE <5> LIVE	872	F	4.5		V
	867	F	4.5		A	LIVE <6> LIVE	873	F	4.5		A
						<7> LIVE	874	F	4.9		V
						<8> LIVE	875	F	4.5		A
FEMALE 44											
7/6	876	F	5.0		V	LIVE <1> LIVE	883	M	4.7		A
	877	F	4.5		A	LIVE <2> LIVE	884	F	4.5		V
	878	F	4.5		V	LIVE <3> LIVE	885	F	4.5		A
	879	F	4.7		A	LIVE <4> LIVE	886	F	4.6		V
	880	F	4.4		V	LIVE <5> LIVE	887	F	4.1		A
	881	F	4.4		A	LIVE <6> LIVE	888	M	5.1		V
	882	M	4.8		V	LIVE <7>					

CONTENTS OF UTERUS (PLAN VIEW)
GROUP 3 (30 MG/KG)

CORPORA LUTEA L/R	---- FETUSES LEFT HORN ----- IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/ V	IMPLANTATION SITES <POS. IN UTERUS>	---- FETUSES RIGHT HORN ---- IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/ V
FEMALE 45											
4/8						F.RES <1> LIVE	133	F	5.1		V
						E.RES <2> LIVE	134	F	5.0		A
	131	M	5.2		V	LIVE <3> LIVE	135	F	5.2		V
	132	M	5.5		A	LIVE <4> LIVE	136	M	5.4		A
						<5> LIVE	137	M	5.3		V
						<6> LIVE	138	F	5.0		A
						<7> LIVE	139	M	5.1		V
						<8> LIVE	140	F	5.0		A
FEMALE 46											
7/7	141	M	5.2		V	LIVE <1> LIVE	148	F	5.0		A
	142	F	4.8		A	LIVE <2> LIVE	149	M	5.6		V
	143	M	5.4		V	LIVE <3> E.RES					
	144	F	5.0		A	LIVE <4> LIVE	150	M	5.4		A
	145	F	5.0		V	LIVE <5> E.RES					
	146	M	5.2		A	LIVE <6> LIVE	151	F	5.1		V
	147	M	5.4		V	LIVE <7> LIVE	152	M	5.2		A
FEMALE 47											
5/5	153	M	4.7		V	LIVE <1> LIVE	155	F	5.0		V
						E.RES <2> LIVE	156	F	4.3		A
	154	M	4.8		A	LIVE <3> E.RES					
						<4> E.RES					
						<5> E.RES					
FEMALE 48											
6/5	157	M	5.2		V	LIVE <1> LIVE	162	M	5.1		A
	158	M	5.2		A	LIVE <2> LIVE	163	F	4.6		V
	159	M	5.4		V	LIVE <3> LIVE	164	M	5.7		A
	160	F	4.6		A	LIVE <4> LIVE	165	M	5.0		V
	161	F	5.1		V	LIVE <5>					
						E.RES <6>					
FEMALE 49	(Not pregnant)										
FEMALE 50											
6/6	166	M	5.0		V	LIVE <1> LIVE	172	F	4.3		V
	167	F	4.6		A	LIVE <2> LIVE	173	F	3.4		A
	168	M	4.7		V	LIVE <3> LIVE	174	M	4.0		V
	169	F	4.2		A	LIVE <4> LIVE	175	M	4.5		A
	170	M	4.7		V	LIVE <5> LIVE	176	F	4.5		V
	171	F	4.5		A	LIVE <6> LIVE	177	M	4.4		A
FEMALE 51											
7/5	178	F	4.8		V	LIVE <1> LIVE	185	M	5.1		A
	179	M	4.9		A	LIVE <2> LIVE	186	F	4.8		V
	180	M	5.1		V	LIVE <3> E.RES					
	181	M	5.4		A	LIVE <4> LIVE	187	F	4.1		A
	182	M	4.6		V	LIVE <5>					
	183	F	4.8		A	LIVE <6>					
	184	F	4.8		V	LIVE <7>					
FEMALE 52											
8/6	188	M	4.6		V	LIVE <1> LIVE	196	M	5.0		V
	189	F	4.3		A	LIVE <2> LIVE	197	F	4.0		A
	190	M	4.4		V	LIVE <3> LIVE	198	M	4.8		V
	191	M	4.5		A	LIVE <4> LIVE	199	F	4.4		A
	192	F	4.5		V	LIVE <5> LIVE	200	F	4.7		V
	193	F	4.7		A	LIVE <6>					
	194	F	4.0		V	LIVE <7>					
	195	F	4.5		A	LIVE <8>					

LIVE - LIVE FETUS E.RES - EMBRYONIC RESORPTION V - VISCERAL EXAMINATION
DEAD - DEAD FETUS F.RES - FETAL RESORPTION A - ALIZARIN RED S SKELETAL STAINING TECHN.

CONTENTS OF UTERUS (PLAN VIEW)
GROUP 3 (30 MG/KG)

CORPORA LUTEA L/R	FETUSES LEFT HORN IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/V	IMPLANTATION SITES <POS. IN UTERUS>	FETUSES RIGHT HORN IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/V
FEMALE 53											
5/6	201	M	5.6		V	LIVE <1> LIVE	206	M	5.2		A
	202	F	4.9		A	LIVE <2> LIVE	207	F	5.4		V
	203	F	4.9		V	LIVE <3> LIVE	208	F	5.0		A
	204	F	5.3		A	LIVE <4> LIVE	209	F	5.2		V
	205	M	5.4		V	LIVE <5> LIVE	210	M	5.2		A
						<6> LIVE	211	F	5.0		V
FEMALE 54											
3/8	212	M	5.6		V	LIVE <1> LIVE	214	M	5.7		V
	213	F	4.7		A	LIVE <2> LIVE	215	F	4.8		A
						<3> LIVE	216	F	5.1		V
						<4> LIVE	217	F	5.2		A
						<5> LIVE	218	M	5.8		V
						<6> LIVE	219	M	5.5		A
						<7> LIVE	220	M	5.5		V
						<8> LIVE	221	M	5.4		A
FEMALE 55											
7/8	365	F	4.5		V	LIVE <1> LIVE	371	M	4.7		V
	366	M	4.7		A	LIVE <2> LIVE	372	M	5.0		A
						E.RES <3> LIVE	373	M	4.8		V
	367	F	4.4		V	LIVE <4> LIVE	374	M	4.6		A
	368	M	4.4		A	LIVE <5> E.RES					
	369	F	4.0		V	LIVE <6> LIVE	375	F	4.4		V
	370	M	5.3		A	LIVE <7> LIVE	376	F	4.3		A
FEMALE 56											
8/5	377	F	4.9		V	LIVE <1> LIVE	385	M	4.6		V
	378	M	4.9		A	LIVE <2> LIVE	386	M	5.3		A
	379	M	4.6		V	LIVE <3> E.RES					
	380	M	4.7		A	LIVE <4> LIVE	387	M	4.9		V
	381	M	5.0		V	LIVE <5> LIVE	388	F	4.9		A
	382	M	5.0		A	LIVE <6>					
	383	M	5.1		V	LIVE <7>					
	384	F	5.1		A	LIVE <8>					
FEMALE 57											
8/8	389	F	4.6		V	LIVE <1> LIVE	397	F	5.0		V
	390	F	4.6		A	LIVE <2> E.RES					
	391	F	4.9		V	LIVE <3> LIVE	398	F	4.9		A
	392	M	5.1		A	LIVE <4> LIVE	399	M	5.0		V
	393	M	5.2		V	LIVE <5> LIVE	400	F	4.1		A
	394	M	4.7		A	LIVE <6> LIVE	401	M	5.1		V
	395	M	4.4		V	LIVE <7> E.RES					
	396	M	5.0		A	LIVE <8>					
FEMALE 58											
7/7	402	F	4.7		V	LIVE <1> LIVE	408	M	4.9		V
	403	F	5.0		A	LIVE <2> LIVE	409	F	4.6		A
	404	F	4.8		V	LIVE <3> LIVE	410	F	4.9		V
						F.RES <4> LIVE	411	F	4.3		A
	405	M	5.1		A	LIVE <5> LIVE	412	M	5.2		V
	406	M	4.9		V	LIVE <6> LIVE	413	F	4.7		A
	407	M	4.8		A	LIVE <7> LIVE	414	M	5.1		V
FEMALE 59											
6/6	415	F	5.0		V	LIVE <1> LIVE	420	F	5.0		A
	416	F	4.9		A	LIVE <2> LIVE	421	F	4.8		V
	417	M	4.8		V	LIVE <3> LIVE	422	F	5.4		A
	418	F	4.7		A	LIVE <4> LIVE	423	F	4.6		V
	419	F	4.9		V	LIVE <5> LIVE	424	F	4.6		A
						<6> LIVE	425	F	4.5		V

LIVE - LIVE FETUS E.RES - EMBRYONIC RESORPTION V - VISCERAL EXAMINATION
DEAD - DEAD FETUS F.RES - FETAL RESORPTION A - ALIZARIN RED S SKELETAL STAINING TECHN.

CONTENTS OF UTERUS (PLAN VIEW)
GROUP 3 (30 MG/KG)

CORPORA LUTEA L/R	---- FETUSES LEFT HORN ---- IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/ V	IMPLANTATION SITES <POS. IN UTERUS>	---- FETUSES RIGHT HORN ---- IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/ V
FEMALE 60											
3/11	700	M	5.1		V	LIVE <1> LIVE	703	M	4.8		A
	701	F	4.7		A	LIVE <2> LIVE	704	F	4.6		V
	702	M	4.8		V	LIVE <3> LIVE	705	F	4.7		A
						<4> LIVE	706	M	5.0		V
						<5> LIVE	707	F	4.6		A
						<6> LIVE	708	M	4.8		V
						<7> LIVE	709	M	4.8		A
						<8> LIVE	710	F	4.7		V
						<9> LIVE	711	F	4.7		A
						<10> LIVE	712	M	4.7		V
						<11> LIVE	713	F	4.4		A
FEMALE 61											
8/5	714	F	4.9		V	LIVE <1> LIVE	721	F	4.7		A
	715	F	4.1		A	LIVE <2> E.RES					
	716	M	4.5		V	LIVE <3> LIVE	722	F	4.1		V
	717	M	4.1		A	LIVE <4> LIVE	723	F	4.4		A
	718	F	3.9		V	LIVE <5>					
						E.RES <6>					
	719	F	4.4		A	LIVE <7>					
	720	F	3.6		V	LIVE <8>					
FEMALE 62											
7/4	724	M	5.4		V	LIVE <1> LIVE	731	F	5.1		A
	725	M	5.4		A	LIVE <2> LIVE	732	F	4.7		V
	726	F	5.1		V	LIVE <3> LIVE	733	M	5.2		A
	727	M	5.3		A	LIVE <4>					
	728	F	4.9		V	LIVE <5>					
	729	M	5.4		A	LIVE <6>					
	730	F	5.1		V	LIVE <7>					
FEMALE 63											
10/7	734	M	4.7		V	LIVE <1> LIVE	743	M	4.8		A
	735	F	4.8		A	LIVE <2> LIVE	744	M	4.7		V
	736	M	4.4		V	LIVE <3> LIVE	745	M	5.1		A
	737	M	4.5		A	LIVE <4> LIVE	746	F	4.7		V
	738	F	3.0		V	LIVE <5> LIVE	747	F	4.7		A
	739	M	4.5		A	LIVE <6> LIVE	748	M	5.3		V
	740	F	4.1		V	LIVE <7> LIVE	749	F	4.0		A
	741	F	4.8		A	LIVE <8>					
	742	M	5.0		V	LIVE <9>					
FEMALE 64											
9/7	750	F	4.1		V	LIVE <1> LIVE	758	M	4.8		V
	751	F	4.8		A	LIVE <2> LIVE	759	F	4.6		A
	752	M	4.7		V	LIVE <3> LIVE	760	F	4.7		V
	753	F	4.5		A	LIVE <4> LIVE	761	M	4.8		A
	754	F	4.8		V	LIVE <5> LIVE	762	F	4.6		V
	755	M	4.8		A	LIVE <6> LIVE	763	F	4.7		A
						E.RES <7> LIVE	764	M	4.9		V
	756	M	4.7		V	LIVE <8>					
	757	F	4.4		A	LIVE <9>					
FEMALE 65											
10/7	889	M	4.8		V	LIVE <1> LIVE	899	F	4.8		V
	890	F	4.9		A	LIVE <2> LIVE	900	F	4.7		A
	891	M	4.6		V	LIVE <3> LIVE	901	F	4.9		V
	892	F	4.6		A	LIVE <4> LIVE	902	M	5.0		A
	893	M	5.0		V	LIVE <5> LIVE	903	M	4.6		V
	894	F	4.3		A	LIVE <6> LIVE	904	M	5.2		A
	895	F	4.7		V	LIVE <7> LIVE	905	M	5.2		V
	896	M	4.5		A	LIVE <8>					
	897	F	4.9		V	LIVE <9>					
	898	M	4.9		A	LIVE <10>					

LIVE - LIVE FETUS E.RES - EMBRYONIC RESORPTION V - VISCERAL EXAMINATION
DEAD - DEAD FETUS F.RES - FETAL RESORPTION A - ALIZARIN RED S SKELETAL STAINING TECHN.

CONTENTS OF UTERUS (PLAN VIEW)
GROUP 3 (30 MG/KG)

CORPORA LUTEA L/R	---- FETUSES LEFT HORN ----- IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/ V	IMPLANTATION SITES <POS. IN UTERUS>	---- FETUSES RIGHT HORN ---- IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/ V
FEMALE 66											
7/9	906	F	4.5		V	LIVE <1> LIVE	913	F	4.7		A
	907	M	4.5		A	LIVE <2> LIVE	914	M	5.1		V
	908	F	4.7		V	LIVE <3> E.RES					
	909	M	5.1		A	LIVE <4> LIVE	915	M	5.3		A
	910	M	4.7		V	LIVE <5> LIVE	916	F	4.9		V
	911	F	4.5		A	LIVE <6> LIVE	917	F	4.8		A
	912	F	4.5		V	LIVE <7> LIVE	918	M	5.0		V
						<8> LIVE	919	M	5.2		A

CONTENTS OF UTERUS (PLAN VIEW)
GROUP 4 (150 MG/KG)

CORPORA LUTEA L/R	---- FETUSES LEFT HORN ----- IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/ V	IMPLANTATION SITES <POS. IN UTERUS>	---- FETUSES RIGHT HORN ---- IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/ V
FEMALE 67											
7/10						E.RES <1> E.RES					
	222	F	5.0		V	LIVE <2> LIVE	227	M	5.2		A
						E.RES <3> E.RES					
	223	F	4.7		A	LIVE <4> LIVE	228	M	4.5		V
	224	M	4.8		V	LIVE <5> E.RES					
	225	F	4.1		A	LIVE <6> LIVE	229	M	5.1		A
	226	M	3.9		V	LIVE <7> LIVE	230	F	5.1		V
						<8> E.RES					
						<9> LIVE	231	F	4.9		A
						<10> LIVE	232	F	4.8		V
FEMALE 68											
7/7	233	F	4.7		V	LIVE <1> LIVE	239	M	4.9		V
	234	F	4.5		A	LIVE <2> LIVE	240	F	4.8		A
	235	F	4.6		V	LIVE <3> E.RES					
	236	F	4.7		A	LIVE <4> LIVE	241	F	4.7		V
	237	M	5.1		V	LIVE <5> LIVE	242	F	4.6		A
	238	M	5.0		A	LIVE <6> LIVE	243	M	5.0		V
						<7> LIVE	244	M	4.7		A
FEMALE 69											
9/7	245	M	4.9		V	LIVE <1> LIVE	253	M	5.2		V
						E.RES <2> LIVE	254	F	4.6		A
	246	F	4.3		A	LIVE <3> LIVE	255	F	4.5		V
	247	F	4.7		V	LIVE <4> LIVE	256	M	4.9		A
	248	F	4.3		A	LIVE <5> LIVE	257	F	4.5		V
	249	F	4.4		V	LIVE <6> LIVE	258	F	4.5		A
	250	M	5.2		A	LIVE <7> LIVE	259	M	5.2		V
	251	F	4.8		V	LIVE <8>					
	252	F	4.6		A	LIVE <9>					
FEMALE 70											
6/10	260	M	5.1		V	LIVE <1> LIVE	265	F	4.9		A
	261	M	5.4		A	LIVE <2> LIVE	266	F	4.9		V
	262	M	5.1		V	LIVE <3> LIVE	267	F	4.9		A
	263	F	4.8		A	LIVE <4> LIVE	268	M	5.3		V
	264	M	5.2		V	LIVE <5> LIVE	269	F	4.9		A
						<6> LIVE	270	M	5.0		V
						<7> LIVE	271	F	4.9		A
						<8> LIVE	272	F	4.6		V
						<9> E.RES					
FEMALE 71											
6/6	273	M	5.1		V	LIVE <1> LIVE	278	F	4.8		A
	274	F	4.1		A	LIVE <2> LIVE	279	F	4.9		V
	275	F	4.5		V	LIVE <3> LIVE	280	M	5.2		A
	276	F	4.5		A	LIVE <4> LIVE	281	F	3.9		V
	277	M	4.3		V	LIVE <5> LIVE	282	M	5.0		A
FEMALE 72											
6/7						E.RES <1> LIVE	287	M	5.2		V
	283	F	4.8		V	LIVE <2> LIVE	288	M	5.0		A
	284	F	4.7		A	LIVE <3> E.RES					
	285	M	5.2		V	LIVE <4> LIVE	289	F	4.6		V
						E.RES <5> LIVE	290	M	5.3		A
	286	F	4.5		A	LIVE <6>					

LIVE - LIVE FETUS E.RES - EMBRYONIC RESORPTION V - VISCERAL EXAMINATION
DEAD - DEAD FETUS F.RES - FETAL RESORPTION A - ALIZARIN RED S SKELETAL STAINING TECHN.

CONTENTS OF UTERUS (PLAN VIEW)
GROUP 4 (150 MG/KG)

CORPORA LUTEA L/R	FETUSES LEFT HORN IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/V	IMPLANTATION SITES <POS. IN UTERUS>	FETUSES RIGHT HORN IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/V
FEMALE 73											
8/7	426	M	5.4		V	LIVE <1> LIVE	431	M	5.8		A
						E.RES <2> LIVE	432	F	4.9		V
	427	F	5.0		A	LIVE <3> LIVE	433	F	5.0		A
	428	F	5.2		V	LIVE <4> LIVE	434	M	5.2		V
	429	M	5.4		A	LIVE <5> LIVE	435	F	5.3		A
	430	M	5.4		V	LIVE <6> LIVE	436	F	5.0		V
						E.RES <7> LIVE	437	F	4.8		A
FEMALE 74											
6/7	438	F	4.8		V	LIVE <1> LIVE	444	F	4.8		V
	439	M	5.2		A	LIVE <2> LIVE	445	F	5.0		A
	440	F	4.6		V	LIVE <3> LIVE	446	F	4.6		V
	441	F	4.9		A	LIVE <4> E.RES					
	442	M	4.9		V	LIVE <5> LIVE	447	M	5.3		A
	443	F	4.8		A	LIVE <6> LIVE	448	F	5.3		V
						<7> E.RES					
FEMALE 75											
8/5	449	M	4.2		V	LIVE <1> LIVE	456	F	4.7		A
						E.RES <2> LIVE	457	F	4.9		V
	450	F	4.6		A	LIVE <3> LIVE	458	F	4.9		A
	451	M	4.9		V	LIVE <4> LIVE	459	M	4.4		V
	452	F	4.4		A	LIVE <5> LIVE	460	M	4.9		A
	453	F	4.8		V	LIVE <6>					
	454	M	4.5		A	LIVE <7>					
	455	F	3.9		V	LIVE <8>					
FEMALE 76	(Not pregnant)										
FEMALE 77											
4/11	461	M	4.8		V	LIVE <1> LIVE	465	F	4.7		V
	462	F	4.8		A	LIVE <2> LIVE	466	F	4.4		A
	463	F	4.6		V	LIVE <3> LIVE	467	F	3.9		V
	464	F	4.5		A	LIVE <4> LIVE	468	M	4.6		A
						<5> LIVE	469	F	4.3		V
						<6> LIVE	470	M	4.4		A
						<7> LIVE	471	M	4.6		V
						<8> LIVE	472	M	4.7		A
						<9> LIVE	473	F	4.3		V
						<10> LIVE	474	F	4.3		A
FEMALE 78											
8/4	475	M	5.2		V	LIVE <1> LIVE	482	M	5.2		A
	476	F	4.9		A	LIVE <2> LIVE	483	M	5.2		V
	477	M	5.0		V	LIVE <3> LIVE	484	M	5.3		A
						E.RES <4> LIVE	485	F	5.1		V
	478	F	4.8		A	LIVE <5>					
	479	F	5.3		V	LIVE <6>					
	480	M	5.1		A	LIVE <7>					
	481	M	5.7		V	LIVE <8>					
FEMALE 79											
4/10	486	F	5.1		V	LIVE <1> LIVE	489	F	4.7		A
	487	F	4.8		A	LIVE <2> LIVE	490	F	4.4		V
	488	M	5.5		V	LIVE <3> LIVE	491	M	5.0		A
						<4> LIVE	492	F	5.1		V
						<5> LIVE	493	M	5.1		A
						<6> LIVE	494	M	5.1		V
						<7> LIVE	495	F	4.6		A
						<8> LIVE	496	M	4.7		V
						<9> E.RES					
						<10> LIVE	497	F	4.2		A

LIVE - LIVE FETUS
DEAD - DEAD FETUS
E.RES - EMBRYONIC RESORPTION
F.RES - FETAL RESORPTION
V - VISCERAL EXAMINATION
A - ALIZARIN RED S SKELETAL STAINING TECHN.

CONTENTS OF UTERUS (PLAN VIEW)
GROUP 4 (150 MG/KG)

CORPORA LUTEA L/R	---- FETUSES LEFT HORN ---- IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/ V	IMPLANTATION SITES <POS. IN UTERUS>	---- FETUSES RIGHT HORN ---- IDENT	SEX	WEIGHT (GRAM)	ANOM. MALF.	A/ V
FEMALE 80	(Not pregnant)										
FEMALE 81	(Death prior sch. necropsy)										
FEMALE 82											
11/6						E.RES <1> LIVE	775	M	5.4		V
	765	F	4.5		V	LIVE <2> LIVE	776	M	5.1		A
	766	M	4.8		A	LIVE <3> LIVE	777	M	5.2		V
	767	M	3.9		V	LIVE <4> LIVE	778	M	5.4		A
	768	F	4.9		A	LIVE <5> LIVE	779	F	4.4		V
	769	M	5.2		V	LIVE <6>					
	770	F	4.5		A	LIVE <7>					
	771	F	4.1		V	LIVE <8>					
	772	M	3.7		A	LIVE <9>					
	773	F	4.6		V	LIVE <10>					
	774	F	4.3		A	LIVE <11>					
FEMALE 83											
6/7	780	F	4.7		V	LIVE <1> LIVE	785	F	4.5		A
	781	F	4.8		A	LIVE <2> LIVE	786	M	4.7		V
	782	M	5.1		V	LIVE <3> LIVE	787	M	4.9		A
						E.RES <4> LIVE	788	F	4.2		V
	783	F	4.4		A	LIVE <5> LIVE	789	F	4.3		A
	784	M	4.9		V	LIVE <6> LIVE	790	M	5.1		V
FEMALE 84											
9/7	791	F	4.3		V	LIVE <1> LIVE	799	F	4.7		V
	792	F	4.4		A	LIVE <2> LIVE	800	M	4.5		A
	793	F	4.1		V	LIVE <3> LIVE	801	M	4.7		V
	794	F	4.5		A	LIVE <4> LIVE	802	M	4.4		A
	795	M	4.1		V	LIVE <5> LIVE	803	F	4.3		V
	796	F	4.5		A	LIVE <6> LIVE	804	M	4.2		A
	797	M	4.4		V	LIVE <7> LIVE	805	M	4.2		V
						E.RES <8>					
	798	M	4.6		A	LIVE <9>					
FEMALE 85											
5/8	920	F	4.2		V	LIVE <1> LIVE	925	F	4.5		A
	921	M	4.4		A	LIVE <2> LIVE	926	F	4.4		V
	922	F	4.6		V	LIVE <3> LIVE	927	F	4.9		A
	923	M	4.8		A	LIVE <4> LIVE	928	F	4.4		V
	924	F	4.5		V	LIVE <5> LIVE	929	F	4.2		A
						<6> LIVE	930	F	4.5		V
						<7> LIVE	931	F	4.4		A
						<8> LIVE	932	F	4.5		V
FEMALE 86											
14/4						E.RES <1> LIVE	936	F	3.8		A
						E.RES <2> LIVE	937	M	4.9		V
						E.RES <3> LIVE	938	M	5.2		A
						E.RES <4> LIVE	939	F	4.8		V
	933	M	4.8		V	LIVE <5>					
						E.RES <6>					
	934	M	5.4		A	LIVE <7>					
						E.RES <8>					
	935	M	5.1		V	LIVE <9>					
						E.RES<10>					
						E.RES<11>					
						E.RES<12>					
						E.RES<13>					
						E.RES<14>					

LIVE - LIVE FETUS E.RES - EMBRYONIC RESORPTION V - VISCERAL EXAMINATION
DEAD - DEAD FETUS F.RES - FETAL RESORPTION A - ALIZARIN RED S SKELETAL STAINING TECHN.

CONTENTS OF UTERUS (PLAN VIEW)
GROUP 4 (150 MG/KG)

CORPORA LUTEA L/R	---- FETUSES LEFT HORN ----- IDENT	SEX	WEIGHT (GRAM)	ANOM. A/ MALF. V	IMPLANTATION SITES <POS. IN UTERUS>	---- FETUSES RIGHT HORN ---- IDENT	SEX	WEIGHT (GRAM)	ANOM. A/ MALF. V
FEMALE 87									
7/6	940	M	5.1	V	LIVE <1> LIVE	946	F	5.0	V
	941	F	4.7	A	LIVE <2> LIVE	947	F	4.6	A
	942	M	5.2	V	LIVE <3> LIVE	948	F	4.6	V
	943	M	4.6	A	LIVE <4> LIVE	949	F	4.6	A
	944	F	4.7	V	LIVE <5> LIVE	950	F	4.9	V
	945	M	5.3	A	LIVE <6> LIVE	951	M	5.2	A
					E.RES <7>				
FEMALE 88									
7/7	952	M	4.8	V	LIVE <1> LIVE	958	F	4.9	V
					E.RES <2> LIVE	959	F	4.5	A
	953	M	5.2	A	LIVE <3> LIVE	960	F	4.7	V
	954	M	4.8	V	LIVE <4> LIVE	961	F	4.7	A
	955	M	4.2	A	LIVE <5> LIVE	962	M	4.6	V
	956	M	4.7	V	LIVE <6>				
	957	M	4.8	A	LIVE <7>				

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

INDIVIDUAL CLINICAL SIGNS

Group (mg/kg)	Female No(s).	Noted on day(s) post coitum	Clinical signs or observations
1 (0)	1 - 22	0 - 21	No clinical signs or observations were noted
2 (10)	23 - 30, 32 - 44	0 - 21	No clinical signs or observations were noted
	31	0 - 9	No clinical signs or observations were noted
		10 - 15	Alopecia affecting right neck region
		16 - 21	No clinical signs or observations were noted
3 (30)	45 - 66	0 - 5	No clinical signs or observations were noted
		6 - 20	Urine with dark discoloration
		21	No clinical signs or observations were noted
4 (150)	67 - 80, 82 - 88	0 - 5	No clinical signs or observations were noted
		6 - 20	Urine with dark discoloration
		21	No clinical signs or observations were noted
	81	0 - 5	No clinical signs or observations were noted
		6	Urine with dark discoloration
		7	Urine with dark discoloration, ruffled fur, incrusted nose (in all probability injured during test item administration), body weight loss 8 grams
		8	Urine with dark discoloration, ruffled fur, body weight loss 6 grams
		9	Urine with dark discoloration, ruffled fur, body weight loss 12 grams, generally poor condition
		10	Found dead in the morning

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

MATING/NECROPSY SCHEDULE AND INDIVIDUAL NECROPSY FINDINGS

Group 1 (0 mg/kg)

Female No.	Male No.*	Day 0 post coitum	Date of necropsy	Necropsy findings
1	12	23-MAR-2004	13-APR-2004	Not pregnant, no abnormal findings
2	42	23-MAR-2004	13-APR-2004	No abnormal findings
3	55	23-MAR-2004	13-APR-2004	No abnormal findings
4	56	23-MAR-2004	13-APR-2004	No abnormal findings
5	68	23-MAR-2004	13-APR-2004	No abnormal findings
6	86	23-MAR-2004	13-APR-2004	No abnormal findings
7	27	24-MAR-2004	14-APR-2004	No abnormal findings
8	46	24-MAR-2004	14-APR-2004	No abnormal findings
9	57	24-MAR-2004	14-APR-2004	No abnormal findings
10	8	25-MAR-2004	15-APR-2004	No abnormal findings
11	21	25-MAR-2004	15-APR-2004	No abnormal findings
12	25	25-MAR-2004	15-APR-2004	No abnormal findings
13	29	25-MAR-2004	15-APR-2004	No abnormal findings
14	30	25-MAR-2004	15-APR-2004	No abnormal findings
15	44	25-MAR-2004	15-APR-2004	No abnormal findings
16	54	25-MAR-2004	15-APR-2004	No abnormal findings
17	77	25-MAR-2004	15-APR-2004	No abnormal findings
18	90	25-MAR-2004	15-APR-2004	No abnormal findings
19	96	25-MAR-2004	15-APR-2004	No abnormal findings
20	23	26-MAR-2004	16-APR-2004	No abnormal findings
21	35	26-MAR-2004	16-APR-2004	No abnormal findings
22	70	26-MAR-2004	16-APR-2004	No abnormal findings

* = Number of the male mated with the female.

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

MATING/NECROPSY SCHEDULE AND INDIVIDUAL NECROPSY FINDINGS

Group 2 (10 mg/kg)

Female No.	Male No.*	Day 0 post coitum	Date of necropsy	Necropsy findings
23	5	23-MAR-2004	13-APR-2004	No abnormal findings
24	41	23-MAR-2004	13-APR-2004	No abnormal findings
25	51	23-MAR-2004	13-APR-2004	No abnormal findings
26	58	23-MAR-2004	13-APR-2004	No abnormal findings
27	59	23-MAR-2004	13-APR-2004	No abnormal findings
28	78	23-MAR-2004	13-APR-2004	No abnormal findings
29	88	23-MAR-2004	13-APR-2004	No abnormal findings
30	19	24-MAR-2004	14-APR-2004	No abnormal findings
31	69	24-MAR-2004	14-APR-2004	No abnormal findings
32	76	24-MAR-2004	14-APR-2004	No abnormal findings
33	93	24-MAR-2004	14-APR-2004	No abnormal findings
34	9	25-MAR-2004	15-APR-2004	No abnormal findings
35	11	25-MAR-2004	15-APR-2004	No abnormal findings
36	16	25-MAR-2004	15-APR-2004	No abnormal findings
37	37	25-MAR-2004	15-APR-2004	No abnormal findings
38	63	25-MAR-2004	15-APR-2004	No abnormal findings
39	71	25-MAR-2004	15-APR-2004	No abnormal findings
40	85	25-MAR-2004	15-APR-2004	No abnormal findings
41	7	26-MAR-2004	16-APR-2004	No abnormal findings
42	33	26-MAR-2004	16-APR-2004	No abnormal findings
43	40	26-MAR-2004	16-APR-2004	No abnormal findings
44	72	26-MAR-2004	16-APR-2004	No abnormal findings

* = Number of the male mated with the female.

MATING/NECROPSY SCHEDULE AND INDIVIDUAL NECROPSY FINDINGS

Group 3 (30 mg/kg)

Female No.	Male No.*	Day 0 post coitum	Date of necropsy	Necropsy findings
45	6	23-MAR-2004	13-APR-2004	No abnormal findings
46	10	23-MAR-2004	13-APR-2004	No abnormal findings
47	43	23-MAR-2004	13-APR-2004	No abnormal findings
48	45	23-MAR-2004	13-APR-2004	No abnormal findings
49	47	23-MAR-2004	13-APR-2004	Not pregnant, uterus contained fluid
50	48	23-MAR-2004	13-APR-2004	No abnormal findings
51	50	23-MAR-2004	13-APR-2004	No abnormal findings
52	53	23-MAR-2004	13-APR-2004	No abnormal findings
53	60	23-MAR-2004	13-APR-2004	No abnormal findings
54	64	23-MAR-2004	13-APR-2004	No abnormal findings
55	15	24-MAR-2004	14-APR-2004	No abnormal findings
56	22	24-MAR-2004	14-APR-2004	No abnormal findings
57	26	24-MAR-2004	14-APR-2004	No abnormal findings
58	74	24-MAR-2004	14-APR-2004	No abnormal findings
59	83	24-MAR-2004	14-APR-2004	No abnormal findings
60	3	25-MAR-2004	15-APR-2004	No abnormal findings
61	17	25-MAR-2004	15-APR-2004	No abnormal findings
62	81	25-MAR-2004	15-APR-2004	No abnormal findings
63	82	25-MAR-2004	15-APR-2004	No abnormal findings
64	94	25-MAR-2004	15-APR-2004	No abnormal findings
65	32	26-MAR-2004	16-APR-2004	No abnormal findings
66	39	26-MAR-2004	16-APR-2004	No abnormal findings

* = Number of the male mated with the female.

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

MATING/NECROPSY SCHEDULE AND INDIVIDUAL NECROPSY FINDINGS

Group 4 (150 mg/kg)

Female No.	Male No.*	Day 0 post coitum	Date of necropsy	Necropsy findings
67	34	23-MAR-2004	13-APR-2004	No abnormal findings
68	38	23-MAR-2004	13-APR-2004	No abnormal findings
69	62	23-MAR-2004	13-APR-2004	No abnormal findings
70	67	23-MAR-2004	13-APR-2004	No abnormal findings
71	73	23-MAR-2004	13-APR-2004	No abnormal findings
72	75	23-MAR-2004	13-APR-2004	No abnormal findings
73	1	24-MAR-2004	14-APR-2004	No abnormal findings
74	18	24-MAR-2004	14-APR-2004	No abnormal findings
75	20	24-MAR-2004	14-APR-2004	No abnormal findings
76	34	24-MAR-2004	14-APR-2004	Not pregnant, no abnormal findings
77	36	24-MAR-2004	14-APR-2004	No abnormal findings
78	49	24-MAR-2004	14-APR-2004	No abnormal findings
79	66	24-MAR-2004	14-APR-2004	No abnormal findings
80	4	25-MAR-2004	15-APR-2004	Not pregnant, no abnormal findings
81	14	25-MAR-2004	05-APR-2004	Found dead, no abnormal findings (A)
82	61	25-MAR-2004	15-APR-2004	No abnormal findings
83	65	25-MAR-2004	15-APR-2004	No abnormal findings
84	80	25-MAR-2004	15-APR-2004	No abnormal findings
85	2	26-MAR-2004	16-APR-2004	No abnormal findings
86	13	26-MAR-2004	16-APR-2004	No abnormal findings
87	24	26-MAR-2004	16-APR-2004	No abnormal findings
88	31	26-MAR-2004	16-APR-2004	No abnormal findings

* = Number of the male mated with the female.

(A) = Because the animal was necropsied the day following the day of death, the content of the uterus was not exactly determinable, but the animal was pregnant.

8 ATTACHMENTS

8.1 ATTACHMENT I

WATER ANALYSES:

- BACTERIOLOGICAL AND CHEMICAL ASSAYS, CONTAMINANT ANALYSIS OF DRINKING WATER

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

BACTERIOLOGICAL ASSAY OF DRINKING WATER, FUELLINSDORF

Official Laboratory	Liestal, 28.01.2004
Basel-Landschaft	Ref.no. 200030334
Sampling point:	35.991.N Net water RCC Ltd, Füllinsdorf, Bldg. 2
Sampled on:	28.01.2004
Sample:	
Time of sampling	7.40-8.40
Water temperature (°C)	11.7

BACTERIOLOGICAL TEST:

Aerobic mesophilic bacteria / ml	0
E.coli / 100 ml	0
Enterococci / 100 ml	0

ASSESSMENT:

At the time of sampling, the tested bacteriological parameters met the requirements for drinking water according to article 275 of the "Eidg. Lebensmittelverordnung".

4410 Liestal, den 18.02.2004

Official Laboratory
The Official Chemist

(signed Dr. [illegible])

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

CHEMICAL WATER ANALYSIS, FUELLINSDORF

Official Laboratory
Basel-Landschaft

Liestal, 28.01.2004
Ref.no. 200030335

Sampling point: 35.991.N Net water, RCC Ltd, Füllinsdorf, Bldg. 2

Sampled on: 28.01.2004

Time of sampling 7.40-8.40

Water temperature (°C) 11.7

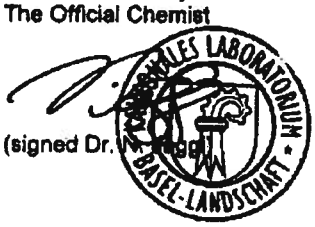
CHEMICAL TEST:

Appearance			clear, colourless
Odor			not remarkable
Taste			not remarkable
UV-absorption at 254 nm/100 cm			1.76
Conductivity		µS/cm	605
Oxygen demand	($KMnO_4$ cons.)	mg/l	2.3
Turbidity	FNU		0.11
Chloride	Cl^-	mg/l	21.8
Nitrate	NO_3^-	mg/l	23.7
Sulphate	SO_4^{--}	mg/l	67.0
Nitrite	NO_2^-	mg/l	<0.005
Total hardness		fr.H°	33.2
Alkaline hardness		fr.H°	24.9
Non carbonate hardness		fr.H°	8.3
Calcium	Ca^{++}	mg/l	117.7
Magnesium	Mg^{++}	mg/l	9.0

ASSESSMENT:

At the time of sampling, the tested chemical parameters met the requirements for drinking water according to article 275 of the "Eidg. Lebensmittelverordnung".

Official Laboratory
The Official Chemist



(signed Dr. [illegible])

4410 Liestal, den 18.02.2004

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

CONTAMINANT ASSAY OF DRINKING WATER, FÜLLINSDORF

RCC Project: 852578

Date of Sampling: 28.01.2004

Sample: H_2O, RCC Ltd, Füllinsdorf, Bldg. 2

PARAMETER	ASSAY LEVEL µg/l	LIMIT * µg/l
Lindane	< 0.05	0.1
Heptachlor	< 0.05	0.1
Malathion	< 0.05	0.1
DDT, total	< 0.05	0.1
Dieldrin	< 0.05	0.1
Cadmium	< 0.5	5
Arsenic	< 3	50
Lead	< 3	50
Mercury	< 1	1
Selenium	< 3	10
Copper	< 4	1500
PCBs (28, 52, 101, 138, 153, 180)	< 0.05	0.1
Nitrosamines, total (DMN, DEN, NPIP, NMORPH)	< 0.002	----

< 0.05 = less than 0.05 microgram per liter

* Schweizer Lebensmittelbuch

February 12, 2004

signed K. Biedermann

8.2 ATTACHMENT II

CHEMICAL ANALYSES OF FEED:

- ASSAY FOR CONTAMINANTS

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

ANALYTICAL TEST REPORT

RCC Study 847194
24. November 2003

Prepared for	PROVIMI KLIBA AG 4303 Kaiseraugst
Attention of	Dr. Isler
Materials tested	KLIBA-NAFAG 3433 Batch 76/03 vom 13.11.03
Test performed	AAS, GC, GC-MS, HPLC
Test results	See attached Table 1
Submitted	E. Dettwiler
Issued by	K. Biedermann

5. Dezember 2003/sco

ATTACHMENT

RCC Study 847194
24. November 2003

Table 1 - Test Results

KLIBA-NAFAG 3433
Batch 78/03 vom 13.11.03

PARAMETER	ASSAY LEVEL mg/kg	LIMIT* mg/kg
Aflatoxins (B1, B2, G1, G2), total	< 0.001	0.005
Estrogens (DES, Hexestrol, Dienestrol), total	< 0.001	0.001
Lindane	< 0.005	0.02
Heptachlor	< 0.005	0.02
Malathion	< 0.5	2.5
DDT, total	< 0.025	0.100
Dieldrin	< 0.005	0.02
Cadmium	0.03	0.160
Arsenic	< 0.15	1.0
Lead	0.27	1.5
Mercury	< 0.05	0.1
Selenium	< 0.15	0.6
Copper	16	----
PCBs	< 0.025	0.05
Nitrosamines (DMN, DEN, NPIP, NMORPH), total	< 0.002	0.010

< 0.001 = less than 0.001 milligram per kilogram
* = USP EPA, Federal Register, Vol. 44, No. 91, May 9, 1979

8.3 ATTACHMENT III

CERTIFICATE OF ANALYSIS

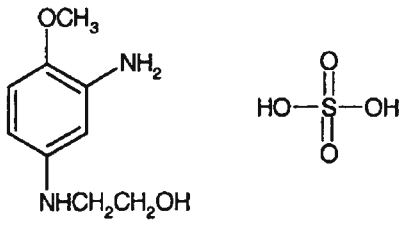
COSMITAL SA

Marly, 19.02.2001 FOF/BR/DOU/bs
Erweitert, Marly, 19.02.2003, FOF/UM
Erweitert, Marly, 11.12.2003, FOF/UM

CERTIFICATE OF ANALYSIS

raw material no.: 23081 **Code:** A000157

Structure:



Molecular formula: $C_9H_{12}N_2O_2.H_2O_4S$ **Molecular weight:** 280.30

name: LEHMANN BLAU

Trade name: HC BLAU AC , HC BLUE AC

Chemical name: 2-Amino-4-(2-hydroxyethyl)amino-anisole-sulfate

Name (INCI): 2-AMINO-4-HYDROXYETHYLAMINO-ANISOLE

CAS-No: 83763-48-8 **EINECS/ELINCS-No:** 280-734-8

Testing material

Sample name: **Sample no:**

Batch: Ch. 57/01 (R96000195; R96000196) **Study no.:** G2000/003

Date of entry: 08.01.96 **Expiry date:** July, 2005

Results

Aspect: pale grey powder

Odour:

Melting point:

Elemental analysis:

Loss on drying: 0.08 weight%

Water content: 5.9 weight%

Sulphated ash: 0.03 weight%

Mass spectrum:

124

NMR spectrum: 93.5 weight%

IR spectrum:

UV/VIS spectrum:

GC:

HPLC: 99.6 area% at the 254 nm
99.7 area% at the 296 nm

Identity and Purity:
The ^{1}H-NMR spectra confirmed the chemical identity of the test substance and resulted in a content of 93.5 weight%. The difference to 100 % is to be due particularly to a high water content of 5.9 weight%. In comparison to the drying loss (0.08 weight%) the water content laid clearly more highly, so that probably crystalline bound water was present. The small ash content (0.03 weight%) showed that the sample contained only small quantities of inorganic components. By means of HPLC the content of the impurity 4-Methoxy-1,3-phenylendiamino sulphate was determined to 0.06 weight%. The sum of NMR content, water content and content of 4-Methoxy-1,3-phenylen-diamino sulphate supplied a satisfying balance of the identified components of the sample of 99.5 weight%. The purity examination by HPLC showed impurities with 0,02 - 0.15 surface %, which might lie in the NMR spectroscopically not detectable trace range. The further evaluation resulted in a HPLC purity of 99.6 surface % in the case of one detection wavelength of 254 nm and 99.7 surface % in the case of 296 nm.

By-products: 0.06 weight% 4-Methoxy-1,3-phenylendiaminsulfate

Solubility: 10g/l in water pH 2.8
1 weight% in acetone / water 1:1 (pH 2.1)
9-10 weight% in DMSO

Stability:

Stability in solution:
For the examination of stability during a period of altogether seven days the HPLC was likewise used by means of UV detection with a wavelength at 243 nm. During the examination the aqueous solutions of the test substance (approx. 5 weight%) as well as the solutions in DMSO (approx. 5 weight%) were stored at ambient temperature and under light exclusion. The results (between 100 and 79,7 % retrieval rate during the storage) indicate a small degradation of the test substance in DMSO and in aqueous solution.

P. Dougoud

8.4 ATTACHMENT IV

ANALYTICAL PHASE REPORT:

- DETERMINATION OF CONCENTRATION, HOMOGENEITY, AND STABILITY OF 2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE IN BI-DISTILLED WATER

ANALYTICAL PHASE REPORT

Analytical Phase to:

2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE: PRENATAL DEVELOPMENTAL TOXICITY STUDY IN THE RAT

Subtitle:

Determination of Concentration, Homogeneity, and Stability of 2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE in Bi-distilled Water

Study Director:

H. Becker (RCC Ltd, Toxicology, Füllinsdorf)

Principal Investigator Analytical Phase:

Dr. D. Flade

Completion Date of Analytical Phase Report:

October 14, 2004

Test Site:

RCC Ltd
Environmental Chemistry &
Pharmanalytics
CH-4452 Itingen / Switzerland

RCC Study No.:

851839

GOOD LABORATORY PRACTICE

STATEMENT OF COMPLIANCE

RCC Study Number :	851839
Study Director :	H. Becker, RCC Ltd, Toxicology, Füllinsdorf / Switzerland
Test Item :	2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE
Principal Investigator Analytical Phase :	Dr. D. Flade
Analytical Phase to :	2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE: PRENATAL DEVELOPMENTAL TOXICITY STUDY IN THE RAT

The analytical phase has been performed in compliance with the Swiss Ordinance relating to Good Laboratory Practice, adopted February 2nd, 2000 [RS 813.016.5]. This Ordinance is based on the OECD Principles of Good Laboratory Practice, as revised in 1997 and adopted November 26th, 1997 by decision of the OECD Council [C(97)186/Final].

Principal Investigator
Analytical Phase: Dr. D. Flade

D. Flade
.....
Date: October 14, 2004

SIGNATURES

Principal Investigator
Analytical Phase: Dr. D. Flade

D Flade
.....
Date: October 14, 2004

Management: Dr. J. Schreitmüller

.....
Date: October 14, 2004

QUALITY ASSURANCE

RCC Ltd, Environmental Chemistry & Pharmanalytics, CH-4452 Itingen / Switzerland

STATEMENT

RCC Study Number :	851839
Study Director :	H. Becker, RCC Ltd, Toxicology, Füllinsdorf / Switzerland
Test Item :	2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE
Principal Investigator Analytical Phase :	Dr. D. Flade
Analytical Phase to :	2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE: PRENATAL DEVELOPMENTAL TOXICITY STUDY IN THE RAT

The general facilities and activities are inspected periodically and the results are reported to the responsible person and the management.

Study procedures were periodically inspected. The phase report was audited by the quality assurance. The dates are given below.

Dates and Types of QA Inspections		Dates of Reports to the Principal Investigator and to the Management
April 05, 2004	Process based (analytical work)	April 05, 2004
October 08/13, 2004	Phase report	October 13, 2004

This statement also confirms that this final phase report reflects the raw data.

Sections of the draft study plan relating to the phase were reviewed and reported to the study director, lead QA and test facility management on: March 10, 2004.

Summary report(s) of study related inspection(s) (if applicable) was/were issued to the study director, lead QA and test facility management.

Quality Assurance: for M. Richter-Auer

S. Zeugin

.....

Date: October 14, 2004

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PREFACE

GENERAL

Analytical Phase to:	2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE: PRENATAL DEVELOPMENTAL TOXICITY STUDY IN THE RAT
Sponsor:	
Study Director: (Test Facility)	H. Becker RCC Ltd Toxicology Operational Unit: Assessment I CH-4414 Füllinsdorf / Switzerland
Test Site:	RCC Ltd Environmental Chemistry & Pharmanalytics Zelgliweg 1 CH-4452 Itingen / Switzerland

RESPONSIBILITIES

Principal Investigator Analytical Phase:	Dr. D. Flade
Reporting:	A. Ullrich
Head of RCC Quality Assurance:	I. Wüthrich

SCHEDULE OF ANALYTICAL PHASE

Experimental Starting Date:	April 13, 2004
Experimental Completion Date:	May 04, 2004
Completion Date of Analytical Phase Report:	October 14, 2004

ARCHIVING

RCC Ltd, CH-4452 Itingen/Switzerland will retain a copy of the study plan, the raw data, and the analytical phase report of the present study for at least ten years. No data will be discarded without the sponsor's consent.

1 PURPOSE

This phase report describes the analytical method employed and the results obtained for concentration, homogeneity, and stability of 2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE in bi-distilled water. The analyses were performed by HPLC analysis based on a method provided by the sponsor.

Analysis of homogeneity was performed by analysing samples of each dose group from three different segments (top, middle, bottom) of the respective mixing container.

Evaluation of stability was performed by analysing samples of each dose group stored at room temperature for four hours.

2 MATERIALS AND METHODS

2.1 TEST ITEM

Detailed information on the test item 2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE as used for analytical purposes is given in the main report.

2.2 SAMPLE PREPARATION AND STORAGE

Test item/vehicle mixtures were prepared by RCC Ltd, Toxicology, Füllinsdorf and about 2 g (weighed to the third decimal place) of each mixture was delivered to the analytical laboratory of RCC Ltd, Environmental Chemistry & Pharmanalytics. These samples for analysis of concentration and homogeneity were stored deep-frozen (about -20 °C) until analysis. Storage stability samples were collected after storage at room temperature for four hours and then delivered to the analytical laboratory where they were stored deep-frozen until analysis.

2.3 ANALYTICAL PROCEDURE

2.3.1 Reagents

Purified water:	In-house prepared by a Milli-Q water purification system (Millipore)
Acetonitrile:	Baker no. 9017
Phosphoric acid:	Baker no. 6024
Methane sulphonic acid	Fluka no. 64280
Di-potassium hydrogen-phosphate:	Merck no. 1.05101
Buffer solution (pH 3.6):	0.192 mL methane sulphonic acid + 0.87 g di-potassium hydrogen phosphate / L water adjusted to pH 3.6 with phosphoric acid
Solvent mixture:	Buffer solution/acetonitrile (88+12 v/v)

2.3.2 Standard Solutions

Stock solutions of the test item in solvent mixture (cf. Section 2.3.1) with concentrations in the range from 308.7 µg/mL to 497.7 µg/mL were prepared by weighing appropriate amounts of the test item accurately into 100-mL volumetric flasks. The flasks were filled to the mark with solvent mixture. Finally, various standard solutions were prepared by respective dilution of these stock solutions with solvent mixture to yield concentrations in the range from 3.982 µg/mL to 123.5 µg/mL. These standard solutions were used for calibration of the HPLC.

2.3.3 Analysis of Samples

The delivered samples were dissolved in 100 mL of solvent mixture (cf. Section 2.3.1). Depending on the dose group, the latter sample solutions were further diluted with solvent mixture to yield concentrations within the calibration range. Finally, a defined aliquot was quantified by HPLC.

2.3.4 High Performance Liquid Chromatographic Determination

Typical Apparatus:	pump:	Merck-Hitachi L-6200
(LC5)	detector:	Merck-Hitachi L-4200
	sampling unit:	Merck-Hitachi L-7200
Column:	LiChrospher 60 RP select B; 5 µm; 250 x 4 mm	
Eluent:	Solvent mixture (cf. Section 2.3.1)	
Flow:	1.0 mL/min	
Wave length:	280 nm	
Injection volume:	20 µL	

2.3.5 Evaluation of Results

Injected samples were quantified by the peak areas (counts) of the test item with reference to the calibration curve. The latter was obtained by correlation of the peak areas of the standard solutions with their corresponding concentrations (µg/mL), using the following equation 1:

$$Y = a + b \cdot X \qquad (1)$$

where

Y = Peak areas of test item in injected sample [counts]
a = Y-axis intercept
b = Slope
X = Concentration of test item in injected sample [µg/mL]

The concentrations of test item in vehicle were calculated according to equation 2:

$$C = \frac{X \cdot V \cdot D \cdot Q}{W \cdot 1000} \qquad (2)$$

where

C = Concentration of test item in vehicle [mg/mL]
X = Concentration of test item in injected sample calculated by equation 1 [µg/mL]
V = Final volume [mL]
D = Dilution factor
Q = Density of test item/vehicle mixtures [assumed to be 1.0 g/mL]
W = Weight of sample [about 2 g, weighed to the third decimal place]

3 RESULTS

This chemical analysis determined concentration, homogeneity, and stability of 2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE in bi-distilled water.

Date of Preparation: 30-MAR-2004:

The mean concentrations of the homogeneity samples were found to be 102.0%, 105.4%, and 100.3% of the nominal concentrations of dose group 2 (1 mg/mL), dose group 3 (3 mg/mL), and dose group 4 (15 mg/mL), respectively. The individual concentrations varied in the range from -2% to +2% of the mean concentrations. Therefore, the test item was found to be homogeneously distributed in the vehicle.

2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE was stable in the vehicle under storage conditions for 4 hours.

Date of Preparation: 15-APR-2004:

The mean concentrations of the homogeneity samples were found to be 99.7%, 97.9%, and 102.2% of the nominal concentrations of dose group 2 (1 mg/mL), dose group 3 (3 mg/mL), and dose group 4 (15 mg/mL), respectively. The individual concentrations varied in the range from -1% to +1% of the mean concentrations. Therefore, the test item was found to be homogeneously distributed in the vehicle.

In conclusion, the results obtained were within the accepted limits defined in the RCC-SOP.

The results obtained for concentration, homogeneity, and stability of the test item in vehicle are presented in Table 2. An example of a calibration curve is shown in Table 1 and typical chromatograms of standard solutions and test samples are presented in Figures 1 and 2.

The tabulated values represent rounded-off results by calculations based on the exact raw data.

Table 1: Example of Calibration Curve

Date of analysis: 13-APR-04

Concentrations (µg/mL)	Peak area (counts)	Concentration corrected (µg/mL)	Peak area corrected (counts)	Bias (%)
3.982	16885	4.172	16050	4.9
9.954	43554	10.25	42265	3.0
19.91	86586	20.05	85968	0.7
39.82	175930	40.40	173365	1.5
69.68	306784	70.21	304438	0.8
99.54	441541	100.9	435511	1.4
5.882	24851	5.987	24391	1.9
19.61	83275	19.30	84651	-1.7
39.22	167554	38.50	170731	-1.9
58.82	253664	58.11	256767	-1.2
78.43	339118	77.58	342847	-1.1
98.04	426169	97.41	428927	-0.6

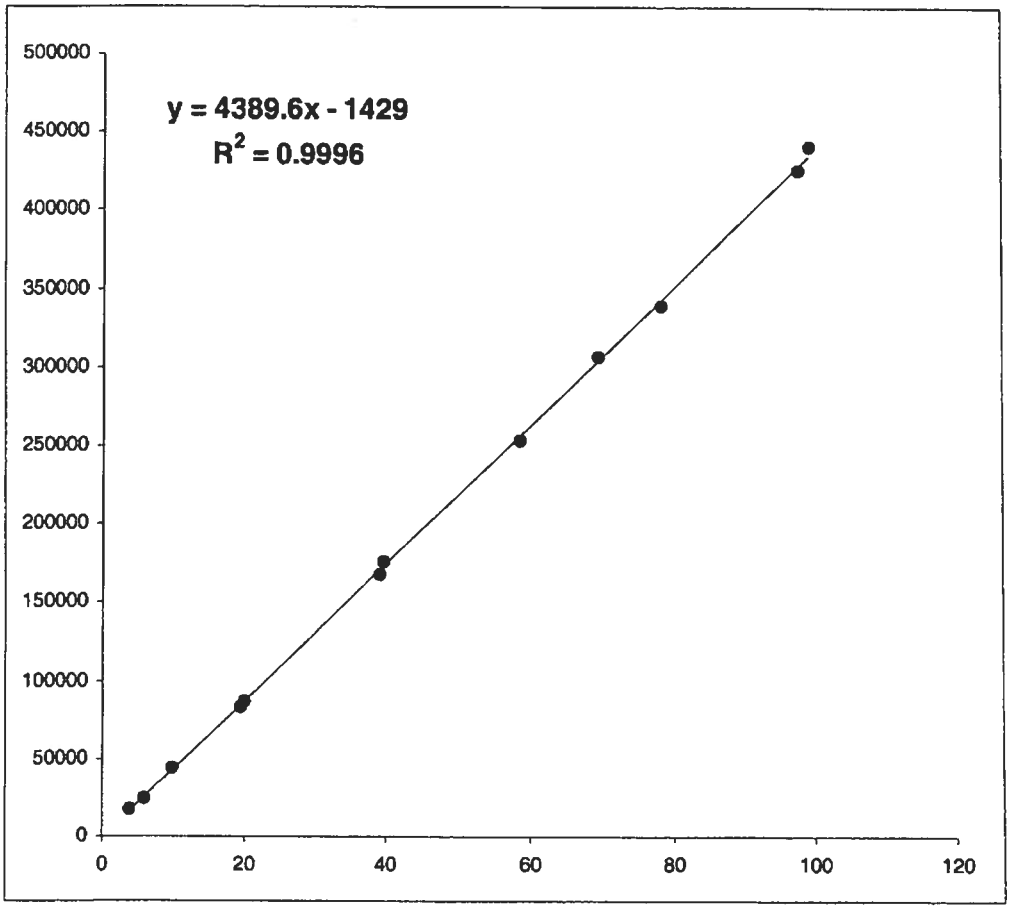


Table 2: Concentration, Homogeneity, and Stability of Test Item in Vehicle

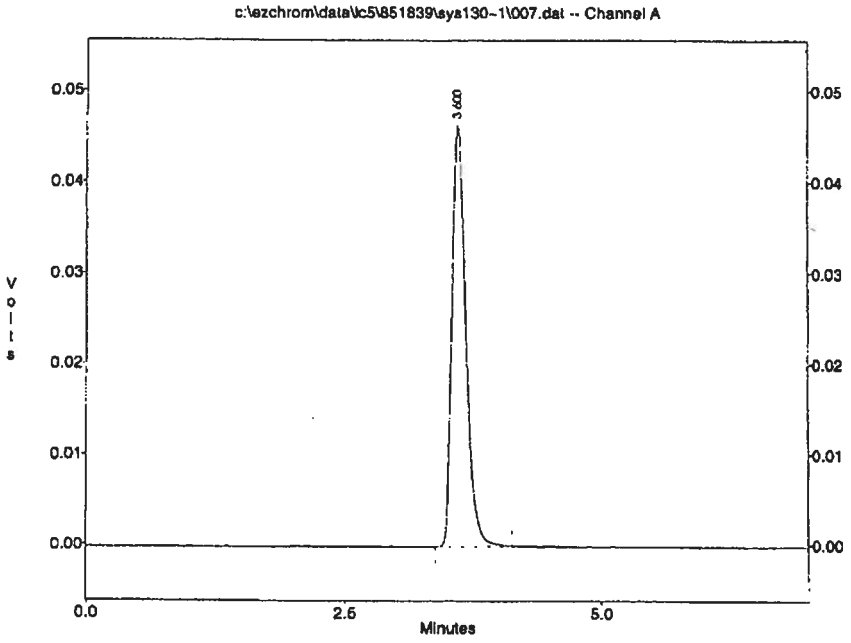
Dose Group	Nominal Conc. (mg/mL)	TMB	Time of Storage[1]	Date of Analysis	Concentration Found			
					(mg/mL)	% of Nom.	Mean % of Nom.	± Dev. in % of Mean
Date of Preparation: 30-MAR-04								
1	---	--	0 h	13-APR-04	0.000	---	---	---
2	1.0	T	0 h	13-APR-04	1.006	100.6	102.0	-1/+2
		M	0 h	13-APR-04	1.036	103.6		
		B	0 h	13-APR-04	1.020	102.0		
		--	4 h	13-APR-04	1.012	101.2	---	---
3	3.0	T	0 h	13-APR-04	3.169	105.6	105.4	±0
		M	0 h	13-APR-04	3.166	105.5		
		B	0 h	13-APR-04	3.152	105.1		
		--	4 h	13-APR-04	3.152	105.1	---	---
4	15.0	T	0 h	13-APR-04	15.17	101.2	100.3	-2/+1
		M	0 h	13-APR-04	17.81	98.7		
		B	0 h	13-APR-04	15.18	101.2		
		--	4 h	13-APR-04	13.81	92.1	---	---
Date of Preparation: 15-APR-04								
1	---	--	0 h	04-MAY-04	0.000	---	---	---
2	1.0	T	0 h	04-MAY-04	1.006	100.6	99.7	-1/+1
		M	0 h	04-MAY-04	0.999	99.9		
		B	0 h	04-MAY-04	0.986	98.6		
3	3.0	T	0 h	04-MAY-04	2.929	97.6	97.9	±0
		M	0 h	04-MAY-04	2.933	97.8		
		B	0 h	04-MAY-04	2.945	98.2		
4	15.0	T	0 h	04-MAY-04	15.28	101.9	102.2	-1/+1
		M	0 h	04-MAY-04	15.54	103.6		
		B	0 h	04-MAY-04	15.18	101.2		

T/M/B: Top/Middle/Bottom (segment of mixing container)
h/d: hours/days
[1] at room temperature

Figure 1: Typical Chromatograms of Standard Solutions

(A) Standard solution: 99.54 µg/mL
(B) Standard solution: 3.982 µg/mL
Date of analysis: 13-APR-04

(A)



(B)

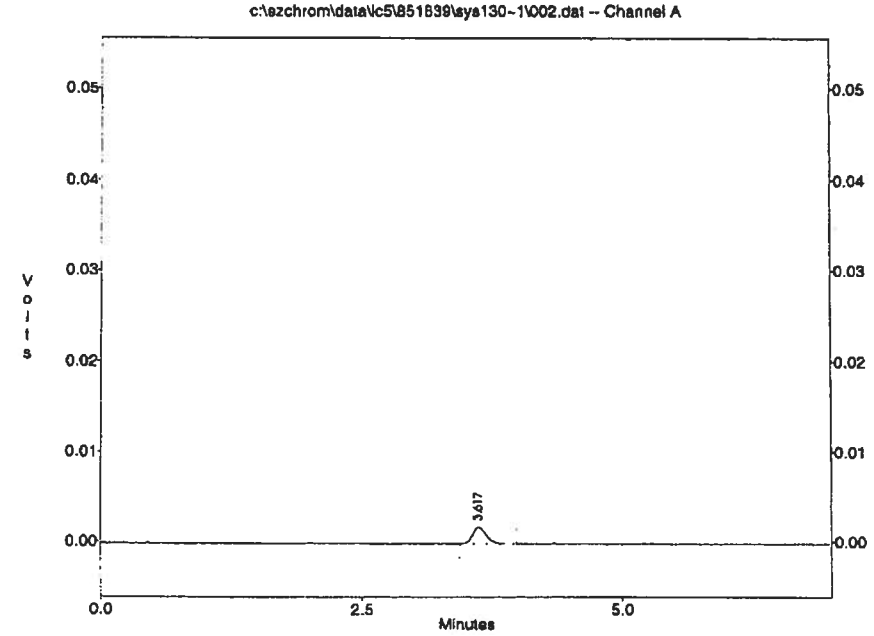


Figure 2: Typical Chromatograms of Test Samples

(A) Dose group 1, control sample, undiluted
(B) Dose group 2 (top), nominal concentration: 1.0 mg/mL, undiluted
Date of analysis: 13-APR-04

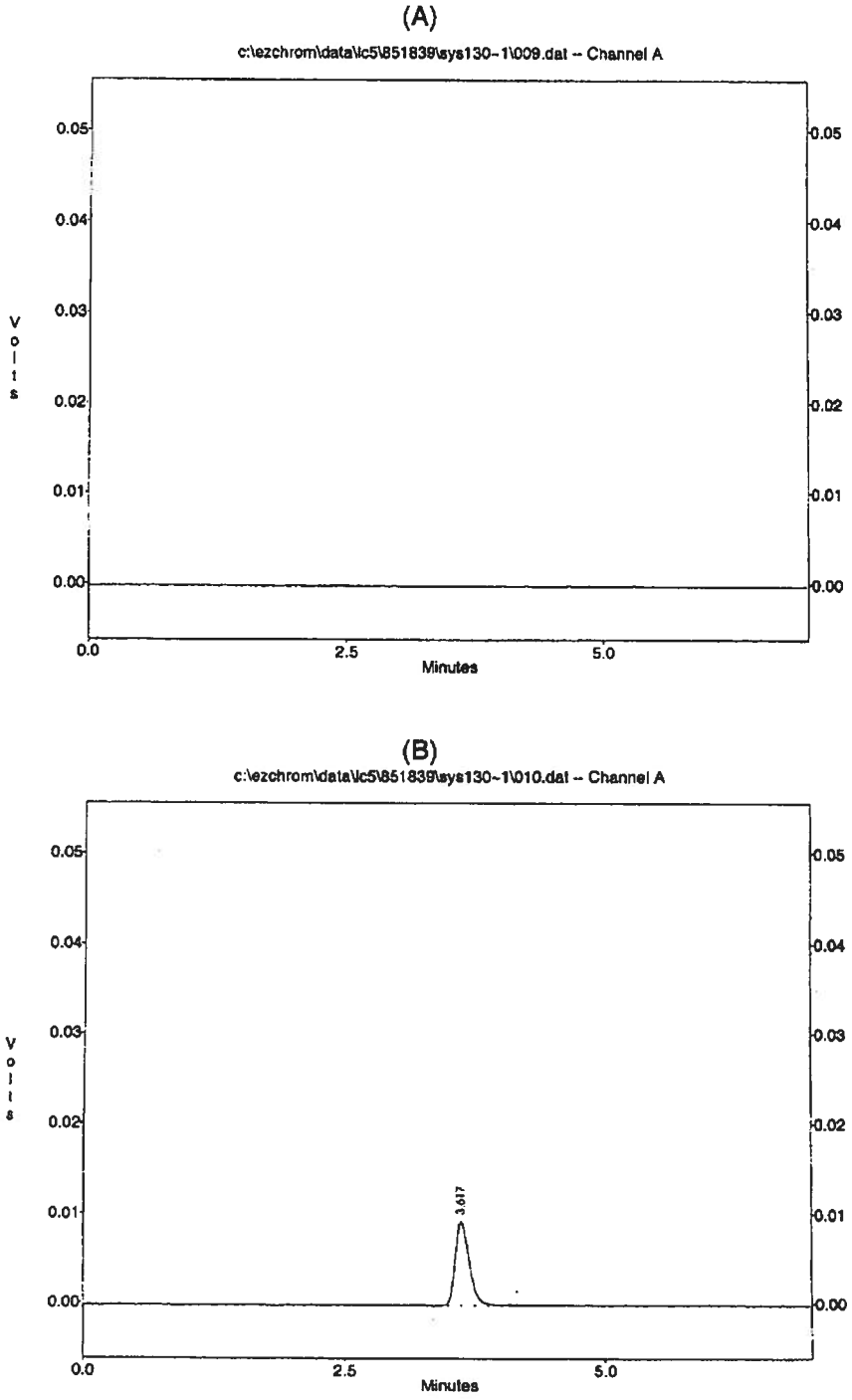
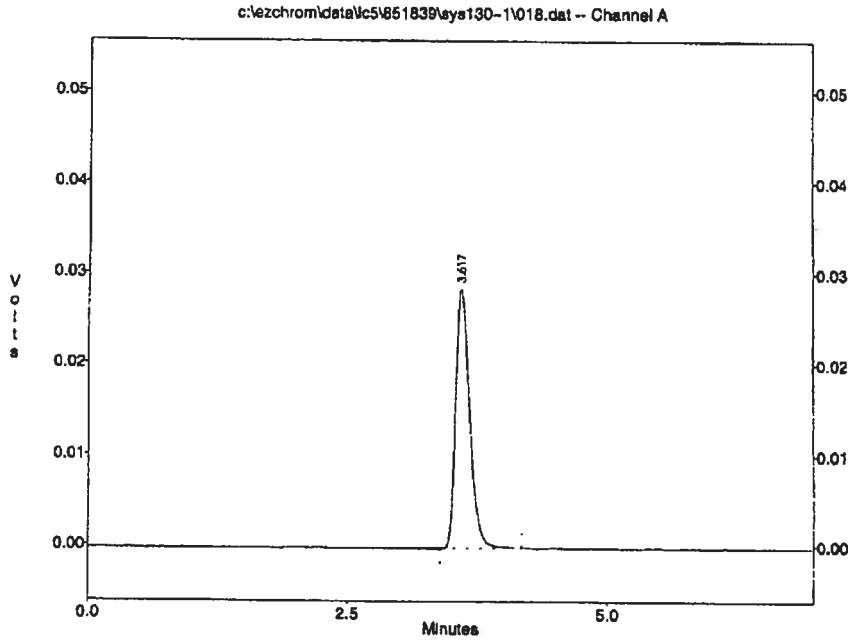


Figure 2: Cont'd

(C) Dose group 4 (top), nominal concentration: 15 mg/mL, diluted 5x

Date of analysis: 13-APR-04

(C)



8.5 ATTACHMENT V

SKELETAL EXAMINATION OF FETUSES - INDIVIDUAL DATA

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

SKELETAL EXAMINATION OF FETUSES - INDIVIDUAL DATA

- GROUP 1 (0 MG/KG) - FETUSES OF DAM NOS. 1 - 22

SKELETAL EXAMINATIONS
GROUP 1 (0 MG/KG)

DAM 2

FETUS 2	NO ABNORMAL FINDING	
FETUS 4	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT

DAM 3

FETUS 7	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 3 PROXIMAL PHALANX, LEFT TOE 4 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 3 PROXIMAL PHALANX, RIGHT TOE 4 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 9	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 3 PROXIMAL PHALANX, LEFT TOE 4 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 3 PROXIMAL PHALANX, RIGHT TOE 4 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 11	NON-OSSIFIED.	TALUS LEFT METATARSALIA 1, LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 3 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT METATARSALIA 1, RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 3 PROXIMAL PHALANX, RIGHT TOE 4 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 13	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 3 PROXIMAL PHALANX, LEFT TOE 4 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 3 PROXIMAL PHALANX, RIGHT TOE 4 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 15	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 3 PROXIMAL PHALANX, LEFT TOE 4 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 3 PROXIMAL PHALANX, RIGHT TOE 4 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT

SKELETAL EXAMINATIONS
GROUP 1 (0 MG/KG)

DAM 3 CONT.

FETUS 17	INCOMPLETELY OSSIFIED	OS PARIETALE, BILATERAL
		OS INTERPARIETALE
		STERNEBRA 5
	NON-OSSIFIED.	DIGIT 1 DISTAL PHALANX, LEFT
		DIGIT 2 PROXIMAL PHALANX, LEFT
		DIGIT 3 PROXIMAL PHALANX, LEFT
		DIGIT 4 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 1 DISTAL PHALANX, RIGHT
		DIGIT 2 PROXIMAL PHALANX, RIGHT
		DIGIT 3 PROXIMAL PHALANX, RIGHT
		DIGIT 4 PROXIMAL PHALANX, RIGHT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		DIGIT 5 DISTAL PHALANX, RIGHT
		TALUS LEFT
		METATARSALIA 1, LEFT
		TOE 2 PROXIMAL PHALANX, LEFT
		TOE 3 PROXIMAL PHALANX, LEFT
		TOE 4 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		METATARSALIA 1, RIGHT
		TOE 2 PROXIMAL PHALANX, RIGHT
		TOE 3 PROXIMAL PHALANX, RIGHT
		TOE 4 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 19	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TALUS LEFT
		TOE 2 PROXIMAL PHALANX, LEFT
		TOE 3 PROXIMAL PHALANX, LEFT
		TOE 4 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 2 PROXIMAL PHALANX, RIGHT
		TOE 3 PROXIMAL PHALANX, RIGHT
		TOE 4 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT

DAM 4

FETUS 22	NON-OSSIFIED.	TALUS LEFT
		TOE 2 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 2 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
		RIB(S), RIGHT
FETUS 24	INCOMPLETELY OSSIFIED	OS INTERPARIETALE
	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 2 PROXIMAL PHALANX, RIGHT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TALUS LEFT
		TOE 2 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TOE 2 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
FETUS 26	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 2 PROXIMAL PHALANX, RIGHT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TALUS LEFT
		METATARSALIA 1, LEFT
		TOE 2 PROXIMAL PHALANX, LEFT
		TOE 3 PROXIMAL PHALANX, LEFT
		TOE 4 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT

SKELETAL EXAMINATIONS
GROUP 1 (0 MG/KG)

DAM 4 CONT.

FETUS 26	NON-OSSIFIED.	METATARSALIA 1, RIGHT
		TOE 2 PROXIMAL PHALANX, RIGHT
		TOE 3 PROXIMAL PHALANX, RIGHT
		TOE 4 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
FETUS 28	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		DIGIT 5 DISTAL PHALANX, RIGHT
		TALUS LEFT
		TOE 2 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 2 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
		RIB(S), RIGHT
FETUS 30	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 2 PROXIMAL PHALANX, RIGHT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT

DAM 5

FETUS 32	NON-OSSIFIED.	TOE 5 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 34	NON-OSSIFIED.	TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 36	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TALUS LEFT
		TOE 2 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 2 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 38	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		DIGIT 5 DISTAL PHALANX, RIGHT
		TOE 2 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TOE 2 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 40	NO ABNORMAL FINDING	

DAM 6

FETUS 44	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 46	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT

SKELETAL EXAMINATIONS
GROUP 1 (0 MG/KG)

DAM 6 CONT.		
FETUS 46	NON-OSSIFIED.	TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 48	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 50	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
FETUS 52	NON-OSSIFIED.	TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 54	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 DISTAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT DIGIT 5 DISTAL PHALANX, RIGHT
DAM 7		
FETUS 292	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
DAM 8		
FETUS 294	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 296	NON-OSSIFIED.	TALUS LEFT TALUS RIGHT
FETUS 298	NO ABNORMAL FINDING	
FETUS 300	NO ABNORMAL FINDING	
FETUS 302	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
FETUS 304	SUPERNUMERARY, ONE.	RIB(S), LEFT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), RIGHT
DAM 9		
FETUS 307	NON-OSSIFIED.	TALUS LEFT TALUS RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
FETUS 309	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 311	NON-OSSIFIED.	TALUS LEFT TALUS RIGHT
DAM 10		
FETUS 499	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT

SKELETAL EXAMINATIONS
GROUP 1 (0 MG/KG)

DAM 10 CONT.

FETUS 499	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 501	INCOMPLETELY OSSIFIED	OS INTERPARIETALE
	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT METATARSALIA 1, LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 3 PROXIMAL PHALANX, LEFT TOE 4 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT METATARSALIA 1, RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 3 PROXIMAL PHALANX, RIGHT TOE 4 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 503	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 505	NO ABNORMAL FINDING	

DAM 11

FETUS 508	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TALUS RIGHT
FETUS 510	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TOE 2 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 512	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 514	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 516	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT

SKELETAL EXAMINATIONS
GROUP 1 (0 MG/KG)

DAM 11 CONT.

FETUS 518	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT
FETUS 520	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TALUS RIGHT

DAM 12

FETUS 523	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT
FETUS 525	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 527	NO ABNORMAL FINDING	
FETUS 529	NO ABNORMAL FINDING	
FETUS 531	NO ABNORMAL FINDING	
FETUS 533	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT

DAM 13

FETUS 536	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 538	NO ABNORMAL FINDING	
FETUS 540	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT

DAM 14

FETUS 542	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT
FETUS 544	NO ABNORMAL FINDING	
FETUS 546	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 548	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 550	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT

SKELETAL EXAMINATIONS
GROUP 1 (0 MG/KG)

DAM 14 CONT.

FETUS 550	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 552	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT

DAM 15

FETUS 555	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), RIGHT
FETUS 557	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT
FETUS 559	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT
FETUS 561	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TOE 2 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 563	NO ABNORMAL FINDING	
FETUS 565	NO ABNORMAL FINDING	
FETUS 567	NON-OSSIFIED.	TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT

DAM 16

FETUS 569	NO ABNORMAL FINDING	
FETUS 571	NO ABNORMAL FINDING	
FETUS 573	NO ABNORMAL FINDING	
FETUS 575	NO ABNORMAL FINDING	
FETUS 577	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 579	NO ABNORMAL FINDING	

DAM 17

FETUS 581	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 583	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT

SKELETAL EXAMINATIONS
GROUP 1 (0 MG/KG)

DAM 17 CONT.

FETUS 583	NON-OSSIFIED.	TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 585	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 587	NO ABNORMAL FINDING	
FETUS 589	NO ABNORMAL FINDING	

DAM 18

FETUS 592	NO ABNORMAL FINDING	
FETUS 594	NO ABNORMAL FINDING	
FETUS 596	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 598	NO ABNORMAL FINDING	
FETUS 600	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 602	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT

DAM 19

FETUS 605	NO ABNORMAL FINDING	
FETUS 607	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 609	NO ABNORMAL FINDING	
FETUS 611	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 3 PROXIMAL PHALANX, LEFT TOE 4 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 3 PROXIMAL PHALANX, RIGHT TOE 4 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT

DAM 20

FETUS 807	NO ABNORMAL FINDING	
FETUS 809	NON-OSSIFIED.	TALUS LEFT

SKELETAL EXAMINATIONS
GROUP 1 (0 MG/KG)

DAM 20 CONT.

FETUS 809	NON-OSSIFIED.	TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 811	NON-OSSIFIED.	TALUS LEFT TALUS RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), RIGHT
FETUS 813	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
FETUS 815	NO ABNORMAL FINDING	
FETUS 817	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT

DAM 21

FETUS 820	NO ABNORMAL FINDING	
FETUS 822	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
FETUS 824	NON-OSSIFIED.	TALUS LEFT TALUS RIGHT
FETUS 826	NON-OSSIFIED.	TALUS LEFT TALUS RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 828	NON-OSSIFIED.	TALUS LEFT TALUS RIGHT

DAM 22

FETUS 830	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
	ABNORMAL FINDING(S)	VARIOUS BONES
FETUS 832	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
FETUS 834	NO ABNORMAL FINDING	
FETUS 836	NO ABNORMAL FINDING	
FETUS 838	INCOMPLETELY OSSIFIED	OS INTERPARIETALE
	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TALUS RIGHT
FETUS 840	NON-OSSIFIED.	TALUS LEFT TALUS RIGHT

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

SKELETAL EXAMINATION OF FETUSES - INDIVIDUAL DATA

- GROUP 2 (10 MG/KG) - FETUSES OF DAM NOS. 23 - 44

SKELETAL EXAMINATIONS
GROUP 2 (10 MG/KG)

DAM 23		
FETUS 56	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 DISTAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT DIGIT 5 DISTAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 58	NON-OSSIFIED.	TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
FETUS 60	NO ABNORMAL FINDING	
FETUS 62	NON-OSSIFIED.	TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
DAM 24		
FETUS 65	NO ABNORMAL FINDING	
FETUS 67	NON-OSSIFIED.	CERVICAL VERTEBRAL BODY 2 CERVICAL VERTEBRAL BODY 3 TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT
FETUS 69	NON-OSSIFIED.	CERVICAL VERTEBRAL BODY 2 TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 71	NO ABNORMAL FINDING	
FETUS 73	NON-OSSIFIED.	TALUS LEFT TALUS RIGHT
FETUS 75	NO ABNORMAL FINDING	
DAM 25		
FETUS 78	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 80	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT TOE 2 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TOE 2 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 82	INCOMPLETELY OSSIFIED	OS PARIETALE, BILATERAL OS INTERPARIETALE
	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT
FETUS 84	NO ABNORMAL FINDING	
FETUS 86	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT

SKELETAL EXAMINATIONS
GROUP 2 (10 MG/KG)

DAM 25 CONT.

FETUS 86	NON-OSSIFIED.	TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 88	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 90	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT

DAM 26

FETUS 93	NON-OSSIFIED.	CERVICAL VERTEBRAL BODY 2 TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
FETUS 95	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 3 PROXIMAL PHALANX, LEFT TOE 4 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 3 PROXIMAL PHALANX, RIGHT TOE 4 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 97	NON-OSSIFIED.	CERVICAL VERTEBRAL BODY 2 DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 99	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TALUS RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT

DAM 27

FETUS 102	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 104	NON-OSSIFIED.	TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 106	NO ABNORMAL FINDING	
FETUS 108	NON-OSSIFIED.	CERVICAL VERTEBRAL BODY 1

SKELETAL EXAMINATIONS
GROUP 2 (10 MG/KG)

DAM 27 CONT.

FETUS 108	NON-OSSIFIED.	CERVICAL VERTEBRAL BODY 2 DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT

DAM 28

FETUS 111	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 113	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 115	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), RIGHT
FETUS 117	NO ABNORMAL FINDING	

DAM 29

FETUS 120	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 122	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 DISTAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT DIGIT 5 DISTAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
FETUS 124	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 DISTAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT DIGIT 5 DISTAL PHALANX, RIGHT TOE 2 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TOE 2 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 126	NO ABNORMAL FINDING	
FETUS 128	NO ABNORMAL FINDING	
FETUS 130	NON-OSSIFIED.	TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT

DAM 30

FETUS 314	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 DISTAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT DIGIT 5 DISTAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 316	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT

SKELETAL EXAMINATIONS
GROUP 2 (10 MG/KG)

DAM 30 CONT.

FETUS 316	NON-OSSIFIED.	DIGIT 5 DISTAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT DIGIT 5 DISTAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 318	NON-OSSIFIED.	TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 320	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 322	NO ABNORMAL FINDING	
FETUS 324	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TALUS RIGHT
FETUS 326	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 DISTAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT DIGIT 5 DISTAL PHALANX, RIGHT

DAM 31

FETUS 328	NO ABNORMAL FINDING	
FETUS 330	NON-OSSIFIED.	TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 332	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 334	NO ABNORMAL FINDING	
FETUS 336	NO ABNORMAL FINDING	

DAM 32

FETUS 339	NO ABNORMAL FINDING	
FETUS 341	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 DISTAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT DIGIT 5 DISTAL PHALANX, RIGHT
FETUS 343	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
FETUS 345	NON-OSSIFIED.	CERVICAL VERTEBRAL BODY 2 TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 347	NO ABNORMAL FINDING	
FETUS 349	NO ABNORMAL FINDING	
FETUS 351	NO ABNORMAL FINDING	

SKELETAL EXAMINATIONS
GROUP 2 (10 MG/KG)

DAM 33

FETUS 353	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 355	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 357	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 359	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), RIGHT
FETUS 361	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 363	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT

DAM 34

FETUS 614	NON-OSSIFIED.	TOE 2 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TOE 2 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 616	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 618	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 620	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT
FETUS 622	INCOMPLETELY OSSIFIED	STERNEBRA 5
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
FETUS 624	NO ABNORMAL FINDING	

DAM 35

FETUS 626	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 628	NO ABNORMAL FINDING	
FETUS 630	NON-OSSIFIED.	TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
	ABNORMAL FINDING(S)	VARIOUS BONES
FETUS 632	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 634	NON-OSSIFIED.	TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 636	NO ABNORMAL FINDING	

DAM 36

FETUS 639	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TOE 2 PROXIMAL PHALANX, LEFT TOE 3 PROXIMAL PHALANX, LEFT TOE 4 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TOE 2 PROXIMAL PHALANX, RIGHT

SKELETAL EXAMINATIONS
GROUP 2 (10 MG/KG)

DAM 36 CONT.

FETUS 639	NON-OSSIFIED.	TOE 3 PROXIMAL PHALANX, RIGHT TOE 4 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 641	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 643	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 DISTAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT DIGIT 5 DISTAL PHALANX, RIGHT TOE 2 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TOE 2 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 645	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 647	NO ABNORMAL FINDING	
FETUS 649	INCOMPLETELY OSSIFIED	OS INTERPARIETALE
	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT

DAM 37

FETUS 651	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT
FETUS 653	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 655	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 657	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 659	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 661	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT

SKELETAL EXAMINATIONS
GROUP 2 (10 MG/KG)

DAM 37 CONT.

FETUS 663	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 665	NO ABNORMAL FINDING	

DAM 38

FETUS 667	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), RIGHT
FETUS 669	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 671	NO ABNORMAL FINDING	
FETUS 673	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE.	RIB(S), LEFT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), RIGHT
FETUS 675	NO ABNORMAL FINDING	
FETUS 677	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT

DAM 39

FETUS 680	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), RIGHT
FETUS 682	NON-OSSIFIED.	TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 684	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 686	NO ABNORMAL FINDING	
FETUS 688	NO ABNORMAL FINDING	

DAM 40

FETUS 691	NO ABNORMAL FINDING	
FETUS 693	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT DIGIT 5 DISTAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 695	NO ABNORMAL FINDING	
FETUS 697	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT

SKELETAL EXAMINATIONS
GROUP 2 (10 MG/KG)

DAM 40 CONT.

FETUS 699	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT

DAM 41

FETUS 843	INCOMPLETELY OSSIFIED	OS INTERPARIETALE
	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 DISTAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT DIGIT 5 DISTAL PHALANX, RIGHT
FETUS 845	INCOMPLETELY OSSIFIED	OS PARIETALE, BILATERAL OS INTERPARIETALE JUGAL, LEFT JUGAL, RIGHT
	NON-OSSIFIED.	TALUS LEFT TALUS RIGHT
FETUS 847	INCOMPLETELY OSSIFIED	OS INTERPARIETALE JUGAL, RIGHT
FETUS 849	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 851	INCOMPLETELY OSSIFIED	OS INTERPARIETALE

DAM 42

FETUS 853	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 855	NO ABNORMAL FINDING	
FETUS 857	NO ABNORMAL FINDING	
FETUS 859	NO ABNORMAL FINDING	
FETUS 861	INCOMPLETELY OSSIFIED	OS OCCIPITALE OS PARIETALE, BILATERAL OS INTERPARIETALE JUGAL, LEFT JUGAL, RIGHT ZYGOMATIC PROCESS OF SQUAMOSAL, LEFT ZYGOMATIC PROCESS OF SQUAMOSAL, RIGHT
	NON-OSSIFIED.	TALUS LEFT TALUS RIGHT

DAM 43

FETUS 863	NO ABNORMAL FINDING	
FETUS 865	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	DIGIT 5 DISTAL PHALANX, LEFT DIGIT 5 DISTAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 867	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TALUS RIGHT
FETUS 869	NO ABNORMAL FINDING	
FETUS 871	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	TALUS LEFT TALUS RIGHT
	ABNORMAL FINDING(S)	VARIOUS BONES

SKELETAL EXAMINATIONS
GROUP 2 (10 MG/KG)

DAM 43 CONT.

FETUS 873	NON-OSSIFIED.	TALUS LEFT
		TALUS RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
FETUS 875	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TALUS LEFT
		TALUS RIGHT

DAM 44

FETUS 877	NON-OSSIFIED.	TALUS LEFT
		TALUS RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
		RIB(S), RIGHT
FETUS 879	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), RIGHT
FETUS 881	NON-OSSIFIED.	DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), RIGHT
FETUS 883	NO ABNORMAL FINDING	
FETUS 885	NON-OSSIFIED.	TALUS LEFT
		TALUS RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
		RIB(S), RIGHT
FETUS 887	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		DIGIT 5 DISTAL PHALANX, RIGHT
		TALUS LEFT
		TALUS RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
		RIB(S), RIGHT

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

SKELETAL EXAMINATION OF FETUSES - INDIVIDUAL DATA

- GROUP 3 (30 MG/KG) - FETUSES OF DAM NOS. 45 - 66

SKELETAL EXAMINATIONS
GROUP 3 (30 MG/KG)

DAM 45

FETUS 132	NON-OSSIFIED.	CERVICAL VERTEBRAL BODY 2
		DIGIT 1 DISTAL PHALANX, LEFT
		DIGIT 2 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 1 DISTAL PHALANX, RIGHT
		DIGIT 2 PROXIMAL PHALANX, RIGHT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		DIGIT 5 DISTAL PHALANX, RIGHT
		TALUS LEFT
		METATARSALIA 1, LEFT
		TOE 2 PROXIMAL PHALANX, LEFT
		TOE 3 PROXIMAL PHALANX, LEFT
		TOE 4 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		METATARSALIA 1, RIGHT
		TOE 2 PROXIMAL PHALANX, RIGHT
		TOE 3 PROXIMAL PHALANX, RIGHT
		TOE 4 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
		RIB(S), RIGHT
FETUS 134	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		DIGIT 5 DISTAL PHALANX, RIGHT
FETUS 136	NO ABNORMAL FINDING	
FETUS 138	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT
		DIGIT 2 DISTAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 2 PROXIMAL PHALANX, RIGHT
		DIGIT 2 DISTAL PHALANX, RIGHT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		DIGIT 5 DISTAL PHALANX, RIGHT
FETUS 140	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, RIGHT

DAM 46

FETUS 142	NON-OSSIFIED.	TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 144	NO ABNORMAL FINDING	
FETUS 146	NO ABNORMAL FINDING	
FETUS 148	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
FETUS 150	NON-OSSIFIED.	DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, RIGHT
		TALUS LEFT
		TALUS RIGHT
FETUS 152	NON-OSSIFIED.	TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT

DAM 47

FETUS 154	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT

SKELETAL EXAMINATIONS
GROUP 3 (30 MG/KG)

DAM 47 CONT.

FETUS 154	NON-OSSIFIED.	DIGIT 2 DISTAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 2 PROXIMAL PHALANX, RIGHT
		DIGIT 2 DISTAL PHALANX, RIGHT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		DIGIT 5 DISTAL PHALANX, RIGHT
		TALUS LEFT
		TOE 2 PROXIMAL PHALANX, LEFT
		TOE 3 PROXIMAL PHALANX, LEFT
		TOE 4 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 2 PROXIMAL PHALANX, RIGHT
		TOE 3 PROXIMAL PHALANX, RIGHT
		TOE 4 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
	ABNORMALLY OSSIFIED	STERNEBRA 4
FETUS 156	NON-OSSIFIED.	TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT

DAM 48

FETUS 158	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), RIGHT
FETUS 160	NON-OSSIFIED.	DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, RIGHT
		TOE 2 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TOE 2 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 162	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 164	NO ABNORMAL FINDING	

DAM 50

FETUS 167	NON-OSSIFIED.	DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 169	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
		RIB(S), RIGHT
FETUS 171	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		DIGIT 5 DISTAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
		RIB(S), RIGHT
FETUS 173	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	CERVICAL VERTEBRAL BODY 1
		CERVICAL VERTEBRAL BODY 2
		CERVICAL VERTEBRAL BODY 5
		DIGIT 2 PROXIMAL PHALANX, LEFT
		DIGIT 3 PROXIMAL PHALANX, LEFT
		DIGIT 4 PROXIMAL PHALANX, LEFT
		METACARPALIA 5, LEFT
		DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 2 PROXIMAL PHALANX, RIGHT
		DIGIT 3 PROXIMAL PHALANX, RIGHT
		DIGIT 4 PROXIMAL PHALANX, RIGHT

SKELETAL EXAMINATIONS
GROUP 3 (30 MG/KG)

DAM 50 CONT.

FETUS 173	NON-OSSIFIED.	METACARPALIA 5, RIGHT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		DIGIT 5 DISTAL PHALANX, RIGHT
		TALUS LEFT
		METATARSALIA 1, LEFT
		TOE 2 PROXIMAL PHALANX, LEFT
		TOE 3 PROXIMAL PHALANX, LEFT
		TOE 4 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		METATARSALIA 1, RIGHT
		TOE 2 PROXIMAL PHALANX, RIGHT
		TOE 3 PROXIMAL PHALANX, RIGHT
		TOE 4 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE.	RIB(S), RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
FETUS 175	NON-OSSIFIED.	TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
		RIB(S), RIGHT
FETUS 177	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 2 PROXIMAL PHALANX, RIGHT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE.	RIB(S), LEFT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), RIGHT

DAM 51

FETUS 179	NO ABNORMAL FINDING	
FETUS 181	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		DIGIT 5 DISTAL PHALANX, RIGHT
FETUS 183	NON-OSSIFIED.	TOE 5 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 185	NON-OSSIFIED.	TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 187	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT
		DIGIT 3 PROXIMAL PHALANX, LEFT
		DIGIT 4 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 2 PROXIMAL PHALANX, RIGHT
		DIGIT 4 PROXIMAL PHALANX, RIGHT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		DIGIT 5 DISTAL PHALANX, RIGHT
		TALUS LEFT
		TOE 2 PROXIMAL PHALANX, LEFT
		TOE 3 PROXIMAL PHALANX, LEFT
		TOE 4 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 2 PROXIMAL PHALANX, RIGHT
		TOE 3 PROXIMAL PHALANX, RIGHT
		TOE 4 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT

SKELETAL EXAMINATIONS
GROUP 3 (30 MG/KG)

DAM 52

FETUS 189	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		DIGIT 5 DISTAL PHALANX, RIGHT
		TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 191	INCOMPLETELY OSSIFIED	OS INTERPARIETALE
	NON-OSSIFIED.	CERVICAL VERTEBRAL BODY 1
		CERVICAL VERTEBRAL BODY 2
		DIGIT 2 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 2 PROXIMAL PHALANX, RIGHT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TALUS LEFT
		TOE 2 PROXIMAL PHALANX, LEFT
		TOE 3 PROXIMAL PHALANX, LEFT
		TOE 4 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 2 PROXIMAL PHALANX, RIGHT
		TOE 3 PROXIMAL PHALANX, RIGHT
		TOE 4 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 193	NON-OSSIFIED.	TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
	ABNORMAL FINDING(S)	VARIOUS BONES
FETUS 195	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 197	NON-OSSIFIED.	CERVICAL VERTEBRAL BODY 1
		CERVICAL VERTEBRAL BODY 2
		STERNEBRA 5
		DIGIT 2 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 2 PROXIMAL PHALANX, RIGHT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
FETUS 199	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		DIGIT 5 DISTAL PHALANX, RIGHT
		TALUS LEFT
		TOE 2 PROXIMAL PHALANX, LEFT
		TOE 3 PROXIMAL PHALANX, LEFT
		TOE 4 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 2 PROXIMAL PHALANX, RIGHT
		TOE 3 PROXIMAL PHALANX, RIGHT
		TOE 4 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT

DAM 53

FETUS 202	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		DIGIT 5 DISTAL PHALANX, RIGHT
		TALUS LEFT
		TOE 2 PROXIMAL PHALANX, LEFT
		TOE 3 PROXIMAL PHALANX, LEFT

SKELETAL EXAMINATIONS
GROUP 3 (30 MG/KG)

DAM 53 CONT.

FETUS 202	NON-OSSIFIED.	TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 2 PROXIMAL PHALANX, RIGHT
		TOE 3 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
		RIB(S), RIGHT
FETUS 204	NON-OSSIFIED.	TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 206	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		DIGIT 5 DISTAL PHALANX, RIGHT
		TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
	ABNORMAL FINDING(S)	VARIOUS BONES
FETUS 208	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		DIGIT 5 DISTAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 210	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT

DAM 54

FETUS 213	NON-OSSIFIED.	TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
		RIB(S), RIGHT
FETUS 215	NON-OSSIFIED.	TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 217	NON-OSSIFIED.	TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 219	NON-OSSIFIED.	TOE 5 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
		RIB(S), RIGHT
FETUS 221	NO ABNORMAL FINDING	

DAM 55

FETUS 366	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 368	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		TALUS LEFT
		TALUS RIGHT

SKELETAL EXAMINATIONS
GROUP 3 (30 MG/KG)

DAM 55 CONT.

FETUS 370	NO ABNORMAL FINDING	
FETUS 372	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TALUS RIGHT
FETUS 374	NON-OSSIFIED.	CERVICAL VERTEBRAL BODY 1 DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TALUS RIGHT
FETUS 376	NO ABNORMAL FINDING	

DAM 56

FETUS 378	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 DISTAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT DIGIT 5 DISTAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 380	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 382	NON-OSSIFIED.	DIGIT 5 DISTAL PHALANX, LEFT DIGIT 5 DISTAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY. . . .	RIB(S), RIGHT
FETUS 384	NO ABNORMAL FINDING	
FETUS 386	NO ABNORMAL FINDING	
FETUS 388	INCOMPLETELY OSSIFIED	OS INTERPARIETALE
	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY. . . .	RIB(S), LEFT

DAM 57

FETUS 390	NON-OSSIFIED.	TOE 2 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TOE 2 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 392	NO ABNORMAL FINDING	
FETUS 394	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TALUS RIGHT
FETUS 396	SUPERNUMERARY, ONE RUDIMENTARY. . . .	RIB(S), RIGHT
FETUS 398	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY. . . .	RIB(S), LEFT
FETUS 400	SUPERNUMERARY, ONE RUDIMENTARY. . . .	RIB(S), LEFT RIB(S), RIGHT

DAM 58

FETUS 403	NO ABNORMAL FINDING	
FETUS 405	NON-OSSIFIED.	CERVICAL VERTEBRAL BODY 3 CERVICAL VERTEBRAL BODY 4

SKELETAL EXAMINATIONS
GROUP 3 (30 MG/KG)

DAM 58 CONT.

FETUS 405	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 DISTAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT DIGIT 5 DISTAL PHALANX, RIGHT
FETUS 407	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 DISTAL PHALANX, LEFT DIGIT 5 DISTAL PHALANX, RIGHT
FETUS 409	NO ABNORMAL FINDING	
FETUS 411	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
FETUS 413	NO ABNORMAL FINDING	

DAM 59

FETUS 416	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 418	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 420	NO ABNORMAL FINDING	
FETUS 422	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 424	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT

DAM 60

FETUS 701	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT
FETUS 703	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 705	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 707	NON-OSSIFIED.	TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 3 PROXIMAL PHALANX, LEFT TOE 4 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 3 PROXIMAL PHALANX, RIGHT TOE 4 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 709	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 711	NO ABNORMAL FINDING	
FETUS 713	NO ABNORMAL FINDING	

SKELETAL EXAMINATIONS
GROUP 3 (30 MG/KG)

DAM 61

FETUS 715	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), RIGHT
FETUS 717	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 719	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
FETUS 721	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 2 PROXIMAL PHALANX, RIGHT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
FETUS 723	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 2 PROXIMAL PHALANX, RIGHT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TOE 2 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TOE 2 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), RIGHT

DAM 62

FETUS 725	NO ABNORMAL FINDING
FETUS 727	NO ABNORMAL FINDING
FETUS 729	NO ABNORMAL FINDING
FETUS 731	NO ABNORMAL FINDING
FETUS 733	NO ABNORMAL FINDING

DAM 63

FETUS 735	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 737	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		DIGIT 5 DISTAL PHALANX, RIGHT
FETUS 739	NON-OSSIFIED.	TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 741	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 743	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, LEFT

SKELETAL EXAMINATIONS
GROUP 3 (30 MG/KG)

DAM 63 CONT.

FETUS 743	NON-OSSIFIED.	TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 745	NON-OSSIFIED.	TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 747	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 749	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 3 PROXIMAL PHALANX, LEFT TOE 4 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 3 PROXIMAL PHALANX, RIGHT TOE 4 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT

DAM 64

FETUS 751	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 753	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 755	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 DISTAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT DIGIT 5 DISTAL PHALANX, RIGHT TALUS LEFT METATARSALIA 1, LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 3 PROXIMAL PHALANX, LEFT TOE 4 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT METATARSALIA 1, RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 3 PROXIMAL PHALANX, RIGHT TOE 4 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 757	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 3 PROXIMAL PHALANX, LEFT TOE 4 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 3 PROXIMAL PHALANX, RIGHT TOE 4 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT

SKELETAL EXAMINATIONS
GROUP 3 (30 MG/KG)

DAM 64 CONT.

FETUS 759	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 761	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 763	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT

DAM 65

FETUS 890	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT
FETUS 892	NO ABNORMAL FINDING	
FETUS 894	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	CERVICAL VERTEBRAL BODY 1 TALUS LEFT TALUS RIGHT
FETUS 896	NO ABNORMAL FINDING	
FETUS 898	NO ABNORMAL FINDING	
FETUS 900	NO ABNORMAL FINDING	
FETUS 902	NO ABNORMAL FINDING	
FETUS 904	NO ABNORMAL FINDING	

DAM 66

FETUS 907	NO ABNORMAL FINDING	
FETUS 909	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 911	NO ABNORMAL FINDING	
FETUS 913	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	TALUS LEFT TALUS RIGHT
FETUS 915	NON-OSSIFIED.	TALUS LEFT TALUS RIGHT
FETUS 917	NO ABNORMAL FINDING	
FETUS 919	NO ABNORMAL FINDING	

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

SKELETAL EXAMINATION OF FETUSES - INDIVIDUAL DATA

- GROUP 4 (150 MG/KG) - FETUSES OF DAM NOS. 67 - 88

SKELETAL EXAMINATIONS
GROUP 4 (150 MG/KG)

DAM 67

FETUS 223	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 225	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 227	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 229	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), RIGHT
FETUS 231	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT

DAM 68

FETUS 234	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 DISTAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT DIGIT 5 DISTAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 236	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 DISTAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT DIGIT 5 DISTAL PHALANX, RIGHT TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 3 PROXIMAL PHALANX, LEFT TOE 4 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 3 PROXIMAL PHALANX, RIGHT TOE 4 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 238	NO ABNORMAL FINDING	
FETUS 240	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 242	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 244	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT

DAM 69

FETUS 246	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 248	NON-OSSIFIED.	TALUS LEFT

SKELETAL EXAMINATIONS
GROUP 4 (150 MG/KG)

DAM 69 CONT.

FETUS 248	NON-OSSIFIED.	TOE 2 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 250	NO ABNORMAL FINDING	
FETUS 252	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 3 PROXIMAL PHALANX, LEFT TOE 4 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 3 PROXIMAL PHALANX, RIGHT TOE 4 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 254	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 DISTAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT DIGIT 5 DISTAL PHALANX, RIGHT TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 3 PROXIMAL PHALANX, LEFT TOE 4 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 3 PROXIMAL PHALANX, RIGHT TOE 4 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 256	INCOMPLETELY OSSIFIED	OS INTERPARIETALE
	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 258	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT

DAM 70

FETUS 261	NO ABNORMAL FINDING	
FETUS 263	NON-OSSIFIED.	TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 265	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), RIGHT
FETUS 267	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 269	NO ABNORMAL FINDING	
FETUS 271	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT

SKELETAL EXAMINATIONS
GROUP 4 (150 MG/KG)

DAM 71

FETUS 274	NON-OSSIFIED.	TALUS LEFT
		TOE 2 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 2 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
		RIB(S), RIGHT
FETUS 276	NON-OSSIFIED.	DIGIT 1 DISTAL PHALANX, LEFT
		DIGIT 2 PROXIMAL PHALANX, LEFT
		DIGIT 4 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 1 DISTAL PHALANX, RIGHT
		DIGIT 2 PROXIMAL PHALANX, RIGHT
		DIGIT 4 PROXIMAL PHALANX, RIGHT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		DIGIT 5 DISTAL PHALANX, RIGHT
		TALUS LEFT
		METATARSALIA 1, LEFT
		TOE 2 PROXIMAL PHALANX, LEFT
		TOE 3 PROXIMAL PHALANX, LEFT
		TOE 4 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		METATARSALIA 1, RIGHT
		TOE 2 PROXIMAL PHALANX, RIGHT
		TOE 3 PROXIMAL PHALANX, RIGHT
		TOE 4 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 278	NON-OSSIFIED.	TALUS LEFT
		TOE 2 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 2 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
FETUS 280	NON-OSSIFIED.	TOE 5 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 282	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT

DAM 72

FETUS 284	SUPERNUMERARY, ONE.	RIB(S), LEFT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), RIGHT
	ABNORMAL FINDING(S)	VARIOUS BONES
FETUS 286	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
		RIB(S), RIGHT
FETUS 288	NO ABNORMAL FINDING	
FETUS 290	NO ABNORMAL FINDING	

DAM 73

FETUS 427	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
FETUS 429	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, RIGHT
	ABNORMAL FINDING(S)	VARIOUS BONES
FETUS 431	NO ABNORMAL FINDING	

SKELETAL EXAMINATIONS
GROUP 4 (150 MG/KG)

DAM 73 CONT.

FETUS 433	NO ABNORMAL FINDING	
FETUS 435	NO ABNORMAL FINDING	
FETUS 437	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TALUS RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT

DAM 74

FETUS 439	NON-OSSIFIED.	DIGIT 5 DISTAL PHALANX, LEFT DIGIT 5 DISTAL PHALANX, RIGHT
FETUS 441	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 443	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 445	NO ABNORMAL FINDING	
FETUS 447	NO ABNORMAL FINDING	

DAM 75

FETUS 450	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	CERVICAL VERTEBRAL BODY 1 DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT
	ABNORMAL FINDING(S)	VARIOUS BONES
FETUS 452	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 454	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TALUS RIGHT
FETUS 456	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 3 PROXIMAL PHALANX, RIGHT TOE 4 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 458	NON-OSSIFIED.	TALUS LEFT TALUS RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
FETUS 460	NON-OSSIFIED.	CERVICAL VERTEBRAL BODY 1 CERVICAL VERTEBRAL BODY 2 CERVICAL VERTEBRAL BODY 3 CERVICAL VERTEBRAL BODY 4 DIGIT 5 PROXIMAL PHALANX, LEFT

SKELETAL EXAMINATIONS
GROUP 4 (150 MG/KG)

DAM 75 CONT.

FETUS 460	NON-OSSIFIED.	DIGIT 5 DISTAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT DIGIT 5 DISTAL PHALANX, RIGHT TALUS LEFT TALUS RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), RIGHT

DAM 77

FETUS 462	SUPERNUMERARY, ONE.	RIB(S), LEFT RIB(S), RIGHT
FETUS 464	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 466	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 DISTAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT DIGIT 5 DISTAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 468	ABNORMALLY OSSIFIED	STERNEBRA 5
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 470	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 472	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT RIB(S), RIGHT
FETUS 474	NO ABNORMAL FINDING	

DAM 78

FETUS 476	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
FETUS 478	NO ABNORMAL FINDING	
FETUS 480	NO ABNORMAL FINDING	
FETUS 482	NON-OSSIFIED.	TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), RIGHT
FETUS 484	NO ABNORMAL FINDING	

DAM 79

FETUS 487	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 489	NO ABNORMAL FINDING	
FETUS 491	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 493	NON-OSSIFIED.	TALUS LEFT TALUS RIGHT
FETUS 495	NO ABNORMAL FINDING	
FETUS 497	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT

SKELETAL EXAMINATIONS
GROUP 4 (150 MG/KG)

DAM 79 CONT.

FETUS 497	NON-OSSIFIED.	TOE 3 PROXIMAL PHALANX, LEFT TOE 4 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 3 PROXIMAL PHALANX, RIGHT TOE 4 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT

DAM 82

FETUS 766	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 768	NO ABNORMAL FINDING	
FETUS 770	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 772	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 DISTAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT DIGIT 5 DISTAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 774	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT
FETUS 776	NON-OSSIFIED.	TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 778	NO ABNORMAL FINDING	

DAM 83

FETUS 781	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 2 PROXIMAL PHALANX, RIGHT DIGIT 5 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 783	NON-OSSIFIED.	TALUS LEFT TOE 2 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 2 PROXIMAL PHALANX, RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 785	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 787	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT DIGIT 5 PROXIMAL PHALANX, RIGHT TALUS LEFT TOE 5 PROXIMAL PHALANX, LEFT TALUS RIGHT TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 789	NON-OSSIFIED.	TOE 5 PROXIMAL PHALANX, LEFT TOE 5 PROXIMAL PHALANX, RIGHT

SKELETAL EXAMINATIONS
GROUP 4 (150 MG/KG)

DAM 84

FETUS 792	NON-OSSIFIED.	TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 794	NON-OSSIFIED.	TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 796	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	TOE 5 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 798	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 800	NON-OSSIFIED.	TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 802	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TALUS LEFT
		TOE 2 PROXIMAL PHALANX, LEFT
		TOE 3 PROXIMAL PHALANX, LEFT
		TOE 4 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 2 PROXIMAL PHALANX, RIGHT
		TOE 3 PROXIMAL PHALANX, RIGHT
		TOE 4 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
		RIB(S), RIGHT
FETUS 804	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT

DAM 85

FETUS 921	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 2 PROXIMAL PHALANX, RIGHT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
		RIB(S), RIGHT
FETUS 923	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
		RIB(S), RIGHT
FETUS 925	NON-OSSIFIED.	CERVICAL VERTEBRAL BODY 2
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
		RIB(S), RIGHT
FETUS 927	INCOMPLETELY OSSIFIED	STERNEBRA 5
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
		RIB(S), RIGHT
FETUS 929	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TALUS LEFT
		TALUS RIGHT
FETUS 931	NON-OSSIFIED.	TALUS LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TALUS RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
		RIB(S), RIGHT

SKELETAL EXAMINATIONS
GROUP 4 (150 MG/KG)

DAM 86

FETUS 934	INCOMPLETELY OSSIFIED	STERNEBRA 5
FETUS 936	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TALUS LEFT
		TALUS RIGHT
	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
		RIB(S), RIGHT
FETUS 938	NO ABNORMAL FINDING	

DAM 87

FETUS 941	NO ABNORMAL FINDING	
FETUS 943	NO ABNORMAL FINDING	
FETUS 945	INCOMPLETELY OSSIFIED	OS PARIETALE, BILATERAL
		OS INTERPARIETALE
	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
FETUS 947	NO ABNORMAL FINDING	
FETUS 949	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
FETUS 951	NO ABNORMAL FINDING	

DAM 88

FETUS 953	SUPERNUMERARY, ONE RUDIMENTARY.	RIB(S), LEFT
FETUS 955	NON-OSSIFIED.	DIGIT 2 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 2 PROXIMAL PHALANX, RIGHT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TOE 2 PROXIMAL PHALANX, LEFT
		TOE 5 PROXIMAL PHALANX, LEFT
		TOE 2 PROXIMAL PHALANX, RIGHT
		TOE 5 PROXIMAL PHALANX, RIGHT
FETUS 957	NO ABNORMAL FINDING	
FETUS 959	INCOMPLETELY OSSIFIED	STERNEBRA 5
	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 DISTAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		DIGIT 5 DISTAL PHALANX, RIGHT
FETUS 961	INCOMPLETELY OSSIFIED	OS INTERPARIETALE
	NON-OSSIFIED.	DIGIT 5 PROXIMAL PHALANX, LEFT
		DIGIT 5 PROXIMAL PHALANX, RIGHT
		TALUS LEFT
		TALUS RIGHT

8.6 ATTACHMENT VI

CARTILAGE EXAMINATION OF FETUSES - INDIVIDUAL DATA

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

CARTILAGE EXAMINATION OF FETUSES - INDIVIDUAL DATA

- GROUP 1 (0 MG/KG) - FETUSES OF DAM NOS. 1 - 22

CARTILAGE EXAMINATIONS
GROUP 1 (0 MG/KG)

DAM 2		
FETUS 2	NO ABNORMAL FINDING	
FETUS 4	NO ABNORMAL FINDING	
DAM 3		
FETUS 7	BRANCHED.	XIPHOID CARTILAGE
FETUS 9	BRANCHED.	XIPHOID CARTILAGE
	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT
		COSTAL CARTILAGE, 11 RIGHT
FETUS 11	BRANCHED.	XIPHOID CARTILAGE
	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT
		COSTAL CARTILAGE, 11 RIGHT
FETUS 13	NO ABNORMAL FINDING	
FETUS 15	NO ABNORMAL FINDING	
FETUS 17	BRANCHED.	XIPHOID CARTILAGE
FETUS 19	NO ABNORMAL FINDING	
DAM 4		
FETUS 22	NO ABNORMAL FINDING	
FETUS 24	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT
		COSTAL CARTILAGE, 11 RIGHT
FETUS 26	BRANCHED.	XIPHOID CARTILAGE
FETUS 28	NO ABNORMAL FINDING	
FETUS 30	NO ABNORMAL FINDING	
DAM 5		
FETUS 32	NO ABNORMAL FINDING	
FETUS 34	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 36	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 38	NO ABNORMAL FINDING	
FETUS 40	NO ABNORMAL FINDING	
DAM 6		
FETUS 44	NO ABNORMAL FINDING	
FETUS 46	BRANCHED.	XIPHOID CARTILAGE
FETUS 48	NO ABNORMAL FINDING	
FETUS 50	BRANCHED.	XIPHOID CARTILAGE
	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT
		COSTAL CARTILAGE, 11 RIGHT
FETUS 52	NO ABNORMAL FINDING	
FETUS 54	NO ABNORMAL FINDING	
DAM 7		
FETUS 292	WITH SMALL HOLE	XIPHOID CARTILAGE

CARTILAGE EXAMINATIONS
GROUP 1 (0 MG/KG)

DAM 8		
FETUS 294	NO ABNORMAL FINDING	
FETUS 296	NO ABNORMAL FINDING	
FETUS 298	LONG.	COSTAL CARTILAGE, 11 LEFT COSTAL CARTILAGE, 11 RIGHT
FETUS 300	NO ABNORMAL FINDING	
FETUS 302	LONG.	COSTAL CARTILAGE, 11 RIGHT
	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT
FETUS 304	SUPERNUMERARY, ONE.	COSTAL CARTILAGE(S), LEFT
DAM 9		
FETUS 307	NO ABNORMAL FINDING	
FETUS 309	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT COSTAL CARTILAGE, 11 RIGHT
FETUS 311	WITH SMALL HOLE	XIPHOID CARTILAGE
DAM 10		
FETUS 499	BRANCHED.	XIPHOID CARTILAGE
FETUS 501	INTERRUPTED	COSTAL CARTILAGE, 11 RIGHT
FETUS 503	NO ABNORMAL FINDING	
FETUS 505	NO ABNORMAL FINDING	
DAM 11		
FETUS 508	BRANCHED.	XIPHOID CARTILAGE
FETUS 510	BRANCHED.	XIPHOID CARTILAGE
FETUS 512	BRANCHED.	XIPHOID CARTILAGE
FETUS 514	BRANCHED.	XIPHOID CARTILAGE
FETUS 516	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 518	NO ABNORMAL FINDING	
FETUS 520	WITH SMALL HOLE	XIPHOID CARTILAGE
DAM 12		
FETUS 523	NO ABNORMAL FINDING	
FETUS 525	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 527	NO ABNORMAL FINDING	
FETUS 529	BRANCHED.	XIPHOID CARTILAGE
	INTERRUPTED	COSTAL CARTILAGE, 11 RIGHT
FETUS 531	BRANCHED.	XIPHOID CARTILAGE
FETUS 533	NO ABNORMAL FINDING	
DAM 13		
FETUS 536	NO ABNORMAL FINDING	
FETUS 538	NO ABNORMAL FINDING	
FETUS 540	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT

CARTILAGE EXAMINATIONS
GROUP 1 (0 MG/KG)

DAM 13 CONT.

FETUS 540	INTERRUPTED	COSTAL CARTILAGE, 11 RIGHT

DAM 14

FETUS 542	NO ABNORMAL FINDING	
FETUS 544	NO ABNORMAL FINDING	
FETUS 546	BRANCHED.	XIPHOID CARTILAGE
FETUS 548	BRANCHED.	XIPHOID CARTILAGE
FETUS 550	INTERRUPTED	COSTAL CARTILAGE, 11 RIGHT
FETUS 552	BRANCHED.	XIPHOID CARTILAGE

DAM 15

FETUS 555	NO ABNORMAL FINDING	
FETUS 557	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 559	NO ABNORMAL FINDING	
FETUS 561	BRANCHED.	XIPHOID CARTILAGE
FETUS 563	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 565	NO ABNORMAL FINDING	
FETUS 567	WITH SMALL HOLE	XIPHOID CARTILAGE

DAM 16

FETUS 569	NO ABNORMAL FINDING	
FETUS 571	NO ABNORMAL FINDING	
FETUS 573	NO ABNORMAL FINDING	
FETUS 575	NO ABNORMAL FINDING	
FETUS 577	NO ABNORMAL FINDING	
FETUS 579	NO ABNORMAL FINDING	

DAM 17

FETUS 581	BRANCHED.	XIPHOID CARTILAGE
FETUS 583	BRANCHED.	XIPHOID CARTILAGE
FETUS 585	NO ABNORMAL FINDING	
FETUS 587	NO ABNORMAL FINDING	
FETUS 589	NO ABNORMAL FINDING	

DAM 18

FETUS 592	BRANCHED.	XIPHOID CARTILAGE
FETUS 594	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 596	NO ABNORMAL FINDING	
FETUS 598	NO ABNORMAL FINDING	
FETUS 600	BRANCHED.	XIPHOID CARTILAGE
FETUS 602	NO ABNORMAL FINDING	

CARTILAGE EXAMINATIONS
GROUP 1 (0 MG/KG)

DAM 19		
FETUS 605	NO ABNORMAL FINDING	
FETUS 607	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 609	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 611	NO ABNORMAL FINDING	
DAM 20		
FETUS 807	INTERRUPTED	COSTAL CARTILAGE, 11 RIGHT
FETUS 809	NO ABNORMAL FINDING	
FETUS 811	NO ABNORMAL FINDING	
FETUS 813	BRANCHED.	XIPHOID CARTILAGE
FETUS 815	NO ABNORMAL FINDING	
FETUS 817	BRANCHED.	XIPHOID CARTILAGE
DAM 21		
FETUS 820	BRANCHED.	XIPHOID CARTILAGE
FETUS 822	NO ABNORMAL FINDING	
FETUS 824	NO ABNORMAL FINDING	
FETUS 826	NO ABNORMAL FINDING	
FETUS 828	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT COSTAL CARTILAGE, 11 RIGHT
DAM 22		
FETUS 830	ABNORMALLY CHONDRIFIED.	CARTILAGINOUS STERNEBRA 5
	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT COSTAL CARTILAGE, 11 RIGHT
	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 832	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT
FETUS 834	NO ABNORMAL FINDING	
FETUS 836	BRANCHED.	XIPHOID CARTILAGE
	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT COSTAL CARTILAGE, 11 RIGHT
FETUS 838	BRANCHED.	XIPHOID CARTILAGE
FETUS 840	NO ABNORMAL FINDING	

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

CARTILAGE EXAMINATION OF FETUSES - INDIVIDUAL DATA

- GROUP 2 (10 MG/KG) - FETUSES OF DAM NOS. 23 - 44

CARTILAGE EXAMINATIONS
GROUP 2 (10 MG/KG)

DAM 23		
FETUS 56	NO ABNORMAL FINDING	
FETUS 58	NO ABNORMAL FINDING	
FETUS 60	NO ABNORMAL FINDING	
FETUS 62	NO ABNORMAL FINDING	
DAM 24		
FETUS 65	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 67	NO ABNORMAL FINDING	
FETUS 69	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 71	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 73	NO ABNORMAL FINDING	
FETUS 75	NO ABNORMAL FINDING	
DAM 25		
FETUS 78	NO ABNORMAL FINDING	
FETUS 80	NO ABNORMAL FINDING	
FETUS 82	NO ABNORMAL FINDING	
FETUS 84	NO ABNORMAL FINDING	
FETUS 86	NO ABNORMAL FINDING	
FETUS 88	WITH SMALL HOLE	XIPHOID CARTILAGE
	CRANIAL SHIFT TO CERVICAL VERTEBRA 5. .	VENTRAL PLATE, LEFT
		VENTRAL PLATE, RIGHT
FETUS 90	NO ABNORMAL FINDING	
DAM 26		
FETUS 93	BRANCHED.	XIPHOID CARTILAGE
FETUS 95	NO ABNORMAL FINDING	
FETUS 97	NO ABNORMAL FINDING	
FETUS 99	NO ABNORMAL FINDING	
DAM 27		
FETUS 102	NO ABNORMAL FINDING	
FETUS 104	NO ABNORMAL FINDING	
FETUS 106	NO ABNORMAL FINDING	
FETUS 108	BRANCHED.	XIPHOID CARTILAGE
DAM 28		
FETUS 111	NO ABNORMAL FINDING	
FETUS 113	INTERRUPTED	COSTAL CARTILAGE, 10 RIGHT
FETUS 115	NO ABNORMAL FINDING	
FETUS 117	NO ABNORMAL FINDING	

CARTILAGE EXAMINATIONS
GROUP 2 (10 MG/KG)

DAM 29		
FETUS 120	NO ABNORMAL FINDING	
FETUS 122	NO ABNORMAL FINDING	
FETUS 124	LONG.	VENTRAL PLATE, RIGHT
FETUS 126	NO ABNORMAL FINDING	
FETUS 128	NO ABNORMAL FINDING	
FETUS 130	NO ABNORMAL FINDING	
DAM 30		
FETUS 314	NO ABNORMAL FINDING	
FETUS 316	NO ABNORMAL FINDING	
FETUS 318	NO ABNORMAL FINDING	
FETUS 320	BRANCHED.	XIPHOID CARTILAGE
FETUS 322	NO ABNORMAL FINDING	
FETUS 324	NO ABNORMAL FINDING	
FETUS 326	NO ABNORMAL FINDING	
DAM 31		
FETUS 328	BRANCHED.	XIPHOID CARTILAGE
FETUS 330	BRANCHED.	XIPHOID CARTILAGE
FETUS 332	NO ABNORMAL FINDING	
FETUS 334	NO ABNORMAL FINDING	
FETUS 336	NO ABNORMAL FINDING	
DAM 32		
FETUS 339	BRANCHED.	XIPHOID CARTILAGE
FETUS 341	BRANCHED.	XIPHOID CARTILAGE
FETUS 343	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT
FETUS 345	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT
FETUS 347	BRANCHED.	XIPHOID CARTILAGE
FETUS 349	NO ABNORMAL FINDING	
FETUS 351	BRANCHED.	XIPHOID CARTILAGE
DAM 33		
FETUS 353	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 355	NO ABNORMAL FINDING	
FETUS 357	NO ABNORMAL FINDING	
FETUS 359	NO ABNORMAL FINDING	
FETUS 361	NO ABNORMAL FINDING	
FETUS 363	NO ABNORMAL FINDING	

CARTILAGE EXAMINATIONS
GROUP 2 (10 MG/KG)

DAM 34

FETUS 614	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 616	NO ABNORMAL FINDING	
FETUS 618	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 620	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 622	BRANCHED.	XIPHOID CARTILAGE
FETUS 624	NO ABNORMAL FINDING	

DAM 35

FETUS 626	NO ABNORMAL FINDING	
FETUS 628	INTERRUPTED	COSTAL CARTILAGE, 11 RIGHT
FETUS 630	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 632	BRANCHED.	XIPHOID CARTILAGE
FETUS 634	BRANCHED.	XIPHOID CARTILAGE
FETUS 636	WITH SMALL HOLE	XIPHOID CARTILAGE

DAM 36

FETUS 639	NO ABNORMAL FINDING	
FETUS 641	NO ABNORMAL FINDING	
FETUS 643	NO ABNORMAL FINDING	
FETUS 645	NO ABNORMAL FINDING	
FETUS 647	NO ABNORMAL FINDING	
FETUS 649	NO ABNORMAL FINDING	

DAM 37

FETUS 651	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 653	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 655	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 657	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT
	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 659	NO ABNORMAL FINDING	
FETUS 661	BRANCHED.	XIPHOID CARTILAGE
FETUS 663	NO ABNORMAL FINDING	
FETUS 665	BRANCHED.	XIPHOID CARTILAGE

DAM 38

FETUS 667	NO ABNORMAL FINDING	
FETUS 669	BRANCHED.	XIPHOID CARTILAGE
FETUS 671	NO ABNORMAL FINDING	
FETUS 673	BRANCHED.	XIPHOID CARTILAGE
	SUPERNUMERARY, ONE.	COSTAL CARTILAGE(S), LEFT
FETUS 675	INTERRUPTED	COSTAL CARTILAGE, 11 RIGHT

CARTILAGE EXAMINATIONS
GROUP 2 (10 MG/KG)

DAM 38 CONT.

FETUS 677	BRANCHED.	XIPHOID CARTILAGE

DAM 39

FETUS 680	NO ABNORMAL FINDING	
FETUS 682	INTERRUPTED	COSTAL CARTILAGE, 11 RIGHT
FETUS 684	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 686	NO ABNORMAL FINDING	
FETUS 688	NO ABNORMAL FINDING	

DAM 40

FETUS 691	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 693	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT
	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 695	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT COSTAL CARTILAGE, 11 RIGHT
	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 697	NO ABNORMAL FINDING	
FETUS 699	BRANCHED.	XIPHOID CARTILAGE

DAM 41

FETUS 843	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT
FETUS 845	NO ABNORMAL FINDING	
FETUS 847	BRANCHED.	XIPHOID CARTILAGE
FETUS 849	BRANCHED.	XIPHOID CARTILAGE
FETUS 851	BRANCHED.	XIPHOID CARTILAGE

DAM 42

FETUS 853	BRANCHED.	XIPHOID CARTILAGE
FETUS 855	NO ABNORMAL FINDING	
FETUS 857	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 859	NO ABNORMAL FINDING	
FETUS 861	NO ABNORMAL FINDING	

DAM 43

FETUS 863	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 865	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 867	NO ABNORMAL FINDING	
FETUS 869	NO ABNORMAL FINDING	
FETUS 871	BRANCHED.	XIPHOID CARTILAGE
FETUS 873	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 875	BRANCHED.	XIPHOID CARTILAGE

CARTILAGE EXAMINATIONS
GROUP 2 (10 MG/KG)

DAM 44

FETUS 877	BRANCHED.	XIPHOID CARTILAGE
FETUS 879	NO ABNORMAL FINDING	
FETUS 881	NO ABNORMAL FINDING	
FETUS 883	NO ABNORMAL FINDING	
FETUS 885	NO ABNORMAL FINDING	
FETUS 887	BRANCHED.	XIPHOID CARTILAGE

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

CARTILAGE EXAMINATION OF FETUSES - INDIVIDUAL DATA

- GROUP 3 (30 MG/KG) - FETUSES OF DAM NOS. 45 - 66

CARTILAGE EXAMINATIONS
GROUP 3 (30 MG/KG)

DAM 45		
FETUS 132	BRANCHED.	XIPHOID CARTILAGE
FETUS 134	BRANCHED.	XIPHOID CARTILAGE
FETUS 136	BRANCHED.	XIPHOID CARTILAGE
FETUS 138	NO ABNORMAL FINDING	
FETUS 140	NO ABNORMAL FINDING	
DAM 46		
FETUS 142	NO ABNORMAL FINDING	
FETUS 144	BRANCHED.	XIPHOID CARTILAGE
FETUS 146	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 148	NO ABNORMAL FINDING	
FETUS 150	NO ABNORMAL FINDING	
FETUS 152	NO ABNORMAL FINDING	
DAM 47		
FETUS 154	BRANCHED.	XIPHOID CARTILAGE
FETUS 156	NO ABNORMAL FINDING	
DAM 48		
FETUS 158	NO ABNORMAL FINDING	
FETUS 160	NO ABNORMAL FINDING	
FETUS 162	NO ABNORMAL FINDING	
FETUS 164	NO ABNORMAL FINDING	
DAM 50		
FETUS 167	NO ABNORMAL FINDING	
FETUS 169	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT COSTAL CARTILAGE, 11 RIGHT
FETUS 171	BRANCHED.	XIPHOID CARTILAGE
FETUS 173	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT COSTAL CARTILAGE, 11 RIGHT
	SUPERNUMERARY, ONE.	COSTAL CARTILAGE(S), RIGHT
FETUS 175	NO ABNORMAL FINDING	
FETUS 177	BRANCHED.	XIPHOID CARTILAGE
	INTERRUPTED	COSTAL CARTILAGE, 11 RIGHT
	SUPERNUMERARY, ONE.	COSTAL CARTILAGE(S), LEFT
DAM 51		
FETUS 179	NO ABNORMAL FINDING	
FETUS 181	BRANCHED.	XIPHOID CARTILAGE
FETUS 183	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 185	NO ABNORMAL FINDING	
FETUS 187	WITH SMALL HOLE	XIPHOID CARTILAGE

CARTILAGE EXAMINATIONS
GROUP 3 (30 MG/KG)

DAM 52		
FETUS 189	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 191	NO ABNORMAL FINDING	
FETUS 193	BRANCHED.	XIPHOID CARTILAGE
FETUS 195	NO ABNORMAL FINDING	
FETUS 197	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 199	BRANCHED.	XIPHOID CARTILAGE
DAM 53		
FETUS 202	NO ABNORMAL FINDING	
FETUS 204	BRANCHED.	XIPHOID CARTILAGE
FETUS 206	NO ABNORMAL FINDING	
FETUS 208	NO ABNORMAL FINDING	
FETUS 210	LONG.	VENTRAL PLATE, RIGHT
DAM 54		
FETUS 213	BRANCHED.	XIPHOID CARTILAGE
FETUS 215	NO ABNORMAL FINDING	
FETUS 217	NO ABNORMAL FINDING	
FETUS 219	NO ABNORMAL FINDING	
FETUS 221	NO ABNORMAL FINDING	
DAM 55		
FETUS 366	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 368	BRANCHED.	XIPHOID CARTILAGE
FETUS 370	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 372	BRANCHED.	XIPHOID CARTILAGE
FETUS 374	NO ABNORMAL FINDING	
FETUS 376	BRANCHED.	XIPHOID CARTILAGE
DAM 56		
FETUS 378	NO ABNORMAL FINDING	
FETUS 380	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 382	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 384	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT COSTAL CARTILAGE, 11 RIGHT
FETUS 386	NO ABNORMAL FINDING	
FETUS 388	NO ABNORMAL FINDING	
DAM 57		
FETUS 390	NO ABNORMAL FINDING	
FETUS 392	NO ABNORMAL FINDING	

CARTILAGE EXAMINATIONS
GROUP 3 (30 MG/KG)

DAM 57 CONT.

FETUS 394	LONG.	COSTAL CARTILAGE, 11 LEFT COSTAL CARTILAGE, 11 RIGHT
FETUS 396	NO ABNORMAL FINDING	
FETUS 398	NO ABNORMAL FINDING	
FETUS 400	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT COSTAL CARTILAGE, 11 RIGHT
	WITH SMALL HOLE	XIPHOID CARTILAGE

DAM 58

FETUS 403	NO ABNORMAL FINDING	
FETUS 405	NO ABNORMAL FINDING	
FETUS 407	NO ABNORMAL FINDING	
FETUS 409	NO ABNORMAL FINDING	
FETUS 411	BRANCHED.	XIPHOID CARTILAGE
FETUS 413	BRANCHED.	XIPHOID CARTILAGE

DAM 59

FETUS 416	INTERRUPTED	COSTAL CARTILAGE, 11 RIGHT
	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 418	BRANCHED.	XIPHOID CARTILAGE
FETUS 420	NO ABNORMAL FINDING	
FETUS 422	BRANCHED.	XIPHOID CARTILAGE
FETUS 424	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT

DAM 60

FETUS 701	NO ABNORMAL FINDING	
FETUS 703	NO ABNORMAL FINDING	
FETUS 705	NO ABNORMAL FINDING	
FETUS 707	NO ABNORMAL FINDING	
FETUS 709	BRANCHED.	XIPHOID CARTILAGE
FETUS 711	NO ABNORMAL FINDING	
FETUS 713	NO ABNORMAL FINDING	

DAM 61

FETUS 715	BRANCHED.	XIPHOID CARTILAGE
FETUS 717	NO ABNORMAL FINDING	
FETUS 719	NO ABNORMAL FINDING	
FETUS 721	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 723	WITH SMALL HOLE	XIPHOID CARTILAGE

DAM 62

FETUS 725	NO ABNORMAL FINDING	
FETUS 727	BRANCHED.	XIPHOID CARTILAGE

CARTILAGE EXAMINATIONS
GROUP 3 (30 MG/KG)

DAM 62 CONT.

FETUS 729	NO ABNORMAL FINDING	
FETUS 731	NO ABNORMAL FINDING	
FETUS 733	CRANIAL SHIFT TO CERVICAL VERTEBRA 5. .	VENTRAL PLATE, RIGHT

DAM 63

FETUS 735	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 737	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 739	BRANCHED.	XIPHOID CARTILAGE
FETUS 741	NO ABNORMAL FINDING	
FETUS 743	BRANCHED.	XIPHOID CARTILAGE
FETUS 745	NO ABNORMAL FINDING	
FETUS 747	NO ABNORMAL FINDING	
FETUS 749	WITH SMALL HOLE	XIPHOID CARTILAGE

DAM 64

FETUS 751	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 753	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 755	NO ABNORMAL FINDING	
FETUS 757	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 759	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 761	BRANCHED.	XIPHOID CARTILAGE
FETUS 763	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT
	WITH SMALL HOLE	XIPHOID CARTILAGE

DAM 65

FETUS 890	BRANCHED.	XIPHOID CARTILAGE
FETUS 892	NO ABNORMAL FINDING	
FETUS 894	NO ABNORMAL FINDING	
FETUS 896	NO ABNORMAL FINDING	
FETUS 898	NO ABNORMAL FINDING	
FETUS 900	NO ABNORMAL FINDING	
FETUS 902	NO ABNORMAL FINDING	
FETUS 904	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT

DAM 66

FETUS 907	NO ABNORMAL FINDING	
FETUS 909	BRANCHED.	XIPHOID CARTILAGE
	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT
		COSTAL CARTILAGE, 11 RIGHT
FETUS 911	LONG.	COSTAL CARTILAGE, 11 LEFT
		COSTAL CARTILAGE, 11 RIGHT
	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 913	BRANCHED.	XIPHOID CARTILAGE

CARTILAGE EXAMINATIONS
GROUP 3 (30 MG/KG)

DAM 66 CONT.

FETUS 915	BRANCHED.	XIPHOID CARTILAGE
FETUS 917	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 919	INTERRUPTED	COSTAL CARTILAGE, 11 RIGHT

RCC STUDY NUMBER 851839
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE

CARTILAGE EXAMINATION OF FETUSES - INDIVIDUAL DATA

- GROUP 4 (150 MG/KG) - FETUSES OF DAM NOS. 67 - 88

CARTILAGE EXAMINATIONS
GROUP 4 (150 MG/KG)

DAM 67		
FETUS 223	BRANCHED.	XIPHOID CARTILAGE
	INTERRUPTED	COSTAL CARTILAGE, 11 RIGHT
FETUS 225	BRANCHED.	XIPHOID CARTILAGE
	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT
		COSTAL CARTILAGE, 11 RIGHT
FETUS 227	BRANCHED.	XIPHOID CARTILAGE
FETUS 229	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 231	WITH SMALL HOLE	XIPHOID CARTILAGE
DAM 68		
FETUS 234	NO ABNORMAL FINDING	
FETUS 236	INTERRUPTED	COSTAL CARTILAGE, 11 RIGHT
FETUS 238	NO ABNORMAL FINDING	
FETUS 240	NO ABNORMAL FINDING	
FETUS 242	BRANCHED.	XIPHOID CARTILAGE
FETUS 244	NO ABNORMAL FINDING	
DAM 69		
FETUS 246	BRANCHED.	XIPHOID CARTILAGE
FETUS 248	NO ABNORMAL FINDING	
FETUS 250	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 252	NO ABNORMAL FINDING	
FETUS 254	INTERRUPTED	COSTAL CARTILAGE, 11 RIGHT
FETUS 256	BRANCHED.	XIPHOID CARTILAGE
FETUS 258	NO ABNORMAL FINDING	
DAM 70		
FETUS 261	BRANCHED.	XIPHOID CARTILAGE
	LONG.	COSTAL CARTILAGE, 11 LEFT
	INTERRUPTED	COSTAL CARTILAGE, 11 RIGHT
FETUS 263	BRANCHED.	XIPHOID CARTILAGE
FETUS 265	BRANCHED.	XIPHOID CARTILAGE
FETUS 267	NO ABNORMAL FINDING	
FETUS 269	BRANCHED.	XIPHOID CARTILAGE
FETUS 271	BRANCHED.	XIPHOID CARTILAGE
DAM 71		
FETUS 274	NO ABNORMAL FINDING	
FETUS 276	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 278	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 280	NO ABNORMAL FINDING	
FETUS 282	WITH SMALL HOLE	XIPHOID CARTILAGE

CARTILAGE EXAMINATIONS
GROUP 4 (150 MG/KG)

DAM 72

FETUS 284	NO ABNORMAL FINDING	
FETUS 286	INTERRUPTED	COSTAL CARTILAGE, 11 RIGHT
FETUS 288	NO ABNORMAL FINDING	
FETUS 290	INTERRUPTED	COSTAL CARTILAGE, 11 RIGHT

DAM 73

FETUS 427	NO ABNORMAL FINDING	
FETUS 429	BRANCHED.	XIPHOID CARTILAGE
FETUS 431	BRANCHED.	XIPHOID CARTILAGE
FETUS 433	NO ABNORMAL FINDING	
FETUS 435	NO ABNORMAL FINDING	
FETUS 437	NO ABNORMAL FINDING	

DAM 74

FETUS 439	LONG.	COSTAL CARTILAGE, 11 LEFT COSTAL CARTILAGE, 11 RIGHT
	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 441	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT
FETUS 443	NO ABNORMAL FINDING	
FETUS 445	INTERRUPTED	COSTAL CARTILAGE, 11 RIGHT
	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 447	WITH SMALL HOLE	XIPHOID CARTILAGE

DAM 75

FETUS 450	ABNORMAL FINDING(S)	VARIOUS CARTILAGES
FETUS 452	BRANCHED.	XIPHOID CARTILAGE
FETUS 454	BRANCHED.	XIPHOID CARTILAGE
FETUS 456	NO ABNORMAL FINDING	
FETUS 458	BRANCHED.	XIPHOID CARTILAGE
FETUS 460	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT
	WITH SMALL HOLE	XIPHOID CARTILAGE

DAM 77

FETUS 462	SUPERNUMERARY, ONE.	COSTAL CARTILAGE(S), LEFT COSTAL CARTILAGE(S), RIGHT
FETUS 464	NO ABNORMAL FINDING	
FETUS 466	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 468	NO ABNORMAL FINDING	
FETUS 470	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT
FETUS 472	NO ABNORMAL FINDING	
FETUS 474	NO ABNORMAL FINDING	

CARTILAGE EXAMINATIONS
GROUP 4 (150 MG/KG)

DAM 78		
FETUS 476	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT
FETUS 478	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 480	NO ABNORMAL FINDING	
FETUS 482	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 484	BRANCHED.	XIPHOID CARTILAGE
DAM 79		
FETUS 487	BRANCHED.	XIPHOID CARTILAGE
FETUS 489	NO ABNORMAL FINDING	
FETUS 491	NO ABNORMAL FINDING	
FETUS 493	BRANCHED.	XIPHOID CARTILAGE
FETUS 495	INTERRUPTED	COSTAL CARTILAGE, 10 RIGHT
FETUS 497	NO ABNORMAL FINDING	
DAM 82		
FETUS 766	LONG.	COSTAL CARTILAGE, 11 LEFT COSTAL CARTILAGE, 11 RIGHT
FETUS 768	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 770	LONG.	COSTAL CARTILAGE, 11 LEFT
FETUS 772	NO ABNORMAL FINDING	
FETUS 774	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT COSTAL CARTILAGE, 11 RIGHT
	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 776	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 778	BRANCHED.	XIPHOID CARTILAGE
DAM 83		
FETUS 781	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 783	NO ABNORMAL FINDING	
FETUS 785	NO ABNORMAL FINDING	
FETUS 787	NO ABNORMAL FINDING	
FETUS 789	WITH SMALL HOLE	XIPHOID CARTILAGE
DAM 84		
FETUS 792	BRANCHED.	XIPHOID CARTILAGE
	INTERRUPTED	COSTAL CARTILAGE, 11 RIGHT
FETUS 794	NO ABNORMAL FINDING	
FETUS 796	NO ABNORMAL FINDING	
FETUS 798	LONG.	COSTAL CARTILAGE, 11 LEFT COSTAL CARTILAGE, 11 RIGHT
FETUS 800	NO ABNORMAL FINDING	
FETUS 802	NO ABNORMAL FINDING	
FETUS 804	NO ABNORMAL FINDING	

CARTILAGE EXAMINATIONS
GROUP 4 (150 MG/KG)

DAM 85		
FETUS 921	INTERRUPTED	COSTAL CARTILAGE, 11 RIGHT
	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 923	BRANCHED.	XIPHOID CARTILAGE
FETUS 925	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 927	BRANCHED.	XIPHOID CARTILAGE
FETUS 929	INTERRUPTED	COSTAL CARTILAGE, 11 RIGHT
FETUS 931	WITH SMALL HOLE	XIPHOID CARTILAGE
DAM 86		
FETUS 934	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 936	NO ABNORMAL FINDING	
FETUS 938	BRANCHED.	XIPHOID CARTILAGE
DAM 87		
FETUS 941	NO ABNORMAL FINDING	
FETUS 943	BRANCHED.	XIPHOID CARTILAGE
FETUS 945	BRANCHED.	XIPHOID CARTILAGE
	INTERRUPTED	COSTAL CARTILAGE, 13 LEFT
FETUS 947	BRANCHED.	XIPHOID CARTILAGE
FETUS 949	INTERRUPTED	COSTAL CARTILAGE, 11 LEFT
		COSTAL CARTILAGE, 11 RIGHT
FETUS 951	NO ABNORMAL FINDING	
DAM 88		
FETUS 953	NO ABNORMAL FINDING	
FETUS 955	NO ABNORMAL FINDING	
FETUS 957	WITH SMALL HOLE	XIPHOID CARTILAGE
FETUS 947	BRANCHED.	XIPHOID CARTILAGE
FETUS 961	WITH SMALL HOLE	XIPHOID CARTILAGE

8.7 ATTACHMENT VII

STUDY PLAN

RCC Study Number 851839

raw material No.: 23081

2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE:

Prenatal Developmental Toxicity Study

in the Rat

Study Plan

RCC

SIGNATURES

STUDY DIRECTOR: H. Becker

.....
date: 11- MAR- 2004

DEPUTY STUDY DIRECTOR: Dr. A. Marburger

.....
date: 11-MAR-2004

TEST FACILITY MANAGEMENT: Dr. H. Fankhauser

.....
date: 11 March 2004

LEAD QUALITY ASSURANCE: V. Gros

.....
date: 11.03.2004

SPONSOR: Wella AG

STUDY MONITOR: Dr. H. Scheffler

.....
date:
March 16, 2004

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1 PREFACE

1.1 GENERAL

Title	2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE: Prenatal developmental toxicity study in the rat
Sponsor	
Study Monitor	
Test Facility	(a) RCC Ltd Toxicology Operational Unit: Safety Assessment I Wölferstrasse 4 CH-4414 Füllinsdorf / Switzerland
Test Site	(b) RCC Ltd Environmental Chemistry & Pharmanalytics Zelgliweg 1 CH-4452 Itingen / Switzerland
Lead QA	RCC Ltd Quality Assurance GLP Toxicology CH-4452 Itingen / Switzerland
Test Site QA	RCC Ltd Quality Assurance GLP Environmental Chemistry & Pharmanalytics CH-4452 Itingen / Switzerland (responsible for test site (b))

1.2 RESPONSIBILITIES

Study Director	H. Becker (a)
Deputy Study Director	Dr. A. Marburger (a)
Technical Coordinator	D. Frei (a)
Principal Investigator: Study Phase: Analytical Chemistry	Dr. D. Flade (b)
Head of Lead QA	I. Wüthrich

1.3 SCHEDULE

Delivery of the female rats	12-MAR-2004
Experimental Starting Date (Initiation of pairing)	22-MAR-2004
Day 0 post coitum for the first mated females	23-MAR-2004
First Treatment (day 6 p.c.)	29-MAR-2004
Start Necropsy	13-APR-2004
Expected last Caesarean section	21-APR-2004
Experimental Completion Date	30-JUL-2004
Draft Report (proposed submission)	28-AUG-2004
Final Report	30 days after receipt of client's acceptance of the draft report

1.4 GOOD LABORATORY PRACTICE

This study will be performed in compliance with the Swiss Ordinance relating to Good Laboratory Practice, adopted February 2nd, 2000[RS 813.016.5]. This Ordinance is based on the OECD Principles of Good Laboratory Practice, as revised in 1997 and adopted November 26th, 1997 by decision of the OECD Council [C (97)186/Final].

The Principal Investigator (PI) will be responsible for compliance with his national GLP regulations for any work performed at his test site and for data provided to RCC for inclusion in the report. The phase report provided by a PI should include a Statement of GLP Compliance signed by the PI and a Quality Assurance Statement signed by an authorized representative of the PI's Quality Assurance.

1.5 ANIMAL WELFARE

In-life part will be performed in an AAALAC-approved laboratory in accordance with the Swiss Animal Protection Law under license no. 23.

1.6 TEST GUIDELINES

This study will be conducted in compliance with OECD guidelines (OECD guideline for testing of chemicals proposal for updating guideline 414, prenatal developmental toxicity study. Adopted: 22nd January 2001) and EEC guidelines (Commission Directive 88/302/EEC, Official Journal of the European Communities L 133, dated May 30, 1988) and US-EPA guidelines (Health Effects Test Guidelines, OPPTS 870.3700 'Prenatal Development Toxicity Study', EPA 712-C-98-207, dated August 1998).

1.7 AMENDMENT AND DEVIATION PROCEDURES

Planned changes to the study plan will be agreed with the Sponsor in advance and subsequently documented in an amendment to the study plan. However, when difficulties in contacting the Sponsor are encountered, Study Director reserves the right to act independently should this be necessary; whereupon the Sponsor is informed as soon as possible. Amendments to the study plan will be issued and signed by the Study Director and Sponsor, and will become effective at the time of Study Director signature. The Sponsor will receive the original amendment, which must be signed and returned to RCC. The amendment will be distributed (see 5. Distribution) and added to all copies of the study plan.

Deviations (unplanned changes) to the study plan will be documented, acknowledged by the Study Director and maintained with the raw data. The report will reflect any deviations. The Sponsor will be promptly informed of any relevant deviations from the study plan.

1.8 ARCHIVING

RCC Ltd (CH-4452 Itingen/Switzerland) will retain the study plan, raw data, sample of test item(s), specimens (as long as the quality permits evaluation) and the final report of the present study for at least ten years. Wet tissue samples will be archived at RCC Ltd for a minimum of five years. Thereafter, in agreement with the Sponsor, these samples may be further archived at RCC Ltd or transferred to another GLP archive facility for the remainder of the prescribed period. No data will be discarded without the Sponsor's consent.

2 PURPOSE

The purpose of this study is to assess the effects of the test item on the pregnant female and on embryonic and fetal development when administered orally by gavage once daily to mated female rats from day 6 (implantation) through to day 20 post coitum (one day prior to scheduled Caesarean section), inclusive.

2.1 RATIONALE FOR CHOICE OF SPECIES, ROUTE OF ADMINISTRATION AND DOSE LEVELS

The rat is a suitable rodent species for development toxicity studies required by regulatory authorities. The oral route is one possible route for human exposure. Dose levels were selected in conjunction with the Sponsor, based on the results of a previous dose range-finding study in pregnant rats (RCC study number 851838, Wella raw material No. 23081). In this study, animals were treated with 0, 10, 30 and 90 mg/kg from day 6 to 20 of pregnancy. Slightly reduced food consumption and body weight gain were noted. Therefore the highest dosage for the main study was increased to 150 mg/kg body weight/day. There was no teratogenic effect.

3 MATERIALS AND METHODS

General Remark: Details of the materials and methods that are not specified in the subsequent sections of this study plan are contained in the appropriate RCC standard operating procedures.

3.1 TEST SYSTEM

Species	Rat HanBrl:WIST (SPF)
Rationale	Specified by the international guidelines as a recommended test system
Source	RCC Ltd Laboratory Animals Services Wölferstrasse 4 CH-4414 Füllinsdorf / Switzerland
Acclimatization	Seven days minimum prior to mating with an evaluation of the health status.
Number of animals	88 mated females, 22 per group
Age at delivery	10 weeks minimum
Body weights at delivery	Target range 180 - 240 grams
Identification (day 0 post coitum)	Individual animal number tattooed on the pinnae

3.2 HUSBANDRY

Conditions	Animals will be housed under standard laboratory conditions: air-conditioned with 10-15 air changes per hour; the environment monitored continuously with recordings of temperature (target range 22 ± 3°C) and relative humidity (target range 30-70%), 12 hours artificial fluorescent light / 12 hours dark with background music played at a centrally defined low volume for at least 8 hours during the light period. The room number will be documented in the raw data and included in the report.
Accommodation	Individually (except during mating) in Makrolon cages (type-3) with wire mesh tops and standardized granulated softwood bedding (Lignocel, Schill AG, CH-4132 Muttenz/Switzerland).
Diet	Pelleted standard Kliba-Nafag 3433 rat/mouse maintenance diet (Provimi Kliba AG, CH-4303 Kaiseraugst/ Switzerland) will be available *ad libitum*. Results of analysis for contaminants will be included in the report.
Water	Tap water in bottles will be available *ad libitum*. Results of the bacteriological, chemical and contaminant analyses scheduled to be conducted at least once yearly by RCC (contaminant analyses only) and by the Official Chemist of the Kanton Basel-Landschaft (bacteriological and chemical analyses) will be included in the report.

3.3 TEST ITEM

The test item and the information concerning the test item were provided by the Sponsor (see analytical certificate pp. 19, 20).

Wella raw material No.	23081
Identity	2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE
Batch number	Ch. 57/01 (R96000195; R96000196)
Cas-No.	83763-48-8
Description	Pale grey powder
Purity	93.5 weight %; determined by NMR
Storage	Keep tightly closed in a dry, cool and well-ventilated place. Protect from humid air and water as well as from heat and direct sunlight.
Expiry date	July, 2005
Stability in the vehicle (water)	See Certificate of Analysis (p. 20)
Safety precautions	Dust mask, gloves and goggles will be applied to ensure personnel security.

3.4 VEHICLE AND CONTROL ITEM

Bi-distilled water will be used as the vehicle for the test item in the dose groups and will be administered as the control item to the females of the control group.

3.5 DOSE FORMULATION

Dose formulations will be prepared in terms of test item as supplied by the Sponsor.

Frequency of dose formulation Daily

The test item will be weighed into a glass beaker on a tared precision balance and the vehicle added (w/v). The mixtures will be prepared using a homogenizer. During the daily administration period, homogeneity will be maintained using a magnetic stirrer.

3.5.1 ANALYSIS OF DOSE FORMULATIONS

During the first and last week of the administration period samples for determination of concentration, homogeneity and stability will be taken. The samples of approximately 2 g will be transferred into flat bottomed flasks and frozen (-25°C to -15°C) pending analyses.

For determination of homogeneity, samples will be taken from the top, middle and bottom of each formulation. The mean values from these analyses will also represent the concentration and stability immediately after preparation.

Further samples for determination of stability will be taken after 4 hours storage at room temperature (22 ± 3°C).

Samples will be sent with dry ice to Dr. D. Flade, RCC Ltd, Environmental Chemistry & Pharmanalytics, CH-4452 Itingen / Switzerland. Analysis will be performed using an external standard method provided by the Sponsor (HPLC). The results of the analyses will be included into the report per phase report from the Principal Investigator.

3.6 STUDY SCHEDULE (SCHEMATIC DIAGRAM)

Days of study		
Acclimatization		
	Pairing	
–	Day 0 post coitum	
–	Day 6 post coitum	(first treatment)
–	Day 20 post coitum	(last treatment)
–	Day 21 post coitum	(Cesarean section, necropsy)

3.7 PROCEDURES, OBSERVATIONS, DATA RECORDING AND COMPILATION

3.7.1 PROCEDURES

Mating

After acclimatization, the females will be housed with the males (one male : one female) in special automatic mating cages, i.e. with synchronized timing to initiate the night mating period, until evidence of copulation is observed. This system will reduce the variation in the copulation times of the different females. The females will be removed and housed individually if:

a) the daily vaginal smear is sperm-positive, or

b) a copulation plug is observed.

This day will be designated day 0 post coitum.

The male rats used for mating are in the possession of RCC. The fertility of these males was proved and will be continuously controlled.

Allocation of mated females to the test groups

Group	Female Numbers	Dose* mg/kg body weight/day
1	1 - 22	0 (vehicle control)
2	23 - 44	10
3	45 - 66	30
4	67 - 88	150

* = Dose levels are in terms of material as supplied by the Sponsor.

Method of allocation

Mated rats will be assigned to the different groups using a computer-generated random algorithm.

Administration

The test item will be administered orally, by gavage, once daily from day 6 (first treatment) through to day 20 post coitum (last treatment). All animals will receive a dose volume of 10 ml/kg body weight with a daily adjustment of the individual volume to the actual body weight. Control animals will be similarly dosed with the vehicle (bi-distilled water) alone.

3.7.2 OBSERVATIONS

Mortality rate

Animals will be checked at least twice daily for mortalities, morbidity or signs of abortion. Moribund animals will be sacrificed by CO_2 and necropsied, including examination of the uterine content. Specimens of abnormal tissue will be fixed in neutral phosphate-buffered 4% formaldehyde solution. Animals found dead will be necropsied.

Signs and/or symptoms

Animals will be observed at least twice daily for clinical signs.

3.7.3 DATA RECORDING

Food consumption

Food consumption will be recorded on 3-day intervals: days 0-3, 3-6, 6-9, 9-12, 12-15, 15-18 and 18-21 post coitum (see 3.7.4: Data Compilation and 3.8: Data Processing).

Body weight

Body weights will be recorded daily from day 0 until day 21 post coitum (see 3.7.4: Data Compilation and 3.8: Data Processing).

Termination of the study

On day 21 post coitum, just prior to expected delivery, females will be killed by CO_2 and the fetuses will be removed by Cesarean section.

Cesarean section and post mortem examination

At necropsy, the main organs of the thoracic and abdominal cavities, in particular the genitals will be examined. Number of corpora lutea in each ovary and the weight of uterus including contents will be recorded.

Tissues with macroscopic abnormalities will be fixed in neutral phosphate-buffered 4% formaldehyde solution for possible microscopic examination.

Uterine contents:

1. In dams at scheduled necropsy:

- number and location of live and dead fetuses
- number and location of early and late (embryonic/ fetal) losses
- uteri that appeared non-gravid will be further examined (e.g. by ammonium sulfide staining) to confirm the non-pregnant status

2. In dams sacrificed or dying before scheduled necropsy:

- number and location of implantation sites
- uteri that appeared non-gravid will be further examined (e.g. by ammonium sulfide staining) to confirm the non-pregnant status

Live fetuses will be removed from the uterus, sexed, weighed individually, examined for gross external abnormalities, killed by subcutaneous injection of sodium pentobarbital (Vetanarcol®) in the scruff and allocated to either visceral or skeletal evaluation (using a computer-generated random program) at an approximate 1:1 ratio within each litter, independent of sex. In the case of gross external malformation, fetuses will be allocated to the alternate technique depending on the type of finding.

1) Fetal visceral examination / microdissection technique: approximately one half of the fetuses per litter will be fixed in Bouin's solution (one fetus per container) for at least two weeks and will be micro-dissected. Serial sections of the head, microdissection of the thorax and abdomen and detailed examination of the major blood vessels will be done. After examination, organs and sections will be preserved in a solution of glycerin/ethanol (one fetus per container). Observations of visceral abnormalities and variations will be recorded.

2) The remaining fetuses will be eviscerated and with the exception of the paws, the skin will be removed and discarded. Carcasses will be processed through solutions of ethanol, glacial acetic acid with Alcian blue (for cartilage staining), potassium hydroxide with Alizarin red S (for clearing and staining ossified bone) and aqueous glycerin for preservation and storage*.

The skeletons will be examined and all abnormal findings and variations will be recorded. The specimens will be preserved individually.

Fetuses with abnormalities will be photographed where applicable.

* = Modification of Inouye, M., (1976) Congenital Abnormalities, 16, pp. 171-173.

3.7.4 DATA COMPILATION

Food consumption, body weight and Caesarean section data will be recorded on-line and compiled by computer (LIMS). Individual skeletal examination of fetuses data will be recorded on data sheets, transferred to and compiled by computer.

All other data will be recorded on data sheets and compiled manually.

3.8 DATA PROCESSING

The mean body weight gain (%), the mean corrected body weight gain (corrected for uterus weight) and the mean daily food consumption will be calculated by a computer program based on on-line recorded data.

The calculations for evaluation of the reproduction data will be performed by a computer program based on on-line recorded data. The following data will be calculated: Pre- and post-implantation losses, embryonic and fetal deaths, live and dead fetuses, abnormal fetuses, sex ratios of fetuses and fetal body weights.

For reproduction data, group mean values will be calculated both on a litter basis and on a percentage per group basis. Mean fetal weights will be calculated from the individual weights both on a per group and on a per litter basis.

Computer-generated values in the tables will represent the rounded-off results of calculations which use the exact raw data values.

3.9 TERMINOLOGY USED IN THE ASSESSMENT OF THE DATA

Empty implantation site	very early resorption or aborted implantation
Embryonic resorption	amorphous mass being resorbed
Fetal resorption	clearly defined fetal body being resorbed
Dead fetus	appearance of live fetus but without induced respiration or movement
Live fetus	breathing and/or moving fetus responding to touch
Abnormality	A structural change in a fetus that would probably impair its health or development. Serious abnormalities, i.e. clearly deleterious abnormalities, will also be distinguished.
Variation	A fetal change that occurs within the normal population under investigation and is unlikely to adversely affect survival or health. This includes a delay in growth or morphogenesis that has otherwise followed a normal pattern of development.
Skeletal variant	Variations in the number and shape of ribs and degree of ossification of phalangeal nuclei and/or sternebrae. Variations in the shape of the vertebral, intercostal and sternebral cartilage.

3.10 STATISTICAL METHODS

The following statistical methods will be used to analyse body weights, food consumption, reproduction and skeletal examination data:

- Means and standard deviations of various data will be calculated and included in the report.
- If the variables can be assumed to follow a normal distribution, the Dunnett many-one t-test, based on a pooled variance estimate, will be used for intergroup comparisons (i.e. single treatment groups against the Control group).
- The Steel test (many-one rank test) will be applied when the data cannot be assumed to follow a normal distribution.
- Fisher's Exact test for 2x2 tables will be applied if the variables can be dichotomized without loss of information.

Additional methods of statistical analysis will be used at the discretion of the statistician. All methods of analysis and the results will be included in the report.

References:

- C.W. Dunnett A Multiple Comparison Procedure for Comparing Several Treatments with a Control, J. Amer. Statist. Assoc. 50, 1096-1121 (1955).
- R.G. Miller Simultaneous Statistical Inference, Springer Verlag, New York (1981).
- R.A. Fisher Statistical Methods for Research Workers, Oliver and Boyd, Edinburgh (1950).

4 REPORTING

A GLP-compliant draft report will be submitted to the Sponsor for scientific review. Following receipt of the Sponsor's comments, a QA-audited final report will be issued.

5 DISTRIBUTION

This study plan will be distributed as follows:

1 copy Study Monitor (the Sponsor will be responsible for internal distribution)

RCC Ltd, TOX, Operational Unit: Safety Assessment I, Füllinsdorf

Original: Study File
1 copy Study Director
1 copy Deputy Study Director
2 copies Technical Coordinator
1 copy QA

RCC Ltd, Services, Itingen

1 copy Logistics

RCC Ltd, Environmental Chemistry & Pharmanalytics, Itingen

1 copy PI, Analytical Phase
1 copy QA

Wella/851839/851839P

11-MAR-2004/brc

6 ATTACHMENT I

CERTIFICATE OF ANALYSIS

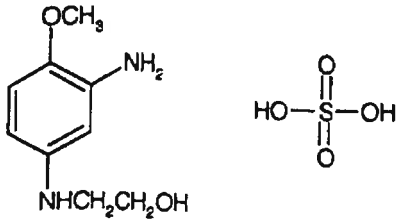
COSMITAL SA

Marly, 19.02.2001 FOF/BR/DOU/bs
Erweitert, Marly, 19.02.2003, FOF/UM
Erweitert, Marly, 11.12.2003, FOF/UM

CERTIFICATE OF ANALYSIS

raw material no.: 23081 **Code:** A000157

Structure:



Molecular formula: $C_9H_{12}N_2O_2.H_2O_4S$ **Molecular weight:** 280.30

Wella name: LEHMANN BLAU

Trade name: HC BLAU AC HC BLUE AC

Chemical name: 2-Amino-4-(2-hydroxyethyl)amino-anisole-sulfate

Name (INCI): 2-AMINO-4-HYDROXYETHYLAMINO-ANISOLE

CAS-No: 83763-48-8 **EINECS/ELINCS-No:** 280-734-8

Testing material

Sample name: **Sample no:**

Batch: Ch. 57/01 (R96000195; R96000196) **Study no.:** G2000/003

Date of entry: 08.01.96 **Expiry date:** July, 2005

Results

Aspect: pale grey powder

Odour:

Melting point:

Elemental analysis:

Loss on drying: 0.08 weight%

Water content: 5.9 weight%

Sulphated ash: 0.03 weight%

Mass spectrum:

NMR spectrum: 93.5 weight%

IR spectrum:

UV/VIS spectrum:

GC:

HPLC: 99.6 area% at the 254 nm
99.7 area% at the 296 nm

Identity and Purity:
The ^{1}H-NMR spectra confirmed the chemical identity of the test substance and resulted in a content of 93.5 weight%. The difference to 100 % is to be due particularly to a high water content of 5.9 weight%. In comparison to the drying loss (0.08 weight%) the water content laid clearly more highly, so that probably crystalline bound water was present. The small ash content (0.03 weight%) showed that the sample contained only small quantities of inorganic components. By means of HPLC the content of the impurity 4-Methoxy-1,3-phenylendiamino sulphate was determined to 0.06 weight%. The sum of NMR content, water content and content of 4-Methoxy-1,3-phenylen-diamino sulphate supplied a satisfying balance of the identified components of the sample of 99.5 weight%. The purity examination by HPLC showed impurities with 0,02 - 0.15 surface %, which might lie in the NMR spectroscopically not detectable trace range. The further evaluation resulted in a HPLC purity of 99.6 surface % in the case of one detection wavelength of 254 nm and 99.7 surface % in the case of 296 nm.

By-products: 0.06 weight% 4-Methoxy-1,3-phenylendiaminsulfate

Solubility: 10g/l in water pH 2.8
1 weight% in acetone / water 1:1 (pH 2.1)
9-10 weight% in DMSO

Stability:

Stability in solution:
For the examination of stability during a period of altogether seven days the HPLC was likewise used by means of UV detection with a wavelength at 243 nm. During the examination the aqueous solutions of the test substance (approx. 5 weight%) as well as the solutions in DMSO (approx. 5 weight%) were stored at ambient temperature and under light exclusion. The results (between 100 and 79,7 % retrieval rate during the storage) indicate a small degradation of the test substance in DMSO and in aqueous solution.

P. Dougoud