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Tour Galilée  
51 Esplanade du Général de Gaulle  
La Défense 10  
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France

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**TEST ITEM**

ETHYL TERTIARY BUTYL ETHER (ETBE)  
CAS No. 637-92-3

**STUDY TITLE**

PRENATAL DEVELOPMENTAL TOXICITY STUDY  
BY THE ORAL ROUTE (GAVAGE) IN RATS

**STUDY DIRECTOR**

Wassila Gaoua

**EXPERIMENTAL COMPLETION DATE**

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**TEST FACILITY**

CIT  
BP 563 - 27005 Evreux - France

**LABORATORY STUDY NUMBER**

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**Safety & Health Research Laboratories**

**IFM Recherche**

S.N.C. au Capital de 846.092 €  
788 060 465 R.C.S. Evreux  
VAT : FR19 788 060 465  
Agrément Crédit Impôt Recherche

B.P. 563 27005 Evreux Cedex France  
Tél. : +33 (0)2 32 29 26 26  
Fax : +33 (0)2 32 67 87 05  
E-mail : CIT@citox.com  
Web site : www.citox.com

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### **STATEMENT OF THE STUDY DIRECTOR**

The study was conducted in compliance with the following Good Laboratory Practice regulations:

- . OECD Principles on Good Laboratory Practice (as revised in 1997), ENV/MC/CHEM (98) 17,
- . Commission Directive 1999/11/EC of 8 March 1999 adapting to technical progress the Principles of Good Laboratory Practice as specified in Council Directive 87/18/EEC on the harmonization of laws, regulations and administrative provisions relating to the application of the Principles of Good Laboratory Practice and the verification of their applications for tests on chemical substances (OJ No. L 77 of 23.3.1999),
- . Décret N° 98-1312 du 31 décembre 1998 concernant les Bonnes Pratiques de Laboratoire (Journal Officiel du 1er janvier 1999), Ministère de l'Economie, des Finances et de l'Industrie,
- . US Environmental Protection Agency, Federal Register, 40 CFR Part 792; Toxic Substances Control Act; Good Laboratory Practice Standards, August 17, 1989 (and subsequent amendments),
- . Japanese Ministry of International Trade and Industry, Good Laboratory Practice Standards, Basic Industries Bureau, KanHogyo No. 39, March 31, 1984.

The study was conducted in compliance with Animal Health regulation, in particular:

- . Council Directive No. 86/609/EEC of 24th November 1986 on the harmonization of laws, regulations or administrative provisions relating to the protection of animals used for experimental or other scientific purposes.

I declare that this report constitutes a true and faithful record of the procedures undertaken and the results obtained during the performance of the study.

This study was performed at CIT, BP 563, 27005 Evreux, France.



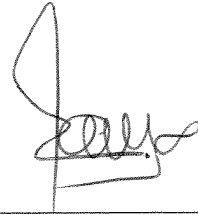
W. Gaoua  
Study Director

Doctor of Reproductive Toxicology, Ph.D.

Study completion date: 5 Jun 2004

**SCIENTISTS INVOLVED IN THE STUDY**

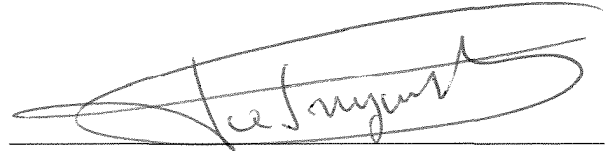
Pharmacy



X. Manciaux  
Doctor of Pharmacy  
Head of Pharmacy

Date: 06 Jan 2004

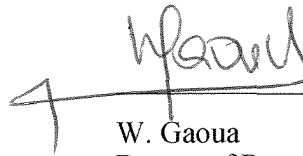
Analytical Chemistry



G. Fabreguettes  
D.E.S.S. (Analytical Chemistry)

Date: 06 Jan 2004

Toxicology



W. Gaoua  
Doctor of Reproductive Toxicology, Ph.D.

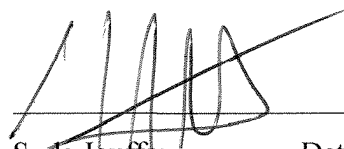
Date: 5 Jan 2004



O. Foulon  
Doctor of Pharmacy, Ph.D.  
Head of Reproductive Toxicology

Date: 5 Jan. 2004

CIT Management



S. de Jouffrey  
Doctor of Veterinary Medicine  
Director of Operations

Date: 06 JAN 2004

**STATEMENT OF QUALITY ASSURANCE UNIT**

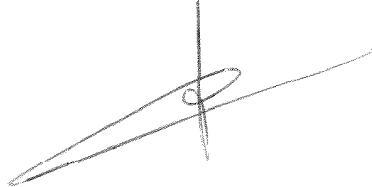
Type of inspection	Dates		
	Inspection	Reported to Study Director (*)	Reported to Management (*)
Study plan	14 March 2003	04 April 2003	09 April 2003
Study	18 April 2003	22 April 2003	19 May 2003
Study	09 October 2003	21 October 2003	13 November 2003
Report	10 October 2003	05 November 2003	19 November 2003

In addition to the above-mentioned inspections, at about the same time as this study described in the present report, process-based and routine facility inspections of critical procedures relevant to this study were also made by the Quality Assurance Unit.

The findings of these inspections were reported to the Study Director and to CIT Management.

The inspections were performed in compliance with CIT Quality Assurance Unit procedures and Principles of Good Laboratory Practice.

The reported methods and procedures were found to describe those used and the results to constitute an accurate and complete reflection of the study raw data.



C. Galli-Kar      Date: 06 Jan. 2004  
Ing. Biol.  
Head of Quality Assurance Unit

(\*) The dates indicated correspond to the dates of signature of audit reports by Study Director and Management.

## **SUMMARY**

The objective of this prenatal developmental toxicity study was to evaluate the potential effects of the test item, ETHYL TERTIARY BUTYL ETHER (ETBE; CAS No. 637-92-3), on pregnancy and embryo-fetal development in Sprague-Dawley rats following daily oral (gavage) administration at doses up to 1000 mg/kg/day from implantation to one day prior to scheduled hysterectomy (that is, day 5 to day 19 *post-coitum*, inclusive).

## **Methods**

A total of four groups of 24 female rats of the Sprague-Dawley strain received the test or control items once a day by oral route (gavage) from day 5 to day 19 *post-coitum* inclusive:

- . one control group received the vehicle alone (corn oil),
- . three groups received ETHYL TERTIARY BUTYL ETHER (ETBE), batch Nos. S02-08-159-I3 and S02-08-159-I3/2 at dose-levels of 250, 500 or 1000 mg/kg/day.

Clinical signs and mortality were checked daily. Body weight and food consumption were recorded at designated intervals.

On day 20 *post-coitum*, the dams were sacrificed and subjected to a macroscopic examination. The fetuses were removed by hysterectomy. The following litter parameters were recorded: weight of gravid uterus of the pregnant females (to allow calculation of corrected body weight gain), number of corpora lutea, implantation sites, early and late resorptions, dead and live fetuses.

The fetuses were weighed, sexed and submitted to external examination. Half of the fetuses from each treatment group were subjected to a detailed examination of soft tissue (serial sections after fixation in Harrison's fluid) while the remain underwent a detailed skeletal examination (following staining of bone with alizarin red and cartilage with alcian blue).

## **Results**

The following results were obtained:

Test group 4: ETHYL TERTIARY BUTYL ETHER (ETBE) at 1000 mg/kg/day:

- . a significantly lower maternal body weight gain (-11%,  $p < 0.05$ ) and net body weight gain (-17%,  $p < 0.01$ ) were recorded over the treatment period,
- . no treatment-related effects on gestational parameters or fetuses.

Test group 2 and 3: ETHYL TERTIARY BUTYL ETHER (ETBE) at 250 and 500 mg/kg/day:

- . no treatment-related effects on dams, gestational parameters or fetuses.



### **Conclusion**

ETHYL TERTIARY BUTYL ETHER (ETBE), when administered daily to pregnant Sprague-Dawley rats from day 5 to day 19 *post-coitum*, was associated with no maternal or embryo-fetal toxicity at dose levels of 250 and 500 mg/kg/day.

Maternotoxicity, as demonstrated by a statistically significant 11% decrease in body weight gain and a 17% decrease in net body weight gain, was recorded at 1000 mg/kg/day. No effect on embryo-fetal development was recorded at this dose-level.

Consequently, the No Observed Effect Level for maternotoxicity is 500 mg/kg/day and the No Observed Effect Level for embryofetal development is 1000 mg/kg/day.

## **1. INTRODUCTION**

### **1.1 OBJECTIVE**

The objective of this prenatal developmental toxicity study was to evaluate the potential effects of the test item, ETHYL TERTIARY BUTYL ETHER (ETBE; CAS No. 637-92-3), on pregnancy and on embryo-fetal development in Sprague-Dawley rats following daily oral (gavage) administration at doses up to 1000 mg/kg/day from implantation to the day prior to the scheduled hysterectomy (that is, day 5 to day 19 *post-coitum* inclusive).

The rat was chosen because it is a rodent species commonly accepted by regulatory authorities for this type of study and the Sprague-Dawley strain was selected since background data from previous studies are available at our laboratory.

The oral route was selected since it is acceptable under OECD guidelines for studies of this type and since uptake of ETBE from the gastrointestinal tract was expected to be rapid and complete.

The dose-levels were selected in agreement with the Sponsor, on the basis of a previously conducted oral range-finding study (*CIT/Study No. 24168 RSR*).

### **1.2 REGULATORY COMPLIANCE**

This study was designed to comply with:

- . OECD guideline No. 414, 22 January 2001,
- . US/EPA guideline OPPTS 870.3700, August 1998,
- . EC Commission Directive 87/302/EEC of Nov. 18, 1987.

## 2. MATERIALS AND METHODS

### 2.1 TEST AND CONTROL ITEMS

#### 2.1.1 Identification

##### 2.1.1.1 Test item

- . Supplier : TOTAL France S.A., Paris-la-Défense, France (purified by SEPAREX, Champagneulles, France)
- . Name : ETHYL TERTIARY BUTYL ETHER (ETBE)
- . Synonym : Ethyl-tert-Butyl Ether, ETBE, 2-ethoxy-2-methylpropane
- . CAS No. : 637-92-3
- . Batch number : S02-08-159-I3/1
- . Expiry date : 25 September 2003
- . Description : colorless liquid
- . Purity : >98%
- . Intended use : oxygenate additive for automotive fuels
- . Container : two aluminium drums
- . Date of receipt : 11 September 2002
- . Storage conditions : at room temperature, in well-closed containers (flammable) protected from light.

An analytical certificate, provided by the Sponsor, is presented in Appendix 1. Confirmation of the correct identity of the test material is the responsibility of the Sponsor.

##### 2.1.1.2 Vehicle

The vehicle was corn oil, batch No. 062K0006, supplied by Sigma (Saint-Quentin-Fallavier, France).

##### 2.1.2 Dosage form preparation

The test item was administered as a solution in the vehicle.

The test item was dissolved in the required quantity of vehicle in order to achieve the concentrations of 62.5, 125 and 250 mg/mL and then homogenized using a magnetic stirrer.

The test item dosage forms were prepared once each week, based upon stability results obtained in a previous study (*CIT/Study No. 24168 RSR*). The dosage forms were stored at room temperature in well-closed bottles in the dark, prior to use. The batch for each treatment level was sub-divided into an appropriate number of aliquots so that one bottle was opened per dose and per day. The residue remaining in each opened bottle was discarded after use.

### 2.1.3 Chemical stability of the dosage forms

The stability of the dosage forms (ETBE concentration in the range 1-333 mg/mL) over a 9-day period at room temperature had been demonstrated in a previous study (*Study No. 24168 RSR*).

#### 2.1.3.1 Homogeneity

Before the start of treatment, two dosage forms containing 62.5 and 250 mg/mL of test item were prepared under conditions representative of those of the study.

Duplicate aliquots were taken from three different levels within each sample (top, middle, bottom) and analyzed for concentration the test item present.

#### 2.1.3.2 Concentration

The concentration of ETBE in samples taken from each dosage form (including the control) prepared for use in weeks 1, 2 and 3 was determined.

The analytical procedure used is presented in Appendix 2.

## 2.2 TEST SYSTEM

### 2.2.1 Animals

Number: 98 time-mated female rats were received at CIT in three batches: on 16 April (32 females), on 17 April (32 females) and on 18 April 2003 (34 females).

Strain and sanitary status: Sprague-Dawley, CrI CD® (SD) IGS BR, *Cesarian Obtained, Barrier Sustained-Virus Antibody Free*, (COBS-VAF®).

Breeder: Charles River Laboratories France, L'Arbresle, France.

Age/Weight: at the beginning of the treatment period, the animals were 11 weeks old and had a mean body weight of 254 g (range: 210 g to 295 g). The females were sexually mature and primigravid.

Mating: females were mated at the breeder's facilities. The day of confirmed mating (detection of a vaginal plug) was designated as day 0 *post-coitum* (*p.c*).

Acclimation: a 4-day acclimation period to the conditions of the study preceded the beginning of the treatment period (arrival of females on day 1 *post-coitum*). The animals were received in three batches, for logistical purposes.

Allocation to study: before the beginning of the treatment period, the animals were allocated to the groups, according to a stratification procedure, so that the average body weight of each group was similar.

Identification: each animal was individually identified by an ear tattoo and received a unique CIT identity number.

### 2.2.2 Environmental conditions

From arrival at CIT, the animals were housed in a barriered rodent unit, under specific pathogen free (SPF) standard laboratory conditions.

The animal room conditions are set as follows:

- . temperature :  $22 \pm 2^{\circ}\text{C}$
- . relative humidity :  $50 \pm 20\%$
- . light/dark cycle : 12h/12h (7:00 - 19:00)
- . ventilation : about 12 cycles/hour of filtered, non-recycled air.

The relevant instrumentation and equipment were checked and calibrated at regular intervals.

The temperature and relative humidity were checked regularly and daily records filed.

The animal room was disinfected before the arrival of the animals and cleaned regularly thereafter.

### 2.2.3 Housing

The animals were housed individually in wire-mesh cages (43.0 x 21.5 x 18.0 cm). A metal tray, containing autoclaved sawdust (SICSA, Alfortville, France), was placed under each cage. The sawdust was changed at least once a week.

The cages were placed in numerical order on the racks.

#### 2.2.4 Food and water

The animals had free access to A04 C pelleted maintenance diet, batch Nos. 30130 and 30227 (SAFE, Villemoisson, Epinay-sur-Orge, France) replenished weekly. The diet formula is presented in Appendix 3.

The animals had free access to bottles containing tap water (filtered with a 0.22 µm filter).

#### 2.2.5 Contaminant analyses

The batches of diet and sawdust were analyzed by the suppliers for composition and contaminant levels.

Bacterial and chemical analyses of water are performed regularly by external laboratories. These analyses include the detection of possible contaminants (pesticides, heavy metals and nitrosamines).

No contaminants were present in the diet, drinking water or sawdust at levels which may be expected to interfere with or prejudice the outcome of the study.

### 2.3 TREATMENT

#### 2.3.1 Treatment groups

##### Rationale for dose-level selection

The dose-levels were selected in agreement with the Sponsor on the basis of a previously conducted study (*CIT/Study No. 24168 RSR*), where ptyalism (excess salivation) and a slight, but statistically significant, decrease in body weight of pregnant females was noted at 1000 mg/kg/day.

Consequently, dose-levels of 250, 500 and 1000 mg/kg/day were selected for this study.

The treatment groups are detailed in the following table:

Group	Number of mated females	Dose-level (mg/kg/day)	Animal numbers
1	24	0	C22141 to C22164
2	24	250	C22165 to C 22188
3	24	500	C22189 to C22212
4	24	1000	C22213 to C22236

#### 2.3.2 Duration

Each animal was dosed once a day, at approximately the same time, from day 5 to day 19 *post-coitum*, inclusive.

### 2.3.3 Administration

The oral route was selected since it is acceptable under OECD guidelines for studies of this type and since uptake of ETBE from the gastrointestinal tract was expected to be rapid and complete. It is also recommended by OECD Guideline 414, and was used in the preliminary range-finding study. The dosage forms were administered by gavage using a glass syringe fitted with a metal gavage tube.

The quantity of dosage form administered to each animal was adjusted according to the most recently recorded body weight.

A constant dosage-volume of 4 mL/kg/day was used.

Control animals (group 1) received the vehicle alone.

The dosage forms were mixed regularly throughout the dosing procedure.

## 2.4 CLINICAL EXAMINATIONS

### 2.4.1 Morbidity and mortality

Each animal was checked for mortality or signs of morbidity:

- . at least twice a day during treatment period,
- . at least once a day on other days.

### 2.4.2 Clinical signs

From arrival, each animal was observed at least once a day as part of routine examinations. From day 5 to day 14 *post-coitum*, each animal was observed at least three times per day (immediately post-dose, 1-hour post-dose, 4-hour post-dose) for clinical signs (including evidence of physical or behavioural changes together with any overt signs of toxicity including abortion/resorption for the females).

From day 15 to day 19 *post-coitum*, animals were observed immediately after dosing and 1 hour post-dosing.

If clinical signs were present on days 15-19 *post-coitum* at the 1-hour observation period, the animals were observed again 4-hours post-dosing.

Observations recorded immediately post-dosing were made while the animals were being handled (prior to return to their cage). Observations at 1-hour and 4-hour post-dosing were made with the animals in their cages in order to minimize disturbance during the later stages of pregnancy.

### 2.4.3 Body weight

The body weight of each female was recorded on days 2, 4, 5, 6, 9, 12, 15, 18, 19 and 20 *post-coitum*.

Net body weight (gross body weight minus gravid uterine weight), as well as the gross and net body weight changes, were also calculated for each female.

### 2.4.4 Food consumption

The quantity of food consumed by each female was recorded over the following intervals: days 2-4, 4-5, 5-6, 6-9, 9-12, 12-15, 15-18, 18-19 and 19-20 *post-coitum*.

## 2.5 SACRIFICE AND TERMINAL EXAMINATIONS

The following examinations were carried out on all females.

### 2.5.1 Hysterectomies

On day 20 *post-coitum*, all females were killed by asphyxiation using carbon dioxide.

The weight of the gravid uterus was recorded at hysterectomy for each pregnant female with at least one live fetus.

The ovaries and uterus from all females were examined to determine:

- . number of corpora lutea,
- . number and distribution of dead and live fetuses,
- . number and distribution of early and late resorptions,
- . number and distribution of implantation sites (or uterine scars).

Early resorptions refer to evidence of implantation without recognizable embryo or fetus.

Late resorptions refer to dead embryo or fetus with external degenerative changes.

In apparently non-pregnant females, the presence of implantation scars on the uterus were checked using an ammonium sulphide staining technique.

### 2.5.2 Macroscopic *post-mortem* examination

All females were submitted to a macroscopic *post-mortem* examination of the principal thoracic and abdominal organs.

A gross evaluation of each placenta was also undertaken.

## 2.6 EXAMINATION OF FETUSES

These following examinations were performed on all litters from females with at least one live fetus.

Whenever necessary, photographs were taken to document fetal findings and kept with the study archives.

Any abnormal fetal findings were recorded according to the glossary of the International Federation of Teratology Societies (IFTS) and classified as malformation or variation:

- . a malformation refers to a permanent structural change that is likely to adversely affect survival or health,
- . a variation refers to a change that occurs within the normal population under investigation and is unlikely to adversely affect survival or health. It might include a delay in growth or morphogenesis that has otherwise followed a normal pattern of development.

### 2.6.1 Body weight

The body weight of each live fetus was recorded.

### 2.6.2 External examination

Each fetus was subject to a detailed external examination, which included all visible structures, surfaces and orifices (including the oral cavity). Any dead fetuses were then discarded and the live fetuses sacrificed by subcutaneous injection of thiopental sodium.



### 2.6.3 Soft tissue examination (Wilson, J.G., 1965)

Approximately half of the live fetuses per litter were fixed in Harrisson's fluid. A detailed soft tissue examination was performed using a free-hand serial sectioning technique (Wilson technique) which included observation of all the organs and structures of the head, neck, thorax and abdomen.

### 2.6.4 Skeletal examination (Peters P.W., 1977)

The remaining live fetuses per litter were fixed in ethyl alcohol and eviscerated. A detailed examination of the skeleton (bone + cartilage) was performed after staining with alizarin red S and alcian blue. This examination included observation of all the bone structures and cartilage of the head, spine, rib cage, pelvis and limbs.

### 2.6.5 Sex of fetuses

The sex of each fetus was determined at the time of evisceration (after fixation in alcohol) or at the time of serial sectioning.

## 2.7 ASSESSMENT OF DATA

Data are expressed as group mean values  $\pm$  standard deviation (maternal body weight and food consumption, fetal body weight and number of corpora lutea, implantations, fetuses and resorptions) or as proportions (pre-implantation loss, post-implantation loss and fetal findings). Whenever necessary, the experimental unit of comparison was the litter. Data of non pregnant females were not included in mean calculation.

The following calculations were made:

$$\text{Pre-implantation loss: } \frac{\text{Number of corpora lutea} - \text{Number of implantation sites}}{\text{Number of corpora lutea}} \times 100$$

$$\text{Post-implantation loss: } \frac{\text{Number of implantation sites} - \text{Number of live fetuses}}{\text{Number of implantation sites}} \times 100$$

$$\text{Fetal or litter incidence: } \frac{\text{Total number of fetuses or litters with a particular finding}}{\text{Total number of fetuses or litters examined}} \times 100$$

$$\text{Mean proportion of affected fetuses: } \frac{\text{Sum of proportion of fetuses affected in each litter}}{\text{Total number of litters examined}} \times 100$$

## 2.8 STATISTICAL ANALYSIS

Final interpretation of the numerical data considered the results of statistical analysis along with other factors such as dose-response relationships and whether the results were toxicologically relevant in the light of other biological and pathological findings.

The litter was the experimental unit for statistical analysis, with fetal body weight analyzed by sex as well as for both sexes combined.

Mean values were compared by one-way analysis of variance and Dunnett test, (mean values being considered as normally distributed and variances being considered as homogeneous). Percentage values were compared by Fisher exact probability test.

## 2.9 ARCHIVING

The following study materials will be retained in the archives of CIT (BP 563, 27005 Evreux, France) for 10 years after the end of the *in vivo* phase of the study:

- . Study plan,
- . raw data,
- . correspondence,
- . final report and possible amendments,
- . stained skeletons,
- . soft tissue sections,
- . sample of the test item.

On completion of this period, the archived study materials will be returned to the Sponsor, or may be archived at CIT for a further period.

The total duration of archiving (depending on regulations) is the responsibility of the Sponsor.

In addition, raw data not specific to the study, including but not limited to certificates of analyses for food, water and sawdust and records of environmental data and equipment calibration are also archived at CIT for at least 30 years.

At the end of the study, all remaining test item (excluding the archive sample(s)) will be returned to the Sponsor unless otherwise stated by the Sponsor.

## 2.10 CHRONOLOGY OF THE STUDY

The chronology of the study is summarized as follows:

Procedure	Date
<b>Study plan approved by:</b>	
. Study Director	9 April 2003
. Study Monitor	16 April 2003
<hr/>	
<b>Mating of females (day 0 <i>post-coitum</i>)</b>	
. First female	15 April 2003
. Last female	17 April 2003
<b>Arrival of females (day 1 <i>post-coitum</i>)</b>	
. First female (experimental starting date)	16 April 2003
. Last female	18 April 2003
<b>First day of treatment (day 5 <i>post-coitum</i>)</b>	
. First female	20 April 2003
. Last female	22 April 2003
<b>Last day of treatment (day 19 <i>post-coitum</i>)</b>	
. First female	4 May 2003
. Last female	6 May 2003
<b>Hysterectomies (day 20 <i>post-coitum</i>)</b>	
. First female	5 May 2003
. Last female (experimental completion date)	7 May 2003

## 2.11 STUDY PLAN ADHERENCE

The study was performed in accordance with Study plan No. 24860 RSR and subsequent amendments.

There were no deviations from the agreed Study plan.

### 3. RESULTS

#### 3.1 CHEMICAL ANALYSIS OF THE DOSAGE FORMS (Appendix 2)

##### 3.1.1 Homogeneity

The results of the analyses demonstrated the good homogeneity of each dosage form analyzed before the study (62.5 and 250 mg/mL).

Furthermore, there was a good correspondence between the nominal and the measured concentrations of the test item in the vehicle.

##### 3.1.2 Concentration

Throughout the study, a satisfactory agreement was observed between the nominal and actual concentrations of the test item in the administered dosage forms since the deviations from nominal concentration were in an acceptable range of  $\pm 10\%$ .

Group	Nominal concentration (mg/mL)	Actual concentration (mg/mL)		
		Week 1	Week 2	Week 3
<b>1</b>	<b>0</b>	BLQ	BLQ	BLQ
	<i>Deviation from nominal value :</i>	<i>nc</i>	<i>nc</i>	<i>nc</i>
<b>2</b>	<b>62.5</b>	60.2	58.6	66.4
	<i>Deviation from nominal value :</i>	<i>-4%</i>	<i>-6%</i>	<i>6%</i>
<b>3</b>	<b>125</b>	122	126	115
	<i>Deviation from nominal value :</i>	<i>-2%</i>	<i>1%</i>	<i>-8%</i>
<b>4</b>	<b>250</b>	229	224	237
	<i>Deviation from nominal value :</i>	<i>-8%</i>	<i>-10%</i>	<i>-5%</i>

BLQ: Below Limit of Quantification (< 0.1 mg/mL)

nc: not calculated

### 3.2 PREGNANCY STATUS OF THE FEMALES (Appendix 4)

The pregnancy status of the females is summarized as follows:

Dose-level (mg/kg/day)	0	250	500	1000
Mated females	24	24	24	24
Non-pregnant females	3	5	4	2
Pregnant females alive at termination	21	19	20	22
Pregnancy rate	87%	79%	83%	92%
Litters subjected to fetal examination	21	19	20	22

In all groups, the pregnancy rate (number of pregnant females/number of mated females) was between 79 and 92% and within the normal range for time-mated rats of this strain obtained from this breeder.

### 3.3 CLINICAL EXAMINATIONS

#### 3.3.1 Mortality (Table 1, Appendix 4)

There was no death in any group.

#### 3.3.2 Clinical signs (Tables 1 and 2, Appendices 5 and 6)

There were no remarkable clinical signs any group. Ptyalism (excess salivation) was noted in 5, 13 or 17 females from the 250, 500 and 1000 mg/kg/day dose groups at various times during the study. It occurred mainly during the middle part of the investigation and (with a single exception) was present immediately post-dosing and had resolved by one hour. It is commonly noted with unpalatable test items administered by gavage, and is therefore not considered as an adverse effect.

Areas of hair loss were observed in one female at both 0 and 1000 mg/kg/day; this sign was not considered to be related to treatment with the test item.

## 3.3.3 Body weight (Figures 1 and 2, Tables 3 to 5, Appendices 7 to 9)

The differences in body weight change and net body weight change are summarized in the table below:

Body weight change and net body weight change

Dose-level (mg/kg/day)	0	250	500	1000
Body weight change (g)				
Days 5 to 9 <i>post-coitum</i>	24	23	23	20
% difference from control		-4	-4	-17
Days 5 to 20 <i>post-coitum</i>				
Days 5 to 20 <i>post-coitum</i>	135	132	134	120*
% difference from control	-	-2	-1	-11
Net body weight change from day 5 (g)				
Net body weight change from day 5 (g)	61.8	59.4	60.0	51.5**
% difference from control	-	-4	-3	-17

\*: p&lt;0.05

\*\*: p&lt;0.01

At 1000 mg/kg/day, a transient reduction in body weight gain was noted at the beginning of the dosing period (-17% over days 5-9 *post-coitum*). Furthermore, mean body weight gain in these animals over the whole dosing period (days 5-20 *post-coitum*) was statistically significantly lower (-11%, p<0.05) than the control group value. Net body weight gain in the 1000 mg/kg/day group (corresponding to the net maternal body weight (carcass) on day 20 *post-coitum* minus maternal body weight on day 5 *post-coitum*) was also significantly lower (-17%, p<0.01) than that of the controls.

## 3.3.4 Food consumption (Figure 3, Table 6, Appendix 10)

Food consumption was unaffected by the treatment.

### 3.4 MACROSCOPIC *POST-MORTEM* EXAMINATION (Table 7, Appendix 11)

With the exception of an enlarged placenta recorded in one female at 500 mg/kg/day, no other macroscopic finding was observed at any dose-level.

### 3.5 LITTER DATA

#### 3.5.1 Pre-implantation loss (Table 8, Appendix 12)

The number of corpora lutea and implantation sites, and therefore the extent of pre-implantation loss, were similar between all groups.

#### 3.5.2 Post-implantation loss (Table 8, Appendix 12)

There was no total resorption seen in any group.

The number (21) and rate (1 per female) of early resorptions was slightly higher at 1000 mg/kg/day when compared to the control group (number = 14, rate = 0.7 per female). The extent of post-implantation loss was consequently minimally increased in the high-dose females (7.5%) in comparison with the controls (5.2%; non-significant). However this incidence for the high dose females was in the range of CIT historical control data (*mean post-implantation loss = 3.4%, minimum = 1.0%, maximum = 8.5%; data collected from 227 litters over a period ranging from January 2001 to November 2001*) and was consequently considered to be unrelated to the treatment.

#### 3.5.3 Live fetuses (Table 8, Appendices 12 and 13)

The number of live fetuses was in a range 11.7 to 12.3 per female, with no treatment-related or statistically significant differences present between the groups. No dead fetuses were found in any group.

#### 3.5.4 Sex ratio (Table 8, Appendix 13)

The sex ratio at 250 mg/kg/day (53.5% male, 46.5% female) was significantly different from the control value. This difference appeared principally related to an unusually low proportion of males (40.8%) and a correspondingly higher number of females (59.2%) in the control group. Further the mean values were comparable to historical control data (*male: minimum = 43.2%, maximum = 53.4%, female: minimum = 46.6%, maximum = 56.8%; data collected from 227 litters over a period ranging from January 2001 to November 2001*).

The sex ratio in the other treated groups (47.3-48.8% male, 51.2-52.7% female) was within the normal range (no dose-response relationship present), suggesting that this observation in the low dose litters was a chance event, unrelated to treatment with ETBE.

#### 3.5.5 Fetal weight (Table 8, Appendix 14)

The fetal weight was unaffected by the treatment.

### 3.6 EXAMINATION OF THE FETUSES (Tables 9 to 15, Appendix 15)

#### 3.6.1 Fetal external examination (Tables 9 and 10)

Except for one fetus with an umbilical hernia (malformation) and a bent tail (variation) at 250 mg/kg/day, no other finding was recorded in any group.

Because this finding was isolated, it was considered to be unrelated to the treatment with the test item.

### 3.6.2 Fetal soft tissue examination (Tables 11 and 12)

#### 3.6.2.1 Fetal soft tissue malformation

There were no malformations in the control and the 250 and 500 mg/kg/day groups.

In the 1000 mg/kg/day treated group, an absence of kidneys, ureters and adrenals was observed in a single fetus.

#### 3.6.2.2 Fetal soft tissue variation

The following findings were noted among the groups:

- . dilated ureters in one fetus from the control, 250 mg/kg/day and 1000 mg/kg/day groups,
- . short uterine horns in one fetus from the 500 mg/kg/day group,
- . dilated renal pelvis in one fetus from the 250 and 1000 mg/kg/day groups.

These few findings which were not dose-related and randomly distributed across the groups, were considered to be unrelated to the treatment.

### 3.6.3 Fetal skeletal examination (Tables 13 to 15)

#### 3.6.3.1 Fetal skeletal malformation

The following malformations were recorded among the groups:

- . misaligned sternebra in one fetus from the control group,
- . at 250 mg/kg/day, fused rib and misshapen sacral vertebra in one fetus, split sternebra and fused ribs in one other fetus,
- . at 500 mg/kg/day, bilateral misshapen ilium noted in one fetus,
- . at 1000 mg/kg/day, absence of one pair of ribs observed in two fetuses, one of which also had an absence of thoracic vertebra.

Because of their low incidence and the absence of any dose-relationship, these malformations were not considered to be related to the treatment with the test item.

#### 3.6.3.2 Fetal skeletal variation

In general, the findings were recorded in all groups without any dose-relationship and/or statistical significance and/or occurred at incidences consistent with historical control background data.

The single exception was a significant increase in the incidence of unossified 4<sup>th</sup> metacarpal at the highest dose: 43/136 fetuses (31.6%,  $p < 0.05$ ) were affected in the 1000 mg/kg/day group, versus 27/135 (20%) in the control group. However, when expressed on a fetus/litter basis, it was not statistically significant (32.4% vs. 21.4%) and within historical control data (*percentage incidence of unossified 4<sup>th</sup> metacarpal: minimum = 2.8%, maximum = 41.1%; data collected from 227 litters over a period ranging from January 2001 to November 2001*). Furthermore, when ossification was incomplete, cartilage was generally present suggesting that this skeletal variation was due to slightly delayed ossification rather than to a persistent alteration. In conclusion, since the above-described findings were isolated, not statistically significant or dose-related at the level of the litter and not associated with any significant delay in ossification of other bones, and since the total incidence of skeletal variations in treated animals did not increase, they were considered to be incidental and of no toxicological significance.



#### 4. CONCLUSION

ETHYL TERTIARY BUTYL ETHER (ETBE), when administered daily to pregnant Sprague-Dawley rats from day 5 to day 19 *post-coitum*, was associated with no maternal or embryo-fetal toxicity at dose levels of 250 and 500 mg/kg/day.

Maternotoxicity, as demonstrated by a statistically significant 11% decrease in body weight gain and a 17% decrease in net body weight gain, was recorded at 1000 mg/kg/day. No effect on embryo-fetal development was recorded at this dose-level.

Consequently, the No Observed Effect Level for maternotoxicity is 500 mg/kg/day and the No Observed Effect Level for embryofetal development is 1000 mg/kg/day.

#### 5. BIBLIOGRAPHICAL REFERENCES

Chahoud I. *et al.* (1999) Classification terms in developmental toxicology: need for harmonization. *Reprod. Toxicol.*, 13 (1): 77-82.

Dunnett C.W. (1955) A multiple comparison procedure for comparing several treatments with a control. *J. Am. Stat. Assoc.*, 50, 1096-1121.

Dunnett C.W. (1964) New tables for multiple comparisons with a control. *Biometrics*, 20, 482-491.

Fisher R.A. (1934) *Statistical methods for research workers* (5th ed). Edinburgh: Oliver and Boyd.

Peters, P.W. (1977) Double staining of fetal skeletons for cartilage and bone. *Methods in Prenatal Toxicology*. Neubert, D., Merker J.J. and Kwasigrock T.E. eds., Georg Thieme Publ., Stuttgart, pp. 153-154.

Salewski E. (1964) Färbemethode zum makroskopischen Nachweis von Implantationstellen am Uterus der Ratte. *Arch. Exp. Path. Pharmak.*, 247, 367.

Wilson J.G. (1965) Methods for administering agents and detecting malformations in experimental animals. In *Teratology, Principles and Techniques*; J.G. Wilson and J. Warkany eds, the University of Chicago Press, Chicago and London, pp 262-277.

Wise L.D. *et al.* (1997) Terminology of Developmental Abnormalities in Common Laboratory Mammals (Version 1). *Teratology*, 55: 249-292.

Figure 1

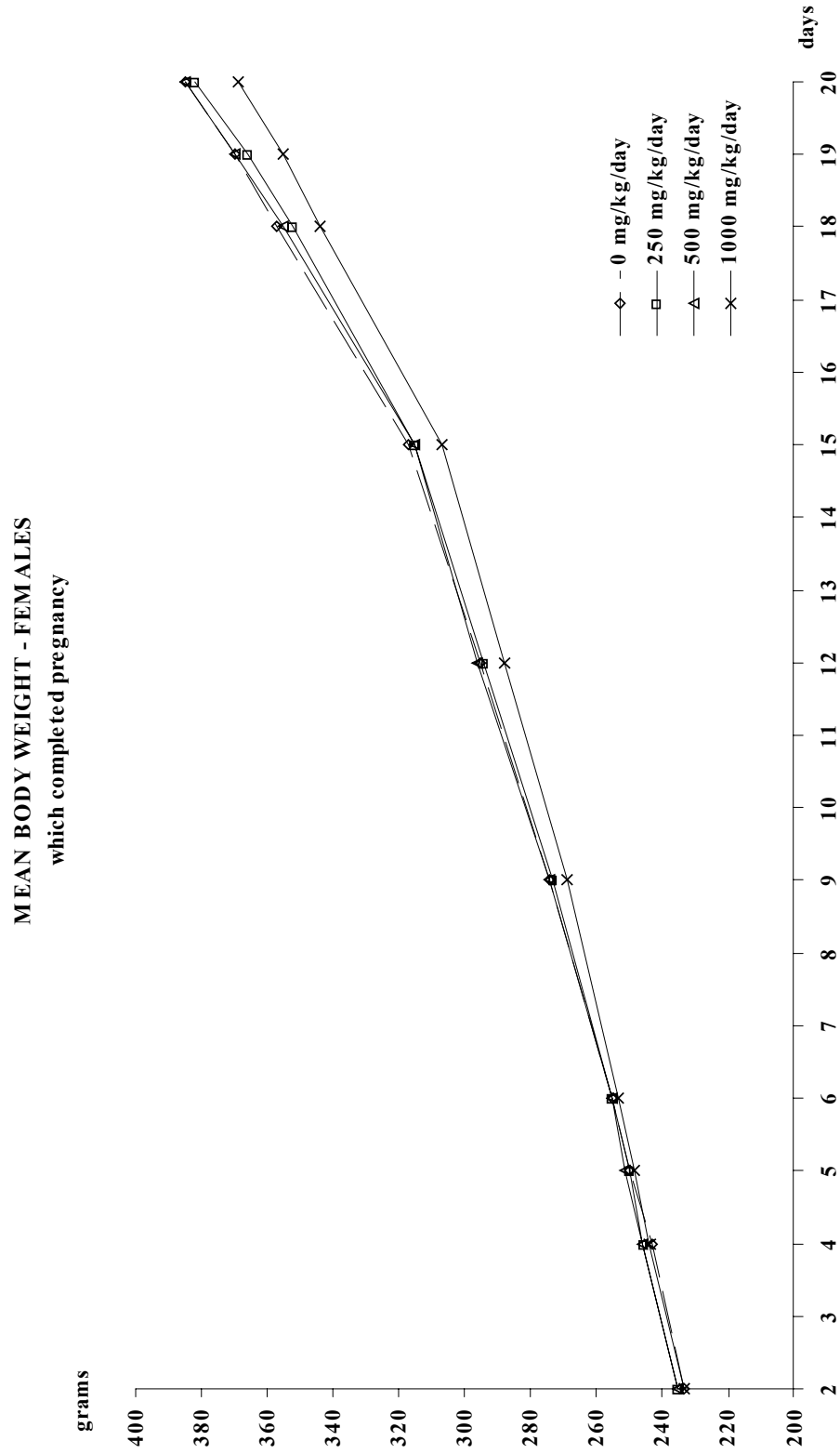


Figure 2

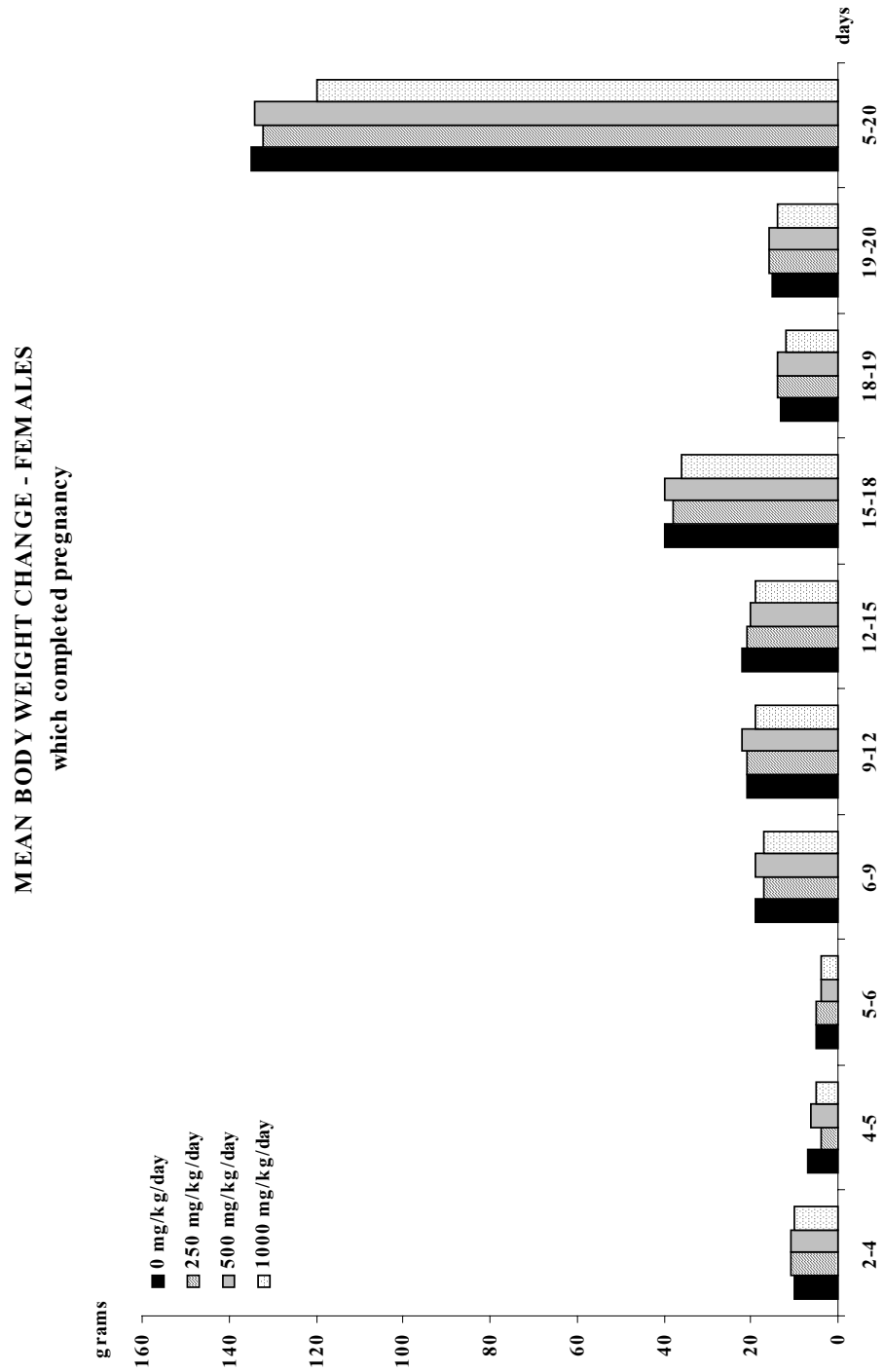


Figure 3

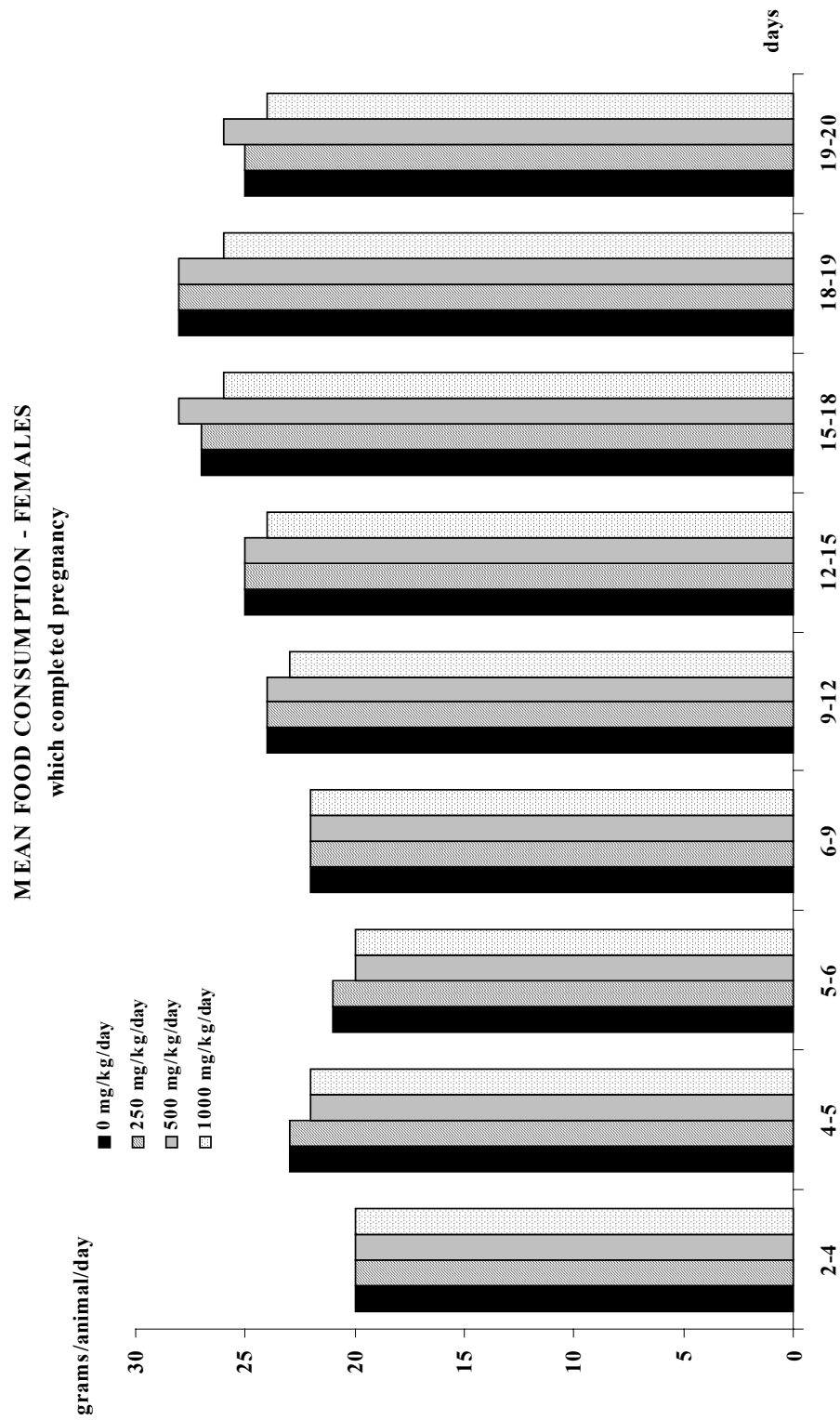


Table: 1

**CLINICAL SIGNS (Summary table/Females/Pregnancy period)**

Dose: (mg/kg/day)	0	250	500	1000
Mortality				
FINAL SACRIFICE	24	24	24	24
Skin				
AREA OF HAIR LOSS ON FORELIMB	1	0	0	1
Normal				
NO REMARKABLE OBSERVATIONS	23	24	24	23

Table 2

**Summary of specific clinical signs observed in principal animals**  
**(Number of females with ptyalism)**

	Day <i>post-coitum</i>														
	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
<b>Ptyalism</b>															
Dose-level: 0 mg/kg/day (24 females observed): No clinical signs															
Dose-level: 250 mg/kg/day (24 females observed)															
Post dosing	0	0	0	2	1	2	1	0	1	1	0	0	0	0	0
1 hour after dosing	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4 hours after dosing	0	0	0	0	0	0	0	0	0	0	-	-	-	-	-
Dose-level: 500 mg/kg/day (24 females observed)															
Post dosing	0	0	2	2	1	1	2	1	3	2	4	1	1	1	0
1 hour after dosing	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4 hours after dosing	0	0	0	0	0	0	0	0	0	0	-	-	-	-	-
Dose-level: 1000 mg/kg/day (24 females observed)															
Post dosing	1	0	4	0	2	4	3	6	5	8	5	2	1	0	0
1 hour after dosing	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4 hours after dosing	0	0	0	0	0	0	0	0	0	0	-	-	-	-	-

- : no recording of clinical signs

Table: 3

**BODY WEIGHT (Mean values/grams/Females/Pregnancy period)**

Dose: (mg/kg/day)		0	250	500	1000
DAY 2	MEAN	233 d	235	235	233
	S.D.	21	19	19	17
	N	21	19	20	22
DAY 4	MEAN	243 d	246	246	244
	S.D.	23	19	24	17
	N	21	19	20	22
DAY 5	MEAN	250 d	250	251	249
	S.D.	21	19	22	17
	N	21	19	20	22
DAY 6	MEAN	255 d	255	255	253
	S.D.	20	19	22	18
	N	21	19	20	22
DAY 9	MEAN	274 d	273	274	269
	S.D.	21	21	25	20
	N	21	19	20	22
DAY 12	MEAN	295 d	294	296	288
	S.D.	23	23	28	20
	N	21	19	20	22
DAY 15	MEAN	317 d	315	315	307
	S.D.	25	24	30	23
	N	21	19	20	22
DAY 18	MEAN	357 d	352	355	344
	S.D.	28	24	35	25
	N	21	19	20	22
DAY 19	MEAN	370 d	366	370	355
	S.D.	30	26	36	27
	N	21	19	20	22
DAY 20	MEAN	385 d	382	385	369
	S.D.	32	27	39	29
	N	21	19	20	22

Statistical key: d=ANOVA + Dunnett-test

Table: 4

**BODY WEIGHT CHANGE (Mean values/grams/Females/Pregnancy period)**

Dose: (mg/kg/day)		0	250	500	1000
DAYS 2 TO 4	MEAN	10 d	11	11	10
	S.D.	5	5	10	4
	N	21	19	20	22
	mean percent change	MEAN%	4.0	4.8	4.6
DAYS 4 TO 5	MEAN	7 d	4	6	5
	S.D.	7	3	8	3
	N	21	19	20	22
	mean percent change	MEAN%	3.2	1.7	2.4
DAYS 5 TO 6	MEAN	5 d	5	4	4
	S.D.	3	3	3	3
	N	21	19	20	22
	mean percent change	MEAN%	2.0	2.2	1.6
DAYS 6 TO 9	MEAN	19 d	17	19	17
	S.D.	5	4	6	5
	N	21	19	20	22
	mean percent change	MEAN%	7.4	6.8	7.2
DAYS 9 TO 12	MEAN	21 d	21	22	19
	S.D.	4	4	6	3
	N	21	19	20	22
	mean percent change	MEAN%	7.7	7.7	7.9
DAYS 12 TO 15	MEAN	22 d	21	20	19
	S.D.	5	3	5	5
	N	21	19	20	22
	mean percent change	MEAN%	7.4	7.1	6.6
DAYS 15 TO 18	MEAN	40 d	38	40	36
	S.D.	7	4	7	5
	N	21	19	20	22
	mean percent change	MEAN%	12.6	12.0	12.7
DAYS 18 TO 19	MEAN	13 d	14	14	12
	S.D.	4	3	3	4
	N	21	19	20	22
	mean percent change	MEAN%	3.7	3.9	4.0
DAYS 19 TO 20	MEAN	15 d	16	16	14
	S.D.	6	3	4	4
	N	21	19	20	22
	mean percent change	MEAN%	4.0	4.4	4.2

Statistical key: d=ANOVA + Dunnett-test



Table: 4 (continued)

**BODY WEIGHT CHANGE (Mean values/grams/Females/Pregnancy period)**

Dose: (mg/kg/day)		0	250	500	1000
DAYS 5 TO 20	MEAN	135 d	132	134	120*
	S.D.	22	12	19	15
	N	21	19	20	22
mean percent change	MEAN%	54.1	53.0	53.1	48.1

Statistical key: d=ANOVA + Dunnett-test \* = p<0.05

Table: 5

**NET BODY WEIGHT CHANGE (Mean values/grams/Females/Pregnancy period)**

Dose: (mg/kg/day)		0	250	500	1000
GRAVID UTERUS	MEAN	73.1 d	72.8	73.9	68.5
	S.D.	21.4	9.1	13.7	12.1
	N	21	19	20	22
CARCASS	MEAN	312.2 d	309.4	311.4	300.6
	S.D.	27.2	22.0	30.0	22.7
	N	21	19	20	22
NET WEIGHT CHANGE FROM DAY 5	MEAN	61.8 d	59.4	60.0	51.5**
	S.D.	13.0	8.1	11.3	10.3
	N	21	19	20	22

Statistical key: d=ANOVA + Dunnett-test \*\* = p<0.01

CARCASS WEIGHT = TERMINAL BODY WEIGHT MINUS UTERINE WEIGHT

NET WEIGHT CHANGE FROM DAY 5 = CARCASS WEIGHT MINUS DAY 5 BODY WEIGHT

Table: 6

**FOOD CONSUMPTION (Mean values/grams per day/Females/Pregnancy period)**

Dose: (mg/kg/day)		0	250	500	1000
DAYS 2 TO 4	MEAN	20 d	20	20	20
	S.D.	4	3	5	2
	N	21	19	20	22
DAYS 4 TO 5	MEAN	23 d	23	22	22
	S.D.	2	3	3	2
	N	21	19	20	22
DAYS 5 TO 6	MEAN	21 d	21	20	20
	S.D.	3	2	3	2
	N	21	19	20	22
DAYS 6 TO 9	MEAN	22 d	22	22	22
	S.D.	2	2	3	2
	N	21	19	20	22
DAYS 9 TO 12	MEAN	24 d	24	24	23
	S.D.	2	3	3	2
	N	21	19	20	22
DAYS 12 TO 15	MEAN	25 d	25	25	24
	S.D.	2	3	3	2
	N	21	19	20	22
DAYS 15 TO 18	MEAN	27 d	27	28	26
	S.D.	3	3	4	3
	N	21	19	20	22
DAYS 18 TO 19	MEAN	28 d	28	28	26
	S.D.	4	5	3	3
	N	21	19	20	22
DAYS 19 TO 20	MEAN	25 d	25	26	24
	S.D.	3	3	4	3
	N	21	19	20	22

Statistical key: d=ANOVA + Dunnett-test

Table: 7

**SUMMARY OF NECROPSY OBSERVATIONS**

Dose: (mg/kg/day)		0	250	500	1000
FEMALES	N	24	24	24	24
PLACENTA/ENVELOP	N	0	0	1	0
PLACENTA: ENLARGED PLACENTA(S)	N	0 f	0	1	0
	%	0.0	0.0	4.2	0.0
NO REMARKABLE OBSERVATIONS		24	24	23	24

Statistical key: f=Fishers exact test

Table: 8

**HYSTERECTOMY DATA (Summary table)**

Dose: (mg/kg/day)		0	250	500	1000
Pregnant Females Alive at Term	N	21	19	20	22
with Total Resorptions	N	0	0	0	0
with all Dead Fetuses	N	0	0	0	0
with Live Fetuses	N	21	19	20	22
Corpora Lutea	TOTAL	317	278	303	326
No. per animal	MEAN	15.1 d	14.6	15.1	14.8
	S.D.	2.1	2.7	2.5	2.9
Implantation Sites	TOTAL	269	242	265	279
No. per animal	MEAN	12.8 d	12.7	13.3	12.7
	S.D.	3.6	1.4	2.1	1.7
Preimplantation Loss	TOTAL	48 f	36	38	47
	%	15.1	12.9	12.5	14.4
Fetuses	N	255	226	246	258
No. per animal	MEAN	12.1 d	11.9	12.3	11.7
	S.D.	3.8	1.3	2.1	1.8
Alive	%	100.0	100.0	100.0	100.0
Dead	%	0.0	0.0	0.0	0.0
Live Fetuses	N	255 f	226	246	258
% of implantation sites		94.8	93.4	92.8	92.5
No. per animal	MEAN	12.1 d	11.9	12.3	11.7
	S.D.	3.8	1.3	2.1	1.8
Dead Fetuses	N	0 f	0	0	0
% of implantation sites		0.0	0.0	0.0	0.0
No. per animal	MEAN	0.0	0.0	0.0	0.0
	S.D.	0.0	0.0	0.0	0.0

Statistical key: d=ANOVA + Dunnett-test    f=Fishers exact test

Table: 8 (continued)

**HYSTERECTOMY DATA (Summary table)**

Dose: (mg/kg/day)		0	250	500	1000
Resorptions + Scars	N	14 f	16	19	21
% of implantation sites		5.2	6.6	7.2	7.5
No. per animal	MEAN	0.7 d	0.8	0.9	1.0
	S.D.	1.1	1.0	1.2	1.2
Implant Scars	N	0 f	0	0	0
% of implantation sites		0.0	0.0	0.0	0.0
No. per animal	MEAN	0.0	0.0	0.0	0.0
	S.D.	0.0	0.0	0.0	0.0
Resorptions: early	N	13 f	14	18	21
% of implantation sites		4.8	5.8	6.8	7.5
No. per animal	MEAN	0.6 d	0.7	0.9	1.0
	S.D.	1.1	0.9	1.2	1.2
Resorptions: late	N	1 f	2	1	0
% of implantation sites		0.4	0.8	0.4	0.0
No. per animal	MEAN	0.0 d	0.1	0.1	0.0
	S.D.	0.2	0.3	0.2	0.0
Postimplantation Loss	TOTAL	14 f	16	19	21
% of implantation sites		5.2	6.6	7.2	7.5
No. per animal	MEAN	0.7 d	0.8	0.9	1.0
	S.D.	1.1	1.0	1.2	1.2
Male Fetuses	N	104 f	121**	120	122
	%	40.8	53.5	48.8	47.3
Female Fetuses	N	151 f	105**	126	136
	%	59.2	46.5	51.2	52.7
Fetal Body Weight (g)	MEAN	3.81 d	3.92	3.83	3.79
	S.D.	0.54	0.31	0.32	0.34
Male Fetuses	MEAN	3.92 d	4.03	3.94	3.91
	S.D.	0.58	0.32	0.35	0.33
Female Fetuses	MEAN	3.77 d	3.82	3.75	3.66
	S.D.	0.50	0.33	0.32	0.39

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test \*\* = p<0.01

Table: 9

**SUMMARY OF FETAL EXTERNAL MALFORMATIONS**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	255	226	246	258
Live	N	255	226	246	258
Dead	N	0	0	0	0
<b>TRUNK</b>					
Litter Incidence	N	0	1	0	0
Fetal Incidence	N	0	1	0	0
<b>UMBILICAL HERNIA</b>					
Fetal Incidence	N	0 f	1	0	0
	%	0.0	0.4	0.0	0.0
Litter Incidence	N	0 f	1	0	0
	%	0.0	5.3	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	0.5	0.0	0.0
	S.D.	0.0	2.1	0.0	0.0
<b>TOTAL FETAL EXTERNAL MALFORMATIONS</b>					
Fetal Incidence	N	0 f	1	0	0
	%	0.0	0.4	0.0	0.0
Litter Incidence	N	0 f	1	0	0
	%	0.0	5.3	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	0.5	0.0	0.0
	S.D.	0.0	2.1	0.0	0.0

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test

Table: 10

**SUMMARY OF FETAL EXTERNAL VARIATIONS**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	255	226	246	258
Live	N	255	226	246	258
Dead	N	0	0	0	0
<b>TAIL</b>					
Litter Incidence	N	0	1	0	0
Fetal Incidence	N	0	1	0	0
<b>BENT TAIL</b>					
Fetal Incidence	N	0 f	1	0	0
	%	0.0	0.4	0.0	0.0
Litter Incidence	N	0 f	1	0	0
	%	0.0	5.3	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	0.5	0.0	0.0
	S.D.	0.0	2.1	0.0	0.0
<b>TOTAL FETAL EXTERNAL VARIATIONS</b>					
Fetal Incidence	N	0 f	1	0	0
	%	0.0	0.4	0.0	0.0
Litter Incidence	N	0 f	1	0	0
	%	0.0	5.3	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	0.5	0.0	0.0
	S.D.	0.0	2.1	0.0	0.0

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test



Table: 11

**SUMMARY OF FETAL SOFT TISSUE MALFORMATIONS**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	20	19	20	22
Fetuses Evaluated	N	120	109	116	122
<b>KIDNEYS</b>					
Litter Incidence	N	0	0	0	1
Fetal Incidence	N	0	0	0	1
<b>ABSENT KIDNEY</b>					
Fetal Incidence	N	0 f	0	0	1
	%	0.0	0.0	0.0	0.8
Litter Incidence	N	0 f	0	0	1
	%	0.0	0.0	0.0	4.5
Affected Fetuses/Litter	MEAN%	0.0 d	0.0	0.0	0.8
	S.D.	0.0	0.0	0.0	3.6
<b>ADRENAL GLANDS</b>					
Litter Incidence	N	0	0	0	1
Fetal Incidence	N	0	0	0	1
<b>ABSENT ADRENAL</b>					
Fetal Incidence	N	0 f	0	0	1
	%	0.0	0.0	0.0	0.8
Litter Incidence	N	0 f	0	0	1
	%	0.0	0.0	0.0	4.5
Affected Fetuses/Litter	MEAN%	0.0 d	0.0	0.0	0.8
	S.D.	0.0	0.0	0.0	3.6
<b>URETER</b>					
Litter Incidence	N	0	0	0	1
Fetal Incidence	N	0	0	0	1
Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test					

Table: 11 (continued)

**SUMMARY OF FETAL SOFT TISSUE MALFORMATIONS**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	20	19	20	22
Fetuses Evaluated	N	120	109	116	122
<b>ABSENT URETER</b>					
Fetal Incidence	N	0 f	0	0	1
	%	0.0	0.0	0.0	0.8
Litter Incidence	N	0 f	0	0	1
	%	0.0	0.0	0.0	4.5
Affected Fetuses/Litter	MEAN%	0.0 d	0.0	0.0	0.8
	S.D.	0.0	0.0	0.0	3.6
<b>TOTAL FETAL SOFT TISSUE MALFORMATIONS</b>					
Fetal Incidence	N	0 f	0	0	1
	%	0.0	0.0	0.0	0.8
Litter Incidence	N	0 f	0	0	1
	%	0.0	0.0	0.0	4.5
Affected Fetuses/Litter	MEAN%	0.0 d	0.0	0.0	0.8
	S.D.	0.0	0.0	0.0	3.6

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test

Table: 12

**SUMMARY OF FETAL SOFT TISSUE VARIATIONS**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	20	19	20	22
Fetuses Evaluated	N	120	109	116	122
<b>KIDNEYS</b>					
Litter Incidence	N	0	1	0	2
Fetal Incidence	N	0	1	0	2
<b>DILATED RENAL PELVIS</b>					
Fetal Incidence	N	0 f	1	0	1
	%	0.0	0.9	0.0	0.8
Litter Incidence	N	0 f	1	0	1
	%	0.0	5.3	0.0	4.5
Affected Fetuses/Litter	MEAN%	0.0 d	0.9	0.0	0.8
	S.D.	0.0	3.8	0.0	3.6
<b>ENLARGED KIDNEY</b>					
Fetal Incidence	N	0 f	0	0	1
	%	0.0	0.0	0.0	0.8
Litter Incidence	N	0 f	0	0	1
	%	0.0	0.0	0.0	4.5
Affected Fetuses/Litter	MEAN%	0.0 d	0.0	0.0	0.8
	S.D.	0.0	0.0	0.0	3.6
<b>UTERUS</b>					
Litter Incidence	N	0	0	1	0
Fetal Incidence	N	0	0	1	0
<b>SHORT UTERINE HORN</b>					
Fetal Incidence	N	0 f	0	1	0
	%	0.0	0.0	0.9	0.0
Litter Incidence	N	0 f	0	1	0
	%	0.0	0.0	5.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	0.0	1.3	0.0
	S.D.	0.0	0.0	5.6	0.0

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test

Table: 12 (continued)

**SUMMARY OF FETAL SOFT TISSUE VARIATIONS**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	20	19	20	22
Fetuses Evaluated	N	120	109	116	122
<b>URETER</b>					
Litter Incidence	N	1	1	0	1
Fetal Incidence	N	1	1	0	1
<b>DILATED URETER</b>					
Fetal Incidence	N	1 f	1	0	1
	%	0.8	0.9	0.0	0.8
Litter Incidence	N	1 f	1	0	1
	%	5.0	5.3	0.0	4.5
Affected Fetuses/Litter	MEAN%	1.0 d	1.1	0.0	0.8
	S.D.	4.5	4.6	0.0	3.6
<b>TOTAL FETAL SOFT TISSUE VARIATIONS</b>					
Fetal Incidence	N	1 f	2	1	3
	%	0.8	1.8	0.9	2.5
Litter Incidence	N	1 f	2	1	3
	%	5.0	10.5	5.0	13.6
Affected Fetuses/Litter	MEAN%	1.0 d	1.9	1.3	2.3
	S.D.	4.5	5.8	5.6	5.9

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test

Table: 13

**SUMMARY OF FETAL SKELETAL MALFORMATIONS**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	135	117	130	136
<b>THORACIC VERT.</b>					
Litter Incidence	N	0	0	0	1
Fetal Incidence	N	0	0	0	1
<b>ABSENT THORACIC VERTEBRA (E)</b>					
Fetal Incidence	N	0 f	0	0	1
	%	0.0	0.0	0.0	0.7
Litter Incidence	N	0 f	0	0	1
	%	0.0	0.0	0.0	4.5
Affected Fetuses/Litter	MEAN%	0.0 d	0.0	0.0	0.9
	S.D.	0.0	0.0	0.0	4.3
<b>SACRAL VERT.</b>					
Litter Incidence	N	0	1	0	0
Fetal Incidence	N	0	1	0	0
<b>MISSHAPEN SACRAL VERTEBRA (E)</b>					
Fetal Incidence	N	0 f	1	0	0
	%	0.0	0.9	0.0	0.0
Litter Incidence	N	0 f	1	0	0
	%	0.0	5.3	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	0.9	0.0	0.0
	S.D.	0.0	3.8	0.0	0.0
<b>STERNEBRA</b>					
Litter Incidence	N	1	1	0	0
Fetal Incidence	N	1	1	0	0

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test

Table: 13 (continued)

**SUMMARY OF FETAL SKELETAL MALFORMATIONS**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	135	117	130	136
<b>MISALIGNED STERNEBRA (E)</b>					
Fetal Incidence	N	1 f	0	0	0
	%	0.7	0.0	0.0	0.0
Litter Incidence	N	1 f	0	0	0
	%	4.8	0.0	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.7 d	0.0	0.0	0.0
	S.D.	3.1	0.0	0.0	0.0
<b>SPLITTED STERNEBRA (E)</b>					
Fetal Incidence	N	0 f	1	0	0
	%	0.0	0.9	0.0	0.0
Litter Incidence	N	0 f	1	0	0
	%	0.0	5.3	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	0.9	0.0	0.0
	S.D.	0.0	3.8	0.0	0.0
<b>RIB</b>					
----					
Litter Incidence	N	0	2	0	2
Fetal Incidence	N	0	2	0	2
<b>ABSENT RIB(S)</b>					
Fetal Incidence	N	0 f	0	0	2
	%	0.0	0.0	0.0	1.5
Litter Incidence	N	0 f	0	0	2
	%	0.0	0.0	0.0	9.1
Affected Fetuses/Litter	MEAN%	0.0 d	0.0	0.0	1.6
	S.D.	0.0	0.0	0.0	5.1

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test

Table: 13 (continued)

**SUMMARY OF FETAL SKELETAL MALFORMATIONS**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	135	117	130	136
<b>FUSED RIBS</b>					
Fetal Incidence	N	0 f	2	0	0
	%	0.0	1.7	0.0	0.0
Litter Incidence	N	0 f	2	0	0
	%	0.0	10.5	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	1.8	0.0	0.0
	S.D.	0.0	5.3	0.0	0.0
<b>PELVIS</b>					
-----					
Litter Incidence	N	0	0	1	0
Fetal Incidence	N	0	0	1	0
<b>MISSHAPEN ILIUM</b>					
Fetal Incidence	N	0 f	0	1	0
	%	0.0	0.0	0.8	0.0
Litter Incidence	N	0 f	0	1	0
	%	0.0	0.0	5.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	0.0	0.8	0.0
	S.D.	0.0	0.0	3.7	0.0
<b>TOTAL FETAL SKELETAL MALFORMATIONS</b>					
Fetal Incidence	N	1 f	2	1	2
	%	0.7	1.7	0.8	1.5
Litter Incidence	N	1 f	2	1	2
	%	4.8	10.5	5.0	9.1
Affected Fetuses/Litter	MEAN%	0.7 d	1.8	0.8	1.6
	S.D.	3.1	5.3	3.7	5.1

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test

Table: 14

**SUMMARY OF FETAL SKELETAL VARIATIONS**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	135	117	130	136
<b>HEAD-SKULL</b>					
Litter Incidence	N	1	4	2	4
Fetal Incidence	N	3	6	4	8
<b>INCOMPLETE OSSIFICATION OF INTERPARIETAL</b>					
Fetal Incidence	N	2 f	4	2	6
	%	1.5	3.4	1.5	4.4
Litter Incidence	N	1 f	4	1	3
	%	4.8	21.1	5.0	13.6
Affected Fetuses/Litter	MEAN%	1.2 d	3.6	2.0	4.6
	S.D.	5.5	7.1	8.9	12.1
<b>INCOMPLETE OSSIFICATION OF SUPRAOCCIPITAL</b>					
Fetal Incidence	N	2 f	0	0	2
	%	1.5	0.0	0.0	1.5
Litter Incidence	N	1 f	0	0	1
	%	4.8	0.0	0.0	4.5
Affected Fetuses/Litter	MEAN%	1.2 d	0.0	0.0	1.5
	S.D.	5.5	0.0	0.0	7.1
<b>INCOMPLETE OSSIFICATION OF FRONTAL</b>					
Fetal Incidence	N	0 f	2	4	2
	%	0.0	1.7	3.1	1.5
Litter Incidence	N	0 f	1	2	1
	%	0.0	5.3	10.0	4.5
Affected Fetuses/Litter	MEAN%	0.0 d	1.8	3.8	1.8
	S.D.	0.0	7.6	13.7	8.5
Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test					



Table: 14 (continued)

**SUMMARY OF FETAL SKELETAL VARIATIONS**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	135	117	130	136
INCOMPLETE OSSIFICATION OF PARIETAL					
Fetal Incidence	N	0 f	0	1	1
	%	0.0	0.0	0.8	0.7
Litter Incidence	N	0 f	0	1	1
	%	0.0	0.0	5.0	4.5
Affected Fetuses/Litter	MEAN%	0.0 d	0.0	1.0	0.9
	S.D.	0.0	0.0	4.5	4.3
HEAD-OTHERS					
Litter Incidence	N	3	3	1	2
Fetal Incidence	N	7	4	1	2
INCOMPLETE OSSIFICATION OF HYOID					
Fetal Incidence	N	3 f	3	0	2
	%	2.2	2.6	0.0	1.5
Litter Incidence	N	2 f	3	0	2
	%	9.5	15.8	0.0	9.1
Affected Fetuses/Litter	MEAN%	1.9 d	2.7	0.0	1.5
	S.D.	6.1	6.4	0.0	4.9
UNOSSIFIED HYOID					
Fetal Incidence	N	4 f	1	1	0
	%	3.0	0.9	0.8	0.0
Litter Incidence	N	2 f	1	1	0
	%	9.5	5.3	5.0	0.0
Affected Fetuses/Litter	MEAN%	2.6 d	0.9	0.8	0.0
	S.D.	8.8	3.8	3.7	0.0

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test

Table: 14 (continued)

**SUMMARY OF FETAL SKELETAL VARIATIONS**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	135	117	130	136
<b>CERVICAL VERT.</b>					
-----					
Litter Incidence	N	0	1	0	0
Fetal Incidence	N	0	1	0	0
<b>UNOSSIFIED CERVICAL VERTEBRA(E)</b>					
Fetal Incidence	N	0 f	1	0	0
	%	0.0	0.9	0.0	0.0
Litter Incidence	N	0 f	1	0	0
	%	0.0	5.3	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	0.9	0.0	0.0
	S.D.	0.0	3.8	0.0	0.0
<b>THORACIC VERT.</b>					
-----					
Litter Incidence	N	7	11	4	10
Fetal Incidence	N	12	18	4	15
<b>INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E)</b>					
Fetal Incidence	N	11 f	16	4	14
	%	8.1	13.7	3.1	10.3
Litter Incidence	N	7 f	10	4	9
	%	33.3	52.6	20.0	40.9
Affected Fetuses/Litter	MEAN%	6.9 d	14.9	3.3	11.2
	S.D.	14.3	19.4	6.8	15.9
<b>THORACIC VERTEBRA(E) : BIPARTITE OSSIFICATION OF CENTRUM</b>					
Fetal Incidence	N	1 f	5	0	1
	%	0.7	4.3	0.0	0.7
Litter Incidence	N	1 f	5	0	1
	%	4.8	26.3	0.0	4.5
Affected Fetuses/Litter	MEAN%	0.7 d	4.1*	0.0	0.6
	S.D.	3.1	7.1	0.0	3.0

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test \* = p<0.05

Table: 14 (continued)

**SUMMARY OF FETAL SKELETAL VARIATIONS**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	135	117	130	136
UNOSSIFIED THORACIC VERTEBRA(E)					
Fetal Incidence	N	0 f	2	0	0
	%	0.0	1.7	0.0	0.0
Litter Incidence	N	0 f	2	0	0
	%	0.0	10.5	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	1.8	0.0	0.0
	S.D.	0.0	5.3	0.0	0.0
THORACIC VERTEBRA(E) : UNOSSIFIED HEMI-CENTRUM					
Fetal Incidence	N	0 f	1	0	0
	%	0.0	0.9	0.0	0.0
Litter Incidence	N	0 f	1	0	0
	%	0.0	5.3	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	0.9	0.0	0.0
	S.D.	0.0	3.8	0.0	0.0
LUMBAR VERT.					
Litter Incidence	N	0	1	1	0
Fetal Incidence	N	0	1	1	0
INCOMPLETE OSSIFICATION OF LUMBAR VERTEBRA(E)					
Fetal Incidence	N	0 f	0	1	0
	%	0.0	0.0	0.8	0.0
Litter Incidence	N	0 f	0	1	0
	%	0.0	0.0	5.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	0.0	0.8	0.0
	S.D.	0.0	0.0	3.7	0.0

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test

Table: 14 (continued)

**SUMMARY OF FETAL SKELETAL VARIATIONS**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	135	117	130	136
<b>LUMBAR VERTEBRA (E) : UNOSSIFIED HEMICENTRUM</b>					
Fetal Incidence	N	0 f	1	0	0
	%	0.0	0.9	0.0	0.0
Litter Incidence	N	0 f	1	0	0
	%	0.0	5.3	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	0.9	0.0	0.0
	S.D.	0.0	3.8	0.0	0.0
<b>SACRAL VERT.</b>					
Litter Incidence	N	1	1	2	0
Fetal Incidence	N	8	1	2	0
<b>INCOMPLETE OSSIFICATION OF SACRAL VERTEBRA (E)</b>					
Fetal Incidence	N	8 f	0	2	0
	%	5.9	0.0	1.5	0.0
Litter Incidence	N	1 f	0	2	0
	%	4.8	0.0	10.0	0.0
Affected Fetuses/Litter	MEAN%	4.8 d	0.0	1.8	0.0
	S.D.	21.8	0.0	5.7	0.0
<b>UNOSSIFIED SACRAL VERTEBRA (E)</b>					
Fetal Incidence	N	3 f	1	1	0
	%	2.2	0.9	0.8	0.0
Litter Incidence	N	1 f	1	1	0
	%	4.8	5.3	5.0	0.0
Affected Fetuses/Litter	MEAN%	1.8 d	0.9	0.8	0.0
	S.D.	8.2	3.8	3.7	0.0

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test

Table: 14 (continued)

**SUMMARY OF FETAL SKELETAL VARIATIONS**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	135	117	130	136
<b>CAUDAL VERT.</b>					
Litter Incidence	N	3	2	2	1
Fetal Incidence	N	10	4	2	1
<b>UNOSSIFIED CAUDAL VERTEBRA (E)</b>					
Fetal Incidence	N	10 f	4	2	1
	%	7.4	3.4	1.5	0.7
Litter Incidence	N	3 f	2	2	1
	%	14.3	10.5	10.0	4.5
Affected Fetuses/Litter	MEAN%	10.1 d	3.1	1.7	0.9
	S.D.	30.0	10.3	5.1	4.3
<b>INCOMPLETE OSSIFICATION OF CAUDAL VERTEBRA (E)</b>					
Fetal Incidence	N	0 f	2	0	0
	%	0.0	1.7	0.0	0.0
Litter Incidence	N	0 f	1	0	0
	%	0.0	5.3	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	1.5	0.0	0.0
	S.D.	0.0	6.6	0.0	0.0
<b>STERNEBRA</b>					
Litter Incidence	N	21	19	20	22
Fetal Incidence	N	123	99	116	104
<b>INCOMPLETE OSSIFICATION OF 5th STERNEBRA</b>					
Fetal Incidence	N	93 f	70	76	61
	%	68.9	59.8	58.5	44.9
Litter Incidence	N	19 f	19	19	21
	%	90.5	100.0	95.0	95.5
Affected Fetuses/Litter	MEAN%	68.2 d	59.7	56.4	45.2
	S.D.	34.9	23.5	31.1	22.1

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test

Table: 14 (continued)

**SUMMARY OF FETAL SKELETAL VARIATIONS**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	135	117	130	136
INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E)					
Fetal Incidence	N	38 f	28	33	29
	%	28.1	23.9	25.4	21.3
Litter Incidence	N	13 f	14	14	13
	%	61.9	73.7	70.0	59.1
Affected Fetuses/Litter	MEAN%	24.8 d	23.6	26.2	21.4
	S.D.	30.0	20.8	24.2	23.7
UNOSSIFIED 5th STERNEBRA					
Fetal Incidence	N	26 f	19	36	36
	%	19.3	16.2	27.7	26.5
Litter Incidence	N	10 f	10	15	14
	%	47.6	52.6	75.0	63.6
Affected Fetuses/Litter	MEAN%	20.9 d	15.3	28.8	27.0
	S.D.	34.7	22.0	25.9	28.9
UNOSSIFIED 6th STERNEBRA					
Fetal Incidence	N	13 f	10	10	8
	%	9.6	8.5	7.7	5.9
Litter Incidence	N	6 f	5	7	5
	%	28.6	26.3	35.0	22.7
Affected Fetuses/Litter	MEAN%	12.1 d	8.4	8.3	6.0
	S.D.	29.7	18.0	15.8	15.0
INCOMPLETE OSSIFICATION OF 6th STERNEBRA					
Fetal Incidence	N	63 f	51	64	57
	%	46.7	43.6	49.2	41.9
Litter Incidence	N	15 f	17	17	18
	%	71.4	89.5	85.0	81.8
Affected Fetuses/Litter	MEAN%	43.7 d	43.5	49.4	42.6
	S.D.	30.1	28.4	33.9	31.3

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test

Table: 14 (continued)

**SUMMARY OF FETAL SKELETAL VARIATIONS**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	135	117	130	136
UNOSSIFIED 1st TO 4th STERNEBRA (E)					
Fetal Incidence	N	8 f	1	1	0
	%	5.9	0.9	0.8	0.0
Litter Incidence	N	1 f	1	1	0
	%	4.8	5.3	5.0	0.0
Affected Fetuses/Litter	MEAN%	4.8 d	0.9	0.8	0.0
	S.D.	21.8	3.8	3.7	0.0
RIB					
----					
Litter Incidence	N	0	2	1	3
Fetal Incidence	N	0	3	2	4
INCOMPLETE OSSIFICATION OF RIB(S)					
Fetal Incidence	N	0 f	0	1	2
	%	0.0	0.0	0.8	1.5
Litter Incidence	N	0 f	0	1	2
	%	0.0	0.0	5.0	9.1
Affected Fetuses/Litter	MEAN%	0.0 d	0.0	0.7	1.7
	S.D.	0.0	0.0	3.2	5.4
SHORT RIB(S)					
Fetal Incidence	N	0 f	1	1	2
	%	0.0	0.9	0.8	1.5
Litter Incidence	N	0 f	1	1	1
	%	0.0	5.3	5.0	4.5
Affected Fetuses/Litter	MEAN%	0.0 d	0.8	0.7	1.8
	S.D.	0.0	3.3	3.2	8.5

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test

Table: 14 (continued)

**SUMMARY OF FETAL SKELETAL VARIATIONS**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	135	117	130	136
<b>WAVY RIB(S)</b>					
Fetal Incidence	N	0 f	2	0	0
	%	0.0	1.7	0.0	0.0
Litter Incidence	N	0 f	1	0	0
	%	0.0	5.3	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	1.5	0.0	0.0
	S.D.	0.0	6.6	0.0	0.0
<b>METACARPAL BONE</b>					
Litter Incidence	N	9	10	9	12
Fetal Incidence	N	27	21	24	43
<b>UNOSSIFIED 4th METACARPAL(S)</b>					
Fetal Incidence	N	27 f	21	24	43*
	%	20.0	17.9	18.5	31.6
Litter Incidence	N	9 f	10	9	12
	%	42.9	52.6	45.0	54.5
Affected Fetuses/Litter	MEAN%	21.4 d	18.2	20.4	32.4
	S.D.	32.5	26.5	33.1	36.0
<b>INCOMPLETE OSSIFICATION OF 1st TO 3rd METACARPALS</b>					
Fetal Incidence	N	8 f	1	1	0
	%	5.9	0.9	0.8	0.0
Litter Incidence	N	1 f	1	1	0
	%	4.8	5.3	5.0	0.0
Affected Fetuses/Litter	MEAN%	4.8 d	0.9	0.8	0.0
	S.D.	21.8	3.8	3.7	0.0

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test \* = p<0.05



Table: 14 (continued)

**SUMMARY OF FETAL SKELETAL VARIATIONS**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	135	117	130	136
UNOSSIFIED 1st TO 3rd METACARPALS					
Fetal Incidence	N	6 f	0	1	0
	%	4.4	0.0	0.8	0.0
Litter Incidence	N	1 f	0	1	0
	%	4.8	0.0	5.0	0.0
Affected Fetuses/Litter	MEAN%	3.6 d	0.0	0.8	0.0
	S.D.	16.4	0.0	3.7	0.0
METATARSAL BONE					
Litter Incidence	N	1	2	1	1
Fetal Incidence	N	7	3	1	1
INCOMPLETE OSSIFICATION OF METATARSAL(S)					
Fetal Incidence	N	3 f	2	1	1
	%	2.2	1.7	0.8	0.7
Litter Incidence	N	1 f	1	1	1
	%	4.8	5.3	5.0	4.5
Affected Fetuses/Litter	MEAN%	1.8 d	1.5	0.8	0.9
	S.D.	8.2	6.6	3.7	4.3
UNOSSIFIED METATARSAL(S)					
Fetal Incidence	N	6 f	1	1	0
	%	4.4	0.9	0.8	0.0
Litter Incidence	N	1 f	1	1	0
	%	4.8	5.3	5.0	0.0
Affected Fetuses/Litter	MEAN%	3.6 d	0.9	0.8	0.0
	S.D.	16.4	3.8	3.7	0.0

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test

Table: 14 (continued)

**SUMMARY OF FETAL SKELETAL VARIATIONS**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	135	117	130	136
<b>PELVIS</b>					
Litter Incidence	N	2	3	3	1
Fetal Incidence	N	9	3	3	1
<b>INCOMPLETE OSSIFICATION OF PUBIS</b>					
Fetal Incidence	N	1 f	3	2	1
	%	0.7	2.6	1.5	0.7
Litter Incidence	N	1 f	3	2	1
	%	4.8	15.8	10.0	4.5
Affected Fetuses/Litter	MEAN%	0.5 d	2.7	1.8	0.9
	S.D.	2.4	6.4	5.7	4.3
<b>UNOSSIFIED PUBIS</b>					
Fetal Incidence	N	8 f	0	1	0
	%	5.9	0.0	0.8	0.0
Litter Incidence	N	1 f	0	1	0
	%	4.8	0.0	5.0	0.0
Affected Fetuses/Litter	MEAN%	4.8 d	0.0	0.8	0.0
	S.D.	21.8	0.0	3.7	0.0
<b>INCOMPLETE OSSIFICATION OF ISCHIUM</b>					
Fetal Incidence	N	8 f	0	0	0
	%	5.9	0.0	0.0	0.0
Litter Incidence	N	1 f	0	0	0
	%	4.8	0.0	0.0	0.0
Affected Fetuses/Litter	MEAN%	4.8 d	0.0	0.0	0.0
	S.D.	21.8	0.0	0.0	0.0

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test

Table: 14 (continued)

**SUMMARY OF FETAL SKELETAL VARIATIONS**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	135	117	130	136
<b>UNOSSIFIED ISCHIUM</b>					
Fetal Incidence	N	0 f	0	1	0
	%	0.0	0.0	0.8	0.0
Litter Incidence	N	0 f	0	1	0
	%	0.0	0.0	5.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	0.0	0.8	0.0
	S.D.	0.0	0.0	3.7	0.0
<b>SPINE</b>					
-----					
Litter Incidence	N	0	0	0	1
Fetal Incidence	N	0	0	0	1
<b>PRESENCE OF 25 PRE-SACRAL VERTEBRAE</b>					
Fetal Incidence	N	0 f	0	0	1
	%	0.0	0.0	0.0	0.7
Litter Incidence	N	0 f	0	0	1
	%	0.0	0.0	0.0	4.5
Affected Fetuses/Litter	MEAN%	0.0 d	0.0	0.0	0.9
	S.D.	0.0	0.0	0.0	4.3
<b>TOTAL FETAL SKELETAL VARIATIONS</b>					
Fetal Incidence	N	125 f	101	116	112
	%	92.6	86.3	89.2	82.4
Litter Incidence	N	21 f	19	20	22
	%	100.0	100.0	100.0	100.0
Affected Fetuses/Litter	MEAN%	93.5 d	85.8	88.9	83.3
	S.D.	16.3	21.9	23.0	21.8

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test

Table: 15

**SUMMARY OF FETAL SKELETAL CARTILAGE**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	135	117	130	136
<b>HEAD-SKULL</b>					
Litter Incidence	N	1	0	0	1
Fetal Incidence	N	2	0	0	2
<b>CARTILAGE OF SUPRACCIPIITAL: PRESENT</b>					
Fetal Incidence	N	2 f	0	0	2
	%	1.5	0.0	0.0	1.5
Litter Incidence	N	1 f	0	0	1
	%	4.8	0.0	0.0	4.5
Affected Fetuses/Litter	MEAN%	1.2 d	0.0	0.0	1.5
	S.D.	5.5	0.0	0.0	7.1
<b>HEAD-OTHERS</b>					
Litter Incidence	N	3	3	1	2
Fetal Incidence	N	7	4	1	2
<b>CARTILAGE OF HYOID: PRESENT</b>					
Fetal Incidence	N	7 f	4	1	2
	%	5.2	3.4	0.8	1.5
Litter Incidence	N	3 f	3	1	2
	%	14.3	15.8	5.0	9.1
Affected Fetuses/Litter	MEAN%	4.5 d	3.6	0.8	1.5
	S.D.	14.1	9.1	3.7	4.9
<b>CERVICAL VERT.</b>					
Litter Incidence	N	0	1	0	0
Fetal Incidence	N	0	1	0	0
Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test					

Table: 15 (continued)

**SUMMARY OF FETAL SKELETAL CARTILAGE**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	135	117	130	136
CARTILAGE OF CERVICAL VERTEBRA(E): FUSED					
Fetal Incidence	N	0 f	1	0	0
	%	0.0	0.9	0.0	0.0
Litter Incidence	N	0 f	1	0	0
	%	0.0	5.3	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	0.9	0.0	0.0
	S.D.	0.0	3.8	0.0	0.0
CARTILAGE OF CERVICAL VERTEBRA(E): ABSENT					
Fetal Incidence	N	0 f	1	0	0
	%	0.0	0.9	0.0	0.0
Litter Incidence	N	0 f	1	0	0
	%	0.0	5.3	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	0.9	0.0	0.0
	S.D.	0.0	3.8	0.0	0.0
CARTILAGE OF CERVICAL VERTEBRA(E): SPLITTED					
Fetal Incidence	N	0 f	1	0	0
	%	0.0	0.9	0.0	0.0
Litter Incidence	N	0 f	1	0	0
	%	0.0	5.3	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	0.9	0.0	0.0
	S.D.	0.0	3.8	0.0	0.0
THORACIC VERT.					
Litter Incidence	N	7	11	4	10
Fetal Incidence	N	12	18	4	15

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test

Table: 15 (continued)

**SUMMARY OF FETAL SKELETAL CARTILAGE**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	135	117	130	136
CARTILAGE OF THORACIC VERTEBRA(E): PRESENT					
Fetal Incidence	N	12 f	17	4	15
	%	8.9	14.5	3.1	11.0
Litter Incidence	N	7 f	11	4	10
	%	33.3	57.9	20.0	45.5
Affected Fetuses/Litter	MEAN%	7.6 d	15.6	3.3	11.8
	S.D.	15.0	19.1	6.8	15.7
CARTILAGE OF THORACIC VERTEBRA(E): ABSENT					
Fetal Incidence	N	0 f	1	0	0
	%	0.0	0.9	0.0	0.0
Litter Incidence	N	0 f	1	0	0
	%	0.0	5.3	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	0.9	0.0	0.0
	S.D.	0.0	3.8	0.0	0.0
CARTILAGE OF THORACIC VERTEBRA(E): MISSHAPEN					
Fetal Incidence	N	0 f	2	0	0
	%	0.0	1.7	0.0	0.0
Litter Incidence	N	0 f	2	0	0
	%	0.0	10.5	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	1.6	0.0	0.0
	S.D.	0.0	4.9	0.0	0.0
CARTILAGE OF THORACIC VERTEBRA(E): FUSED					
Fetal Incidence	N	0 f	1	0	0
	%	0.0	0.9	0.0	0.0
Litter Incidence	N	0 f	1	0	0
	%	0.0	5.3	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	0.9	0.0	0.0
	S.D.	0.0	3.8	0.0	0.0

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test

Table: 15 (continued)

**SUMMARY OF FETAL SKELETAL CARTILAGE**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	135	117	130	136
CARTILAGE OF THORACIC VERTEBRA(E) : BIPARTITE					
Fetal Incidence	N	0 f	1	0	0
	%	0.0	0.9	0.0	0.0
Litter Incidence	N	0 f	1	0	0
	%	0.0	5.3	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	0.9	0.0	0.0
	S.D.	0.0	3.8	0.0	0.0
CARTILAGE OF THORACIC VERTEBRA(E) : MISALIGNED					
Fetal Incidence	N	0 f	1	0	0
	%	0.0	0.9	0.0	0.0
Litter Incidence	N	0 f	1	0	0
	%	0.0	5.3	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	0.9	0.0	0.0
	S.D.	0.0	3.8	0.0	0.0
CARTILAGE OF THORACIC VERTEBRA(E) : SPLITTED					
Fetal Incidence	N	0 f	2	0	0
	%	0.0	1.7	0.0	0.0
Litter Incidence	N	0 f	2	0	0
	%	0.0	10.5	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	1.8	0.0	0.0
	S.D.	0.0	5.3	0.0	0.0
LUMBAR VERT.					
Litter Incidence	N	0	1	1	0
Fetal Incidence	N	0	1	1	0

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test

Table: 15 (continued)

**SUMMARY OF FETAL SKELETAL CARTILAGE**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	135	117	130	136
CARTILAGE OF LUMBAR VERTEBRA(E) : PRESENT					
Fetal Incidence	N	0 f	1	1	0
	%	0.0	0.9	0.8	0.0
Litter Incidence	N	0 f	1	1	0
	%	0.0	5.3	5.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	0.9	0.8	0.0
	S.D.	0.0	3.8	3.7	0.0
SACRAL VERT.					
Litter Incidence	N	1	1	2	0
Fetal Incidence	N	8	1	2	0
CARTILAGE OF SACRAL VERTEBRA(E) : PRESENT					
Fetal Incidence	N	8 f	1	2	0
	%	5.9	0.9	1.5	0.0
Litter Incidence	N	1 f	1	2	0
	%	4.8	5.3	10.0	0.0
Affected Fetuses/Litter	MEAN%	4.8 d	0.9	1.8	0.0
	S.D.	21.8	3.8	5.7	0.0
CAUDAL VERT.					
Litter Incidence	N	3	2	2	1
Fetal Incidence	N	10	4	2	1
CARTILAGE OF CAUDAL VERTEBRA(E) : PRESENT					
Fetal Incidence	N	10 f	4	2	1
	%	7.4	3.4	1.5	0.7
Litter Incidence	N	3 f	2	2	1
	%	14.3	10.5	10.0	4.5
Affected Fetuses/Litter	MEAN%	10.1 d	3.1	1.7	0.9
	S.D.	30.0	10.3	5.1	4.3

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test



Table: 15 (continued)

**SUMMARY OF FETAL SKELETAL CARTILAGE**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	135	117	130	136
<b>STERNEBRA</b>					
Litter Incidence	N	21	19	20	22
Fetal Incidence	N	123	98	116	104
<b>CARTILAGE OF STERNEBRA(E) : PRESENT</b>					
Fetal Incidence	N	123 f	98	116	104
	%	91.1	83.8	89.2	76.5
Litter Incidence	N	21 f	19	20	22
	%	100.0	100.0	100.0	100.0
Affected Fetuses/Litter	MEAN%	92.1 d	82.7	88.9	77.3
	S.D.	19.2	23.9	23.0	24.3
<b>RIB</b>					
Litter Incidence	N	0	4	1	3
Fetal Incidence	N	0	5	2	4
<b>CARTILAGE OF RIB(S) : PRESENT</b>					
Fetal Incidence	N	0 f	4*	1	2
	%	0.0	3.4	0.8	1.5
Litter Incidence	N	0 f	3	1	2
	%	0.0	15.8	5.0	9.1
Affected Fetuses/Litter	MEAN%	0.0 d	3.1	0.7	1.8
	S.D.	0.0	7.9	3.2	5.9
<b>CARTILAGE OF RIB(S) : ABSENT</b>					
Fetal Incidence	N	0 f	0	1	2
	%	0.0	0.0	0.8	1.5
Litter Incidence	N	0 f	0	1	2
	%	0.0	0.0	5.0	9.1
Affected Fetuses/Litter	MEAN%	0.0 d	0.0	0.7	1.7
	S.D.	0.0	0.0	3.2	5.4

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test \* = p<0.05

Table: 15 (continued)

**SUMMARY OF FETAL SKELETAL CARTILAGE**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	135	117	130	136
<b>CARTILAGE OF RIB(S) : FUSED</b>					
Fetal Incidence	N	0 f	1	0	0
	%	0.0	0.9	0.0	0.0
Litter Incidence	N	0 f	1	0	0
	%	0.0	5.3	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	0.9	0.0	0.0
	S.D.	0.0	3.8	0.0	0.0
<b>METACARPAL BONE</b>					
Litter Incidence	N	9	10	9	12
Fetal Incidence	N	27	21	24	43
<b>CARTILAGE OF METACARPAL BONE(S) : PRESENT</b>					
Fetal Incidence	N	27 f	21	22	43*
	%	20.0	17.9	16.9	31.6
Litter Incidence	N	9 f	10	8	12
	%	42.9	52.6	40.0	54.5
Affected Fetuses/Litter	MEAN%	21.4 d	18.2	18.7	32.4
	S.D.	32.5	26.5	31.4	36.0
<b>ABSENCE OF CARTILAGE STAINING</b>					
Fetal Incidence	N	0 f	1	2	0
	%	0.0	0.9	1.5	0.0
Litter Incidence	N	0 f	1	2	0
	%	0.0	5.3	10.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	0.9	1.7	0.0
	S.D.	0.0	3.8	5.1	0.0

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test \* = p<0.05

Table: 15 (continued)

**SUMMARY OF FETAL SKELETAL CARTILAGE**

Dose: (mg/kg/day)		0	250	500	1000
Litters Evaluated	N	21	19	20	22
Fetuses Evaluated	N	135	117	130	136
<b>METATARSAL BONE</b>					
Litter Incidence	N	1	2	1	1
Fetal Incidence	N	7	3	1	1
<b>CARTILAGE OF METATARSAL BONE(S) : ABSENT</b>					
Fetal Incidence	N	0 f	1	0	0
	%	0.0	0.9	0.0	0.0
Litter Incidence	N	0 f	1	0	0
	%	0.0	5.3	0.0	0.0
Affected Fetuses/Litter	MEAN%	0.0 d	0.8	0.0	0.0
	S.D.	0.0	3.3	0.0	0.0
<b>CARTILAGE OF METATARSAL BONE(S) : PRESENT</b>					
Fetal Incidence	N	7 f	2	1	1
	%	5.2	1.7	0.8	0.7
Litter Incidence	N	1 f	2	1	1
	%	4.8	10.5	5.0	4.5
Affected Fetuses/Litter	MEAN%	4.2 d	1.6	0.8	0.9
	S.D.	19.1	4.9	3.7	4.3
<b>PELVIS</b>					
Litter Incidence	N	2	3	3	1
Fetal Incidence	N	9	3	3	1
<b>CARTILAGE OF PELVIC GIRDLE: PRESENT</b>					
Fetal Incidence	N	9 f	3	3	1
	%	6.7	2.6	2.3	0.7
Litter Incidence	N	2 f	3	3	1
	%	9.5	15.8	15.0	4.5
Affected Fetuses/Litter	MEAN%	5.3 d	2.7	2.7	0.9
	S.D.	21.8	6.4	6.5	4.3

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test

Table: 15 (continued)

**SUMMARY OF FETAL SKELETAL CARTILAGE**

Dose: (mg/kg/day)		0	250	500	1000
TOTAL FETAL SKELETAL CARTILAGE					
Fetal Incidence	N	125 f	101	116	111
	%	92.6	86.3	89.2	81.6
Litter Incidence	N	21 f	19	20	22
	%	100.0	100.0	100.0	100.0
Affected Fetuses/Litter	MEAN%	93.5 d	85.8	88.9	82.6
	S.D.	16.3	21.9	23.0	22.1

Statistical key: d=ANOVA + Dunnett-test f=Fishers exact test

**APPENDICES**

1. Analytical certificate of the test item

## TOTAL FINA ELF

RAFFINAGE ET MARKETING  
DIRECTION RECHERCHE  
Centre de Recherche de SOLAIZE

Destinataire / To : JP. GENNART (RM/RAF/HSE)

### MEMO

Expéditeur / From : C. CHAMBON

Tél. : 04-78-02-61-70

Fax : 04-78-02-60-89

Date : 26/09/2002

Copies :

Référence : RM/RAF/RECH/CRES/CMA - 2002/403 cc/cc

**OBJET / Subject : Characterization of a purified ETBE sample  
Service request # RM/RAF/RECH/CRES/CMA-2002/365  
(Analyse Shift # B16272)**

In order to study the toxicity of ETBE on the reproduction, the Research Center of Solaize has been requested to characterize a sample of purified ETBE.  
The initial ETBE, supplied by Feyzin Refinery was purified by a subcontractor.

Analysis was done by gas chromatography according to an internal method (reference MA0146). The compounds identification was realised by gas chromatography coupled with a mass spectrometer detector.

As this kind of analysis is not done frequently by the Research Center, the repeatability of the method applied to an ETBE sample is unknown. Also, measurement precision cannot be provided.

The results and the chromatogram obtained are presented in the following pages.

No EtOH presence has been detected by GC-MS : it means that if EtOH is present, its content level is lower than 0.01% mass/mass.

Accessibilité :  
B.P. 22  
69360 - SOLAIZE  
(France)

CONFIDENTIEL

TOTALFINAELF

LIBRE

RM/RAF/RECH/CRES/CMA - 2002/403 cc/cc

2 / 3

<b>Compounds</b>	<b>Content % m/m</b>	<b>Content % v/v</b>
n-butane	0.03	0.05
Isopentane	0.43	0.53
Isobutene + 1-butene	0.01	0.01
Trans-2-butene	0.12	0.15
Cis-2-butene	0.25	0.30
3-méthyl-1-butene	0.13	0.15
C <sub>5</sub> -olefin	0.03	0.03
C <sub>5</sub> -olefin	0.04	0.05
C <sub>8</sub> -olefin	0.15	0.16
C <sub>8</sub> -olefin	0.05	0.05
C <sub>8</sub> -olefin	0.03	0.03
ABT (Tertio butyl alcool)	0.06	0.06
ETBE	98.37 min.	98.14
ESBE (Ethyl sec. butyl ether)	0.15	0.15
C <sub>7</sub> Oxygenated compound	0.04	0.04
C <sub>7</sub> Oxygenated compound	0.08	0.08
Unknown compound	0.01	

It is important to notice that the results in % v/v have been obtained using average density for the unknown compounds (C8-olefins for example).

Analysis was realised by D. FADEL (+33-(0)4-78-02-62-63) and S. JACQUETTON (+33-(0)4-78-02-63-40).

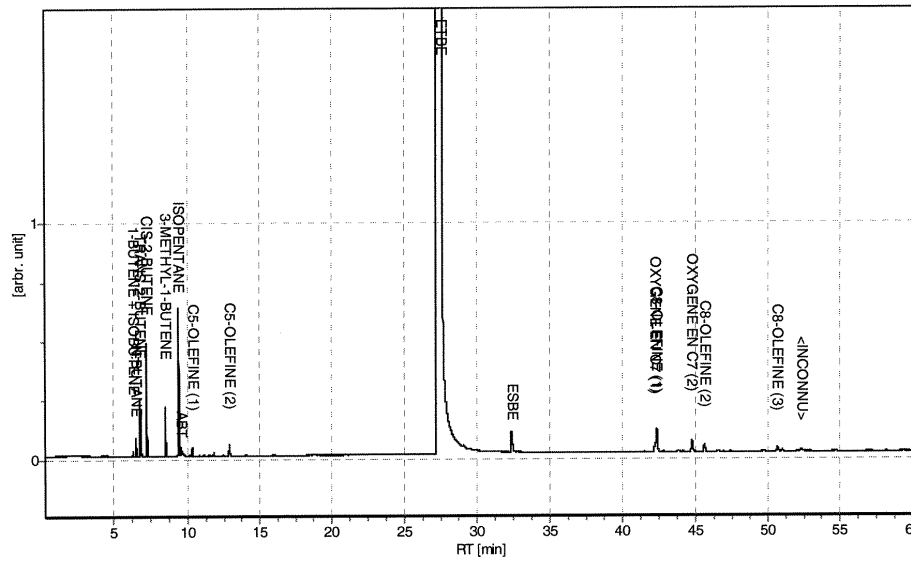
C. CHAMBON



RM/RAF/RECH/CRES/CMA - 2002/403 cc/cc

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Annexe : chromatogram obtained according to the internal method MA0146



2. Determination of ETHYL TERTIARY BUTYL ETHER (ETBE) in the dosage forms

## Determination of ETHL TERTIARY BUTYL ETHER (ETBE) in the dosage form

### Principle

An aliquot of each dosage form was sampled, appropriately diluted and then analyzed by Gas Liquid Chromatography with Flame Ionization Detection (FID). The concentration of the test item was determined from a calibration curve of peak area against concentration of ETHL TERTIARY BUTYL ETHER (ETBE) in standard solutions (external standard calibration).

The analytical method used was validated according to CIT standard procedure before a previous study with the test item (*CIT/Study No. 24168 RSR*). The validation results (presented in the *24168 RSR* study report) demonstrated the suitability of the method for analysis of the samples of the study.

### Sample preparation

An aliquot (1 mL) of each test dosage form under magnetic stirring was sampled (weighed accurately) in a tube and diluted ten-fold with diethyl ether. Subsequently, serial dilutions in diethyl ether were carried out to achieve target concentrations in a range 5-200 µg/mL of test item.

The control dosage form was diluted 20-fold with diethyl ether before analysis.

From the aliquot of dosage form sampled (weighed accurately), the real volume of the aliquot analyzed was determined (taking into account the density of each preparation) and the value of the first dilution factor calculated.

### Chromatographic conditions (GLC/FID)

Column	: DB5 (J&W Scientific) length = 30 m inner diameter = 0.53 mm film thickness = 5 µm
Vector gas	: Helium pressure = 10 psi flow-rate = 15 mL/min
Autosampler	: Varian 8100
Injector	: Temperature = 250°C split mode injection leak flow rate = 150 mL/min (split ratio = 1/10) injected volume = 2 µL
Detector	: Flame Ionization Detection temperature = 300°C Air flow rate = 300 mL/min Hydrogen flow rate = 30 mL/min Make-up flow rate (Helium) = 10 mL/min
Oven	: Varian 3400

Column temperature : initial temperature = 50°C (3 min)  
final temperature = 200°C  
ramp = 25°C/min

Data acquisition software : Multichrom 2 (Fisons Instruments)

Retention time of test item : approx 2 min

Analysis time : 3 min

### **Calibration curve**

Peak areas were determined for standard solutions ranging from 5 µg/mL to 200 µg/mL of test item (six levels). A calibration curve was obtained by linear regression analysis of peak areas against concentrations.

The regression analysis of the calibration data gave an equation of the following form:

$$Y = a X + b$$

where  
Y = peak area of ETHL TERTIARY BUTYL ETHER (ETBE) (µVs),  
X = concentration of ETHL TERTIARY BUTYL ETHER (ETBE) (mg/mL),  
a = slope value  
b = intercept

### **Assay**

Diluted samples of dosage form were analyzed by Gas Liquid Chromatography with FID detection.

Each sample was diluted appropriately, and one injection was performed for each final dilution.

The test item peak area was determined for each sample and the corresponding concentration was calculated using the equation obtained from the calibration data.

All the results are expressed as mg/mL of ETHL TERTIARY BUTYL ETHER (ETBE).

### **Results**

The results are presented in Tables 1 and 2.

**Table 1: HOMOGENEITY OF ETHYL TERTIARY BUTYL ETHER (ETBE)  
IN THE DOSAGE FORMS**

Nominal concentration (mg/mL)	Sampling level	Obtained concentration (mg/mL)			Mean (n=6) CV [1]
		Assay 1	Assay 2	Mean	
62.5	Top	57.4	58.5	58.0	57.8
	Middle	57.1	60.1	58.6	CV = 4 %
	Bottom	59.5	54.4	57.0	-7%
250	Top	242	253	248	234
	Middle	225	230	228	CV = 5 %
	Bottom	225	226	226	-7%

CV: coefficient of variation ( 100 x SD/mean)

[1] Deviation from nominal value (%)

**Table 2: CONCENTRATION OF ETHYL TERTIARY BUTYL ETHER (ETBE)  
IN THE ADMINISTERED DOSAGE FORMS**

Group	Nominal concentration (mg/mL)	Actual concentration (mg/mL)		
		Week 1	Week 2	Week 3
<b>1</b>	<b>0</b>	BLQ	BLQ	BLQ
	<i>Deviation from nominal value :</i>	<i>nc</i>	<i>nc</i>	<i>nc</i>
<b>2</b>	<b>62.5</b>	60.2	58.6	66.4
	<i>Deviation from nominal value :</i>	<i>-4%</i>	<i>-6%</i>	<i>6%</i>
<b>3</b>	<b>125</b>	122	126	115
	<i>Deviation from nominal value :</i>	<i>-2%</i>	<i>1%</i>	<i>-8%</i>
<b>4</b>	<b>250</b>	229	224	237
	<i>Deviation from nominal value :</i>	<i>-8%</i>	<i>-10%</i>	<i>-5%</i>

BLQ: Below Limit of Quantification (< 0.1 mg/mL)

nc: not calculated

### 3. Diet formula

Ref: A04  
**COMPLETE DIET**

**RAT AND MOUSE MAINTENANCE DIET**

Appearance: 15 mm diameter pellets or powder

Conditioning: 20 kg double paper bag with aluminium on the outside

Daily portion: Rat 15-25 g, Mouse 5-10 g, water *ad libitum*.

**FORMULA %**

Cereals and cereal biproducts .....	83.9
Vegetable protein (soya bean meal, yeast) .....	8
Animal protein (fish) .....	4
Vitamin and mineral mixture .....	4.1

**AVERAGE ANALYSIS %**

Calorific value (KCal/kg) .....	2900
Moisture .....	12
Proteins .....	16
Lipids .....	3
Carbohydrates (N.F.E.) .....	60
Fibre .....	4
Minerals (ash) .....	5

	MINERALS (calculated in mg/kg)		
	Nat val.	CMV val.	Total
P .....	5900	0	5900
Ca .....	3300	5000	8300
K .....	6700	0	6700
Na .....	900	1600	2500
Mg .....	1900	100	2000
Mn .....	20	40	60
Fe .....	90	150	240
Cu .....	Traces	15	16
Zn .....	40	45	85
Co .....	T	1.5	1.5
I .....	0.3	0	0.3

**AMINO ACID VALUES**

(calculated in mg/kg)

Arginine .....	9800
Cystine .....	2300
Lysine .....	7700
Methionine .....	2800
Tryptophan .....	1900
Glycine .....	8100

**FATTY ACID VALUES**

(calculated in mg/kg)

Palmitic acid .....	4000
Palmitoleic acid .....	600
Stearic acid .....	Traces
Oleic acid .....	6400
Linoleic acid .....	12400
Linolenic acid .....	90

	VITAMINS (calculated per kg)		
	Nat val.	CMV val.	Total
Vitamin A	Traces	7500 IU	7500 IU
Vitamin D3	Traces	1000 IU	1000 IU
Vitamin B1	6 mg	1 mg	7 mg
Vitamin B2	2 mg	4.5 mg	6.5 mg
Vitamin B3	10 mg	6.5 mg	16.5 mg
Vitamin B6	1.3 mg	1.3 mg	2.6 mg
Vitamin B12	0.01 mg	0.01 mg	0.02 mg
Vitamin E	15 mg	15 mg	30 mg
Vitamin K3	0.25 mg	2.25 mg	2.5 mg
Vitamin PP	60 mg	15 mg	75 mg
Folic acid	0.5 mg	0 mg	0.5 mg
Biotin	0.04 mg	0 mg	0.04 mg
Choline	1200 mg	400 mg	1600 mg

Available under quality "Control Ref.: A04 C "

SAFE, 7 rue Galliéni, Villemoisson, 91360 Epinay-sur-Orge

Tel: 01.69.04.03.57 - Fax: 01.69.04.81.97

(Ref. Doc. UAR: 2000)



4. Individual pregnancy status of females  
Fin sac : final sacrifice  
Pg : pregnant  
NotPg : not pregnant

**PREGNANCY STATUS OF FEMALES (Individual data)**

Dose: 0 mg/kg/day

ANIMAL#	DATE PREGNANT	DATE OF DEL	SCHED. SAC	ACTUAL DEATH	STATUS CODES
C22141	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22142	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22143	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22144	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22145	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22146	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22147	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22148	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/NotPg
C22149	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22150	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22151	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22152	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22153	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22154	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22155	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22156	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22157	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg
C22158	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/NotPg
C22159	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg
C22160	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/NotPg
C22161	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg
C22162	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg
C22163	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg
C22164	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg

**PREGNANCY STATUS OF FEMALES (Individual data)**

Dose: 250 mg/kg/day

ANIMAL#	DATE PREGNANT	DATE OF DEL	SCHED. SAC	ACTUAL DEATH	STATUS CODES
C22165	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/NotPg
C22166	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/NotPg
C22167	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22168	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22169	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22170	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/NotPg
C22171	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22172	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/NotPg
C22173	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22174	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22175	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22176	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/NotPg
C22177	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22178	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22179	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22180	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22181	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg
C22182	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg
C22183	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg
C22184	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg
C22185	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg
C22186	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg
C22187	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg
C22188	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg

**PREGNANCY STATUS OF FEMALES (Individual data)**

Dose: 500 mg/kg/day

ANIMAL#	DATE PREGNANT	DATE OF DEL	SCHED. SAC	ACTUAL DEATH	STATUS CODES
C22189	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22190	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22191	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22192	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22193	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22194	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22195	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/NotPg
C22196	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22197	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22198	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22199	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22200	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22201	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22202	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22203	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22204	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22205	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg
C22206	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/NotPg
C22207	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg
C22208	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/NotPg
C22209	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg
C22210	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/NotPg
C22211	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg
C22212	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg

**PREGNANCY STATUS OF FEMALES (Individual data)**

Dose: 1000 mg/kg/day

ANIMAL#	DATE PREGNANT	DATE OF DEL	SCHED. SAC	ACTUAL DEATH	STATUS CODES
C22213	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22214	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22215	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22216	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22217	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22218	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/NotPg
C22219	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22220	15-APR-03		5-MAY-03	5-MAY-03	Fin sac/Pg
C22221	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22222	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22223	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22224	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22225	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22226	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22227	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/Pg
C22228	16-APR-03		6-MAY-03	6-MAY-03	Fin sac/NotPg
C22229	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg
C22230	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg
C22231	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg
C22232	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg
C22233	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg
C22234	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg
C22235	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg
C22236	17-APR-03		7-MAY-03	7-MAY-03	Fin sac/Pg

## 5. Individual clinical signs

**CLINICAL HISTORY (Individual findings/Females/Pregnancy period)**

Dose: 0 mg/kg/day

ANIMAL#	OBSERVATIONS	DAYS OBSERVED	
C22141	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22142	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22143	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22144	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22145	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22146	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22147	Normal Mortality Skin	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE AREA OF HAIR LOSS ON FORELIMB, L	5 to 16 20 17 to end
C22148	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22149	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to 18, 20 20
C22150	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22151	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22152	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22153	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22154	Normal	NO REMARKABLE CLINICAL OBSERVATIONS	5 to end

**CLINICAL HISTORY (Individual findings/Females/Pregnancy period)**

Dose: 0 mg/kg/day

ANIMAL#	OBSERVATIONS	DAYS OBSERVED
C22154 (CONTINUED) Mortality	FINAL SACRIFICE	20
C22155 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22156 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22157 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22158 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22159 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22160 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22161 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22162 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22163 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22164 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20



**CLINICAL HISTORY (Individual findings/Females/Pregnancy period)**

Dose: 250 mg/kg/day

ANIMAL#	OBSERVATIONS	DAYS OBSERVED
C22165 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22166 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22167 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22168 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22169 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22170 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22171 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22172 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22173 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22174 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22175 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22176 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22177 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22178 Normal	NO REMARKABLE CLINICAL OBSERVATIONS	5 to end

**CLINICAL HISTORY (Individual findings/Females/Pregnancy period)**

Dose: 250 mg/kg/day

ANIMAL#		OBSERVATIONS	DAYS OBSERVED
C22178	(CONTINUED) Mortality	FINAL SACRIFICE	20
C22179	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22180	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22181	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22182	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22183	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22184	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22185	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22186	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22187	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22188	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20

**CLINICAL HISTORY (Individual findings/Females/Pregnancy period)**

Dose: 500 mg/kg/day

ANIMAL#	OBSERVATIONS	DAYS OBSERVED
C22189 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22190 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22191 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22192 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22193 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22194 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22195 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22196 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22197 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22198 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22199 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22200 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22201 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22202 Normal	NO REMARKABLE CLINICAL OBSERVATIONS	5 to end

**CLINICAL HISTORY (Individual findings/Females/Pregnancy period)**

Dose: 500 mg/kg/day

ANIMAL#		OBSERVATIONS	DAYS OBSERVED
C22202	(CONTINUED) Mortality	FINAL SACRIFICE	20
C22203	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22204	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22205	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22206	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22207	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22208	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22209	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22210	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22211	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22212	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20

**CLINICAL HISTORY (Individual findings/Females/Pregnancy period)**

Dose: 1000 mg/kg/day

ANIMAL#	OBSERVATIONS	DAYS OBSERVED
C22213	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE
C22214	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE
C22215	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE
C22216	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE
C22217	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE
C22218	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE
C22219	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE
C22220	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE
C22221	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE
C22222	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE
C22223	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE
C22224	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE
C22225	Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE
C22226	Normal	NO REMARKABLE CLINICAL OBSERVATIONS

**CLINICAL HISTORY (Individual findings/Females/Pregnancy period)**

Dose: 1000 mg/kg/day

ANIMAL#	OBSERVATIONS	DAYS OBSERVED
C22226 (CONTINUED) Mortality	FINAL SACRIFICE	20
C22227 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22228 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22229 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22230 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22231 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22232 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22233 Normal Mortality Skin	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE AREA OF HAIR LOSS ON FORELIMB, B	5 to 14 20 15 to end
C22234 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22235 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20
C22236 Normal Mortality	NO REMARKABLE CLINICAL OBSERVATIONS FINAL SACRIFICE	5 to end 20

6. Specific clinical signs observed in principal animals









- 7. Individual body weight values
  - Fin sac : final sacrifice
  - Pg : pregnant
  - NotPg : not pregnant

**BODY WEIGHT (Individual values/grams/Females/Pregnancy period)**

Dose: 0 mg/kg/day

FEMALE#		DAY OF PREGNANCY									
		2	4	5	6	9	12	15	18	19	20
C22141	SP	197	209	215	222	234	249	262	294	304	314
C22142	SP	222	235	242	247	262	286	306	337	351	365
C22143	SP	222	231	240	247	262	289	308	354	370	392
C22144	SP	227	237	245	247	265	284	305	346	360	372
C22145	SP	232	238	240	244	259	272	287	319	329	326
C22146	SP	236	245	244	252	269	286	305	340	354	370
C22147	SP	236	244	249	255	276	293	314	359	375	391
C22148	SN	276	278	279	287	287	302	305	316	318	315
C22149	SP	193	184	218	228	246	270	297	348	365	387
C22150	SP	232	247	255	257	279	298	315	354	371	389
C22151	SP	235	246	250	257	279	302	329	370	376	390
C22152	SP	240	247	251	253	275	293	312	349	358	370
C22153	SP	241	249	253	262	274	302	321	362	372	386
C22154	SP	251	258	265	265	274	301	331	373	385	404
C22155	SP	253	265	269	272	294	313	341	389	406	424
C22156	SP	272	281	286	292	309	334	348	391	401	417
C22157	SP	200	210	216	219	240	263	286	324	336	358
C22158	SN	219	216	222	228	235	237	250	253	254	252
C22159	SP	220	229	235	238	260	279	307	348	362	381
C22160	SN	230	238	245	252	264	260	271	275	277	274
C22161	SP	230	249	255	262	291	308	329	379	396	411
C22162	SP	247	259	269	274	300	323	356	398	418	434
C22163	SP	249	260	268	271	291	308	330	350	354	365
C22164	SP	269	281	295	297	318	343	371	415	435	446
MEAN		233	243	250	255	274	295	317	357	370	385
S.D.		21	23	21	20	21	23	25	28	30	32
N		21	21	21	21	21	21	21	21	21	21

SP=Fin sac/Pg      SN=Fin sac/NotPg

**BODY WEIGHT (Individual values/grams/Females/Pregnancy period)**

Dose: 250 mg/kg/day

FEMALE#		DAY OF PREGNANCY									
		2	4	5	6	9	12	15	18	19	20
C22165	SN	205	203	210	215	223	227	235	249	244	240
C22166	SN	222	234	233	243	256	266	254	264	261	255
C22167	SP	223	245	245	258	279	306	327	370	387	399
C22168	SP	226	230	237	243	256	277	289	324	333	344
C22169	SP	232	246	248	253	268	290	313	357	371	388
C22170	SN	236	239	242	246	249	252	259	266	267	262
C22171	SP	238	255	256	259	271	296	313	351	366	378
C22172	SN	262	269	267	267	276	278	270	288	280	289
C22173	SP	201	211	216	223	241	267	287	324	336	350
C22174	SP	222	228	231	239	256	276	298	335	347	362
C22175	SP	235	241	250	252	271	290	314	359	371	386
C22176	SN	239	235	239	245	251	254	270	278	279	276
C22177	SP	243	253	255	259	274	292	316	346	357	375
C22178	SP	251	267	273	279	306	335	361	399	413	432
C22179	SP	254	268	268	271	288	307	328	368	382	401
C22180	SP	268	277	283	290	308	336	357	396	412	428
C22181	SP	204	223	225	231	242	264	284	319	329	347
C22182	SP	219	230	231	240	255	274	294	330	343	360
C22183	SP	221	224	228	233	249	261	281	318	335	347
C22184	SP	230	244	250	255	273	293	319	359	375	389
C22185	SP	231	239	249	249	266	286	305	342	353	373
C22186	SP	245	250	255	258	276	290	313	352	366	384
C22187	SP	250	259	263	268	290	310	327	361	371	392
C22188	SP	267	282	288	292	313	336	353	384	407	429
MEAN		235	246	250	255	273	294	315	352	366	382
S.D.		19	19	19	19	21	23	24	24	26	27
N		19	19	19	19	19	19	19	19	19	19

SP=Fin sac/Pg      SN=Fin sac/NotPg

**BODY WEIGHT (Individual values/grams/Females/Pregnancy period)**

Dose: 500 mg/kg/day

FEMALE#		DAY OF PREGNANCY									
		2	4	5	6	9	12	15	18	19	20
C22189	SP	207	218	224	225	237	254	266	306	315	330
C22190	SP	219	230	234	238	255	278	290	327	341	357
C22191	SP	224	230	236	238	256	273	288	319	338	345
C22192	SP	226	210	245	253	275	299	317	360	373	389
C22193	SP	232	245	249	252	268	289	302	336	351	362
C22194	SP	235	245	251	257	279	300	320	362	377	397
C22195	SN	239	249	254	251	274	278	266	276	262	271
C22196	SP	258	275	277	287	310	345	361	399	417	432
C22197	SP	203	209	215	220	232	254	274	306	319	326
C22198	SP	221	233	231	236	256	275	294	327	337	353
C22199	SP	235	245	249	255	271	291	315	363	374	392
C22200	SP	237	246	249	254	267	286	311	347	367	381
C22201	SP	244	285	280	277	311	340	368	414	423	444
C22202	SP	251	269	273	279	290	320	347	393	407	429
C22203	SP	255	267	272	278	289	313	340	379	394	413
C22204	SP	265	278	286	288	311	338	349	401	412	430
C22205	SP	207	217	221	225	242	257	279	310	325	337
C22206	SN	218	231	233	242	255	249	246	252	254	249
C22207	SP	223	231	236	239	257	268	289	316	328	342
C22208	SN	225	239	243	249	269	280	270	277	263	276
C22209	SP	240	251	256	256	276	299	320	368	385	403
C22210	SN	245	245	247	256	263	262	277	288	282	283
C22211	SP	251	260	263	269	288	309	330	381	398	419
C22212	SP	265	277	283	285	311	326	348	394	411	428
MEAN		235	246	251	255	274	296	315	355	370	385
S.D.		19	24	22	22	25	28	30	35	36	39
N		20	20	20	20	20	20	20	20	20	20

SP=Fin sac/Pg      SN=Fin sac/NotPg

**BODY WEIGHT (Individual values/grams/Females/Pregnancy period)**

Dose: 1000 mg/kg/day

FEMALE#		DAY OF PREGNANCY									
		2	4	5	6	9	12	15	18	19	20
C22213	SP	214	221	225	231	236	260	273	305	316	323
C22214	SP	218	228	230	231	247	263	276	308	319	328
C22215	SP	224	235	238	239	243	268	284	318	332	339
C22216	SP	225	235	243	247	265	283	299	335	351	361
C22217	SP	233	244	250	255	271	286	306	345	360	374
C22218	SN	234	240	238	241	243	249	243	255	257	259
C22219	SP	246	253	255	254	282	305	320	354	360	375
C22220	SP	252	267	268	275	298	321	338	379	398	414
C22221	SP	211	223	223	222	241	255	272	309	313	324
C22222	SP	215	221	233	234	251	272	288	311	310	323
C22223	SP	237	245	251	254	270	288	308	346	355	374
C22224	SP	237	242	250	251	270	291	311	356	369	385
C22225	SP	244	255	259	266	280	295	319	353	364	378
C22226	SP	247	262	266	273	284	306	329	379	392	411
C22227	SP	258	274	277	280	301	323	347	378	391	402
C22228	SN	264	260	267	271	276	279	292	305	301	293
C22229	SP	208	223	230	231	252	269	280	317	332	343
C22230	SP	210	223	228	234	251	272	288	326	336	353
C22231	SP	224	235	244	247	261	277	302	336	348	368
C22232	SP	225	234	243	247	268	283	312	346	359	378
C22233	SP	243	254	262	266	283	306	327	363	373	381
C22234	SP	244	255	261	269	281	297	317	352	364	375
C22235	SP	254	268	274	278	298	316	341	382	393	416
C22236	SP	265	266	270	273	291	304	329	364	380	395
MEAN		233	244	249	253	269	288	307	344	355	369
S.D.		17	17	17	18	20	20	23	25	27	29
N		22	22	22	22	22	22	22	22	22	22

SP=Fin sac/Pg      SN=Fin sac/NotPg

8. Individual body weight change values  
Fin sac : final sacrifice  
Pg : pregnant  
NotPg : not pregnant



**BODY WEIGHT CHANGE (Individual values/grams/Females/Pregnancy period)**

Dose: 0 mg/kg/day

FEMALE#		DAY OF PREGNANCY									
		2 - 4	4 - 5	5 - 6	6 - 9	9 - 12	12 - 15	15 - 18	18 - 19	19 - 20	5 - 20
C22141	SP	12	6	7	13	14	13	32	10	10	100
C22142	SP	13	7	5	15	25	20	31	15	14	123
C22143	SP	9	9	7	15	27	19	45	16	22	152
C22144	SP	10	8	3	18	19	21	41	13	12	127
C22145	SP	7	2	4	15	13	15	32	11	-3	86
C22146	SP	9	0	8	17	17	19	35	14	16	126
C22147	SP	8	5	6	21	17	21	46	16	16	142
C22148	SN	2	1	8	0	16	3	10	3	-3	36
C22149	SP	-9	34	10	18	25	27	51	17	22	169
C22150	SP	15	8	3	22	19	16	40	17	18	134
C22151	SP	12	4	6	23	23	27	42	6	13	139
C22152	SP	6	4	2	22	18	20	36	10	12	119
C22153	SP	8	4	9	11	28	20	41	10	14	133
C22154	SP	7	7	0	9	27	29	42	12	19	139
C22155	SP	11	5	3	22	19	28	48	16	18	154
C22156	SP	9	5	6	17	24	14	44	9	17	131
C22157	SP	10	6	3	21	23	22	38	13	22	142
C22158	SN	-3	6	5	8	2	13	3	1	-2	30
C22159	SP	9	6	3	23	18	28	41	14	19	146
C22160	SN	7	7	7	12	-4	11	4	1	-3	29
C22161	SP	18	7	6	29	18	21	50	18	15	156
C22162	SP	13	10	5	26	23	33	42	20	16	165
C22163	SP	11	8	4	19	18	21	21	4	11	97
C22164	SP	13	14	2	21	26	28	44	19	11	150
MEAN		10	7	5	19	21	22	40	13	15	135
S.D.		5	7	3	5	4	5	7	4	6	22
N		21	21	21	21	21	21	21	21	21	21

SP=Fin sac/Pg      SN=Fin sac/NotPg

**BODY WEIGHT CHANGE (Individual values/grams/Females/Pregnancy period)**

Dose: 250 mg/kg/day

FEMALE#		DAY OF PREGNANCY									
		2 - 4	4 - 5	5 - 6	6 - 9	9 - 12	12 - 15	15 - 18	18 - 19	19 - 20	5 - 20
C22165	SN	-1	7	5	8	3	8	14	-5	-4	30
C22166	SN	13	-2	10	13	10	-12	10	-3	-6	23
C22167	SP	22	0	13	21	27	21	44	16	12	154
C22168	SP	4	7	7	12	21	13	34	10	11	107
C22169	SP	14	3	5	16	22	23	44	14	16	139
C22170	SN	3	4	4	3	3	7	8	1	-6	20
C22171	SP	17	2	3	12	25	17	38	15	12	121
C22172	SN	7	-2	0	9	2	-9	19	-8	9	23
C22173	SP	10	5	7	18	26	20	37	12	15	134
C22174	SP	7	3	8	17	19	22	38	12	15	131
C22175	SP	6	10	2	19	19	24	45	11	15	136
C22176	SN	-4	4	6	6	2	16	8	1	-4	36
C22177	SP	10	2	4	15	18	24	30	12	18	120
C22178	SP	16	6	6	27	29	27	38	14	20	159
C22179	SP	14	0	3	18	18	21	40	15	18	133
C22180	SP	9	6	7	19	28	21	39	16	15	145
C22181	SP	19	2	6	12	22	20	36	10	19	122
C22182	SP	12	1	9	15	19	20	36	13	17	129
C22183	SP	4	4	5	16	12	20	37	17	12	119
C22184	SP	14	6	4	19	20	26	40	17	14	139
C22185	SP	9	9	0	17	19	20	37	11	20	125
C22186	SP	5	5	4	18	15	23	39	14	18	129
C22187	SP	9	4	5	22	20	17	34	11	21	129
C22188	SP	15	6	3	22	23	16	31	23	22	141
MEAN		11	4	5	17	21	21	38	14	16	132
S.D.		5	3	3	4	4	3	4	3	3	12
N		19	19	19	19	19	19	19	19	19	19

SP=Fin sac/Pg      SN=Fin sac/NotPg

**BODY WEIGHT CHANGE (Individual values/grams/Females/Pregnancy period)**

Dose: 500 mg/kg/day

FEMALE#		DAY OF PREGNANCY									
		2 - 4	4 - 5	5 - 6	6 - 9	9 - 12	12 - 15	15 - 18	18 - 19	19 - 20	5 - 20
C22189	SP	11	6	2	12	17	13	39	10	15	107
C22190	SP	10	4	4	17	23	12	37	14	16	123
C22191	SP	6	6	3	18	17	15	31	19	7	109
C22192	SP	-16	35	7	22	24	17	44	13	16	144
C22193	SP	13	4	3	16	21	13	34	15	10	113
C22194	SP	10	6	6	21	21	20	42	15	20	146
C22195	SN	10	5	-2	23	4	-13	10	-14	9	18
C22196	SP	17	2	10	23	35	16	39	17	16	155
C22197	SP	6	6	5	13	22	19	33	13	7	112
C22198	SP	12	-2	5	20	19	19	34	10	16	122
C22199	SP	10	4	6	17	20	24	48	11	17	143
C22200	SP	9	3	6	13	19	25	36	20	14	132
C22201	SP	41	-5	-3	35	29	28	46	9	20	164
C22202	SP	18	5	5	11	30	27	47	13	22	155
C22203	SP	12	5	6	11	25	27	38	15	20	142
C22204	SP	12	8	2	23	28	11	52	11	18	144
C22205	SP	10	4	3	17	15	22	31	15	12	115
C22206	SN	13	2	9	14	-6	-3	6	3	-5	16
C22207	SP	8	5	3	18	11	21	27	13	13	106
C22208	SN	15	4	6	20	10	-9	6	-14	13	33
C22209	SP	11	5	0	21	23	21	48	17	18	147
C22210	SN	0	2	9	7	-1	15	11	-6	1	35
C22211	SP	9	3	6	19	21	21	51	17	21	155
C22212	SP	12	6	3	26	15	22	47	17	18	146
MEAN		11	6	4	19	22	20	40	14	16	134
S.D.		10	8	3	6	6	5	7	3	4	19
N		20	20	20	20	20	20	20	20	20	20

SP=Fin sac/Pg      SN=Fin sac/NotPg

**BODY WEIGHT CHANGE (Individual values/grams/Females/Pregnancy period)**

Dose: 1000 mg/kg/day

FEMALE#		DAY OF PREGNANCY									
		2 - 4	4 - 5	5 - 6	6 - 9	9 - 12	12 - 15	15 - 18	18 - 19	19 - 20	5 - 20
C22213	SP	7	4	6	5	24	14	32	11	8	98
C22214	SP	10	2	1	16	16	13	32	11	9	98
C22215	SP	10	4	1	4	24	16	35	14	7	101
C22216	SP	10	8	4	19	17	17	36	16	10	118
C22217	SP	11	6	5	15	15	20	40	15	13	124
C22218	SN	5	-2	3	2	6	-6	11	2	3	21
C22219	SP	7	2	-1	27	23	16	33	7	14	120
C22220	SP	15	2	7	23	23	17	41	19	16	146
C22221	SP	11	0	-1	19	15	16	37	5	11	102
C22222	SP	6	11	2	17	21	16	23	-1	13	91
C22223	SP	9	6	3	16	18	20	39	9	19	123
C22224	SP	5	8	1	19	21	20	45	13	15	135
C22225	SP	11	4	7	14	15	24	34	11	14	119
C22226	SP	15	4	8	11	22	22	50	14	19	145
C22227	SP	16	3	2	22	22	24	31	13	11	124
C22228	SN	-3	7	5	5	3	13	13	-4	-8	27
C22229	SP	15	7	1	21	17	11	37	15	11	113
C22230	SP	13	5	6	17	21	16	38	10	17	125
C22231	SP	11	9	3	14	16	25	34	12	19	124
C22232	SP	10	9	4	21	15	28	35	13	19	135
C22233	SP	11	8	3	18	23	20	36	10	8	118
C22234	SP	12	6	8	12	16	20	35	12	11	114
C22235	SP	14	6	3	21	18	25	41	11	23	142
C22236	SP	0	4	3	18	13	25	35	16	15	126
MEAN		10	5	4	17	19	19	36	12	14	120
S.D.		4	3	3	5	3	5	5	4	4	15
N		22	22	22	22	22	22	22	22	22	22

SP=Fin sac/Pg      SN=Fin sac/NotPg

9. Individual net body weight change values

Fin sac : final sacrifice

Pg : pregnant

NotPg : not pregnant

**NET BODY WEIGHT CHANGE (Individual values/grams/Females/Pregnancy period)**

Dose: 0 mg/kg/day

ANIMAL#		UTERUS WEIGHT	CARCASS WEIGHT	NET WEIGHT CHANGE FROM DAY 5	WEIGHT CHANGE FROM DAY 5
C22141	SP	65	249	34	100
C22142	SP	71	294	52	123
C22143	SP	82	310	70	152
C22144	SP	76	295	51	127
C22145	SP	25	301	62	86
C22146	SP	65	305	61	126
C22147	SP	86	305	56	142
C22148	SN				36
C22149	SP	81	306	88	169
C22150	SP	71	318	64	134
C22151	SP	75	314	64	139
C22152	SP	80	290	39	119
C22153	SP	77	309	56	133
C22154	SP	86	318	53	139
C22155	SP	84	339	70	154
C22156	SP	60	357	70	131
C22157	SP	82	276	60	142
C22158	SN				30
C22159	SP	82	299	64	146
C22160	SN				29
C22161	SP	93	318	63	156
C22162	SP	102	331	62	165
C22163	SP	7	357	90	97
C22164	SP	82	364	69	150
MEAN		73.1	312.2	61.8	134.8
S.D.		21.4	27.2	13.0	21.5
N		21	21	21	21

CARCASS WEIGHT = TERMINAL BODY WEIGHT MINUS UTERINE WEIGHT

NET WEIGHT CHANGE FROM DAY 5 = CARCASS WEIGHT MINUS DAY 5 BODY WEIGHT

SP=Fin sac/Pg      SN=Fin sac/NotPg

**NET BODY WEIGHT CHANGE (Individual values/grams/Females/Pregnancy period)**

Dose: 250 mg/kg/day

ANIMAL#	UTERUS WEIGHT	CARCASS WEIGHT	NET WEIGHT CHANGE FROM DAY 5	WEIGHT CHANGE FROM DAY 5	
C22165	SN			30	
C22166	SN			23	
C22167	SP	79	319	74	154
C22168	SP	60	284	47	107
C22169	SP	71	317	68	139
C22170	SN			20	
C22171	SP	69	308	52	121
C22172	SN			23	
C22173	SP	68	283	66	134
C22174	SP	77	285	54	131
C22175	SP	77	309	59	136
C22176	SN			36	
C22177	SP	64	311	56	120
C22178	SP	90	343	69	159
C22179	SP	71	330	63	133
C22180	SP	89	338	56	145
C22181	SP	59	289	64	122
C22182	SP	70	290	59	129
C22183	SP	63	285	57	119
C22184	SP	80	309	58	139
C22185	SP	84	289	41	125
C22186	SP	73	310	56	129
C22187	SP	64	328	65	129
C22188	SP	74	354	66	141
MEAN	72.8	309.4	59.4	132.2	
S.D.	9.1	22.0	8.1	12.4	
N	19	19	19	19	

CARCASS WEIGHT = TERMINAL BODY WEIGHT MINUS UTERINE WEIGHT

NET WEIGHT CHANGE FROM DAY 5 = CARCASS WEIGHT MINUS DAY 5 BODY WEIGHT

SP=Fin sac/Pg      SN=Fin sac/NotPg

**NET BODY WEIGHT CHANGE (Individual values/grams/Females/Pregnancy period)**

Dose: 500 mg/kg/day

ANIMAL#	UTERUS WEIGHT	CARCASS WEIGHT	NET WEIGHT CHANGE FROM DAY 5	WEIGHT CHANGE FROM DAY 5
C22189	SP 63	267	43	107
C22190	SP 61	296	63	123
C22191	SP 57	287	52	109
C22192	SP 81	308	63	144
C22193	SP 55	306	57	113
C22194	SP 81	316	65	146
C22195	SN			18
C22196	SP 67	365	88	155
C22197	SP 55	271	57	112
C22198	SP 67	285	55	122
C22199	SP 85	307	58	143
C22200	SP 90	291	42	132
C22201	SP 81	362	82	164
C22202	SP 96	333	60	155
C22203	SP 76	338	66	142
C22204	SP 88	342	56	144
C22205	SP 70	266	45	115
C22206	SN			16
C22207	SP 51	291	55	106
C22208	SN			33
C22209	SP 80	323	67	147
C22210	SN			35
C22211	SP 92	327	63	155
C22212	SP 83	345	63	146
MEAN	73.9	311.4	60.0	133.9
S.D.	13.7	30.0	11.3	18.8
N	20	20	20	20

CARCASS WEIGHT = TERMINAL BODY WEIGHT MINUS UTERINE WEIGHT

NET WEIGHT CHANGE FROM DAY 5 = CARCASS WEIGHT MINUS DAY 5 BODY WEIGHT

SP=Fin sac/Pg      SN=Fin sac/NotPg



**NET BODY WEIGHT CHANGE (Individual values/grams/Females/Pregnancy period)**

Dose: 1000 mg/kg/day

ANIMAL#	UTERUS WEIGHT	CARCASS WEIGHT	NET WEIGHT CHANGE FROM DAY 5	WEIGHT CHANGE FROM DAY 5
C22213	SP 56	267	42	98
C22214	SP 61	267	37	98
C22215	SP 70	270	32	101
C22216	SP 66	295	52	118
C22217	SP 71	303	53	124
C22218	SN			21
C22219	SP 67	308	53	120
C22220	SP 81	333	65	146
C22221	SP 63	262	39	102
C22222	SP 53	271	38	91
C22223	SP 72	302	51	123
C22224	SP 69	315	65	135
C22225	SP 74	304	46	119
C22226	SP 100	312	46	145
C22227	SP 60	342	65	124
C22228	SN			27
C22229	SP 54	289	59	113
C22230	SP 60	293	65	125
C22231	SP 75	293	49	124
C22232	SP 71	307	64	135
C22233	SP 66	314	52	118
C22234	SP 50	326	64	114
C22235	SP 92	324	50	142
C22236	SP 77	318	49	126
MEAN	68.5	300.6	51.5	120.0
S.D.	12.1	22.7	10.3	15.3
N	22	22	22	22

CARCASS WEIGHT = TERMINAL BODY WEIGHT MINUS UTERINE WEIGHT

NET WEIGHT CHANGE FROM DAY 5 = CARCASS WEIGHT MINUS DAY 5 BODY WEIGHT

SP=Fin sac/Pg      SN=Fin sac/NotPg

10. Individual food consumption values
  - Fin sac : final sacrifice
  - Pg : pregnant
  - NotPg : not pregnant

**FOOD CONSUMPTION (Individual values/grams per day/Females/Pregnancy period)**

Dose: 0 mg/kg/day

FEMALE#		DAY OF PREGNANCY									
		2 - 4	4 - 5	5 - 6	6 - 9	9 - 12	12 - 15	15 - 18	18 - 19	19 - 20	
C22141	SP	19	21	19	19	20	21	21	22	19	
C22142	SP	21	25	19	20	23	23	23	23	25	
C22143	SP	19	23	22	21	25	26	28	27	30	
C22144	SP	19	24	18	21	23	24	25	25	25	
C22145	SP	18	21	18	20	20	23	26	28	24	
C22146	SP	19	21	18	20	21	23	25	26	25	
C22147	SP	22	24	24	24	26	27	28	30	26	
C22148	SN	18	15	19	16	20	19	18	19	19	
C22149	SP	8	23	26	24	27	27	31	31	28	
C22150	SP	23	25	22	24	26	23	28	27	26	
C22151	SP	22	21	20	24	25	25	26	28	22	
C22152	SP	19	21	17	21	21	22	24	27	18	
C22153	SP	21	21	24	21	24	24	26	25	23	
C22154	SP	22	25	19	20	22	26	29	27	27	
C22155	SP	21	24	24	24	27	31	31	36	32	
C22156	SP	20	23	19	21	24	24	28	30	24	
C22157	SP	10	20	18	21	24	23	26	23	24	
C22158	SN	13	16	18	17	16	18	17	17	14	
C22159	SP	17	20	19	22	23	25	28	25	25	
C22160	SN	18	19	18	20	18	19	18	22	14	
C22161	SP	20	23	22	26	25	23	29	30	24	
C22162	SP	22	23	23	24	27	27	29	27	24	
C22163	SP	23	24	22	22	24	26	30	30	28	
C22164	SP	26	30	22	24	28	30	32	35	24	
MEAN		20	23	21	22	24	25	27	28	25	
S.D.		4	2	3	2	2	2	3	4	3	
N		21	21	21	21	21	21	21	21	21	

SP=Fin sac/Pg      SN=Fin sac/NotPg

**FOOD CONSUMPTION (Individual values/grams per day/Females/Pregnancy period)**

Dose: 250 mg/kg/day

FEMALE#		DAY OF PREGNANCY								
		2 - 4	4 - 5	5 - 6	6 - 9	9 - 12	12 - 15	15 - 18	18 - 19	19 - 20
C22165	SN	16	20	18	17	18	19	19	19	17
C22166	SN	20	20	19	19	19	16	14	15	12
C22167	SP	13	26	25	26	28	29	30	31	27
C22168	SP	16	22	18	18	20	21	22	23	20
C22169	SP	18	21	21	21	24	27	28	27	28
C22170	SN	18	22	17	17	18	19	16	18	16
C22171	SP	19	22	20	19	22	24	25	25	24
C22172	SN	17	21	19	16	18	19	22	15	22
C22173	SP	17	20	20	21	25	23	25	26	23
C22174	SP	22	22	22	23	23	23	25	26	22
C22175	SP	22	25	21	24	29	28	36	44	22
C22176	SN	14	19	16	17	18	19	18	21	15
C22177	SP	21	22	18	22	23	24	26	27	24
C22178	SP	22	26	23	26	28	28	30	28	26
C22179	SP	21	19	19	22	23	24	29	28	29
C22180	SP	26	28	25	28	32	30	32	34	30
C22181	SP	21	22	21	20	22	25	27	24	25
C22182	SP	19	19	23	21	23	22	25	25	23
C22183	SP	18	21	21	21	20	22	26	28	23
C22184	SP	22	25	22	22	25	26	29	30	23
C22185	SP	20	23	19	20	22	23	24	23	23
C22186	SP	19	20	19	21	21	24	27	28	24
C22187	SP	19	22	18	23	23	25	27	26	26
C22188	SP	22	25	24	24	27	26	26	33	31
MEAN		20	23	21	22	24	25	27	28	25
S.D.		3	3	2	2	3	3	3	5	3
N		19	19	19	19	19	19	19	19	19

SP=Fin sac/Pg      SN=Fin sac/NotPg

**FOOD CONSUMPTION (Individual values/grams per day/Females/Pregnancy period)**

Dose: 500 mg/kg/day

FEMALE#		DAY OF PREGNANCY								
		2 - 4	4 - 5	5 - 6	6 - 9	9 - 12	12 - 15	15 - 18	18 - 19	19 - 20
C22189	SP	19	20	12	18	18	19	21	20	20
C22190	SP	20	22	20	20	22	24	26	29	26
C22191	SP	17	21	18	19	21	23	23	27	21
C22192	SP	2	18	21	24	25	25	27	25	27
C22193	SP	20	24	21	23	24	27	27	28	26
C22194	SP	19	22	21	22	24	26	27	29	27
C22195	SN	19	21	18	21	20	15	17	8	16
C22196	SP	23	23	25	25	29	30	31	33	31
C22197	SP	19	22	19	20	22	23	26	29	22
C22198	SP	21	20	20	20	22	22	25	24	21
C22199	SP	22	24	21	22	25	27	31	26	26
C22200	SP	22	23	22	21	22	24	27	30	21
C22201	SP	23	18	12	25	29	28	34	33	30
C22202	SP	23	25	21	23	25	27	29	28	28
C22203	SP	25	27	21	25	26	29	33	33	37
C22204	SP	28	27	25	27	30	29	32	29	28
C22205	SP	18	19	18	19	19	21	23	23	21
C22206	SN	20	21	23	22	19	16	17	19	11
C22207	SP	17	19	18	19	20	21	23	23	24
C22208	SN	19	21	22	24	25	18	19	11	17
C22209	SP	20	23	19	23	25	27	32	28	26
C22210	SN	16	20	20	19	20	23	22	21	18
C22211	SP	22	19	21	22	24	26	29	29	31
C22212	SP	22	23	22	25	26	26	33	31	29
MEAN		20	22	20	22	24	25	28	28	26
S.D.		5	3	3	3	3	3	4	3	4
N		20	20	20	20	20	20	20	20	20

SP=Fin sac/Pg      SN=Fin sac/NotPg

**FOOD CONSUMPTION (Individual values/grams per day/Females/Pregnancy period)**

Dose: 1000 mg/kg/day

FEMALE#		DAY OF PREGNANCY								
		2 - 4	4 - 5	5 - 6	6 - 9	9 - 12	12 - 15	15 - 18	18 - 19	19 - 20
C22213	SP	18	20	20	18	21	21	24	18	20
C22214	SP	20	21	19	19	19	20	21	19	21
C22215	SP	20	22	18	17	21	22	24	22	20
C22216	SP	19	25	23	22	23	26	25	25	24
C22217	SP	22	24	24	24	23	24	26	26	26
C22218	SN	18	19	16	18	16	17	19	18	18
C22219	SP	18	21	17	24	24	26	24	24	27
C22220	SP	22	24	23	24	24	26	26	29	29
C22221	SP	20	18	16	20	20	22	24	24	20
C22222	SP	22	27	21	24	24	23	22	23	20
C22223	SP	18	20	17	20	20	24	26	26	25
C22224	SP	23	26	21	23	26	27	30	30	27
C22225	SP	20	22	22	21	22	24	26	29	24
C22226	SP	23	24	22	21	25	24	31	31	27
C22227	SP	23	25	22	24	25	25	29	30	27
C22228	SN	19	22	19	18	18	20	20	20	13
C22229	SP	20	21	19	21	22	22	24	24	22
C22230	SP	15	19	19	21	23	23	26	27	26
C22231	SP	22	22	21	19	23	24	25	24	23
C22232	SP	18	22	20	22	23	25	28	26	25
C22233	SP	21	23	20	23	27	27	30	26	20
C22234	SP	21	23	24	21	25	25	27	29	25
C22235	SP	23	24	22	23	25	25	30	25	26
C22236	SP	15	21	19	21	22	24	27	26	25
MEAN		20	22	20	22	23	24	26	26	24
S.D.		2	2	2	2	2	2	3	3	3
N		22	22	22	22	22	22	22	22	22

SP=Fin sac/Pg      SN=Fin sac/NotPg

11. Individual necropsy observations
  - Fin sac : final sacrifice
  - Pg : pregnant
  - NotPg : not pregnant

**INDIVIDUAL NECROPSY OBSERVATIONS**

Dose: 0 mg/kg/day

FEMALE#	ORGAN	OBSERVATION
C22141	SP	NO GROSS NECROPSY FINDINGS
C22142	SP	NO GROSS NECROPSY FINDINGS
C22143	SP	NO GROSS NECROPSY FINDINGS
C22144	SP	NO GROSS NECROPSY FINDINGS
C22145	SP	NO GROSS NECROPSY FINDINGS
C22146	SP	NO GROSS NECROPSY FINDINGS
C22147	SP	NO GROSS NECROPSY FINDINGS
C22148	SN	NO GROSS NECROPSY FINDINGS
C22149	SP	NO GROSS NECROPSY FINDINGS
C22150	SP	NO GROSS NECROPSY FINDINGS
C22151	SP	NO GROSS NECROPSY FINDINGS
C22152	SP	NO GROSS NECROPSY FINDINGS
C22153	SP	NO GROSS NECROPSY FINDINGS
C22154	SP	NO GROSS NECROPSY FINDINGS
C22155	SP	NO GROSS NECROPSY FINDINGS
C22156	SP	NO GROSS NECROPSY FINDINGS
C22157	SP	NO GROSS NECROPSY FINDINGS
C22158	SN	NO GROSS NECROPSY FINDINGS
C22159	SP	NO GROSS NECROPSY FINDINGS

SP=Fin sac/Pg      SN=Fin sac/NotPg



### INDIVIDUAL NECROPSY OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	ORGAN	OBSERVATION
C22160	SN	NO GROSS NECROPSY FINDINGS
C22161	SP	NO GROSS NECROPSY FINDINGS
C22162	SP	NO GROSS NECROPSY FINDINGS
C22163	SP	NO GROSS NECROPSY FINDINGS
C22164	SP	NO GROSS NECROPSY FINDINGS

SP=Fin sac/Pg

SN=Fin sac/NotPg

### INDIVIDUAL NECROPSY OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	ORGAN	OBSERVATION
C22165	SN	NO GROSS NECROPSY FINDINGS
C22166	SN	NO GROSS NECROPSY FINDINGS
C22167	SP	NO GROSS NECROPSY FINDINGS
C22168	SP	NO GROSS NECROPSY FINDINGS
C22169	SP	NO GROSS NECROPSY FINDINGS
C22170	SN	NO GROSS NECROPSY FINDINGS
C22171	SP	NO GROSS NECROPSY FINDINGS
C22172	SN	NO GROSS NECROPSY FINDINGS
C22173	SP	NO GROSS NECROPSY FINDINGS
C22174	SP	NO GROSS NECROPSY FINDINGS
C22175	SP	NO GROSS NECROPSY FINDINGS
C22176	SN	NO GROSS NECROPSY FINDINGS
C22177	SP	NO GROSS NECROPSY FINDINGS
C22178	SP	NO GROSS NECROPSY FINDINGS
C22179	SP	NO GROSS NECROPSY FINDINGS
C22180	SP	NO GROSS NECROPSY FINDINGS
C22181	SP	NO GROSS NECROPSY FINDINGS
C22182	SP	NO GROSS NECROPSY FINDINGS
C22183	SP	NO GROSS NECROPSY FINDINGS

SP=Fin sac/Pg      SN=Fin sac/NotPg

### INDIVIDUAL NECROPSY OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	ORGAN	OBSERVATION
C22184	SP	NO GROSS NECROPSY FINDINGS
C22185	SP	NO GROSS NECROPSY FINDINGS
C22186	SP	NO GROSS NECROPSY FINDINGS
C22187	SP	NO GROSS NECROPSY FINDINGS
C22188	SP	NO GROSS NECROPSY FINDINGS

SP=Fin sac/Pg

### INDIVIDUAL NECROPSY OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	ORGAN	OBSERVATION
C22189	SP	NO GROSS NECROPSY FINDINGS
C22190	SP	NO GROSS NECROPSY FINDINGS
C22191	SP	NO GROSS NECROPSY FINDINGS
C22192	SP	NO GROSS NECROPSY FINDINGS
C22193	SP	NO GROSS NECROPSY FINDINGS
C22194	SP	NO GROSS NECROPSY FINDINGS
C22195	SN	NO GROSS NECROPSY FINDINGS
C22196	SP	NO GROSS NECROPSY FINDINGS
C22197	SP	NO GROSS NECROPSY FINDINGS
C22198	SP	NO GROSS NECROPSY FINDINGS
C22199	SP	NO GROSS NECROPSY FINDINGS
C22200	SP	NO GROSS NECROPSY FINDINGS
C22201	SP	NO GROSS NECROPSY FINDINGS
C22202	SP	NO GROSS NECROPSY FINDINGS
C22203	SP	NO GROSS NECROPSY FINDINGS
C22204	SP	NO GROSS NECROPSY FINDINGS
C22205	SP	NO GROSS NECROPSY FINDINGS
C22206	SN	NO GROSS NECROPSY FINDINGS
C22207	SP	PLACENTIA/ENVELOP PLACENTIA: ENLARGED PLACENTIA(S) Number 3

SP=Fin sac/Pg      SN=Fin sac/NotPg

### INDIVIDUAL NECROPSY OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	ORGAN	OBSERVATION
C22208	SN	NO GROSS NECROPSY FINDINGS
C22209	SP	NO GROSS NECROPSY FINDINGS
C22210	SN	NO GROSS NECROPSY FINDINGS
C22211	SP	NO GROSS NECROPSY FINDINGS
C22212	SP	NO GROSS NECROPSY FINDINGS

SP=Fin sac/Pg      SN=Fin sac/NotPg

### INDIVIDUAL NECROPSY OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	ORGAN	OBSERVATION
C22213	SP	NO GROSS NECROPSY FINDINGS
C22214	SP	NO GROSS NECROPSY FINDINGS
C22215	SP	NO GROSS NECROPSY FINDINGS
C22216	SP	NO GROSS NECROPSY FINDINGS
C22217	SP	NO GROSS NECROPSY FINDINGS
C22218	SN	NO GROSS NECROPSY FINDINGS
C22219	SP	NO GROSS NECROPSY FINDINGS
C22220	SP	NO GROSS NECROPSY FINDINGS
C22221	SP	NO GROSS NECROPSY FINDINGS
C22222	SP	NO GROSS NECROPSY FINDINGS
C22223	SP	NO GROSS NECROPSY FINDINGS
C22224	SP	NO GROSS NECROPSY FINDINGS
C22225	SP	NO GROSS NECROPSY FINDINGS
C22226	SP	NO GROSS NECROPSY FINDINGS
C22227	SP	NO GROSS NECROPSY FINDINGS
C22228	SN	NO GROSS NECROPSY FINDINGS
C22229	SP	NO GROSS NECROPSY FINDINGS
C22230	SP	NO GROSS NECROPSY FINDINGS
C22231	SP	NO GROSS NECROPSY FINDINGS

SP=Fin sac/Pg      SN=Fin sac/NotPg

### INDIVIDUAL NECROPSY OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	ORGAN	OBSERVATION
C22232	SP	NO GROSS NECROPSY FINDINGS
C22233	SP	NO GROSS NECROPSY FINDINGS
C22234	SP	NO GROSS NECROPSY FINDINGS
C22235	SP	NO GROSS NECROPSY FINDINGS
C22236	SP	NO GROSS NECROPSY FINDINGS

SP=Fin sac/Pg

12. Individual hysterectomy data  
Fin sac : final sacrifice  
Pg : pregnant  
NotPg : not pregnant



**HYSTERECTOMY DATA (Individual values)**

Dose: 0 mg/kg/day

FEMALE#	CORPORA LUTEA	IMPLANT SITES	RESORPTIONS			DEAD FETUSES		LIVE FETUSES		IMPLANTATION LOSS		AVERAGE FETAL BODY WEIGHT		
			SCARS	EARLY	LATE	TOTAL	MALE	FEMALE	MALE	FEMALE	PRE		POST	
C22141	SP	14	13	0	2	0	2	0	0	2	9	1	2	3.91
C22142	SP	15	13	0	0	0	0	0	0	5	8	2	0	3.43
C22143	SP	18	13	0	0	0	0	0	0	7	6	5	0	4.19
C22144	SP	13	13	0	0	0	0	0	0	5	8	0	0	3.79
C22145	SP	10	3	0	0	0	0	0	0	2	1	7	0	4.54
C22146	SP	15	13	0	2	0	2	0	0	1	10	2	2	3.91
C22147	SP	16	13	0	0	0	0	0	0	5	8	3	0	4.21
C22148	SN	7	0											
C22149	SP	15	14	0	0	0	0	0	0	9	5	1	0	3.51
C22150	SP	16	16	0	0	0	0	0	0	8	8	0	0	2.09
C22151	SP	13	13	0	2	0	2	0	0	2	9	0	2	4.45
C22152	SP	17	13	0	1	0	1	0	0	6	6	4	1	4.09
C22153	SP	17	13	0	0	0	0	0	0	6	7	4	0	3.74
C22154	SP	15	15	0	0	0	0	0	0	2	13	0	0	3.73
C22155	SP	20	14	0	0	0	0	0	0	5	9	6	0	3.68
C22156	SP	13	13	0	4	0	4	0	0	6	3	0	4	4.45
C22157	SP	14	14	0	0	0	0	0	0	4	10	0	0	3.79
C22158	SN	0	0											
C22159	SP	13	13	0	0	0	0	0	0	4	9	0	0	4.00
C22160	SN	0	0											
C22161	SP	15	15	0	0	0	0	0	0	10	5	0	0	4.13
C22162	SP	17	17	0	0	0	0	0	0	6	11	0	0	3.81
C22163	SP	15	2	0	0	1	1	0	0	1	0	13	1	2.97
C22164	SP	16	16	0	2	0	2	0	0	8	6	0	2	3.67
TOTAL		317	269	0	13	1	14	0	0	104	151	48	14	
MEAN		15.1	12.8	0.0	0.6	0.0	0.7	0.0	0.0	5.0	7.2	2.29	0.67	3.81
S.D.		2.1	3.6	0.0	1.1	0.2	1.1	0.0	0.0	2.6	3.2	3.32	1.11	0.54
N		21	21	21	21	21	21	21	21	21	21	21	21	21

SP=Fin sac/Pg      SN=Fin sac/NotPg

**HYSTERECTOMY DATA (Individual values)**

Dose: 250 mg/kg/day

FEMALE#	CORPORA		IMPLANT SITES	RESORPTIONS			DEAD FETUSES		LIVE FETUSES		IMPLANTATION LOSS		AVERAGE FETAL BODY WEIGHT	
	LUTEA			SCARS	EARLY	LATE	TOTAL	MALE	FEMALE	MALE	FEMALE	PRE		POST
C22165	SN	0	0											
C22166	SN	9	0											
C22167	SP	12	12	0	0	0	0	0	0	6	6	0	0	4.23
C22168	SP	12	11	0	1	0	1	0	0	7	3	1	1	3.94
C22169	SP	11	11	0	0	0	0	0	0	5	6	0	0	3.90
C22170	SN	12	0											
C22171	SP	12	12	0	0	0	0	0	0	7	5	0	0	3.38
C22172	SN	10	0											
C22173	SP	17	13	0	0	0	0	0	0	8	5	4	0	3.12
C22174	SP	13	12	0	0	0	0	0	0	5	7	1	0	3.99
C22175	SP	15	13	0	0	0	0	0	0	10	3	2	0	3.96
C22176	SN	8	0											
C22177	SP	17	12	0	2	0	2	0	0	5	5	5	2	4.27
C22178	SP	18	14	0	0	0	0	0	0	8	6	4	0	4.00
C22179	SP	13	13	0	2	0	2	0	0	6	5	0	2	4.27
C22180	SP	15	15	0	1	0	1	0	0	5	9	0	1	4.32
C22181	SP	15	11	0	1	0	1	0	0	5	5	4	1	3.71
C22182	SP	15	14	0	1	1	2	0	0	8	4	1	2	3.86
C22183	SP	14	11	0	0	0	0	0	0	4	7	3	0	3.67
C22184	SP	16	13	0	0	0	0	0	0	7	6	3	0	4.07
C22185	SP	14	13	0	0	0	0	0	0	10	3	1	0	4.12
C22186	SP	22	15	0	2	1	3	0	0	3	9	7	3	4.03
C22187	SP	12	12	0	2	0	2	0	0	4	6	0	2	4.04
C22188	SP	15	15	0	2	0	2	0	0	8	5	0	2	3.64
TOTAL		278	242	0	14	2	16	0	0	121	105	36	16	
MEAN		14.6	12.7	0.0	0.7	0.1	0.8	0.0	0.0	6.4	5.5	1.89	0.84	3.92
S.D.		2.7	1.4	0.0	0.9	0.3	1.0	0.0	0.0	2.0	1.7	2.11	1.01	0.31
N		19	19	19	19	19	19	19	19	19	19	19	19	19

SP=Fin sac/Pg      SN=Fin sac/NotPg

**HYSTERECTOMY DATA (Individual values)**

Dose: 500 mg/kg/day

FEMALE#	CORPORA		IMPLANT SITES	RESORPTIONS			DEAD FETUSES		LIVE FETUSES		IMPLANTATION LOSS		AVERAGE FETAL BODY WEIGHT	
	LUTEA			SCARS	EARLY	LATE	TOTAL	MALE	FEMALE	MALE	FEMALE	PRE		POST
C22189	SP	14	12	0	0	0	0	0	0	5	7	2	0	3.13
C22190	SP	10	10	0	1	0	1	0	0	3	6	0	1	4.20
C22191	SP	11	10	0	1	0	1	0	0	3	6	1	1	3.92
C22192	SP	14	14	0	0	0	0	0	0	8	6	0	0	3.71
C22193	SP	12	10	0	1	0	1	0	0	3	6	2	1	4.04
C22194	SP	19	14	0	0	0	0	0	0	7	7	5	0	3.65
C22195	SN	8	0											
C22196	SP	16	16	0	5	0	5	0	0	7	4	0	5	3.97
C22197	SP	16	12	0	2	0	2	0	0	5	5	4	2	3.63
C22198	SP	14	14	0	2	0	2	0	0	7	5	0	2	3.65
C22199	SP	15	13	0	0	0	0	0	0	5	8	2	0	4.24
C22200	SP	16	14	0	0	0	0	0	0	5	9	2	0	3.96
C22201	SP	15	13	0	0	0	0	0	0	4	9	2	0	4.09
C22202	SP	15	15	0	0	0	0	0	0	7	8	0	0	4.05
C22203	SP	14	13	0	0	0	0	0	0	7	6	1	0	3.74
C22204	SP	17	14	0	0	1	1	0	0	6	7	3	1	4.41
C22205	SP	14	14	0	1	0	1	0	0	4	9	0	1	3.61
C22206	SN	7	0											
C22207	SP	19	10	0	1	0	1	0	0	4	5	9	1	3.17
C22208	SN	10	0											
C22209	SP	15	14	0	1	0	1	0	0	9	4	1	1	3.97
C22210	SN	4	0											
C22211	SP	19	16	0	1	0	1	0	0	10	5	3	1	3.88
C22212	SP	18	17	0	2	0	2	0	0	11	4	1	2	3.64
TOTAL		303	265	0	18	1	19	0	0	120	126	38	19	
MEAN		15.1	13.3	0.0	0.9	0.1	0.9	0.0	0.0	6.0	6.3	1.90	0.95	3.83
S.D.		2.5	2.1	0.0	1.2	0.2	1.2	0.0	0.0	2.3	1.7	2.20	1.19	0.32
N		20	20	20	20	20	20	20	20	20	20	20	20	20

SP=Fin sac/Pg      SN=Fin sac/NotPg

**HYSTERECTOMY DATA (Individual values)**

Dose: 1000 mg/kg/day

FEMALE#	CORPORA		IMPLANT SITES	RESORPTIONS			DEAD FETUSES		LIVE FETUSES		IMPLANTATION LOSS		AVERAGE FETAL BODY WEIGHT	
	LUTEA			SCARS	EARLY	LATE	TOTAL	MALE	FEMALE	MALE	FEMALE	PRE		POST
C22213	SP	15	11	0	0	0	0	0	0	3	8	4	0	3.29
C22214	SP	11	11	0	0	0	0	0	0	5	6	0	0	3.79
C22215	SP	15	12	0	0	0	0	0	0	3	9	3	0	3.72
C22216	SP	15	12	0	0	0	0	0	0	5	7	3	0	3.33
C22217	SP	15	15	0	2	0	2	0	0	10	3	0	2	3.66
C22218	SN	10	0											
C22219	SP	14	12	0	1	0	1	0	0	4	7	2	1	3.90
C22220	SP	15	13	0	0	0	0	0	0	3	10	2	0	3.98
C22221	SP	12	12	0	1	0	1	0	0	4	7	0	1	3.75
C22222	SP	11	11	0	2	0	2	0	0	6	3	0	2	3.63
C22223	SP	13	12	0	1	0	1	0	0	5	6	1	1	4.16
C22224	SP	15	13	0	0	0	0	0	0	8	5	2	0	3.97
C22225	SP	20	12	0	0	0	0	0	0	7	5	8	0	4.14
C22226	SP	18	16	0	0	0	0	0	0	9	7	2	0	4.20
C22227	SP	14	14	0	4	0	4	0	0	6	4	0	4	3.75
C22228	SN	0	0											
C22229	SP	14	13	0	3	0	3	0	0	8	2	1	3	3.21
C22230	SP	12	11	0	1	0	1	0	0	6	4	1	1	3.95
C22231	SP	18	13	0	0	0	0	0	0	6	7	5	0	3.47
C22232	SP	15	14	0	1	0	1	0	0	4	9	1	1	3.51
C22233	SP	14	14	0	3	0	3	0	0	6	5	0	3	4.06
C22234	SP	12	9	0	0	0	0	0	0	3	6	3	0	3.28
C22235	SP	23	16	0	1	0	1	0	0	6	9	7	1	4.16
C22236	SP	15	13	0	1	0	1	0	0	5	7	2	1	4.45
TOTAL		326	279	0	21	0	21	0	0	122	136	47	21	
MEAN		14.8	12.7	0.0	1.0	0.0	1.0	0.0	0.0	5.5	6.2	2.14	0.95	3.79
S.D.		2.9	1.7	0.0	1.2	0.0	1.2	0.0	0.0	2.0	2.2	2.23	1.17	0.34
N		22	22	22	22	22	22	22	22	22	22	22	22	22

SP=Fin sac/Pg      SN=Fin sac/NotPg

13. Individual uterine contents

Fin sac : final sacrifice

Pg : pregnant

NotPg : not pregnant





**UTERINE CONTENTS (Individual values)**

Dose: 500 mg/kg/day

FEMALE#	IMPLANT #																																
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30			
C22189	FA	MA	FA	MA	/FA	MA	FA	FA	MA	MA	FA	FA																					Fin sac/Pg
C22190	FA	MA	MA	FA	MA	FA	FA	/FA	FA	E																						Fin sac/Pg	
C22191	FA	FA	FA	FA	MA	MA	MA	/FA	E	FA																						Fin sac/Pg	
C22192	MA	FA	MA	FA	MA	FA	FA	MA	/MA	FA	FA	MA	MA	MA																		Fin sac/Pg	
C22193	FA	FA	MA	MA	FA	FA	/MA	E	FA	FA																						Fin sac/Pg	
C22194	FA	MA	MA	MA	FA	FA	/MA	FA	MA	MA	FA	MA	FA	FA																		Fin sac/Pg	
C22195																																Fin sac/NotPg	
C22196	MA	FA	FA	E	MA	MA	E	MA	/FA	MA	MA	E	FA	MA	E	E																Fin sac/Pg	
C22197	E	MA	E	FA	FA	MA	/FA	FA	FA	MA	MA	MA																				Fin sac/Pg	
C22198	MA	MA	MA	FA	MA	E	E	/FA	MA	FA	FA	FA	MA	MA																		Fin sac/Pg	
C22199	FA	MA	FA	FA	FA	MA	MA	/FA	FA	FA	FA	MA	MA																			Fin sac/Pg	
C22200	MA	FA	FA	MA	/MA	FA	FA	FA	FA	MA	FA	FA	FA	MA																		Fin sac/Pg	
C22201	MA	FA	FA	MA	FA	/FA	FA	FA	FA	MA	FA	MA	FA	MA																		Fin sac/Pg	
C22202	FA	MA	MA	FA	/FA	FA	MA	MA	FA	MA	MA	MA	FA	MA	FA	FA																Fin sac/Pg	
C22203	FA	FA	MA	FA	MA	FA	MA	FA	/MA	FA	MA	MA	MA																			Fin sac/Pg	
C22204	FA	FA	FA	FA	MA	MA	MA	MA	/MA	FA	MA	FA	L	FA																		Fin sac/Pg	
C22205	FA	MA	FA	FA	FA	FA	MA	MA	FA	/FA	FA	MA	E	FA																		Fin sac/Pg	
C22206																																Fin sac/NotPg	
C22207	MA	FA	FA	/E	FA	MA	FA	FA	MA	MA																						Fin sac/Pg	
C22208																																Fin sac/NotPg	
C22209	MA	MA	MA	MA	/FA	FA	FA	E	FA	MA	MA	MA	MA	MA																		Fin sac/Pg	
C22210																																Fin sac/NotPg	
C22211	MA	MA	MA	E	MA	MA	MA	/FA	FA	MA	MA	FA	MA	FA	FA	MA																Fin sac/Pg	
C22212	FA	MA	MA	MA	MA	MA	MA	FA	FA	MA	MA	/MA	MA	MA	E	FA	E															Fin sac/Pg	

M MALE F FEMALE / DENOTES POSITION OF CERVIX  
A-ALIVE E-EARLY RESORPTION L-LATE RESORPTION S-SCAR D-DEAD FEIUS



**UTERINE CONTENTS (Individual values)**

Dose: 1000 mg/kg/day

FEMALE#	IMPLANT #																																
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30			
C22213	FA	MA	FA	MA	/FA	FA	FA	FA	FA	MA	FA																						Fin sac/Pg
C22214	FA	MA	MA	FA	FA	MA	MA	/MA	FA	FA	FA																						Fin sac/Pg
C22215	MA	MA	FA	FA	FA	FA	/FA	FA	MA	FA	FA	FA																					Fin sac/Pg
C22216	MA	FA	MA	FA	MA	/MA	FA	MA	FA	FA	FA	FA																					Fin sac/Pg
C22217	MA	E	MA	MA	E	FA	MA	/FA	MA	MA	MA	MA	MA	MA	MA	FA																	Fin sac/Pg
C22218																																	Fin sac/NotPg
C22219	FA	FA	FA	FA	/E	MA	FA	MA	FA	MA	MA	FA																					Fin sac/Pg
C22220	FA	FA	FA	FA	FA	FA	FA	FA	/FA	MA	MA	FA	MA																				Fin sac/Pg
C22221	FA	FA	E	FA	MA	FA	/MA	FA	FA	MA	FA	MA																					Fin sac/Pg
C22222	MA	E	MA	FA	MA	/MA	FA	MA	E	MA	FA																						Fin sac/Pg
C22223	FA	MA	E	FA	FA	MA	/FA	MA	MA	FA	FA	MA																					Fin sac/Pg
C22224	FA	MA	MA	MA	/MA	MA	FA	FA	MA	FA	MA	MA	FA																				Fin sac/Pg
C22225	FA	MA	MA	FA	FA	MA	/MA	FA	FA	MA	MA	MA																					Fin sac/Pg
C22226	FA	MA	MA	MA	FA	MA	/FA	MA	FA	FA	FA	MA	MA	MA	MA	FA	MA																Fin sac/Pg
C22227	MA	MA	FA	E	MA	FA	FA	/MA	E	E	MA	MA	FA	E																			Fin sac/Pg
C22228																																	Fin sac/NotPg
C22229	MA	E	E	MA	MA	FA	FA	E	MA	/MA	MA	MA	MA																				Fin sac/Pg
C22230	FA	MA	MA	/FA	MA	MA	MA	FA	FA	MA	E																						Fin sac/Pg
C22231	FA	MA	MA	FA	MA	FA	MA	/FA	MA	FA	FA	MA																					Fin sac/Pg
C22232	FA	FA	E	FA	MA	FA	FA	MA	MA	/FA	MA	FA	FA	FA																			Fin sac/Pg
C22233	MA	E	MA	FA	E	MA	FA	/FA	MA	MA	MA	FA	E	FA																			Fin sac/Pg
C22234	FA	MA	MA	FA	FA	/FA	FA	FA	MA																								Fin sac/Pg
C22235	MA	MA	E	FA	MA	FA	FA	FA	MA	/FA	FA	FA	FA	MA	FA	MA																	Fin sac/Pg
C22236	E	FA	MA	MA	FA	FA	FA	MA	/FA	FA	FA	MA	MA																				Fin sac/Pg

M MALE F FEMALE / DENOTES POSITION OF CERVIX  
A-ALIVE E-EARLY RESORPTION L-LATE RESORPTION S-SCAR D-DEAD FEIUS

14. Individual fetal body weights

Fin sac : final sacrifice

Pg : pregnant

NotPg : not pregnant

**INDIVIDUAL FETAL BODY WEIGHTS (grams)**

Dose: 0 mg/kg/day

FEMALE#	MEAN	FETUS#														
		1 16	2 17	3 18	4 19	5 20	6 21	7 22	8 23	9 24	10 25	11 26	12 27	13 28	14 29	15 30
C22141	3.91	3.60	E	4.04	3.97	3.75	3.77	3.99	3.77/	E	4.37	3.76	3.94	4.03		
C22142	3.43	3.51	3.30	3.61/	3.31	3.27	3.39	3.35	3.61	3.47	3.37	3.54	3.49	3.31		
C22143	4.19	4.37	4.02	4.44	4.20	4.43/	4.27	4.15	4.42	3.95	4.03	4.13	4.02	4.05		
C22144	3.79	3.53	3.54	3.97	3.89	4.09	4.06	3.60/	3.31	3.77	3.57	3.80	4.02	4.08		
C22145	4.54	4.79/	4.65	4.19												
C22146	3.91	E/	3.97	4.20	3.74	3.79	4.11	3.92	3.59	E	4.21	4.01	3.68	3.80		
C22147	4.21	3.78	4.51	4.31	3.97	4.35	4.50/	4.14	3.98	4.03	4.65	4.16	4.09	4.28		
C22148	SN															
C22149	3.51	3.35	3.57	3.46	3.31	3.59	3.64	3.46	3.81/	3.17	3.68	3.88	3.45	3.34	3.40	
C22150	2.09	1.89	2.12	2.10	2.22	2.21	2.18	2.11	2.07/	2.16	2.15	2.06	1.90	1.94	2.04	2.15
		2.20														
C22151	4.45	4.37	4.68	4.31	4.37	E	4.15	4.62/	E	4.06	4.54	4.56	4.79	4.45		
C22152	4.09	3.92	4.05	3.94	4.44	4.10	3.90	4.13/	4.07	E	4.36	4.17	3.81	4.13		
C22153	3.74	3.72	3.95	3.59	3.50	3.71	3.61	3.73	4.01	3.85/	3.81	3.85	3.55	3.72		
C22154	3.73	3.81	1.76	4.18	3.59	3.76	3.89	3.93/	4.18	4.13	3.81	3.94	3.79	3.99	3.75	3.49
C22155	3.68	3.37	3.79	3.37	3.54	3.88	3.63	3.82/	3.90	4.07	3.58	3.82	3.71	3.55	3.51	
C22156	4.45	4.49	4.39	E	E	4.34	4.31	4.28	4.43/	4.41	4.83	4.53	E	E		
C22157	3.79	3.92	3.64	3.85	3.66	3.73	3.86	3.92/	3.83	3.94	4.09	3.79	3.41	3.84	3.51	
C22158	SN															
C22159	4.00	3.57	3.81	3.99	4.10	4.49	3.83	3.85	4.03/	4.37	4.10	4.07	3.85	3.92		
C22160	SN															
C22161	4.13	3.81	4.19	4.24	4.06	4.12	3.79	4.24	4.36/	3.84	4.37	4.21	4.40	3.91	4.11	4.29
C22162	3.81	2.60	3.77	4.09	3.46	4.25	3.84	3.73	3.84	3.68	4.15/	4.17	4.12	3.95	3.82	3.65
		3.83	3.87													
C22163	2.97	2.97	L/													
C22164	3.67	3.35	2.97	4.16	3.89	3.87	3.57	3.75	3.22	E	4.01/	3.55	3.84	4.08	3.15	E
		3.90														
MEAN	3.81															
S.D.	0.54															
N	21															

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

SN=Fin sac/NotPg

**INDIVIDUAL FETAL BODY WEIGHTS (grams)**

Dose: 250 mg/kg/day

FEMALE#	MEAN	FETUS#														
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
		16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
C22165	SN															
C22166	SN															
C22167	4.23	4.75	4.20	4.84	4.07	4.23	4.16	4.29	4.38/	4.13	3.89	3.96	3.88			
C22168	3.94	3.73	4.04	3.82	3.55	3.95	4.14/	4.25	E	4.16	4.00	3.79				
C22169	3.90	4.07	3.84	3.90	3.74	3.65	3.80/	3.65	3.72	4.16	4.33	3.99				
C22170	SN															
C22171	3.38	3.19	3.15	3.71	3.74	3.46	3.80/	3.06	3.75	3.76	3.04	2.86	3.06			
C22172	SN															
C22173	3.12	2.54	3.01	2.42	3.13	3.27	3.39/	3.49	3.13	3.54	3.13	3.45	3.21	2.82		
C22174	3.99	4.26	4.37	4.14/	3.68	3.98	3.75	3.71	3.97	3.72	3.70	3.99	4.57			
C22175	3.96	3.97	3.96	4.19	3.98	3.81/	4.32	4.09	3.93	3.81	3.76	3.61	4.04	4.04		
C22176	SN															
C22177	4.27	4.04	4.46	4.03	4.61	4.25	4.19/	4.28	E	4.31	E	4.06	4.42			
C22178	4.00	4.00	3.88	4.06	3.89	3.77	4.16	4.25/	4.03	3.92	4.11	3.90	3.91	3.74	4.33	
C22179	4.27	E	4.04	4.21	4.10	4.11	4.16/	4.79	4.27	4.04	4.71	4.25	E	4.28		
C22180	4.32	4.52	4.38	4.28	E	4.01	4.04/	4.42	4.76	4.48	4.37	4.24	4.38	4.11	4.16	4.26
C22181	3.71	3.71	3.97	3.79	E	3.46	3.11	3.44	4.08/	3.71	3.81	4.01				
C22182	3.86	3.66	4.10	3.88	E	3.97	4.26/	3.83	3.47	3.78	3.82	L	3.63	4.01	3.86	
C22183	3.67	3.70	3.56	3.98	3.82	4.09	3.59	1.88	3.41/	4.00	4.40	3.93				
C22184	4.07	3.67	4.16	4.16	4.07	4.29	4.12	4.22/	4.00	4.00	3.92	4.10	4.16	4.09		
C22185	4.12	4.05	4.35	4.42	4.21	4.08	4.07	4.35/	4.27	3.49	4.11	4.06	3.89	4.16		
C22186	4.03	4.02	3.97	E	4.03	4.50	4.04	L	4.00	4.37	3.78/	E	3.26	4.18	4.28	3.95
C22187	4.04	4.23	4.30	3.97	3.91	3.77	3.96/	4.04	4.30	4.04	E	3.84	E			
C22188	3.64	3.58	3.00	3.79	4.06	3.60	3.57	3.79	3.70/	3.33	3.89	3.44	E	E	3.57	4.01
MEAN	3.92															
S.D.	0.31															
N	19															

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

SN=Fin sac/NotPg

**INDIVIDUAL FETAL BODY WEIGHTS (grams)**

Dose: 500 mg/kg/day

FEMALE#	MEAN	FETUS#														
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
		16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
C22189	3.13	2.90	3.60	3.39	3.25/	2.89	3.31	2.75	3.10	3.08	3.16	3.06	3.09			
C22190	4.20	4.29	4.12	4.47	4.19	4.32	3.99	4.08/	4.35	3.99	E					
C22191	3.92	3.79	3.69	3.74	3.84	3.97	4.23	4.16/	3.99	E	3.90					
C22192	3.71	3.36	3.39	3.83	3.78	3.60	3.64	3.67	3.57/	3.95	4.00	3.57	4.11	3.89	3.55	
C22193	4.04	3.75	3.78	4.12	4.29	3.82	4.25/	4.15	E	3.90	4.32					
C22194	3.65	3.51	3.75	4.06	3.84	3.60	3.42/	3.96	3.51	3.86	3.85	3.55	3.63	3.25	3.29	
C22195	SN															
C22196	3.97	3.55	3.85	3.83	E	4.15	4.26	E	4.41/	3.54	4.22	4.06	E	3.98	3.78	E
		E														
C22197	3.63	E	3.82	E	3.63	3.98	3.73/	3.81	3.32	2.67	3.93	3.91	3.53			
C22198	3.65	4.03	3.74	3.96	3.67	4.01	E	E/	3.90	4.06	3.41	3.82	3.77	1.67	3.82	
C22199	4.24	4.10	4.41	4.28	4.28	4.03	4.25	4.42/	3.94	4.37	4.29	4.20	4.31	4.22		
C22200	3.96	4.26	3.81	3.90	4.29/	4.11	4.01	3.80	3.93	3.31	3.83	3.72	4.17	3.94	4.31	
C22201	4.09	4.17	4.19	3.94	4.22	4.00/	4.11	4.12	3.85	4.13	4.21	3.86	4.08	4.23		
C22202	4.05	4.05	4.32	4.14	4.11/	3.95	4.02	3.93	4.01	3.88	4.08	4.15	4.17	3.97	4.00	3.90
C22203	3.74	3.74	3.72	4.34	2.40	3.93	3.66	3.05	3.86/	3.67	3.97	4.17	3.90	4.18		
C22204	4.41	3.99	4.12	4.58	4.35	4.66	4.37	4.64	4.40/	4.53	4.17	4.60	4.63	L	4.28	
C22205	3.61	3.54	3.71	3.67	3.44	3.56	3.43	3.93	3.58	3.59/	3.89	3.65	4.11	E	2.84	
C22206	SN															
C22207	3.17	2.80	3.37	3.32/	E	3.21	2.99	3.19	3.05	3.39	3.20					
C22208	SN															
C22209	3.97	4.07	4.09	4.12	3.78/	3.95	3.77	3.75	E	3.87	3.91	4.14	3.94	3.86	4.31	
C22210	SN															
C22211	3.88	3.88	4.04	3.55	E	4.23	3.76	3.87/	3.98	3.76	3.98	4.19	3.69	3.84	3.89	3.78
		3.81														
C22212	3.64	3.50	3.66	3.52	3.38	3.49	4.11	3.74	3.57	3.34	3.71	3.39/	3.70	3.99	3.89	E
		3.64	E													
MEAN	3.83															
S.D.	0.32															
N	20															

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

SN=Fin sac/NotPg

**INDIVIDUAL FETAL BODY WEIGHTS (grams)**

Dose: 1000 mg/kg/day

FEMALE#	MEAN	FETUS#														
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
		16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
C22213	3.29	3.10	3.46	3.35	3.55/	3.20	3.40	3.10	3.31	3.18	3.33	3.17				
C22214	3.79	3.55	4.01	3.91	3.77	3.79	3.84	3.82/	3.91	3.81	3.64	3.60				
C22215	3.72	3.80	3.88	3.06	3.37	3.68	3.86/	3.97	4.00	3.89	4.16	3.75	3.25			
C22216	3.33	3.26	3.50	3.37	3.09	3.66/	3.55	3.44	3.47	3.25	2.74	3.56	3.05			
C22217	3.66	3.88	E	3.77	3.61	E	3.44	3.67/	3.53	3.46	3.75	3.68	3.82	3.86	3.85	3.22
C22218	SN															
C22219	3.90	3.54	4.34	3.89	3.84/	E	4.00	3.69	3.92	3.81	4.26	3.98	3.59			
C22220	3.98	3.79	3.73	3.97	3.97	4.21	3.78	3.98	3.84/	3.90	4.05	4.29	4.10	4.12		
C22221	3.75	3.68	3.59	E	3.71	3.89	3.71/	4.01	3.48	3.53	4.05	3.79	3.86			
C22222	3.63	4.20	E	3.30	3.56	3.74/	4.15	2.10	4.05	E	3.79	3.80				
C22223	4.16	3.99	4.02	E	4.07	3.95	4.25/	4.35	4.27	4.50	3.99	4.17	4.23			
C22224	3.97	3.82	4.04	4.05	4.21/	3.97	4.13	3.77	3.85	4.05	4.23	3.60	3.96			
C22225	4.14	3.79	4.22	4.16	4.11	4.08	4.50/	4.45	4.10	4.06	4.19	3.99	4.00			
C22226	4.20	4.16	4.47	4.35	4.27	3.84	4.54/	3.91	4.13	3.91	4.22	3.92	4.32	4.15	4.36	4.49
C22227	3.75	3.34	3.98	3.59	E	3.79	3.57	3.62/	3.98	E	E	3.91	4.00	3.71	E	
C22228	SN															
C22229	3.21	3.79	E	E	3.34	3.69	2.99	2.66	E	3.47/	2.28	4.09	3.31	2.45		
C22230	3.95	3.73	4.21	4.24/	3.80	3.81	4.34	3.78	3.82	3.85	3.89	E				
C22231	3.47	3.21	3.80	3.55	3.48	3.43	3.45	3.84/	3.47	3.73	3.21	3.30	3.24	3.39		
C22232	3.51	3.53	3.25	E	3.68	3.90	3.64	3.31	3.66	3.67/	3.33	3.81	3.09	3.57	3.18	
C22233	4.06	3.69	E	4.06	4.12	E	4.35	4.14/	4.09	4.30	4.13	4.24	3.89	E	3.61	
C22234	3.28	3.43	3.20	3.15	3.31	3.13/	3.41	3.40	2.66	3.81						
C22235	4.16	3.97	4.52	E	3.88	4.30	4.17	4.11	4.13	4.46/	4.02	4.24	4.42	4.05	4.26	3.82
C22236	4.45	E	4.29	4.72	4.64	4.37	4.56	4.03	4.56/	4.53	4.32	4.44	4.25	4.65		
MEAN	3.79															
S.D.	0.34															
N	22															

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

SN=Fin sac/NotPg

15. Individual fetal observations

Fin sac : final sacrifice

Pg : pregnant

NotPg : not pregnant

**INDIVIDUAL FETAL OBSERVATIONS**

Dose: 0 mg/kg/day

FEMALE#	FETUS#	(SEX)	WEIGHT(G)	OBSERVATION
C22141	SP	1 F	3.60	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF HYOID: PRESENT V UNOSSIFIED HYOID C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
		3 M	4.04	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
		4 F	3.97	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
		5 F	3.75	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
		6 F	3.77	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th V UNOSSIFIED 5th STERNEBRA
		7 F	3.99	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
		8 F	3.77	NO OBSERVED EXTERNAL FINDINGS THORACIC VERTEBRA(E) DAMAGED AT THE PREPARATION OF THE FETUS 3rd V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
		10 M	4.37	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
		11 F	3.76	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th

CLASS CODES: V-Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg



### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22141	(CONTINUED)		
	12 F	3.94	V INCOMPLETE OSSIFICATION OF 6th STERNEBRA NO OBSERVED EXTERNAL FINDINGS V DILATED URETER, LEFT
	13 F	4.03	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA (E) : PRESENT 5th V UNOSSIFIED 5th STERNEBRA
C22142	SP 1 M	3.51	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), RIGHT C CARTILAGE OF METACARPAL BONE(S) : PRESENT, RIGHT 4th
	2 F	3.30	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	3.61	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	4 F	3.31	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	3.27	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA (E) Centrum: 11th C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT 11th C CARTILAGE OF STERNEBRA (E) : PRESENT 5th and 6th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 3rd and 4th
	6 F	3.39	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	3.35	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22142	(CONTINUED)		
			C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT 4th
			V UNOSSIFIED 4th METACARPAL(S), LEFT
	8 M	3.61	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 M	3.47	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA
			C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th
			V UNOSSIFIED 6th STERNEBRA
			V UNOSSIFIED 4th METACARPAL(S), BILATERAL
			C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	10 F	3.37	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 M	3.54	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA
			C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	12 F	3.49	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 M	3.31	NO OBSERVED EXTERNAL FINDINGS
			C CARTILAGE OF STERNEBRA(E) : PRESENT 6th
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
			V UNOSSIFIED 4th METACARPAL(S), BILATERAL
			C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
C22143	SP 1 M	4.37	NO OBSERVED EXTERNAL FINDINGS METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	2 M	4.02	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	4.44	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	4 F	4.20	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 M	4.43	NO OBSERVED EXTERNAL FINDINGS

CLASS CODES: V-Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22143	(CONTINUED)		
	6 M	4.27	NO OBSERVED SKELETAL FINDINGS NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	4.15	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	8 M	4.42	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	3.95	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	10 F	4.03	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 M	4.13	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	12 F	4.02	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 F	4.05	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF HYOID C CARTILAGE OF HYOID: PRESENT
C22144	SP 1 F	3.53	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	2 F	3.54	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	3.97	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	4 M	3.89	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 M	4.09	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA

CLASS CODES: V-Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22144	(CONTINUED)		
	6 F	4.06	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	3.60	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E): PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	8 F	3.31	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	3.77	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E): PRESENT 5th and 6th V UNOSSIFIED 6th STERNEBRA
	10 F	3.57	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 M	3.80	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E): PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	12 M	4.02	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 M	4.08	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E): PRESENT 5th
C22145	SP 1 M	4.79	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E): PRESENT 5th METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 3rd and 4th
	2 M	4.65	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	4.19	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22145	(CONTINUED)		C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
C22146	SP 2 F	3.97	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	3 F	4.20	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	4 F	3.74	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	5 F	3.79	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	6 F	4.11	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	7 F	3.92	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	8 F	3.59	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, LEFT 3th
	10 F	4.21	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 F	4.01	NO OBSERVED EXTERNAL FINDINGS THORACIC VERTEBRA(E) DAMAGED AT THE PREPARATION OF THE FETUS 5th V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22146	(CONTINUED)		
			METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	12 M	3.68	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 F	3.80	NO OBSERVED EXTERNAL FINDINGS THORACIC VERTEBRA(E) DAMAGED AT THE PREPARATION OF THE FETUS 5th, 6th C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
C22147	SP 1 M	3.78	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th
	2 M	4.51	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	4.31	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	4 F	3.97	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	4.35	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th
	6 M	4.50	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	4.14	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) Centrum 10th, 12th V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22147	(CONTINUED)		
			C CARTILAGE OF THORACIC VERTEBRA(E) : PRESENT 10th, 12th
	8 F	3.98	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	4.03	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 2nd to 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd, 4th M MISALIGNED STERNEBRA(E) 3rd
	10 M	4.65	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 F	4.16	NO OBSERVED EXTERNAL FINDINGS V THORACIC VERTEBRA(E) : BIPARTITE OSSIFICATION OF CENIRUM 11th V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th C CARTILAGE OF THORACIC VERTEBRA(E) : PRESENT 11th
	12 F	4.09	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 F	4.28	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
C22149	SP 1 M	3.35	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	2 M	3.57	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS

CLASS CODES: M=Malformation V=Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22149	(CONTINUED)		
	3 M	3.46	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th,6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	4 F	3.31	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	3.59	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th,6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S) , BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	6 M	3.64	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	3.46	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	8 M	3.81	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	3.17	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th,6th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S) , BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	10 M	3.68	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 M	3.88	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	12 M	3.45	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 M	3.34	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th

CLASS CODES: V=Variation C=Cartilage  
SEX CODE: M-Male F-Female

SP=Fin sac/Pg



### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT(G)	OBSERVATION
C22149	(CONTINUED) 14 F	3.40	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
C22150	SP 1 F	1.89	NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Interparietal C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 1st, 3rd, 4th C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT 1st V INCOMPLETE OSSIFICATION OF SACRAL VERTEBRA(E) 2nd and 3rd: right and left arches 4th: centrum C CARTILAGE OF SACRAL VERTEBRA(E) : PRESENT 2nd to 4th V UNOSSIFIED CAUDAL VERTEBRA(E) 1st to 3rd C CARTILAGE OF CAUDAL VERTEBRA(E) : PRESENT 1st to 3rd C CARTILAGE OF STERNEBRA(E) : PRESENT 1st to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 1st, 3rd V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA V UNOSSIFIED 1st TO 4th STERNEBRA(E) 2nd, 4th V UNOSSIFIED 4th METACARPAL(S) , BILATERAL V INCOMPLETE OSSIFICATION OF 1st TO 3rd METACARPALS, BILATERAL 3rd V UNOSSIFIED 1st TO 3rd METACARPALS, BILATERAL 1st METATARSAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, LEFT 1st to 4th V INCOMPLETE OSSIFICATION OF METATARSAL(S) , RIGHT 1st C CARTILAGE OF METATARSAL BONE(S) : PRESENT, RIGHT 1st, 4th V UNOSSIFIED METATARSAL(S) , RIGHT 4th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT(G)	OBSERVATION
C22150	(CONTINUED)		
			C CARTILAGE OF PELVIC GIRDLE: PRESENT, BILATERAL Pubis, ischium
			V UNOSSIFIED PUBIS, BILATERAL
			V INCOMPLETE OSSIFICATION OF ISCHIUM, BILATERAL
			V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) 1st: centrum
	2 M	2.12	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	2.10	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF HYOID: PRESENT V UNOSSIFIED HYOID C CARTILAGE OF METACARPAL BONE(S): PRESENT, BILATERAL Right: 1st Bilateral: 3rd, 4th C CARTILAGE OF THORACIC VERTEBRA(E): PRESENT 1st V INCOMPLETE OSSIFICATION OF SACRAL VERTEBRA(E) 1st to 3rd: right and left arches C CARTILAGE OF SACRAL VERTEBRA(E): PRESENT 1st to 4th V UNOSSIFIED SACRAL VERTEBRA(E) 4th V UNOSSIFIED CAUDAL VERTEBRA(E) 1st to 3rd C CARTILAGE OF CAUDAL VERTEBRA(E): PRESENT 1st to 3rd C CARTILAGE OF STERNEBRA(E): PRESENT 1st to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 1st V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA V UNOSSIFIED 1st TO 4th STERNEBRA(E) 2nd to 4th METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, LEFT 1st V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METATARSAL BONE(S): PRESENT, BILATERAL 2nd to 4th V INCOMPLETE OSSIFICATION OF 1st TO 3rd METACARPALS, BILATERAL 3rd

CLASS CODES: V=Variation C=Cartilage  
SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22150	(CONTINUED)		V UNOSSIFIED 1st TO 3rd METACARPALS, RIGHT 1st V INCOMPLETE OSSIFICATION OF METATARSAL(S), BILATERAL 2nd, 3rd V UNOSSIFIED METATARSAL(S), BILATERAL 4th C CARTILAGE OF PELVIC GIRDLE: PRESENT, BILATERAL Pubis, ischium V UNOSSIFIED PUBIS, BILATERAL V INCOMPLETE OSSIFICATION OF ISCHIUM, BILATERAL V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA (E) 1st: centrum
	4 M	2.22	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 M	2.21	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF HYOID C CARTILAGE OF HYOID: PRESENT THORACIC VERTEBRA (E) DAMAGED AT THE PREPARATION OF THE FETUS 4th C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT 1st V INCOMPLETE OSSIFICATION OF SACRAL VERTEBRA (E) 2nd, 3rd: right and left arches C CARTILAGE OF SACRAL VERTEBRA (E) : PRESENT 2nd to 4th V UNOSSIFIED SACRAL VERTEBRA (E) 4th V UNOSSIFIED CAUDAL VERTEBRA (E) 1st to 3rd C CARTILAGE OF CAUDAL VERTEBRA (E) : PRESENT 1st to 3rd C CARTILAGE OF STERNEBRA (E) : PRESENT 1st to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA (E) 1st, 3rd V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA V UNOSSIFIED 1st TO 4th STERNEBRA (E) 2nd, 4th V UNOSSIFIED 4th METACARPAL(S), BILATERAL

CLASS CODES: V-Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22150	(CONTINUED)		<p>V INCOMPLETE OSSIFICATION OF 1st TO 3rd METACARPALS, BILATERAL 3rd</p> <p>V UNOSSIFIED 1st TO 3rd METACARPALS, BILATERAL 1st</p> <p>C CARTILAGE OF METATARSAL BONE(S) : PRESENT, BILATERAL 4th</p> <p>V UNOSSIFIED METATARSAL(S), BILATERAL 4th</p> <p>C CARTILAGE OF PELVIC GIRDLE: PRESENT, BILATERAL Pubis, ischium</p> <p>V UNOSSIFIED PUBIS, BILATERAL</p> <p>V INCOMPLETE OSSIFICATION OF ISCHIUM, BILATERAL</p> <p>V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) 1st: centrum</p> <p>C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 1st, 3rd, 4th</p>
	6 M	2.18	<p>NO OBSERVED EXTERNAL FINDINGS</p> <p>NO OBSERVED VISCERAL FINDINGS</p>
	7 F	2.11	<p>NO OBSERVED EXTERNAL FINDINGS</p> <p>V INCOMPLETE OSSIFICATION OF SUPRAOCCIPITAL</p> <p>C CARTILAGE OF SUPRAOCCIPITAL: PRESENT</p> <p>C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL Left: 4th Bilateral: 1st</p> <p>C CARTILAGE OF THORACIC VERTEBRA(E) : PRESENT 1st</p> <p>V INCOMPLETE OSSIFICATION OF SACRAL VERTEBRA(E) 2nd, 3rd: right and left arches</p> <p>C CARTILAGE OF SACRAL VERTEBRA(E) : PRESENT 2nd to 4th</p> <p>V UNOSSIFIED SACRAL VERTEBRA(E) 4th</p> <p>V UNOSSIFIED CAUDAL VERTEBRA(E) 1st to 3rd</p> <p>C CARTILAGE OF CAUDAL VERTEBRA(E) : PRESENT 1st to 3rd</p> <p>C CARTILAGE OF STERNEBRA(E) : PRESENT 1st to 6th</p> <p>V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 1st</p>

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22150	(CONTINUED)		V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA V UNOSSIFIED 1st TO 4th STERNEBRA(E) 2nd to 4th METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th V UNOSSIFIED 4th METACARPAL(S), LEFT V INCOMPLETE OSSIFICATION OF 1st TO 3rd METACARPALS, BILATERAL 1st HINDLIMB(S) DAMAGED AT THE PREPARATION OF THE FETUS, LEFT Fibula METATARSAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, LEFT 1st to 4th C CARTILAGE OF METATARSAL BONE(S): PRESENT, RIGHT 4th V UNOSSIFIED METATARSAL(S), RIGHT 4th C CARTILAGE OF PELVIC GIRDLE: PRESENT, BILATERAL Pubis, ischium V UNOSSIFIED PUBIS, BILATERAL V INCOMPLETE OSSIFICATION OF ISCHIUM, BILATERAL V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) 1st: centrum
	8 F	2.07	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 M	2.16	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF HYOID C CARTILAGE OF HYOID: PRESENT THORACIC VERTEBRA (E) DAMAGED AT THE PREPARATION OF THE FETUS 4th V INCOMPLETE OSSIFICATION OF SACRAL VERTEBRA(E) 2nd, 3rd: right and left arches 4th: centrum C CARTILAGE OF SACRAL VERTEBRA(E): PRESENT 2nd to 4th V UNOSSIFIED CAUDAL VERTEBRA(E) 1st to 3rd C CARTILAGE OF CAUDAL VERTEBRA(E): PRESENT 1st to 3rd C CARTILAGE OF STERNEBRA(E): PRESENT 1st to 6th

CLASS CODES: V=Variation C=Cartilage  
SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22150	(CONTINUED)		<p>V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 1st, 3rd, 4th</p> <p>V UNOSSIFIED 5th STERNEBRA</p> <p>V UNOSSIFIED 6th STERNEBRA</p> <p>V UNOSSIFIED 1st TO 4th STERNEBRA(E) 2nd</p> <p>V UNOSSIFIED 4th METACARPAL(S), BILATERAL</p> <p>C CARTILAGE OF METACARPAL BONE(S): PRESENT, BILATERAL 1st, 4th</p> <p>V INCOMPLETE OSSIFICATION OF 1st TO 3rd METACARPALS, RIGHT 1st</p> <p>V UNOSSIFIED 1st TO 3rd METACARPALS, LEFT 1st</p> <p>C CARTILAGE OF METATARSAL BONE(S): PRESENT, BILATERAL 4th</p> <p>V UNOSSIFIED METATARSAL(S), BILATERAL 4th</p> <p>C CARTILAGE OF PELVIC GIRDLE: PRESENT, BILATERAL Pubis, ischium</p> <p>V UNOSSIFIED PUBIS, BILATERAL</p> <p>V INCOMPLETE OSSIFICATION OF ISCHIUM, BILATERAL</p>
	10 F	2.15	<p>NO OBSERVED EXTERNAL FINDINGS</p> <p>NO OBSERVED VISCERAL FINDINGS</p>
	11 F	2.06	<p>NO OBSERVED EXTERNAL FINDINGS</p> <p>V INCOMPLETE OSSIFICATION OF INTERPARIETAL</p> <p>V INCOMPLETE OSSIFICATION OF SUPRAOCCIPITAL</p> <p>C CARTILAGE OF SUPRAOCCIPITAL: PRESENT</p> <p>C CARTILAGE OF HYOID: PRESENT</p> <p>V UNOSSIFIED HYOID</p> <p>V INCOMPLETE OSSIFICATION OF SACRAL VERTEBRA(E) 1st to 3rd: right and left arches 3rd, 4th: centrum</p> <p>C CARTILAGE OF SACRAL VERTEBRA(E): PRESENT 1st to 4th</p> <p>V UNOSSIFIED CAUDAL VERTEBRA(E) 1st to 3rd</p> <p>C CARTILAGE OF CAUDAL VERTEBRA(E): PRESENT 1st to 3rd</p> <p>C CARTILAGE OF STERNEBRA(E): PRESENT 1st to 6th</p>

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT(G)	OBSERVATION
C22150	(CONTINUED)		V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 1st, 3rd V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA V UNOSSIFIED 1st TO 4th STERNEBRA(E) 2nd, 4th RIB(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 13th V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S): PRESENT, BILATERAL 1st, 3rd, 4th V INCOMPLETE OSSIFICATION OF 1st TO 3rd METACARPALS, BILATERAL 3rd V UNOSSIFIED 1st TO 3rd METACARPALS, BILATERAL 1st METATARSAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, BILATERAL Right: 1st to 4th Left: 4th C CARTILAGE OF PELVIC GIRDLE: PRESENT, BILATERAL Pubis, ischium V UNOSSIFIED PUBIS, BILATERAL V INCOMPLETE OSSIFICATION OF ISCHIUM, BILATERAL
	12 F	1.90	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 M	1.94	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF INTERPARIETAL V INCOMPLETE OSSIFICATION OF SACRAL VERTEBRA(E) 2nd, 3rd: right and left arches C CARTILAGE OF SACRAL VERTEBRA(E): PRESENT 2nd, 3rd V UNOSSIFIED CAUDAL VERTEBRA(E) 1st to 3rd C CARTILAGE OF CAUDAL VERTEBRA(E): PRESENT 1st to 3rd C CARTILAGE OF STERNEBRA(E): PRESENT 1st to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 1st, 3rd V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22150	(CONTINUED)		
			V UNOSSIFIED 1st TO 4th STERNEBRA(E) 2nd, 4th
			V UNOSSIFIED 4th METACARPAL(S), BILATERAL
			C CARTILAGE OF METACARPAL BONE(S): PRESENT, BILATERAL 1st, 4th
			V INCOMPLETE OSSIFICATION OF 1st TO 3rd METACARPALS, BILATERAL 1st
			C CARTILAGE OF METATARSAL BONE(S): PRESENT, BILATERAL 4th
			V UNOSSIFIED METATARSAL(S), BILATERAL 4th
			C CARTILAGE OF PELVIC GIRDLE: PRESENT, BILATERAL Pubis, ischium
			V UNOSSIFIED PUBIS, BILATERAL
			V INCOMPLETE OSSIFICATION OF ISCHIUM, BILATERAL
14 F	2.04		NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
15 M	2.15		NO OBSERVED EXTERNAL FINDINGS
			C CARTILAGE OF HYOID: PRESENT
			V UNOSSIFIED HYOID
			THORACIC VERTEBRA(E) DAMAGED AT THE PREPARATION OF THE FETUS 4th
			V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) 1st: centrum
			C CARTILAGE OF THORACIC VERTEBRA(E): PRESENT 1st
			V INCOMPLETE OSSIFICATION OF SACRAL VERTEBRA(E) 2nd, 3rd: right and left arches 4th: centrum
			C CARTILAGE OF SACRAL VERTEBRA(E): PRESENT 2nd to 4th
			V UNOSSIFIED CAUDAL VERTEBRA(E) 1st to 3rd
			C CARTILAGE OF CAUDAL VERTEBRA(E): PRESENT 1st to 3rd
			C CARTILAGE OF STERNEBRA(E): PRESENT 1st to 6th
			V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 1st, 3rd
			V UNOSSIFIED 5th STERNEBRA

CLASS CODES: V-Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg



### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22150	(CONTINUED)		V UNOSSIFIED 6th STERNEBRA V UNOSSIFIED 1st TO 4th STERNEBRA(E) 2nd, 4th V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 1st, 3rd, 4th V INCOMPLETE OSSIFICATION OF 1st TO 3rd METACARPALS, BILATERAL 3rd V UNOSSIFIED 1st TO 3rd METACARPALS, BILATERAL 1st METATARSAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 3rd, 4th V INCOMPLETE OSSIFICATION OF METATARSAL(S), LEFT 4th C CARTILAGE OF METATARSAL BONE(S) : PRESENT, LEFT 4th C CARTILAGE OF PELVIC GIRDLE: PRESENT, BILATERAL Pubis, ischium V UNOSSIFIED PUBIS, BILATERAL V INCOMPLETE OSSIFICATION OF ISCHIUM, BILATERAL
	16 M	2.20	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
C22151	SP 1 F	4.37	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	2 M	4.68	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	4.31	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	4 F	4.37	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	6 F	4.15	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22151	(CONTINUED)		
			C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	7 F	4.62	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	4.06	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) Centrum: 1st C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT 1st V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	10 M	4.54	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 F	4.56	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	12 F	4.79	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 F	4.45	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
C22152	SP 1 F	3.92	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	2 M	4.05	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	3.94	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22152	(CONTINUED)		
	4 M	4.44	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 M	4.10	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	6 F	3.90	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 M	4.13	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	8 M	4.07	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	10 F	4.36	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	11 F	4.17	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	12 F	3.81	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	13 M	4.13	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
C22153	SP 1 F	3.72	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	2 F	3.95	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	3.59	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	4 F	3.50	NO OBSERVED EXTERNAL FINDINGS

CLASS CODES: V-Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22153	(CONTINUED)		
	5 M	3.71	NO OBSERVED VISCERAL FINDINGS NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	6 M	3.61	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	3.73	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	8 M	4.01	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	3.85	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	10 M	3.81	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 F	3.85	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	12 M	3.55	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 M	3.72	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th
C22154	SP 1 F	3.81	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT 1st C CARTILAGE OF STERNEBRA(E) : PRESENT 4th to 6th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22154	(CONTINUED)		V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) 1st: centrum
	2 F	1.76	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	4.18	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E): PRESENT 5th
	4 F	3.59	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	3.76	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E): PRESENT 5th, 6th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	6 F	3.89	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	3.93	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E): PRESENT 5th, 6th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	8 M	4.18	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	4.13	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E): PRESENT 5th, 6th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	10 F	3.81	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 F	3.94	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E): PRESENT 5th, 6th

CLASS CODES: V=Variation C=Cartilage  
SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22154	(CONTINUED)		
			V UNOSSIFIED 5th STERNEBRA
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	12 F	3.79	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 F	3.99	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	14 F	3.75	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	15 F	3.49	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th V UNOSSIFIED 5th STERNEBRA
C22155	SP 1 F	3.37	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th, 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V UNOSSIFIED 6th STERNEBRA
	2 M	3.79	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	3.37	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), BILATERAL 4th C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	4 F	3.54	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 M	3.88	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA

CLASS CODES: V-Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22155	(CONTINUED)		C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th RIB(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 13th cartilage
	6 F	3.63	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 M	3.82	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th, 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), LEFT C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT 4th
	8 M	3.90	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 M	4.07	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, LEFT 4th
	10 F	3.58	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 F	3.82	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	12 F	3.71	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS

CLASS CODES: V-Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22155	(CONTINUED)		
	13 F	3.55	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th, 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th
	14 F	3.51	V INCOMPLETE OSSIFICATION OF 6th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
C22156	SP 1 M	4.49	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	2 M	4.39	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	4.34	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	6 F	4.31	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 M	4.28	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	8 M	4.43	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	4.41	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	10 M	4.83	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 M	4.53	NO OBSERVED EXTERNAL FINDINGS

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg



### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22156	(CONTINUED)		C CARTILAGE OF STERNEBRA(E) : PRESENT 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
C22157	SP 1 M	3.92	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	2 F	3.64	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	3.85	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 6th and 5th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), LEFT C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT 4th
	4 F	3.66	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	3.73	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), LEFT C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT 4th
	6 F	3.86	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 M	3.92	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 2nd and 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th METATARSAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th

CLASS CODES: V=Variation C=Cartilage  
SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22157	(CONTINUED)		
	8 F	3.83	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	3.94	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th and 6th
	10 M	4.09	V INCOMPLETE OSSIFICATION OF 6th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 M	3.79	NO OBSERVED EXTERNAL FINDINGS METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th V UNOSSIFIED 4th METACARPAL(S), LEFT C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT 4th V INCOMPLETE OSSIFICATION OF 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA (E) 1st, 2nd and 4th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 1st, 2nd, 4th to 6th
	12 F	3.41	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 F	3.84	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA (E) : PRESENT 5th and 6th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	14 F	3.51	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
C22159	SP 1 F	3.57	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	2 F	3.81	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	3.99	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT 12th

CLASS CODES: V=Variation C=Cartilage  
SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22159	(CONTINUED)		V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA (E) 12th: centrum
	4 F	4.10	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 M	4.49	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	6 F	3.83	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	3.85	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	8 M	4.03	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 M	4.37	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	10 F	4.10	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 F	4.07	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	12 F	3.85	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 M	3.92	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
C22161	SP 1 F	3.81	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 4th to 6th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

**INDIVIDUAL FETAL OBSERVATIONS**

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT(G)	OBSERVATION
C22161	(CONTINUED)		V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), LEFT C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT 4th
	2 M	4.19	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	4.24	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th
	4 M	4.06	V INCOMPLETE OSSIFICATION OF 6th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 M	4.12	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	6 F	3.79	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	4.24	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th
	8 M	4.36	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	3.84	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 2nd, 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd, 4th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), BILATERAL

CLASS CODES: V-Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22161	(CONTINUED)		
			C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	10 M	4.37	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 M	4.21	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	12 M	4.40	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 F	3.91	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th
	14 M	4.11	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	15 M	4.29	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
C22162	SP 1 M	2.60	NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Hyoid V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	2 M	3.77	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	4.09	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	4 F	3.46	NO OBSERVED EXTERNAL FINDINGS

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22162	(CONTINUED)		
	5 M	4.25	NO OBSERVED VISCERAL FINDINGS NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Hyoid V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA (E) Centrum: 10th and 12th C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT 10th and 12th V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	6 F	3.84	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	3.73	NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Parietal bones, interparietal and supraoccipital bones V UNOSSIFIED CAUDAL VERTEBRA (E) 2nd and 3rd C CARTILAGE OF CAUDAL VERTEBRA (E) : PRESENT 2nd and 3rd C CARTILAGE OF STERNEBRA (E) : PRESENT 2nd, 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA (E) 2nd and 4th V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th V INCOMPLETE OSSIFICATION OF PUBIS, BILATERAL C CARTILAGE OF PELVIC GIRDLE: PRESENT, BILATERAL Pelvis bones
	8 F	3.84	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	3.68	NO OBSERVED EXTERNAL FINDINGS THORACIC VERTEBRA (E) DAMAGED AT THE PREPARATION OF THE FETUS 4th V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th and 6th

CLASS CODES: V=Variation C=Cartilage  
SEX CODE: M=Male F=Female

SP=Fin sac/Pg

**INDIVIDUAL FETAL OBSERVATIONS**

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22162	(CONTINUED)		
	10 M	4.15	V INCOMPLETE OSSIFICATION OF 6th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 M	4.17	NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Hyoid
	12 F	4.12	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 F	3.95	NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Hyoid
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th
	14 F	3.82	V INCOMPLETE OSSIFICATION OF 6th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	15 F	3.65	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th
	16 F	3.83	V INCOMPLETE OSSIFICATION OF 6th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	17 F	3.87	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
C22163	SP 1 M	2.97	NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Frontal bones, parietal bones, interparietal bone V UNOSSIFIED CAUDAL VERTEBRA(E) 3rd C CARTILAGE OF CAUDAL VERTEBRA(E) : PRESENT 3rd C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22163	(CONTINUED)		V UNOSSIFIED 4th METACARPAL(S), LEFT C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT 4th PELVIS BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS, LEFT Pubis bone
C22164	SP 1 M	3.35	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	2 F	2.97	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	4.16	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	4 F	3.89	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	3.87	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	6 M	3.57	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	3.75	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th, 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA

CLASS CODES: V-Variation C=Cartilage  
SEX CODE: M-Male F-Female

SP=Fin sac/Pg



### INDIVIDUAL FETAL OBSERVATIONS

Dose: 0 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22164	(CONTINUED)		
	8 M	3.22	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	10 M	4.01	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA STERNEBRA (E) DAMAGED AT THE PREPARATION OF THE FETUS 1st V UNOSSIFIED 4th METACARPAL(S) , BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	11 M	3.55	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	12 M	3.84	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA STERNEBRA (E) DAMAGED AT THE PREPARATION OF THE FETUS 1st
	13 M	4.08	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	14 F	3.15	NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT Parietal V UNOSSIFIED 4th METACARPAL(S) , BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	16 F	3.90	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS

CLASS CODES: V-Variation C-Cartilage  
SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS#	(SEX)	WEIGHT (G)	OBSERVATION
C22167	SP	1 M	4.75	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
		2 M	4.20	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	4.84	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th	
		4 F	4.07	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	5 F	4.23	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th	
		6 F	4.16	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS METATARSAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 3rd, 4th
	7 M	4.29	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS	
	8 M	4.38	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS	
	9 F	4.13	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th	
	10 F	3.89	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS	
	11 M	3.96	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th	
		12 F	3.88	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
C22168	SP	1 F	3.73	NO OBSERVED EXTERNAL FINDINGS

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22168	(CONTINUED)		
			V INCOMPLETE OSSIFICATION OF HYOID
			C CARTILAGE OF HYOID: PRESENT
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
			5th and 6th
	2 M	4.04	NO OBSERVED EXTERNAL FINDINGS
			NO OBSERVED VISCERAL FINDINGS
	3 M	3.82	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA (E)
			Centrum: 13th
			C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT
			13th
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA
			C CARTILAGE OF STERNEBRA (E) : PRESENT
			4th, 5th and 6th
			V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA (E)
			4th
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	4 M	3.55	NO OBSERVED EXTERNAL FINDINGS
			NO OBSERVED VISCERAL FINDINGS
	5 F	3.95	NO OBSERVED EXTERNAL FINDINGS
			C CARTILAGE OF STERNEBRA (E) : PRESENT
			6th
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	6 M	4.14	NO OBSERVED EXTERNAL FINDINGS
			NO OBSERVED VISCERAL FINDINGS
	7 M	4.25	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA
			C CARTILAGE OF STERNEBRA (E) : PRESENT
			5th
	9 M	4.16	NO OBSERVED EXTERNAL FINDINGS
			NO OBSERVED VISCERAL FINDINGS
	10 M	4.00	NO OBSERVED EXTERNAL FINDINGS
			HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS
			Hyoid
			C CARTILAGE OF STERNEBRA (E) : PRESENT
			6th
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	11 F	3.79	NO OBSERVED EXTERNAL FINDINGS
			NO OBSERVED VISCERAL FINDINGS

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

## INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS#	(SEX)	WEIGHT (G)	OBSERVATION
C22169	SP	1 M	4.07	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
		2 F	3.84	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	3 F	3.90	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
		4 F	3.74	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	5 F	3.65	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
		6 M	3.80	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	7 F	3.65	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
		8 F	3.72	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 M	9 M	4.16	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
		10 M	4.33	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
		11 M	3.99	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
C22171	SP	1 M	3.19	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th, 6th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22171	(CONTINUED)		
			V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th
			V UNOSSIFIED 5th STERNEBRA
			V UNOSSIFIED 6th STERNEBRA
			METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT
			V UNOSSIFIED 4th METACARPAL(S), LEFT
			C CARTILAGE OF METACARPAL BONE(S): PRESENT, LEFT 4th
	2 M	3.15	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	3.71	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E): PRESENT 5th, 6th
	4 M	3.74	V INCOMPLETE OSSIFICATION OF 6th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	3.46	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E): PRESENT 2nd, 4th, 5th, 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd, 4th V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA RIB(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 13th
	6 M	3.80	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	3.06	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E): PRESENT 4th, 5th, 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S): PRESENT, BILATERAL 4th
	8 M	3.75	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS

CLASS CODES: V=Variation C=Cartilage  
SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22171	(CONTINUED)		
	9 M	3.76	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	10 F	3.04	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 M	2.86	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th, 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th V UNOSSIFIED 4th METACARPAL(S) , LEFT 4th C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT 4th
	12 F	3.06	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
C22173	SP 1 F	2.54	NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Hyoid C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT 1st, 12th V UNOSSIFIED CAUDAL VERTEBRA (E) 3rd C CARTILAGE OF CAUDAL VERTEBRA (E) : PRESENT 3rd C CARTILAGE OF STERNEBRA(E) : PRESENT 2nd and 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd, 4th V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA HINDLIMB(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT Femur, fibula, tibia

CLASS CODES: V-Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22173	(CONTINUED)		
			V INCOMPLETE OSSIFICATION OF METATARSAL(S) , BILATERAL 4th
			C CARTILAGE OF METATARSAL BONE(S) : ABSENT, BILATERAL 4th
			V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA (E) 1st, 12th: centrum
	2 M	3.01	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	2.42	NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS, LEFT Parietal
			V UNOSSIFIED CAUDAL VERTEBRA (E) 3rd
			C CARTILAGE OF CAUDAL VERTEBRA (E) : PRESENT 2nd, 3rd
			V INCOMPLETE OSSIFICATION OF CAUDAL VERTEBRA (E) 2nd
			C CARTILAGE OF STERNEBRA (E) : PRESENT 4th to 6th
			V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA (E) 4th
			V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA
			STERNEBRA (E) DAMAGED AT THE PREPARATION OF THE FETUS 1st
			V UNOSSIFIED 4th METACARPAL(S) , RIGHT C CARTILAGE OF METACARPAL BONE(S) : PRESENT, RIGHT 4th
	4 M	3.13	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 M	3.27	NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Hyoid
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th, 6th
	6 F	3.39	V INCOMPLETE OSSIFICATION OF 6th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 M	3.49	NO OBSERVED EXTERNAL FINDINGS

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

## INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22173	(CONTINUED)		
			C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th
			V UNOSSIFIED 5th STERNEBRA
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
			C CARTILAGE OF RIB(S) : PRESENT, RIGHT 13th
			V SHORT RIB(S), RIGHT 13th
	8 M	3.13	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 M	3.54	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA
			C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	10 F	3.13	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 M	3.45	NO OBSERVED EXTERNAL FINDINGS THORACIC VERTEBRA(E) DAMAGED AT THE PREPARATION OF THE FETUS 5th
			C CARTILAGE OF STERNEBRA(E) : PRESENT 4th to 6th
			V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th
			V UNOSSIFIED 5th STERNEBRA
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	12 F	3.21	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 F	2.82	NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Supraoccipital
			V UNOSSIFIED CAUDAL VERTEBRA (E) 3rd
			C CARTILAGE OF CAUDAL VERTEBRA(E) : PRESENT 2nd, 3rd
			V INCOMPLETE OSSIFICATION OF CAUDAL VERTEBRA(E) 2nd
			C CARTILAGE OF STERNEBRA(E) : PRESENT 4th to 6th
			V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg



### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22173	(CONTINUED)		V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA V INCOMPLETE OSSIFICATION OF METATARSAL(S) , BILATERAL 4th C CARTILAGE OF METATARSAL BONE(S) : PRESENT, BILATERAL 4th V INCOMPLETE OSSIFICATION OF PUBIS, BILATERAL C CARTILAGE OF PELVIC GIRDLE: PRESENT, BILATERAL Pubis
C22174	SP 1 F	4.26	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 2nd and 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 1st
	2 M	4.37	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	4.14	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	4 M	3.68	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 M	3.98	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	6 F	3.75	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	3.71	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	8 F	3.97	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	3.72	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF INTERPARIETAL

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22174	(CONTINUED)		
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 2nd to 6th
			V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd to 4th
			V UNOSSIFIED 6th STERNEBRA
	10 F	3.70	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 M	3.99	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
			METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	12 M	4.57	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
C22175	SP 1 M	3.97	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	2 M	3.96	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	4.19	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	4 F	3.98	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 M	3.81	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	6 M	4.32	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 M	4.09	NO OBSERVED EXTERNAL FINDINGS
			C CARTILAGE OF STERNEBRA (E) : PRESENT 1st
			V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 1st
	8 M	3.93	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22175	(CONTINUED)		
	9 M	3.81	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	10 F	3.76	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 M	3.61	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF INTERPARIETAL V INCOMPLETE OSSIFICATION OF HYOID C CARTILAGE OF HYOID: PRESENT C CARTILAGE OF STERNEBRA(E) : PRESENT 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th V UNOSSIFIED 4th METACARPAL(S) , RIGHT C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT 4th
	12 F	4.04	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 M	4.04	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
C22177	SP 1 F	4.04	NO OBSERVED EXTERNAL FINDINGS METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	2 M	4.46	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	4.03	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	4 M	4.61	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	4.25	NO OBSERVED EXTERNAL FINDINGS STERNEBRA (E) DAMAGED AT THE PREPARATION OF THE FETUS 1st and 5th METATARSAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22177	(CONTINUED)		
	6 F	4.19	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 M	4.28	NO OBSERVED EXTERNAL FINDINGS STERNEBRA (E) DAMAGED AT THE PREPARATION OF THE FETUS 5th
	9 M	4.31	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 F	4.06	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E): PRESENT 2nd and 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd
	12 M	4.42	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
C22178	SP 1 M	4.00	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E): PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	2 F	3.88	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	4.06	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E): PRESENT 5th
	4 M	3.89	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	3.77	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E): PRESENT 4th, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th
	6 M	4.16	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 M	4.25	NO OBSERVED EXTERNAL FINDINGS

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22178	(CONTINUED)		
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 4th, 5th
			V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA (E) 4th
	8 F	4.03	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 M	3.92	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA (E) : PRESENT 4th, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA (E) 4th
	10 F	4.11	V UNOSSIFIED 5th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 M	3.90	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	12 F	3.91	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 F	3.74	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 4th, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA (E) 4th
	14 M	4.33	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
C22179	SP 2 M	4.04	NO OBSERVED EXTERNAL FINDINGS HEAD BONE (S) DAMAGED AT THE PREPARATION OF THE FETUS Hyoid V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	3 M	4.21	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	4 M	4.10	NO OBSERVED EXTERNAL FINDINGS

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22179	(CONTINUED)		V INCOMPLETE OSSIFICATION OF FRONTAL, BILATERAL HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Hyoid V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) 11th and 12th C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT 11th and 12th V THORACIC VERTEBRA(E) : BIPARTITE OSSIFICATION OF CENTRUM 10th C CARTILAGE OF THORACIC VERTEBRA (E) : MISSHAPEN 10th V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	5 F	4.11	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	6 F	4.16	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	7 M	4.79	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	8 F	4.27	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF FRONTAL, BILATERAL V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	9 F	4.04	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	10 M	4.71	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF INTERPARIETAL C CARTILAGE OF STERNEBRA(E) : PRESENT 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA PELVIS BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS, LEFT Pubis bone
	11 F	4.25	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS

CLASS CODES: V=Variation C=Cartilage  
SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22179	(CONTINUED) 13 M	4.28	NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Hyoid V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
C22180	SP 1 F	4.52	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	2 F	4.38	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	4.28	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT 10th V THORACIC VERTEBRA (E) : BIPARTITE OSSIFICATION OF CENTRUM 10th V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	5 F	4.01	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	6 F	4.04	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	7 F	4.42	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	8 M	4.76	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	9 M	4.48	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	10 M	4.37	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA (E) : PRESENT 6th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22180	(CONTINUED)		
	11 M	4.24	V INCOMPLETE OSSIFICATION OF 6th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	12 F	4.38	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	13 F	4.11	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	14 F	4.16	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th V UNOSSIFIED 5th STERNEBRA
	15 F	4.26	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
C22181	SP 1 M	3.71	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA RIB(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 8th to 10th V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	2 M	3.97	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	3.79	NO OBSERVED EXTERNAL FINDINGS THORACIC VERTEBRA(E) DAMAGED AT THE PREPARATION OF THE FETUS 8th V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA STERNEBRA(E) DAMAGED AT THE PREPARATION OF THE FETUS 4th RIB(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 7th V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	5 F	3.46	NO OBSERVED EXTERNAL FINDINGS

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg



### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22181	(CONTINUED)		
	6 F	3.11	NO OBSERVED VISCERAL FINDINGS NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) Centrum: 12th C CARTILAGE OF THORACIC VERTEBRA(E) : PRESENT 12th C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA STERNEBRA(E) DAMAGED AT THE PREPARATION OF THE FETUS 1st and 2nd METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th V UNOSSIFIED 4th METACARPAL(S), LEFT C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT 4th V INCOMPLETE OSSIFICATION OF PUBIS, BILATERAL C CARTILAGE OF PELVIC GIRDLE: PRESENT, BILATERAL Pubis bones
	7 F	3.44	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	8 M	4.08	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF INTERPARIETAL V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) Centrum: 1st C CARTILAGE OF THORACIC VERTEBRA(E) : PRESENT 1st V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 2nd and 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd PELVIS BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT Ischium bone
	9 F	3.71	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	10 F	3.81	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) Centrum: 11th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22181	(CONTINUED)		
			C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT 11th
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA
			C CARTILAGE OF STERNEBRA (E) : PRESENT 5th and 6th
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
			V UNOSSIFIED 4th METACARPAL(S) , BILATERAL
			C CARTILAGE OF METACARPAL BONE (S) : PRESENT, BILATERAL 4th
	11 M	4.01	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
C22182	SP 1 F	3.66	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th V UNOSSIFIED 4th METACARPAL(S) , BILATERAL C CARTILAGE OF METACARPAL BONE (S) : PRESENT, BILATERAL 4th
	2 M	4.10	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	3.88	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 4th, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA (E) 4th
	5 M	3.97	NO OBSERVED EXTERNAL FINDINGS V DILATED RENAL PELVIS, RIGHT
	6 M	4.26	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	7 M	3.83	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	8 F	3.47	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA

CLASS CODES: V-Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22182	(CONTINUED)		
	9 M	3.78	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	10 M	3.82	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) Centrum: 11th C CARTILAGE OF THORACIC VERTEBRA(E) : PRESENT 11th V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	12 F	3.63	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 F	4.01	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) Centrum: 11th C CARTILAGE OF THORACIC VERTEBRA(E) : PRESENT 11th V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V UNOSSIFIED 4th METACARPAL(S) , BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	14 M	3.86	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
C22183	SP 1 F	3.70	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	2 F	3.56	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	3.98	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	4 F	3.82	NO OBSERVED EXTERNAL FINDINGS V DILATED URETER, LEFT
	5 M	4.09	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT(G)	OBSERVATION
C22183	(CONTINUED)		
	6 F	3.59	C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	1.88	M UMBILICAL HERNIA V BENT TAIL HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Interparietal bone V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) 3rd, 7th, 11th C CARTILAGE OF THORACIC VERTEBRA(E) : PRESENT 2nd, 3rd, 9th, 10th, 11th, 12th and 13th V THORACIC VERTEBRA(E) : BIPARTITE OSSIFICATION OF CENTRUM 9th and 13th C CARTILAGE OF THORACIC VERTEBRA(E) : SPLITTED 1st and 4th V UNOSSIFIED THORACIC VERTEBRA(E) Centrum: 1st, 2nd, 4th, 6th, 10th and 12th C CARTILAGE OF SACRAL VERTEBRA(E) : PRESENT 2nd to 4th V UNOSSIFIED SACRAL VERTEBRA(E) Centrum: 2nd and 4th V UNOSSIFIED CAUDAL VERTEBRA(E) Centrum: 1st to 3rd; arches: 2nd and 3rd C CARTILAGE OF CAUDAL VERTEBRA(E) : PRESENT 1st to 3rd C CARTILAGE OF STERNEBRA(E) : PRESENT 1st to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 1st and 3rd V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 1st TO 4th STERNEBRA(E) 2nd and 4th M FUSED RIBS, RIGHT 4th and 5th, 7th and 8th C CARTILAGE OF RIB(S) : FUSED, RIGHT 1st and 2nd; 4th and 5th, 7th and 8th with 9th; 11th and 12th V UNOSSIFIED 4th METACARPAL(S), BILATERAL

CLASS CODES: M=Malformation V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22183	(CONTINUED)		<p>C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 1st and 4th</p> <p>V INCOMPLETE OSSIFICATION OF 1st TO 3rd METACARPALS, BILATERAL 1st</p> <p>METATARSAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 1st to 4th</p> <p>C CARTILAGE OF METATARSAL BONE(S) : PRESENT, LEFT 4th</p> <p>V UNOSSIFIED METATARSAL(S), LEFT 4th</p> <p>V INCOMPLETE OSSIFICATION OF PUBIS, BILATERAL</p> <p>C CARTILAGE OF PELVIC GIRDLE: PRESENT, BILATERAL Pubis bone</p> <p>M MISSHAPEN SACRAL VERTEBRA(E) 3rd</p> <p>C CARTILAGE OF THORACIC VERTEBRA(E) : FUSED 6th and 7th</p> <p>C CARTILAGE OF LUMBAR VERTEBRA(E) : PRESENT 6th</p> <p>C ABSENCE OF CARTILAGE STAINING, UNILATERAL</p> <p>V LUMBAR VERTEBRA(E) : UNOSSIFIED HEMICENTRUM, UNILATERAL 6th</p>
	8 F	3.41	<p>NO OBSERVED EXTERNAL FINDINGS</p> <p>NO OBSERVED VISCERAL FINDINGS</p>
	9 M	4.00	<p>NO OBSERVED EXTERNAL FINDINGS</p> <p>V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) Centrum: 13th</p> <p>C CARTILAGE OF THORACIC VERTEBRA(E) : PRESENT 13th</p> <p>V INCOMPLETE OSSIFICATION OF 5th STERNEBRA</p> <p>C CARTILAGE OF STERNEBRA(E) : PRESENT 5th</p>
	10 M	4.40	<p>NO OBSERVED EXTERNAL FINDINGS</p> <p>NO OBSERVED VISCERAL FINDINGS</p>
	11 F	3.93	<p>NO OBSERVED EXTERNAL FINDINGS</p> <p>THORACIC VERTEBRA(E) DAMAGED AT THE PREPARATION OF THE FETUS 8th</p> <p>V INCOMPLETE OSSIFICATION OF 5th STERNEBRA</p> <p>C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th</p>

CLASS CODES: M=Malformation V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22183	(CONTINUED)		V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
C22184	SP 1 F	3.67	NO OBSERVED EXTERNAL FINDINGS THORACIC VERTEBRA(E) DAMAGED AT THE PREPARATION OF THE FETUS 5th PELVIS BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS, LEFT Pubis bone
	2 M	4.16	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	4.16	NO OBSERVED EXTERNAL FINDINGS STERNEBRA (E) DAMAGED AT THE PREPARATION OF THE FETUS 4th and 5th PELVIS BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS, LEFT Pubis bone
	4 F	4.07	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 M	4.29	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	6 M	4.12	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	4.22	NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Hyoid C CARTILAGE OF STERNEBRA(E) : PRESENT 5th V UNOSSIFIED 5th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 3rd METATARSAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, LEFT 1st to 4th
	8 M	4.00	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	4.00	NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Hyoid V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22184	(CONTINUED)		
	10 F	3.92	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 M	4.10	NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Left parietal bone and interparietal bone STERNEBRA (E) DAMAGED AT THE PREPARATION OF THE FETUS 2nd PELVIS BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS, LEFT Pubis bone
	12 M	4.16	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 F	4.09	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
C22185	SP 1 M	4.05	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) Centrum: 10th and 12th C CARTILAGE OF THORACIC VERTEBRA(E) : PRESENT 10th and 12th V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	2 M	4.35	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	4.42	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	4 M	4.21	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	4.08	NO OBSERVED EXTERNAL FINDINGS V THORACIC VERTEBRA(E) : BIPARTITE OSSIFICATION OF CENTRUM 4th C CARTILAGE OF THORACIC VERTEBRA(E) : MISSHAPEN 4th V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22185	(CONTINUED)		
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA C CARTILAGE OF RIB(S) : PRESENT, RIGHT 13th V WAVY RIB(S), RIGHT 13th
	6 M	4.07	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 M	4.35	NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Hyoid V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	8 M	4.27	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 M	3.49	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 2nd, 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd and 4th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), LEFT C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT 4th
	10 M	4.11	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 F	4.06	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	12 M	3.89	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 F	4.16	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th C CARTILAGE OF RIB(S) : PRESENT, RIGHT 12th

CLASS CODES: V-Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg



### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22185	(CONTINUED)		V WAVY RIB(S), RIGHT 12th
C22186	SP 1 F	4.02	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF HYOID C CARTILAGE OF HYOID: PRESENT C CARTILAGE OF STERNEBRA(E): PRESENT 5th and 6th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	2 F	3.97	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	4 F	4.03	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E): PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	5 M	4.50	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	6 M	4.04	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E): PRESENT 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	8 F	4.00	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	4.37	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E): PRESENT 5th
	10 F	3.78	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	12 F	3.26	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF HYOID: PRESENT

CLASS CODES: V-Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

## INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22186	(CONTINUED)		<p>V UNOSSIFIED HYOID</p> <p>V UNOSSIFIED CERVICAL VERTEBRA(E) Right arch of 2nd vertebra</p> <p>C CARTILAGE OF CERVICAL VERTEBRA(E) : FUSED 1st and 2nd</p> <p>V THORACIC VERTEBRA(E) : BIPARTITE OSSIFICATION OF CENTRUM 8th and 10th</p> <p>V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) 2nd, 6th, 7th, 9th and 12th</p> <p>C CARTILAGE OF THORACIC VERTEBRA(E) : PRESENT 3rd: left side only, 6th, 7th, 8th, 9th, 10th and 12th</p> <p>V UNOSSIFIED THORACIC VERTEBRA(E) Centrum: 1st and 3rd; left arch: 3rd</p> <p>V INCOMPLETE OSSIFICATION OF 5th STERNEBRA</p> <p>C CARTILAGE OF STERNEBRA(E) : PRESENT 3rd to 6th</p> <p>V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th</p> <p>V INCOMPLETE OSSIFICATION OF 6th STERNEBRA</p> <p>M SPLITTED STERNEBRA(E) 3rd</p> <p>C CARTILAGE OF RIB(S) : PRESENT, RIGHT 3rd and 4th</p> <p>M FUSED RIBS, RIGHT 3rd and 4th</p> <p>METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th</p> <p>V UNOSSIFIED 4th METACARPAL(S), LEFT</p> <p>C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT 4th</p> <p>C CARTILAGE OF CERVICAL VERTEBRA(E) : ABSENT Right arch of 2nd vertebra</p> <p>V THORACIC VERTEBRA(E) : UNOSSIFIED HEMI-CENTRUM, UNILATERAL 3rd</p> <p>C CARTILAGE OF THORACIC VERTEBRA(E) : ABSENT 3rd unossified hemicentrum</p> <p>C CARTILAGE OF THORACIC VERTEBRA(E) : BIPARTITE 6th and 10th</p> <p>C CARTILAGE OF THORACIC VERTEBRA(E) : MISALIGNED 2nd and 4th</p>

CLASS CODES: M=Malformation V=Variation C=Cartilage

SEX CODE: M-Male F-Female

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22186	(CONTINUED)		
			C CARTILAGE OF THORACIC VERTEBRA (E) : SPLITTED 1st
			C CARTILAGE OF CERVICAL VERTEBRA (E) : SPLITTED 6th
	13 F	4.18	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	14 M	4.28	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	15 F	3.95	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
C22187	SP 1 M	4.23	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA (E) Centrum: 1st, 10th to 13th C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT 1st, 10th to 13th METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th V UNOSSIFIED 4th METACARPAL(S), LEFT C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT 4th
	2 F	4.30	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	3.97	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA (E) Centrum: 1st, 11th to 13th C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT 1st, 11th to 13th V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 4th and 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA (E) 4th
	4 F	3.91	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	3.77	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	6 F	3.96	NO OBSERVED EXTERNAL FINDINGS

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22187	(CONTINUED)		
	7 F	4.04	NO OBSERVED VISCERAL FINDINGS NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA (E) Centrum: 9th to 12th C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT 9th to 12th
	8 F	4.30	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 M	4.04	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th METATARSAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	11 M	3.84	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
C22188	SP 1 M	3.58	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 2nd, 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), BILATERAL 4th C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA (E) 4th
	2 M	3.00	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	3.79	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 4th, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA (E) 4th V UNOSSIFIED 4th METACARPAL(S), BILATERAL 4th C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th

CLASS CODES: V-Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22188	(CONTINUED)		
	4 M	4.06	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	3.60	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 2nd, 4th, 5th, 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd, 4th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S) , BILATERAL 4th C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	6 M	3.57	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 M	3.79	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th V UNOSSIFIED 4th METACARPAL(S) , BILATERAL 4th C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	8 F	3.70	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 M	3.33	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S) , BILATERAL 4th C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	10 M	3.89	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 F	3.44	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA (E) Centrum 12th C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 250 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22188	(CONTINUED)		V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th V UNOSSIFIED 4th METACARPAL(S), LEFT 4th C CARTILAGE OF METACARPAL BONE(S): PRESENT, LEFT 4th C CARTILAGE OF THORACIC VERTEBRA (E): PRESENT 12th
	14 F	3.57	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	15 M	4.01	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E): PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA

CLASS CODES: V-Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22189	SP 1 F	2.90	NO OBSERVED EXTERNAL FINDINGS
			HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS
			Hyoid
			THORACIC VERTEBRA(E) DAMAGED AT THE PREPARATION OF THE FETUS
			8th
			V UNOSSIFIED CAUDAL VERTEBRA(E)
			3rd
			C CARTILAGE OF CAUDAL VERTEBRA(E) : PRESENT
			3rd
			C CARTILAGE OF STERNEBRA(E) : PRESENT
2nd, 4th to 6th			
V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E)			
2nd and 4th			
V UNOSSIFIED 5th STERNEBRA			
V UNOSSIFIED 6th STERNEBRA			
V UNOSSIFIED 4th METACARPAL(S) , BILATERAL			
C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL			
4th			
METATARSAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT			
4th			
V INCOMPLETE OSSIFICATION OF PUBIS, BILATERAL			
C CARTILAGE OF PELVIC GIRDLE: PRESENT, BILATERAL			
Pubis bones			
2 M	3.60	NO OBSERVED EXTERNAL FINDINGS	
3 F	3.39	NO OBSERVED EXTERNAL FINDINGS	
		NO OBSERVED VISCERAL FINDINGS	
		NO OBSERVED EXTERNAL FINDINGS	
		V INCOMPLETE OSSIFICATION OF 5th STERNEBRA	
		C CARTILAGE OF STERNEBRA(E) : PRESENT	
		5th and 6th	
		V INCOMPLETE OSSIFICATION OF 6th STERNEBRA	
		STERNEBRA(E) DAMAGED AT THE PREPARATION OF THE FETUS	
		1st	
		V UNOSSIFIED 4th METACARPAL(S) , BILATERAL	
		C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL	
		4th	
		METATARSAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT	
		1st to 4th	
4 M	3.25	NO OBSERVED EXTERNAL FINDINGS	
		NO OBSERVED VISCERAL FINDINGS	

CLASS CODES: V-Variation C-Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT(G)	OBSERVATION
C22189	(CONTINUED)		
	5 F	2.89	NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Hyoid C CARTILAGE OF STERNEBRA(E) : PRESENT 2nd, 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd and 4th V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S) , BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	6 M	3.31	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	2.75	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S) , BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	8 F	3.10	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 M	3.08	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA RIB(S) DAMAGED AT THE PREPARATION OF THE FETUS, LEFT 1st V UNOSSIFIED 4th METACARPAL(S) , BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	10 M	3.16	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 F	3.06	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th

CLASS CODES: V=Variation C=Cartilage  
SEX CODE: M-Male F-Female

SP=Fin sac/Pg



### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22189	(CONTINUED)		V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th V UNOSSIFIED 4th METACARPAL(S), LEFT C ABSENCE OF CARTILAGE STAINING, LEFT 4th
	12 F	3.09	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
C22190	SP 1 F	4.29	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th V UNOSSIFIED 5th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	2 M	4.12	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	4.47	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	4 F	4.19	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 M	4.32	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	6 F	3.99	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	4.08	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	8 F	4.35	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	3.99	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 1st and 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 1st

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22190	(CONTINUED)		V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
C22191	SP 1 F	3.79	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S) , BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	2 F	3.69	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	3.74	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th V UNOSSIFIED 4th METACARPAL(S) , BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	4 F	3.84	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 M	3.97	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	6 M	4.23	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 M	4.16	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	8 F	3.99	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	10 F	3.90	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th V UNOSSIFIED 5th STERNEBRA
C22192	SP 1 M	3.36	NO OBSERVED EXTERNAL FINDINGS

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22192	(CONTINUED)		
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th,6th
			V UNOSSIFIED 6th STERNEBRA
	2 F	3.39	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	3.83	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	4 F	3.78	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 M	3.60	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	6 F	3.64	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	3.67	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	8 M	3.57	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 M	3.95	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 4th to 6th
			V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA (E) 4th
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA C CARTILAGE OF RIB(S) : ABSENT, BILATERAL 13th
			V SHORT RIB(S) , BILATERAL 13th
	10 F	4.00	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 F	3.57	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	12 M	4.11	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 M	3.89	NO OBSERVED EXTERNAL FINDINGS

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22192	(CONTINUED)		
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th V INCOMPLETE OSSIFICATION OF RIB(S) , RIGHT 13th C CARTILAGE OF RIB(S) : PRESENT 13th
	14 M	3.55	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
C22193	SP 1 F	3.75	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	2 F	3.78	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	4.12	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 2nd, 5th, 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	4 M	4.29	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	3.82	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th, 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	6 F	4.25	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 M	4.15	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22193	(CONTINUED)		
	9 F	3.90	V UNOSSIFIED 5th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	10 F	4.32	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th
C22194	SP 1 F	3.51	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	2 M	3.75	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	4.06	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	4 M	3.84	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	3.60	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	6 F	3.42	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 M	3.96	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	8 F	3.51	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22194	(CONTINUED)		
	9 M	3.86	NO OBSERVED EXTERNAL FINDINGS STERNEBRA (E) DAMAGED AT THE PREPARATION OF THE FETUS 5th, 6th
	10 M	3.85	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 F	3.55	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA (E) : PRESENT 5th, 6th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	12 M	3.63	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 F	3.25	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	14 F	3.29	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
C22196	SP 1 M	3.55	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA (E) 4th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	2 F	3.85	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	3.83	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA (E) 4th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22196	(CONTINUED)		
	5 M	4.15	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	6 M	4.26	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	8 M	4.41	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	3.54	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	10 M	4.22	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 M	4.06	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	13 F	3.98	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	14 M	3.78	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
C22197	SP 2 M	3.82	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	4 F	3.63	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	3.98	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	6 M	3.73	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	3.81	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th

CLASS CODES: V-Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22197	(CONTINUED)		
			V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	8 F	3.32	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	2.67	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 3rd to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 3rd and 4th V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th METATARSAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 1st to 4th
	10 M	3.93	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 M	3.91	NO OBSERVED EXTERNAL FINDINGS METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	12 M	3.53	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
C22198	SP 1 M	4.03	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	2 M	3.74	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	3.96	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF FRONTAL, BILATERAL C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	4 F	3.67	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg



### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22198	(CONTINUED)		
	5 M	4.01	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	8 F	3.90	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 M	4.06	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	10 F	3.41	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 F	3.82	NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Interparietal bone V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	12 F	3.77	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 M	1.67	NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Interparietal and supraoccipital bones C CARTILAGE OF HYOID: PRESENT Hyoid V UNOSSIFIED HYOID V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) Centrum: 2nd and 3rd C CARTILAGE OF THORACIC VERTEBRA(E) : PRESENT 2nd and 3rd V INCOMPLETE OSSIFICATION OF LUMBAR VERTEBRA(E) Centrum: 6th C CARTILAGE OF LUMBAR VERTEBRA(E) : PRESENT 6th V INCOMPLETE OSSIFICATION OF SACRAL VERTEBRA(E) 2nd: right and left arches

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22198	(CONTINUED)		C CARTILAGE OF SACRAL VERTEBRA(E) : PRESENT 2nd to 4th V UNOSSIFIED SACRAL VERTEBRA(E) 3rd and 4th V UNOSSIFIED CAUDAL VERTEBRA(E) 1st to 3rd C CARTILAGE OF CAUDAL VERTEBRA(E) : PRESENT 1st to 3rd C CARTILAGE OF STERNEBRA(E) : PRESENT 1st to 6th V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA V UNOSSIFIED 1st TO 4th STERNEBRA(E) 1st to 4th METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 1st to 4th V UNOSSIFIED 4th METACARPAL(S), LEFT C ABSENCE OF CARTILAGE STAINING, LEFT 1st to 4th V INCOMPLETE OSSIFICATION OF 1st TO 3rd METACARPALS, LEFT 2nd V UNOSSIFIED 1st TO 3rd METACARPALS, LEFT 1st and 3rd V INCOMPLETE OSSIFICATION OF METATARSAL(S), RIGHT 1st to 4th C CARTILAGE OF METATARSAL BONE(S) : PRESENT, BILATERAL 1st to 4th V UNOSSIFIED METATARSAL(S), LEFT 1st to 4th C CARTILAGE OF PELVIC GIRDLE: PRESENT, BILATERAL Pubis, ischium and ilium bones V UNOSSIFIED PUBIS, BILATERAL V UNOSSIFIED ISCHIUM, BILATERAL M MISSHAPEN ILIUM, BILATERAL
	14 M	3.82	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
C22199	SP 1 F	4.10	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	2 M	4.41	NO OBSERVED EXTERNAL FINDINGS

CLASS CODES: M=Malformation V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

**INDIVIDUAL FETAL OBSERVATIONS**

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22199	(CONTINUED)		
	3 F	4.28	NO OBSERVED VISCERAL FINDINGS NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	4 F	4.28	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	4.03	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	6 M	4.25	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 M	4.42	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	8 F	3.94	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	4.37	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	10 F	4.29	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 F	4.20	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	12 M	4.31	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 M	4.22	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
C22200	SP 1 M	4.26	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd V INCOMPLETE OSSIFICATION OF 6th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 2nd,5th,6th
	2 F	3.81	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	3.90	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	4 M	4.29	NO OBSERVED EXTERNAL FINDINGS

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22200	(CONTINUED)		
	5 M	4.11	NO OBSERVED VISCERAL FINDINGS NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th,6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	6 F	4.01	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	3.80	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th,6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	8 F	3.93	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	3.31	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th,6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	10 M	3.83	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 F	3.72	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th,6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	12 F	4.17	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 F	3.94	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th,6th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	14 M	4.31	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
C22201	SP 1 M	4.17	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th

CLASS CODES: V-Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22201	(CONTINUED)		
	2 F	4.19	V UNOSSIFIED 5th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	3.94	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	4 M	4.22	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	4.00	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th V UNOSSIFIED 5th STERNEBRA
	6 F	4.11	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	4.12	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th V UNOSSIFIED 5th STERNEBRA
	8 F	3.85	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	4.13	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th V UNOSSIFIED 5th STERNEBRA
	10 M	4.21	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 F	3.86	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th V UNOSSIFIED 5th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	12 F	4.08	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 M	4.23	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th V UNOSSIFIED 5th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, LEFT 1st
C22202	SP 1 F	4.05	NO OBSERVED EXTERNAL FINDINGS

CLASS CODES: V=Variation C=Cartilage  
SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22202	(CONTINUED)		
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th,6th
	2 M	4.32	V INCOMPLETE OSSIFICATION OF 6th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	4.14	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th,6th
	4 F	4.11	V INCOMPLETE OSSIFICATION OF 6th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	3.95	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	6 F	4.02	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 M	3.93	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th,6th
	8 M	4.01	V INCOMPLETE OSSIFICATION OF 6th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	3.88	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th,6th
	10 M	4.08	V INCOMPLETE OSSIFICATION OF 6th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 M	4.15	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th,6th
	12 M	4.17	V INCOMPLETE OSSIFICATION OF 6th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS

CLASS CODES: V=Variation C=Cartilage  
SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22202	(CONTINUED)		
	13 F	3.97	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th,6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	14 F	4.00	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	15 F	3.90	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th,6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
C22203	SP 1 F	3.74	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA
	2 F	3.72	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	4.34	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 2nd, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd
	4 F	2.40	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 M	3.93	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	6 F	3.66	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 M	3.05	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 2nd, 4th, 5th, 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd, 4th

CLASS CODES: V=Variation C=Cartilage  
SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22203	(CONTINUED)		
			V UNOSSIFIED 5th STERNEBRA
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
			V UNOSSIFIED 4th METACARPAL(S), BILATERAL
			C CARTILAGE OF METACARPAL BONE(S): PRESENT, BILATERAL 4th
	8 F	3.86	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 M	3.67	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E): PRESENT 5th, 6th
	10 F	3.97	V INCOMPLETE OSSIFICATION OF 6th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 M	4.17	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E): PRESENT 4th, 5th, 6th
			V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th
	12 M	3.90	V INCOMPLETE OSSIFICATION OF 6th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 M	4.18	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E): PRESENT 5th, 6th
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
C22204	SP 1 F	3.99	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) Centrum 12th
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E): PRESENT 5th
			C CARTILAGE OF THORACIC VERTEBRA(E): PRESENT 12th
	2 F	4.12	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	4.58	NO OBSERVED EXTERNAL FINDINGS

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg



### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22204	(CONTINUED)		
			C CARTILAGE OF STERNEBRA(E) : PRESENT 6th
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
4 F	4.35		NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
5 M	4.66		NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA
			C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
6 M	4.37		NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
7 M	4.64		NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA
			C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
8 M	4.40		NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
9 M	4.53		NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA
			C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th
			V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th
10 F	4.17		NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
11 M	4.60		NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA
			C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th
			V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th
			METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
12 F	4.63		NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
14 F	4.28		NO OBSERVED EXTERNAL FINDINGS
			C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th
			V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22204	(CONTINUED)		V UNOSSIFIED 5th STERNEBRA
C22205	SP 1 F	3.54	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) 13th C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT 13th V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	2 M	3.71	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	3.67	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	4 F	3.44	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	3.56	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	6 F	3.43	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 M	3.93	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	8 M	3.58	NO OBSERVED EXTERNAL FINDINGS

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22205	(CONTINUED)		
	9 F	3.59	NO OBSERVED VISCERAL FINDINGS NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Interparietal C CARTILAGE OF STERNEBRA (E) : PRESENT 2nd, 4th, 5th, 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA (E) 2nd, 4th V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA V UNOSSIFIED 4th METACARPAL (S) , BILATERAL C CARTILAGE OF METACARPAL BONE (S) : PRESENT, BILATERAL 4th
	10 F	3.89	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 F	3.65	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL (S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th V UNOSSIFIED 4th METACARPAL (S) , LEFT C CARTILAGE OF METACARPAL BONE (S) : PRESENT, LEFT 4th
	12 M	4.11	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	14 F	2.84	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA (E) : PRESENT 4th, 5th, 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA (E) 4th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL (S) , BILATERAL C CARTILAGE OF METACARPAL BONE (S) : PRESENT, BILATERAL 4th
C22207	SP 1 M	2.80	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF INTERPARIETAL

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22207	(CONTINUED)		V INCOMPLETE OSSIFICATION OF FRONTAL, BILATERAL V INCOMPLETE OSSIFICATION OF PARIETAL, BILATERAL V INCOMPLETE OSSIFICATION OF SACRAL VERTEBRA(E) Centrum: 3rd C CARTILAGE OF SACRAL VERTEBRA(E) : PRESENT 3rd V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 2nd, 5th and 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd V INCOMPLETE OSSIFICATION OF 6th STERNEBRA RIB(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 2nd METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th V UNOSSIFIED 4th METACARPAL(S) , LEFT C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT 4th
	2 F	3.37	NO OBSERVED EXTERNAL FINDINGS V SHORT UTERINE HORN, BILATERAL
	3 F	3.32	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S) , BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	5 F	3.21	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	6 M	2.99	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF FRONTAL, BILATERAL C CARTILAGE OF STERNEBRA(E) : PRESENT 2nd, 5th and 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th

CLASS CODES: V=Variation C=Cartilage  
SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT(G)	OBSERVATION
C22207	(CONTINUED)		V UNOSSIFIED 4th METACARPAL(S), LEFT C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT 4th V INCOMPLETE OSSIFICATION OF PUBIS, LEFT C CARTILAGE OF PELVIC GIRDLE: PRESENT, LEFT Pubis bone
	7 F	3.19	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	8 F	3.05	NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Interparietal bone C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	9 M	3.39	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	10 M	3.20	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF INTERPARIETAL V INCOMPLETE OSSIFICATION OF FRONTAL, BILATERAL V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) Centrum: 13th C CARTILAGE OF THORACIC VERTEBRA(E) : PRESENT 13th V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 2nd, 5th and 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
C22209	SP 1 M	4.07	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22209	(CONTINUED)		
	2 M	4.09	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	4.12	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th STERNEBRA (E) DAMAGED AT THE PREPARATION OF THE FETUS 6th RIB(S) DAMAGED AT THE PREPARATION OF THE FETUS, BILATERAL Right: 6th and 7th, left: 8th and 9th
	4 M	3.78	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	3.95	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	6 F	3.77	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	3.75	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th METATARSAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	9 F	3.87	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	10 M	3.91	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	11 M	4.14	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	12 M	3.94	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	13 M	3.86	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	14 M	4.31	NO OBSERVED EXTERNAL FINDINGS

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22209	(CONTINUED)		V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
C22211	SP 1 M	3.88	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	2 M	4.04	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	3.55	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA (E) : PRESENT 5th V UNOSSIFIED 5th STERNEBRA
	5 M	4.23	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	6 M	3.76	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	7 M	3.87	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	8 F	3.98	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA (E) : PRESENT 4th, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA (E) 4th V UNOSSIFIED 5th STERNEBRA
	9 F	3.76	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	10 M	3.98	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	11 M	4.19	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	12 F	3.69	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA (E) : PRESENT 4th, 5th, 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA (E) 4th

CLASS CODES: V=Variation C=Cartilage  
SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22211	(CONTINUED)		
			V UNOSSIFIED 5th STERNEBRA
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	13 M	3.84	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	14 F	3.89	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th
	15 F	3.78	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	16 M	3.81	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V UNOSSIFIED 4th METACARPAL(S), LEFT C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT 4th
C22212	SP 1 F	3.50	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	2 M	3.66	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	3.52	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	4 M	3.38	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 M	3.49	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th

CLASS CODES: V=Variation C=Cartilage  
SEX CODE: M-Male F-Female

SP=Fin sac/Pg



### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22212	(CONTINUED)		
			V UNOSSIFIED 5th STERNEBRA
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
			V UNOSSIFIED 4th METACARPAL(S), BILATERAL
			C CARTILAGE OF METACARPAL BONE(S): PRESENT, BILATERAL 4th
	6 M	4.11	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 M	3.74	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA
			C CARTILAGE OF STERNEBRA(E): PRESENT 5th, 6th
	8 F	3.57	V INCOMPLETE OSSIFICATION OF 6th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	3.34	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA
			C CARTILAGE OF STERNEBRA(E): PRESENT 4th to 6th
			V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th
	10 M	3.71	V INCOMPLETE OSSIFICATION OF 6th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 M	3.39	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA
			C CARTILAGE OF STERNEBRA(E): PRESENT 5th, 6th
	12 M	3.70	V INCOMPLETE OSSIFICATION OF 6th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 M	3.99	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA
			C CARTILAGE OF STERNEBRA(E): PRESENT 5th
	14 M	3.89	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	16 F	3.64	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA
			C CARTILAGE OF STERNEBRA(E): PRESENT 2nd, 5th, 6th

CLASS CODES: V-Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 500 mg/kg/day

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FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22212	(CONTINUED)		V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd V INCOMPLETE OSSIFICATION OF 6th STERNEBRA

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CLASS CODES: V-Variation

SEX CODE: M-Male F-Female

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT(G)	OBSERVATION
C22213	SP 1 F	3.10	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th V UNOSSIFIED 4th METACARPAL(S), LEFT C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT 4th
	2 M	3.46	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	3.35	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	4 M	3.55	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	3.20	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 2nd, 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd and 4th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	6 F	3.40	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	3.10	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 4th to 6th

CLASS CODES: V-Variation C-Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22213	(CONTINUED)		
			V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th
			V UNOSSIFIED 5th STERNEBRA
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
			V UNOSSIFIED 4th METACARPAL(S), BILATERAL
			C CARTILAGE OF METACARPAL BONE(S): PRESENT, BILATERAL 4th
	8 F	3.31	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	3.18	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF SUPRAOCCIPITAL
			C CARTILAGE OF SUPRAOCCIPITAL: PRESENT
			C CARTILAGE OF STERNEBRA(E): PRESENT 4th to 6th
			V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th
			V UNOSSIFIED 5th STERNEBRA
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
			V UNOSSIFIED 4th METACARPAL(S), BILATERAL
			C CARTILAGE OF METACARPAL BONE(S): PRESENT, BILATERAL 4th
	10 M	3.33	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 F	3.17	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF SUPRAOCCIPITAL
			C CARTILAGE OF SUPRAOCCIPITAL: PRESENT
			C CARTILAGE OF STERNEBRA(E): PRESENT 5th and 6th
			V UNOSSIFIED 5th STERNEBRA
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
			METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
			V UNOSSIFIED 4th METACARPAL(S), LEFT
			C CARTILAGE OF METACARPAL BONE(S): PRESENT, LEFT 4th
C22214	SP 1 F	3.55	NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Hyoid THORACIC VERTEBRA(E) DAMAGED AT THE PREPARATION OF THE FETUS 11th, 12th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22214	(CONTINUED)		
			C CARTILAGE OF STERNEBRA(E) : PRESENT 4th to 6th
			V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th
			V UNOSSIFIED 5th STERNEBRA
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	2 M	4.01	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	3.91	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Hyoid
			C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th
	4 F	3.77	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	3.79	NO OBSERVED EXTERNAL FINDINGS
			C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th
			V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	6 M	3.84	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 M	3.82	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 2nd, 5th
			V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd,
	8 M	3.91	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	3.81	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th
			V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th
	10 F	3.64	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS

CLASS CODES: V-Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22214	(CONTINUED)		
	11 F	3.60	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
C22215	SP 1 M	3.80	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V UNOSSIFIED 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th V UNOSSIFIED 4th METACARPAL(S), LEFT 4th C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT 4th
	2 M	3.88	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	3.06	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA RIB(S) DAMAGED AT THE PREPARATION OF THE FETUS, BILATERAL 13th METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, LEFT 1st V UNOSSIFIED 4th METACARPAL(S), BILATERAL 4th C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	4 F	3.37	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	3.68	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22215	(CONTINUED)		
			V UNOSSIFIED 5th STERNEBRA
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
			V UNOSSIFIED 4th METACARPAL(S), BILATERAL
			C CARTILAGE OF METACARPAL BONE(S): PRESENT, BILATERAL
			4th
	6 F	3.86	NO OBSERVED EXTERNAL FINDINGS
			NO OBSERVED VISCERAL FINDINGS
	7 F	3.97	NO OBSERVED EXTERNAL FINDINGS
			C CARTILAGE OF STERNEBRA(E): PRESENT
			5th, 6th
			V UNOSSIFIED 5th STERNEBRA
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
			METATARSAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT
			3rd, 4th
	8 F	4.00	NO OBSERVED EXTERNAL FINDINGS
			NO OBSERVED VISCERAL FINDINGS
	9 M	3.89	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA
			C CARTILAGE OF STERNEBRA(E): PRESENT
			5th, 6th
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
			V UNOSSIFIED 4th METACARPAL(S), BILATERAL
			C CARTILAGE OF METACARPAL BONE(S): PRESENT, BILATERAL
			4th
	10 F	4.16	NO OBSERVED EXTERNAL FINDINGS
			NO OBSERVED VISCERAL FINDINGS
	11 F	3.75	NO OBSERVED EXTERNAL FINDINGS
			C CARTILAGE OF STERNEBRA(E): PRESENT
			5th, 6th
			V UNOSSIFIED 5th STERNEBRA
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
			METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT
			4th
			V UNOSSIFIED 4th METACARPAL(S), LEFT
			C CARTILAGE OF METACARPAL BONE(S): PRESENT, LEFT
			4th
	12 F	3.25	NO OBSERVED EXTERNAL FINDINGS
			NO OBSERVED VISCERAL FINDINGS
C22216	SP 1 M	3.26	NO OBSERVED EXTERNAL FINDINGS

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22216	(CONTINUED)		C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th, 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 3th, 4th V UNOSSIFIED 4th METACARPAL(S), LEFT 4th C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT 4th
	2 F	3.50	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	3.37	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 2nd, 4th, 5th, 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd, 4th V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA
	4 F	3.09	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 M	3.66	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), BILATERAL 4th C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	6 M	3.55	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	3.44	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF HYOID C CARTILAGE OF HYOID: PRESENT C CARTILAGE OF STERNEBRA(E) : PRESENT 2nd, 5th, 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd

CLASS CODES: V=Variation C=Cartilage  
SEX CODE: M-Male F-Female

SP=Fin sac/Pg



### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22216	(CONTINUED)		
			V UNOSSIFIED 5th STERNEBRA
			V UNOSSIFIED 6th STERNEBRA
			V UNOSSIFIED 4th METACARPAL(S), BILATERAL
			4th
			C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL
			4th
	8 M	3.47	NO OBSERVED EXTERNAL FINDINGS
			NO OBSERVED VISCERAL FINDINGS
	9 F	3.25	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA
			C CARTILAGE OF STERNEBRA(E) : PRESENT
			5th, 6th
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
			V UNOSSIFIED 4th METACARPAL(S), BILATERAL
			C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL
			4th
	10 F	2.74	NO OBSERVED EXTERNAL FINDINGS
			NO OBSERVED VISCERAL FINDINGS
	11 F	3.56	NO OBSERVED EXTERNAL FINDINGS
			C CARTILAGE OF STERNEBRA(E) : PRESENT
			2nd, 4th, 5th, 6th
			V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E)
			2nd, 4th
			V UNOSSIFIED 5th STERNEBRA
			V UNOSSIFIED 6th STERNEBRA
			METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT
			4th
			V UNOSSIFIED 4th METACARPAL(S), LEFT
			4th
			C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT
			4th
	12 F	3.05	NO OBSERVED EXTERNAL FINDINGS
			NO OBSERVED VISCERAL FINDINGS
C22217	SP 1 M	3.88	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA
			C CARTILAGE OF STERNEBRA(E) : PRESENT
			5th, 6th
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
			METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT
			4th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22217	(CONTINUED)		
	3 M	3.77	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	4 M	3.61	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	6 F	3.44	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 M	3.67	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	8 F	3.53	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 M	3.46	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	10 M	3.75	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 M	3.68	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	12 M	3.82	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 M	3.86	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	14 M	3.85	NO OBSERVED EXTERNAL FINDINGS V DILATED RENAL PELVIS, RIGHT
	15 F	3.22	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
C22219	SP 1 F	3.54	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA

CLASS CODES: V-Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22219	(CONTINUED)		
			C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
			V UNOSSIFIED 4th METACARPAL(S), LEFT
			C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT 4th
	2 F	4.34	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	3.89	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
			V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	4 F	3.84	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	6 M	4.00	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF HYOID C CARTILAGE OF HYOID: PRESENT V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
			V UNOSSIFIED 4th METACARPAL(S), LEFT C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT 4th
	7 F	3.69	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	8 M	3.92	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	9 F	3.81	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	10 M	4.26	NO OBSERVED EXTERNAL FINDINGS

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22219	(CONTINUED)		
			V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	11 M	3.98	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	12 F	3.59	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
C22220	SP 1 F	3.79	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	2 F	3.73	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	3.97	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) Centrum: 12th C CARTILAGE OF THORACIC VERTEBRA(E) : PRESENT 12th C CARTILAGE OF STERNEBRA(E) : PRESENT 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	4 F	3.97	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	4.21	NO OBSERVED EXTERNAL FINDINGS METATARSAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	6 F	3.78	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	3.98	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th

CLASS CODES: V=Variation C=Cartilage  
SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22220	(CONTINUED)		
	8 F	3.84	V INCOMPLETE OSSIFICATION OF 6th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	3.90	NO OBSERVED EXTERNAL FINDINGS THORACIC VERTEBRA (E) DAMAGED AT THE PREPARATION OF THE FETUS 4th V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	10 M	4.05	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 M	4.29	NO OBSERVED EXTERNAL FINDINGS METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	12 F	4.10	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 M	4.12	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
C22221	SP 1 F	3.68	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	2 F	3.59	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	4 F	3.71	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	5 M	3.89	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	6 F	3.71	NO OBSERVED EXTERNAL FINDINGS METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th V UNOSSIFIED 4th METACARPAL(S), LEFT C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT 4th

CLASS CODES: V=Variation C=Cartilage  
SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22221	(CONTINUED)		
	7 M	4.01	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	8 F	3.48	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, LEFT 1st V UNOSSIFIED 4th METACARPAL(S), RIGHT C CARTILAGE OF METACARPAL BONE(S) : PRESENT, RIGHT 4th
	9 F	3.53	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	10 M	4.05	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	11 F	3.79	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	12 M	3.86	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
C22222	SP 1 M	4.20	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA (E) Centrum: 11th C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT 11th V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 4th and 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA (E) 4th
	3 M	3.30	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	4 F	3.56	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22222	(CONTINUED)		
	5 M	3.74	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	6 M	4.15	NO OBSERVED EXTERNAL FINDINGS STERNEBRA (E) DAMAGED AT THE PREPARATION OF THE FETUS 6th METACARPAL (S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	7 F	2.10	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	8 M	4.05	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 4th and 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA (E) 4th
	10 M	3.79	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 F	3.80	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th METACARPAL (S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 1st
C22223	SP 1 F	3.99	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	2 M	4.02	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	4 F	4.07	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA (E) : PRESENT 5th V UNOSSIFIED 5th STERNEBRA
	5 F	3.95	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	6 M	4.25	NO OBSERVED EXTERNAL FINDINGS METACARPAL (S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	7 F	4.35	NO OBSERVED EXTERNAL FINDINGS

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22223	(CONTINUED)		
	8 M	4.27	NO OBSERVED VISCERAL FINDINGS NO OBSERVED EXTERNAL FINDINGS METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, LEFT 1st
	9 M	4.50	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	10 F	3.99	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF RIB(S) , RIGHT 13th C CARTILAGE OF RIB(S) : ABSENT, RIGHT 13th
	11 F	4.17	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	12 M	4.23	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) Centrum: 12th C CARTILAGE OF THORACIC VERTEBRA(E) : PRESENT 12th V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
C22224	SP 1 F	3.82	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	2 M	4.04	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	4.05	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	4 M	4.21	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 M	3.97	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	6 M	4.13	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	3.77	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	8 F	3.85	NO OBSERVED EXTERNAL FINDINGS

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg



### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22224	(CONTINUED)		
	9 M	4.05	NO OBSERVED VISCERAL FINDINGS NO OBSERVED EXTERNAL FINDINGS V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th METATARSAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	10 F	4.23	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 M	3.60	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th V UNOSSIFIED 4th METACARPAL(S), LEFT C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT 4th
	12 M	3.96	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 F	3.96	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
C22225	SP 1 F	3.79	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	2 M	4.22	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	4.16	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	4 F	4.11	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	4.08	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22225	(CONTINUED)		
	6 M	4.50	NO OBSERVED EXTERNAL FINDINGS V ENLARGED KIDNEY, RIGHT Dark color
	7 M	4.45	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	8 F	4.10	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	4.06	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	10 M	4.19	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 M	3.99	NO OBSERVED EXTERNAL FINDINGS METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	12 M	4.00	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
C22226	SP 1 F	4.16	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	2 M	4.47	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	4.35	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	4 M	4.27	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	3.84	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22226	(CONTINUED)		
	6 M	4.54	V UNOSSIFIED 5th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	3.91	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th
	8 M	4.13	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	3.91	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th
	10 F	4.22	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 F	3.92	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	12 M	4.32	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 M	4.15	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 4th, 5th, 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	14 M	4.36	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	15 F	4.49	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	16 M	4.19	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS

CLASS CODES: V-Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

## INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22227	1 M	3.34	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA (E) : PRESENT 5th V UNOSSIFIED 5th STERNEBRA
	2 M	3.98	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 F	3.59	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA (E) Centrum: 11th C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT 11th C CARTILAGE OF STERNEBRA (E) : PRESENT 5th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF RIB (S) , LEFT 13th METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, LEFT 1st V UNOSSIFIED 4th METACARPAL(S) , LEFT C CARTILAGE OF METACARPAL BONE (S) : PRESENT, LEFT 4th C CARTILAGE OF RIB (S) : PRESENT, LEFT 13th
	5 M	3.79	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	6 F	3.57	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA (E) : PRESENT 5th V UNOSSIFIED 5th STERNEBRA STERNEBRA (E) DAMAGED AT THE PREPARATION OF THE FETUS 6th METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	7 F	3.62	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	8 M	3.98	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA (E) Centrum: 11th C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT 11th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22227	(CONTINUED)		
			V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	11 M	3.91	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	12 M	4.00	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	13 F	3.71	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
C22229	SP 1 M	3.79	NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Hyoid V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	4 M	3.34	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 M	3.69	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	6 F	2.99	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	2.66	NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS, LEFT Parietal STERNEBRA (E) DAMAGED AT THE PREPARATION OF THE FETUS 1st to 6th V UNOSSIFIED 4th METACARPAL(S), BILATERAL

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22229	(CONTINUED)		
	9 M	3.47	C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	10 M	2.28	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA (E) Centrum: 1st C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT 1st C CARTILAGE OF STERNEBRA (E) : PRESENT 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA (E) 4th V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA V INCOMPLETE OSSIFICATION OF METATARSAL(S) , BILATERAL 4th C CARTILAGE OF METATARSAL BONE(S) : PRESENT, BILATERAL 4th V INCOMPLETE OSSIFICATION OF PUBIS, BILATERAL C CARTILAGE OF PELVIC GIRDLE: PRESENT, BILATERAL Pubis bone
	11 M	4.09	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	12 M	3.31	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA (E) Centrum: 1st C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT 1st V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	13 M	2.45	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
C22230	SP 1 F	3.73	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22230	(CONTINUED)		
			METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 3rd and 4th
	2 M	4.21	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	3 M	4.24	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	4 F	3.80	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 M	3.81	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E): PRESENT 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	6 M	4.34	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 M	3.78	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E): PRESENT 2nd and 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	8 F	3.82	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 F	3.85	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E): PRESENT 5th
	10 M	3.89	RIB(S) DAMAGED AT THE PREPARATION OF THE FETUS, LEFT 1st to 3rd NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
C22231	SP 1 F	3.21	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E): PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th

CLASS CODES: V=Variation C=Cartilage  
SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22231	(CONTINUED)		
	2 M	3.80	NO OBSERVED EXTERNAL FINDINGS V DILATED URETER, LEFT
	3 M	3.55	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th, 6th V UNOSSIFIED 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	4 F	3.48	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 M	3.43	NO OBSERVED EXTERNAL FINDINGS V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	6 F	3.45	NO OBSERVED EXTERNAL FINDINGS M ABSENT KIDNEY, RIGHT M ABSENT ADRENAL, RIGHT M ABSENT URETER, RIGHT
	7 M	3.84	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	8 F	3.47	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 M	3.73	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th, 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	10 F	3.21	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 F	3.30	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA (E) : PRESENT 4th, 5th

CLASS CODES: M=Malformation V=Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg



### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22231	(CONTINUED)		V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	12 F	3.24	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	13 M	3.39	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF THORACIC VERTEBRA(E) : PRESENT 12th V THORACIC VERTEBRA(E) : BIPARTITE OSSIFICATION OF CENTRUM 12th C CARTILAGE OF STERNEBRA(E) : PRESENT 2nd, 5th, 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
C22232	SP 1 F	3.53	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF INTERPARIETAL C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA RIB(S) DAMAGED AT THE PREPARATION OF THE FETUS, LEFT 2nd V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	2 F	3.25	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	4 F	3.68	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V UNOSSIFIED 5th STERNEBRA

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22232	(CONTINUED)		
	5 M	3.90	V INCOMPLETE OSSIFICATION OF 6th STERNEBRA NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	6 F	3.64	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA (E) : PRESENT 5th and 6th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	7 F	3.31	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	8 M	3.66	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA (E) Centrum: 12th C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT 12th C CARTILAGE OF STERNEBRA (E) : PRESENT 5th V UNOSSIFIED 5th STERNEBRA STERNEBRA (E) DAMAGED AT THE PREPARATION OF THE FETUS 6th RIB(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 6th and 7th
	9 M	3.67	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	10 F	3.33	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF INTERPARIETAL C CARTILAGE OF STERNEBRA (E) : PRESENT 5th and 6th V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	11 M	3.81	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	12 F	3.09	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA (E) Centrum: 9th and 10th

CLASS CODES: V-Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22232	(CONTINUED)		
			C CARTILAGE OF THORACIC VERTEBRA(E) : PRESENT 9th and 10th
			C CARTILAGE OF STERNEBRA(E) : PRESENT 4th and 5th
			V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th
			V UNOSSIFIED 5th STERNEBRA
			M ABSENT RIB(S), BILATERAL 13th
			V UNOSSIFIED 4th METACARPAL(S), BILATERAL
			C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	13 F	3.57	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	14 F	3.18	NO OBSERVED EXTERNAL FINDINGS
			C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th
			V UNOSSIFIED 5th STERNEBRA
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
			V UNOSSIFIED 4th METACARPAL(S), RIGHT
			C CARTILAGE OF METACARPAL BONE(S) : PRESENT, RIGHT 4th
C22233	SP 1 M	3.69	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) Centrum: 12th
			C CARTILAGE OF THORACIC VERTEBRA(E) : PRESENT 12th
			C CARTILAGE OF STERNEBRA(E) : PRESENT 6th
			V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	3 M	4.06	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	4 F	4.12	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF INTERPARIETAL
	6 M	4.35	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	4.14	NO OBSERVED EXTERNAL FINDINGS
			V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) Centrum: 3rd

CLASS CODES: M=Malformation V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22233	(CONTINUED)		
			C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT 3rd
	8 F	4.09	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 M	4.30	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF INTERPARIETAL V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th
	10 M	4.13	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	11 M	4.24	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	12 F	3.89	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	14 F	3.61	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA (E) Centrum: 11th C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT 11th C CARTILAGE OF STERNEBRA (E) : PRESENT 5th V UNOSSIFIED 5th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), LEFT C CARTILAGE OF METACARPAL BONE(S) : PRESENT, LEFT 4th
C22234	SP 1 F	3.43	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA (E) Centrum: 9th C CARTILAGE OF THORACIC VERTEBRA (E) : PRESENT 9th V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA (E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	2 M	3.20	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

## INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22234	(CONTINUED)		
	3 M	3.15	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 4th to 6th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 4th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA M ABSENT RIB(S), BILATERAL One pair V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th V PRESENCE OF 25 PRE-SACRAL VERTEBRAE M ABSENT THORACIC VERTEBRA (E) One
	4 F	3.31	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	5 F	3.13	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF INTERPARIETAL V INCOMPLETE OSSIFICATION OF FRONTAL, BILATERAL V UNOSSIFIED CAUDAL VERTEBRA(E) 3rd C CARTILAGE OF CAUDAL VERTEBRA(E) : PRESENT 3rd C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA C CARTILAGE OF RIB(S) : PRESENT, BILATERAL V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th METATARSAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th V SHORT RIB(S), BILATERAL 13th
	6 F	3.41	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	7 F	3.40	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF INTERPARIETAL

CLASS CODES: M=Malformation V=Variation C=Cartilage

SEX CODE: M=Male F=Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22234	(CONTINUED)		
			V INCOMPLETE OSSIFICATION OF FRONTAL, BILATERAL V INCOMPLETE OSSIFICATION OF PARIETAL, BILATERAL V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA V UNOSSIFIED 4th METACARPAL(S), BILATERAL C CARTILAGE OF METACARPAL BONE(S) : PRESENT, BILATERAL 4th
	8 F	2.66	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	9 M	3.81	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA C CARTILAGE OF RIB(S) : ABSENT, BILATERAL 13th V SHORT RIB(S), BILATERAL 13th
C22235	SP 1 M	3.97	NO OBSERVED EXTERNAL FINDINGS HEAD BONE(S) DAMAGED AT THE PREPARATION OF THE FETUS Hyoid
	2 M	4.52	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	4 F	3.88	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	5 M	4.30	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	6 F	4.17	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th
	7 F	4.11	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	8 F	4.13	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th

CLASS CODES: V=Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22235	(CONTINUED)		
	9 M	4.46	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	10 F	4.02	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	11 F	4.24	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	12 F	4.42	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	13 F	4.05	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	14 M	4.26	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 2nd, 5th V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd
	15 F	3.82	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	16 M	3.98	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
C22236	SP 2 F	4.29	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA METACARPAL(S) DAMAGED AT THE PREPARATION OF THE FETUS, RIGHT 4th
	3 M	4.72	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	4 M	4.64	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF THORACIC VERTEBRA(E) Centrum: 11th C CARTILAGE OF THORACIC VERTEBRA(E) : PRESENT 11th
	5 F	4.37	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	6 F	4.56	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 2nd V INCOMPLETE OSSIFICATION OF 1st TO 4th STERNEBRA(E) 2nd

CLASS CODES: V=Variation C=Cartilage  
SEX CODE: M-Male F-Female

SP=Fin sac/Pg

### INDIVIDUAL FETAL OBSERVATIONS

Dose: 1000 mg/kg/day

FEMALE#	FETUS# (SEX)	WEIGHT (G)	OBSERVATION
C22236	(CONTINUED)		
	7 F	4.03	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	8 M	4.56	NO OBSERVED EXTERNAL FINDINGS C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V UNOSSIFIED 5th STERNEBRA V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	9 F	4.53	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	10 F	4.32	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED SKELETAL FINDINGS
	11 F	4.44	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS
	12 M	4.25	NO OBSERVED EXTERNAL FINDINGS V INCOMPLETE OSSIFICATION OF 5th STERNEBRA C CARTILAGE OF STERNEBRA(E) : PRESENT 5th and 6th V INCOMPLETE OSSIFICATION OF 6th STERNEBRA
	13 M	4.65	NO OBSERVED EXTERNAL FINDINGS NO OBSERVED VISCERAL FINDINGS

CLASS CODES: V-Variation C=Cartilage

SEX CODE: M-Male F-Female

SP=Fin sac/Pg



## 16. Study plan and amendment



**ETHYL TERTIARY BUTYL ETHER (ETBE)**

**PRENATAL DEVELOPMENTAL TOXICITY STUDY  
BY THE ORAL ROUTE (GAVAGE) IN RATS**

**Test facility** : CIT  
BP 563 - 27005 Evreux  
France

**Sponsor** : TOTALFINAELF

**Address** : J.P. Gennart  
Tour Gallilée  
51 Esplanade du Général de Gaulle  
La Défense 10  
92907 Paris-1a-Défense CEDEX  
France

**Study Monitor** : A.K. Mallett  
PO Box 705  
Woking  
Surrey GU23 7XP  
United Kingdom

**Study Director** : W. Gaoua

**Deputy Study Director** : G. Chevalier

**Study Number** : 24860 RSR

*Final study plan of 09 April 2003*

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## 1. INTRODUCTION

### 1.1 Objective

The objective of this prenatal developmental toxicity study is to evaluate the potential toxic effects of the test item, ETHYL TERTIARY BUTYL ETHER (ETBE), on the pregnant female and on embryonic and fetal development following daily oral administration (gavage) to pregnant female rats from implantation to the day prior to the scheduled hysterectomy (day 5 to day 19 *post-coitum* inclusive).

### 1.2 Regulatory compliance

This study plan has been designed to comply with:

- OECD guideline No. 414, 22 January 2001,
- US/EPA guideline OPPTS 870.3700, August 1998,
- EC Commission Directive 87/302/EEC of Nov. 18, 1987.

The study will be conducted in compliance with the following Good Laboratory Practice regulations:

- OECD Principles on Good Laboratory Practice (as revised in 1997), ENV/MC/CHEM (98) 17,
- Commission Directive 1999/11/EC of 8 March 1999 adapting to technical progress the Principles of Good Laboratory Practice as specified in Council Directive 87/18/EEC on the harmonization of laws, regulations and administrative provisions relating to the application of the Principles of Good Laboratory Practice and the verification of their applications for tests on chemical substances (OJ No. L 77 of 23.3.1999),
- Décret N° 98-1312 du 31 décembre 1998 concernant les Bonnes Pratiques de Laboratoire (Journal Officiel du 1er janvier 1999), Ministère de l'Economie, des Finances et de l'Industrie,
- US Environmental Protection Agency, Federal Register, 40 CFR Part 792; Toxic Substances Control Act; Good Laboratory Practice Standards, August 17, 1989 (and subsequent amendments),
- Japanese Ministry of International Trade and Industry, Good Laboratory Practice Standards, Basic Industries Bureau, KanHogyo No. 39, March 31, 1984.

The study will be conducted in compliance with Animal Health regulation, in particular:

- Council Directive No. 86/609/EEC of 24th November 1986 on the harmonization of laws, regulations or administrative provisions relating to the protection of animals used for experimental or other scientific purposes.

## 2. TEST AND CONTROL ITEMS

### 2.1 Identification

#### 2.1.1 Test item

**Name:** ETHYL TERTIARY BUTYL ETHER (ETBE)

**Synonyms:** Ethyl-tert-Butyl Ether, ETBE, 2-ethoxy-2-methylpropane

**CAS No.:** 637-92-3

**Batch No.:** S02-08-159-I3 and S02-08-159-I3/2

**Supplier:** SEPAREX, Champigneulles, France

**Description:** colorless liquid

**Purity:** >98%

**Impurities:** ...(1)...

**Storage conditions:** at room temperature, in well-closed containers (flammable) in the dark

**Expiry date:** ...(1)...

**Intended use:** oxygenate additive for automotive fuels

Purity, composition, stability and expiry date which refer to the batch(es) to be used and handling conditions will be indicated in the test item data sheet (to be completed by the Sponsor). An analytical certificate will also be provided by the Sponsor.

Confirmation of identity of the test item is the responsibility of the Sponsor.

#### 2.1.2 Vehicle

**Name:** corn oil (Sigma, Saint-Quentin-Fallavier, France)

**Batch No.:** will be documented in the raw data and specified in the study report

### 2.2 Dosage form preparation

The test item will be administered as a solution in the vehicle. The test item dosage forms will be prepared once a week according to the demonstrated stability results obtained in a previous study: (CIT/Study No. 24168 RSR) and will be stored at room temperature (in a well closed bottle) in the dark prior to use. Each batch for each treatment level will be sub-divided into a suitable number of aliquots so that one bottle per dose per day will be opened for dosing, and the remainder discarded.

### 2.3 Chemical analysis of the dosage forms

#### 2.3.2 Homogeneity

Before treatment, homogeneity of the dosing preparation will be confirmed at the lowest and highest concentrations prepared for use.

Duplicate samples will be taken from three levels (top, middle and bottom) with administration device to be used in the study, and analyzed for concentration of the test item.

#### 2.3.3 Concentration

During the treatment period, a check of the concentrations will be performed on solutions of each control and test item dosage forms weekly along the treatment period.

All analyses will be performed by CIT, using a method provided by the Sponsor.

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(1) To be specified by a study plan amendment.

### 3. TEST SYSTEM

#### 3.1 Animals

**Number:** 96 time-mated female rats.

**Strain and sanitary status:** Sprague-Dawley, CrI CD<sup>®</sup> (SD) IGS BR, *Caesarian Obtained, Barrier Sustained-Virus Antibody Free (COBS-VAF<sup>®</sup>)*.

**Reason for selection of species:** the rat is a rodent species commonly accepted by regulatory authorities for this type of study and background data from previous studies is available at our laboratory.

**Breeder:** Charles River Laboratories France, l'Arbresle, France.

**Age:** at the beginning of the treatment period, the females will be 10-11 weeks old. The females will be sexually mature and primigravid.

**Mating:** females will be mated at the breeder's facilities. The day of confirmed mating (detection of a vaginal plug) will be designated day 0 *post-coitum* (p.c.).

**Acclimation:** the animals will be acclimated for a period of at least 4 days before the beginning of the treatment period (arrival of females on day 1 *post-coitum*). The animals may be supplied in several batches, for logistical purpose.

**Allocation to group:** during the acclimation period, the animals will be allocated to the groups, according to a stratification procedure based on body weight.

**Identification:** the animals are individually identified by an ear tattoo (unique CIT identity number).

#### 3.2 Environmental conditions

From arrival at CIT, the animals will be housed in a barriered rodent unit, under specific pathogen free (SPF) standard laboratory conditions.

The animal room conditions will be set as follows:

- temperature :  $22 \pm 2^{\circ}\text{C}$ ,
- relative humidity :  $50 \pm 20\%$ ,
- light/dark cycle : 12 h/12 h (07:00 - 19:00),
- ventilation : about 12 cycles/hour of filtered, non-recycled air.

The corresponding instrumentation and equipment are checked and calibrated at regular intervals. The temperature and relative humidity are recorded continuously and the records are checked daily and filed.

The animal room will be disinfected before the arrival of the animals and cleaned regularly thereafter.

#### 3.3 Housing

The animals will be individually housed in wire-mesh cages (43.0 x 21.5 x 18.0 cm). A metal tray containing autoclaved sawdust (SICSA, Alfortville, France) will be placed under each cage. The sawdust will be changed at least once a week.

The cages will be placed in numerical order on the racks.

#### 3.4 Food and water

All animals will have free access to A04 C pelleted maintenance diet (SAFE, Villemoisson, Epinay-sur-Orge, France) distributed weekly and to tap water (filtered with a 0.22  $\mu\text{m}$  filter) contained in bottles.

### 3.5 Contaminant analyses

The batches of diet and sawdust are analysed by the suppliers for composition and contaminant levels.

Bacterial and chemical analyses of water are performed regularly by external laboratories. These analyses include the detection of possible contaminants (pesticides, heavy metals and nitrosamines).

It will be ensured that no contaminants that may interfere with or prejudice the outcome of the study are present in the diet, drinking water or sawdust.

## 4. TREATMENT

### 4.1 Treatment groups

#### Rationale for dose-level selection

The dose-levels were selected in agreement with the Sponsor, on the basis of a previously conducted study (CIT/Study No. 24168 RSR). In this previous reproduction/developmental dose range-finding study, except for a slight significant decrease on body weight of pregnant females at 1000 mg/kg/day and ptyalism in most animals given 1000 mg/kg/day over the study, no effect on mating, pregnancy, lactation or litter data parameters was noted at 50, 250 and 1000 mg/kg/day.

Consequently, dose-levels of 250, 500 and 1000 mg/kg/day were selected for this study. The treatment groups are detailed in the following table:

Group	Number of mated females	Dose-level (mg/kg/day)	Concentration (mg/mL)
1	24	0	0
2	24	250	62.5
3	24	500	125
4	24	1000	250

### 4.2 Duration

Each animal will be dosed once a day, at approximately the same time, from day 5 to day 19 *post-coitum* inclusive.



### 4.3 Administration

The oral route was selected based upon agreement with the Competent Authority requesting this study. It is also recommended by OECD Guideline 414, and was used in the preliminary range-finding study. The dosage form will be administered by gavage using a glass syringe fitted with a metal gavage tube.

The quantity of dosage forms administered to each animal will be adjusted according to the most recently recorded body weight.

A constant dosage-volume of 4 mL/kg/day will be used.

Control animals (group 1) will receive the vehicle alone.

The dosage forms will be mixed regularly throughout the dosing procedure.

## 5. CLINICAL EXAMINATIONS

### 5.1 Morbidity and mortality

Each animal will be checked for mortality and signs of morbidity: at least twice a day during treatment period; at least once a day on other days.

Any animal showing signs of poor clinical condition, especially if death appears imminent, or any female having aborted, will be humanely killed.

Any female found dead or killed prematurely will be subjected to a macroscopic *post-mortem* examination (see § 6.2).

### 5.2 Clinical signs

From arrival, each animal will be observed at least once a day as part of routine examinations. From days 5 to 14 *post-coitum*, each animal will be observed at least three times per day (immediately post-dose, 1 hour post-dose, 4 hour post-dose) for the recording of clinical signs (including evidence of physical or behavioural changes together with any signs of overt toxicity including abortion/resorption for the females).

From days 15 to 19 *post-coitum*, animals will be observed immediately after dosing and 1 hour post-dosing.

If clinical signs are present at the 1 hour observation period, the animals will be observed again 4-hour post-dosing (1).

Observations recorded immediately post-dosing will be made while the animals are being handled. Observations made 1 hour and 4 hours post-dosing will be made with the animals in their cages in order to minimise disturbing the animals during the later stages of pregnancy.

This initial schedule may be modified by an amendment to the study plan in the event of any unexpected clinical finding, or if no clinical signs are present.

### 5.3 Body weight

The body weight of each female will be recorded on days 2, 4, 5, 6, 9, 12, 15, 18, 19 and 20 *post-coitum*.

The net body weight will be calculated (gross body weight minus gravid uterus weight) as well as the gross and net body weight changes.

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(1) Will be specified by a study plan amendment.

#### **5.4 Food consumption**

The quantity of food consumed by each female will be recorded for the following intervals: days 2-4, 4-5, 5-6, 6-9, 9-12, 12-15, 15-18, 18-19 and 19-20 *post-coitum*.

### **6. SACRIFICE AND TERMINAL EXAMINATIONS**

These examinations will be carried out in all females.

#### **6.1 Hysterectomies**

On day 20 *post-coitum*, all females will be killed by asphyxiation using carbon dioxide. The weight of the gravid uterus will be recorded for each pregnant female (with at least one live fetus) at hysterectomy.

The ovaries and uterus of the females will be examined to determine:

- number of corpora lutea,
- number and distribution of dead and live fetuses,
- number and distribution of early and late resorptions,
- number and distribution of implantation sites (or uterine scars).

Early resorptions refer to evidence of implantation without recognizable embryo or fetus. Late resorptions refer to dead embryo or fetus with external degenerative changes.

In apparently non-pregnant females, the presence of implantation scars on the uterus will be checked using the ammonium sulphide staining technique.

#### **6.2 Macroscopic *post-mortem* examination**

All females will be submitted to a macroscopic *post-mortem* examination of the principal thoracic and abdominal organs.

A gross evaluation of placentas will also be undertaken.

The number of corpora lutea and implantation sites will be recorded whenever possible in the females that die, abort, or are killed prematurely.

Whenever necessary, photographs will be taken to document findings and kept with the study archives.

### **7. EXAMINATION OF THE FETUSES**

These examinations will be carried out on all litters (females with at least one live fetus).

Whenever necessary, photographs of the fetuses will be taken to document findings and kept with the study archives.

The fetal findings will be described according to the glossary of the International Federation of Teratology Societies (IFTS) and classified as malformations or variations:

- malformation refers to permanent structural change that is likely to adversely affect the survival or health,
- variation refers to a change that occurs within the normal population under investigation and is unlikely to adversely affect the survival or health (this might include a delay in growth or morphogenesis that has otherwise followed a normal pattern of development).

#### **7.1 Body weight**

The body weight of each live fetus will be recorded.

## 7.2 External examination

Each fetus will be subjected to a detailed external examination which will include the observation of all visible structures, surfaces and orifices (including the oral cavity). Dead fetuses will then be discarded.

The live fetuses will be then killed by subcutaneous injection of thiopental sodium.

## 7.3 Soft tissue examination (Wilson, J.G, 1965)

Approximately half of the live fetuses in each litter will be fixed with Harrison's fluid. A detailed soft tissue examination will be performed according to a free-hand serial sectioning technique, which will include the observation of all the organs and structures of the head, neck, thorax and abdomen.

## 7.4 Skeletal examination (Peters P.W.: 1977)

The remaining live fetuses per litter will be fixed with ethyl alcohol and eviscerated.

A detailed examination of the skeleton (bone + cartilage) will be performed after staining with alizarin red S and alcian blue. This examination will include the observation of all the bone and cartilage structures of the head, spine, rib cage, pelvis and limbs.

## 7.5 Sex of fetuses

The sex of each live fetus will be determined at the time of evisceration (after fixation in alcohol) or at the time of serial sectioning. The sex of each dead fetus will be determined at the time of hysterectomy.

## 8. ASSESSMENT OF DATA

Data will be expressed as group mean values  $\pm$  standard deviation (maternal body weight and food consumption, fetal body weight and number of corpora lutea, implantations, fetuses and resorptions) or as proportions (pre-implantation loss, post-implantation loss, fetal findings). Whenever necessary, the experimental unit of comparison will be the litter.

The following calculations will be made:

$$\text{Pre-implantation loss: } \frac{\text{Number of corpora lutea} - \text{Number of implantation sites}}{\text{Number of corpora lutea}} \times 100$$

$$\text{Post-implantation loss: } \frac{\text{Number of implantation sites} - \text{Number of live fetuses}}{\text{Number of implantation sites}} \times 100$$

$$\text{Fetal or litter incidence: } \frac{\text{Total number of fetuses or litters with a particular finding}}{\text{Total number of fetuses or litters examined}} \times 100$$

$$\text{Mean proportion of affected fetuses: } \frac{\text{Sum of proportion of fetuses affected in each litter}}{\text{Total number of litters examined}} \times 100$$

## 9. STATISTICAL ANALYSIS

Final interpretation of the numerical data will consider the results of statistical analysis along with other factors such as dose-response relationships and whether the results were toxicologically relevant in the light of other biological- and pathological findings.

The litter will be the experimental unit for statistical analysis, with fetal body weight analyzed by sex as well as for both sexes combined. In addition, fetal body weights will be analyzed by a nested analysis of covariance (ANCOVA: fetal weights nested within dams nested within groups, with litter size as a covariant).

Other parameters will be evaluated for statistical significance using parametric or non-parametric methods, as appropriate. A detailed description of these methods will be the subject of a specific amendment to the study plan.

## 10. BIBLIOGRAPHICAL REFERENCES

- Chahoud, I. et al.: Classification terms in developmental toxicology: need for harmonisation.
- Dunnett, C.W.: A multiple comparison procedure for comparing several treatments with a control. J. Am. Stat. Assoc., 1955, 50, 1096-1121.
- Dunnett, C.W.: New tables for multiple comparisons with a control. Biometrics, 1964, 20, 482-491.
- Fisher, R.A.: Statistical methods for research workers (5<sup>th</sup> ed). Edinburgh: Oliver and Boyd (1934).
- Peters P.W.: Double staining of fetal skeletons for cartilage and bone, in "Methods in Prenatal Toxicology", D. Neubert, H.J. Merker and T.E. Kwasigroch Eds; Georg Thieme Publ. Stuttgart, 1977, pp 153-154.
- Salewski (E.): Färbemethode zum makroskopischen Nachweis von Implantationstellen am Uterus der Ratte. Arch. Exp. Path. Pharmak., 247, 367 (1964).
- Wilson, J.G.: Methods for administering agents and detecting malformations in experimental animals. In Teratology, Principles and Techniques; J.G. Wilson and J. Warkany eds, the University of Chicago Press, Chicago and London, 1965, pp 262-277.
- Wise L.D. et al.: Terminology of Developmental Abnormalities in Common Laboratory Mammals (Version 1), Teratology, 1997, 55, 249-292.

## 11. AMENDMENTS TO THE STUDY PLAN

If necessary, amendments to the study plan will be made after discussion between the Study Director and the Study Monitor, and authorization by the Sponsor.

## 12. REPORTING

The Study Monitor will be informed of any significant findings at any time during the course of the study.

The final report in English (with a summary in French), will contain all data collected during the study. It will include sufficient information for compliance with the Guidelines listed in section 1.2 of this study plan.

Number of copies of the final report: seven (six bound + one unbound).

Proposed issue of the draft report: 13 weeks after completion of the last hysterectomy.

In the case of additional investigations being requested, the Study Monitor will be informed of any change in the delay of the report.

On issue of the final report, an electronic version will be provided as a PDF file (to include a copy of all signed pages, certificate of analysis and appendices).

## 13. QUALITY ASSURANCE UNIT

The study will be subjected to Quality Assurance monitoring in order to ensure compliance with GLP, specifically:

- (i) The study plan will be checked for compliance with GLP requirements.
- (ii) Specific and/or process-based inspections will be performed in order to ensure that the conduct of the study complies with Standard Operating Procedures.
- (iii) Data audit will be undertaken to ensure the reliability and integrity of the study data.
- (iv) The study report will be reviewed by the Quality Assurance Unit in order to ensure that the report faithfully reflects the data generated during the study and the study findings.

The dates on which the findings of critical inspections and reviews are reported to the Study Director and CIT management will be specified in the study report.

## 14. ARCHIVING

The following study materials will be retained in the archives of CIT (BP 563 – 27005 Evreux, France) for 10 years after the end of the *in vivo* phase of the study:

- study plan and possible amendments,
- raw data,
- correspondence,
- final report and possible amendments,
- stained skeletons,
- soft tissue sections,
- samples of the test item,
- photographs (where appropriate).

On completion of this period, the archived study materials will be returned to the Sponsor, or may be archived at CIT for a further period (at additional cost).

The total duration of archiving (depending on regulations) will be the responsibility of the Sponsor.

In addition raw data not specific to the study, including but not limited to, certificates of analyses for food, water and bedding (if applicable) and records of environmental data and equipment calibration will also be archived by CIT for at least 30 years.

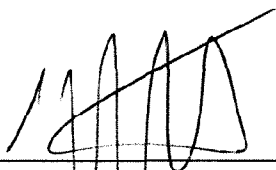
At the end of the study or utilization all remaining test item (excluding the archive sample(s)) will be returned to the Sponsor unless otherwise stated by the Sponsor.

## 15. PROPOSED TIME SCHEDULE

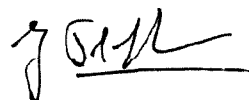
Arrival of the first mated females  
(experimental starting date): 16 April 2003  
First day of treatment: 21 April 2003  
First day of hysterectomy: 05 May 2003  
Last day of hysterectomy  
(experimental completion date): 07 May 2003  
Draft report: 03 September 2003

In the case of relevant modification of the time schedule, the Study Monitor will be informed and the dates will be documented in the raw data and in the study report.

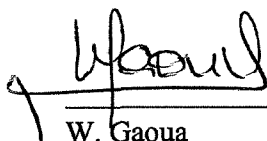
Study plan approved by:



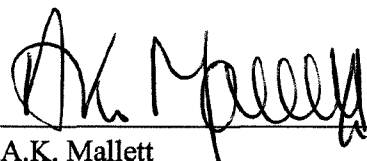
S. de Jouffrey or R. Forster  
CIT Scientific Management  
Date: 09 April 2003



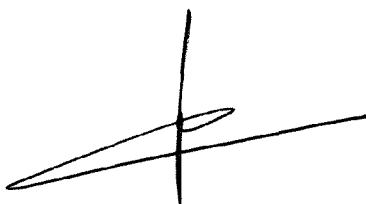
J.P. Gennart  
Sponsor  
Date: 24 September 2003



W. Gaoua  
CIT Study Director  
Date: 09 Apr 2003



A.K. Mallett  
Study Monitor  
Date: 16 April 2003



C. Galli-Kar  
CIT Head of Quality Assurance Unit  
Date: 09 April 2003

**AMENDMENT TO STUDY PLAN**

STUDY No.: 24860 RSR  
SPONSOR: TOTAL France SA  
TEST ITEM: ETHYL TERTIARY BUTYL ETHER (ETBE)  
STUDY TITLE: PRENATAL DEVELOPMENTAL TOXICITY STUDY BY THE ORAL  
ROUTE (GAVAGE) IN RATS  
AMENDMENT No.: 1 Page 1/1

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**Justification:** - add information unavailable at the time of finalisation of the study plan  
- change the name of the Sponsor facility

**Date of application:** 24 April 2003 (first day of dosing, §2)  
7 May 2003 (end of the dosing period, § 9)

*Modify in the study report the name of the Sponsor as mentioned below:*  
TOTAL France SA instead of TOTALFINAELF

*Amend the chapter as indicated by the underlined and crossed words*

**2. TEST AND CONTROL ITEMS**

**2.1 Identification**

**2.1.1 Test item**

**Name:** ETHYL TERTIARY BUTYL ETHER (ETBE)  
**Synonyms:** Ethyl-tert-Butyl Ether, ETBE, 2-ethoxy-2-methylpropane  
**CAS No.:** 637-92-3  
**Batch No.:** S02-08-159-I3/1 and S02-08-159-I3/2

.....  
**Expiry date :** 25 September 2003

*Amend the chapter below as indicated by the underlined words*

**9. STATISTICAL ANALYSIS**

Final interpretation.....and pathological findings.  
The litter will be the experimental unit for statistical analysis, with fetal body weight analyzed by sex as well as for both sexes combined.  
Mean values will be compared by one-way analysis of variance and Dunnet test, (mean values being considered as normally distributed and variances being considered as homogeneous).  
Percentages values were compared by Fisher exact probability test.

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Scientific Management	Study Director	Study Monitor	Sponsors Representative
S. de Jouffrey or R. Forster	W.Gaoua	A.K. Mallet	J.P. Gennart
Date: 17 Nov. '03	Date: 17 Nov 2003	Date: 30/11/03	Date: 24/12/03
Signature:	Signature:	Signature:	Signature:

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