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American Chemistry Council Good Chemistry Makes It Possible

June 3, 2005

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Attention: TSCA Section 8(e) Coordinator

RE: Combined 28-day Repeated Dose Oral Toxicity Study with Reproductive/Developmental Toxicity Screening Test (OECD 422) of Polyethylbenzene Bottoms (PEB) in Rats

Dear Sir or Madam:

The American Chemistry Council Ethylbenzene Panel (Panel) submits this letter on behalf of its members[1] pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA) to inform EPA of data from a Combined 28-day Repeated Dose Toxicity Study with Reproductive/Developmental Toxicity Screening study (OECD 422) that was conducted on Polyethylbenzene Bottoms (CAS No. 68987-42-8) under the HPV Challenge Program. This submission only reports hazard. The Panel has not made a determination as to whether a significant risk of injury to health or the environment is presented by these findings.

The Panel conducted a Combined 28-day Repeated Dose Oral Toxicity Study with Reproductive/Developmental Toxicity Screening study (OECD 422) at WIL Research Laboratories on a Polyethylbenzene Bottoms stream. Sprague Dawley rats received gavage doses of 0, 20, 80 or 320 mg/kg/day in corn oil for 28 days. Preliminary pathology review of high dose animals (320 mg/kg/day) identified the following target

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[1] The sponsors of the Polyethylbenzene Bottoms (PEB) in the HPV program are: Chevron Phillips Chemical Company, The Dow Chemical Company, Innovene, Lyondell Chemical Company, NOVA Chemicals Inc, and Total Petrochemicals USA Inc.

tissues: liver (hepatocellular hypertrophy) [males], kidneys (mineralization) [males], thyroid (follicular cell hypertrophy) [males and females], and thymus (atrophy) [females]. Unaudited draft data tables of the histopathology findings are attached. The pathology review has been extended to cover the mid and low dose level for the target tissues and it is currently underway. The data analysis portion of the study is presently ongoing at the laboratory. The final report will be provided to EPA, once it becomes available.

If you have any questions, please contact me at 301 924 2006 or Elizabeth_Moran@americanchemistry.com.

Yours truly,

Elizabeth J. Moran, Ph.D.
Manager, Ethylbenzene Panel

Attachment: Unaudited Draft Data Tables

D R A F T - LOCKED AND UNLOCKED
----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	12	12	12	12
NUMBER OF ANIMALS EXAMINED	12	0	0	12
ADRENAL CORTEX				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	11
-VACUOLATION, CYTOPLASMIC	0	NA	NA	1
MINIMAL	NONE	NA	NA	1
ADRENAL MEDULLA				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12
AORTA				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12
STERNEBRAE				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12
MARROW, STERN				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12

1- 0 MG/KG/DAY 2- 20 MG/KG/DAY 3- 80 MG/KG/DAY 4- 320 MG/KG/DAY
NA = NOT APPLICABLE

D R A F T - LOCKED AND UNLOCKED
----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	12	12	12	12
NUMBER OF ANIMALS EXAMINED	12	0	0	12
BRAIN				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12
CECUM				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12
COLON				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12
DUODENUM				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12
EPIDIDYMIDES				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12
ESOPHAGUS				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12

1- 0 MG/KG/DAY 2- 20 MG/KG/DAY 3- 80 MG/KG/DAY 4- 320 MG/KG/DAY
NA = NOT APPLICABLE

D R A F T - LOCKED AND UNLOCKED
----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	12	12	12	12
NUMBER OF ANIMALS EXAMINED	12	0	0	12
EYES/OPTIC N.				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12
HEART				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	9	NA	NA	10
-CARDIOMYOPATHY	2	NA	NA	2
MINIMAL	2	NA	NA	2
-INFLAMMATION, SUBACUTE	1	NA	NA	0
MINIMAL	1	NA	NA	NONE
ILEUM				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12
JEJUNUM				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12
KIDNEYS				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	1	NA	NA	2
-BASOPHILIC TUBULES	9	NA	NA	10
MINIMAL	9	NA	NA	10

1- 0 MG/KG/DAY 2- 20 MG/KG/DAY 3- 80 MG/KG/DAY 4- 320 MG/KG/DAY
NA = NOT APPLICABLE

D R A F T - LOCKED AND UNLOCKED
----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	12	12	12	12
NUMBER OF ANIMALS EXAMINED	12	0	0	12
KIDNEYS - CONTINUED				
-MINERALIZATION	2	NA	NA	8
MINIMAL	2	NA	NA	6
MILD	NONE	NA	NA	2
-INFLAMMATION, SUBACUTE	5	NA	NA	2
MINIMAL	5	NA	NA	2
LYMPH NODE, MAND				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	10	NA	NA	7
-HEMORRHAGE	1	NA	NA	2
MINIMAL	1	NA	NA	1
MILD	NONE	NA	NA	1
-HYPERPLASIA, LYMPHOID	0	NA	NA	1
MINIMAL	NONE	NA	NA	1
-PLASMACYTOSIS, MEDULLARY	1	NA	NA	2
MINIMAL	1	NA	NA	2
LAC. GLAND EXOR				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	11	NA	NA	12
-INFILTRATE, LYMPHOCYTE	1	NA	NA	0
MINIMAL	1	NA	NA	NONE

1- 0 MG/KG/DAY 2- 20 MG/KG/DAY 3- 80 MG/KG/DAY 4- 320 MG/KG/DAY
NA = NOT APPLICABLE

D R A F T - LOCKED AND UNLOCKED
----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	12	12	12	12
NUMBER OF ANIMALS EXAMINED	12	0	0	12
LIVER				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	5	NA	NA	0
-INFILTRATE, MONONUCLEAR	6	NA	NA	6
MINIMAL	6	NA	NA	6
-VACUOLATION, HEPATOCELLULAR	1	NA	NA	0
MINIMAL	1	NA	NA	NONE
-HYPERTROPHY, HEPATOCELLULAR	1	NA	NA	10
MINIMAL	1	NA	NA	10
LYMPH NODE, MES				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	10	NA	NA	11
-HISTIOCYTOSIS, SINUS	2	NA	NA	1
MINIMAL	1	NA	NA	1
MILD	1	NA	NA	NONE
LUNGS				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	9	NA	NA	10
-INFLAMMATION, SUBACUTE	1	NA	NA	0
MILD	1	NA	NA	NONE
-HEMORRHAGE	1	NA	NA	0
MINIMAL	1	NA	NA	NONE

1- 0 MG/KG/DAY 2- 20 MG/KG/DAY 3- 80 MG/KG/DAY 4- 320 MG/KG/DAY
NA = NOT APPLICABLE

D R A F T - LOCKED AND UNLOCKED
----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	12	12	12	12
NUMBER OF ANIMALS EXAMINED	12	0	0	12
LUNGS - CONTINUED				
-MACROPHAGES, ALVEOLAR	1	NA	NA	2
MINIMAL	1	NA	NA	2
NERVE, SCIATIC				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12
PANCREAS				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	11	NA	NA	12
-INFLAMMATION, SUBACUTE	1	NA	NA	0
MINIMAL	1	NA	NA	NONE
PITUITARY				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12
PROSTATE				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12

1- 0 MG/KG/DAY 2- 20 MG/KG/DAY 3- 80 MG/KG/DAY 4- 320 MG/KG/DAY
NA = NOT APPLICABLE

D R A F T - LOCKED AND UNLOCKED
----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	12	12	12	12
NUMBER OF ANIMALS EXAMINED	12	0	0	12
RECTUM				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12
SPINAL CORD				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12
SAL. GLAND MAND				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12
STOMACH, GLAN				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12
STOMACH, NON				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12
SKELETAL MUSCLE				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	10	NA	NA	11
-INFLAMMATION, SUBACUTE	2	NA	NA	1
MINIMAL	2	NA	NA	1

1- 0 MG/KG/DAY 2- 20 MG/KG/DAY 3- 80 MG/KG/DAY 4- 320 MG/KG/DAY
NA = NOT APPLICABLE

D R A F T - LOCKED AND UNLOCKED
----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	12	12	12	12
NUMBER OF ANIMALS EXAMINED	12	0	0	12
SKIN				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	11	NA	NA	12
-ULCERATION	1	NA	NA	0
MILD	1	NA	NA	NONE
SPLEEN				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12
SEMINAL VESICLES				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	11	NA	NA	12
-DECREASED SECRETION	1	NA	NA	0
MINIMAL	1	NA	NA	NONE
TESTES				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12
COAGULATING GL				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	11	NA	NA	12
-DECREASED SECRETION	1	NA	NA	0
MINIMAL	1	NA	NA	NONE

1- 0 MG/KG/DAY 2- 20 MG/KG/DAY 3- 80 MG/KG/DAY 4- 320 MG/KG/DAY
NA = NOT APPLICABLE

D R A F T - LOCKED AND UNLOCKED
----- MALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	12	12	12	12
NUMBER OF ANIMALS EXAMINED	12	0	0	12
THYROID GLANDS				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	5
-HYPERTROPHY, FOLLICULAR CELL	0	NA	NA	7
MINIMAL	NONE	NA	NA	7
PARATHYROIDS				
TOTAL NUMBER EXAMINED	9	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10
NOT EXAMINED	3	NA	NA	2
THYMUS				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12
TRACHEA				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12
URINARY BLADDER				
TOTAL NUMBER EXAMINED	12	NA	NA	12
EXAMINED, UNREMARKABLE	12	NA	NA	12

1- 0 MG/KG/DAY 2- 20 MG/KG/DAY 3- 80 MG/KG/DAY 4- 320 MG/KG/DAY
NA = NOT APPLICABLE

D R A F T - LOCKED AND UNLOCKED
----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	12	12	12	12
NUMBER OF ANIMALS EXAMINED	11	0	0	10
ADRENAL CORTEX				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10
ADRENAL MEDULLA				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10
AORTA				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10
STERNEBRAE				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10
MARROW, STERN				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10
BRAIN				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10

1- 0 MG/KG/DAY 2- 20 MG/KG/DAY 3- 80 MG/KG/DAY 4- 320 MG/KG/DAY
NA = NOT APPLICABLE

D R A F T - LOCKED AND UNLOCKED
----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	12	12	12	12
NUMBER OF ANIMALS EXAMINED	11	0	0	10
CECUM				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10
COLON				
TOTAL NUMBER EXAMINED	11	NA	NA	9
EXAMINED, UNREMARKABLE	11	NA	NA	9
NOT EXAMINED	0	NA	NA	1
DUODENUM				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10
ESOPHAGUS				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10
EYES/OPTIC N.				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10
HEART				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10

1- 0 MG/KG/DAY 2- 20 MG/KG/DAY 3- 80 MG/KG/DAY 4- 320 MG/KG/DAY
NA = NOT APPLICABLE

D R A F T - LOCKED AND UNLOCKED
----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	12	12	12	12
NUMBER OF ANIMALS EXAMINED	11	0	0	10
ILEUM				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	8
-HYPERPLASIA, LYMPHOID	1	NA	NA	2
MINIMAL	NONE	NA	NA	1
MILD	1	NA	NA	1
JEJUNUM				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10
KIDNEYS				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	7	NA	NA	5
-BASOPHILIC TUBULES	2	NA	NA	2
MINIMAL	2	NA	NA	2
-MINERALIZATION	4	NA	NA	4
MINIMAL	2	NA	NA	3
MILD	2	NA	NA	1
-INFLAMMATION, SUBACUTE	0	NA	NA	1
MINIMAL	NONE	NA	NA	1

1- 0 MG/KG/DAY 2- 20 MG/KG/DAY 3- 80 MG/KG/DAY 4- 320 MG/KG/DAY
NA = NOT APPLICABLE

D R A F T - LOCKED AND UNLOCKED
----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	12	12	12	12
NUMBER OF ANIMALS EXAMINED	11	0	0	10
LYMPH NODE, MAND				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	8	NA	NA	8
-HEMORRHAGE	2	NA	NA	2
MINIMAL	2	NA	NA	2
-PLASMACYTOSIS, MEDULLARY	2	NA	NA	0
MILD	2	NA	NA	NONE
LAC. GLAND EXOR				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10
LIVER				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	7	NA	NA	3
-INFILTRATE, MONONUCLEAR	4	NA	NA	7
MINIMAL	4	NA	NA	7
-NECROSIS, HEPATOCELLULAR	0	NA	NA	1
MINIMAL	NONE	NA	NA	1
LYMPH NODE, MES				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10

1- 0 MG/KG/DAY 2- 20 MG/KG/DAY 3- 80 MG/KG/DAY 4- 320 MG/KG/DAY
NA = NOT APPLICABLE

D R A F T - LOCKED AND UNLOCKED
----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	12	12	12	12
NUMBER OF ANIMALS EXAMINED	11	0	0	10
LUNGS				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	6	NA	NA	8
-INFLAMMATION, SUBACUTE	1	NA	NA	0
MINIMAL	1	NA	NA	NONE
-HEMORRHAGE	1	NA	NA	0
MILD	1	NA	NA	NONE
-MACROPHAGES, ALVEOLAR	3	NA	NA	2
MINIMAL	3	NA	NA	2
MAMMARY GLAND				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	0	NA	NA	0
-HYPERPLASIA, GLANDULAR	11	NA	NA	10
MINIMAL	1	NA	NA	NONE
MILD	9	NA	NA	9
MODERATE	1	NA	NA	1
-DILATATION, GLANDULAR	9	NA	NA	9
MINIMAL	1	NA	NA	NONE
MILD	8	NA	NA	8
MODERATE	NONE	NA	NA	1

1- 0 MG/KG/DAY 2- 20 MG/KG/DAY 3- 80 MG/KG/DAY 4- 320 MG/KG/DAY
NA = NOT APPLICABLE

D R A F T - LOCKED AND UNLOCKED
----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	12	12	12	12
NUMBER OF ANIMALS EXAMINED	11	0	0	10
NERVE, SCIATIC				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10
OVIDUCTS				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10
OVARIES				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10
PANCREAS				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10
-ATROPHY, ACINAR	2	NA	NA	0
MINIMAL	2	NA	NA	NONE
PITUITARY				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10

1- 0 MG/KG/DAY 2- 20 MG/KG/DAY 3- 80 MG/KG/DAY 4- 320 MG/KG/DAY
NA = NOT APPLICABLE

D R A F T - LOCKED AND UNLOCKED
----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	12	12	12	12
NUMBER OF ANIMALS EXAMINED	11	0	0	10
RECTUM				
TOTAL NUMBER EXAMINED	10	NA	NA	10
EXAMINED, UNREMARKABLE	10	NA	NA	10
NOT EXAMINED	1	NA	NA	0
SPINAL CORD				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10
SAL. GLAND MAND				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10
STOMACH, GLAN				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10
STOMACH, NON				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10
SKELETAL MUSCLE				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10

1- 0 MG/KG/DAY 2- 20 MG/KG/DAY 3- 80 MG/KG/DAY 4- 320 MG/KG/DAY
NA = NOT APPLICABLE

D R A F T - LOCKED AND UNLOCKED
----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	12	12	12	12
NUMBER OF ANIMALS EXAMINED	11	0	0	10
SKIN				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10
SPLEEN				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	0	NA	NA	0
-HEMATOPOIESIS, EXTRAMEDULLARY	11	NA	NA	10
MINIMAL	11	NA	NA	8
MILD	NONE	NA	NA	2
-ACCESSORY SPLEEN	1	NA	NA	0
PRESENT	1	NA	NA	NONE
THYROID GLANDS				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	5
-HYPERTROPHY, FOLLICULAR CELL	0	NA	NA	5
MINIMAL	NONE	NA	NA	5
PARATHYROIDS				
TOTAL NUMBER EXAMINED	9	NA	NA	7
EXAMINED, UNREMARKABLE	9	NA	NA	7
NOT EXAMINED	2	NA	NA	3

1- 0 MG/KG/DAY 2- 20 MG/KG/DAY 3- 80 MG/KG/DAY 4- 320 MG/KG/DAY
NA = NOT APPLICABLE

D R A F T - LOCKED AND UNLOCKED
----- FEMALE -----

GROUP:	1	2	3	4
NUMBER OF ANIMALS IN DOSE GROUP	12	12	12	12
NUMBER OF ANIMALS EXAMINED	11	0	0	10
THYMUS				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	7
-ATROPHY	0	NA	NA	3
MINIMAL	NONE	NA	NA	1
MODERATE	NONE	NA	NA	2
TRACHEA				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10
URINARY BLADDER				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10
UTERUS				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	11	NA	NA	10
VAGINA				
TOTAL NUMBER EXAMINED	11	NA	NA	10
EXAMINED, UNREMARKABLE	9	NA	NA	10
-EXUDATE, SUPPURATIVE	2	NA	NA	0
MINIMAL	1	NA	NA	NONE
MILD	1	NA	NA	NONE

1- 0 MG/KG/DAY 2- 20 MG/KG/DAY 3- 80 MG/KG/DAY 4- 320 MG/KG/DAY
NA = NOT APPLICABLE