PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 0 (0 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
7 (CONTINUED)			
	10	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH,6TH	
		V 13TH RIB(S) SHORTENED	L
	12	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
	14	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
	16	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH,6TH	
8	1	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
	3	NOTHING ABNORMAL DETECTED	
	6	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	8	R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
	10	NOTHING ABNORMAL DETECTED	
	12	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,6TH	
		M STERNEBRA(E) BIPARTITE, OSSIFICATION CENTERS DISLOCATED 5TH	
	14	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 2ND,6TH	
		V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
		M STERNEBRA(E) BIPARTITE, OSSIFICATION CENTERS DISLOCATED 5TH, ADDITIONALLY REDUCED IN SIZE	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 9TH,10TH,11TH	
		M THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (ASYMMETR.) 13TH	
		V ACCESSORY THORACIC VERTEBRA 14TH	
		V ACCESSORY 14TH RIB(S) BOTH ONLY RUDIMENTARY	B

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 0 (0 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
8 (CONTINUED)			
	16	NOTHING ABNORMAL DETECTED	
	18	NOTHING ABNORMAL DETECTED	
9	1	V STERNEBRA(E) OF IRREGULAR SHAPE	5TH
	3	NOTHING ABNORMAL DETECTED	
	5	V STERNEBRA(E) OF IRREGULAR SHAPE	5TH
	7	V STERNEBRA(E) OF IRREGULAR SHAPE	4TH,5TH
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.)	9TH,11TH
	9	R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.)	9TH
	11	V STERNEBRA(E) OF IRREGULAR SHAPE	5TH
	13	R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED	1ST
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.)	11TH
	15	NOTHING ABNORMAL DETECTED	
10	1	V STERNEBRA(E) OF IRREGULAR SHAPE	4TH,5TH
	3	NOTHING ABNORMAL DETECTED	
	5	NOTHING ABNORMAL DETECTED	
	7	V STERNEBRA(E) OF IRREGULAR SHAPE	6TH
	9	NOTHING ABNORMAL DETECTED	
	11	NOTHING ABNORMAL DETECTED	
	13	R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.)	9TH
11	1	V STERNEBRA(E) OF IRREGULAR SHAPE	4TH
		V STERNEBRA(E) BIPARTITE	5TH, ADDITIONALLY REDUCED IN SIZE
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE	6TH
	3	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER	5TH

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 0 (0 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
11 (CONTINUED)			
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
	5	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,6TH	
	7	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH,6TH	
	9	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		M THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (ASYMMETR.) 12TH	
	11	NOTHING ABNORMAL DETECTED	
	13	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
		R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 10TH	
	15	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH,6TH	
		R SKULL INCOMPLETELY OSSIFIED	
12	1	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		V RUDIMENTARY CERVICAL RIB(S)	R
	3	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	8	NOTHING ABNORMAL DETECTED	
	10	NOTHING ABNORMAL DETECTED	
	12	NOTHING ABNORMAL DETECTED	
	14	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		V 13TH RIB(S) SHORTENED	R
13	1	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH,5TH	
	4	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,5TH,6TH	
	6	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
	9	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 0 (0 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
13 (CONTINUED)			
	12	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH,6TH	
		R STERNEBRA(E) NOT OSSIFIED 5TH	
	14	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH,6TH (5TH ADDITIONALLY REDUCED IN SIZE, 6TH INCOMPLETELY OSSIFIED)	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 10TH	
14	1	NOTHING ABNORMAL DETECTED	
	3	V STERNEBRA(E) OF IRREGULAR SHAPE 2ND,3RD,4TH,5TH	
		V 13TH RIB(S) SHORTENED	L
	7	NOTHING ABNORMAL DETECTED	
	9	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	11	R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 13TH	
	13	V 13TH RIB(S) SHORTENED	B
15	1	NOTHING ABNORMAL DETECTED	
	3	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		V RUDIMENTARY CERVICAL RIB(S)	R
		V 13TH RIB(S) SHORTENED	L
	5	R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 8TH	
	7	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
	9	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
	11	R STERNEBRA(E) NOT OSSIFIED 5TH	
		V 13TH RIB(S) SHORTENED	R
	13	R STERNEBRA(E) NOT OSSIFIED 5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 0 (0 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
15 (CONTINUED)			
		M THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (ASYMMETR.)	4TH
		R SKULL INCOMPLETELY OSSIFIED	
16	2	NOTHING ABNORMAL DETECTED	
	4	NOTHING ABNORMAL DETECTED	
	6	V STERNEBRA(E) OF IRREGULAR SHAPE	5TH,6TH
	8	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE	6TH
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.)	9TH,10TH
17	1	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER	5TH, ADDITIONALLY REDUCED IN SIZE
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE	6TH
	3	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER	5TH, ADDITIONALLY REDUCED IN SIZE
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE	6TH
	5	V STERNEBRA(E) OF IRREGULAR SHAPE	5TH
	7	NOTHING ABNORMAL DETECTED	
	9	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE	5TH
	12	V STERNEBRA(E) OF IRREGULAR SHAPE	5TH
	14	NOTHING ABNORMAL DETECTED	
18	1	V STERNEBRA(E) OF IRREGULAR SHAPE	1ST,4TH
		R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER	5TH, ADDITIONALLY REDUCED IN SIZE
	3	V STERNEBRA(E) OF IRREGULAR SHAPE	5TH
	5	V STERNEBRA(E) OF IRREGULAR SHAPE	4TH,5TH
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED	1ST

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 0 (0 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
18 (CONTINUED)			
		M THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (ASYMMETR.) 7TH,12TH	
	7	R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 11TH	
19	1	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
		V 13TH RIB(S) SHORTENED	R
	3	NOTHING ABNORMAL DETECTED	
	6	NOTHING ABNORMAL DETECTED	
	8	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	10	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH,6TH	
	12	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	14	NOTHING ABNORMAL DETECTED	
20	1	NOTHING ABNORMAL DETECTED	
	3	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH	
		V 13TH RIB(S) SHORTENED	L
	5	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		M THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (ASYMMETR.) 5TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 10TH	
	7	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
	9	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	11	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH,6TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 11TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 0 (0 MG/KG BW/D)

FEMALE#	FETUS#		OBSERVATION	POSITION/GRADE
21	1		NOTHING ABNORMAL DETECTED	
	3		NOTHING ABNORMAL DETECTED	
	5	V	STERNEBRA(E) OF IRREGULAR SHAPE 4TH,5TH	
		R	THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 10TH	
	7	R	STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH	
	10		NOTHING ABNORMAL DETECTED	
	12	V	STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
		R	STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
22	1		NOTHING ABNORMAL DETECTED	
	3	V	STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	5		NOTHING ABNORMAL DETECTED	
	7	V	STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	9	V	STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH,5TH	
	11		NOTHING ABNORMAL DETECTED	
	13	V	STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		R	STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
23	1	V	13TH RIB(S) SHORTENED	R
	3	R	STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH	
	5	R	STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
	7	R	STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
	9	R	STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
	11		NOTHING ABNORMAL DETECTED	
	13		NOTHING ABNORMAL DETECTED	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 0 (0 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
23 (CONTINUED)			
	17	R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.)	10TH
24	1	NOTHING ABNORMAL DETECTED	
	3	NOTHING ABNORMAL DETECTED	
	5	V STERNEBRA(E) OF IRREGULAR SHAPE	3RD,4TH,5TH
	7	NOTHING ABNORMAL DETECTED	
	9	NOTHING ABNORMAL DETECTED	
	11	R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.)	12TH
	13	NOTHING ABNORMAL DETECTED	
25	1	V STERNEBRA(E) OF IRREGULAR SHAPE	5TH
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.)	10TH
	3	V STERNEBRA(E) BIPARTITE	5TH
	6	R STERNEBRA(E) NOT OSSIFIED	5TH
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE	6TH
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.)	9TH
	8	V STERNEBRA(E) OF IRREGULAR SHAPE	5TH
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE	6TH
	10	V STERNEBRA(E) OF IRREGULAR SHAPE	5TH
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.)	9TH
	12	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE	6TH
		V STERNEBRA(E) OF IRREGULAR SHAPE	5TH
	14	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE	5TH

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 1 (100 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
26	1	R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 10TH	
		V ACCESSORY 14TH RIB(S) ONLY RUDIMENTARY	R
	3	R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
27	1	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	5	NOTHING ABNORMAL DETECTED	
	7	NOTHING ABNORMAL DETECTED	
	9	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 2ND,5TH,6TH	
		V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST,2ND	
	11	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST,2ND	
	14	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
28	3	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH	
	5	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH	
	7	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
	9	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		V 13TH RIB(S) SHORTENED	B
	11	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH, ADDITIONALLY REDUCED IN SIZE	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 1 (100 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
28 (CONTINUED)		V RUDIMENTARY CERVICAL RIB(S)	L
	13	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
29	1	NOTHING ABNORMAL DETECTED	
	3	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH	
		M THORACIC VERTEBRAL BODY/BODIES BIPARTITE (ASYMMETRICAL) 11TH	
	5	NOTHING ABNORMAL DETECTED	
	8	NOTHING ABNORMAL DETECTED	
	10	R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
	12	NOTHING ABNORMAL DETECTED	
	14	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH,6TH	
	16	NOTHING ABNORMAL DETECTED	
	18	NOTHING ABNORMAL DETECTED	
30	1	R SKULL INCOMPLETELY OSSIFIED	
	3	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 9TH	
		M THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (ASYMMETR.) 11TH	
		R SKULL INCOMPLETELY OSSIFIED	
	5	NOTHING ABNORMAL DETECTED	
	7	V STERNEBRA(E) OF IRREGULAR SHAPE 6TH, ADDITIONALLY INCOMPLETELY OSSIFIED	
	9	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH	
	11	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
	13	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH,6TH	
	15	NOTHING ABNORMAL DETECTED	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 1 (100 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
31	1	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH, ADDITIONALLY REDUCED IN SIZE	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 11TH	
		V 13TH RIB(S) SHORTENED	B
	3	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH	
		R STERNEBRA(E) NOT OSSIFIED 5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		V 13TH RIB(S) SHORTENED	B
	5	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
	7	NOTHING ABNORMAL DETECTED	
	9	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
	11	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
		R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
	13	R STERNEBRA(E) NOT OSSIFIED 5TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 12TH	
	15	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 1 (100 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
31 (CONTINUED)			
		M STERNEBRA(E) BIPARTITE, OSSIFICATION CENTERS DISLOCATED 5TH, ADDITIONALLY REDUCED IN SIZE	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 12TH	
32	1	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 5TH,9TH,11TH,12TH	
	3	R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 11TH,12TH	
	6	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH, ADDITIONALLY REDUCED IN SIZE	
	8	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
	10	V STERNEBRA(E) OF IRREGULAR SHAPE 2ND	
		R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		M THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (ASYMMETR.) 9TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 10TH,11TH	
	12	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		V 13TH RIB(S) SHORTENED	L
	14	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 11TH	
	17	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 10TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 1 (100 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
33	1	R STERNEBRA(E) NOT OSSIFIED 5TH	
	3	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
		R STERNEBRA(E) NOT OSSIFIED 5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		V RUDIMENTARY CERVICAL RIB(S)	L
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
	5	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH, ADDITIONALLY REDUCED IN SIZE	
	7	R STERNEBRA(E) NOT OSSIFIED 5TH	
		V STERNEBRA(E) OF IRREGULAR SHAPE 6TH	
		V 13TH RIB(S) SHORTENED	R
	9	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH,6TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 12TH	
	11	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
	13	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	16	R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
	18	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
34	1	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH	
	3	NOTHING ABNORMAL DETECTED	
	6	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	8	NOTHING ABNORMAL DETECTED	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 1 (100 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
34 (CONTINUED)			
	10	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 9TH	
	12	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD	
		R STERNEBRA(E) NOT OSSIFIED 5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 10TH	
	14	NOTHING ABNORMAL DETECTED	
35	1	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	3	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH,5TH	
	5	NOTHING ABNORMAL DETECTED	
	7	R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 9TH	
	10	R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
	12	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
	14	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
36	1	V 13TH RIB(S) SHORTENED	L
	3	NOTHING ABNORMAL DETECTED	
	5	NOTHING ABNORMAL DETECTED	
	7	NOTHING ABNORMAL DETECTED	
	10	R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 8TH	
	12	M THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (ASYMMETR.) 1ST, ADDITIONALLY REDUCED IN SIZE	
	14	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 1 (100 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
37	1	NOTHING ABNORMAL DETECTED	
	4	NOTHING ABNORMAL DETECTED	
	6	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
39	1	NOTHING ABNORMAL DETECTED	
	3	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	5	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
	7	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH	
	9	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	12	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 11TH	
	14	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
		V 13TH RIB(S) SHORTENED	R
40	1	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
	3	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
	5	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	7	R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 1ST, ADDITIONALLY REDUCED IN SIZE	
	9	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
	11	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,5TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 1 (100 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
43	1	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
	3	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH	
	5	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	7	R STERNEBRA(E) NOT OSSIFIED 5TH	
	9	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	11	R STERNEBRA(E) NOT OSSIFIED 5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
44	1	NOTHING ABNORMAL DETECTED	
	3	R HYOID BONE INCOMPLETELY OSSIFIED	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
	5	R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 11TH	
	7	M THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (ASYMMETR.) 6TH,12TH	
		V ACCESSORY 14TH RIB(S) BOTH ONLY RUDIMENTARY	B
	9	R THORACIC VERTEBR. BODY/BODIES-ONLY ONE OSSIFICATION CENTER 1ST	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 12TH	
	11	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,5TH	
	13	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
	15	NOTHING ABNORMAL DETECTED	
	17	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH	
		R STERNEBRA(E) NOT OSSIFIED 5TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 1 (100 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
44 (CONTINUED)			
		M MANDIBLE SHORTENED	
45	1	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER	5TH
	3	NOTHING ABNORMAL DETECTED	
	5	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE	5TH
	7	V STERNEBRA(E) OF IRREGULAR SHAPE	5TH
	9	NOTHING ABNORMAL DETECTED	
	12	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE	5TH
		V STERNEBRA(E) OF IRREGULAR SHAPE	6TH
46	1	V STERNEBRA(E) OF IRREGULAR SHAPE	3RD,4TH,5TH
	3	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER	5TH
	5	V STERNEBRA(E) OF IRREGULAR SHAPE	5TH
	7	V STERNEBRA(E) OF IRREGULAR SHAPE	5TH
	10	NOTHING ABNORMAL DETECTED	
	12	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER	5TH
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.)	11TH
	14	V STERNEBRA(E) OF IRREGULAR SHAPE	4TH,5TH
	16	NOTHING ABNORMAL DETECTED	
	18	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER	5TH, ADDITIONALLY REDUCED IN SIZE
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE	6TH
47	1	V STERNEBRA(E) OF IRREGULAR SHAPE	3RD,4TH
		R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER	5TH, ADDITIONALLY REDUCED IN SIZE

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 1 (100 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
47 (CONTINUED)			
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
		M THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (ASYMMETR.) 11TH	
	3	R STERNEBRA(E) NOT OSSIFIED 5TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 9TH	
	5	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH, ADDITIONALLY REDUCED IN SIZE	
		V STERNEBRA(E) OF IRREGULAR SHAPE 6TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
	7	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		V 13TH RIB(S) SHORTENED	R
	9	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 2ND	
		V STERNEBRA(E) OF IRREGULAR SHAPE 3RD	
		R STERNEBRA(E) NOT OSSIFIED 4TH,5TH,6TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
	11	R STERNEBRA(E) NOT OSSIFIED 5TH	
		V RUDIMENTARY CERVICAL RIB(S)	R
48	1	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,5TH	
	4	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	6	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	9	V STERNEBRA(E) OF IRREGULAR SHAPE 1ST	
	11	NOTHING ABNORMAL DETECTED	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 1 (100 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
48 (CONTINUED)			
	13	NOTHING ABNORMAL DETECTED	
	15	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 11TH	
49	1	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		V 13TH RIB(S) SHORTENED	R
	3	NOTHING ABNORMAL DETECTED	
	5	R STERNEBRA(E) NOT OSSIFIED 5TH	
		V 13TH RIB(S) SHORTENED	L
	7	NOTHING ABNORMAL DETECTED	
	9	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		V 13TH RIB(S) SHORTENED	L
	11	V STERNEBRA(E) BIPARTITE 1ST	
		R STERNEBRA(E) NOT OSSIFIED 5TH	
		V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
	15	R STERNEBRA(E) NOT OSSIFIED 5TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 2 (400 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
51	1	V STERNEBRA(E) OF IRREGULAR SHAPE	5TH
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE	6TH
	3	V STERNEBRA(E) OF IRREGULAR SHAPE	5TH
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.)	10TH
	5	NOTHING ABNORMAL DETECTED	
	7	V STERNEBRA(E) OF IRREGULAR SHAPE	4TH
		R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER	5TH
	10	NOTHING ABNORMAL DETECTED	
	12	V STERNEBRA(E) OF IRREGULAR SHAPE	2ND,3RD,4TH,5TH
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE	6TH
	14	NOTHING ABNORMAL DETECTED	
	16	V STERNEBRA(E) OF IRREGULAR SHAPE	5TH
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE	6TH
52	1	V STERNEBRA(E) OF IRREGULAR SHAPE	4TH,5TH
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE	6TH
	3	V STERNEBRA(E) OF IRREGULAR SHAPE	5TH
	5	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE	6TH
	7	V STERNEBRA(E) OF IRREGULAR SHAPE	4TH,5TH
	9	NOTHING ABNORMAL DETECTED	
	11	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE	6TH
	14	V STERNEBRA(E) OF IRREGULAR SHAPE	6TH

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 2 (400 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
52 (CONTINUED)			
		V 13TH RIB(S) SHORTENED	B
54	1	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	3	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 9TH	
	5	R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 9TH,10TH,13TH	
55	1	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
	3	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH, ADDITIONALLY REDUCED IN SIZE	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
	5	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 10TH	
	7	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
	9	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
	11	R STERNEBRA(E) NOT OSSIFIED 5TH	
		V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
56	1	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
	3	V 13TH RIB(S) SHORTENED	L
	5	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH	
	7	V STERNEBRA(E) OF IRREGULAR SHAPE 1ST,4TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 2 (400 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
56 (CONTINUED)			
		R STERNEBRA(E) NOT OSSIFIED 5TH	
		M STERNEBRA(E) BIPARTITE, OSSIFICATION CENTERS DISLOCATED 2ND,3RD	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 1ST,4TH,5TH,6TH,8TH,9TH,11TH,13TH (1ST ADDITIONALLY REDUCED IN SIZE)	
		M THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (ASYMMETR.) 2ND, ADDITIONALLY REDUCED IN SIZE	
		R THORACIC VERTEBRAL BODY/BODIES BIPARTITE (SYMMETRICAL) 7TH,10TH,12TH	
	9	NOTHING ABNORMAL DETECTED	
	11	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
	13	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
57	1	NOTHING ABNORMAL DETECTED	
	3	NOTHING ABNORMAL DETECTED	
	5	NOTHING ABNORMAL DETECTED	
	7	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		V 13TH RIB(S) SHORTENED	R
	9	NOTHING ABNORMAL DETECTED	
	11	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 9TH	
	13	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,5TH	
	15	R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 6TH	
58	2	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
	8	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		M THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (ASYMMETR.) 10TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 2 (400 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
58 (CONTINUED)			
	10	NOTHING ABNORMAL DETECTED	
	12	NOTHING ABNORMAL DETECTED	
59	1	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
		R STERNEBRA(E) NOT OSSIFIED 5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
	5	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
	7	R STERNEBRA(E) NOT OSSIFIED 5TH,6TH	
		R HYOID BONE INCOMPLETELY OSSIFIED	
	9	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH	
	11	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,6TH	
		M STERNEBRA(E) BIPARTITE, OSSIFICATION CENTERS DISLOCATED 5TH	
	14	NOTHING ABNORMAL DETECTED	
	16	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,5TH	
	18	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
60	2	R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
		V ACCESSORY 14TH RIB(S) BOTH ONLY RUDIMENTARY	B
	5	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
		R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH, ADDITIONALLY REDUCED IN SIZE	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 9TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 2 (400 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
60 (CONTINUED)			
	7	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		M THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (ASYMMETR.) 6TH	
	10	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	12	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
61	1	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,5TH	
	3	V 13TH RIB(S) SHORTENED	B
	5	V 13TH RIB(S) SHORTENED	L
	7	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		V 13TH RIB(S) SHORTENED	L
	9	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
	11	NOTHING ABNORMAL DETECTED	
	13	NOTHING ABNORMAL DETECTED	
	15	NOTHING ABNORMAL DETECTED	
	17	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
62	1	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH	
		R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 9TH	
	3	R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 10TH	
	5	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH,6TH	
	7	M THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (ASYMMETR.) 9TH	
	9	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 2 (400 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
62 (CONTINUED)			
		V 13TH RIB(S) SHORTENED	L
	11	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
64	1	NOTHING ABNORMAL DETECTED	
	3	NOTHING ABNORMAL DETECTED	
	5	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	8	M THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (ASYMMETR.) 2ND	
	10	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 11TH	
	12	NOTHING ABNORMAL DETECTED	
	14	NOTHING ABNORMAL DETECTED	
	16	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH,6TH	
65	1	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH,6TH	
	3	NOTHING ABNORMAL DETECTED	
	5	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH,6TH	
	7	R STERNEBRA(E) NOT OSSIFIED 5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 9TH	
	9	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,5TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 13TH	
	11	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
	13	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 2 (400 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
65 (CONTINUED)			
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		V 13TH RIB(S) SHORTENED	B
	15	NOTHING ABNORMAL DETECTED	
66	1	R STERNEBRA(E) NOT OSSIFIED 5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
	3	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH,6TH	
	6	R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 11TH	
	9	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	11	V 13TH RIB(S) SHORTENED	L
	13	NOTHING ABNORMAL DETECTED	
	15	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH, ADDITIONALLY REDUCED IN SIZE	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
	16	V STERNEBRA(E) OF IRREGULAR SHAPE 1ST,4TH	
		V STERNEBRA(E) BIPARTITE 2ND,3RD (2ND ADDITIONALLY REDUCED IN SIZE)	
		R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH, ADDITIONALLY REDUCED IN SIZE	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		R SKULL INCOMPLETELY OSSIFIED	
		R TYMPANIC ANNULUS INCOMPLETELY OSSIFIED	L
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
		V 13TH RIB(S) SHORTENED	B
		V WAVY RIB(S)	R
		M LUMBAR VERTEBRA ABSENT	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 2 (400 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
66 (CONTINUED)			
		R OS PUBIS INCOMPLETELY OSSIFIED	
67	1	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 9TH	
	4	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 2ND, ADDITIONALLY REDUCED IN SIZE	
		V STERNEBRA(E) OF IRREGULAR SHAPE 3RD	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 4TH	
		R STERNEBRA(E) NOT OSSIFIED 5TH,6TH	
		R SKULL INCOMPLETELY OSSIFIED	
		R THORACIC VERTEBR. BODY/BODIES-ONLY ONE OSSIFICATION CENTER 1ST, ADDITIONALLY REDUCED IN SIZE	
	6	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	8	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,5TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 7TH	
	11	R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 9TH,11TH	
	14	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,5TH	
	16	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
69	1	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		V RUDIMENTARY CERVICAL RIB(S)	R
	3	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 2 (400 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
69 (CONTINUED)			
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 10TH	
	5	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		V RUDIMENTARY CERVICAL RIB(S)	R
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 9TH	
	7	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		V RUDIMENTARY CERVICAL RIB(S)	L
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 1ST,9TH,10TH	
	10	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH,6TH	
70	1	R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
	4	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
	6	NOTHING ABNORMAL DETECTED	
	8	R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
	10	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH	
	12	NOTHING ABNORMAL DETECTED	
71	1	NOTHING ABNORMAL DETECTED	
	4	NOTHING ABNORMAL DETECTED	
	6	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
	8	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH	
	10	V STERNEBRA(E) OF IRREGULAR SHAPE 1ST	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 2 (400 MG/KG BW/D)

FEMALE#	FETUS#		OBSERVATION	POSITION/GRADE
71 (CONTINUED)				
	12		NOTHING ABNORMAL DETECTED	
	14	V	RUDIMENTARY CERVICAL RIB(S)	L
72	1	R	STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH,6TH	
		R	THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
	3	V	STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	5	R	HYOID BONE INCOMPLETELY OSSIFIED	
		R	SKULL INCOMPLETELY OSSIFIED	
		R	THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 10TH	
	7	V	STERNEBRA(E) OF IRREGULAR SHAPE 4TH,5TH	
	9	R	STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH, ADDITIONALLY REDUCED IN SIZE	
	11	R	STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		R	THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
	13		NOTHING ABNORMAL DETECTED	
	15	R	THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
73	1	V	13TH RIB(S) SHORTENED	R
	3	V	STERNEBRA(E) OF IRREGULAR SHAPE 2ND,3RD,4TH,5TH	
	5		NOTHING ABNORMAL DETECTED	
	7	R	THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 11TH	
	9	R	THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 12TH	
	12		NOTHING ABNORMAL DETECTED	
	14	R	THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 10TH	
74	1		NOTHING ABNORMAL DETECTED	
	3	V	STERNEBRA(E) OF IRREGULAR SHAPE 5TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 2 (400 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
74 (CONTINUED)			
	5	V ACCESSORY LUMBAR VERTEBRA	
	7	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH,5TH	
	9	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH,5TH (5TH ADDITIONALLY REDUCED IN SIZE)	
	11	NOTHING ABNORMAL DETECTED	
	13	M STERNEBRA(E) BIPARTITE, OSSIFICATION CENTERS DISLOCATED 5TH, ADDITIONALLY REDUCED IN SIZE	
	15	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 3 (1,000 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
76	1	NOTHING ABNORMAL DETECTED	
	3	V STERNEBRA(E) OF IRREGULAR SHAPE	3RD,4TH
		V STERNEBRA(E) BIPARTITE	5TH, ADDITIONALLY REDUCED IN SIZE
	5	V STERNEBRA(E) OF IRREGULAR SHAPE	4TH,5TH
	7	V STERNEBRA(E) OF IRREGULAR SHAPE	2ND,3RD,4TH
	9	V STERNEBRA(E) BIPARTITE	5TH
	12	V STERNEBRA(E) OF IRREGULAR SHAPE	5TH
	14	V STERNEBRA(E) OF IRREGULAR SHAPE	5TH
	16	V STERNEBRA(E) OF IRREGULAR SHAPE	3RD
77	1	V STERNEBRA(E) OF IRREGULAR SHAPE	4TH
		V STERNEBRA(E) BIPARTITE	5TH, ADDITIONALLY REDUCED IN SIZE
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE	6TH
	3	NOTHING ABNORMAL DETECTED	
	5	NOTHING ABNORMAL DETECTED	
	7	V STERNEBRA(E) OF IRREGULAR SHAPE	3RD,4TH,5TH
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.)	11TH
	9	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE	5TH
		V STERNEBRA(E) OF IRREGULAR SHAPE	6TH
	11	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE	6TH
	13	V STERNEBRA(E) OF IRREGULAR SHAPE	5TH
	15	V STERNEBRA(E) OF IRREGULAR SHAPE	4TH,6TH (6TH ADDITIONALLY REDUCED IN SIZE)

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 3 (1,000 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
77 (CONTINUED)			
		R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 3RD, ADDITIONALLY REDUCED IN SIZE	
	17	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH,6TH (5TH ADDITIONALLY REDUCED IN SIZE)	
78	1	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	3	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
		V 13TH RIB(S) SHORTENED	R
	5	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		V 13TH RIB(S) SHORTENED	B
	7	R STERNEBRA(E) NOT OSSIFIED 5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		V 13TH RIB(S) SHORTENED	R
	9	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		V 13TH RIB(S) SHORTENED	R
	11	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH, ADDITIONALLY REDUCED IN SIZE	
	13	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
		V STERNEBRA(E) BIPARTITE 5TH, ADDITIONALLY REDUCED IN SIZE	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
		V 13TH RIB(S) SHORTENED	R
		V 13TH RIB(S) ABSENT	L
	15	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 3 (1,000 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
79	1	M CLEFT STERNUM IN THE REGION FROM 2ND TH 6TH STERNEBRAE (1ST,2ND,3RD,4TH,6TH STERNEBRAE BIPARTITE, 5TH STERNEBRA NOT OSSIFIED)	
	3	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	5	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	7	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,5TH	
	11	NOTHING ABNORMAL DETECTED	
	14	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		M THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (ASYMMETR.) 2ND	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 10TH	
80	1	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	3	NOTHING ABNORMAL DETECTED	
	7	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 2ND	
	9	NOTHING ABNORMAL DETECTED	
	11	R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 10TH	
	13	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		V 13TH RIB(S) SHORTENED	B
	16	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH, ADDITIONALLY REDUCED IN SIZE	
		V 13TH RIB(S) SHORTENED	L
81	1	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	3	V STERNEBRA(E) OF IRREGULAR SHAPE 6TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 3 (1,000 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
81 (CONTINUED)			
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		V 13TH RIB(S) SHORTENED	R
	5	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	7	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 10TH	
		V 13TH RIB(S) SHORTENED	L
	9	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
	11	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		R STERNEBRA(E) NOT OSSIFIED 5TH	
	13	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH	
		M STERNEBRA(E) BIPARTITE, OSSIFICATION CENTERS DISLOCATED 5TH, ADDITIONALLY REDUCED IN SIZE	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
	15	NOTHING ABNORMAL DETECTED	
82	2	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,5TH	
		V RUDIMENTARY CERVICAL RIB(S)	B
		M THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (ASYMMETR.) 11TH	
	4	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		V 13TH RIB(S) SHORTENED	R
	6	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	8	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH, ADDITIONALLY REDUCED IN SIZE	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 3 (1,000 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
82 (CONTINUED)			
	10	NOTHING ABNORMAL DETECTED	
	12	V STERNEBRA(E) OF IRREGULAR SHAPE 6TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 1ST, ADDITIONALLY REDUCED IN SIZE	
	14	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
83	1	V STERNEBRA(E) OF IRREGULAR SHAPE 2ND,3RD,4TH,5TH	
		V 13TH RIB(S) SHORTENED	R
	3	NOTHING ABNORMAL DETECTED	
	5	NOTHING ABNORMAL DETECTED	
	7	NOTHING ABNORMAL DETECTED	
	9	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	11	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
	13	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
	15	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
84	1	V STERNEBRAE FUSED 1ST WITH 2ND, BOTH ADDITIONALLY OF IRREGULAR SHAPE	
		V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH	
		R STERNEBRA(E) NOT OSSIFIED 5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		M SCAPULA(E) DEFORMED	B
		V CLAVICULA DEFORMED	B
		R SKULL INCOMPLETELY OSSIFIED	
		R THORACIC VERTEBR. BODY/BODIES-ONLY ONE OSSIFICATION CENTER 1ST,6TH,9TH (1ST ADDITIONALLY REDUCED IN SIZE)	
		M THORACIC VERTEBRAL BODY/BODIES BIPARTITE (ASYMMETRICAL) 5TH,11TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 3 (1,000 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
84 (CONTINUED)			
		V WAVY RIB(S)	B
		R VERTEBRAL COLUMN INCOMPLETELY OSSIFIED CONCERNING PARTS OF THE THORACIC AND THE WHOLE LUMBAR AND SACRAL VERTEBRAE	
	3	V 13TH RIB(S) SHORTENED	L
	7	V 13TH RIB(S) SHORTENED	R
	10	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,5TH,6TH	
	13	V 13TH RIB(S) SHORTENED	L
	15	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH,5TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 10TH	
		V 13TH RIB(S) SHORTENED	R
85	1	R STERNEBRA(E) NOT OSSIFIED 5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
	3	V STERNEBRA(E) OF IRREGULAR SHAPE 2ND,3RD,4TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH,6TH	
	5	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH,6TH	
	7	R STERNEBRA(E) NOT OSSIFIED 5TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
	9	V STERNEBRA(E) OF IRREGULAR SHAPE 2ND,3RD,4TH,5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		M THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (ASYMMETR.) 11TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 13TH	
	11	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 3 (1,000 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
85 (CONTINUED)			
	13	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH, ADDITIONALLY REDUCED IN SIZE	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
	15	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,5TH	
86	2	V STERNEBRA(E) OF IRREGULAR SHAPE 1ST,6TH	
		V ACCESSORY STERNEBRA ABOVE 1ST STERNEBRA, SMALLER THAN THE OTHERS	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 11TH	
		V 13TH RIB(S) SHORTENED	R
	4	V STERNEBRA(E) OF IRREGULAR SHAPE 6TH	
		V 13TH RIB(S) SHORTENED	R
	7	V STERNEBRA(E) OF IRREGULAR SHAPE 6TH	
		V 13TH RIB(S) SHORTENED	L
	9	NOTHING ABNORMAL DETECTED	
	11	V 13TH RIB(S) SHORTENED	B
	13	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH,6TH	
87	2	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,5TH	
	4	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH, ADDITIONALLY REDUCED IN SIZE	
		V STERNEBRA(E) OF IRREGULAR SHAPE 6TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 10TH	
	7	NOTHING ABNORMAL DETECTED	
	9	V STERNEBRA(E) OF IRREGULAR SHAPE 6TH	
	11	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 3 (1,000 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
87 (CONTINUED)			
	13	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,6TH	
		R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH, ADDITIONALLY REDUCED IN SIZE	
88	1	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	3	R STERNEBRA(E) NOT OSSIFIED 5TH	
		V 13TH RIB(S) SHORTENED	B
	5	NOTHING ABNORMAL DETECTED	
	7	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		M THORACIC VERTEBRAL BODY/BODIES BIPARTITE (ASYMMETRICAL) 13TH	
	9	NOTHING ABNORMAL DETECTED	
	12	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 8TH	
89	1	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
		V STERNEBRA(E) BIPARTITE 5TH, ADDITIONALLY REDUCED IN SIZE	
	3	NOTHING ABNORMAL DETECTED	
	5	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,5TH	
	8	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH	
		M STERNEBRA(E) BIPARTITE, OSSIFICATION CENTERS DISLOCATED 5TH	
		V RUDIMENTARY CERVICAL RIB(S)	R
	10	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,6TH (6TH ADDITIONALLY INCOMPLETELY OSSIFIED)	
		R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 11TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 3 (1,000 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
89 (CONTINUED)			
	12	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	14	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 2ND,3RD,6TH	
		R STERNEBRA(E) NOT OSSIFIED 5TH	
		R THORACIC VERTEBR. BODY/BODIES-ONLY ONE OSSIFICATION CENTER 1ST	
		M THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (ASYMMETR.) 10TH	
90	1	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
		R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH, ADDITIONALLY REDUCED IN SIZE	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 10TH	
	3	R STERNEBRA(E) NOT OSSIFIED 5TH	
		V RUDIMENTARY CERVICAL RIB(S)	L
	5	R STERNEBRA(E) NOT OSSIFIED 5TH	
	7	V STERNEBRA(E) OF IRREGULAR SHAPE 2ND,3RD,4TH,5TH	
	9	V STERNEBRA(E) OF IRREGULAR SHAPE 2ND,3RD	
		V 13TH RIB(S) SHORTENED	L
	12	R STERNEBRA(E) NOT OSSIFIED 5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
	14	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
	16	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH,6TH	
	18	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH	
		R STERNEBRA(E) NOT OSSIFIED 5TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 3 (1,000 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
90 (CONTINUED)			
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		V 13TH RIB(S) SHORTENED	R
	20	NOTHING ABNORMAL DETECTED	
91	1	NOTHING ABNORMAL DETECTED	
	3	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH,6TH	
		R STERNEBRA(E) NOT OSSIFIED 5TH	
	5	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
	7	R STERNEBRA(E) NOT OSSIFIED 5TH	
		V STERNEBRA(E) OF IRREGULAR SHAPE 6TH	
	9	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,5TH	
	11	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
92	1	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH,5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		M THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (ASYMMETR.) 1ST, ADDITIONALLY REDUCED IN SIZE	
	3	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 10TH,13TH	
	5	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
	7	NOTHING ABNORMAL DETECTED	
	9	NOTHING ABNORMAL DETECTED	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 3 (1,000 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
93	1	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	4	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		R LUMBAR VERTEBRAL ARCH(ES) INCOMPLETELY OSSIFIED 4TH	L
	6	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 11TH	
	8	NOTHING ABNORMAL DETECTED	
	10	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 11TH	
	12	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 8TH,12TH	
		V 13TH RIB(S) SHORTENED	B
	14	R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
94	1	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	3	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 11TH	
	5	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	7	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	9	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD	
		R STERNEBRA(E) NOT OSSIFIED 5TH,6TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 3 (1,000 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
94 (CONTINUED)			
		R METACARPAL BONES INCOMPLETELY OSSIFIED	B
		R SKULL INCOMPLETELY OSSIFIED	
		V 13TH RIB(S) SHORTENED	L
		R SACRAL VERTEBRAL ARCH(ES) INCOMPLETELY OSSIFIED 3RD	B
		R SACRAL VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 4TH	
		R SACRAL VERTEBRAL ARCH(ES) NOT OSSIFIED 4TH	B
		R VERTEBRAL COLUMN INCOMPLETELY OSSIFIED CONCERNING THE THORACIC VERTEBRAE	
		V WAVY RIB(S)	B
	11	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	13	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH	
95	1	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 9TH	
	3	V STERNEBRA(E) OF IRREGULAR SHAPE 1ST	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 11TH	
	5	V STERNEBRA(E) OF IRREGULAR SHAPE 1ST	
		V ACCESSORY STERNEBRA ABOVE 1ST STERNEBRA, ONLY RUDIMENTARY	
	8	R STERNEBRA(E) NOT OSSIFIED 5TH	
		V RUDIMENTARY CERVICAL RIB(S)	L
	11	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH, ADDITIONALLY REDUCED IN SIZE	
		R STERNEBRA(E) NOT OSSIFIED 5TH,6TH	
		R SKULL INCOMPLETELY OSSIFIED	
		M THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (ASYMMETR.) 1ST, ADDITIONALLY REDUCED IN SIZE	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 3 (1,000 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
98 (CONTINUED)			
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
	14	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,6TH	
		R STERNEBRA(E) NOT OSSIFIED 5TH	
		V 13TH RIB(S) SHORTENED	B
99	1	NOTHING ABNORMAL DETECTED	
	4	NOTHING ABNORMAL DETECTED	
	6	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
	8	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	10	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
	12	NOTHING ABNORMAL DETECTED	
	14	NOTHING ABNORMAL DETECTED	
100	1	NOTHING ABNORMAL DETECTED	
	3	V STERNEBRA(E) OF IRREGULAR SHAPE 3RD,4TH	
		R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH	
	6	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	8	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	10	V STERNEBRA(E) BIPARTITE 5TH, ADDITIONALLY REDUCED IN SIZE	
		V STERNEBRA(E) OF IRREGULAR SHAPE 6TH	
	12	V STERNEBRA(E) OF IRREGULAR SHAPE 4TH,5TH	
	14	R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER 5TH	
	16	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH,6TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

PROJECT NO. 30R0246/93046: PRENATAL TOXICITY STUDY IN RATS
ORAL ADMINISTRATION (GAVAGE)
INDIVIDUAL FETAL SKELETAL OBSERVATIONS

TEST GROUP 3 (1,000 MG/KG BW/D)

FEMALE#	FETUS#	OBSERVATION	POSITION/GRADE
95 (CONTINUED)			
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 9TH,10TH,12TH,13TH	
		V ACCESSORY LUMBAR VERTEBRA	
		R METATARSAL BONES INCOMPLETELY OSSIFIED	B
	14	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
96	1	NOTHING ABNORMAL DETECTED	
	3	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
	6	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		V 13TH RIB(S) SHORTENED	L
	8	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
		R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 6TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
	12	NOTHING ABNORMAL DETECTED	
	14	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
		R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.) 11TH	
		R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED 1ST	
98	2	R STERNEBRA(E) NOT OSSIFIED 5TH	
		V 13TH RIB(S) SHORTENED	B
	4	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH,6TH	
	6	NOTHING ABNORMAL DETECTED	
	8	R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE 5TH	
	10	V STERNEBRA(E) OF IRREGULAR SHAPE 5TH	
	12	R STERNEBRA(E) NOT OSSIFIED 5TH	

POSITION/GRADE CODE: R-RIGHT, L-LEFT, B-BILATERAL , 1-SLIGHT, 2-MODERATE, 3-MARKED, P-PRESENT
FINDING CODE: M-MALFORMATION V-VARIATION R-RETARDATION U-UNCLASSIFIED OBSERVATION

BASF

BASF
Abteilung Toxikologie
Department of Toxicology
D-67056 Ludwigshafen, FRG

OCT 04 1994

he0033

REPORT

Study of the
Prenatal Toxicity of

UVINUL T 150

in Wistar Rats After Oral Administration
(Gavage)

Project No.: 30R0246/93046

VOLUME III OF III

SUPPLEMENT

Testing facility: BASF Aktiengesellschaft
Department of Toxicology
D-67056 Ludwigshafen/Rhein, FRG

Dieses Dokument enthält Betriebs- und Geschäftsgeheimnisse der BASF. Es ist Eigentum der BASF und darf nur zu dem von BASF vorgesehenen Zweck verwendet werden. Jede andere oder darüber hinausgehende Verwendung, Verwertung, Weitergabe, Vervielfältigung oder Veröffentlichung bedarf der Einwilligung der BASF.

This document contains manufacturing and trade secrets of BASF. It is the property of BASF and may be used only for that purpose for which it was intended by BASF. Every other or additional use, exploitation, reproduction, publication or submission to other parties require the written permission of BASF.

CONTENTS OF SUPPLEMENT

1. Analyses of the suspensions of test substance

2. Historical control data

1. Analyses of the suspensions of test substance

04. May 1994/Wi
ZAX/OF, E 210
Frau Dr. Nowakowsky
Tel. 45226
- 94L00155 -

Analytical Report
- Homogeneity of Uvinul T 150 in olive oil DAB 10 -

Sender:	Dr. Hellwig, ZHT, Z 470
Project no.:	30R0246/93046
Test substance:	Uvinul T 150
Batch no.:	08-0083
Carrier:	olive oil DAB 10
Date of sample preparation:	05. April 1994
Date of receipt of samples:	05. April 1994
Study period:	06. - 07. April 1994
Storage conditions before start of test:	Freezer
Analytical method:	Normal phase HPLC
Apparatus:	Modular HPLC system with UV/VIS detector
Reagents:	n-heptane; absolute ethanol; Uvinul T 150 as reference standard and olive oil DAB 10 (both delivered by the sender)
Sample preparation:	Dilution of test substance and samples with eluent
Measuring parameters:	
Columns:	LiChrosorb CN, 5 µm (250 x 4 mm, Merck)
Mobile phase:	93 % n-heptane + 7 % ethanol (v/v)
Flow:	1.1 ml/min
Injection volume:	20 µl
Temperature:	ambient temperature
Detection:	UV/VIS 290 nm

04. May 1994/Wi
ZAX/OF, E 210
Frau Dr. Nowakowsky
Tel. 45226
- 94L00155 -

Analytical Report
- Homogeneity of Uvinul T 150 in olive oil DAB 10 -

Results:

Sample No.	expected conc. [g/100 ml]	analytical value [g/100 ml]
3	2	2.01
4	2	1.95
5	2	2.03
6	2	1.93
7	2	2.00
8	2	2.01
9	8	8.03
10	8	8.00
11	20	18.71
12	20	19.62
13	20	19.49
14	20	19.30
15	20	19.87
16	20	19.67

Remarks:

The analytical values indicated above are mean of two injections of the same solution. Only single determinations were carried out because the samples had to be used completely.

04. May 1994/Wi
ZAX/OF, E 210
Frau Dr. Nowakowsky
Tel. 45226
- 94L00155 -

Analytical Report
- Homogeneity of Uvinul T 150 in olive oil DAB 10 -

Discussion of results:

The test substance is homogeneously distributed in the carrier.

The determination were carried out according to the guidelines of GLP.

Retention of records: GLP archives, ZAX, E 210

Nowakowsky ... 05.05.94 ...
Study director
(Dr. Nowakowsky)

Date (d.m.y.)

ZAX Analytik

BASF

STATEMENT OF THE QUALITY ASSURANCE UNIT

ZAX-No (analytical study) 94 L 00155

ZAX is the code of the analytical department of BASF, Ludwigshafen (Germany)
ZAX-No is the ZAX-code of the analytical study

ZHT-No (substance) 93 / 246
(project) 30 R 0246 / 93046

Test substance " Uvinul T 150 "

Title of report Analytical Report:
Homogeneity of Uvinul T 150 in olive oil DAB 10

Study director Dr. NOWAKOWSKY

Date of report 04.May 94
Date of signature 05.May 94

The laboratories and the conduct of analytical studies are inspected in regular intervals. Besides these general inspections we inspected the following items concerning this special study. - Findings are reported to analytical study director and his management.

Inspection of	Date of inspection	Reported to study director and management
Raw data:	15.Jun.94	15.Jun.94
Analytical report: final	15.Jun.94	15.Jun.94

Ludwigshafen

Sold

QAU: SOLD

15.Jun.94

Date

(Sold, 24.05.94)

BASF

04. May 1994/Wi
ZAX/OF, E 210
Frau Dr. Nowakowsky
Tel. 45226
- 94L00174 -

Analytical Report
- Concentration Control of Uvinul T 150 in olive oil DAB 10 -

Sender:	Dr. Hellwig, ZHT, Z 470
Project no.:	30R0246/93046
Test substance:	Uvinul T 150
Batch no.:	08-0083
Carrier:	olive oil DAB 10
Date of sample preparation:	14. April 1994
Date of receipt of samples:	14. April 1994
Study period:	15. - 16. April 1994
Storage conditions before start of test:	Freezer
Analytical method:	Normal phase HPLC
Apparatus:	Modular HPLC system with UV/VIS detector
Reagents:	n-heptane; absolute ethanol; Uvinul T 150 as reference standard and olive oil DAB 10 (both delivered by the sender)
Sample preparation:	Dilution of test substance and samples with eluent
Measuring parameters:	
Columns:	LiChrosorb CN, 5 µm (250 x 4 mm, Merck)
Mobile phase:	93 % n-heptane + 7 % ethanol (v/v)
Flow:	1.1 ml/min
Injection volume:	20 µl
Temperature:	ambient temperature
Detection:	UV/VIS 290 nm

04. May 1994/Wi
ZAX/OF, E 210
Frau Dr. Nowakowsky
Tel. 45226
- 94L00174 -

Analytical Report
- Concentration Control of Uvinul T 150 in olive oil DAB 10 -

Results:

Sample No.	expected conc. [g/100 ml]	analytical value [g/100 ml]
3	2	2.06
4	2	2.06
5	8	7.98
6	8	7.85
7	20	19.6
8	20	19.5

Remarks:

The analytical values indicated above are mean of two injections of the same solution. Only single determinations were carried out because the samples had to be used completely.

Discussion of results:

The concentrations found correspond to the values expected.

The determination were carried out according to the guidelines of GLP.

Retention of records: GLP archives, ZAX, E 210

Study director
(Dr. Nowakowsky)

05.05.94
Date (d.m.y.)

ZAX Analytik

BASF

STATEMENT OF THE QUALITY ASSURANCE UNIT

ZAX-No (analytical study)	94 L 00174

ZAX is the code of the analytical department of BASF, Ludwigshafen (Germany)
ZAX-No is the ZAX-code of the analytical study

ZHT-No (substance) (project)	93 / 246 30 R 0246 / 93046

Test substance " Uvinul T 150 "

Title of report Analytical Report:
Concentration control of Uvinul T 150
in olive oil DAB 10

Study director Dr. NOWAKOWSKY

Date of report 04.May 94
Date of signature 05.May 94

The laboratories and the conduct of analytical studies are inspected in regular intervals. Besides these general inspections we inspected the following items concerning this special study. - Findings are reported to analytical study director and his management.

Inspection of	Date of inspection	Reported to study director and management
Raw data:	15.Jun.94	15.Jun.94
Analytical report: final	15.Jun.94	15.Jun.94

Ludwigshafen

Sold

QAU: SOLD

15.Jun.94

Date

(Sold, 24.05.94)

2. Historical control data

16-AUG-94

TABLE : HCD 001

SPECIES RAT

STRAIN WISTAR
SUPPLIER Dr. K. Thomae

HISTORICAL CONTROL DATA

MEAN MATERNAL BODY WEIGHTS DURING GESTATION -- GRAMS

	NO. OF ANIMALS	MEAN	RANGE OF ACTUAL VALUES		95 % SPREAD 2.5%	97.5%
DAY 0	548	231.9	196.4	305.1	199.5	264.3
DAY 1	548	236.0	200.1	299.8	203.2	268.7
DAY 3	548	248.3	209.3	313.5	214.6	282.0
DAY 6	548	262.0	223.1	329.2	227.1	296.8
DAY 8	548	269.6	229.1	337.7	233.9	305.2
DAY 10	548	280.1	237.1	350.8	243.3	316.9
DAY 13	548	297.8	244.0	367.9	258.9	336.7
DAY 15	548	310.5	244.3	387.2	269.5	351.6
DAY 17	548	333.4	244.3	416.4	287.1	379.7
DAY 19	49	349.5	303.9	380.7	309.8	389.2
DAY 20	548	383.1	248.6	479.8	323.7	442.5

SPECIES RAT

STRAIN WISTAR
SUPPLIER Dr. K. Thomae

HISTORICAL CONTROL DATA

REPRODUCTION DATA

			RANGE (per study)	
Females Mated	N	605		
Pregnant	N	548		
	%	91		
Aborted	N	0		
Premature Births	N	0		
Dams with Viable Fetuses	N	545		
Dams with all Resorptions	N	3		
Female Mortality	N	0		
	%	0.0		
Pregnant at C-section	N	548		
	%	91		
Corpora Lutea	N	8747		
	MEAN	16.0	14.4	17.3
	S.D.	2.25		
Implantation Sites	N	7991		
	MEAN	14.6	11.9	16.0
	S.D.	3.29		
Preimplantation Loss	%	9.1	2.3	20.1
	S.D.	16.08		
Postimplantation Loss	%	7.3	4.4	15.7
	S.D.	10.92		
Dams with Resorptions	N	320		
	%	58		
Resorptions	N	548		
	MEAN	1.0	0.6	2.4
	S.D.	1.38		
	MEAN %	7.3	4.4	15.7
	S.D.	10.92		
Dead Fetuses	N	0		
Viable Fetuses	N	7426		
Litter Size	MEAN	13.6	11.1	14.9
	S.D.	3.34		
Viable Male Fetuses	N	3799		
	%	51		

17-AUG-94

TABLE : HCD 003

SPECIES RAT

STRAIN WISTAR
SUPPLIER Dr. K. Thomae

HISTORICAL CONTROL DATA

PLACENTAL WEIGHTS -- GRAMS

	NO. OF LITTERS	MEAN	RANGE OF ACTUAL VALUES		95 % SPREAD 2.5%	97.5%
MALES	545	0.45	0.33	0.74	0.34	0.55
FEMALES	541	0.43	0.31	0.74	0.33	0.54
BOTH	546	0.44	0.32	0.70	0.34	0.54

17-AUG-94

TABLE : HCD 004

SPECIES RAT

STRAIN WISTAR
SUPPLIER Dr. K. Thomae

HISTORICAL CONTROL DATA

MEAN FETAL WEIGHTS -- GRAMS

	NO. OF LITTERS	MEAN	RANGE OF ACTUAL VALUES		95 % SPREAD 2.5%	97.5%
MALES	545	4.0	3.2	4.7	3.5	4.5
FEMALES	541	3.8	3.0	4.6	3.3	4.3
BOTH	546	3.9	3.3	4.6	3.4	4.3

17-AUG-94

TABLE : HCD 005

SPECIES RAT

STRAIN WISTAR
SUPPLIER Dr. K. Thomae

HISTORICAL CONTROL DATA

FETAL EXTERNAL MALFORMATIONS

	FETUSES N	FETUSES %	%RANGE (per study) %	%RANGE (per study) %	LITTERS N	LITTERS %	%RANGE (per study) %	%RANGE (per study) %
NUMBER EVALUATED	7426				545			
Live	7426							
Dead	0							
M ANASARCA	4	0.05	0.0	0.6	4	0.7	0.0	9.1
M CLEFT PALATE	6	0.08	0.0	1.2	3	0.6	0.0	4.5
TOTAL FETAL EXTERNAL MALFORMATIONS	9	0.1			6	1.1		

OBSERVATION CODE: M=Malformation

HISTORICAL CONTROL DATA IN RATS

STRAIN: CHBB/THOM (SPF)

STATUS: March 29, 1990

	Vehicle Controls N	Controls Incl. Unaffected Dosages N	% of total Malformations	% of Fetuses
SKELETAL DEFECTS				
Cleft Vertebra	10	63	28.0	0.11
Wavy Ribs	6	22	9.78	0.04
Hemivertebra	5	22	9.78	0.04
Misaligned Vertebrae	3	15	6.67	0.03
Osteogenesis Imperfecta of Limbs	5	11	4.89	0.02
Fused Ribs	3	11	4.89	0.02
Bifid Ribs	4	10	4.44	0.02
Fused Vertebrae	4	12	5.33	0.02
Cranial Dysostosis	2	3	1.33	< 0.01
Syndactyly	3	3	1.33	< 0.01
Oligodactyly	3	3	1.33	< 0.01
Ectrodactyly	0	1	0.44	< 0.01
Fused Sternebrae	2	8	3.56	0.01
Missing Sacral Vertebra	0	8	3.56	0.01
Extra Sternebrae	0	1	0.44	< 0.01
VISCERAL DEFECTS				
Anal and Urethral Atresy	0	8	3.56	0.01
Situs Inversus	0	3	1.33	< 0.01
Hydronephrosis	1	4	1.78	< 0.01
Cor Triloculare	0	2	0.89	< 0.01
Ventricular Sepal Defect	1	1	0.44	< 0.01
Missing Ureter	2	2	0.89	< 0.01

Table: HCD 028

(Historical control data from the breeder)

HISTORICAL CONTROL DATA IN RATS

STRAIN: CHEB/THOM (SPF)

STATUS: March 29, 1990

	Vehicle Controls N	Controls Incl. Unaffected Dosages N	% of total Malformations	% of Fetuses
LITTERS EXAMINED	1137	4627		
FETUSES EXAMINED	13752	57810		
MALFORMATIONS	53 (0.38 %)	225 (0.39 %)		

TYPE OF MALFORMATIONS

EXTERNAL DEFECTS

Hydrocephalus	6	15	6.66	0.03
Brachygnathia Inferior	5	10	4.44	0.02
Monstrosity	0	3	1.33	< 0.01
Brachygnathia Superior	2	3	1.33	< 0.01
Microstomia	1	4	1.78	< 0.01
Exencephaly	1	4	1.78	< 0.01
Macrophtalmia	0	1	0.44	< 0.01
Microphtalmia	1	4	1.78	< 0.01
Cleft Palate	3	5	2.22	< 0.01
Macroglossia	1	1	0.44	< 0.01
Microglossia	0	1	0.44	< 0.01
Agnathia	0	1	0.44	< 0.01
Anophtalmia	0	1	0.44	< 0.01
Microtia	0	1	0.44	< 0.01
Meningoencephalocele	0	1	0.44	< 0.01
Anasarca	1	13	5.78	0.02
Acaudia	0	11	4.89	0.02
Gastroschisis	0	6	2.67	0.01
Curly Tail	0	1	0.44	< 0.01
Kinky Tail	0	1	0.44	< 0.01
Anal Atresy	2	8	3.56	0.01

Table: HCD 027

(Historical control data from the breeder)

DATUM : 29.03.1990
DATE : 29.03.1990

BASIS-DATEN
HISTORICAL-VALUES

RATTE
RATS

FETEN-PARAMETER
FETUSES-PARAMETER

BEI SCHNITTENTBINDUNG
AT HYSTERECTOMY

FETEN-PARAMETER
FETUSES-PARAMETER

TATISTIKEN TATISTICS	FETEN- GEWICHT(G) WEIGHT OF FETUS(G)	PRAEIMPL.- VERLUST(%) PRAEIMPL.- LOSS(%)	RESORPT.- RATE(%) RESORPT.- RATE(%)	WUERFE MIT/LITTERS WITH MISSB. MALFORM. 0	1	>1	VARIAT. VARIAT. 0	1	>1
VERS. / STUD.	10	10	10	10	10	10	10	10	10
GRUP. / GROUPS	26	26	26	26	26	26	26	26	26
WUERFE/LITTERS	393	393	393	393	393	393	393	393	393
1W(TOTAL)	5.34	9.94	7.64	94.7	4.8	.5	61.7	19.2	19.1
1W(MIN)	4.82	0.00	1.67	71.4	0.0	0.0	0.0	0.0	0.0
1W(MAX)	5.58	25.16	24.81	100.0	18.2	14.3	84.2	50.0	50.0
SD(TOTAL)	.32	15.65	11.00						
SD(COMMON)	.30	15.43	10.39						
X(MIN)	3.47	0.00	0.00						
X(MAX)	6.50	86.67	80.00						
UTG / LTL (95%)	4.71	0.00	0.00						
OTG / UTL (95%)	5.97	40.62	29.21						

TABLE: HCD 026

(Historical control data from the breeder)

DATUM : 29.03.1990
DATE : 29.03.1990

BASIS-DATEN
HISTORICAL-VALUES

RATTE
RATS

FETEN-PARAMETER
FETUSES-PARAMETER

BEI SCHNITTENTBINDUNG
AT HYSTERECTOMY

WURF-PARAMETER
LITTER-PARAMETER

STATISTIKEN STATISTICS	CORPORA-LUTEA CORPORA-LUTEA	IMPLAN-TATIONEN IMPLAN-TATIONS	LEBENDE FETEN VIABLE FETUSES	TOTE FETEN DEAD FETUSES	SEX(%-LEBEND) SEX(%-VIABLE) MAENNL. MALE	WEIBL. FEMALE	RESORPTIONEN/RESORPTIONS TOTAL TOTAL	FRUEH EARLY	SPAET LATE
N VERS. / STUD.	10	10	10	10	10	10	10	10	10
N GRUP. / GROUPS	26	26	26	26	26	26	26	26	26
N WUERFE/LITTERS	393	393	393	393	393	393	393	393	393
MW(TOTAL)	15.58	14.03	12.97	.01	50.94	49.05	1.05	.87	.18
MW(MIN)	13.50	12.46	10.64	0.00	40.09	24.44	.25	.17	0.00
MW(MAX)	17.50	15.25	15.00	.06	75.56	59.91	2.91	2.64	.83
SD(TOTAL)	2.02	2.94	3.12	.11	14.98	14.99	1.41	1.26	.46
SD(COMMON)	1.95	2.96	3.08	.11	14.71	14.72	1.34	1.21	.44
X(MIN)	6.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00
X(MAX)	22.00	20.00	19.00	1.00	100.00	100.00	11.00	9.00	2.00
UTG / LTL (95%)	11.63	8.26	6.86	0.00	21.58	19.68	0.00	0.00	0.00
OTG / UTL (95%)	19.53	19.79	19.07	.23	80.29	78.42	3.81	3.34	1.07

Historical control values for one skeletal variation (sternebra(e) of irregular shape)

Oral prenatal toxicity studies in Wistar rats
carried out in BASF's Department of Toxicology

Study No.	Study period	Fetuses evaluated (N)	Litters evaluated (N)	Fetal incidence N(%)	Litter incidence N(%)	Affected fetuses/litter (mean %)
91081	Apr/May 92	116	18	51(44)	16(89)	43.9
91096	Sep/Oct 92	161	23	69(43)	22(96)	41.6
91101	Nov/Dec 92	168	22	51(30)	21(95)	29.8
91122	Jun/Jul 93	168	24	71(42)	22(92)	41.6
92063	Apr/May 93	175	23	56(32)	22(96)	32.0

Range		Fetuses evaluated (N)	Litters evaluated (N)	Fetal incidence (%)	Litter incidence (%)	Affected fetuses/litter (mean %)
	minimum	116	18	20	71	19.0
	maximum	193	25	44	100	46.2

Historical control values for one skeletal variation (sternebra(e) of irregular shape)

Oral prenatal toxicity studies in Wistar rats
carried out in BASF's Department of Toxicology

Study No.	Study period	Fetuses evaluated (N)	Litters evaluated (N)	Fetal incidence N(%)	Litter incidence N(%)	Affected fetuses/litter (mean %)
84085	Jan/Feb 88	147	24	59(40)	20(83)	37.2
84086	Mar/Apr 88	172	25	58(34)	21(84)	34.6
88035	Sep 88	163	23	72(44)	22(96)	42.8
88036	Sep/Oct 88	193	25	65(34)	24(96)	34.0
88073	Mar/Apr 89	144	21	29(20)	15(71)	19.0
89025	Mar/Apr 90	132	19	36(27)	17(89)	29.7
89059	Mar/Apr 90	169	25	40(24)	19(76)	23.8
89096	Feb 91	172	24	58(34)	21(88)	34.1
89102	Apr 91	137	20	55(40)	20(100)	39.0
89117	May 93	171	23	67(39)	21(91)	38.9
89118	Jun/Jul 93	169	24	74(44)	24(100)	46.2
90077	Jan/Feb 91	148	23	61(41)	20(87)	38.6
90088	Feb-Apr 91	167	22	56(34)	21(95)	34.0
90104	Jun 91	171	25	64(37)	23(92)	35.4
90116	Jul/Aug 91	177	23	61(34)	22(96)	35.1
91013	Jul 91	158	24	66(42)	22(92)	41.0
91030	Oct/Nov 91	154	21	63(41)	20(95)	43.5
91070	Apr/May 93	145	20	49(34)	18(90)	36.8
91071	Mar 92	174	24	64(37)	22(92)	36.8

Date: June 06, 1994

Historical control values for retardations

HCD 023

Oral prenatal toxicity studies in Wistar rats
carried out in BASF's Department of Toxicology

Study No.	Study period		Fetuses evaluated (N)	Litters evaluated (N)	Fetal incidence N(%)	Litter incidence N(%)	Affected fetuses/litter (mean %)
90104	Jun 91	Skeletal	171	25	71(42)	22(88)	41.2
		Total	333	25	71(21)	22(88)	23.1
90116	Jul/Aug 91	Skeletal	177	23	81(46)	19(83)	44.2
		Total	343	23	81(24)	19(83)	22.9
91013	Jul 91	Skeletal	158	24	43(27)	19(79)	27.3
		Total	306	24	43(14)	19(79)	14.1
91030	Oct/Nov 91	Skeletal	154	21	60(39)	19(90)	39.3
		Total	293	21	60(20)	19(90)	20.6
91070	Apr/May 93	Skeletal	145	20	77(53)	18(90)	50.3
		Total	280	20	77(28)	18(90)	26.2
91071	Mar 92	Skeletal	174	24	54(31)	22(92)	30.7
		Total	338	24	54(16)	22(92)	15.8
91081	Apr/May 92	Skeletal	116	18	43(37)	16(89)	35.6
		Total	222	18	43(19)	16(89)	18.7
91096	Sep/Oct 92	Skeletal	161	23	102(63)	21(91)	59.1
		Total	312	23	102(33)	21(91)	30.4
91101	Nov/Dec 92	Skeletal	168	22	121(72)	22(100)	71.5
		Total	318	22	121(38)	22(100)	37.8
91122	Jun/Jul 93	Skeletal	168	24	78(46)	22(92)	47.8
		Total	326	24	78(24)	22(92)	24.5
92063	Apr/May 93	Skeletal	175	23	111(63)	23(100)	63.5
		Total	340	23	111(33)	23(100)	32.7

Range			Fetuses evaluated (N)	Litters evaluated (N)	Fetal incidence (%)	Litter incidence (%)	Affected fetuses/litter (mean %)
	Skeletal	minimum	116	18	27	68	27.3
		maximum	193	25	72	100	71.5
	Total	minimum	222	18	14	68	14.1
		maximum	366	25	38	100	37.8

Historical control values for retardations

Oral prenatal toxicity studies in Wistar rats
carried out in BASF's Department of Toxicology

Study No.	Study period		Fetuses evaluated (N)	Litters evaluated (N)	Fetal incidence N(%)	Litter incidence N(%)	Affected fetuses/litter (mean %)
84085	Jan/Feb 88	Skeletal	147	24	58(39)	22(92)	42.3
		Total	279	24	58(21)	22(92)	22.4
84086	Mar/Apr 88	Skeletal	172	25	59(34)	22(88)	33.8
		Total	337	25	59(17)	22(88)	17.3
88035	Sep 88	Skeletal	163	23	68(42)	18(78)	40.4
		Total	313	23	68(22)	18(78)	21.0
88036	Sep/Oct 88	Skeletal	193	25	54(28)	17(68)	27.3
		Total	366	25	54(15)	17(68)	14.4
88073	Mar/Apr 89	Skeletal	144	21	64(44)	18(86)	41.8
		Total	275	21	64(23)	18(86)	21.6
89025	Mar/Apr 90	Skeletal	132	19	49(37)	18(95)	38.0
		Total	259	19	49(19)	18(95)	19.7
89059	Mar/Apr 90	Skeletal	169	25	70(41)	21(84)	40.8
		Total	326	25	70(21)	21(84)	21.4
89096	Feb 91	Skeletal	172	24	63(37)	22(92)	38.5
		Total	334	24	63(19)	22(92)	20.1
89102	Apr 91	Skeletal	137	20	71(52)	18(90)	54.5
		Total	266	20	71(27)	18(90)	28.2
89117	May 93	Skeletal	171	23	82(48)	22(96)	47.4
		Total	329	23	82(25)	22(96)	24.6
89118	Jun/Jul 93	Skeletal	169	24	100(59)	23(96)	61.3
		Total	326	24	100(31)	23(96)	33.8
90077	Jan/Feb 91	Skeletal	148	23	58(39)	20(87)	41.2
		Total	282	23	58(21)	20(87)	21.9
90088	Feb-Apr 91	Skeletal	167	22	74(44)	22(100)	43.8
		Total	322	22	74(23)	22(100)	22.8

Date:June 06,1994

Historical control values for variations

TABLE: HCD 021

Oral prenatal toxicity studies in Wistar rats
carried out in BASF's Department of Toxicology

Study No.	Study period		Fetuses evaluated (N)	Litters evaluated (N)	Fetal incidence N(%)	Litter incidence N(%)	Affected fetuses/litter (mean %)
91071	Mar 92	External	338	24	0(0)	0(0)	0
		Visceral	164	24	8(4.9)	8(33)	4.9
		Skeletal	174	24	71(41)	22(92)	41.2
		Total	338	24	79(23)	22(92)	23.6
91081	Apr/May 92	External	222	18	0(0)	0(0)	0
		Visceral	106	18	13(12)	10(56)	13.6
		Skeletal	116	18	55(47)	16(89)	46.6
		Total	222	18	68(31)	18(100)	31.5
91096	Sep/Oct 92	External	312	23	0(0)	0(0)	0
		Visceral	151	23	25(17)	13(57)	20.2
		Skeletal	161	23	79(49)	23(100)	49.6
		Total	312	23	104(33)	23(100)	35.2
91101	Nov/Dec 92	External	318	22	0(0)	0(0)	0
		Visceral	150	22	14(9.3)	9(41)	9.6
		Skeletal	168	22	64(38)	21(95)	37.5
		Total	318	22	78(25)	21(95)	24.4
91122	Jun/Jul 93	External	326	24	0(0)	0(0)	0
		Visceral	158	24	21(13)	12(50)	13.7
		Skeletal	168	24	82(49)	23(96)	48.5
		Total	326	24	103(32)	24(100)	31.6
92063	Apr/May 93	External	340	23	0(0)	0(0)	0
		Visceral	165	23	11(6.7)	8(35)	6.7
		Skeletal	175	23	72(41)	22(96)	41.0
		Total	340	23	83(24)	22(96)	24.2

Range			Fetuses evaluated (N)	Litters evaluated (N)	Fetal incidence (%)	Litter incidence (%)	Affected fetuses/litter (mean %)
	External	minimum	222	18	0	0	0
		maximum	366	25	0	0	0
	Visceral	minimum	106	18	4.9	35	4.9
		maximum	173	25	55	100	55.6
	Skeletal	minimum	116	18	32	81	30.7
		maximum	193	25	54	100	52.7
	Total	minimum	222	18	23	91	23.6
		maximum	366	25	47	100	47.0

Date:June 06,1994

Historical control values for variations

TABLE: HCD 020

Oral prenatal toxicity studies in Wistar rats
carried out in BASF's Department of Toxicology

Study No.	Study period		Fetuses evaluated (N)	Litters evaluated (N)	Fetal incidence N(%)	Litter incidence N(%)	Affected fetuses/litter (mean %)
89117	May 93	External	329	23	0(0)	0(0)	0
		Visceral	158	23	17(11)	9(39)	11.0
		Skeletal	171	23	86(50)	22(96)	49.6
		Total	329	23	103(31)	22(96)	31.0
89118	Jun/Jul 93	External	326	24	0(0)	0(0)	0
		Visceral	157	23	21(13)	12(52)	13.7
		Skeletal	169	24	82(49)	24(100)	51.0
		Total	326	24	103(32)	24(100)	34.8
90077	Jan/Feb 91	External	282	23	0(0)	0(0)	0
		Visceral	134	23	22(16)	12(52)	15.2
		Skeletal	148	23	74(50)	21(91)	46.6
		Total	282	23	96(34)	21(91)	31.6
90088	Feb-Apr 91	External	322	22	0(0)	0(0)	0
		Visceral	155	22	11(7.1)	8(36)	8.1
		Skeletal	167	22	66(40)	21(95)	39.8
		Total	322	22	77(24)	21(95)	24.6
90104	Jun 91	External	333	25	0(0)	0(0)	0
		Visceral	162	24	12(7.4)	10(42)	7.5
		Skeletal	171	25	82(48)	23(92)	44.7
		Total	333	25	94(28)	23(92)	26.4
90116	Jul/Aug 91	External	343	23	0(0)	0(0)	0
		Visceral	166	23	29(17)	14(61)	16.8
		Skeletal	177	23	75(42)	22(96)	42.8
		Total	343	23	104(30)	23(100)	30.4
91013	Jul 91	External	306	24	0(0)	0(0)	0
		Visceral	148	24	18(12)	14(58)	13.6
		Skeletal	158	24	76(48)	23(96)	47.8
		Total	306	24	94(31)	24(100)	31.4
91030	Oct/Nov 91	External	293	21	0(0)	0(0)	0
		Visceral	139	21	18(13)	10(48)	16.0
		Skeletal	154	21	70(45)	20(95)	47.9
		Total	293	21	88(30)	20(95)	32.9
91070	Apr/May 93	External	280	20	0(0)	0(0)	0
		Visceral	135	20	14(10)	7(35)	10.3
		Skeletal	145	20	58(40)	18(90)	42.4
		Total	280	20	72(26)	19(95)	27.1

Date:June 06,1994

Historical control values for variations

TABLE: HCD 019

Oral prenatal toxicity studies in Wistar rats
carried out in BASF's Department of Toxicology

Study No.	Study period		Fetuses evaluated (N)	Litters evaluated (N)	Fetal incidence N(%)	Litter incidence N(%)	Affected fetuses/litter (mean %)
84085	Jan/Feb 88	External	279	24	0(0)	0(0)	0
		Visceral	132	24	44(33)	23(96)	38.5
		Skeletal	147	24	79(54)	23(96)	52.4
		Total	279	24	123(44)	24(100)	45.5
84086	Mar/Apr 88	External	337	25	0(0)	0(0)	0
		Visceral	165	25	68(41)	24(96)	42.7
		Skeletal	172	25	76(44)	23(92)	44.7
		Total	337	25	144(43)	24(96)	43.6
88035	Sep 88	External	313	23	0(0)	0(0)	0
		Visceral	150	23	39(26)	14(61)	24.8
		Skeletal	163	23	88(54)	22(96)	52.7
		Total	313	23	127(41)	22(96)	39.5
88036	Sep/Oct 88	External	366	25	0(0)	0(0)	0
		Visceral	173	25	96(55)	25(100)	55.6
		Skeletal	193	25	76(39)	24(96)	39.4
		Total	366	25	172(47)	25(100)	47.0
88073	Mar/Apr 89	External	275	21	0(0)	0(0)	0
		Visceral	131	21	56(43)	20(95)	43.9
		Skeletal	144	21	46(32)	17(81)	30.7
		Total	275	21	102(37)	21(100)	36.7
89025	Mar/Apr 90	External	259	19	0(0)	0(0)	0
		Visceral	127	19	20(16)	10(53)	14.0
		Skeletal	132	19	56(42)	18(95)	44.6
		Total	259	19	76(29)	19(100)	30.1
89059	Mar/Apr 90	External	326	25	0(0)	0(0)	0
		Visceral	157	25	34(22)	17(68)	22.6
		Skeletal	169	25	60(36)	22(88)	35.2
		Total	326	25	94(29)	23(92)	29.1
89096	Feb 91	External	334	24	0(0)	0(0)	0
		Visceral	162	24	16(9.9)	11(46)	9.8
		Skeletal	172	24	66(38)	23(96)	38.6
		Total	334	24	82(25)	24(100)	25.1
89102	Apr 91	External	266	20	0(0)	0(0)	0
		Visceral	129	20	14(11)	10(50)	11.6
		Skeletal	137	20	68(50)	20(100)	48.2
		Total	266	20	82(31)	20(100)	30.4

Date:June 06,1994

Historical control values for malformations

TABLE: HCD 018

Oral prenatal toxicity studies in Wistar rats
carried out in BASF's Department of Toxicology

Study No.	Study period		Fetuses evaluated (N)	Litters evaluated (N)	Fetal incidence N(%)	Litter incidence N(%)	Affected fetuses/litter (mean %)
91071	Mar 92	External	338	24	0(0)	0(0)	0
		Visceral	164	24	0(0)	0(0)	0
		Skeletal	174	24	8(4.6)	6(25)	4.2
		Total	338	24	8(2.4)	6(25)	2.2
91081	Apr/May 92	External	222	18	0(0)	0(0)	0
		Visceral	106	18	1(0.9)	1(5.6)	1.9
		Skeletal	116	18	5(4.3)	4(22)	4.2
		Total	222	18	6(2.7)	5(28)	3.0
91096	Sep/Oct 92	External	312	23	0(0)	0(0)	0
		Visceral	151	23	0(0)	0(0)	0
		Skeletal	161	23	9(5.6)	7(30)	5.2
		Total	312	23	9(2.9)	7(30)	2.7
91101	Nov/Dec 92	External	318	22	2(0.6)	2(9.1)	0.6
		Visceral	150	22	0(0)	0(0)	0
		Skeletal	168	22	7(4.2)	5(23)	3.9
		Total	318	22	7(2.2)	5(23)	2.0
91122	Jun/Jul 93	External	326	24	0(0)	0(0)	0
		Visceral	158	24	0(0)	0(0)	0
		Skeletal	168	24	5(3.0)	5(21)	3.3
		Total	326	24	5(1.5)	5(21)	1.7
92063	Apr/May 93	External	340	23	4(1.2)	1(4.3)	1.0
		Visceral	165	23	0(0)	0(0)	0
		Skeletal	175	23	7(4.0)	6(26)	3.9
		Total	340	23	9(2.6)	6(26)	2.5

Range			Fetuses evaluated (N)	Litters evaluated (N)	Fetal incidence (%)	Litter incidence (%)	Affected fetuses/litter (mean %)
	External	minimum	222	18	0	0	0
		maximum	366	25	1.2	9.1	1.0
	Visceral	minimum	106	18	0	0	0
		maximum	173	25	1.9	13	1.9
	Skeletal	minimum	116	18	0.6	4.3	0.5
		maximum	193	25	10	43	8.7
	Total	minimum	222	18	0.3	4.3	0.3
		maximum	366	25	5.7	43	4.8

Date:June 06,1994

Historical control values for malformations

TABLE: HCD 017

Oral prenatal toxicity studies in Wistar rats
carried out in BASF's Department of Toxicology

Study No.	Study period		Fetuses evaluated (N)	Litters evaluated (N)	Fetal incidence N(%)	Litter incidence N(%)	Affected fetuses/litter (mean %)
89117	May 93	External	329	23	0(0)	0(0)	0
		Visceral	158	23	0(0)	0(0)	0
		Skeletal	171	23	12(7.0)	7(30)	6.7
		Total	329	23	12(3.6)	7(30)	3.5
89118	Jun/Jul 93	External	326	24	0(0)	0(0)	0
		Visceral	157	23	0(0)	0(0)	0
		Skeletal	169	24	8(4.7)	8(33)	4.5
		Total	326	24	8(2.5)	8(33)	2.3
90077	Jan/Feb 91	External	282	23	1(0.4)	1(4.3)	0.3
		Visceral	134	23	1(0.7)	1(4.3)	0.6
		Skeletal	148	23	15(10)	10(43)	8.7
		Total	282	23	16(5.7)	10(43)	4.8
90088	Feb-Apr 91	External	322	22	0(0)	0(0)	0
		Visceral	155	22	0(0)	0(0)	0
		Skeletal	167	22	13(7.8)	8(36)	8.0
		Total	322	22	13(4.0)	8(36)	4.1
90104	Jun 91	External	333	25	0(0)	0(0)	0
		Visceral	162	24	0(0)	0(0)	0
		Skeletal	171	25	7(4.1)	6(24)	3.8
		Total	333	25	7(2.1)	6(24)	1.9
90116	Jul/Aug 91	External	343	23	0(0)	0(0)	0
		Visceral	166	23	0(0)	0(0)	0
		Skeletal	177	23	2(1.1)	2(8.7)	1.0
		Total	343	23	2(0.6)	2(8.7)	0.5
91013	Jul 91	External	306	24	1(0.3)	1(4.2)	0.3
		Visceral	148	24	0(0)	0(0)	0
		Skeletal	158	24	10(6.3)	8(33)	6.0
		Total	306	24	11(3.6)	9(38)	3.4
91030	Oct/Nov 91	External	293	21	0(0)	0(0)	0
		Visceral	139	21	0(0)	0(0)	0
		Skeletal	154	21	4(2.6)	2(9.5)	2.4
		Total	293	21	4(1.4)	2(9.5)	1.2
91070	Apr/May 93	External	280	20	0(0)	0(0)	0
		Visceral	135	20	0(0)	0(0)	0
		Skeletal	145	20	4(2.8)	3(15)	2.3
		Total	280	20	4(1.4)	3(15)	1.2

Date:June 06,1994

Historical control values for malformations

TABLE: HCD 016

Oral prenatal toxicity studies in Wistar rats
carried out in BASF's Department of Toxicology

Study No.	Study period		Fetuses evaluated (N)	Litters evaluated (N)	Fetal incidence N(%)	Litter incidence N(%)	Affected fetuses/litter (mean %)
84085	Jan/Feb 88	External	279	24	1(0.4)	1(4.2)	0.3
		Visceral	132	24	0(0)	0(0)	0
		Skeletal	147	24	5(3.4)	5(21)	3.6
		Total	279	24	5(1.8)	5(21)	1.9
84086	Mar/Apr 88	External	337	25	0(0)	0(0)	0
		Visceral	165	25	0(0)	0(0)	0
		Skeletal	172	25	8(4.7)	7(28)	4.5
		Total	337	25	8(2.4)	7(28)	2.2
88035	Sep 88	External	313	23	0(0)	0(0)	0
		Visceral	150	23	0(0)	0(0)	0
		Skeletal	163	23	1(0.6)	1(4.3)	0.5
		Total	313	23	1(0.3)	1(4.3)	0.3
88036	Sep/Oct 88	External	366	25	0(0)	0(0)	0
		Visceral	173	25	0(0)	0(0)	0
		Skeletal	193	25	5(2.6)	3(12)	2.4
		Total	366	25	5(1.4)	3(12)	1.3
88073	Mar/Apr 89	External	275	21	0(0)	0(0)	0
		Visceral	131	21	0(0)	0(0)	0
		Skeletal	144	21	2(1.4)	2(9.5)	1.3
		Total	275	21	2(0.7)	2(9.5)	0.7
89025	Mar/Apr 90	External	259	19	0(0)	0(0)	0
		Visceral	127	19	1(0.8)	1(5.3)	0.8
		Skeletal	132	19	9(6.8)	7(37)	7.2
		Total	259	19	10(3.9)	8(42)	4.1
89059	Mar/Apr 90	External	326	25	0(0)	0(0)	0
		Visceral	157	25	0(0)	0(0)	0
		Skeletal	169	25	11(6.5)	7(28)	6.5
		Total	326	25	11(3.4)	7(28)	3.3
89096	Feb 91	External	334	24	0(0)	0(0)	0
		Visceral	162	24	3(1.9)	3(13)	1.7
		Skeletal	172	24	10(5.8)	8(33)	6.0
		Total	334	24	13(3.9)	10(42)	3.9
89102	Apr 91	External	266	20	0(0)	0(0)	0
		Visceral	129	20	2(1.6)	2(10)	1.5
		Skeletal	137	20	3(2.2)	3(15)	2.1
		Total	266	20	5(1.9)	5(25)	1.8

17-AUG-94

TABLE : HCD 015

SPECIES RAT

STRAIN WISTAR
SUPPLIER Dr. K. Thomae

HISTORICAL CONTROL DATA

FETAL SKELETAL RETARDATIONS

	FETUSES N	%	%RANGE (per study) %	%	LITTERS N	%	%RANGE (per study) %	%
NUMBER EVALUATED	3851				545			
Live	3851							
Dead	0							
R SACRAL VERTEBRA(E) NOT OSSIFIED	1	0.03	0.0	0.6	1	0.2	0.0	4.3
R CAUDAL VERTEBRA(E) NOT OSSIFIED	2	0.05	0.0	0.6	2	0.4	0.0	4.3
R STERNEBRA(E) NOT OSSIFIED	266	6.9	1.7	13.0	178	32.7	11.1	52.4
R STERNEBRA(E) INCOMPLETELY OSSIFIED OR REDUCED IN SIZE	711	18.5	6.8	54.8	319	58.5	34.8	95.5
R STERNEBRA(E)-ONLY ONE OSSIFICATION CENTER	485	12.6	5.0	19.2	278	51.0	26.1	69.6
R METACARPAL BONES INCOMPLETELY OSSIFIED	4	0.1	0.0	1.2	4	0.7	0.0	9.1
R HINDLIMB(S) INCOMPLETELY OSSIFIED	2	0.05	0.0	1.2	2	0.4	0.0	9.1
R HINDLIMB(S) NOT OSSIFIED	1	0.03	0.0	0.6	1	0.2	0.0	4.5
R METATARSAL BONES INCOMPLETELY OSSIFIED	3	0.08	0.0	0.6	3	0.6	0.0	4.5
R METATARSAL BONES NOT OSSIFIED	1	0.03	0.0	0.6	1	0.2	0.0	4.5
R OS PUBIS NOT OSSIFIED	1	0.03	0.0	0.6	1	0.2	0.0	4.3
R OS ISCHIUM NOT OSSIFIED	1	0.03	0.0	0.6	1	0.2	0.0	4.3
R OS PUBIS INCOMPLETELY OSSIFIED	2	0.05	0.0	0.7	2	0.4	0.0	4.3
TOTAL FETAL SKELETAL RETARDATIONS	1711	44.4			486	89.2		

OBSERVATION CODE: R=Retardation

SPECIES RAT

STRAIN WISTAR
SUPPLIER Dr. K. Thomae

HISTORICAL CONTROL DATA

FETAL SKELETAL RETARDATIONS

	FETUSES N	%	%RANGE (per study) %	%	LITTERS N	%	%RANGE (per study) %	%
NUMBER EVALUATED	3851				545			
Live	3851							
Dead	0							
R HYOID BONE INCOMPLETELY OSSIFIED	9	0.2	0.0	1.2	9	1.7	0.0	9.1
R HYOID BONE NOT OSSIFIED	4	0.1	0.0	1.2	4	0.7	0.0	8.7
R SKULL INCOMPLETELY OSSIFIED	13	0.3	0.0	1.3	12	2.2	0.0	8.3
R CERVICAL VERTEBRAL ARCH(ES) INCOMPLETELY OSSIFIED	1	0.03	0.0	0.6	1	0.2	0.0	4.0
R THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETR.)	445	11.6	5.8	22.0	278	51.0	29.2	72.7
R THORACIC VERTEBRAL BODY/BODIES NOT OSSIFIED	5	0.1	0.0	1.2	5	0.9	0.0	9.1
R THORACIC VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED	310	8.0	0.0	49.1	124	22.8	0.0	100.0
R THORACIC VERTEBRAL BODY/BODIES BIPARTITE (SYMMETRICAL)	11	0.3	0.0	2.8	10	1.8	0.0	14.3
R THORACIC VERTEBR. BODY/BODIES-ONLY ONE OSSIFICATION CENTER	14	0.4	0.0	1.8	14	2.6	0.0	12.0
R LUMBAR VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (SYMMETRICAL)	2	0.05	0.0	0.6	2	0.4	0.0	4.3
R LUMBAR VERTEBRAL BODY/BODIES-ONLY ONE OSSIFICATION CENTER	1	0.03	0.0	0.6	1	0.2	0.0	4.3
R LUMBAR VERTEBRAL ARCH(ES) INCOMPLETELY OSSIFIED	6	0.2	0.0	1.2	5	0.9	0.0	5.6
R LUMBAR VERTEBRAL BODY/BODIES NOT OSSIFIED	1	0.03	0.0	0.6	1	0.2	0.0	4.3
R LUMBAR VERTEBRAL BODY/BODIES INCOMPLETELY OSSIFIED	1	0.03	0.0	0.6	1	0.2	0.0	4.3
R SACRAL VERTEBRAL ARCH(ES) INCOMPLETELY OSSIFIED	2	0.05	0.0	1.5	2	0.4	0.0	10.0
R SACRAL VERTEBRAL BODY/BODIES NOT OSSIFIED	1	0.03	0.0	0.6	1	0.2	0.0	4.3
R SACRAL VERTEBRA(E) INCOMPLETELY OSSIFIED	2	0.05	0.0	0.6	2	0.4	0.0	4.5

OBSERVATION CODE: R=Retardation

17-AUG-94

TABLE : HCD 013

SPECIES RAT

STRAIN WISTAR
SUPPLIER Dr. K. Thomae

HISTORICAL CONTROL DATA

FETAL SKELETAL VARIATIONS

	FETUSES N	FETUSES %	%RANGE (per study) %	%RANGE (per study) %	LITTERS N	LITTERS %	%RANGE (per study) %	%RANGE (per study) %
NUMBER EVALUATED	3851				545			
Live	3851							
Dead	0							
V ACCESSORY THORACIC VERTEBRA	2	0.05	0.0	0.8	2	0.4	0.0	5.3
V ACCESSORY LUMBAR VERTEBRA	5	0.1	0.0	2.3	3	0.6	0.0	5.3
V STERNEBRA(E) OF IRREGULAR SHAPE	1395	36.2	20.1	44.2	495	90.8	71.4	100.0
V STERNEBRA(E) BIPARTITE	78	2.0	0.0	6.8	66	12.1	0.0	31.6
V ACCESSORY STERNEBRA	7	0.2	0.0	0.7	7	1.3	0.0	4.8
V ACCESSORY 14TH RIB(S)	45	1.2	0.0	4.1	36	6.6	0.0	16.0
V RUDIMENTARY CERVICAL RIB(S)	99	2.6	0.0	6.3	78	14.3	0.0	30.4
V 13TH RIB(S) ABSENT	1	0.03	0.0	0.6	1	0.2	0.0	4.0
V 13TH RIB(S) SHORTENED	306	7.9	3.0	13.5	181	33.2	13.6	54.5
V FLYING RIB(S)	1	0.03	0.0	0.6	1	0.2	0.0	4.0
V WAVY RIB(S)	1	0.03	0.0	0.6	1	0.2	0.0	4.2
TOTAL FETAL SKELETAL VARIATIONS	1707	44.3			513	94.1		

OBSERVATION CODE: V=Variation

17-AUG-94

TABLE : HCD 012

SPECIES RAT

STRAIN WISTAR
SUPPLIER Dr. K. Thomae

HISTORICAL CONTROL DATA

FETAL SKELETAL MALFORMATIONS

	FETUSES N	%	%RANGE (per study) %	%	LITTERS N	%	%RANGE (per study) %	%
NUMBER EVALUATED	3851				545			
Live	3851							
Dead	0							
M SEVERAL RIBS SEVERELY MALFORMED	1	0.03	0.0	0.7	1	0.2	0.0	4.2
M SUPERNUMERARY RIB	1	0.03	0.0	0.5	1	0.2	0.0	4.0
M RIB(S) ABSENT	3	0.08	0.0	1.2	3	0.6	0.0	9.1
TOTAL FETAL SKELETAL MALFORMATIONS	170	4.4			130	23.9		

OBSERVATION CODE: M=Malformation

17-AUG-94

TABLE : HCD 011

SPECIES RAT

STRAIN WISTAR
SUPPLIER Dr. K. Thomae

HISTORICAL CONTROL DATA

FETAL SKELETAL MALFORMATIONS

	FETUSES N	%	%RANGE (per study) %	%	LITTERS N	%	%RANGE (per study) %	%
NUMBER EVALUATED	3851				545			
Live	3851							
Dead	0							
M FETUS WITH MULTIPLE MALFORMATIONS OF RIBS AND VERTEBR. COL.	2	0.05	0.0	0.7	2	0.4	0.0	4.3
M MANDIBLE FUSED	1	0.03	0.0	0.7	1	0.2	0.0	4.3
M VERTEBRAE FUSED AND/OR OF IRREGULAR SHAPE	2	0.05	0.0	1.1	1	0.2	0.0	4.3
M CERVICAL VERTEBRAL ARCHES FUSED	2	0.05	0.0	1.2	2	0.4	0.0	8.0
M THORACIC VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (ASYMMETR.)	128	3.3	0.0	8.8	101	18.5	0.0	39.1
M THORACIC VERTEBRAL BODY/BODIES BIPARTITE (ASYMMETRICAL)	23	0.6	0.0	1.9	22	4.0	0.0	13.0
M THORACIC VERTEBRA ABSENT	4	0.1	0.0	1.2	4	0.7	0.0	9.1
M DIFF.THORAC.VERT.BOD. AND/OR ARCHES SEVERELY MALFORMED	1	0.03	0.0	0.7	1	0.2	0.0	4.2
M THORACIC VERTEBRAL BODY/BODIES DISLOCATED	1	0.03	0.0	0.6	1	0.2	0.0	4.0
M LUMBAR VERTEBRAL BODY/BODIES DUMBBELL-SHAPED (ASYMMETR.)	1	0.03	0.0	0.5	1	0.2	0.0	4.0
M LUMBAR VERTEBRA ABSENT	1	0.03	0.0	0.6	1	0.2	0.0	4.0
M LUMBAR VERTEBRAE FUSED AND/OR OF IRREGULAR SHAPE	1	0.03	0.0	0.8	1	0.2	0.0	5.3
M DIFF.LUMB.VERTEBR.BOD. AND/OR ARCHES SEVERELY MALFORMED	1	0.03	0.0	0.6	1	0.2	0.0	4.3
M LUMBAR VERTEBRAL BODY/BODIES BIPARTITE (ASYMMETRICAL)	2	0.05	0.0	0.6	2	0.4	0.0	4.3
M STERNEBRA(E) BIPARTITE, OSSIFICATION CENTERS DISLOCATED	21	0.5	0.0	1.8	21	3.9	0.0	13.6
M STERNEBRAE SEVERELY FUSED (BONY PLATE)	1	0.03	0.0	0.6	1	0.2	0.0	4.5
M FUSED RIBS	1	0.03	0.0	0.6	1	0.2	0.0	4.0

OBSERVATION CODE: M=Malformation

17-AUG-94

TABLE : HCD 010

SPECIES RAT

STRAIN WISTAR
SUPPLIER Dr. K. Thomae

HISTORICAL CONTROL DATA

FETAL SOFT TISSUE UNCLASSIFIED FINDINGS

	FETUSES N	%	%RANGE (per study) %	%	LITTERS N	%	%RANGE (per study) %	%
NUMBER EVALUATED	3574				543			
Live	3574							
Dead	0							
U BLOODY IMBIBITION OF KIDNEY(S)	2	0.06	0.0	0.7	2	0.4	0.0	4.3
TOTAL FETAL SOFT TISSUE UNCLASSIFIED FINDINGS	2	0.06			2	0.4		

OBSERVATION CODE: U=Unclassified

17-AUG-94

TABLE : HCD 009

SPECIES RAT

STRAIN WISTAR
SUPPLIER Dr. K. Thomae

HISTORICAL CONTROL DATA

FETAL SOFT TISSUE VARIATIONS

	FETUSES N	FETUSES %	%RANGE (per study) %	%RANGE (per study) %	LITTERS N	LITTERS %	%RANGE (per study) %	%RANGE (per study) %
NUMBER EVALUATED	3574				543			
Live	3574							
Dead	0							
V DILATED RENAL PELVIS	638	17.9	4.9	54.3	310	57.1	33.3	100.0
V HYDROURETER	176	4.9	0.0	17.9	122	22.5	0.0	64.0
TOTAL FETAL SOFT TISSUE VARIATIONS	641	17.9			310	57.1		

OBSERVATION CODE: V=Variation

17-AUG-94

TABLE : HCD 008

SPECIES RAT

STRAIN WISTAR
SUPPLIER Dr. K. Thomae

HISTORICAL CONTROL DATA

FETAL SOFT TISSUE MALFORMATIONS

	FETUSES N	%	%RANGE (per study) %	%	LITTERS N	%	%RANGE (per study) %	%
NUMBER EVALUATED	3574				543			
Live	3574							
Dead	0							
M SITUS INVERSUS	1	0.03	0.0	0.8	1	0.2	0.0	5.3
M HYDROCEPHALY	3	0.08	0.0	1.6	3	0.6	0.0	10.0
M DILATATION OF BOTH VENTRICLES (GLOBULAR SHAPED HEART)	3	0.08	0.0	1.2	3	0.6	0.0	8.3
M DEXTROCARDIA	1	0.03	0.0	0.6	1	0.2	0.0	4.2
M HEART: DILATATION OF RIGHT VENTRICLE	1	0.03	0.0	0.8	1	0.2	0.0	5.0
TOTAL FETAL SOFT TISSUE MALFORMATIONS	8	0.2			8	1.5		

OBSERVATION CODE: M=Malformation

SPECIES RAT

STRAIN WISTAR
SUPPLIER Dr. K. Thomae

HISTORICAL CONTROL DATA

FETAL EXTERNAL UNCLASSIFIED FINDINGS

	FETUSES N	%	%RANGE (per study) %	%	LITTERS N	%	%RANGE (per study) %	%
NUMBER EVALUATED	7426				545			
Live	7426							
Dead	0							
U PLACENTAE FUSED	13	0.2	0.0	1.1	12	2.2	0.0	10.0
U BLOOD COAGULUM AROUND PLACENTA	10	0.1	0.0	1.8	4	0.7	0.0	9.5
TOTAL FETAL EXTERNAL UNCLASSIFIED FINDINGS	22	0.3			15	2.8		

OBSERVATION CODE: U=Unclassified

17-AUG-94

TABLE : HCD 006

SPECIES RAT

STRAIN WISTAR
SUPPLIER Dr. K. Thomae

HISTORICAL CONTROL DATA

FETAL EXTERNAL VARIATIONS

	FETUSES N	FETUSES %	%RANGE (per study) %	%RANGE (per study) %	LITTERS N	LITTERS %	%RANGE (per study) %	%RANGE (per study) %
NUMBER EVALUATED	7426				545			
Live	7426							
Dead	0							
TOTAL FETAL EXTERNAL VARIATIONS	0	0.0			0	0.0		

Confidential

TRANSLATION

BASF
Abteilung Toxikologie
Department of Toxicology

6700 Ludwigshafen
West Germany

*/kh-ru-gl; 32

JUL 25 1988

REPORT

Study on the oral toxicity of

2,4,6-TRIANILINO-P-(CARBO-2'-ETHYL-HEXYL-1'-OXI)-1,3,5-TRIAZINE

in rats

Administration in the diet

over 3 months

Project No. 30C0200/8625

VOLUME II

TABLES

Dieses Dokument enthält Betriebs- und Geschäftsgeheimnisse der BASF. Es ist Eigentum der BASF und darf nur zu dem von BASF vorgesehenen Zweck verwendet werden. Jede andere oder darüber hinausgehende Verwendung, Verwertung, Weitergabe, Vervielfältigung oder Veröffentlichung bedarf der Einwilligung der BASF.

This document contains manufacturing and trade secrets of BASF. It is the property of BASF and may be used only for that purpose for which it was intended by BASF. Every other or additional use, exploitation, reproduction, publication or submission to other parties require the written permission of BASF.

CONTENTS OF TABLES

	Table
A CLINICAL EXAMINATIONS	
Key to the abbreviations, page A1	
Feed consumption (gram) - individual values	
Test groups 0 - 3, male animals	A 001 - A 008
Test groups 0 - 3, female animals	A 009 - A 016
Body weight (gram) - individual values	
Test groups 0 - 3, male animals	A 017 - A 024
Test groups 0 - 3, female animals	A 025 - A 032
B CLINICAL CHEMISTRY AND HEMATOLOGY	
Key to the abbreviations, pages B1 - B4	
Hematological examinations	
- Individual values	
- male animals	B 001 - B 002
- female animals	B 003 - B 004
Differential blood count	
- Individual values	
- male animals	B 005 - B 012
- female animals	B 013 - B 020
Clotting analyses	
- Individual values	
- male animals	B 021 - B 022
- female animals	B 023 - B 024
Enzymes	
- Individual values	
- male animals	B 025 - B 026
- female animals	B 027 - B 028
Blood chemistry	
- Individual values	
- male animals	B 029 - B 032
- female animals	B 033 - B 036

Annex: ANALYSIS OF TEST SUBSTANCE IN THE VEHICLE

- Homogeneity in the vehicle
- Stability in the vehicle
- Concentration control analyses

BASF
Abteilung Toxikologie
Department of Toxicology

KEY TO THE ABBREVIATIONS USED IN PART A OF THE TABLES

FC	= feed consumption (feed intake)
BODYWT	= body weight
G	= weight in grams
M	= mean
SD	= standard deviation
N	= number of animals for the calculation of M and SD
PPM	= dose in parts per million
NR	= value was determined and documented in the raw data, but was not taken into account in the calculation of means ("outlier")

The figures in the top row of each table indicate the time to which the data on the specific parameter refer.

a) Feed consumption (Tables 001 - 016)

Feed consumption was determined once a week during the administration period.

b) Body weight (Tables 017 - 032)

The body weights were determined once a week during the administration period.

BASF TOXICOLOGY
PROJECT NUMBER 30C0200/8625

3-MONTH FEEDING STUDY OF TCT IN RATS

INDIVIDUAL DATA WITH MEANS

FOOD CONSUMPTION/ANIMAL/DAY

PRINT DATE

M A L E S		day 7	day 14	day 21	day 28	day 35	day 42	day 49
	ANIMAL	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G
GROUP 0								
0 PPM	1	26.8	28.6	29.7	26.9	31.1	29.6	26.5
	2	25.6	27.6	26.6	26.6	26.0	26.0	26.5
	3	25.9	25.9	27.1	25.6	26.2	27.6	25.1
	4	25.9	26.6	26.6	25.3	25.4	26.0	24.6
	5	27.5	28.5	28.3	28.0	27.6	27.8	27.6
	6	25.8	26.1	25.9	25.7	26.2	25.2	27.4
	7	25.1	26.9	25.9	25.7	26.4	25.8	24.6
	8	27.3	29.0	28.1	27.5	26.6	27.4	27.2
	9	25.4	26.4	25.7	26.2	26.4	27.1	26.6
	10	24.8	26.4	26.1	25.5	25.4	24.7	25.5
	M	26.0	27.2	27.0	26.3	26.7	26.7	26.2
	SD	0.9	1.1	1.3	0.9	1.7	1.5	1.1
	N	10	10	10	10	10	10	10

BASF TOXICOLOGY
PROJECT NUMBER 30C0200/8625

3-MONTH FEEDING STUDY OF TCT IN RATS

INDIVIDUAL DATA WITH MEANS

FOOD CONSUMPTION/ANIMAL/DAY

PRINT DATE

M A L E S

	ANIMAL	day 63 FC/DAY G	day 70 FC/DAY G	day 77 FC/DAY G	day 84 FC/DAY G	day 91 FC/DAY G
GROUP 0						
0 PPM	1	29.1	28.7	29.9	29.5	28.7
	2	27.1	26.9	27.2	28.0	24.5
	3	27.9	28.0	29.0	28.8	28.9
	4	26.0	25.6	27.5	20.9	30.0
	5	29.0	28.6	29.5	29.4	28.7
	6	26.5	25.8	26.5	27.0	26.3
	7	25.6	22.2	27.1	26.1	26.5
	8	27.3	26.7	26.9	26.7	25.5
	9	26.8	27.7	27.3	28.4	26.7
	10	25.6	25.3	23.2	25.2	26.4
	M	27.1	26.6	27.4	27.0	27.2
	SD	1.3	2.0	1.9	2.6	1.8
	N	10	10	10	10	10

TABLE

BASF TOXICOLOGY
PROJECT NUMBER 30C0200/8625

3-MONTH FEEDING STUDY OF TCT IN RATS

INDIVIDUAL DATA WITH MEANS

FOOD CONSUMPTION/ANIMAL/DAY

PRINT DATE

M A L E S		day 7	day 14	day 21	day 28	day 35	day 42	day 49
	ANIMAL	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G
GROUP 1								
1000 PPM	11	27.4	29.0	28.8	28.1	28.0	27.1	28.2
	12	27.4	29.2	29.0	28.1	29.9	28.6	30.1
	13	26.4	26.4	24.6	26.4	26.1	26.3	26.3
	14	24.9	26.8	26.1	25.1	25.9	25.0	26.0
	15	26.2	27.8	28.5	27.7	27.9	28.3	27.2
	16	30.7	31.1	29.0	29.4	29.2	29.2	30.1
	17	28.3	29.2	28.0	25.1	26.3	26.4	27.9
	18	27.8	28.2	28.2	28.2	28.6	28.4	28.9
	19	25.1	25.9	26.0	25.0	24.7	24.2	25.5
	20	26.7	28.6	28.1	26.3	26.8	26.7	26.8
	M	27.1	28.2	27.6	26.9	27.3	27.0	27.7
	SD	1.7	1.6	1.5	1.6	1.6	1.6	1.6
	N	10	10	10	10	10	10	10

TABLE

BASF TOXICOLOGY
PROJECT NUMBER 30C0200/8625 3-MONTH FEEDING STUDY OF TCT IN RATS

INDIVIDUAL DATA WITH MEANS FOOD CONSUMPTION/ANIMAL/DAY PRINT DATE

M A L E S		day 63	day 70	day 77	day 84	day 91
	ANIMAL	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G
GROUP 1						
1000 PPM	11	27.6	27.2	27.7	27.5	27.6
	12	29.1	28.1	29.5	28.2	29.1
	13	24.7	25.1	25.8	25.0	24.9
	14	25.4	25.3	27.5	26.3	27.2
	15	27.8	27.0	27.1	29.0	28.3
	16	30.5	30.1	29.3	29.5	28.7
	17	27.2	27.9	27.9	27.4	27.3
	18	30.7	31.0	36.3	29.8	30.0
	19	25.2	25.2	25.6	25.4	24.4
	20	25.4	25.4	26.6	25.7	26.8
	M	27.4	27.2	28.3	27.4	27.4
	SD	2.2	2.1	3.1	1.7	1.7
	N	10	10	10	10	10

BASF TOXICOLOGY
PROJECT NUMBER 30C0200/8625

3-MONTH FEEDING STUDY OF TCT IN RATS

INDIVIDUAL DATA WITH MEANS

FOOD CONSUMPTION/ANIMAL/DAY

PRINT DATE

M A L E S		day 7	day 14	day 21	day 28	day 35	day 42	day 49
	ANIMAL	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G
GROUP 2								
4000 PPM	21	26.3	29.0	28.6	26.9	27.5	27.2	26.5
	22	26.9	28.6	NR	32.2	29.6	27.8	28.5
	23	28.7	29.4	30.5	29.9	31.3	31.3	32.1
	24	27.5	29.2	28.8	28.9	28.4	29.6	27.7
	25	26.2	26.2	26.6	25.7	26.0	26.7	25.3
	26	27.0	28.2	29.5	29.7	29.5	28.9	29.1
	27	25.9	27.9	26.4	25.5	25.2	26.4	25.4
	28	26.9	28.3	30.0	29.0	28.2	30.6	28.8
	29	25.5	27.4	25.9	25.1	25.1	25.8	26.6
	30	25.8	27.0	27.7	27.1	27.1	27.1	27.5
	M	26.7	28.1	28.2	28.0	27.8	28.1	27.8
	SD	0.9	1.0	1.7	2.3	2.0	1.9	2.0
	N	10	10	9	10	10	10	10

BASF TOXICOLOGY
PROJECT NUMBER 30C0200/8625 3-MONTH FEEDING STUDY OF TCT IN RATS

INDIVIDUAL DATA WITH MEANS FOOD CONSUMPTION/ANIMAL/DAY PRINT DATI

M A L E S		day 63	day 70	day 77	day 84	day 91
	ANIMAL	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G
GROUP 2						
4000 PPM	21	25.8	25.3	26.1	25.2	25.3
	22	27.4	23.3	29.6	26.5	27.0
	23	32.0	31.4	31.3	30.5	31.6
	24	24.0	30.2	27.2	28.3	27.7
	25	25.5	25.2	25.6	25.4	24.4
	26	29.6	30.6	30.4	29.0	28.2
	27	26.0	26.0	27.3	25.9	25.9
	28	28.9	27.5	30.5	29.5	31.5
	29	26.5	26.5	26.5	26.5	27.3
	30	26.6	27.6	21.9	30.4	28.4
	M	27.2	27.4	27.7	27.7	27.7
	SD	2.3	2.6	2.9	2.0	2.4
	N	10	10	10	10	10

BASF TOXICOLOGY
PROJECT NUMBER 30C0200/8625 3-MONTH FEEDING STUDY OF TCT IN RATS

INDIVIDUAL DATA WITH MEANS FOOD CONSUMPTION/ANIMAL/DAY PRINT DATE 10-FEB-87

M A L E S		day 7	day 14	day 21	day 28	day 35	day 42	day 49	day 56
	ANIMAL	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G
GROUP 3									
16000 PPM	31	26.2	27.2	26.6	26.2	27.5	27.5	26.7	27.1
	32	26.6	29.9	29.2	28.8	29.7	29.7	29.8	29.7
	33	26.9	27.6	28.0	26.8	28.0	28.4	29.0	28.2
	34	25.4	26.6	27.7	27.6	27.3	25.8	25.9	26.1
	35	26.6	29.5	30.0	29.6	28.9	29.0	29.8	29.5
	36	29.6	31.4	31.2	31.4	31.0	31.5	33.8	32.8
	37	25.1	25.6	25.1	24.9	25.9	25.2	25.0	24.8
	38	25.2	25.8	25.2	23.8	26.4	26.5	25.8	25.7
	39	25.7	26.2	26.4	25.5	26.8	26.9	26.6	27.7
	40	24.6	27.1	26.7	26.0	26.6	26.3	26.7	26.8
	M	26.2	27.7	27.6	27.1	27.8	27.7	27.9	27.8
	SD	1.4	1.9	2.0	2.3	1.6	1.9	2.7	2.3
	N	10	10	10	10	10	10	10	10

TABLE A 008

BASF TOXICOLOGY
PROJECT NUMBER 30C0200/8625 3-MONTH FEEDING STUDY OF TCT IN RATS

INDIVIDUAL DATA WITH MEANS FOOD CONSUMPTION/ANIMAL/DAY PRINT DATE 10-FEB-87

M A L E S		day 63	day 70	day 77	day 84	day 91
	ANIMAL	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G
GROUP 3						
16000 PPM	31	27.3	27.6	26.7	24.5	27.9
	32	29.3	28.8	30.2	28.4	28.6
	33	29.0	28.6	29.2	29.2	29.2
	34	27.1	25.5	25.6	25.8	24.8
	35	29.4	28.4	29.4	27.8	28.8
	36	31.5	31.7	32.6	32.0	32.6
	37	25.0	25.3	24.9	24.6	23.9
	38	25.6	25.5	26.3	24.8	26.6
	39	26.1	26.1	25.3	25.9	26.6
	40	26.2	26.1	26.0	25.8	24.5
	M	27.6	27.3	27.6	26.9	27.4
	SD	2.1	2.1	2.5	2.4	2.6
	N	10	10	10	10	10

TABLE A 009

BASF TOXICOLOGY
PROJECT NUMBER 30C0200/8625

3-MONTH FEEDING STUDY OF TCT IN RATS

INDIVIDUAL DATA WITH MEANS

FOOD CONSUMPTION/ANIMAL/DAY

PRINT DATE 10-FEB-87

F E M A L E S		day 7	day 14	day 21	day 28	day 35	day 42	day 49	day 56
	ANIMAL	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G
GROUP 0									
0 PPM	41	17.8	16.6	18.5	18.0	18.3	16.8	19.2	19.0
	42	17.7	15.6	17.8	18.2	17.8	16.9	17.7	19.7
	43	21.6	19.9	20.3	19.7	19.7	16.2	18.6	19.6
	44	15.6	16.0	17.1	17.0	17.4	17.2	17.1	16.6
	45	19.6	22.1	21.7	21.1	22.0	22.7	21.1	21.6
	46	21.5	20.2	19.7	21.7	21.2	20.8	20.0	21.7
	47	19.5	18.0	16.9	17.5	18.9	17.2	18.7	19.1
	48	16.9	16.2	17.5	16.9	16.2	16.8	16.9	17.4
	49	17.3	17.8	17.3	17.8	17.6	17.4	17.3	17.8
	50	15.4	14.0	14.2	14.7	14.3	13.8	14.8	15.9
	M	18.3	17.6	18.1	18.3	18.3	17.6	18.1	18.9
	SD	2.2	2.5	2.1	2.1	2.3	2.5	1.8	1.9
	N	10	10	10	10	10	10	10	10

TABLE A 010

BASF TOXICOLOGY
PROJECT NUMBER 30C0200/8625 3-MONTH FEEDING STUDY OF TCT IN RATS

INDIVIDUAL DATA WITH MEANS ' FOOD CONSUMPTION/ANIMAL/DAY PRINT DATE 10-FEB-87

F E M A L E S		day 63	day 70	day 77	day 84	day 91
	ANIMAL	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G
GROUP 0						
0 PPM	41	19.1	20.6	20.9	20.0	19.8
	42	18.0	17.6	19.1	19.9	19.4
	43	20.3	18.9	20.7	20.1	21.2
	44	16.7	17.6	17.8	17.5	17.3
	45	22.1	21.0	22.1	21.7	21.3
	46	20.6	19.0	20.8	20.9	20.1
	47	19.9	18.5	17.6	17.8	19.3
	48	16.9	17.2	17.8	18.3	16.3
	49	18.3	18.2	19.0	19.2	18.1
	50	14.6	14.8	16.0	17.0	15.9
	M	18.6	18.3	19.2	19.2	18.9
	SD	2.2	1.8	1.9	1.6	1.9
	N	10	10	10	10	10

BASF TOXICOLOGY
PROJECT NUMBER 30C0200/8625

3-MONTH FEEDING STUDY OF TCT IN RATS

INDIVIDUAL DATA WITH MEANS

FOOD CONSUMPTION/ANIMAL/DAY

PRINT DATE 10-FEB-87

F E M A L E S		day 7	day 14	day 21	day 28	day 35	day 42	day 49	day 56
	ANIMAL	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G	FC/DAY G
GROUP 1									
1000 PPM	51	18.8	18.1	17.8	18.1	19.4	18.6	19.5	19.2
	52	20.4	19.6	20.0	19.4	21.8	20.0	19.8	19.4
	53	19.9	20.7	20.9	19.9	21.5	22.7	16.5	22.2
	54	17.5	16.9	18.6	16.8	17.2	17.1	19.4	17.5
	55	18.9	17.3	18.9	17.2	16.9	17.9	19.0	19.9
	56	18.4	19.0	18.2	16.9	18.2	17.4	18.3	16.1
	57	18.9	18.4	20.7	18.5	17.8	19.0	19.8	18.5
	58	18.7	18.3	18.7	18.8	17.7	16.6	17.6	18.7
	59	18.8	18.0	18.9	17.6	16.9	18.2	18.7	17.7
	60	19.0	17.9	17.5	18.0	20.1	18.4	19.3	18.6
	M	18.9	18.4	19.0	18.1	18.8	18.6	18.8	18.8
	SD	0.8	1.1	1.2	1.0	1.8	1.8	1.1	1.6
	N	10	10	10	10	10	10	10	10