C Number:	R14001B
Study Gender:	Female
PWG Approval Date	See web page for date of PWG Approval

Experiment Number: R14001B
Test Type: Teratology
Route: Oral Gavage
Species/Strain: Rat/Harlan Sprague Dawley

R11: Fetal Defect Summary
Test Compound: 4-Methylcyclohexanemethanol
CAS Number: 34885-03-5

Date Report Requested: 08/24/2018
Time Report Requested: 09:08:12
Lab: Southern Research

	Treatment Groups (mg/kg/day)				
	0	**50**	**100**	**200**	**400**
All Exams					
No. Fetuses	296	283	279	247	254
No. Litters	23	21	21	19	21
Malformation					
Affected fetuses	15 (5.07) ** ##	14 (4.95)	15 (5.38)	15 (6.07)	59 (23.23) ** ##
Affected litters	10 (43.48) *	11 (52.38)	7 (33.33)	10 (52.63)	15 (71.43)
Variation					
Affected fetuses	92 (31.08) ** #	65 (22.97) *	86 (30.82)	98 (39.68) *	99 (38.98) *
Affected litters	21 (91.30)	20 (95.24)	18 (85.71)	17 (89.47)	20 (95.24)
Gross Finding					
Affected fetuses	1 (0.34)	4 (1.41)	3 (1.08)	1 (0.40)	3 (1.18)
Affected litters	1 (4.35)	3 (14.29)	1 (4.76)	1 (5.26)	3 (14.29)
External					
No. Fetuses	296	283	279	247	254
No. Litters	23	21	21	19	21
Malformation					
Affected fetuses	0 (0.00)	2 (0.71)	0 (0.00)	0 (0.00)	2 (0.79)
Affected litters	0 (0.00)	2 (9.52)	0 (0.00)	0 (0.00)	2 (9.52)
Gross Finding					
Affected fetuses	1 (0.34)	4 (1.41)	3 (1.08)	1 (0.40)	3 (1.18)
Affected litters	1 (4.35)	3 (14.29)	1 (4.76)	1 (5.26)	3 (14.29)

	Treatment Groups (mg/kg/day)				
	0	**50**	**100**	**200**	**400**
Visceral					
No. Fetuses	296	283	279	247	254
No. Litters	23	21	21	19	21
Malformation					
Affected fetuses	12 (4.05) ** ##	9 (3.18)	9 (3.23)	8 (3.24)	24 (9.45) ** #
Affected litters	8 (34.78)	7 (33.33)	5 (23.81)	5 (26.32)	12 (57.14)
Variation					
Affected fetuses	16 (5.41)	8 (2.83)	12 (4.30)	8 (3.24)	14 (5.51)
Affected litters	10 (43.48)	5 (23.81)	6 (28.57)	6 (31.58)	9 (42.86)
Head					
No. Fetuses	155	146	145	128	131
No. Litters	23	21	21	19	21
NO VISIBLE LESIONS PRESENT					
Skeletal - Body					
No. Fetuses	295	283	279	247	253
No. Litters	23	21	21	19	21
Malformation					
Affected fetuses	3 (1.02) ** ##	3 (1.06)	6 (2.15)	7 (2.83)	40 (15.81) ** ##
Affected litters	3 (13.04) **	3 (14.29)	3 (14.29)	5 (26.32)	12 (57.14) **
Variation					
Affected fetuses	76 (25.76) ** #	59 (20.85)	79 (28.32)	87 (35.22) *	88 (34.78) *
Affected litters	21 (91.30)	19 (90.48)	17 (80.95)	17 (89.47)	20 (95.24)

	Treatment Groups (mg/kg/day)				
	0	**50**	**100**	**200**	**400**
Skeletal - Skull					
No. Fetuses	141	137	134	119	123
No. Litters	23	21	21	19	21
Malformation					
Affected fetuses	0 (0.00)	1 (0.73)	0 (0.00)	0 (0.00)	0 (0.00)
Affected litters	0 (0.00)	1 (4.76)	0 (0.00)	0 (0.00)	0 (0.00)
Variation					
Affected fetuses	6 (4.26)	2 (1.46)	3 (2.24)	5 (4.20)	2 (1.63)
Affected litters	5 (21.74)	2 (9.52)	2 (9.52)	5 (26.32)	2 (9.52)
Placental					
No. Fetuses	296	283	279	247	253
No. Litters	23	21	21	19	21

NO VISIBLE LESIONS PRESENT

LEGEND

Upper row denotes number of affected fetuses (%) and lower row the number of affected litters (%)

Trend and pairwise significance levels are determined using one-sided tests.

Statistical analysis for litter data and for fetal data ignoring the litter effects were performed by Cochran-Armitage (trend) and Fisher Exact (pairwise) tests.

* Statistically significant at P <= 0.05

** Statistically significant at P <= 0.01

Statistical analysis for fetal data including litter effects was performed by using a Generalized Linear Mixed Model, where the Dam ID was the random effect for both trend and pairwise analysis.

Statistically significant at P <= 0.05 (litter based analysis)

Statistically significant at P <= 0.01 (litter based analysis)

Statistical significance for the control group indicates a significant trend test

Statistical significance for a treatment group indicates a significant pairwise test compared to the vehicle control group

** END OF REPORT **