

Experiment Number: R20084C

Test Type: Teratology

Route: Oral Gavage

Species/Strain: Rat/Harlan Sprague Dawley

R11: Fetal Defect Summary

Test Compound: Dimethylethanolamine

CAS Number: 108-01-0

Date Report Requested: 02/22/2017

Time Report Requested: 12:42:09

Lab: Southern Research

C Number: R20084C

Cage Range: All

Date Range: All

Reasons For Removal: All

Removal Date Range: All

Treatment Groups: All

Study Gender: Female

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	Treatment Groups (mg/kg/day)			
	0	250	500	1000
All Exams				
No. Fetuses	209	265	260	260
No. Litters	19	20	20	22
Malformation				
Affected fetuses	9 (4.31)	6 (2.26)	6 (2.31)	7 (2.69)
Affected litters	8 (42.11)	5 (25.00)	5 (25.00)	4 (18.18)
Variation				
Affected fetuses	69 (33.01) ** ##	76 (28.68)	78 (30.00)	127 (48.85) ** ##
Affected litters	17 (89.47)	20 (100.00)	20 (100.00)	21 (95.45)
Gross Finding				
Affected fetuses	3 (1.44)	2 (0.75)	1 (0.38)	6 (2.31)
Affected litters	2 (10.53)	2 (10.00)	1 (5.00)	4 (18.18)
External				
No. Fetuses	209	265	260	260
No. Litters	19	20	20	22
Malformation				
Affected fetuses	1 (0.48)	2 (0.75)	1 (0.38)	3 (1.15)
Affected litters	1 (5.26)	2 (10.00)	1 (5.00)	2 (9.09)
Gross Finding				
Affected fetuses	1 (0.48)	2 (0.75)	1 (0.38)	5 (1.92)
Affected litters	1 (5.26)	2 (10.00)	1 (5.00)	3 (13.64)

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	Treatment Groups (mg/kg/day)			
	0	250	500	1000
Visceral				
No. Fetuses	209	265	260	260
No. Litters	19	20	20	22
Malformation				
Affected fetuses	4 (1.91)	1 (0.38)	4 (1.54)	3 (1.15)
Affected litters	4 (21.05)	1 (5.00)	4 (20.00)	3 (13.64)
Variation				
Affected fetuses	11 (5.26)	14 (5.28)	16 (6.15)	19 (7.31)
Affected litters	7 (36.84)	11 (55.00)	9 (45.00)	14 (63.64)
Gross Finding				
Affected fetuses	0 (0.00)	0 (0.00)	0 (0.00)	1 (0.38)
Affected litters	0 (0.00)	0 (0.00)	0 (0.00)	1 (4.55)
Skeletal - Body				
No. Fetuses	209	264	260	260
No. Litters	19	20	20	22
Malformation				
Affected fetuses	7 (3.35) ** ##	3 (1.14)	1 (0.38) * #	1 (0.38) * #
Affected litters	6 (31.58) *	3 (15.00)	1 (5.00) *	1 (4.55) *
Variation				
Affected fetuses	58 (27.75) ** ##	57 (21.59)	60 (23.08)	102 (39.23) ** #
Affected litters	17 (89.47)	18 (90.00)	18 (90.00)	19 (86.36)

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	Treatment Groups (mg/kg/day)			
	0	250	500	1000
Skeletal - Skull				
No. Fetuses	100	128	126	128
No. Litters	18	20	20	20
Variation				
Affected fetuses	2 (2.00) ** ##	8 (6.25)	5 (3.97)	16 (12.50) ** #
Affected litters	2 (11.11) *	7 (35.00)	4 (20.00)	10 (50.00) *

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LEGEND

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

No p-values are reported unless there are at least two observations in one or more of the dose groups

Statistical analysis performed by Cochran-Armitage (trend) and Fisher Exact (pairwise) tests

Statistical analysis with litter based adjustments performed by Generalized Linear Mixed Models where the dam identification was the random effect

* Statistically significant at $P \leq 0.05$

** Statistically significant at $P \leq 0.01$

Statistically significant at $P \leq 0.05$ (litter based analysis)

Statistically significant at $P \leq 0.01$ (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

Skeletal-body examination was not performed on one fetus in the 250 mg/kg group

**** END OF REPORT ****