

**Experiment Number:** R20084C

**Test Type:** Teratology

**Route:** Oral Gavage

**Species/Strain:** Rat/Harlan Sprague Dawley

**C Number:**

R20084C

**Cage Range:**

All

**Date Range:**

All

**Reasons For Removal:**

All

**Removal Date Range:**

All

**Treatment Groups:**

All

**Study Gender:**

Female

**R10: Fetal Defects**

**Test Compound:** Dimethylethanolamine

**CAS Number:** 108-01-0

**Date Report Requested:** 02/22/2017

**Time Report Requested:** 12:42:01

**Lab:** Southern Research

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Classification	Treatment Groups (mg/kg/day)				
	0	250	500	1000	
Total number of fetuses examined	209	265	260	260	
<b>External</b>					
No. Fetuses examined	209	265	260	260	
No. Litters examined	19	20	20	22	
<b>Body - General</b>					
Body, Subcutaneous hemorrhage	Gross Finding	1 (0.48) 1 (5.26)	2 (0.75) 2 (10.00)	1 (0.38) 1 (5.00)	5 (1.92) 3 (13.64)
<b>Extremities</b>					
Limb, hind, right, Bent	Malformation	0 (0.0) 0 (0.00)	0 (0.0) 0 (0.00)	0 (0.0) 0 (0.00)	1 (0.38) 1 (4.55)
Tail, Bent	Malformation	0 (0.0) 0 (0.00)	1 (0.38) 1 (5.00)	1 (0.38) 1 (5.00)	2 (0.77) 1 (4.55)
<b>Head</b>					
Head, Meningocele	Malformation	1 (0.48) 1 (5.26)	0 (0.0) 0 (0.00)	0 (0.0) 0 (0.00)	0 (0.0) 0 (0.00)
<b>Trunk</b>					
General, Omphalocele	Malformation	0 (0.0) 0 (0.00)	1 (0.38) 1 (5.00)	0 (0.0) 0 (0.00)	0 (0.0) 0 (0.00)

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		0	250	500	1000
<b>Visceral</b>					
No. Fetuses examined		209	265	260	260
No. Litters examined		19	20	20	22
<b>General</b>					
General, Fluid-filled thorax	Gross Finding	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.38)
		0 (0.00)	0 (0.00)	0 (0.00)	1 (4.55)
<b>Heart</b>					
Aortic valve, Misshapen	Malformation	2 (0.96)	1 (0.38)	3 (1.15)	1 (0.38)
		2 (10.53)	1 (5.00)	3 (15.00)	1 (4.55)
Atrium, right, Large	Malformation	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.38)
		0 (0.00)	0 (0.00)	0 (0.00)	1 (4.55)
Ventricle, bilateral, Thick Wall	Malformation	1 (0.48)	0 (0.0)	0 (0.0)	0 (0.0)
		1 (5.26)	0 (0.00)	0 (0.00)	0 (0.00)
Ventricle, bilateral, Ventricular septum defect	Malformation	1 (0.48)	0 (0.0)	0 (0.0)	0 (0.0)
		1 (5.26)	0 (0.00)	0 (0.00)	0 (0.00)
<b>Major Vessels</b>					
Aortic arch, Absent	Malformation	0 (0.0)	0 (0.0)	1 (0.38)	0 (0.0)
		0 (0.00)	0 (0.00)	1 (5.00)	0 (0.00)
Carotid artery, left, Malpositioned	Variation	0 (0.0)	0 (0.0)	1 (0.38)	0 (0.0)
		0 (0.00)	0 (0.00)	1 (5.00)	0 (0.00)
Innominate artery, Absent	Variation	3 (1.44) ** ##	4 (1.51)	6 (2.31)	12 (4.62) * #
		3 (15.79) *	4 (20.00)	4 (20.00)	10 (45.45) *
Innominate artery, Atresia	Malformation	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.38)
		0 (0.00)	0 (0.00)	0 (0.00)	1 (4.55)
Innominate artery, Short	Variation	6 (2.87)	7 (2.64)	8 (3.08)	5 (1.92)
		4 (21.05)	7 (35.00)	6 (30.00)	4 (18.18)
Pulmonary artery/trunk, Dilated	Malformation	1 (0.48)	0 (0.0)	0 (0.0)	0 (0.0)
		1 (5.26)	0 (0.00)	0 (0.00)	0 (0.00)
Subclavian artery, right, Dilated	Variation	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.38)

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		0	250	500	1000
		0 (0.00)	0 (0.00)	0 (0.00)	1 (4.55)
<b>Thoracic Viscera</b>					
Thymus, Supernumerary	Variation	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.38)
		0 (0.00)	0 (0.00)	0 (0.00)	1 (4.55)
<b>Urinary Tract</b>					
Renal pelvis, Dilated	Variation	0 (0.0)	1 (0.38)	1 (0.38)	1 (0.38)
		0 (0.00)	1 (5.00)	1 (5.00)	1 (4.55)
Renal pelvis, bilateral, Dilated	Variation	0 (0.0)	0 (0.0)	1 (0.38)	0 (0.0)
		0 (0.00)	0 (0.00)	1 (5.00)	0 (0.00)
Renal pelvis, left, Dilated	Variation	0 (0.0)	1 (0.38)	0 (0.0)	0 (0.0)
		0 (0.00)	1 (5.00)	0 (0.00)	0 (0.00)
Renal pelvis, right, Dilated	Variation	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.38)
		0 (0.00)	0 (0.00)	0 (0.00)	1 (4.55)
Ureter, Dilated	Variation	3 (1.44)	3 (1.13)	2 (0.77)	2 (0.77)
		2 (10.53)	3 (15.00)	2 (10.00)	2 (9.09)
Ureter, bilateral, Dilated	Variation	1 (0.48)	1 (0.38)	1 (0.38)	0 (0.0)
		1 (5.26)	1 (5.00)	1 (5.00)	0 (0.00)
Ureter, left, Dilated	Variation	1 (0.48)	2 (0.75)	1 (0.38)	2 (0.77)
		1 (5.26)	2 (10.00)	1 (5.00)	2 (9.09)
Ureter, right, Dilated	Variation	1 (0.48)	0 (0.0)	0 (0.0)	0 (0.0)
		1 (5.26)	0 (0.00)	0 (0.00)	0 (0.00)
	<b>Head</b>				
No. Fetuses examined		109	137	134	132
No. Litters examined		18	20	20	22

NO VISIBLE LESIONS PRESENT

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	0	250	500	1000
<b>Skeletal - Body</b>				
No. Fetuses examined	209	264	260	260
No. Litters examined	19	20	20	22
<b>Pelvic Girdle</b>				
Pubis, left, Incomplete ossification	Variation	0 (0.0)	0 (0.0)	2 (0.77)
		0 (0.00)	0 (0.00)	1 (4.55)
<b>Ribs</b>				
Costal cartilage, 6th right, Nodulated	Variation	1 (0.48)	0 (0.0)	2 (0.77)
		1 (5.26)	0 (0.00)	2 (9.09)
Costal cartilage, 8th right, Nodulated	Variation	0 (0.0)	0 (0.0)	0 (0.0)
		0 (0.00)	1 (5.00)	0 (0.00)
Costal cartilage, 9th right, Nodulated	Variation	1 (0.48)	0 (0.0)	0 (0.0)
		1 (5.26)	0 (0.00)	0 (0.00)
<b>Supernumerary Rib</b>				
Thoracolumbar, Full	Malformation	7 (3.35) ** ##	3 (1.14)	1 (0.38) * #
		6 (31.58) *	3 (15.00)	1 (5.00) *
Thoracolumbar, Short	Variation	56 (26.79) ** ##	56 (21.21)	100 (38.46) ** #
		17 (89.47)	18 (90.00)	19 (86.36)
Thoracolumbar, bilateral, Full	Malformation	1 (0.48)	0 (0.0)	0 (0.0)
		1 (5.26)	0 (0.00)	0 (0.00)
Thoracolumbar, bilateral, Short	Variation	17 (8.13) ** ##	11 (4.17)	39 (15.0) *
		8 (42.11) *	7 (35.00)	16 (72.73) *
Thoracolumbar, left, Full	Malformation	3 (1.44) *	1 (0.38)	0 (0.0)
		3 (15.79) *	1 (5.00)	0 (0.00)
Thoracolumbar, left, Short	Variation	23 (11.0) * #	32 (12.12)	45 (17.31) * #
		14 (73.68)	17 (85.00)	17 (77.27)
Thoracolumbar, right, Full	Malformation	3 (1.44)	2 (0.76)	1 (0.38)
		3 (15.79)	2 (10.00)	1 (4.55)
Thoracolumbar, right, Short	Variation	16 (7.66)	13 (4.92)	9 (3.46) * #
				16 (6.15)

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		0	250	500	1000
		10 (52.63)	10 (50.00)	8 (40.00)	10 (45.45)
<b>Vertebrae</b>					
Thoracic centrum, 10th, Incomplete ossification	Variation	0 (0.0)	0 (0.0)	1 (0.38)	0 (0.0)
		0 (0.00)	0 (0.00)	1 (5.00)	0 (0.00)
Thoracic centrum, 11th, Incomplete ossification	Variation	0 (0.0)	1 (0.38)	0 (0.0)	0 (0.0)
		0 (0.00)	1 (5.00)	0 (0.00)	0 (0.00)
	<b>Skeletal - Skull</b>				
No. Fetuses examined		100	128	126	128
No. Litters examined		18	20	20	20
<b>Skull</b>					
General, Isolated ossification site	Variation	1 (1.0)	5 (3.91)	3 (2.38)	3 (2.34)
		1 (5.56)	5 (25.00)	2 (10.00)	2 (10.00)
General, Supernumerary site	Variation	1 (1.0) ** ##	3 (2.34)	2 (1.59)	13 (10.16) ** #
		1 (5.56) **	3 (15.00)	2 (10.00)	10 (50.00) **

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## LEGEND

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

No p-values are reported for the 'Normal' observation entries

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 \*\***