

Experiment Number: R20263B

Test Type: Teratology

Route: Oral Gavage - Constant Volume

Species/Strain: Rat/Sprague-Dawley

C Number:

R20263B

Study Gender:

Female

PWG Approval Date

See web page for date of PWG Approval

R10: Fetal Defects

Test Compound: Tris (chloropropyl) phosphate

CAS Number: 13674-84-5

Date Report Requested: 08/21/2018

Time Report Requested: 12:08:39

Lab: RTI

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Classification	Treatment Groups (mg/kg/day)				
	0	162.5	325	650	
Total number of fetuses examined	599	300	270	259	
	External				
No. Fetuses examined	588	297	270	259	
No. Litters examined	43	21	21	20	
head					
Cranium, Meningoencephalocele	Malformation	0 (0.0)	1 (0.34)	0 (0.0)	0 (0.0)
		0 (0.00)	1 (4.76)	0 (0.00)	0 (0.00)
placenta					
Placenta, Discolored	Gross Finding	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.39)
		0 (0.00)	0 (0.00)	0 (0.00)	1 (5.00)
Placenta, Enlarged	Gross Finding	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.39)
		0 (0.00)	0 (0.00)	0 (0.00)	1 (5.00)
Placenta, Fused	Gross Finding	2 (0.34)	2 (0.67)	0 (0.0)	2 (0.77)
		1 (2.33)	1 (4.76)	0 (0.00)	1 (5.00)

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	0	162.5	325	650
Visceral				
No. Fetuses examined	599	299	270	259
No. Litters examined	44	21	21	20
abdomen				
Kidney, left, Accessory kidney without ureter	0 (0.0)	1 (0.33)	0 (0.0)	0 (0.0)
	0 (0.00)	1 (4.76)	0 (0.00)	0 (0.00)
Kidney, right, Agenesis	1 (0.17)	0 (0.0)	0 (0.0)	0 (0.0)
	1 (2.27)	0 (0.00)	0 (0.00)	0 (0.00)
Renal pelvis, right, Dilated	2 (0.33)	0 (0.0)	0 (0.0)	0 (0.0)
	2 (4.55)	0 (0.00)	0 (0.00)	0 (0.00)
general				
Abdomen, right side, Mass, encapsulated, discolored	1 (0.17)	0 (0.0)	0 (0.0)	0 (0.0)
	1 (2.27)	0 (0.00)	0 (0.00)	0 (0.00)
heart				
Ventricular septum, Septum defect	1 (0.17)	0 (0.0)	0 (0.0)	0 (0.0)
	1 (2.27)	0 (0.00)	0 (0.00)	0 (0.00)
pelvis				
Ureter, Distended, total	92 (15.36) ** #	35 (11.71)	14 (5.19) ** ##	24 (9.27) **
	30 (68.18)	15 (71.43)	5 (23.81) **	12 (60.00)
Ureter, Hydroureter, total	1 (0.17)	0 (0.0)	1 (0.37)	0 (0.0)
	1 (2.27)	0 (0.00)	1 (4.76)	0 (0.00)
Ureter, bilateral, Distended	47 (7.85) ** #	14 (4.68) *	7 (2.59) ** #	10 (3.86) *
	19 (43.18)	10 (47.62)	3 (14.29) *	6 (30.00)
Ureter, bilateral, Hydroureter	1 (0.17)	0 (0.0)	0 (0.0)	0 (0.0)
	1 (2.27)	0 (0.00)	0 (0.00)	0 (0.00)
Ureter, left, Distended	22 (3.67)	9 (3.01)	4 (1.48)	9 (3.47)
	16 (36.36)	8 (38.10)	3 (14.29)	7 (35.00)
Ureter, left, Hydroureter	0 (0.0)	0 (0.0)	1 (0.37)	0 (0.0)
	0 (0.00)	0 (0.00)	1 (4.76)	0 (0.00)
Ureter, right, Distended	23 (3.84) *	12 (4.01)	3 (1.11) * #	5 (1.93)

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	Classification	Treatment Groups (mg/kg/day)			
		0	162.5	325	650
		15 (34.09)	4 (19.05)	1 (4.76) **	4 (20.00)
thorax (excluding heart)					
Aorta, Malpositioned	Malformation	1 (0.17)	0 (0.0)	0 (0.0)	0 (0.0)
		1 (2.27)	0 (0.00)	0 (0.00)	0 (0.00)
Aortic arch, Agenesis	Malformation	1 (0.17)	1 (0.33)	0 (0.0)	0 (0.0)
		1 (2.27)	1 (4.76)	0 (0.00)	0 (0.00)
Ductus arteriosus, Agenesis	Malformation	1 (0.17)	0 (0.0)	0 (0.0)	0 (0.0)
		1 (2.27)	0 (0.00)	0 (0.00)	0 (0.00)
Innominate artery, Agenesis	Variation	9 (1.5)	2 (0.67)	1 (0.37)	4 (1.54)
		7 (15.91)	2 (9.52)	1 (4.76)	4 (20.00)
Lung, left lobe, Small	Malformation	1 (0.17)	0 (0.0)	0 (0.0)	0 (0.0)
		1 (2.27)	0 (0.00)	0 (0.00)	0 (0.00)
	Head				
No. Fetuses examined		299	148	138	121
No. Litters examined		44	21	21	18
eyes					
Eye, bilateral, Anophthalmia	Malformation	0 (0.0)	1 (0.68)	0 (0.0)	0 (0.0)
		0 (0.00)	1 (4.76)	0 (0.00)	0 (0.00)
Retina, bilateral, Folded	Malformation	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.83)
		0 (0.00)	0 (0.00)	0 (0.00)	1 (5.56)
head					
Lateral ventricle, left, Enlarged half	Variation	0 (0.0)	1 (0.68)	0 (0.0)	0 (0.0)
		0 (0.00)	1 (4.76)	0 (0.00)	0 (0.00)
Nasal sinus, Enlarged, total	Malformation	1 (0.33)	1 (0.68)	1 (0.72)	0 (0.0)
		1 (2.27)	1 (4.76)	1 (4.76)	0 (0.00)
Nasal sinus, bilateral, Enlarged	Malformation	0 (0.0)	1 (0.68)	0 (0.0)	0 (0.0)
		0 (0.00)	1 (4.76)	0 (0.00)	0 (0.00)
Nasal sinus, left, Enlarged	Malformation	1 (0.33)	0 (0.0)	1 (0.72)	0 (0.0)
		1 (2.27)	0 (0.00)	1 (4.76)	0 (0.00)

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	Classification	Treatment Groups (mg/kg/day)			
		0	162.5	325	650
Skeletal - Body					
No. Fetuses examined		599	300	270	259
No. Litters examined		44	21	21	20
ribs					
Rib cartilage, Discontinuous	Malformation	0 (0.0)	1 (0.33)	0 (0.0)	0 (0.0)
		0 (0.00)	1 (4.76)	0 (0.00)	0 (0.00)
Rib cartilage, VIII attached to sternum	Malformation	1 (0.17)	0 (0.0)	0 (0.0)	0 (0.0)
		1 (2.27)	0 (0.00)	0 (0.00)	0 (0.00)
Rib, Discontinuous	Malformation	1 (0.17)	0 (0.0)	0 (0.0)	0 (0.0)
		1 (2.27)	0 (0.00)	0 (0.00)	0 (0.00)
Rib, Floating extra	Variation	0 (0.0)	0 (0.0)	1 (0.37)	0 (0.0)
		0 (0.00)	0 (0.00)	1 (4.76)	0 (0.00)
Rib, Lumbar I full	Malformation	4 (0.67)	4 (1.33)	2 (0.74)	3 (1.16)
		4 (9.09)	3 (14.29)	1 (4.76)	2 (10.00)
Rib, Lumbar I rudimentary	Variation	82 (13.69) ** #	65 (21.67) **	61 (22.59) ** #	56 (21.62) **
		29 (65.91)	17 (80.95)	17 (80.95)	15 (75.00)
Rib, left, Intercostal rib	Malformation	1 (0.17)	0 (0.0)	0 (0.0)	0 (0.0)
		1 (2.27)	0 (0.00)	0 (0.00)	0 (0.00)
sternebrae					
Sternebra II, Incomplete ossification	Variation	1 (0.17)	0 (0.0)	0 (0.0)	0 (0.0)
		1 (2.27)	0 (0.00)	0 (0.00)	0 (0.00)
Sternebra V, Incomplete ossification	Variation	2 (0.33)	1 (0.33)	4 (1.48)	0 (0.0)
		2 (4.55)	1 (4.76)	3 (14.29)	0 (0.00)
Sternebra(e), Extra ossification site between sternebrae	Variation	3 (0.5)	1 (0.33)	0 (0.0)	0 (0.0)
		2 (4.55)	1 (4.76)	0 (0.00)	0 (0.00)
Sternebra(e), Incomplete ossification, total	Variation	3 (0.5)	1 (0.33)	4 (1.48)	0 (0.0)
		3 (6.82)	1 (4.76)	3 (14.29)	0 (0.00)
Sternebra(e), Misaligned (>2, not V)	Variation	1 (0.17)	0 (0.0)	0 (0.0)	0 (0.0)
		1 (2.27)	0 (0.00)	0 (0.00)	0 (0.00)
thoracic vertebrae					

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Thoracic centrum cartilage, Normal ossification, Dumbbell cartilage	Variation	0 (0.0)	1 (0.33)	0 (0.0)	0 (0.0)
		0 (0.00)	1 (4.76)	0 (0.00)	0 (0.00)
Thoracic centrum, Bipartite ossification, Bipartite cartilage	Malformation	1 (0.17)	0 (0.0)	0 (0.0)	0 (0.0)
		1 (2.27)	0 (0.00)	0 (0.00)	0 (0.00)
Thoracic centrum, Bipartite ossification, Dumbbell cartilage	Variation	1 (0.17)	0 (0.0)	2 (0.74)	1 (0.39)
		1 (2.27)	0 (0.00)	2 (9.52)	1 (5.00)
Thoracic centrum, Bipartite ossification, Normal cartilage	Variation	2 (0.33)	3 (1.0)	1 (0.37)	1 (0.39)
		2 (4.55)	2 (9.52)	1 (4.76)	1 (5.00)
Thoracic centrum, Bipartite ossification, Normal or Dumbbell cartilage	Variation	3 (0.5)	3 (1.0)	3 (1.11)	2 (0.77)
		3 (6.82)	2 (9.52)	3 (14.29)	1 (5.00)
Thoracic centrum, Dumbbell ossification, Dumbbell cartilage	Variation	3 (0.5)	1 (0.33)	2 (0.74)	2 (0.77)
		2 (4.55)	1 (4.76)	2 (9.52)	2 (10.00)
Thoracic centrum, Dumbbell ossification, Normal cartilage	Variation	7 (1.17)	4 (1.33)	4 (1.48)	7 (2.7)
		6 (13.64)	3 (14.29)	4 (19.05)	3 (15.00)
Thoracic centrum, Dumbbell ossification, Normal or Dumbbell cartilage	Variation	10 (1.67)	5 (1.67)	6 (2.22)	9 (3.47)
		8 (18.18)	4 (19.05)	5 (23.81)	4 (20.00)
Thoracic centrum, Fused	Malformation	1 (0.17)	0 (0.0)	0 (0.0)	0 (0.0)
		1 (2.27)	0 (0.00)	0 (0.00)	0 (0.00)
Thoracic centrum, Unilateral ossification, Bipartite cartilage	Malformation	1 (0.17)	0 (0.0)	0 (0.0)	0 (0.0)
		1 (2.27)	0 (0.00)	0 (0.00)	0 (0.00)
Thoracic centrum, Unossified, Bipartite cartilage	Malformation	1 (0.17)	0 (0.0)	0 (0.0)	0 (0.0)
		1 (2.27)	0 (0.00)	0 (0.00)	0 (0.00)
Skeletal - Skull					
No. Fetuses examined		300	152	132	132
No. Litters examined		44	21	21	20
skull					
Interparietal, Incomplete ossification	Variation	1 (0.33)	0 (0.0)	0 (0.0)	0 (0.0)
		1 (2.27)	0 (0.00)	0 (0.00)	0 (0.00)

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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 $P \leq 0.05$

** Statistically significant at $P \leq 0.01$

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 $P \leq 0.05$ (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

**** END OF REPORT ****