

Study Number: I20263

Test Type: TOX

Route: Dosing in Feed

Species/Strain: Rat/Harlan Sprague Dawley

Study Number:

I20263

Study Gender:

Both

PWG Approval Date:

See web page for date of PWG Approval

Version:

v1.3.2

Stat Version:

v2.7.2A

PA46s: Summary of Gross Pathology

Test Compound: Tris (chloropropyl) phosphate

CAS Number: 13674-84-5

Date Report Requested: 09/15/2021

Time Report Requested: 14:35:28

Lab: Burleson Research Technologies

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Lab: Burleson Research Technologies

F0 Female

Treatment Groups (ppm)

	0	2500	5000	10000
Disposition Summary				
Animals Initially In Study	30	30	30	30
Censored				
Early Deaths				
Sacrificed, Moribund		1		2
Survivors				
Scheduled Sacrifice, Terminal	30	29	30	28
Number of Animals Examined		1	1	2

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

None

HEMATOLYMPHOID SYSTEM

None

INTEGUMENTARY SYSTEM

None

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F0 Female

Treatment Groups (ppm)

0

2500

5000

10000

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

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Lab: Burleson Research Technologies

F1 Male: KLH

Treatment Groups (ppm)

	0	2500	5000	10000	15 mg/kg CPS
Disposition Summary					
Animals Initially In Study	12	12	12	11	8
Censored				1	
Early Deaths					
Survivors					
Scheduled Sacrifice, Terminal	12	12	12	10	8
Number of Animals Examined				1	

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

None

HEMATOLYMPHOID SYSTEM

None

INTEGUMENTARY SYSTEM

None

MUSCULOSKELETAL SYSTEM

None

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Lab: Burleson Research Technologies

F1 Male: KLH

Treatment Groups (ppm)

0

2500

5000

10000

15 mg/kg CPS

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

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F1 Female: KLH

Treatment Groups (ppm)

	0	2500	5000	10000	15 mg/kg CPS
Disposition Summary					
Animals Initially In Study	12	12	12	12	8
Censored					
Early Deaths					
Survivors					
Scheduled Sacrifice, Terminal	12	12	12	12	8
Number of Animals Examined					

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

None

HEMATOLYMPHOID SYSTEM

None

INTEGUMENTARY SYSTEM

None

MUSCULOSKELETAL SYSTEM

None

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F1 Female: KLH

Treatment Groups (ppm)

0

2500

5000

10000

15 mg/kg CPS

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

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Lab: Burleson Research Technologies

F1 Male: CTL

Treatment Groups (ppm)

	0	2500	5000	10000	15 mg/kg CPS
Disposition Summary					
Animals Initially In Study	12	12	12	12	8
Censored					
Early Deaths					
Sacrificed, Moribund		1			
Survivors					
Scheduled Sacrifice, Terminal	12	11	12	12	8
Number of Animals Examined	12	12	12	12	8

ALIMENTARY SYSTEM

LIVER	(12)	(12)	(12)	(12)	(0)
DISCOLORATION; MILD, YELLOW		1 (8.3%)			
ENLARGED		1 (8.3%)			
SOFT		1 (8.3%)			

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

CARCASS	(12)	(12)	(12)	(12)	(0)
THIN		1 (8.3%)			

GENITAL SYSTEM

None

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F1 Male: CTL

Treatment Groups (ppm)

	0	2500	5000	10000	15 mg/kg CPS
HEMATOLYMPHOID SYSTEM					
SPLEEN	(0)	(0)	(0)	(0)	(8)
SMALL; MODERATE	0				8 (100.0%) **
THYMUS	(0)	(0)	(0)	(0)	(8)
SMALL; MARKED	0				8 (100.0%) **
INTEGUMENTARY SYSTEM					
None					
MUSCULOSKELETAL SYSTEM					
None					
NERVOUS SYSTEM					
None					
RESPIRATORY SYSTEM					
None					
SPECIAL SENSES SYSTEM					
None					
URINARY SYSTEM					
None					

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Lab: Burlison Research Technologies

F1 Female: CTL

Treatment Groups (ppm)

	0	2500	5000	10000	15 mg/kg CPS
Disposition Summary					
Animals Initially In Study	12	12	12	12	8
Censored			1		
Early Deaths					
Survivors					
Scheduled Sacrifice, Terminal	12	12	11	12	8
Number of Animals Examined	6	6	6	6	4
ALIMENTARY SYSTEM					
LIVER	(6)	(6)	(6)	(6)	(0)
MALFORMATION			1 (16.7%)		
CARDIOVASCULAR SYSTEM					
None					
ENDOCRINE SYSTEM					
None					
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
None					
HEMATOLYMPHOID SYSTEM					
SPLEEN	(0)	(0)	(0)	(0)	(4)
SMALL; MODERATE	0				4 (100.0%) **
THYMUS	(0)	(0)	(0)	(0)	(4)
SMALL; MARKED	0				4 (100.0%) **

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F1 Female: CTL

Treatment Groups (ppm)

0

2500

5000

10000

15 mg/kg CPS

INTEGUMENTARY SYSTEM

None

MUSCULOSKELETAL SYSTEM

DIAPHRAGM

(6)

(6)

(6)

(6)

(0)

DEFORMITY

1 (16.7%)

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

LUNG

(6)

(6)

(6)

(6)

(0)

SMALL

1 (16.7%)

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

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Lab: Burlison Research Technologies

F1 Male: Immunopath

Treatment Groups (ppm)

	0	2500	5000	10000	15 mg/kg CPS
Disposition Summary					
Animals Initially In Study	12	12	12	11	8
Censored					
Early Deaths					
Survivors					
Scheduled Sacrifice, Terminal	12	12	12	11	8
Number of Animals Examined	12	12	12	11	8
ALIMENTARY SYSTEM					
LIVER	(12)	(12)	(12)	(11)	(8)
DEFORMITY	8 (66.7%)	10 (83.3%)	9 (75.0%)	7 (63.6%)	4 (50.0%)
ENLARGED; MODERATE				1 (9.1%)	
MALFORMATION	2 (16.7%)	8 (66.7%) *	6 (50.0%)	6 (54.5%)	4 (50.0%)
SMALL; MILD		2 (16.7%)	1 (8.3%)		
CARDIOVASCULAR SYSTEM					
None					
ENDOCRINE SYSTEM					
None					
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
TESTIS, RIGHT	(0)	(0)	(0)	(0)	(8)
ADHESION	0				3 (37.5%) *
DISCOLORATION; MILD, RED					1 (12.5%)

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Lab: Burlison Research Technologies

F1 Male: Immunopath

Treatment Groups (ppm)

	0	2500	5000	10000	15 mg/kg CPS
HEMATOLYMPHOID SYSTEM					
LYMPH NODE, POPLITEAL	(12)	(12)	(12)	(11)	(8)
PIGMENTATION; BLACK, MILD	5 (41.7%)	9 (75.0%)	6 (50.0%)	1 (9.1%)	
PIGMENTATION; BLACK, MINIMAL	7 (58.3%)	4 (33.3%)	1 (8.3%)	4 (36.4%)	
PIGMENTATION; BLACK, MODERATE	6 (50.0%)	2 (16.7%)		4 (36.4%)	
SPLEEN	(12)	(12)	(12)	(11)	(8)
ENLARGED; MILD	1 (8.3%)				
NODULE; RED			1 (8.3%)	1 (9.1%)	1 (12.5%)
SMALL; MARKED					2 (25.0%)
SMALL; MILD					1 (12.5%)
THYMUS	(0)	(0)	(0)	(0)	(8)
SMALL; MARKED	0				7 (87.5%) **
INTEGUMENTARY SYSTEM					
None					
MUSCULOSKELETAL SYSTEM					
BONE, FEMUR, LEFT	(0)	(0)	(0)	(0)	(8)
CALLUS; MODERATE					1 (12.5%)
NERVOUS SYSTEM					
None					
RESPIRATORY SYSTEM					
None					
SPECIAL SENSES SYSTEM					
None					

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Lab: Burlison Research Technologies

F1 Male: Immunopath

Treatment Groups (ppm)

	0	2500	5000	10000	15 mg/kg CPS
URINARY SYSTEM					
KIDNEY	(12)	(12)	(12)	(11)	(0)
DEFORMITY				1 (9.1%)	
KIDNEY, RIGHT	(12)	(12)	(12)	(11)	(0)
DEFORMITY				1 (9.1%)	
URINARY BLADDER	(12)	(12)	(12)	(11)	(0)
ENLARGED; MILD				1 (9.1%)	

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F1 Female: Immunopath

Treatment Groups (ppm)

	0	2500	5000	10000	15 mg/kg CPS
Disposition Summary					
Animals Initially In Study	12	12	12	11	8
Censored		1			
Early Deaths					
Survivors					
Scheduled Sacrifice, Terminal	12	11	12	11	8
Number of Animals Examined	12	11	12	11	8

ALIMENTARY SYSTEM

LIVER	(12)	(11)	(12)	(11)	(8)
DEFORMITY	9 (75.0%)	4 (36.4%)	6 (50.0%)	7 (63.6%)	6 (75.0%)
ENLARGED; MILD		1 (9.1%)			
MALFORMATION	7 (58.3%)	9 (81.8%)	6 (50.0%)	4 (36.4%)	7 (87.5%)
NODULE; DARK					1 (12.5%)
NODULE; FIRM	1 (8.3%)				
NODULE			1 (8.3%)		
SMALL; MILD	1 (8.3%)				4 (50.0%)

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

ADRENAL GLAND, RIGHT	(12)	(11)	(12)	(11)	(8)
SMALL; MARKED	1 (8.3%)				

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

None

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F1 Female: Immunopath

Treatment Groups (ppm)

	0	2500	5000	10000	15 mg/kg CPS
HEMATOLYMPHOID SYSTEM					
LYMPH NODE, POPLITEAL	(12)	(11)	(12)	(11)	(8)
PIGMENTATION; BLACK, MILD	5 (41.7%)	5 (45.5%)	5 (41.7%)	2 (18.2%)	
PIGMENTATION; BLACK, MINIMAL	4 (33.3%)	1 (9.1%)	2 (16.7%)	5 (45.5%)	1 (12.5%)
PIGMENTATION; BLACK, MODERATE		3 (27.3%)	1 (8.3%)		
SPLEEN	(12)	(11)	(12)	(11)	(8)
ENLARGED; MILD		1 (9.1%)			
NODULE; RED				1 (9.1%)	1 (12.5%)
NODULE	1 (8.3%)		1 (8.3%)		
SMALL; MILD					1 (12.5%)
SMALL; MODERATE	0				4 (50.0%) *
THYMUS	(0)	(0)	(0)	(0)	(8)
SMALL; MARKED	0				6 (75.0%) **
SMALL; MODERATE					1 (12.5%)

INTEGUMENTARY SYSTEM

None

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

None

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Treatment Groups (ppm)

0

2500

5000

10000

15 mg/kg CPS

URINARY SYSTEM

None

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LEGEND

Censored animals are scheduled for sacrifice prior to the end of the study. The censored animals are included in the pathology data.

Number of animals examined for each tissue shown in parentheses. If none of the animals examined have the specific lesion then there is a blank for that dose group for that specific lesion. The exception to this is if statistical significance is found for a lesion and the control group has no animals with the lesion then a 0 is included for the control group on the table for that lesion.

Number (percent) of animals affected given for each observation

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

Statistical analysis for the positive control group compared to the vehicle control group was performed using the Fisher Exact test.

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

* Statistically significant at $P \leq 0.05$

** Statistically significant at $P \leq 0.01$

SXXX – General toxicity endpoints only are reported for this cohort. No immune function data reported due to study quality.

CPS = Cyclophosphamide

**** END OF REPORT ****