

Study Number: C15011B-01
Test Type: TOX
Route: Whole-Body Inhalation
Species/Strain: Rat/Harlan Sprague Dawley

PA10X: Statistical Analysis of Non-Neoplastic Lesions
Test Compound: 2-Ethyltoluene
CAS Number: 611-14-3

Date Report Requested: 03/17/2021
Time Report Requested: 05:57:37
Lab: Battelle

Study Number: C15011B-01
Study Gender: Both
PWG Approval Date: See web page for date of PWG Approval
Version: v1.1.8

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F0 Female

Treatment Groups (ppm)

	0	150	300	600	900	1200
Disposition Summary						
Animals Initially In Study	12	12	12	12	12	12
Censored			1	1	2	
Early Deaths						
Found Dead						4
Sacrificed, Moribund					4	8
Survivors						
Scheduled Sacrifice, Terminal	12	12	11	11	6	
Number Animals Examined Microscopically					2	10

ALIMENTARY SYSTEM

LIVER	(0)	(0)	(0)	(0)	(2)	(4)
CENTRIOBULAR; HEMORRHAGE					2 (100%)	4 (100%)
HEPATODIAPHRAGMATIC NODULE						1 (25%)
CENTRIOBULAR; NECROSIS					2 (100%)	4 (100%)
STOMACH, FORESTOMACH	(0)	(0)	(0)	(0)	(2)	(10)
HEMORRHAGE					2 (100%)	10 (100%)
ULCER; FOCAL						3 (30%)
ULCER; MULTIPLE						1 (10%)
STOMACH, GLANDULAR	(0)	(0)	(0)	(0)	(2)	(10)
EROSION; FOCAL						2 (20%)
HEMORRHAGE					1 (50%)	1 (10%)
ULCER; FOCAL						1 (10%)

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

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F0 Female

Treatment Groups (ppm)

0 150 300 600 900 1200

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

None

HEMATOLYMPHOID SYSTEM

LYMPH NODE, MESENTERIC

(0)

(0)

(0)

(0)

(0)

(1)

SINUS ERYTHROCYTOSIS

1 (100%)

INTEGUMENTARY SYSTEM

None

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

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F1 Male : F1 Biosample

	Treatment Groups (ppm)	
	0	600
Disposition Summary		
Animals Initially In Study	6	6
Censored		3
Early Deaths		
Found Dead		2
Sacrificed, Moribund		1
Survivors		
Scheduled Sacrifice, Terminal	6	
Number Animals Examined Microscopically		5
ALIMENTARY SYSTEM		
None		
CARDIOVASCULAR SYSTEM		
None		
ENDOCRINE SYSTEM		
None		
GENERAL BODY SYSTEM		
None		
GENITAL SYSTEM		
None		
HEMATOLYMPHOID SYSTEM		
THYMUS	(0)	(1)
EDEMA		1 (100%) [1]
HEMORRHAGE		1 (100%) [1]
LYMPHOCYTE; NECROSIS		1 (100%) [1]

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F1 Male : F1 Biosample

Treatment Groups (ppm)

0

600

INTEGUMENTARY SYSTEM

SKIN

EDEMA

(0)

(1)

1 (100%) [1]

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

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F1 Female : F1 Biosample

Treatment Groups (ppm)

0

600

Disposition Summary

Animals Initially In Study

6

6

Censored

2

Early Deaths

Found Dead

3

Sacrificed, Moribund

1

Survivors

Scheduled Sacrifice, Terminal

6

Number Animals Examined Microscopically

5

ALIMENTARY SYSTEM

STOMACH, FORESTOMACH

(0)

(1)

HEMORRHAGE

1 (100%) [1]

STOMACH, GLANDULAR

(0)

(4)

HEMORRHAGE

1 (25%) [1]

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

None

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F1 Female : F1 Biosample

Treatment Groups (ppm)

0

600

HEMATOLYMPHOID SYSTEM

LYMPH NODE, MESENTERIC

SINUS ERYTHROCYTOSIS

(0)

(1)

1 (100%) [1]

INTEGUMENTARY SYSTEM

None

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

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F1 Male : F1 Core

Treatment Groups (ppm)

	0	150	300	600
Disposition Summary				
Animals Initially In Study	8	8	8	8
Censored				4
Early Deaths				
Found Dead				3
Sacrificed, Moribund				1
Survivors				
Scheduled Sacrifice, Terminal	8	8	8	
Number Animals Examined Microscopically	8	8	8	8
ALIMENTARY SYSTEM				
LIVER	(8)	(1)	(8)	(8)
CENTRIOBULAR; HEMORRHAGE	0 *			3 (37.5%) [3]
HEPATODIAPHRAGMATIC NODULE		1 (100%) [1]		
CENTRIOBULAR; NECROSIS	0 **			7 (87.5%) [7] **
STOMACH, GLANDULAR	(0)	(0)	(0)	(5)
HEMORRHAGE				3 (60%) [3]
CARDIOVASCULAR SYSTEM				
None				
ENDOCRINE SYSTEM				
None				
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
None				

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F1 Male : F1 Core

Treatment Groups (ppm)

	0	150	300	600
HEMATOLYMPHOID SYSTEM				
None				
INTEGUMENTARY SYSTEM				
SKIN	(0)	(0)	(0)	(2)
HEMORRHAGE				1 (50%) [1]
MUSCULOSKELETAL SYSTEM				
None				
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
LUNG	(8)	(0)	(8)	(8)
ALVEOLUS; CRYSTALS	1 (12.5%) [1]			
ALVEOLUS; HEMORRHAGE			1 (12.5%) [1]	1 (12.5%) [1]
NOSE	(8)	(8)	(8)	(8)
OLFACTORY EPITHELIUM; ATROPHY; DIFFUSE	0	8 (100%) [8] **	8 (100%) [8] **	
ATROPHY; NEURONAL	0	8 (100%) [8] **	8 (100%) [8] **	
OLFACTORY EPITHELIUM; DEGENERATION; DIFFUSE	0 **			8 (100%) [8] **
SPECIAL SENSES SYSTEM				
None				
URINARY SYSTEM				
KIDNEY	(8)	(0)	(8)	(8)
PELVIS; DILATION			1 (12.5%) [1]	2 (25%) [2]
NEPHROPATHY	1 (12.5%) [1]		4 (50%) [4]	2 (25%) [2]

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F1 Female : F1 Core

Treatment Groups (ppm)

	0	150	300	600
Disposition Summary				
Animals Initially In Study	8	8	8	8
Censored				5
Early Deaths				
Found Dead				2
Sacrificed, Moribund				1
Survivors				
Scheduled Sacrifice, Terminal	8	8	8	
Number Animals Examined Microscopically	8	8	8	8
ALIMENTARY SYSTEM				
LIVER	(8)	(2)	(8)	(8)
CENTRIOBULAR; HEMORRHAGE	0 *			3 (37.5%) [3]
HEPATODIAPHRAGMATIC NODULE		2 (100%) [2]		
CENTRIOBULAR; NECROSIS	0 **			8 (100%) [8] **
STOMACH, GLANDULAR	(0)	(0)	(0)	(7)
HEMORRHAGE				3 (42.9%) [3]
CARDIOVASCULAR SYSTEM				
None				
ENDOCRINE SYSTEM				
None				
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
None				

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F1 Female : F1 Core

	Treatment Groups (ppm)			
	0	150	300	600
HEMATOLYMPHOID SYSTEM				
LYMPH NODE, MESENTERIC	(0)	(0)	(0)	(1)
SINUS ERYTHROCYTOSIS				1 (100%) [1]
THYMUS	(0)	(0)	(0)	(2)
NECROSIS				2 (100%) [2]
INTEGUMENTARY SYSTEM				
None				
MUSCULOSKELETAL SYSTEM				
None				
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
NOSE	(8)	(8)	(8)	(8)
OLFACTORY EPITHELIUM; ATROPHY; DIFFUSE	0	8 (100%) [8] **	8 (100%) [8] **	
ATROPHY; NEURONAL	0	8 (100%) [8] **	8 (100%) [8] **	
OLFACTORY EPITHELIUM; DEGENERATION; DIFFUSE	0 **			8 (100%) [8] **
SPECIAL SENSES SYSTEM				
None				
URINARY SYSTEM				
KIDNEY	(8)	(0)	(8)	(8)
PELVIS; LEFT; DILATION			1 (12.5%) [1]	
PELVIS; INFLAMMATION; ACUTE				1 (12.5%) [1]
NEPHROPATHY	2 (25%) [2]		4 (50%) [4]	1 (12.5%) [1]

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LEGEND

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 of animals with observation reported with percent incidence in parentheses

No statistical analysis was performed on the F0 or F1 Biosample animals.

Statistical analysis of F1 Core animals was performed by Cochran-Armitage (trend) and Fisher Exact (pairwise) tests.

Dose groups were excluded from trend and pairwise tests if only selected organs in the group were examined.

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

All trend and pairwise p-values are reported as one-sided.

* Statistically significant at $P \leq 0.05$

** Statistically significant at $P \leq 0.01$

**** END OF REPORT ****