

Study Number: C94043-03

Test Type: TOX

Route: Dosing in Water

Species/Strain: Rat/Harlan Sprague Dawley

PA10R: Statistical Analysis of Non-Neoplastic Lesions with Litter Incidence

Test Compound: Sodium Metavanadate

CAS Number: 13718-26-8

Date Report Requested: 02/14/2022

Time Report Requested: 06:23:17

Lab: Battelle with EPL

Study Number:

C94043-03

Study Gender:

Both

PWG Approval Date:

See web page for date of PWG Approval

Version:

v1.3.7

Stat Version:

S

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F1 Male : F1 Core Animals

Treatment Groups (mg/L)

0 31.3 62.5 125 250 500

Disposition Summary

Animals Initially In Study	10	10	10	10	10	13
Censored						
Early Deaths						
Sacrificed, Moribund						1
Survivors						
Scheduled Sacrifice, Terminal	10	10	10	10	10	12
Number Animals Examined Microscopically	10	10	10	10	10	13
Total number litters	10	10	10	10	10	4

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	Treatment Groups (mg/L)					
	0	31.3	62.5	125	250	500
ALIMENTARY SYSTEM						
INTESTINE, LARGE, CECUM	(10)	(10)	(10)	(10)	(10)	(13)
EPITHELIUM; HYPERPLASIA					2 (20%) [2]	1 (7.7%) [1]
EPITHELIUM; NECROSIS						1 (7.7%) [1]
INTESTINE, LARGE, RECTUM	(10)	(10)	(10)	(10)	(9)	(13)
EPITHELIUM; HYPERPLASIA						1 (7.7%) [1]
INTESTINE, SMALL, DUODENUM	(10)	(0)	(0)	(0)	(10)	(13)
EPITHELIUM; HYPERPLASIA						1 (7.7%) [1]
INTESTINE, SMALL, ILEUM	(10)	(10)	(9)	(9)	(10)	(13)
EPITHELIUM; HYPERPLASIA	0 **			5 (55.6%) [5] *	9 (90%) [9] **	12 (92.3%) [4] **
INTESTINE, SMALL, JEJUNUM	(10)	(0)	(10)	(10)	(10)	(13)
EPITHELIUM; HYPERPLASIA	0 **			1 (10%) [1]	6 (60%) [6] **	7 (53.8%) [4] **
LYMPHOID TISSUE; HYPERPLASIA						1 (7.7%) [1]
INTESTINE, SMALL: ANY SITE	(10)	(10)	(10)	(10)	(10)	(13)
EPITHELIUM, HYPERPLASIA	0 **			5 (50%) [5] *	9 (90%) [9] **	13 (100%) [4] **
INTESTINE: ANY SITE	(10)	(10)	(10)	(10)	(10)	(13)
EPITHELIUM, HYPERPLASIA	0 **			5 (50%) [5] *	9 (90%) [9] **	13 (100%) [4] **
PANCREAS	(10)	(0)	(0)	(0)	(0)	(13)
ACINUS; SECRETORY DEPLETION						1 (7.7%) [1]
STOMACH, GLANDULAR	(10)	(10)	(10)	(10)	(10)	(13)
EPITHELIUM; ATROPHY						1 (7.7%) [1]
MINERAL	3 (30%) [3]	4 (40%) [4]	6 (60%) [6]	5 (50%) [5]	3 (30%) [3]	9 (69.2%) [3]

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F1 Male : F1 Core Animals

	Treatment Groups (mg/L)					
	0	31.3	62.5	125	250	500
CARDIOVASCULAR SYSTEM						
HEART	(10)	(0)	(0)	(0)	(0)	(13)
VALVE; ANGIECTASIS						1 (7.7%) [1]
CARDIOMYOPATHY	2 (20%) [2]					
VALVE; HEMORRHAGE						1 (7.7%) [1]
EPICARDIUM; INFLAMMATION; CHRONIC						1 (7.7%) [1]
VALVE; INFLAMMATION; CHRONIC						1 (7.7%) [1]
ENDOCRINE SYSTEM						
ADRENAL GLAND	(10)	(0)	(0)	(0)	(0)	(13)
ACCESSORY ADRENOCORTICAL NODULE						1 (7.7%) [1]
CORTEX; CYTOPLASMIC VACUOLATION						1 (7.7%) [1]
PITUITARY GLAND	(10)	(0)	(0)	(0)	(0)	(13)
PARS DISTALIS; CYST	1 (10%) [1]					
PARS INTERMEDIA; CYST						1 (7.7%) [1]
THYROID GLAND	(10)	(0)	(0)	(0)	(0)	(13)
CYST	2 (20%) [2]					2 (15.4%) [2]
ECTOPIC TISSUE, THYMUS						1 (7.7%) [1]
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
PREPUTIAL GLAND	(10)	(0)	(0)	(0)	(0)	(13)
INFILTRATE, CELLULAR; LYMPHOCYTE						2 (15.4%) [1]
INFLAMMATION; CHRONIC-ACTIVE						1 (7.7%) [1]
TESTIS	(10)	(0)	(0)	(0)	(0)	(13)
GERMINAL EPITHELIUM; DEGENERATION	1 (10%) [1]					

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F1 Male : F1 Core Animals

	Treatment Groups (mg/L)					
	0	31.3	62.5	125	250	500
HEMATOLYMPHOID SYSTEM						
LYMPH NODE, MANDIBULAR	(10)	(0)	(0)	(0)	(0)	(13)
LYMPHOCYTE; APOPTOSIS						1 (7.7%) [1]
LYMPH NODE, MESENTERIC	(10)	(0)	(0)	(0)	(0)	(13)
HYPERPLASIA; LYMPHOCYTE	3 (30%) [3]					2 (15.4%) [2]
SPLEEN	(10)	(0)	(0)	(0)	(0)	(13)
ATROPHY						1 (7.7%) [1]
HYPERPLASIA; LYMPHOCYTE						2 (15.4%) [2]
THYMUS	(10)	(0)	(0)	(0)	(0)	(13)
LYMPHOCYTE; APOPTOSIS						1 (7.7%) [1]
INTEGUMENTARY SYSTEM						
None						
MUSCULOSKELETAL SYSTEM						
None						
NERVOUS SYSTEM						
None						
RESPIRATORY SYSTEM						
None						
SPECIAL SENSES SYSTEM						
HARDERIAN GLAND	(10)	(0)	(0)	(0)	(0)	(13)
ATROPHY	1 (10%) [1]					
INFILTRATE, CELLULAR; LYMPHOCYTE	3 (30%) [3]					3 (23.1%) [2]

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Treatment Groups (mg/L)

	0	31.3	62.5	125	250	500
URINARY SYSTEM						
KIDNEY	(10)	(10)	(10)	(10)	(10)	(13)
UROTHELIUM; ANGIECTASIS		1 (10%) [1]				
CHRONIC PROGRESSIVE NEPHROPATHY	10 (100%) [10]	10 (100%) [10]	10 (100%) [10]	10 (100%) [10]	10 (100%) [10]	12 (92.3%) [4]
PELVIS; DILATION			1 (10%) [1]	1 (10%) [1]		1 (7.7%) [1]
RENAL TUBULE; PIGMENT						1 (7.7%) [1]

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F1 Female : F1 Core Animals

Treatment Groups (mg/L)

0 31.3 62.5 125 250 500

Disposition Summary

Animals Initially In Study	10	10	10	10	10	12
Censored						
Early Deaths						
Sacrificed, Moribund						2
Survivors						
Scheduled Sacrifice, Terminal	10	10	10	10	10	10
Number Animals Examined Microscopically	10	10	10	10	10	12
Total number litters	10	10	10	10	10	4

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F1 Female : F1 Core Animals

	Treatment Groups (mg/L)					
	0	31.3	62.5	125	250	500
ALIMENTARY SYSTEM						
INTESTINE, LARGE, CECUM	(10)	(0)	(0)	(10)	(10)	(12)
EPITHELIUM; HYPERPLASIA						2 (16.7%) [2]
EPITHELIUM; NECROSIS						1 (8.3%) [1]
INTESTINE, LARGE, COLON	(10)	(0)	(0)	(10)	(10)	(12)
EPITHELIUM; HYPERPLASIA						2 (16.7%) [2]
INTESTINE, LARGE, RECTUM	(10)	(0)	(0)	(10)	(10)	(12)
EPITHELIUM; HYPERPLASIA						1 (8.3%) [1]
INTESTINE, SMALL, ILEUM	(9)	(0)	(10)	(10)	(10)	(12)
EPITHELIUM; HYPERPLASIA	0 **			4 (40%) [4]	9 (90%) [9] **	12 (100%) [4] **
INTESTINE, SMALL, JEJUNUM	(10)	(0)	(0)	(10)	(10)	(12)
EPITHELIUM; HYPERPLASIA	0 **			1 (10%) [1]		6 (50%) [4] *
INTESTINE, SMALL: ANY SITE	(10)	(0)	(10)	(10)	(10)	(12)
EPITHELIUM, HYPERPLASIA	0 **			4 (40%) [4] *	9 (90%) [9] **	12 (100%) [4] **
INTESTINE: ANY SITE	(10)	(0)	(10)	(10)	(10)	(12)
EPITHELIUM, HYPERPLASIA	0 **			4 (40%) [4] *	9 (90%) [9] **	12 (100%) [4] **
LIVER	(10)	(0)	(0)	(0)	(0)	(12)
HEPATOCYTE; VACUOLATION						1 (8.3%) [1]
SALIVARY GLANDS	(10)	(0)	(0)	(0)	(0)	(12)
PAROTID GLAND; BASOPHILIC FOCUS; MULTIPLE						1 (8.3%) [1]
SUBMANDIBULAR GLAND; SECRETORY DEPLETION						1 (8.3%) [1]
STOMACH, GLANDULAR	(10)	(0)	(0)	(10)	(10)	(12)
EPITHELIUM; ATROPHY						1 (8.3%) [1]
MINERAL	1 (10%) [1]				5 (50%) [5]	3 (25%) [3]
CARDIOVASCULAR SYSTEM						
None						

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F1 Female : F1 Core Animals

	Treatment Groups (mg/L)					
	0	31.3	62.5	125	250	500
ENDOCRINE SYSTEM						
ADRENAL GLAND	(10)	(0)	(0)	(0)	(0)	(12)
ACCESSORY ADRENOCORTICAL NODULE						1 (8.3%) [1]
THYROID GLAND	(10)	(0)	(0)	(0)	(0)	(12)
CYST						1 (8.3%) [1]
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
CLITORAL GLAND	(10)	(0)	(0)	(0)	(0)	(12)
DUCT; DILATION						1 (8.3%) [1]
INFILTRATE, CELLULAR; LYMPHOCYTE						2 (16.7%) [2]
INFLAMMATION; CHRONIC-ACTIVE						1 (8.3%) [1]
UTERUS	(10)	(0)	(0)	(1)	(0)	(12)
ENDOMETRIUM; HYPERPLASIA; CYSTIC						1 (8.3%) [1]
HEMATOLYMPHOID SYSTEM						
BONE MARROW	(10)	(0)	(0)	(0)	(0)	(12)
HYPOCELLULARITY						2 (16.7%) [2]
LYMPH NODE, MANDIBULAR	(10)	(0)	(0)	(0)	(0)	(12)
ATROPHY						2 (16.7%) [2]
LYMPH NODE, MESENTERIC	(10)	(0)	(0)	(0)	(0)	(11)
HYPERPLASIA; LYMPHOCYTE						2 (18.2%) [1]
SPLEEN	(10)	(0)	(0)	(0)	(0)	(12)
ATROPHY						2 (16.7%) [2]
THYMUS	(10)	(0)	(0)	(0)	(0)	(12)
ATROPHY						2 (16.7%) [2]

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Treatment Groups (mg/L)

0 31.3 62.5 125 250 500

INTEGUMENTARY SYSTEM

None

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

LUNG	(10)	(0)	(0)	(0)	(0)	(12)
INFILTRATE, CELLULAR; HISTIOCYTE	1 (10%) [1]					

SPECIAL SENSES SYSTEM

HARDERIAN GLAND	(10)	(0)	(0)	(0)	(0)	(12)
INFILTRATE, CELLULAR; LYMPHOCYTE	1 (10%) [1]					

URINARY SYSTEM

KIDNEY	(10)	(10)	(10)	(10)	(10)	(12)
CHRONIC PROGRESSIVE NEPHROPATHY	5 (50%) [5] *	5 (50%) [5]	3 (30%) [3]	8 (80%) [8]	4 (40%) [4]	10 (83.3%) [4]
METAPLASIA; OSSEOUS			1 (10%) [1]			
NEPHROBLASTOMATOSIS		1 (10%) [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

Number of litters with observations shown in square brackets for F1 animals. F1 litter incidence based on the number of F0 dams.

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

For some animals in the middle dose groups, an organ was analyzed only after a gross lesion was detected. These findings were not analyzed statistically against the control group.

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 $P \leq 0.01$

The 500 mg/L group for the F1 Core animals contained multiple animals per litter, but all other groups contained only one animal per sex per litter. Litter-based methods were not used in the analysis of the F1 Core animals.

**** END OF REPORT ****