

Study Number: C08004-03

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: Vanadyl sulfate

CAS Number: 27774-13-6

Date Report Requested: 02/14/2022

Time Report Requested: 06:14:20

Lab: Battelle with EPL

Study Number:

C08004-03

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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Species/Strain: Rat/Harlan Sprague Dawley

F1 Male : F1 Core Animals

	Treatment Groups (mg/L)					
	0	21.0	41.9	83.8	168	335
Disposition Summary						
Animals Initially In Study	10	10	10	10	10	10
Censored						
Early Deaths						
Survivors						
Scheduled Sacrifice, Terminal	10	10	10	10	10	10
Number Animals Examined Microscopically	10			3	10	10
Total number litters	10			3	10	10
ALIMENTARY SYSTEM						
INTESTINE, LARGE, CECUM EPITHELIUM; HYPERPLASIA	(10) 0 *	(0)	(0)	(0)	(10)	(10) 4 (40%) [4] *
INTESTINE, LARGE, RECTUM HYPERPLASIA; LYMPHOCYTE	(10)	(0)	(0)	(3) 1 (33.3%) [1]	(0)	(10)
INTESTINE, SMALL, ILEUM EPITHELIUM; HYPERPLASIA	(10) 0 **	(0)	(0)	(0)	(10) 3 (30%) [3]	(10) 9 (90%) [9] **
INTESTINE, SMALL, JEJUNUM MINERAL	(10)	(0)	(0)	(0)	(0)	(10) 1 (10%) [1]
INTESTINE, SMALL: ANY SITE EPITHELIUM, HYPERPLASIA	(10) 0 **	(0)	(0)	(0)	(10) 3 (30%) [3]	(10) 9 (90%) [9] **
INTESTINE: ANY SITE EPITHELIUM, HYPERPLASIA	(10) 0 **	(0)	(0)	(3)	(10) 3 (30%) [3]	(10) 9 (90%) [9] **
LIVER HEPATODIAPHRAGMATIC NODULE	(10) 1 (10%) [1]	(0)	(0)	(0)	(1) 1 (100%) [1]	(10)
INFILTRATION, CELLULAR; MONONUCLEAR CELL						1 (10%) [1]
STOMACH, GLANDULAR MINERAL	(10) 7 (70%) [7]	(0)	(0)	(0)	(0)	(10) 6 (60%) [6]

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	0	21.0	41.9	83.8	168	335
CARDIOVASCULAR SYSTEM						
HEART	(10)	(0)	(0)	(0)	(0)	(10)
CARDIOMYOPATHY	1 (10%) [1]					
ENDOCRINE SYSTEM						
ADRENAL GLAND	(10)	(0)	(0)	(0)	(0)	(10)
CORTEX; CYTOPLASMIC VACUOLATION						1 (10%) [1]
CORTEX; HYPERTROPHY; FOCAL						1 (10%) [1]
THYROID GLAND	(10)	(0)	(0)	(0)	(0)	(10)
THYMUS; ECTOPIC TISSUE	1 (10%) [1]					1 (10%) [1]
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
PREPUTIAL GLAND	(10)	(0)	(0)	(0)	(0)	(10)
INFLAMMATION; CHRONIC-ACTIVE	3 (30%) [3]					2 (20%) [2]
SEMINAL VESICLE	(10)	(0)	(0)	(0)	(0)	(10)
SECRETORY DEPLETION						1 (10%) [1]
HEMATOLYMPHOID SYSTEM						
LYMPH NODE, MANDIBULAR	(10)	(0)	(0)	(0)	(0)	(10)
FOLLICLES; LYMPHOCYTE; HYPERPLASIA						1 (10%) [1]
INTEGUMENTARY SYSTEM						
None						
MUSCULOSKELETAL SYSTEM						
None						

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Treatment Groups (mg/L)

0 21.0 41.9 83.8 168 335

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

LUNG	(10)	(0)	(0)	(0)	(0)	(9)
EOSINOHLIC CRYSTAL(S)						1 (11.1%) [1]
EPITHELIUM; ALVEOLUS; HYPERPLASIA						2 (22.2%) [2]
ALVEOLUS; INFILTRATION, CELLULAR; HISTIOCYTE						1 (11.1%) [1]
INFLAMMATION; CHRONIC-ACTIVE						1 (11.1%) [1]

SPECIAL SENSES SYSTEM

HARDERIAN GLAND	(10)	(0)	(0)	(0)	(0)	(10)
INFILTRATION, CELLULAR; MONONUCLEAR CELL	1 (10%) [1]					1 (10%) [1]

URINARY SYSTEM

KIDNEY	(10)	(0)	(0)	(0)	(0)	(10)
CHRONIC PROGRESSIVE NEPHROPATHY	10 (100%) [10]					10 (100%) [10]

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F1 Female : F1 Core Animals

	Treatment Groups (mg/L)					
	0	21.0	41.9	83.8	168	335
Disposition Summary						
Animals Initially In Study	10	10	10	10	10	10
Censored						
Early Deaths						
Survivors						
Scheduled Sacrifice, Terminal	10	10	10	10	10	10
Number Animals Examined Microscopically	10		10	10	10	10
Total number litters	10		10	10	10	10
ALIMENTARY SYSTEM						
INTESTINE, LARGE, CECUM EPITHELIUM; HYPERPLASIA	(10) 0 *	(0)	(0)	(0)	(10)	(10) 4 (40%) [4] *
INTESTINE, LARGE, RECTUM HYPERPLASIA; LYMPHOCYTE	(10)	(0)	(0)	(0)	(1) 1 (100%) [1]	(10)
INTESTINE, SMALL, ILEUM EPITHELIUM; HYPERPLASIA	(10) 0 **	(0)	(10)	(10)	(10) 4 (40%) [4] *	(10) 9 (90%) [9] **
INTESTINE, SMALL: ANY SITE EPITHELIUM, HYPERPLASIA	(10) 0 **	(0)	(10)	(10)	(10) 4 (40%) [4] *	(10) 9 (90%) [9] **
INTESTINE: ANY SITE EPITHELIUM, HYPERPLASIA	(10) 0 **	(0)	(10)	(10)	(10) 4 (40%) [4] *	(10) 10 (100%) [10] **
STOMACH, GLANDULAR MINERAL	(10) 4 (40%) [4]	(0)	(0)	(0)	(0)	(10) 1 (10%) [1]
CARDIOVASCULAR SYSTEM						
None						
ENDOCRINE SYSTEM						
THYROID GLAND THYMUS; ECTOPIC TISSUE	(9)	(0)	(0)	(0)	(0)	(10) 1 (10%) [1]

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Treatment Groups (mg/L)

0 21.0 41.9 83.8 168 335

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

CLITORAL GLAND

(10) (0) (0) (0) (0) (9)

DUCT; DILATION

1 (10%) [1] 1 (11.1%) [1]

INFILTRATION, CELLULAR; MONONUCLEAR CELL

3 (30%) [3] 2 (22.2%) [2]

HEMATOLYMPHOID SYSTEM

None

INTEGUMENTARY SYSTEM

None

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

LUNG

(10) (0) (0) (0) (0) (10)

ALVEOLUS; INFILTRATION, CELLULAR; HISTIOCYTE

1 (10%) [1] 2 (20%) [2]

SPECIAL SENSES SYSTEM

HARDERIAN GLAND

(10) (0) (0) (0) (0) (10)

INFILTRATION, CELLULAR; MONONUCLEAR CELL

2 (20%) [2]

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0

21.0

41.9

83.8

168

335

URINARY SYSTEM

KIDNEY	(10)	(0)	(0)	(0)	(0)	(10)
CHRONIC PROGRESSIVE NEPHROPATHY	5 (50%) [5]					7 (70%) [7]
CORTEX; CYST	1 (10%) [1]					
INFLAMMATION; CHRONIC	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 $P \leq 0.01$

**** END OF REPORT ****