

Study Number: I99067

Test Type: TOX

Route: Oral Gavage

Species/Strain: Rat/Harlan Sprague Dawley

Study Number:

Study Gender:

PWG Approval Date:

Version:

Stat Version:

PA10 Subchronic: Statistical Analysis of Non-Neoplastic Lesions

Test Compound: Echinacea purpurea root extract

CAS Number: 90028-20-9

Final

I99067

Female

See web page for date of PWG Approval

v1.7.0

2023.04.04S

Date Report Requested: 08/26/2024

Time Report Requested: 16:38:04

Lab: BRT with CRL

Study Number: I99067

Test Type: TOX

Route: Oral Gavage

Species/Strain: Rat/Harlan Sprague Dawley

PA10 Subchronic: Statistical Analysis of Non-Neoplastic Lesions

Test Compound: Echinacea purpurea root extract

CAS Number: 90028-20-9

Final

Date Report Requested: 08/26/2024

Time Report Requested: 16:38:04

Lab: BRT with CRL

Female : Immunopath

Treatment Groups (mg/kg)

	0	125	250	500	1000	2000
Disposition Summary						
Animals Initially In Study	12	12	12	12	12	12
Censored				1		
Early Deaths						
Survivors						
Scheduled Sacrifice, Terminal	12	12	12	11	12	12
Number Animals Examined Microscopically	12	12	12	11	12	12

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

ADRENAL GLAND	(12)	(12)	(12)	(11)	(12)	(12)
ACCESSORY ADRENOCORTICAL NODULE	2 (16.7%)	2 (16.7%)	4 (33.3%)	3 (27.3%)	2 (16.7%)	3 (25%)
CORTEX; HYPERPLASIA; FOCAL			2 (16.7%)			
CORTEX; HYPERTROPHY; FOCAL		2 (16.7%)				1 (8.3%)
CORTEX; VACUOLATION; CYTOPLASMIC, FOCAL						1 (8.3%)

GENERAL BODY SYSTEM

None

HEMATOPOIETIC SYSTEM

None

Study Number: I99067

Test Type: TOX

Route: Oral Gavage

Species/Strain: Rat/Harlan Sprague Dawley

PA10 Subchronic: Statistical Analysis of Non-Neoplastic Lesions

Test Compound: Echinacea purpurea root extract

CAS Number: 90028-20-9

Final

Date Report Requested: 08/26/2024

Time Report Requested: 16:38:04

Lab: BRT with CRL

Female : Immunopath

	Treatment Groups (mg/kg)					
	0	125	250	500	1000	2000
HEPATOBIILIARY SYSTEM						
LIVER	(12)	(12)	(12)	(11)	(12)	(12)
BILE DUCT; HYPERPLASIA	2 (16.7%)	2 (16.7%)				1 (8.3%)
INFLAMMATION; FOCAL	6 (50%)	3 (25%)	1 (8.3%)	5 (45.5%)	6 (50%)	3 (25%)
IMMUNE SYSTEM						
LYMPH NODE, MESENTERIC	(12)	(12)	(12)	(11)	(12)	(12)
CORTEX, GERMINAL CENTER; INCREASED NUMBER		1 (8.3%)	1 (8.3%)	1 (9.1%)		1 (8.3%)
LYMPH NODE, POPLITEAL	(7)	(12)	(12)	(11)	(12)	(11)
CORTEX, GERMINAL CENTER; INCREASED NUMBER			1 (8.3%)	1 (9.1%)		
SPLEEN	(12)	(12)	(12)	(11)	(11)	(11)
FOLLICLE; APOPTOSIS; INCREASED	1 (8.3%)					
FOLLICLE, GERMINAL CENTER; INCREASED NUMBER			1 (8.3%)	1 (9.1%)	1 (9.1%)	
THYMUS	(12)	(12)	(12)	(11)	(12)	(12)
CYST	1 (8.3%)			2 (18.2%)		
MEDULLA; INCREASED NUMBER; LYMPHOCYTE						1 (8.3%)
INTEGUMENTARY SYSTEM						
None						
MUSCULOSKELETAL SYSTEM						
None						
NERVOUS SYSTEM						
None						
REPRODUCTIVE SYSTEM						
None						

Study Number: I99067

Test Type: TOX

Route: Oral Gavage

Species/Strain: Rat/Harlan Sprague Dawley

PA10 Subchronic: Statistical Analysis of Non-Neoplastic Lesions

Test Compound: Echinacea purpurea root extract

CAS Number: 90028-20-9

Final

Date Report Requested: 08/26/2024

Time Report Requested: 16:38:04

Lab: BRT with CRL

Female : Immunopath

Treatment Groups (mg/kg)

	0	125	250	500	1000	2000
RESPIRATORY SYSTEM						
LUNG	(12)	(12)	(12)	(11)	(12)	(12)
BRONCHUS; FOREIGN MATERIAL	1 (8.3%)					
INFILTRATION CELLULAR; HISTIOCYTE	2 (16.7%)	1 (8.3%)	2 (16.7%)	2 (18.2%)		1 (8.3%)
INFLAMMATION; ACUTE	1 (8.3%)					1 (8.3%)
INFLAMMATION; CHRONIC					1 (8.3%)	
ARTERY; MINERAL	1 (8.3%)					
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
KIDNEY	(12)	(12)	(12)	(11)	(12)	(12)
CHRONIC PROGRESSIVE NEPHROPATHY	4 (33.3%)	2 (16.7%)	4 (33.3%)	1 (9.1%)	3 (25%)	4 (33.3%)
RENAL TUBULE; MINERAL	2 (16.7%)	1 (8.3%)	4 (33.3%)	3 (27.3%)	5 (41.7%)	4 (33.3%)

Study Number: I99067

Test Type: TOX

Route: Oral Gavage

Species/Strain: Rat/Harlan Sprague Dawley

PA10 Subchronic: Statistical Analysis of Non-Neoplastic Lesions

Test Compound: Echinacea purpurea root extract

CAS Number: 90028-20-9

Final

Date Report Requested: 08/26/2024

Time Report Requested: 16:38:04

Lab: BRT with CRL

LEGEND

In the rows with the tissue names, the number of animals examined for each tissue is shown in parentheses.

In the rows with the lesion names, the number of animals with observation are reported with percent incidence in parentheses. If none of the animals examined have the specific lesion, 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; in that case a 0 is included for the control group on the table for that lesion.

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

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 ****