

Study Number: I10353

Test Type: TOX

Route: Oral Gavage

Species/Strain: Mouse/B6C3F1/N

C Number:

Study Gender:

PWG Approval Date

PA10X: Statistical Analysis of Non-Neoplastic Lesions

Test Compound: Benzo(a)pyrene

CAS Number: 50-32-8

I10353

Female

See web page for date of PWG Approval

Date Report Requested: 06/12/2019

Time Report Requested: 12:30:07

Lab: BRT with ILS

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Treatment Groups (mg/kg)

	0	2	5	9	19	38	75	150
Disposition Summary								
Animals Initially In Study	8	8	8	8	8	8	8	8
Early Deaths								
Scheduled Deaths								
Scheduled sacrifice, terminal (SD 28)	8	8	8	8	8	8	8	8
Number of Animals Examined	8	8	8	8	8	8	8	8
ALIMENTARY SYSTEM								
ESOPHAGUS	(0)	(0)	(1)	(0)	(0)	(0)	(0)	(0)
INFLAMMATION; CHRONIC			1 (100%)					
CARDIOVASCULAR SYSTEM								
None								
ENDOCRINE SYSTEM								
ADRENAL GLAND	(8)	(8)	(8)	(8)	(8)	(8)	(8)	(8)
ACCESSORY ADRENOCORTICAL NODULE			1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	
SUBCAPSULAR; HYPERPLASIA	8 (100%)	8 (100%)	8 (100%)	8 (100%)	8 (100%)	8 (100%)	8 (100%)	7 (87.5%)
GENERAL BODY SYSTEM								
None								
GENITAL SYSTEM								
OVARY	(8)	(8)	(8)	(8)	(8)	(8)	(8)	(8)
CORPUS LUTEUM; DECREASED NUMBER	0 **						4 (50%) *	8 (100%) **

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HEMATOLYMPHOID SYSTEM

	0	2	5	9	19	38	75	150
LYMPH NODE, MESENTERIC	(8)	(8)	(8)	(8)	(8)	(8)	(8)	(8)
PARACORTEX; INCREASED AREA	0 **		1 (12.5%)	2 (25%)	2 (25%)	8 (100%) **	5 (62.5%) *	7 (87.5%) **
PARACORTEX; LYMPHOCYTE; INCREASED NUMBER	0 **		1 (12.5%)	2 (25%)	2 (25%)	8 (100%) **	5 (62.5%) *	7 (87.5%) **
SPLEEN	(8)	(8)	(8)	(8)	(8)	(8)	(8)	(8)
CONGESTION			1 (12.5%)		1 (12.5%)			
PERIARTERIOULAR LYMPHOID SHEATH; DECREASED AREA; FOCAL		1 (12.5%)						
RED PULP; DECREASED HEMATOPOIETIC CELLS	0 **							2 (25%)
PERIARTERIOULAR LYMPHOID SHEATH; DECREASED LYMPHOCYTES; FOCAL		1 (12.5%)					1 (12.5%)	
PERIARTERIOULAR LYMPHOID SHEATH; DECREASED LYMPHOCYTES	0 **				2 (25%)	3 (37.5%)	3 (37.5%)	4 (50%) *
FOLLICLES; GERMINAL CENTER; DECREASED NUMBER	0 **	1 (12.5%)	1 (12.5%)	1 (12.5%)	3 (37.5%)	5 (62.5%) *	8 (100%) **	8 (100%) **
MARGINAL ZONE; INCREASED AREA		1 (12.5%)						
FOLLICLES; GERMINAL CENTER; INCREASED NUMBER			1 (12.5%)					
WHITE PULP; PIGMENTED MACROPHAGE; INCREASED NUMBER	1 (12.5%)							
THYMUS	(8)	(8)	(8)	(8)	(8)	(8)	(8)	(8)
CORTEX/MEDULLA RATIO - DECREASED	0 **	1 (12.5%)		2 (25%)	3 (37.5%)	6 (75%) **	7 (87.5%) **	8 (100%) **
CYST	7 (87.5%)	4 (50%)	5 (62.5%)	5 (62.5%)	6 (75%)	7 (87.5%)	6 (75%)	6 (75%)
CORTEX; DECREASED AREA	0 **			2 (25%)	3 (37.5%)	6 (75%) **	7 (87.5%) **	7 (87.5%) **
MEDULLA; DECREASED AREA	0 **				2 (25%)	2 (25%)	2 (25%)	6 (75%) **
CORTEX; LYMPHOCYTE; DECREASED NUMBER	0 **			2 (25%)	3 (37.5%)	6 (75%) **	7 (87.5%) **	8 (100%) **
MEDULLA; LYMPHOCYTE; DECREASED NUMBER	0 **			1 (12.5%)	2 (25%)	2 (25%)	3 (37.5%)	8 (100%) **
ECTOPIC TISSUE	2 (25%)					1 (12.5%)		1 (12.5%)

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	Treatment Groups (mg/kg)							
	0	2	5	9	19	38	75	150
CORTEX; APOPTOTIC LYMPHOCYTE; INCREASED NUMBER	0 **				1 (12.5%)	2 (25%)	1 (12.5%)	8 (100%) **
MEDULLA; APOPTOTIC LYMPHOCYTE; INCREASED NUMBER	0 **						1 (12.5%)	7 (87.5%) **
CAPSULE; MONONUCLEAR CELL; INFILTRATE, CELLULAR				1 (12.5%)				
CAPSULE; INFILTRATION, ADIPOCYTES								1 (12.5%)
INTEGUMENTARY SYSTEM								
None								
MUSCULOSKELETAL SYSTEM								
None								
NERVOUS SYSTEM								
None								
RESPIRATORY SYSTEM								
LUNG	(8)	(8)	(8)	(8)	(8)	(8)	(8)	(8)
CONGESTION				4 (50%) *		2 (25%)	2 (25%)	
HEMORRHAGE				1 (12.5%)	1 (12.5%)	1 (12.5%)		1 (12.5%)
INFLAMMATION; CHRONIC-ACTIVE	1 (12.5%)							1 (12.5%)
SPECIAL SENSES SYSTEM								
None								
URINARY SYSTEM								
KIDNEY	(8)	(8)	(8)	(8)	(8)	(8)	(8)	(8)
PELVIS; INFILTRATE, CELLULAR; MIXED								1 (12.5%)
INFILTRATE, CELLULAR; MIXED		2 (25%)	2 (25%)	2 (25%)		1 (12.5%)	1 (12.5%)	
NEPHROPATHY			1 (12.5%)	1 (12.5%)	1 (12.5%)		1 (12.5%)	1 (12.5%)

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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

Statistical analysis performed by Cochran-Armitage (trend) and Fisher Exact (pairwise) 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

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 ****