

Study Number: C08022

Test Type: TOX

Route: Nose-Only Inhalation

Species/Strain: Mouse/B6C3F1/N

Study Number:

Study Gender:

PWG Approval Date

PA10X: Statistical Analysis of Non-Neoplastic Lesions

Test Compound: Aspergillus fumigatus mold

CAS Number: ASPERGILLUS

C08022

Both

See web page for date of PWG Approval

Date Report Requested: 05/01/2020

Time Report Requested: 14:34:27

Lab: Battelle

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Male

Treatment Groups

	Air Control	Heat Inactivated Particle Control	Viable Aspergillus fumigatus
Disposition Summary			
Animals Initially In Study	10	10	10
Early Deaths			
Scheduled Deaths			
Scheduled sacrifice, terminal (SD 87)	10	10	10
Number of Animals Examined	10	10	10
ALIMENTARY SYSTEM			
LIVER	(10)	(10)	(10)
INFLAMMATION; FOCAL	2 (20%)	2 (20%)	3 (30%)
STOMACH, GLANDULAR	(10)	(10)	(10)
GLANDS; CYST	1 (10%)		
MINERAL	1 (10%)		
CARDIOVASCULAR SYSTEM			
None			
ENDOCRINE SYSTEM			
ADRENAL GLAND	(10)	(10)	(10)
CAPSULE; ACCESSORY ADRENAL CORTICAL NODULE		1 (10%)	
CORTEX; HYPERTROPHY; FOCAL	1 (10%)		
GENERAL BODY SYSTEM			
None			
GENITAL SYSTEM			
None			

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Treatment Groups

	Air Control	Heat Inactivated Particle Control	Viable Aspergillus fumigatus
HEMATOLYMPHOID SYSTEM			
LYMPH NODE, BRONCHIAL FUNGUS	(7)	(9) 2 (22.2%)	(9)
LYMPHOCYTE; HYPERPLASIA			6 (66.7%) * ##
PLASMA CELL; HYPERPLASIA			5 (55.6%) * #
INFLAMMATION; GRANULOMATOUS			1 (11.1%)
INTEGUMENTARY SYSTEM			
None			
MUSCULOSKELETAL SYSTEM			
None			
NERVOUS SYSTEM			
None			
RESPIRATORY SYSTEM			
LARYNX	(10)	(10)	(10)
EPIGLOTTIS; METAPLASIA; SQUAMOUS	3 (30%)		9 (90%) ** ##
LUNG	(10)	(10)	(10)
BALT; FUNGUS		4 (40%) *	
FUNGUS		5 (50%) *	1 (10%)
BALT; LYMPHOCYTE; HYPERPLASIA		7 (70%) **	10 (100%) **
BRONCHIOLE; EPITHELIUM; HYPERPLASIA			9 (90%) ** ##
ARTERY; MEDIAL; HYPERTROPHY			10 (100%) ** ##
INFLAMMATION; CHRONIC		3 (30%)	
INFLAMMATION; CHRONIC ACTIVE			10 (100%) ** ##
GOBLET CELL; METAPLASIA			10 (100%) ** ##
METAPLASIA; OSSEOUS			1 (10%)
ARTERY; THROMBUS			1 (10%)

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Treatment Groups

Air Control

**Heat Inactivated Particle
Control**

**Viable Aspergillus
fumigatus**

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

KIDNEY

NEPHROPATHY; CHRONIC PROGRESSIVE

(10)

3 (30%)

(10)

1 (10%)

(10)

3 (30%)

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Female

Treatment Groups

	Air Control	Heat Inactivated Particle Control	Viable Aspergillus fumigatus
Disposition Summary			
Animals Initially In Study	10	10	10
Early Deaths			
Found Dead	1	1	
Scheduled Deaths			
Scheduled sacrifice, terminal (SD 87)	9	9	10
Number of Animals Examined	10	10	10
ALIMENTARY SYSTEM			
LIVER	(10)	(10)	(10)
INFLAMMATION; FOCAL	7 (70%)	4 (40%)	4 (40%)
CARDIOVASCULAR SYSTEM			
None			
ENDOCRINE SYSTEM			
ADRENAL GLAND	(10)	(9)	(10)
CAPSULE; ACCESSORY ADRENAL CORTICAL NODULE		1 (11.1%)	
CORTEX; SUBCAPSULAR; HYPERPLASIA; BILATERAL	6 (60%)	4 (44.4%)	6 (60%)
CORTEX; SUBCAPSULAR; HYPERPLASIA		1 (11.1%)	
PARATHYROID GLAND	(8)	(8)	(9)
CYST; CONGENITAL	1 (12.5%)		
THYMUS; ECTOPIC TISSUE		1 (12.5%)	2 (22.2%)
THYROID GLAND	(10)	(10)	(10)
THYMUS; ECTOPIC TISSUE	1 (10%)		
GENERAL BODY SYSTEM			
None			

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GENITAL SYSTEM			
OVARY	(10)	(10)	(10)
FOLLICLE; POLYOVULAR	2 (20%)		1 (10%)
UTERUS	(10)	(10)	(10)
ENDOMETRIUM; HYPERPLASIA; CYSTIC STROMAL; POLYP		2 (20%)	1 (10%)
HEMATOLYMPHOID SYSTEM			
LYMPH NODE, BRONCHIAL	(8)	(10)	(10)
FUNGUS			1 (10%)
LYMPHOCYTE; HYPERPLASIA		1 (10%)	9 (90%) ** ##
PLASMA CELL; HYPERPLASIA			8 (80%) ** ##
PIGMENT	1 (12.5%)		
SPLEEN	(10)	(10)	(10)
LYMPHOCYTE; HYPERPLASIA INCREASED, EMH		2 (20%)	1 (10%)
INTEGUMENTARY SYSTEM			
None			
MUSCULOSKELETAL SYSTEM			
None			
NERVOUS SYSTEM			
None			

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	Treatment Groups		
	Air Control	Heat Inactivated Particle Control	Viable Aspergillus fumigatus
RESPIRATORY SYSTEM			
LARYNX	(10)	(9)	(10)
SQUAMOUS EPITHELIUM; HYPERPLASIA			1 (10%)
EPIGLOTTIS; METAPLASIA; SQUAMOUS EPITHELIUM; ULCER		1 (11.1%)	9 (90%) ** ##
LUNG	(10)	(10)	(10)
CONGESTION		1 (10%)	
BALT; FUNGUS		1 (10%)	
FUNGUS			10 (100%) ** ##
BALT; LYMPHOCYTE; HYPERPLASIA		8 (80%) **	10 (100%) **
BRONCHIOLE; EPITHELIUM; HYPERPLASIA		1 (10%)	8 (80%) ** ##
ARTERY; MEDIAL; HYPERTROPHY			10 (100%) ** ##
INFLAMMATION; CHRONIC		7 (70%) **	
INFLAMMATION; CHRONIC ACTIVE		1 (10%)	10 (100%) ** ##
GOBLET CELL; METAPLASIA		1 (10%)	10 (100%) ** ##
SPECIAL SENSES SYSTEM			
None			
URINARY SYSTEM			
KIDNEY	(10)	(10)	(10)
NEPHROPATHY; CHRONIC PROGRESSIVE	1 (10%)	1 (10%)	3 (30%)

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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

Pairwise significance for all comparisons are determined using one-sided Fisher's exact tests.

* Statistically significant pairwise difference from Air Control at $P \leq 0.05$

** Statistically significant pairwise difference from Air Control at $P \leq 0.01$

Statistically significant pairwise difference from Heat Inactivated Particle Control at $P \leq 0.05$

Statistically significant pairwise difference from Heat Inactivated Particle Control at $P \leq 0.01$

**** END OF REPORT ****