

Study Number: C08022

Test Type: TOX

Route: Nose-Only Inhalation

Species/Strain: Mouse/B6C3F1/N

C Number:

Study Gender:

PWG Approval Date

PA18: Incidence Rates of Non-Neoplastic Lesions by Anatomic Site [a] with Average Severity Grades [b]

Test Compound: Aspergillus fumigatus mold

CAS Number: ASPERGILLUS

C08022

Both

See web page for date of PWG Approval

Date Report Requested: 11/25/2019

Time Report Requested: 13:17:28

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			
Survivors			
Scheduled sacrifice, terminal (SD 87)	10	10	10
Animals Examined Microscopically	10	10	10
ALIMENTARY SYSTEM			
ESOPHAGUS	(10)	(10)	(10)
GALLBLADDER	(10)	(10)	(10)
INTESTINE, LARGE, CECUM	(10)	(10)	(10)
INTESTINE, LARGE, COLON	(10)	(10)	(10)
INTESTINE, LARGE, RECTUM	(10)	(10)	(10)
INTESTINE, SMALL, DUODENUM	(10)	(10)	(10)
INTESTINE, SMALL, ILEUM	(10)	(10)	(10)
INTESTINE, SMALL, JEJUNUM	(10)	(10)	(10)
LIVER	(10)	(10)	(10)
INFLAMMATION; FOCAL	2 [1.0]	2 [1.0]	3 [1.0]
PANCREAS	(10)	(10)	(10)
SALIVARY GLANDS	(10)	(10)	(10)
STOMACH, FORESTOMACH	(10)	(10)	(10)
STOMACH, GLANDULAR	(10)	(10)	(10)
GLANDS; CYST	1		
MINERAL	1 [1.0]		
CARDIOVASCULAR SYSTEM			
AORTA	(10)	(10)	(10)
HEART	(10)	(10)	(10)

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	Treatment Groups		
	Air Control	Heat Inactivated Particle Control	Viable Aspergillus fumigatus
ENDOCRINE SYSTEM			
ADRENAL GLAND	(10)	(10)	(10)
CAPSULE; ACCESSORY ADRENAL CORTICAL NODULE		1	
CORTEX; HYPERTROPHY; FOCAL	1 [1.0]		
ISLETS, PANCREATIC	(10)	(10)	(9)
PARATHYROID GLAND	(7)	(8)	(8)
PITUITARY GLAND	(9)	(10)	(10)
THYROID GLAND	(10)	(10)	(10)
GENERAL BODY SYSTEM			
No Tissues/Organs Examined			
GENITAL SYSTEM			
EPIDIDYMIS	(10)	(10)	(10)
PREPUTIAL GLAND	(10)	(10)	(10)
PROSTATE	(10)	(10)	(10)
SEMINAL VESICLE	(10)	(10)	(10)
TESTES	(10)	(10)	(10)
HEMATOLYMPHOID SYSTEM			
BONE MARROW	(10)	(10)	(10)
LYMPH NODE, BRONCHIAL	(7)	(9)	(9)
FUNGUS		2	
LYMPHOCYTE; HYPERPLASIA			6 [1.8]
PLASMA CELL; HYPERPLASIA			5 [1.6]
INFLAMMATION; GRANULOMATOUS			1 [1.0]
LYMPH NODE, MANDIBULAR	(10)	(10)	(10)
LYMPH NODE, MEDIASTINAL	(0)	(4)	(1)
LYMPH NODE, MESENTERIC	(10)	(10)	(10)
SPLEEN	(10)	(10)	(10)
THYMUS	(10)	(10)	(10)

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	Treatment Groups		
	Air Control	Heat Inactivated Particle Control	Viable Aspergillus fumigatus
Male			
INTEGUMENTARY SYSTEM			
SKIN	(10)	(10)	(10)
MUSCULOSKELETAL SYSTEM			
BONE, FEMUR	(10)	(10)	(10)
NERVOUS SYSTEM			
BRAIN	(10)	(10)	(10)
RESPIRATORY SYSTEM			
LARYNX	(10)	(10)	(10)
EPIGLOTTIS; METAPLASIA; SQUAMOUS	3 [1.0]		9 [1.0]
LUNG	(10)	(10)	(10)
BALT; FUNGUS		4	
FUNGUS		5	1
BALT; LYMPHOCYTE; HYPERPLASIA		7 [1.0]	10 [1.0]
BRONCHIOLE; EPITHELIUM; HYPERPLASIA			9 [1.0]
ARTERY; MEDIAL; HYPERTROPHY			10 [2.1]
INFLAMMATION; CHRONIC		3 [1.7]	
INFLAMMATION; CHRONIC ACTIVE			10 [2.7]
GOBLET CELL; METAPLASIA			10 [1.9]
METAPLASIA; OSSEOUS			1 [1.0]
ARTERY; THROMBUS			1
NOSE	(10)	(10)	(10)
TRACHEA	(10)	(10)	(10)
SPECIAL SENSES SYSTEM			
EYE	(10)	(10)	(10)
HARDERIAN GLAND	(10)	(10)	(10)

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Male

Treatment Groups

	Air Control	Heat Inactivated Particle Control	Viable Aspergillus fumigatus
URINARY SYSTEM			
KIDNEY	(10)	(10)	(10)
NEPHROPATHY; CHRONIC PROGRESSIVE	3 [1.0]	1 [1.0]	3 [1.0]
URINARY BLADDER	(10)	(10)	(10)

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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	
Survivors			
Scheduled sacrifice, terminal (SD 87)	9	9	10
Animals Examined Microscopically	10	10	10
ALIMENTARY SYSTEM			
ESOPHAGUS	(10)	(10)	(10)
GALLBLADDER	(10)	(10)	(9)
INTESTINE, LARGE, CECUM	(10)	(10)	(10)
INTESTINE, LARGE, COLON	(10)	(10)	(10)
INTESTINE, LARGE, RECTUM	(10)	(10)	(10)
INTESTINE, SMALL, DUODENUM	(10)	(10)	(10)
INTESTINE, SMALL, ILEUM	(10)	(10)	(10)
INTESTINE, SMALL, JEJUNUM	(10)	(9)	(10)
LIVER	(10)	(10)	(10)
INFLAMMATION; FOCAL	7 [1.0]	4 [1.0]	4 [1.0]
PANCREAS	(10)	(10)	(10)
SALIVARY GLANDS	(10)	(10)	(10)
STOMACH, FORESTOMACH	(10)	(10)	(10)
STOMACH, GLANDULAR	(10)	(10)	(10)
CARDIOVASCULAR SYSTEM			
AORTA	(10)	(10)	(10)
HEART	(10)	(10)	(10)

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Female

	Treatment Groups		
	Air Control	Heat Inactivated Particle Control	Viable Aspergillus fumigatus
ENDOCRINE SYSTEM			
ADRENAL GLAND	(10)	(9)	(10)
CAPSULE; ACCESSORY ADRENAL CORTICAL NODULE		1	
CORTEX; SUBCAPSULAR; HYPERPLASIA; BILATERAL	6 [1.0]	4 [1.0]	6 [1.0]
CORTEX; SUBCAPSULAR; HYPERPLASIA		1 [1.0]	
ISLETS, PANCREATIC	(10)	(10)	(10)
PARATHYROID GLAND	(8)	(8)	(9)
CYST; CONGENITAL	1		
THYMUS; ECTOPIC TISSUE		1	2
PITUITARY GLAND	(9)	(10)	(10)
THYROID GLAND	(10)	(10)	(10)
THYMUS; ECTOPIC TISSUE	1		
GENERAL BODY SYSTEM			
No Tissues/Organs Examined			
GENITAL SYSTEM			
CERVIX	(10)	(10)	(10)
CLITORAL GLAND	(9)	(9)	(9)
OVARY	(10)	(10)	(10)
FOLLICLE; POLYOVULAR	2		1
UTERUS	(10)	(10)	(10)
ENDOMETRIUM; HYPERPLASIA; CYSTIC		2 [1.0]	
STROMAL; POLYP			1
VAGINA	(10)	(10)	(10)

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Female

	Treatment Groups		
	Air Control	Heat Inactivated Particle Control	Viable Aspergillus fumigatus
HEMATOLYMPHOID SYSTEM			
BONE MARROW	(10)	(10)	(10)
LYMPH NODE, BRONCHIAL	(8)	(10)	(10)
FUNGUS			1
LYMPHOCYTE; HYPERPLASIA		1 [1.0]	9 [1.8]
PLASMA CELL; HYPERPLASIA			8 [1.5]
PIGMENT	1 [1.0]		
LYMPH NODE, MANDIBULAR	(10)	(10)	(10)
LYMPH NODE, MEDIASTINAL	(1)	(3)	(1)
LYMPH NODE, MESENTERIC	(10)	(10)	(10)
SPLEEN	(10)	(10)	(10)
LYMPHOCYTE; HYPERPLASIA			1 [1.0]
INCREASED, EMH		2 [1.0]	
THYMUS	(10)	(10)	(10)
INTEGUMENTARY SYSTEM			
MAMMARY GLAND	(10)	(9)	(10)
SKIN	(10)	(10)	(10)
MUSCULOSKELETAL SYSTEM			
BONE, FEMUR	(10)	(10)	(10)
NERVOUS SYSTEM			
BRAIN	(10)	(10)	(10)

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	Air Control	Heat Inactivated Particle Control	Viable Aspergillus fumigatus
RESPIRATORY SYSTEM			
LARYNX	(10)	(9)	(10)
SQUAMOUS EPITHELIUM; HYPERPLASIA			1 [1.0]
EPIGLOTTIS; METAPLASIA; SQUAMOUS EPITHELIUM; ULCER		1 [1.0]	9 [1.0]
LUNG	(10)	(10)	(10)
CONGESTION		1 [1.0]	
BALT; FUNGUS		1	
FUNGUS			10
BALT; LYMPHOCYTE; HYPERPLASIA		8 [1.0]	10 [1.4]
BRONCHIOLE; EPITHELIUM; HYPERPLASIA		1 [1.0]	8 [1.0]
ARTERY; MEDIAL; HYPERTROPHY			10 [2.6]
INFLAMMATION; CHRONIC		7 [1.9]	
INFLAMMATION; CHRONIC ACTIVE		1 [3.0]	10 [2.8]
GOBLET CELL; METAPLASIA		1 [1.0]	10 [1.8]
NOSE	(10)	(10)	(10)
TRACHEA	(10)	(10)	(10)
SPECIAL SENSES SYSTEM			
EYE	(10)	(10)	(10)
HARDERIAN GLAND	(10)	(9)	(10)
URINARY SYSTEM			
KIDNEY	(10)	(10)	(10)
NEPHROPATHY; CHRONIC PROGRESSIVE	1 [1.0]	1 [1.0]	3 [1.0]
URINARY BLADDER	(10)	(10)	(10)

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LEGEND

[a] Number of animals examined given for each tissue. If none of the animals examined have the specific lesion then there is a blank for that dose group for that specific lesion.

[b] Mean severity grade denoted by 1 - minimal, 2 - mild, 3 - moderate, 4 - marked

Number of animals with observation reported with mean severity grade in square brackets

Phase day range of terminal sacrifice shown in parentheses in disposition summary

SD – Study Day

**** END OF REPORT ****