

**Experiment Number:** 20701 - 02

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH  
AVERAGE SEVERITY GRADES[b]**

**Date Report Requested:** 02/22/2013

**Test Type:** 90-DAY

Nanoscale material (Fullerene-C60 1 micron)

**Time Report Requested:** 07:59:02

**Route:** RESPIRATORY EXPOSURE NASAL

**CAS Number:** 99685-96-8

**First Dose M/F:** 11/05/07 / 11/05/07

**Species/Strain:** MICE/B6C3F1

**Lab:** BNW

F2\_Rev.1\_M3

**NTP Study Number:** C20701  
**Lock Date:** 02/24/2009  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 3.0.1.1\_001  
**PWG Approval Date:** NONE

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Species/Strain: MICE/B6C3F1

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B6C3F1 MICE MALE	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
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**Disposition Summary**

Animals Initially In Study	10	10	10	10
Early Deaths				
Moribund Sacrifice		1		
Survivors				
Terminal Sacrifice	10	9	10	10
Animals Examined Microscopically	10	10	10	10

## ALIMENTARY SYSTEM

Esophagus	(10)	(1)	(0)	(10)
Gallbladder	(9)	(1)	(0)	(8)
Intestine Large, Cecum	(10)	(1)	(0)	(10)
Intestine Large, Colon	(10)	(1)	(0)	(10)
Intestine Large, Rectum	(10)	(1)	(0)	(10)
Intestine Small, Duodenum	(10)	(1)	(0)	(10)
Intestine Small, Ileum	(10)	(1)	(0)	(10)
Intestine Small, Jejunum	(10)	(1)	(0)	(10)
Liver	(10)	(1)	(0)	(10)
Inflammation, Granulomatous				1 [1.0]
Necrosis	1 [1.0]			
Pancreas	(10)	(1)	(0)	(10)
Salivary Glands	(10)	(1)	(0)	(10)
Stomach, Forestomach	(10)	(1)	(0)	(10)
Hyperplasia, Squamous		1 [2.0]		
Ulcer		1 [1.0]		
Stomach, Glandular	(10)	(1)	(0)	(10)

## CARDIOVASCULAR SYSTEM

Blood Vessel	(10)	(0)	(0)	(9)
Heart	(10)	(1)	(0)	(10)

a - Number of animals examined microscopically at site and number of animals with lesion

b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

Test Type: 90-DAY

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Species/Strain: MICE/B6C3F1

Lab: BNW

B6C3F1 MICE MALE	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
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## ENDOCRINE SYSTEM

Adrenal Cortex	(10)	(1)	(0)	(10)
Adrenal Medulla	(10)	(1)	(0)	(10)
Islets, Pancreatic	(10)	(1)	(0)	(10)
Parathyroid Gland	(5)	(1)	(0)	(6)
Pituitary Gland	(10)	(1)	(0)	(10)
Thyroid Gland	(10)	(1)	(0)	(10)

## GENERAL BODY SYSTEM

None

## GENITAL SYSTEM

Epididymis	(10)	(10)	(10)	(10)
Preputial Gland	(10)	(1)	(0)	(10)
Prostate	(10)	(1)	(0)	(10)
Seminal Vesicle	(10)	(1)	(0)	(10)
Testes	(10)	(10)	(10)	(10)
Germinal Epithelium, Degeneration			1 [1.0]	

## HEMATOPOIETIC SYSTEM

Bone Marrow	(10)	(1)	(0)	(10)
Lymph Node, Bronchial	(6)	(4)	(5)	(9)
Pigmentation	2 [1.0]	1 [1.0]	2 [1.0]	9 [2.9]
Lymph Node, Mandibular	(5)	(1)	(0)	(4)
Lymph Node, Mediastinal	(1)	(0)	(0)	(4)
Lymph Node, Mesenteric	(9)	(1)	(0)	(10)
Spleen	(10)	(1)	(0)	(10)
Thymus	(10)	(1)	(0)	(10)

a - Number of animals examined microscopically at site and number of animals with lesion

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Lab: BNW

B6C3F1 MICE MALE	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
<b>INTEGUMENTARY SYSTEM</b>				
Skin	(10)	(1)	(0)	(10)
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone	(10)	(1)	(0)	(10)
<b>NERVOUS SYSTEM</b>				
Brain	(10)	(1)	(0)	(10)
<b>RESPIRATORY SYSTEM</b>				
Larynx	(10)	(9)	(10)	(10)
Metaplasia, Squamous	1 [1.0]		5 [1.0]	9 [1.1]
Squamous Epithelium, Hyperplasia		1 [2.0]		
Lung	(10)	(10)	(10)	(10)
Hemorrhage		1 [1.0]		
Infiltration Cellular, Histiocyte			10 [2.9]	10 [3.9]
Inflammation, Chronic Active			10 [1.0]	10 [1.9]
Pigmentation			10 [3.2]	10 [3.8]
Nose	(10)	(1)	(0)	(10)
Olfactory Epithelium, Accumulation, Hyaline Droplet				1 [1.0]
Respiratory Epithelium, Accumulation, Hyaline Droplet				1 [1.0]
Trachea	(10)	(1)	(0)	(10)
<b>SPECIAL SENSES SYSTEM</b>				
Eye	(10)	(1)	(0)	(10)
Harderian Gland	(10)	(1)	(0)	(10)
Inflammation, Acute	7 [1.9]			7 [1.4]

a - Number of animals examined microscopically at site and number of animals with lesion

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Nanoscale material (Fullerene-C60 1 micron)

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Route: RESPIRATORY EXPOSURE NASAL

CAS Number: 99685-96-8

First Dose M/F: 11/05/07 / 11/05/07

Species/Strain: MICE/B6C3F1

Lab: BNW

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B6C3F1 MICE MALE	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
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URINARY SYSTEM

Kidney	(10)	(10)	(10)	(10)
Nephropathy	1 [1.0]	2 [1.0]		2 [1.0]
Papilla, Infiltration Cellular, Polymorphonuclear	1 [2.0]			
Renal Tubule, Necrosis	1 [2.0]		1 [1.0]	3 [1.3]
Urinary Bladder	(10)	(1)	(0)	(10)

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\*\*\* END OF MALE \*\*\*

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B6C3F1 MICE FEMALE	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
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**Disposition Summary**

Animals Initially In Study	10	10	10	10
Early Deaths				
Survivors				
Terminal Sacrifice	10	10	10	10
Animals Examined Microscopically	10	10	10	10

## ALIMENTARY SYSTEM

Esophagus	(10)	(0)	(0)	(10)
Gallbladder	(10)	(0)	(0)	(7)
Intestine Large, Cecum	(10)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(10)
Intestine Small, Duodenum	(10)	(0)	(0)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(10)
Liver	(10)	(0)	(0)	(10)
Necrosis				1 [2.0]
Pancreas	(10)	(0)	(0)	(10)
Salivary Glands	(10)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(10)
Stomach, Glandular	(10)	(0)	(0)	(10)

## CARDIOVASCULAR SYSTEM

Blood Vessel	(7)	(0)	(0)	(10)
Heart	(10)	(0)	(0)	(10)

## ENDOCRINE SYSTEM

Adrenal Cortex	(10)	(0)	(0)	(10)
Adrenal Medulla	(10)	(0)	(0)	(8)
Islets, Pancreatic	(10)	(0)	(0)	(10)

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B6C3F1 MICE FEMALE	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Parathyroid Gland	(6)	(0)	(0)	(4)
Pituitary Gland	(10)	(0)	(0)	(10)
Thyroid Gland	(10)	(0)	(0)	(10)

## GENERAL BODY SYSTEM

None

## GENITAL SYSTEM

Clitoral Gland	(9)	(0)	(0)	(8)
Ovary	(10)	(0)	(0)	(10)
Uterus	(10)	(0)	(0)	(10)

## HEMATOPOIETIC SYSTEM

Bone Marrow	(10)	(0)	(0)	(10)
Lymph Node, Bronchial	(5)	(6)	(5)	(6)
Pigmentation	2 [1.0]	3 [1.0]	1 [1.0]	6 [2.7]
Lymph Node, Mandibular	(6)	(0)	(0)	(6)
Lymph Node, Mediastinal	(2)	(0)	(0)	(4)
Lymph Node, Mesenteric	(9)	(0)	(0)	(10)
Spleen	(10)	(0)	(0)	(10)
Thymus	(10)	(0)	(0)	(10)

## INTEGUMENTARY SYSTEM

Mammary Gland	(10)	(0)	(0)	(10)
Inflammation, Acute				1 [1.0]
Skin	(10)	(0)	(0)	(10)

## MUSCULOSKELETAL SYSTEM

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B6C3F1 MICE FEMALE	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Bone	(10)	(0)	(0)	(10)
<b>NERVOUS SYSTEM</b>				
Brain	(10)	(0)	(0)	(10)
<b>RESPIRATORY SYSTEM</b>				
Larynx	(10)	(8)	(10)	(10)
Metaplasia, Squamous		1 [1.0]	6 [1.0]	9 [1.2]
Lung	(10)	(10)	(10)	(10)
Hemorrhage	1 [1.0]			
Infiltration Cellular, Histiocyte			10 [2.4]	10 [4.0]
Inflammation, Chronic Active			3 [1.0]	10 [2.0]
Pigmentation			10 [2.9]	10 [4.0]
Nose	(10)	(0)	(0)	(10)
Olfactory Epithelium, Accumulation, Hyaline Droplet				2 [1.0]
Respiratory Epithelium, Accumulation, Hyaline Droplet	5 [1.0]			4 [1.3]
Trachea	(10)	(0)	(0)	(10)
<b>SPECIAL SENSES SYSTEM</b>				
Eye	(10)	(0)	(0)	(10)
Cornea, Necrosis	1 [1.0]			
Harderian Gland	(10)	(0)	(0)	(10)
Inflammation, Acute	3 [1.0]			7 [1.0]
<b>URINARY SYSTEM</b>				
Kidney	(10)	(0)	(0)	(10)
Nephropathy	1 [1.0]			1 [1.0]
Urinary Bladder	(10)	(0)	(0)	(10)

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B6C3F1 MICE FEMALE

0 mg/m3

2 mg/m3

15 mg/m3

30 mg/m3

---

\*\*\* END OF REPORT \*\*\*

a - Number of animals examined microscopically at site and number of animals with lesion

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