

Experiment Number: 20725 - 04

**P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS
ABRIDGED) (a)**

Date Report Requested: 04/15/2016

Test Type: CHRONIC

2,3-Butanedione

Time Report Requested: 10:33:42

Route: RESPIRATORY EXPOSURE WHOLE BODY

CAS Number: 431-03-8

First Dose M/F: 08/31/09 / 08/31/09

Species/Strain: MICE/B6C3F1

Lab: BNW

F1_Mice

NTP Study Number: C20725
Lock Date: 10/11/2012
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 3.0.2.3_002
PWG Approval Date: 01/25/2016

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Route: RESPIRATORY EXPOSURE WHOLE BODY

CAS Number: 431-03-8

First Dose M/F: 08/31/09 / 08/31/09

Species/Strain: MICE/B6C3F1

Lab: BNW

B6C3F1 MICE MALE	Control	12.5 ppm	25 ppm	50 ppm
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Disposition Summary

Animals Initially In Study	50	50	50	50
Early Deaths				
Accidentally Killed		1		
Moribund Sacrifice	6	5	4	14
Natural Death	9	5	9	11
Survivors				
Terminal Sacrifice	35	39	37	25
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Gallbladder	(45)	(42)	(43)	(43)
Intestine Large, Cecum	(46)	(48)	(47)	(48)
Intestine Large, Colon	(46)	(47)	(48)	(47)
Intestine Large, Rectum	(46)	(46)	(45)	(49)
Intestine Small, Duodenum	(45)	(47)	(44)	(44)
Hepatoblastoma, Metastatic, Liver	1 (2%)			
Polyp Adenomatous	1 (2%)			
Intestine Small, Ileum	(45)	(47)	(44)	(46)
Sarcoma, Metastatic, Uncertain Primary Site	1 (2%)			
Intestine Small, Jejunum	(44)	(46)	(43)	(43)
Sarcoma, Metastatic, Uncertain Primary Site	1 (2%)			
Liver	(50)	(50)	(50)	(50)
Hemangiosarcoma				1 (2%)
Hepatoblastoma	1 (2%)		1 (2%)	
Hepatocellular Adenoma	6 (12%)	9 (18%)	11 (22%)	3 (6%)
Hepatocellular Adenoma, Multiple	11 (22%)	7 (14%)	4 (8%)	1 (2%)
Hepatocellular Carcinoma	10 (20%)	6 (12%)	5 (10%)	6 (12%)
Hepatocellular Carcinoma, Multiple	7 (14%)	5 (10%)	8 (16%)	
Hepatocholangiocarcinoma			1 (2%)	
Hepatocholangiocarcinoma, Multiple	1 (2%)			
Sarcoma, Metastatic, Uncertain Primary Site	1 (2%)			
Mesentery	(4)	(1)	(5)	(0)

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

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First Dose M/F: 08/31/09 / 08/31/09

Species/Strain: MICE/B6C3F1

Lab: BNW

B6C3F1 MICE MALE	Control	12.5 ppm	25 ppm	50 ppm
Hepatoblastoma, Metastatic, Liver			1 (20%)	
Hepatocellular Carcinoma, Metastatic, Liver			1 (20%)	
Hepatocholangiocarcinoma, Metastatic, Liver			1 (20%)	
Sarcoma, Metastatic, Uncertain Primary Site	1 (25%)			
Pancreas	(48)	(48)	(50)	(50)
Hepatoblastoma, Metastatic, Liver			1 (2%)	
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
Sarcoma, Metastatic, Uncertain Primary Site	1 (2%)			
Salivary Glands	(50)	(49)	(50)	(50)
Stomach, Forestomach	(48)	(48)	(49)	(50)
Sarcoma, Metastatic, Uncertain Primary Site	1 (2%)			
Squamous Cell Papilloma		1 (2%)		
Stomach, Glandular	(47)	(48)	(49)	(49)
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
Tooth	(2)	(2)	(1)	(0)

CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(49)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung			1 (2%)	
Hemangioma				1 (2%)
Hemangiosarcoma	1 (2%)			
Hepatocellular Carcinoma, Metastatic, Liver	1 (2%)			
Hepatocholangiocarcinoma, Metastatic, Liver	1 (2%)			

ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(49)	(50)	(50)
Adenoma		1 (2%)	1 (2%)	
Subcapsular, Adenoma	2 (4%)	7 (14%)	3 (6%)	2 (4%)
Adrenal Medulla	(50)	(48)	(50)	(50)
Islets, Pancreatic	(48)	(48)	(49)	(50)
Adenoma			2 (4%)	

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

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Species/Strain: MICE/B6C3F1

Lab: BNW

B6C3F1 MICE MALE	Control	12.5 ppm	25 ppm	50 ppm
Parathyroid Gland	(40)	(39)	(44)	(37)
Pituitary Gland	(50)	(49)	(50)	(50)
Thyroid Gland	(50)	(49)	(50)	(50)
Follicular Cell, Adenoma		1 (2%)	1 (2%)	

GENERAL BODY SYSTEM

Tissue NOS	(0)	(0)	(0)	(1)
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GENITAL SYSTEM

Epididymis	(49)	(49)	(50)	(49)
Hepatoblastoma, Metastatic, Liver			1 (2%)	
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
Preputial Gland	(50)	(49)	(50)	(49)
Prostate	(49)	(49)	(49)	(50)
Carcinoma, Metastatic, Urinary Bladder			1 (2%)	
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
Seminal Vesicle	(49)	(49)	(50)	(50)
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
Testes	(49)	(49)	(50)	(49)

HEMATOPOIETIC SYSTEM

Bone Marrow	(48)	(47)	(50)	(49)
Hemangiosarcoma, Metastatic, Spleen		2 (4%)		
Mast Cell Tumor Malignant	1 (2%)			
Lymph Node	(5)	(1)	(3)	(8)
Pancreatic, Hepatoblastoma, Metastatic, Liver			1 (33%)	
Renal, Hepatocholangiocarcinoma, Metastatic, Liver	1 (20%)			
Lymph Node, Bronchial	(34)	(43)	(38)	(31)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung			1 (3%)	
Hepatocholangiocarcinoma, Metastatic, Liver	1 (3%)			

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

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Lab: BNW

B6C3F1 MICE MALE	Control	12.5 ppm	25 ppm	50 ppm
Lymph Node, Mandibular	(36)	(33)	(30)	(32)
Lymph Node, Mediastinal	(37)	(33)	(38)	(32)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung	1 (3%)		1 (3%)	
Hepatoblastoma, Metastatic, Liver			1 (3%)	
Hepatocholangiocarcinoma, Metastatic, Liver	1 (3%)		1 (3%)	
Sarcoma, Metastatic, Uncertain Primary Site	1 (3%)			
Lymph Node, Mesenteric	(47)	(47)	(49)	(47)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung	1 (2%)			
Hepatocellular Carcinoma, Metastatic, Liver	1 (2%)			
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
Sarcoma, Metastatic, Uncertain Primary Site	1 (2%)			
Spleen	(48)	(49)	(50)	(50)
Hemangiosarcoma		2 (4%)		
Thymus	(43)	(42)	(44)	(30)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung			1 (2%)	
Hepatocholangiocarcinoma, Metastatic, Liver	1 (2%)			
Sarcoma, Metastatic, Uncertain Primary Site	1 (2%)			

INTEGUMENTARY SYSTEM

Mammary Gland	(1)	(0)	(0)	(1)
Skin	(50)	(49)	(50)	(49)
Carcinoma		1 (2%)		

MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(2)	(4)	(5)	(2)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung	1 (50%)		1 (20%)	
Hepatoblastoma, Metastatic, Liver			1 (20%)	
Hepatocholangiocarcinoma, Metastatic, Liver	1 (50%)		1 (20%)	

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Lab: BNW

B6C3F1 MICE MALE	Control	12.5 ppm	25 ppm	50 ppm
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NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(50)
Peripheral Nerve	(0)	(2)	(1)	(1)
Spinal Cord	(0)	(2)	(1)	(1)

RESPIRATORY SYSTEM

Larynx	(49)	(49)	(49)	(50)
Lung	(50)	(49)	(50)	(50)
Alveolar/Bronchiolar Adenoma	4 (8%)	5 (10%)	5 (10%)	4 (8%)
Alveolar/Bronchiolar Adenoma, Multiple	1 (2%)			
Alveolar/Bronchiolar Carcinoma	4 (8%)	3 (6%)	4 (8%)	2 (4%)
Alveolar/Bronchiolar Carcinoma, Multiple	1 (2%)		2 (4%)	1 (2%)
Hepatoblastoma, Metastatic, Liver	1 (2%)		1 (2%)	
Hepatocellular Carcinoma, Metastatic, Liver	4 (8%)	2 (4%)	7 (14%)	
Hepatocholangiocarcinoma, Metastatic, Liver	1 (2%)		1 (2%)	
Nose	(49)	(48)	(50)	(50)
Turbinate, Polyp	1 (2%)			
Trachea	(48)	(49)	(49)	(49)

SPECIAL SENSES SYSTEM

Eye	(49)	(49)	(50)	(50)
Harderian Gland	(50)	(49)	(50)	(50)
Adenoma	3 (6%)	6 (12%)	2 (4%)	3 (6%)
Carcinoma		1 (2%)		1 (2%)

URINARY SYSTEM

Kidney	(49)	(50)	(50)	(50)
Hepatocellular Carcinoma, Metastatic, Liver			1 (2%)	

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

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Species/Strain: MICE/B6C3F1

Lab: BNW

B6C3F1 MICE MALE	Control	12.5 ppm	25 ppm	50 ppm
Hepatocholangiocarcinoma, Metastatic, Liver	1 (2%)			
Urinary Bladder	(49)	(48)	(50)	(49)
Carcinoma			1 (2%)	
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
<hr/>				
SYSTEMIC LESIONS				
Multiple Organ	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma		1 (2%)	2 (4%)	
Lymphoma Malignant	6 (12%)	4 (8%)	3 (6%)	2 (4%)

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

* Number of animals with any tissue examined microscopically

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Species/Strain: MICE/B6C3F1

Lab: BNW

B6C3F1 MICE MALE	Control	12.5 ppm	25 ppm	50 ppm
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Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	37	37	36	18
Total Primary Neoplasms	61	60	56	27
Total Animals with Benign Neoplasms	22	27	21	11
Total Benign Neoplasms	29	37	29	14
Total Animals with Malignant Neoplasms	27	20	24	12
Total Malignant Neoplasms	32	23	27	13
Total Animals with Metastatic Neoplasms	8	5	11	
Total Metastatic Neoplasms	28	6	33	
Total Animals with Malignant Neoplasms Uncertain Primary Site	1			
Total Animals with Neoplasms Uncertain- Benign or Malignant				
Total Uncertain Neoplasms				

*** END OF MALE ***

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

b - Primary tumors: all tumors except metastatic tumors

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Lab: BNW

B6C3F1 MICE FEMALE	Control	12.5 ppm	25 ppm	50 ppm
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Disposition Summary

Animals Initially In Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	10	6	4	15
Natural Death	4	4	4	17
Survivors				
Moribund Sacrifice				1
Terminal Sacrifice	36	40	42	17
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Gallbladder	(42)	(45)	(45)	(37)
Hemangiosarcoma, Metastatic, Liver		1 (2%)		
Intestine Large, Cecum	(47)	(49)	(50)	(41)
Intestine Large, Colon	(47)	(49)	(50)	(46)
Intestine Large, Rectum	(49)	(49)	(46)	(43)
Intestine Small, Duodenum	(47)	(48)	(49)	(38)
Polyp Adenomatous			1 (2%)	
Intestine Small, Ileum	(47)	(48)	(49)	(39)
Intestine Small, Jejunum	(46)	(49)	(49)	(39)
Liver	(50)	(50)	(50)	(50)
Granulosa-Theca Tumor Malignant, Metastatic, Ovary	1 (2%)			
Hemangiosarcoma		1 (2%)		1 (2%)
Hemangiosarcoma, Metastatic, Skeletal Muscle				1 (2%)
Hepatoblastoma	1 (2%)	1 (2%)		
Hepatocellular Adenoma	4 (8%)	10 (20%)	7 (14%)	2 (4%)
Hepatocellular Adenoma, Multiple	2 (4%)	1 (2%)		1 (2%)
Hepatocellular Carcinoma	4 (8%)	4 (8%)	3 (6%)	
Hepatocellular Carcinoma, Multiple	1 (2%)	1 (2%)		
Mesentery	(6)	(10)	(4)	(1)
Hemangiosarcoma, Metastatic, Skeletal Muscle				1 (100%)
Hepatoblastoma, Metastatic, Liver	1 (17%)			

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Lab: BNW

B6C3F1 MICE FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Hepatocellular Carcinoma, Metastatic, Liver		1 (10%)		
Pancreas	(50)	(50)	(50)	(47)
Granulosa-Theca Tumor Malignant, Metastatic, Ovary	1 (2%)			
Salivary Glands	(49)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(49)
Granulosa-Theca Tumor Malignant, Metastatic, Ovary	1 (2%)			
Squamous Cell Papilloma		1 (2%)		
Stomach, Glandular	(49)	(50)	(50)	(46)
Granulosa-Theca Tumor Malignant, Metastatic, Ovary	1 (2%)			
Tooth	(1)	(0)	(0)	(0)

CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(50)	(50)	(50)
Hemangiosarcoma, Metastatic, Skeletal Muscle				1 (2%)
Heart	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung			1 (2%)	

ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)
Capsule, Hemangiosarcoma, Metastatic, Skeletal Muscle				1 (2%)
Subcapsular, Adenoma	1 (2%)			
Adrenal Medulla	(50)	(50)	(49)	(50)
Pheochromocytoma Benign	1 (2%)			
Islets, Pancreatic	(49)	(50)	(49)	(48)
Parathyroid Gland	(38)	(39)	(46)	(46)
Pituitary Gland	(49)	(49)	(50)	(48)
Pars Distalis, Adenoma	2 (4%)	4 (8%)	2 (4%)	
Pars Distalis, Carcinoma		1 (2%)	1 (2%)	
Pars Intermedia, Adenoma		1 (2%)		1 (2%)

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Lab: BNW

B6C3F1 MICE FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Pars Intermedia, Carcinoma	1 (2%)			
Thyroid Gland Carcinoma	(50)	(49)	(48)	(50)
Follicular Cell, Adenoma	1 (2%)		1 (2%)	

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(47)	(49)	(48)	(44)
Hemangiosarcoma, Metastatic, Spleen			1 (2%)	
Ovary	(49)	(50)	(49)	(50)
Cystadenoma		2 (4%)	3 (6%)	
Granulosa-Theca Tumor Malignant	1 (2%)			
Hemangioma			1 (2%)	
Hemangiosarcoma, Metastatic, Spleen			1 (2%)	
Luteoma		1 (2%)	3 (6%)	
Teratoma Benign		1 (2%)		
Periovarian Tissue, Hemangiosarcoma, Metastatic, Skeletal Muscle				1 (2%)
Periovarian Tissue, Hepatoblastoma, Metastatic, Liver	1 (2%)			
Uterus	(50)	(50)	(50)	(50)
Granular Cell Tumor Benign			1 (2%)	
Hemangioma				1 (2%)
Polyp Stromal		2 (4%)	2 (4%)	

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(49)
Hemangiosarcoma, Metastatic, Spleen		1 (2%)	1 (2%)	
Lymph Node	(11)	(10)	(11)	(7)
Iliac, Hepatoblastoma, Metastatic, Liver	1 (9%)			

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Lab: BNW

B6C3F1 MICE FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Pancreatic, Hepatocellular Carcinoma, Metastatic, Liver		1 (10%)		
Lymph Node, Bronchial	(40)	(42)	(43)	(43)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung			1 (2%)	
Lymph Node, Mandibular	(39)	(47)	(45)	(39)
Carcinoma, Metastatic, Harderian Gland	1 (3%)			
Lymph Node, Mediastinal	(40)	(38)	(41)	(33)
Hemangiosarcoma, Metastatic, Spleen			1 (2%)	
Hepatoblastoma, Metastatic, Liver	1 (3%)			
Lymph Node, Mesenteric	(49)	(50)	(50)	(45)
Granulosa-Theca Tumor Malignant, Metastatic, Ovary	1 (2%)			
Spleen	(50)	(50)	(50)	(48)
Hemangiosarcoma		1 (2%)	2 (4%)	
Thymus	(47)	(50)	(49)	(45)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung			1 (2%)	
Hepatoblastoma, Metastatic, Liver	1 (2%)			

INTEGUMENTARY SYSTEM

Mammary Gland	(49)	(50)	(50)	(49)
Adenoma	1 (2%)			
Skin	(50)	(50)	(50)	(50)
Basal Cell Carcinoma	1 (2%)			
Melanoma Malignant		1 (2%)		
Neural Crest Tumor		1 (2%)		
Squamous Cell Carcinoma				1 (2%)
Subcutaneous Tissue, Fibrosarcoma		1 (2%)	1 (2%)	

MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(6)	(1)	(3)	(4)

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Lab: BNW

B6C3F1 MICE FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung			1 (33%)	
Granulosa-Theca Tumor Malignant, Metastatic, Ovary	1 (17%)			
Hemangiosarcoma				1 (25%)
Sarcoma	1 (17%)			
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Pituitary Gland		1 (2%)		
Peripheral Nerve	(2)	(1)	(2)	(2)
Spinal Cord	(2)	(1)	(2)	(2)
RESPIRATORY SYSTEM				
Larynx	(49)	(50)	(50)	(49)
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	3 (6%)	4 (8%)	2 (4%)	1 (2%)
Alveolar/Bronchiolar Adenoma, Multiple		1 (2%)		
Alveolar/Bronchiolar Carcinoma	2 (4%)	1 (2%)	2 (4%)	
Alveolar/Bronchiolar Carcinoma, Multiple	1 (2%)			
Carcinoma, Metastatic, Harderian Gland	1 (2%)			
Hepatoblastoma, Metastatic, Liver	1 (2%)			
Hepatocellular Carcinoma, Metastatic, Liver		2 (4%)		
Nose	(50)	(50)	(50)	(50)
Adenocarcinoma				2 (4%)
Carcinoma, Metastatic, Harderian Gland	1 (2%)			
Pleura	(0)	(0)	(1)	(0)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung			1 (100%)	
Trachea	(50)	(49)	(50)	(50)
SPECIAL SENSES SYSTEM				

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Lab: BNW

B6C3F1 MICE FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Ear	(0)	(0)	(0)	(1)
Eye	(50)	(49)	(50)	(49)
Carcinoma, Metastatic, Harderian Gland	1 (2%)			
Harderian Gland	(50)	(50)	(50)	(50)
Adenoma	3 (6%)	3 (6%)	3 (6%)	2 (4%)
Carcinoma	1 (2%)			

URINARY SYSTEM

Kidney	(50)	(50)	(50)	(49)
Carcinoma	1 (2%)			
Urinary Bladder	(50)	(50)	(50)	(49)

SYSTEMIC LESIONS

Multiple Organ	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma	1 (2%)	3 (6%)		1 (2%)
Lymphoma Malignant	9 (18%)	6 (12%)	16 (32%)	4 (8%)

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

* Number of animals with any tissue examined microscopically

Test Type: CHRONIC

2,3-Butanedione

Time Report Requested: 10:33:42

Route: RESPIRATORY EXPOSURE WHOLE BODY

CAS Number: 431-03-8

First Dose M/F: 08/31/09 / 08/31/09

Species/Strain: MICE/B6C3F1

Lab: BNW

B6C3F1 MICE FEMALE	Control	12.5 ppm	25 ppm	50 ppm
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	34	33	34	13
Total Primary Neoplasms	43	53	51	18
Total Animals with Benign Neoplasms	15	24	22	6
Total Benign Neoplasms	18	31	25	8
Total Animals with Malignant Neoplasms	24	19	23	9
Total Malignant Neoplasms	25	21	26	10
Total Animals with Metastatic Neoplasms	3	6	3	1
Total Metastatic Neoplasms	16	8	9	5
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain- Benign or Malignant		1		
Total Uncertain Neoplasms		1		

*** END OF REPORT ***

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

b - Primary tumors: all tumors except metastatic tumors