

**Experiment Number:** 20006 - 03

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

**Date Report Requested:** 04/16/2013

**Test Type:** CHRONIC

Indole-3-carbinol

**Time Report Requested:** 09:53:55

**Route:** GAVAGE

**CAS Number:** 700-06-1

**First Dose M/F:** 03/14/07 / 03/15/07

**Species/Strain:** RATS/HSD

**Lab:** BAT

F1\_HSD

**NTP Study Number:** C20006B  
**Lock Date:** 06/21/2010  
**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

Test Type: CHRONIC

Indole-3-carbinol

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Route: GAVAGE

CAS Number: 700-06-1

First Dose M/F: 03/14/07 / 03/15/07

Species/Strain: RATS/HSD

Lab: BAT

Harlan Sprague Dawley RATS MALE	0 mg/kg	75 mg/kg	150 mg/kg	300 mg/kg
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**Disposition Summary**

<b>Animals Initially In Study</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>
<b>Early Deaths</b>				
<b>Dosing Accident</b>				<b>1</b>
<b>Moribund Sacrifice</b>	<b>14</b>	<b>23</b>	<b>15</b>	<b>20</b>
<b>Natural Death</b>	<b>16</b>	<b>14</b>	<b>18</b>	<b>17</b>
<b>Survivors</b>				
<b>Terminal Sacrifice</b>	<b>20</b>	<b>13</b>	<b>17</b>	<b>12</b>
<b>Animals Examined Microscopically</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>

## ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Lipoma		1 (2%)		
Intestine Large, Colon	(50)	(50)	(50)	(50)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(43)	(48)	(47)	(48)
Carcinoma		1 (2%)		
Intestine Small, Ileum	(35)	(43)	(42)	(38)
Intestine Small, Jejunum	(40)	(39)	(40)	(42)
Carcinoma				1 (2%)
Liver	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Pancreas				1 (2%)
Hepatocellular Adenoma	1 (2%)			
Hepatocellular Carcinoma				1 (2%)
Mesentery	(2)	(2)	(1)	(0)
Fat, Sarcoma			1 (100%)	
Oral Mucosa	(50)	(50)	(50)	(50)
Squamous Cell Carcinoma	1 (2%)		1 (2%)	1 (2%)
Pancreas	(50)	(50)	(50)	(49)
Carcinoma				1 (2%)
Mixed Tumor Malignant			1 (2%)	
Acinus, Adenoma	4 (8%)	1 (2%)	4 (8%)	4 (8%)
Acinus, Adenoma, Multiple	1 (2%)	3 (6%)		1 (2%)

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

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Species/Strain: RATS/HSD

Lab: BAT

Harlan Sprague Dawley RATS MALE	0 mg/kg	75 mg/kg	150 mg/kg	300 mg/kg
Salivary Glands	(50)	(50)	(49)	(50)
Schwannoma Malignant	1 (2%)			1 (2%)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Squamous Cell Carcinoma	1 (2%)		1 (2%)	
Squamous Cell Papilloma			1 (2%)	
Stomach, Glandular	(50)	(50)	(50)	(50)
Tongue	(0)	(0)	(0)	(1)
Squamous Cell Papilloma				1 (100%)
Tooth	(1)	(0)	(1)	(0)

## CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(50)	(50)	(50)
Aorta, Fibrous Histiocytoma, Metastatic, Skin				1 (2%)
Heart	(50)	(50)	(50)	(50)
Schwannoma Malignant	1 (2%)	1 (2%)		

## ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(49)	(50)	(50)
Adenoma		1 (2%)		
Carcinoma		1 (2%)		1 (2%)
Adrenal Medulla	(50)	(49)	(50)	(50)
Pheochromocytoma Benign	5 (10%)	5 (10%)	4 (8%)	3 (6%)
Pheochromocytoma Complex	1 (2%)			
Pheochromocytoma Malignant	2 (4%)	1 (2%)	1 (2%)	
Bilateral, Pheochromocytoma Benign			1 (2%)	1 (2%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	2 (4%)	1 (2%)	1 (2%)	
Parathyroid Gland	(43)	(46)	(50)	(47)
Carcinoma		1 (2%)		
Pituitary Gland	(50)	(49)	(50)	(47)
Pars Distalis, Adenoma	5 (10%)	8 (16%)	9 (18%)	8 (17%)
Pars Distalis, Carcinoma		1 (2%)		
Thyroid Gland	(50)	(46)	(48)	(47)

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Harlan Sprague Dawley RATS MALE	0 mg/kg	75 mg/kg	150 mg/kg	300 mg/kg
Bilateral, C-cell, Adenoma	2 (4%)		1 (2%)	
C-cell, Adenoma	11 (22%)	9 (20%)	8 (17%)	4 (9%)
C-cell, Carcinoma		1 (2%)	1 (2%)	
Follicular Cell, Adenoma		1 (2%)		

## GENERAL BODY SYSTEM

None

## GENITAL SYSTEM

Epididymis	(50)	(50)	(50)	(50)
Preputial Gland	(50)	(50)	(49)	(50)
Prostate	(50)	(50)	(50)	(50)
Seminal Vesicle	(49)	(50)	(50)	(50)
Testes	(49)	(50)	(50)	(50)
Interstitial Cell, Adenoma	3 (6%)	2 (4%)	2 (4%)	2 (4%)

## HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(4)	(8)	(8)	(6)
Lymph Node, Mandibular	(50)	(50)	(49)	(50)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Hemangiosarcoma	1 (2%)			1 (2%)
Spleen	(50)	(50)	(50)	(50)
Thymus	(46)	(49)	(49)	(47)
Neural Crest Tumor				1 (2%)
Thymoma Benign	1 (2%)	1 (2%)		

## INTEGUMENTARY SYSTEM

Mammary Gland	(50)	(50)	(50)	(50)
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Fibroadenoma	1 (2%)	1 (2%)	1 (2%)	
Skin	(50)	(50)	(50)	(50)
Basal Cell Carcinoma	1 (2%)	1 (2%)		
Keratoacanthoma	4 (8%)			
Squamous Cell Carcinoma	1 (2%)		1 (2%)	
Squamous Cell Papilloma	1 (2%)		1 (2%)	1 (2%)
Sebaceous Gland, Adenoma		1 (2%)		
Subcutaneous Tissue, Fibroma	5 (10%)	2 (4%)	5 (10%)	2 (4%)
Subcutaneous Tissue, Fibrosarcoma	1 (2%)	2 (4%)	1 (2%)	1 (2%)
Subcutaneous Tissue, Fibrous Histiocytoma	1 (2%)			1 (2%)
Subcutaneous Tissue, Sarcoma		2 (4%)		
Subcutaneous Tissue, Schwannoma Malignant			1 (2%)	
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone	(50)	(50)	(50)	(50)
Vertebra, Osteoma				1 (2%)
<b>NERVOUS SYSTEM</b>				
Brain	(50)	(50)	(50)	(50)
Glioma Malignant		1 (2%)		
Medulloblastoma Mal			1 (2%)	
Meningioma Malignant		1 (2%)		
Cerebellum, Glioma Malignant				1 (2%)
Spinal Cord	(0)	(2)	(1)	(0)
<b>RESPIRATORY SYSTEM</b>				
Lung	(49)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma			1 (2%)	
Carcinoma, Metastatic, Adrenal Cortex				1 (2%)
Fibrous Histiocytoma, Metastatic, Skin				1 (2%)
Squamous Cell Carcinoma		1 (2%)		

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Nose	(50)	(50)	(50)	(50)
Trachea	(50)	(50)	(50)	(50)

## SPECIAL SENSES SYSTEM

Ear	(0)	(0)	(1)	(0)
Eye	(50)	(50)	(49)	(49)
Harderian Gland	(50)	(50)	(49)	(50)
Lacrimal Gland	(1)	(2)	(4)	(0)

## URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
Renal Tubule, Adenoma	1 (2%)			1 (2%)
Urinary Bladder	(50)	(50)	(50)	(50)

## SYSTEMIC LESIONS

Multiple Organ	*(50)	*(50)	*(50)	*(50)
Leukemia Granulocytic				1 (2%)
Lymphoma Malignant			1 (2%)	1 (2%)
Mesothelioma Malignant	1 (2%)	1 (2%)		

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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Harlan Sprague Dawley RATS MALE	0 mg/kg	75 mg/kg	150 mg/kg	300 mg/kg
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**Tumor Summary for Males**

Total Animals with Primary Neoplasms (b)	33	32	31	33
Total Primary Neoplasms	60	53	50	42
Total Animals with Benign Neoplasms	27	23	26	25
Total Benign Neoplasms	47	37	39	29
Total Animals with Malignant Neoplasms	12	15	10	12
Total Malignant Neoplasms	13	16	11	12
Total Animals with Metastatic Neoplasms				3
Total Metastatic Neoplasms				4
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain- Benign or Malignant				1
Total Uncertain Neoplasms				1

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\*\*\* 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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**Disposition Summary**

<b>Animals Initially In Study</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>
<b>Early Deaths</b>				
<b>Dosing Accident</b>		<b>1</b>		<b>1</b>
<b>Moribund Sacrifice</b>	<b>24</b>	<b>22</b>	<b>23</b>	<b>11</b>
<b>Natural Death</b>	<b>5</b>	<b>8</b>	<b>7</b>	<b>8</b>
<b>Survivors</b>				
<b>Moribund Sacrifice</b>		<b>1</b>	<b>1</b>	
<b>Terminal Sacrifice</b>	<b>21</b>	<b>18</b>	<b>19</b>	<b>30</b>
<b>Animals Examined Microscopically</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>

## ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Intestine Large, Cecum	(50)	(50)	(50)	(48)
Intestine Large, Colon	(50)	(50)	(50)	(48)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(48)	(47)	(48)	(47)
Intestine Small, Ileum	(47)	(47)	(48)	(47)
Intestine Small, Jejunum	(47)	(46)	(48)	(48)
Liver	(50)	(50)	(50)	(48)
Adenocarcinoma, Metastatic, Uterus			2 (4%)	1 (2%)
Hepatocellular Adenoma	2 (4%)	1 (2%)	4 (8%)	
Hepatocellular Carcinoma		1 (2%)		
Mesentery	(0)	(2)	(2)	(1)
Fat, Adenocarcinoma, Metastatic, Uterus		1 (50%)	1 (50%)	1 (100%)
Fat, Squamous Cell Carcinoma, Metastatic, Uterus			1 (50%)	
Oral Mucosa	(50)	(50)	(50)	(50)
Squamous Cell Carcinoma				2 (4%)
Pancreas	(50)	(49)	(49)	(48)
Adenocarcinoma, Metastatic, Uterus		1 (2%)	1 (2%)	1 (2%)
Sarcoma Stromal, Metastatic, Uterus	1 (2%)			
Acinus, Adenoma		1 (2%)		1 (2%)
Salivary Glands	(50)	(49)	(48)	(50)

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



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Species/Strain: RATS/HSD

Lab: BAT

Harlan Sprague Dawley RATS FEMALE	0 mg/kg	75 mg/kg	150 mg/kg	300 mg/kg
Stomach, Forestomach	(50)	(50)	(50)	(49)
Adenocarcinoma, Metastatic, Uterus				1 (2%)
Sarcoma Stromal, Metastatic, Uterus	1 (2%)			
Squamous Cell Carcinoma	1 (2%)			1 (2%)
Stomach, Glandular	(50)	(49)	(50)	(49)
Adenocarcinoma, Metastatic, Uterus				1 (2%)
Carcinoma		1 (2%)		
Tongue	(1)	(1)	(0)	(1)
Tooth	(0)	(1)	(0)	(0)

## CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(50)	(50)	(50)
Aorta, Squamous Cell Carcinoma, Metastatic, Lung			1 (2%)	
Heart	(50)	(50)	(50)	(49)
Hemangioma			1 (2%)	
Schwannoma Malignant		2 (4%)		
Squamous Cell Carcinoma, Metastatic, Lung			1 (2%)	

## ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(48)
Adenocarcinoma, Metastatic, Uterus				1 (2%)
Adenoma		1 (2%)	1 (2%)	
Sarcoma Stromal, Metastatic, Uterus	1 (2%)			
Adrenal Medulla	(50)	(50)	(50)	(48)
Pheochromocytoma Benign		2 (4%)	2 (4%)	
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma		1 (2%)		
Carcinoma			1 (2%)	
Parathyroid Gland	(47)	(49)	(46)	(49)
Pituitary Gland	(50)	(50)	(50)	(49)
Schwannoma Malignant, Metastatic, Peripheral Nerve		1 (2%)		

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Lab: BAT

Harlan Sprague Dawley RATS FEMALE	0 mg/kg	75 mg/kg	150 mg/kg	300 mg/kg
Pars Distalis, Adenoma	18 (36%)	18 (36%)	19 (38%)	8 (16%)
Thyroid Gland	(49)	(49)	(48)	(47)
C-cell, Adenoma	11 (22%)	9 (18%)	5 (10%)	10 (21%)
C-cell, Carcinoma		1 (2%)		1 (2%)
Follicular Cell, Adenoma			1 (2%)	

## GENERAL BODY SYSTEM

None

## GENITAL SYSTEM

Clitoral Gland	(50)	(50)	(50)	(50)
Ovary	(50)	(50)	(50)	(49)
Adenocarcinoma, Metastatic, Uterus			1 (2%)	
Granulosa Cell Tumor Benign			1 (2%)	
Granulosa-Theca Tumor Benign	1 (2%)			
Tubulostromal Carcinoma	1 (2%)			
Uterus	(50)	(50)	(50)	(50)
Adenocarcinoma		1 (2%)	4 (8%)	3 (6%)
Adenocarcinoma, Multiple				1 (2%)
Polyp Stromal	10 (20%)	10 (20%)	13 (26%)	9 (18%)
Sarcoma Stromal	1 (2%)		2 (4%)	1 (2%)
Sarcoma Stromal, Multiple	1 (2%)			
Squamous Cell Carcinoma			1 (2%)	
Vagina	(2)	(1)	(0)	(2)
Polyp	1 (50%)			
Sarcoma Stromal, Metastatic, Uterus				1 (50%)
Schwannoma Malignant	1 (50%)	1 (100%)		1 (50%)

## HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(7)	(6)	(4)	(3)

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Harlan Sprague Dawley RATS FEMALE	0 mg/kg	75 mg/kg	150 mg/kg	300 mg/kg
Pancreatic, Sarcoma Stromal, Metastatic, Uterus	1 (14%)			
Renal, Adenocarcinoma, Metastatic, Uterus				1 (33%)
Lymph Node, Mandibular	(50)	(49)	(49)	(50)
Lymph Node, Mesenteric	(50)	(50)	(50)	(48)
Adenocarcinoma, Metastatic, Uterus				1 (2%)
Sarcoma Stromal, Metastatic, Uterus	1 (2%)			
Spleen	(50)	(50)	(50)	(48)
Thymus	(47)	(50)	(49)	(50)
Adenocarcinoma, Metastatic, Uterus				1 (2%)
Squamous Cell Carcinoma, Metastatic, Lung			1 (2%)	

## INTEGUMENTARY SYSTEM

Mammary Gland	(50)	(50)	(50)	(50)
Adenoma	3 (6%)	1 (2%)		2 (4%)
Carcinoma	3 (6%)	2 (4%)	2 (4%)	
Fibroadenoma	18 (36%)	23 (46%)	20 (40%)	17 (34%)
Fibroadenoma, Multiple	11 (22%)	8 (16%)	4 (8%)	6 (12%)
Myoepithelioma	1 (2%)			
Skin	(50)	(50)	(50)	(50)
Basal Cell Carcinoma			1 (2%)	
Fibrosarcoma				1 (2%)
Hemangiosarcoma	1 (2%)			
Schwannoma Malignant	1 (2%)			
Subcutaneous Tissue, Fibroma	1 (2%)			4 (8%)
Subcutaneous Tissue, Fibrosarcoma	1 (2%)			
Subcutaneous Tissue, Sarcoma				1 (2%)
Subcutaneous Tissue, Schwannoma Malignant			1 (2%)	

## MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Cranium, Osteoma				1 (2%)
Periosteum, Sarcoma				1 (2%)

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Harlan Sprague Dawley RATS FEMALE	0 mg/kg	75 mg/kg	150 mg/kg	300 mg/kg
Skeletal Muscle	(1)	(0)	(1)	(1)
Adenocarcinoma, Metastatic, Uterus				1 (100%)
Sarcoma	1 (100%)			

## NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(50)
Glioma Malignant				1 (2%)
Granular Cell Tumor Benign	1 (2%)			
Peripheral Nerve	(0)	(2)	(0)	(0)
Trigeminal, Schwannoma Malignant		1 (50%)		
Spinal Cord	(0)	(1)	(0)	(0)

## RESPIRATORY SYSTEM

Lung	(50)	(50)	(50)	(49)
Adenocarcinoma, Metastatic, Uterus		1 (2%)	1 (2%)	1 (2%)
Alveolar/Bronchiolar Adenoma	1 (2%)		1 (2%)	
Cystic Keratinizing Epithelioma		1 (2%)		
Squamous Cell Carcinoma, Multiple			1 (2%)	
Mediastinum, Sarcoma	1 (2%)			
Nose	(49)	(50)	(49)	(50)
Trachea	(50)	(50)	(50)	(50)

## SPECIAL SENSES SYSTEM

Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)
Schwannoma Malignant, Metastatic, Peripheral Nerve		1 (2%)		

## URINARY SYSTEM

Kidney	(50)	(50)	(50)	(48)
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Harlan Sprague Dawley RATS FEMALE	0 mg/kg	75 mg/kg	150 mg/kg	300 mg/kg
Adenocarcinoma, Metastatic, Uterus				1 (2%)
Capsule, Adenocarcinoma, Metastatic, Uterus			1 (2%)	
Renal Tubule, Adenoma			1 (2%)	
Renal Tubule, Adenoma, Multiple			1 (2%)	
Urinary Bladder	(49)	(50)	(50)	(50)
Squamous Cell Carcinoma			1 (2%)	

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**SYSTEMIC LESIONS**

Multiple Organ	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma	1 (2%)			
Leukemia Mononuclear		2 (4%)		
Lymphoma Malignant			1 (2%)	1 (2%)

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\* Number of animals with any tissue examined microscopically

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Harlan Sprague Dawley RATS FEMALE	0 mg/kg	75 mg/kg	150 mg/kg	300 mg/kg
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**Tumor Summary for Females**

Total Animals with Primary Neoplasms (b)	46	44	46	37
Total Primary Neoplasms	93	88	89	73
Total Animals with Benign Neoplasms	40	40	41	35
Total Benign Neoplasms	79	76	74	58
Total Animals with Malignant Neoplasms	14	11	15	15
Total Malignant Neoplasms	14	12	15	15
Total Animals with Metastatic Neoplasms	1	2	4	3
Total Metastatic Neoplasms	5	5	11	13
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain- Benign or Malignant				
Total Uncertain Neoplasms				

\*\*\* 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