

**TDMs No.** 20006 - 01

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

**Date Report Reqsted:** 06/04/2007

**Test Type:** 90-DAY

INDOLE-3-CARBINOL

**Time Report Reqsted:** 16:29:44

**Route:** GAVAGE

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

**First Dose M/F:** 08/31/04 / 08/30/04

**Species/Strain:** RATS/F 344

**Lab:** SRI

F1\_R2

**C Number:** C20006  
**Lock Date:** 03/07/2006  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**TDMSE Version:** 1.7.0

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CAS Number: 700-06-1

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Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>Disposition Summary</b>					
Animals Initially in Study	10	10	10	10	10
Early Deaths					
Survivors					
Terminal Sacrifice	10	10	10	10	10
Animals Examined Microscopically	10	10	10	10	10
<b>ALIMENTARY SYSTEM</b>					
Esophagus	(10)	(0)	(0)	(0)	(0)
Inflammation, Chronic					
Intestine Small, Duodenum	(10)	(10)	(10)	(10)	(10)
Lamina Propria, Lipidosis				1 [1.0]	10 [1.2]
Lymphatic, Ectasia				1 [1.0]	10 [1.2]
Intestine Small, Jejunum	(10)	(9)	(10)	(10)	(10)
Lamina Propria, Lipidosis		1 [1.0]	1 [1.0]	5 [1.0]	10 [2.3]
Lymphatic, Ectasia		1 [1.0]	1 [1.0]	5 [1.0]	10 [2.3]
Liver	(10)	(10)	(10)	(10)	(10)
Hemorrhage	2 [1.5]			1 [1.0]	
Hepatodiaphragmatic Nodule			1	1	
Infiltration Cellular, Mixed Cell					
Capsule, Fibrosis				1 [1.0]	
Hepatocyte, Necrosis				1 [1.0]	1 [1.0]
Hepatocyte, Vacuolization Cytoplasmic	4 [1.0]	4 [1.3]	2 [1.5]	4 [1.0]	2 [1.0]
Mesentery	(2)	(0)	(0)	(0)	(0)
Accessory Spleen	1				
Fat, Necrosis	1 [2.0]				
<b>CARDIOVASCULAR SYSTEM</b>					
Heart	(10)	(0)	(0)	(0)	(0)
Cardiomyopathy	1 [1.0]				
Infiltration Cellular, Mixed Cell	3 [1.0]				
<b>ENDOCRINE SYSTEM</b>					

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)

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Lab: SRI

FISCHER 344 RATS MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)
Accessory Adrenal Cortical Nodule	2 [1.5]				
<b>GENERAL BODY SYSTEM</b>					
None					
<b>GENITAL SYSTEM</b>					
None					
<b>HEMATOPOIETIC SYSTEM</b>					
Lymph Node, Mesenteric	(7)	(10)	(9)	(10)	(10)
Hemorrhage	1 [1.0]				
Lipidosis		2 [1.0]	1 [1.0]		5 [1.4]
Lymphatic, Ectasia		2 [1.0]	1 [1.0]		5 [1.4]
Spleen	(10)	(0)	(0)	(0)	(0)
Pigmentation	3 [1.0]				
<b>INTEGUMENTARY SYSTEM</b>					
None					
<b>MUSCULOSKELETAL SYSTEM</b>					
None					
<b>NERVOUS SYSTEM</b>					
None					
<b>RESPIRATORY SYSTEM</b>					
Lung	(10)	(0)	(0)	(0)	(0)
Hemorrhage					
Inflammation, Chronic	3 [1.0]				

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Lab: SRI

FISCHER 344 RATS MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Alveolar Epithelium, Hyperplasia	1 [1.0]				
Nose	(10)	(0)	(0)	(0)	(0)
Nasolacrimal Duct, Inflammation, Chronic	1 [2.0]				
<b>SPECIAL SENSES SYSTEM</b>					
Harderian Gland	(10)	(0)	(0)	(0)	(0)
Inflammation, Chronic					
<b>URINARY SYSTEM</b>					
Kidney	(10)	(0)	(0)	(0)	(0)
Nephropathy					

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)

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First Dose M/F: 08/31/04 / 08/30/04

Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS MALE

300 MG/KG

**Disposition Summary**

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

## ALIMENTARY SYSTEM

Esophagus	(9)
Inflammation, Chronic	1 [1.0]
Intestine Small, Duodenum	(10)
Lamina Propria, Lipidosis	10 [2.2]
Lymphatic, Ectasia	10 [2.2]
Intestine Small, Jejunum	(10)
Lamina Propria, Lipidosis	10 [3.5]
Lymphatic, Ectasia	10 [3.5]
Liver	(10)
Hemorrhage	
Hepatodiaphragmatic Nodule	
Infiltration Cellular, Mixed Cell	1 [1.0]
Capsule, Fibrosis	
Hepatocyte, Necrosis	
Hepatocyte, Vacuolization Cytoplasmic	2 [1.0]
Mesentery	(0)
Accessory Spleen	
Fat, Necrosis	

## CARDIOVASCULAR SYSTEM

Heart	(10)
Cardiomyopathy	3 [1.0]
Infiltration Cellular, Mixed Cell	3 [1.0]

## ENDOCRINE SYSTEM

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)

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INDOLE-3-CARBINOL

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Species/Strain: RATS/F 344

Lab: SRI

**FISCHER 344 RATS MALE**

**300 MG/KG**

Adrenal Cortex  
Accessory Adrenal Cortical Nodule

(10)  
1 [1.0]

**GENERAL BODY SYSTEM**

None

**GENITAL SYSTEM**

None

**HEMATOPOIETIC SYSTEM**

Lymph Node, Mesenteric  
Hemorrhage  
Lipidosis  
Lymphatic, Ectasia  
Spleen  
Pigmentation

(10)  
1 [1.0]  
10 [3.0]  
10 [3.0]  
(10)  
1 [1.0]

**INTEGUMENTARY SYSTEM**

None

**MUSCULOSKELETAL SYSTEM**

None

**NERVOUS SYSTEM**

None

**RESPIRATORY SYSTEM**

Lung  
Hemorrhage  
Inflammation, Chronic

(10)  
1 [2.0]

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

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FISCHER 344 RATS MALE	300 MG/KG
Alveolar Epithelium, Hyperplasia Nose Nasolacrimal Duct, Inflammation, Chronic	(10)
<b>SPECIAL SENSES SYSTEM</b>	
Harderian Gland Inflammation, Chronic	(10) 1 [1.0]
<b>URINARY SYSTEM</b>	
Kidney Nephropathy	(10) 2 [1.0]

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

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Species/Strain: RATS/F 344

Lab: SRI

FISCHER 344 RATS FEMALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>Disposition Summary</b>					
Animals Initially in Study	10	10	10	10	10
Early Deaths					
Survivors					
Terminal Sacrifice	10	10	10	10	10
Animals Examined Microscopically	10	10	10	10	10
<b>ALIMENTARY SYSTEM</b>					
Intestine Small, Duodenum	(10)	(10)	(10)	(10)	(10)
Lamina Propria, Lipidosis					9 [1.0]
Lymphatic, Ectasia					9 [1.0]
Intestine Small, Jejunum	(10)	(10)	(10)	(10)	(10)
Lamina Propria, Lipidosis			1 [1.0]	10 [1.0]	10 [1.8]
Lymphatic, Ectasia			1 [1.0]	10 [1.0]	10 [1.8]
Liver	(10)	(10)	(10)	(10)	(10)
Eosinophilic Focus	1				
Hemorrhage				1 [1.0]	
Hepatodiaphragmatic Nodule					2
Infiltration Cellular, Mixed Cell	2 [1.5]	1 [1.0]	2 [1.0]	1	2 [1.0]
Mesentery	(0)	(0)	(1)	(0)	(1)
Fat, Necrosis			1 [3.0]		1 [2.0]
Pancreas	(10)	(0)	(0)	(0)	(0)
Atrophy					
<b>CARDIOVASCULAR SYSTEM</b>					
Heart	(10)	(0)	(0)	(0)	(0)
Cardiomyopathy	2 [1.0]				
<b>ENDOCRINE SYSTEM</b>					
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)
Accessory Adrenal Cortical Nodule	2 [1.0]				
Pituitary Gland	(10)	(0)	(1)	(0)	(0)
Rathke's Cleft, Hemorrhage			1 [2.0]		

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Lab: SRI

FISCHER 344 RATS FEMALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
<b>GENERAL BODY SYSTEM</b>					
None					
<b>GENITAL SYSTEM</b>					
Ovary Cyst	(10)	(0)	(0)	(0)	(0)
<b>HEMATOPOIETIC SYSTEM</b>					
Lymph Node	(0)	(0)	(1)	(0)	(0)
Mediastinal, Hemorrhage			1 [2.0]		
Mediastinal, Hyperplasia, Lymphoid			1 [4.0]		
Lymph Node, Mesenteric	(10)	(10)	(10)	(10)	(10)
Lipidosis					3 [1.3]
Lymphatic, Ectasia					3 [1.3]
Spleen	(10)	(0)	(0)	(0)	(0)
Pigmentation	2 [2.0]				
<b>INTEGUMENTARY SYSTEM</b>					
Skin	(10)	(0)	(0)	(0)	(0)
Cyst Epithelial Inclusion					
<b>MUSCULOSKELETAL SYSTEM</b>					
None					
<b>NERVOUS SYSTEM</b>					
None					
<b>RESPIRATORY SYSTEM</b>					
Lung	(10)	(0)	(0)	(0)	(0)

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

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FISCHER 344 RATS FEMALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Hemorrhage Nose Inflammation, Chronic	1 [2.0] (10) 1 [1.0]	(0)	(0)	(0)	(0)
<b>SPECIAL SENSES SYSTEM</b>					
Harderian Gland Inflammation, Suppurative	(10)	(0)	(0)	(0)	(0)
<b>URINARY SYSTEM</b>					
Kidney Nephropathy	(10)	(0)	(0)	(0)	(0)

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FISCHER 344 RATS FEMALE

300 MG/KG

**Disposition Summary**

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

## ALIMENTARY SYSTEM

Intestine Small, Duodenum	(10)
Lamina Propria, Lipidosis	10 [2.4]
Lymphatic, Ectasia	10 [2.4]
Intestine Small, Jejunum	(10)
Lamina Propria, Lipidosis	10 [3.0]
Lymphatic, Ectasia	10 [3.0]
Liver	(10)
Eosinophilic Focus	
Hemorrhage	
Hepatodiaphragmatic Nodule	
Infiltration Cellular, Mixed Cell	
Mesentery	(1)
Fat, Necrosis	1 [2.0]
Pancreas	(10)
Atrophy	2 [1.0]

## CARDIOVASCULAR SYSTEM

Heart	(10)
Cardiomyopathy	

## ENDOCRINE SYSTEM

Adrenal Cortex	(10)
Accessory Adrenal Cortical Nodule	1 [1.0]
Pituitary Gland	(10)
Rathke's Cleft, Hemorrhage	

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FISCHER 344 RATS FEMALE

300 MG/KG

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Ovary	(10)
Cyst	1

HEMATOPOIETIC SYSTEM

Lymph Node	(0)
Mediastinal, Hemorrhage	
Mediastinal, Hyperplasia, Lymphoid	
Lymph Node, Mesenteric	(10)
Lipidosis	9 [3.2]
Lymphatic, Ectasia	9 [3.2]
Spleen	(10)
Pigmentation	4 [1.8]

INTEGUMENTARY SYSTEM

Skin	(10)
Cyst Epithelial Inclusion	1

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

Lung	(10)
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**FISCHER 344 RATS FEMALE**

**300 MG/KG**

Hemorrhage	1 [2.0]
Nose	(10)
Inflammation, Chronic	1 [1.0]

**SPECIAL SENSES SYSTEM**

Harderian Gland	(10)
Inflammation, Suppurative	1 [2.0]

**URINARY SYSTEM**

Kidney	(10)
Nephropathy	2 [1.0]

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