Test Type: 90-DAY

Route: GAVAGE

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

INDOLE-3-CARBINOL

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

Species/Strain: RATS/F 344

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 Date Report Regsted: 06/04/2007

Time Report Regsted: 16:29:44 First Dose M/F: 08/31/04 / 08/30/04

Species/Strain: RATS/F 344

Test Type: 90-DAY

Route: GAVAGE

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

INDOLE-3-CARBINOL CAS Number: 700-06-1

Date Report Reqsted: 06/04/2007

Time Report Reqsted: 16:29:44 First Dose M/F: 08/31/04 / 08/30/04

Lab: SRI

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

Species/Strain: RATS/F 344

Test Type: 90-DAY

Route: GAVAGE

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

INDOLE-3-CARBINOL CAS Number: 700-06-1

Date Report Reqsted: 06/04/2007

Time Report Reqsted: 16:29:44 First Dose M/F: 08/31/04 / 08/30/04

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

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)

Species/Strain: RATS/F 344

Test Type: 90-DAY

Route: GAVAGE

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

INDOLE-3-CARBINOL CAS Number: 700-06-1

Date Report Reqsted: 06/04/2007

Time Report Reqsted: 16:29:44 First Dose M/F: 08/31/04 / 08/30/04

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

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

Route: GAVAGE

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

INDOLE-3-CARBINOL CAS Number: 700-06-1

Date Report Reqsted: 06/04/2007

Time Report Reqsted: 16:29:44 First Dose M/F: 08/31/04 / 08/30/04

Lab: SRI

Species/Strain: RATS/F 344

FISCHER 344 RATS MALE	300 MG/KG	
Disposition Summary		
Animals Initially in Study Early Deaths	10	
Survivors Terminal Sacrifice Animals Examined Microscopically	10 10	
ALIMENTARY SYSTEM		
Esophagus Inflammation, Chronic Intestine Small, Duodenum Lamina Propria, Lipidosis Lymphatic, Ectasia Intestine Small, Jejunum Lamina Propria, Lipidosis Lymphatic, Ectasia Liver Hemorrhage Hepatodiaphragmatic Nodule Infiltration Cellular, Mixed Cell Capsule, Fibrosis Hepatocyte, Necrosis Hepatocyte, Vacuolization Cytoplasmic Mesentery Accessory Spleen Fat, Necrosis	(9) 1 [1.0] (10) 10 [2.2] 10 [2.2] (10) 10 [3.5] 10 [3.5] (10)  1 [1.0]  2 [1.0] (0)	
CARDIOVASCULAR SYSTEM		
Heart Cardiomyopathy Infiltration Cellular, Mixed Cell	(10) 3 [1.0] 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)

Test Type: 90-DAY

Route: GAVAGE

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

INDOLE-3-CARBINOL CAS Number: 700-06-1

Date Report Reqsted: 06/04/2007

Time Report Reqsted: 16:29:44 First Dose M/F: 08/31/04 / 08/30/04

Species/Str	ain: R	ATS/	F 344

·	
FISCHER 344 RATS MALE	300 MG/KG
Adrenal Cortex	(10)
Accessory Adrenal Cortical Nodule	1 [1.0]
GENERAL BODY SYSTEM	
None	
GENITAL SYSTEM	
None	
HEMATOPOIETIC SYSTEM	
Lymph Node, Mesenteric Hemorrhage	(10) 1 [1.0]
Lipidosis Lymphatic, Ectasia	10 [3.0] 10 [3.0] 10 [3.0]
Spleen	(10)
Pigmentation	1 [1.0]
INTEGUMENTARY SYSTEM	
None	
MUSCULOSKELETAL SYSTEM	
None	
NERVOUS SYSTEM	
None	
RESPIRATORY SYSTEM	
Lung	(10)
Hemorrhage Inflammation, Chronic	1 [2.0]

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)

Species/Strain: RATS/F 344

Test Type: 90-DAY

Route: GAVAGE

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

INDOLE-3-CARBINOL CAS Number: 700-06-1

Date Report Reqsted: 06/04/2007

Time Report Reqsted: 16:29:44 First Dose M/F: 08/31/04 / 08/30/04

Lab: SRI

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

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

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)

Species/Strain: RATS/F 344

Test Type: 90-DAY

Route: GAVAGE

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

INDOLE-3-CARBINOL CAS Number: 700-06-1

Date Report Reqsted: 06/04/2007
Time Report Reqsted: 16:29:44

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

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

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)

Species/Strain: RATS/F 344

Test Type: 90-DAY

Route: GAVAGE

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

INDOLE-3-CARBINOL CAS Number: 700-06-1

Date Report Reqsted: 06/04/2007

Time Report Reqsted: 16:29:44 First Dose M/F: 08/31/04 / 08/30/04

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

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)

Species/Strain: RATS/F 344

Test Type: 90-DAY

Route: GAVAGE

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

INDOLE-3-CARBINOL CAS Number: 700-06-1

Date Report Reqsted: 06/04/2007

Time Report Reqsted: 16:29:44 First Dose M/F: 08/31/04 / 08/30/04

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)
SPECIAL SENSES SYSTEM					
Harderian Gland Inflammation, Suppurative	(10)	(0)	(0)	(0)	(0)
URINARY SYSTEM					
Kidney Nephropathy	(10)	(0)	(0)	(0)	(0)

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)

Species/Strain: RATS/F 344

Test Type: 90-DAY

Route: GAVAGE

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

INDOLE-3-CARBINOL CAS Number: 700-06-1

Date Report Reqsted: 06/04/2007

Time Report Reqsted: 16:29:44 First Dose M/F: 08/31/04 / 08/30/04

Lab: SRI

FISCHER 344 RATS FEMALE	300 MG/KG		
Disposition Summary			
Animals Initially in Study Early Deaths Survivors	10		
Terminal Sacrifice Animals Examined Microscopically	10 10		
ALIMENTARY SYSTEM			
Intestine Small, Duodenum Lamina Propria, Lipidosis Lymphatic, Ectasia Intestine Small, Jejunum Lamina Propria, Lipidosis Lymphatic, Ectasia Liver Eosinophilic Focus Hemorrhage Hepatodiaphragmatic Nodule Infiltration Cellular, Mixed Cell	(10) 10 [2.4] 10 [2.4] (10) 10 [3.0] 10 [3.0] (10)		
Mesentery Fat, Necrosis Pancreas Atrophy	(1) 1 [2.0] (10) 2 [1.0]		
CARDIOVASCULAR SYSTEM			
Heart Cardiomyopathy	(10)		
ENDOCRINE SYSTEM			
Adrenal Cortex Accessory Adrenal Cortical Nodule Pituitary Gland	(10) 1 [1.0] (10)		

Rathke's Cleft, Hemorrhage

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)

Species/Strain: RATS/F 344

Test Type: 90-DAY

Route: GAVAGE

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

INDOLE-3-CARBINOL CAS Number: 700-06-1

Date Report Reqsted: 06/04/2007

Time Report Reqsted: 16:29:44 First Dose M/F: 08/31/04 / 08/30/04

FISCHER 344 RATS FEMALE	300 MG/KG	
GENERAL BODY SYSTEM		
None		
GENITAL SYSTEM		
Ovary Cyst	(10) 1	
HEMATOPOIETIC SYSTEM		
Lymph Node Mediastinal, Hemorrhage Mediastinal, Hyperplasia, Lymphoid	(0)	
Lymph Node, Mesenteric	(10)	
Lipidosis Lymphatic, Ectasia	9 [3.2] 9 [3.2]	
Spleen	9 [3.2] (10)	
Pigmentation	4 [1.8]	
INTEGUMENTARY SYSTEM		
Skin	(10)	
Cyst Epithelial Inclusion	1	
MUSCULOSKELETAL SYSTEM		
None		
NERVOUS SYSTEM		
None		
RESPIRATORY SYSTEM		
Lung	(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)

Species/Strain: RATS/F 344

Test Type: 90-DAY

Route: GAVAGE

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

INDOLE-3-CARBINOL CAS Number: 700-06-1

Date Report Reqsted: 06/04/2007

Time Report Reqsted: 16:29:44 First Dose M/F: 08/31/04 / 08/30/04

Lab: SRI

FISCHER 344 RATS FEMALE	300 MG/KG	
Hemorrhage Nose Inflammation, Chronic	1 [2.0] (10) 1 [1.0]	
SPECIAL SENSES SYSTEM		
Harderian Gland Inflammation, Suppurative	(10) 1 [2.0]	
URINARY SYSTEM		
Kidney Nephropathy	(10) 2 [1.0]	

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

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)