TDMS No. 20006 - 01 Test Type: 90-DAY Route: GAVAGE

Species/Strain: RATS/F 344

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

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

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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 Reqsted:** 06/04/2007 **Time Report Reqsted:** 16:29:44 **First Dose M/F:** 08/31/04 / 08/30/04

Lab: SRI

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 Inflammation, Chronic	(10)	(0)	(0)	(0)	(0)
Intestine Small, Duodenum Lamina Propria, Lipidosis Lymphatic, Ectasia	(10)	(10)	(10)	(10) 1 (10%) 1 (10%)	(10) 10 (100%) 10 (100%)
Intestine Small, Jejunum Lamina Propria, Lipidosis Lymphatic, Ectasia	(10)	(9) 1 (11%) 1 (11%)	(10) 1 (10%) 1 (10%)	(10) 5 (50%) 5 (50%)	(10) 10 (100%) 10 (100%)
Liver Hemorrhage Hepatodiaphragmatic Nodule Infiltration Cellular, Mixed Cell	(10) 2 (20%)	(10)	(10) 1 (10%)	(10) 1 (10%) 1 (10%)	(10)
Capsule, Fibrosis Hepatocyte, Necrosis Hepatocyte, Vacuolization Cytoplasmic	4 (40%)	4 (40%)	2 (20%)	1 (10%) 1 (10%) 4 (40%)	1 (10%) 2 (20%)
Mesentery Accessory Spleen Fat, Necrosis	(2) 1 (50%) 1 (50%)	(0)	(0)	(0)	(0)
CARDIOVASCULAR SYSTEM					
Heart Cardiomyopathy Infiltration Cellular, Mixed Cell	(10) 1 (10%) 3 (30%)	(0)	(0)	(0)	(0)
ENDOCRINE SYSTEM					
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)

**TDMS No.** 20006 - 01 **Test Type:** 90-DAY

Species/Strain: RATS/F 344

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

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
Accessory Adrenal Cortical Nodule	2 (20%)				
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
None					
HEMATOPOIETIC SYSTEM					
Lymph Node, Mesenteric Hemorrhage	(7) 1 (14%)	(10)	(9)	(10)	(10)
Lipidosis	1 (1470)	2 (20%)	1 (11%)		5 (50%) 5 (50%)
Lymphatic, Ectasia Spleen	(10)	2 (20%) (0)	1 (11%) (0)	(0)	5 (50%) (0)
Pigmentation	3 (30%)				
INTEGUMENTARY SYSTEM					
None					
MUSCULOSKELETAL SYSTEM					
None					
NERVOUS SYSTEM					
None					
RESPIRATORY SYSTEM					
Lung	(10)	(0)	(0)	(0)	(0)
Hemorrhage Inflammation, Chronic Alveolar Epithelium, Hyperplasia	3 (30%) 1 (10%)				

**TDMS No.** 20006 - 01 **Test Type:** 90-DAY

Species/Strain: RATS/F 344

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

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

Route: GAVAGE
Species/Strain: RATS/F 344

**TDMS No.** 20006 - 01 **Test Type:** 90-DAY

FISCHER 344 RATS MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 MG/KG	150 MG/KG
Nose Nasolacrimal Duct, Inflammation, Chronic	(10) 1 (10%)	(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

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		
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 (11%) (10) 10 (100%) 10 (100%) (10) 10 (100%) 10 (100%) (10)  1 (10%)  2 (20%) (0)		
CARDIOVASCULAR SYSTEM			
Heart Cardiomyopathy Infiltration Cellular, Mixed Cell	(10) 3 (30%) 3 (30%)		
ENDOCRINE SYSTEM			
Adrenal Cortex	(10)		

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

**TDMS No.** 20006 - 01 **Test Type:** 90-DAY

Species/Strain: RATS/F 344

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		
Accessory Adrenal Cortical Nodule	1 (10%)		
	. (1070)		
GENERAL BODY SYSTEM			
None			
GENITAL SYSTEM			
None			
HEMATOPOIETIC SYSTEM			
Lymph Node, Mesenteric Hemorrhage Lipidosis Lymphatic, Ectasia Spleen Pigmentation	(10) 1 (10%) 10 (100%) 10 (100%) (10) 1 (10%)		
INTEGUMENTARY SYSTEM			
None			
MUSCULOSKELETAL SYSTEM			
None			
NERVOUS SYSTEM			
None			
RESPIRATORY SYSTEM			
Lung Hemorrhage Inflammation, Chronic Alveolar Epithelium, Hyperplasia	(10) 1 (10%)		

**TDMS No.** 20006 - 01 **Test Type:** 90-DAY

Species/Strain: RATS/F 344

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

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	
Nose	(10)	
Nasolacrimal Duct, Inflammation, Chronic	(10)	
SPECIAL SENSES SYSTEM		
Harderian Gland Inflammation, Chronic	(10) 1 (10%)	
URINARY SYSTEM		
	(40)	
Kidney Nephropathy	(10) 2 (20%)	

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

**TDMS No.** 20006 - 01 **Test Type:** 90-DAY

Species/Strain: RATS/F 344

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

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

(0)

(0)

(0)

(0)

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 (90%) 9 (90%)
Intestine Small, Jejunum Lamina Propria, Lipidosis Lymphatic, Ectasia	(10)	(10)	(10) 1 (10%) 1 (10%)	(10) 10 (100%) 10 (100%)	(10) 10 (100%) 10 (100%)
Liver Eosinophilic Focus Hemorrhage	(10) 1 (10%)	(10)	(10)	(10) ´ 1 (10%)	(10) ´
Hepatodiaphragmatic Nodule Infiltration Cellular, Mixed Cell	2 (20%)	1 (10%)	2 (20%)	1 (10%)	2 (20%) 2 (20%)
Mesentery Fat, Necrosis Pancreas	(0) (10)	(0) (0)	(1) 1 (100%) (0)	(0) (0)	(1) 1 (100%) (0)
Atrophy	(14)	(-/	(-)	(-)	
CARDIOVASCULAR SYSTEM					
Heart Cardiomyopathy	(10) 2 (20%)	(0)	(0)	(0)	(0)

(10)

2 (20%) (10)

**TDMS No.** 20006 - 01

Adrenal Cortex

Pituitary Gland

Accessory Adrenal Cortical Nodule

Rathke's Cleft, Hemorrhage

Species/Strain: RATS/F 344

Test Type: 90-DAY

Route: GAVAGE

(0)

(0)

(0)

(1)

1 (100%)

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

# **TDMS No.** 20006 - 01 Test Type: 90-DAY

Species/Strain: RATS/F 344

Route: GAVAGE

### P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Date Report Reqsted: 06/04/2007 INDOLE-3-CARBINOL Time Report Reqsted: 16:29:44 First Dose M/F: 08/31/04 / 08/30/04

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

Lab: SRI

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 (100%)	(0)	(0)
Mediastinal, Hyperplasia, Lymphoid Lymph Node, Mesenteric	(10)	(10)	1 (100%) (10)	(10)	(10)
Lipidosis Lymphatic, Ectasia	(1-5)	(1.5)	(1-5)	()	3 (30%) 3 (30%)
Spleen Pigmentation	(10) 2 (20%)	(0)	(0)	(O)	(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

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	

**TDMS No.** 20006 - 01 **Test Type:** 90-DAY

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 (10%) (10) 1 (10%)	(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)

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	10		
Survivors 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 Mesentery	(10) 10 (100%) 10 (100%) (10) 10 (100%) 10 (100%) (10)		
Fat, Necrosis Pancreas Atrophy	1 (100%) (10) 2 (20%)		
CARDIOVASCULAR SYSTEM			
Heart Cardiomyopathy	(10)		
ENDOCRINE SYSTEM			
Adrenal Cortex Accessory Adrenal Cortical Nodule Pituitary Gland Rathke's Cleft, Hemorrhage	(10) 1 (10%) (10)		

**TDMS No.** 20006 - 01 **Test Type:** 90-DAY

Species/Strain: RATS/F 344

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

TDMS No. 20006 - 01 Test Type: 90-DAY Route: GAVAGE

Species/Strain: RATS/F 344

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		
GENERAL BODY SYSTEM			
None			
GENITAL SYSTEM			
Ovary Cyst	(10) 1 (10%)		
HEMATOPOIETIC SYSTEM			
Lymph Node Mediastinal, Hemorrhage Mediastinal, Hyperplasia, Lymphoid Lymph Node, Mesenteric Lipidosis Lymphatic, Ectasia Spleen Pigmentation	(0) (10) 9 (90%) 9 (90%) (10) 4 (40%)		
INTEGUMENTARY SYSTEM			
Skin Cyst Epithelial Inclusion	(10) 1 (10%)		
MUSCULOSKELETAL SYSTEM			
None			
NERVOUS SYSTEM			
None			
RESPIRATORY SYSTEM			
Lung	(10)		

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

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	1 (10%)
Nose Inflammation, Chronic	(10) 1 (10%)
SPECIAL SENSES SYSTEM	
Harderian Gland Inflammation, Suppurative	(10) 1 (10%)
URINARY SYSTEM	
Kidney Nephropathy	(10) 2 (20%)

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

**TDMS No.** 20006 - 01

Species/Strain: RATS/F 344

Test Type: 90-DAY

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