TDMS No. 20203 - 01 Test Type: 90-DAY Route: GAVAGE

Species/Strain: RATS/F344/N Tac

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

Green tea extract

CAS Number: GREENTEAEXTR

F_RD

C Number: C20203

Lock Date: 11/14/2006

Cage Range: ALL

Date Range: ALL

Reasons For Removal: ALL

Removal Date Range: ALL

Treatment Groups: Include ALL

Study Gender: Both

TDMSE Version: 2.1.0

Date Report Requested: 04/15/2009 Time Report Requested: 08:55:05 First Dose M/F: 04/17/06 / 04/18/06

TDMS No. 20203 - 01 P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Test Type: 90-DAY

Species/Strain: RATS/F344/N Tac

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Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009 Time Report Requested: 08:55:05 First Dose M/F: 04/17/06 / 04/18/06

Fischer 344-Taconic RATS MALE	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/k
Disposition Summary						
Animals Initially in Study Early Deaths Survivors	10	10	10	10	10	10
Terminal Sacrifice Animals Examined Microscopically	10 10	10 10	10 10	10 10	10 10	10 10
ALIMENTARY SYSTEM						
Liver Clear Cell Focus	(10)	(10) 1 (10%)	(10)	(10)	(10)	(10)
Hepatodiaphragmatic Nodule Infiltration Cellular, Mononuclear Cell Bile Duct, Hyperplasia	1 (10%) 7 (70%)	1 (10%) 1 (10%) 9 (90%) 1 (10%)	7 (70%)	5 (50%)	1 (10%) 8 (80%)	2 (20%) 4 (40%)
Stomach, Glandular Inflammation	(10)	(0)	(0)	(0)	(0)	(10) 1 (10%)
CARDIOVASCULAR SYSTEM						
Heart Cardiomyopathy	(10) 9 (90%)	(0)	(0)	(0)	(0)	(10) 8 (80%)
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Vacuolization Cytoplasmic Thyroid Gland Ultimobranchial Cyst	3 (30%) (10) 1 (10%)	(0)	(0)	(0)	(0)	(10)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Epididymis	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation Preputial Gland	1 (10%) (10)	(0)	(0)	(0)	(0)	(10)

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

TDMS No. 20203 - 01

Test Type: 90-DAY Route: GAVAGE

Nose

Inflammation

Nerve, Atrophy

Glands, Olfactory Epithelium, Hyperplasia

Lamina Propria, Pigmentation, Histiocyte

Nasopharyngeal Duct, Degeneration

Nasopharyngeal Duct, Inflammation

Olfactory Epithelium, Atrophy

Species/Strain: RATS/F344/N Tac

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Lab: BAT

(10)

3 (30%)

3 (30%)

3 (30%)

2 (20%)

5 (50%)

3 (30%)

(10)

5 (50%)

7 (70%)

2 (20%) 3 (30%) 3 (30%)

10 (100%) 9 (90%)

Species/Strain: RATS/F344/N Tac					Lab: BAT	
Fischer 344-Taconic RATS MALE	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Inflammation Testes Seminiferous Tubule, Degeneration	9 (90%) (10) 3 (30%)	(10) 1 (10%)	(10) 2 (20%)	(10) 3 (30%)	(10) 3 (30%)	9 (90%) (10) 7 (70%)
HEMATOPOIETIC SYSTEM						
Lymph Node, Mandibular Ectasia	(10)	(10)	(10) 1 (10%)	(10)	(10)	(10)
Hyperplasia, Lymphoid Hyperplasia, Plasma Cell Lymph Node, Mesenteric Hyperplasia, Lymphoid	3 (30%) 5 (50%) (10)	10 (100%) (10) 1 (10%)	2 (20%) 7 (70%) (10)	9 (90%) (10)	1 (10%) 8 (80%) (10)	2 (20%) 8 (80%) (10)
Infiltration Cellular, Histiocyte Thymus Atrophy	(10)	2 (20%) (10)	6 (60%) (10)	7 (70%) (10) 1 (10%)	7 (70%) (10)	7 (70%) (8) 5 (63%)
INTEGUMENTARY SYSTEM						
None						
MUSCULOSKELETAL SYSTEM						
None						
NERVOUS SYSTEM						
None						
RESPIRATORY SYSTEM						
Lung Hemorrhage	(10) 6 (60%)	(0)	(0)	(0)	(0)	(10)
Inflammation	9 (90%)	(40)	(10)	(10)	(10)	7 (70%)

(10)

2 (20%)

(10)

3 (30%)

(10)

1 (10%)

2 (20%)

(10)

2 (20%)

1 (10%)

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

TDMS No. 20203 - 01 **Test Type:** 90-DAY

Species/Strain: RATS/F344/N Tac

Route: GAVAGE

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

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009 Time Report Requested: 08:55:05 First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

Fischer 344-Taconic RATS MALE	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Olfactory Epithelium, Hyperplasia, Basal Cell Olfactory Epithelium, Metaplasia Olfactory Epithelium, Necrosis Olfactory Epithelium, Pigmentation Respiratory Epithelium, Atrophy Respiratory Epithelium, Hyperplasia Respiratory Epithelium, Metaplasia,	1 (10%)		1 (10%)		1 (10%) 6 (60%) 1 (10%) 4 (40%) 2 (20%)	1 (10%) 10 (100%) 3 (30%) 5 (50%) 1 (10%) 4 (40%) 1 (10%)
Squamous Respiratory Epithelium, Necrosis Trachea Inflammation	(10) 1 (10%)	(0)	(0)	(0)	(0)	1 (10%) (10)
SPECIAL SENSES SYSTEM						
Harderian Gland Inflammation	(10) 1 (10%)	(0)	(0)	(0)	(0)	(10)
URINARY SYSTEM						
Kidney Mineralization Nephropathy	(10) 8 (80%)	(0)	(0)	(0)	(0)	(10) 2 (20%) 5 (50%)

*** END OF MALE ***

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

TDMS No. 20203 - 01 Test Type: 90-DAY Green tea extract

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009 Time Report Requested: 08:55:05 First Dose M/F: 04/17/06 / 04/18/06

Fischer 344-Taconic RATS FEMALE	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/k
Disposition Summary						
Animals Initially in Study Early Deaths Natural Death	10	10	10 1	10	10	10
Survivors Terminal Sacrifice Animals Examined Microscopically	10 10	10 10	9 10	10 10	10 10	10 10
ALIMENTARY SYSTEM						
Liver Hepatodiaphragmatic Nodule Infiltration Cellular, Mononuclear Cell Inflammation, Chronic Mitosis Mixed Cell Focus Pigmentation Bile Duct, Hyperplasia Hepatocyte, Necrosis Oval Cell, Hyperplasia	(10) 1 (10%) 9 (90%)	(10) 8 (80%)	(10) 1 (10%) 6 (60%)	(10) 2 (20%) 7 (70%)	(10) 1 (10%) 8 (80%)	(10) 2 (20%) 7 (70%) 1 (10%) 2 (20%) 1 (10%) 2 (20%) 3 (30%) 1 (10%) 3 (30%)
Periportal, Hypertrophy Pancreas Atrophy Inflammation, Chronic Active	(10) 1 (10%)	(0)	(1)	(0)	(0)	2 (20%) (10) 1 (10%) 1 (10%)
Acinus, Atrophy Stomach, Glandular Hyperplasia	1 (10%) 1 (10%) (10)	(0)	(1)	(0)	(0)	(10) 1 (10%)
CARDIOVASCULAR SYSTEM						
Heart Cardiomyopathy	(10) 9 (90%)	(0)	(1) 1 (100%)	(0)	(0)	(10) 6 (60%)
ENDOCRINE SYSTEM						
Adrenal Cortex Vacuolization Cytoplasmic Pituitary Gland Cyst	(10) (10)	(0) (0)	(1) (1)	(O) (O)	(O) (O)	(10) 1 (10%) (10) 1 (10%)

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TDMS No. 20203 - 01

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: RATS/F344/N Tac

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

Green tea extract

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Fischer 344-Taconic RATS FEMALE	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland Inflammation	(10) 5 (50%)	(0)	(1) 1 (100%)	(0)	(0)	(10) 2 (20%)
HEMATOPOIETIC SYSTEM						
Lymph Node, Mandibular Hyperplasia, Lymphoid Hyperplasia, Plasma Cell Lymph Node, Mesenteric Atrophy Infiltration Cellular, Histiocyte Thymus Atrophy	(10) 3 (30%) 4 (40%) (10) 8 (80%) (10)	(10) 4 (40%) 5 (50%) (10) 10 (100%) (10)	(10) 1 (10%) 7 (70%) (10) 9 (90%) (10)	(10) 1 (10%) 7 (70%) (10) 7 (70%) (10)	(10) 7 (70%) (10) 7 (70%) (10)	(10) 2 (20%) 8 (80%) (10) 1 (10%) 6 (60%) (10) 6 (60%)
INTEGUMENTARY SYSTEM						
None						
MUSCULOSKELETAL SYSTEM None						
NERVOUS SYSTEM None						
RESPIRATORY SYSTEM						
Lung Hemorrhage Inflammation	(10) 1 (10%) 8 (80%)	(0)	(1) 1 (100%)	(0)	(0)	(10) 2 (20%) 9 (90%)
Metaplasia, Osseous Nose Infiltration Cellular, Mononuclear Cell	(10)	(10)	(10)	(10)	(10)	1 (10%) (10) 1 (10%)

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TDMS No. 20203 - 01 **Test Type:** 90-DAY

Species/Strain: RATS/F344/N Tac

Route: GAVAGE

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Date Report Requested: 04/15/2009 Time Report Requested: 08:55:05 First Dose M/F: 04/17/06 / 04/18/06

Lab: BAT

Fischer 344-Taconic RATS FEMALE	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Inflammation Glands, Olfactory Epithelium, Hyperplasia Lamina Propria, Pigmentation, Histiocyte	2 (20%)	1 (10%)	1 (10%)	4 (40%) 2 (20%)	10 (100%) 1 (10%)	8 (80%) 4 (40%) 1 (10%)
Nasopharyngeal Duct, Degeneration Nerve, Atrophy Olfactory Epithelium, Atrophy		1 (10%)	1 (10%)	1 (10%)	2 (20%) 4 (40%)	5 (50%) 7 (70%)
Olfactory Epithelium, Hyperplasia, Basal Cell		1 (10%)	1 (1078)	1 (10%)	- (- - - - - - - - - -	
Olfactory Epithelium, Metaplasia Olfactory Epithelium, Pigmentation Respiratory Epithelium, Hyperplasia				2 (20%) 1 (10%)	5 (50%) 3 (30%) 1 (10%)	4 (40%) 5 (50%)
PECIAL SENSES SYSTEM						
Eye Atrophy	(10)	(1)	(1)	(0)	(0)	(10) 1 (10%)
Cornea, Degeneration Harderian Gland Inflammation	(10) 1 (10%)	1 (100%) (0)	(1)	(0)	(0)	(10) 1 (10%)
RINARY SYSTEM						
Kidney Mineralization Nephropathy	(10) 5 (50%)	(0)	(1)	(0)	(0)	(10) 5 (50%) 1 (10%)

*** END OF REPORT ***

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