

TDMS No. 20008 - 03
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Milk thistle extract
CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
Time Report Requested: 11:00:55
First Dose M/F: 03/04/03 / 03/04/03
Lab: SRI

F1_R2

C Number: C20008
Lock Date: 06/29/2006
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.0.0

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SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF Milk thistle extract

MALE RATS

Organ

Adrenal Cortex

Bone: Femur

Brain

Eye

Eye: Bilateral

Heart

Kidney

Kidney: Transitional Epithelium

Liver

Liver: Bile Duct

Lung

Lymph Node, Mesenteric

Nose

Nose: Respiratory Epithelium

Pancreas

Pituitary Gland: Pars Distalis

Preputial Gland

Skin

Skin: Epidermis

Spleen

Morphology

Accessory Adrenal Cortical Nodule

Hyperplasia Focal

Hypertrophy Focal

Osteopetrosis

Hemorrhage

Cataract

Edema

Cataract

Cardiomyopathy

Inflammation

Mineralization

Hyperplasia

Angiectasis

Eosinophilic Focus

Infarct

Infiltration Cellular Mixed Cell

Hyperplasia

Infiltration Cellular Histiocyte

Hyperplasia Lymphoid

Pigmentation

Inflammation Chronic

Thrombosis

Hyperplasia

Atrophy

Hyperplasia

Hyperplasia Focal

Hyperplasia

Hyperkeratosis

Inflammation Chronic

Hyperplasia

Hematopoietic Cell Proliferation

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SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF Milk thistle extract

Thyroid Gland: C-Cell
Thyroid Gland: Follicular Cell

Hyperplasia
Hyperplasia Focal

FEMALE RATS

Organ

Adrenal Cortex

Adrenal Medulla
Bone Marrow
Brain

Clitoral Gland
Eye
Eye: Retina
Kidney

Kidney: Renal Tubule
Liver

Liver: Bile Duct
Lung
Lymph Node, Mesenteric

Lymph Node: Mediastinal

Mammary Gland
Mammary Gland: Duct
Nose
Ovary
Pituitary Gland: Pars Distalis

Morphology

Accessory Adrenal Cortical Nodule
Degeneration Fatty
Hyperplasia
Hyperplasia
Compression
Hemorrhage
Cyst
Cataract
Degeneration
Infarct
Mineralization
Nephropathy
Vacuolization Cytoplasmic
Accumulation, Hyaline Droplet
Clear Cell Focus
Eosinophilic Focus
Mixed Cell Focus
Necrosis Focal
Hyperplasia
Inflammation Chronic
Hyperplasia Lymphoid
Pigmentation
Hyperplasia Lymphoid
Pigmentation
Hyperplasia Focal
Ectasia
Foreign Body
Cyst
Hyperplasia Focal

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SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF Milk thistle extract

Spleen
Spleen: Lymphoid Follicle
Stomach, Glandular
Thyroid Gland
Thyroid Gland: Follicular Cell

Pigmentation
Hyperplasia
Erosion
Degeneration Cystic
Hyperplasia Focal

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Adrenal Cortex
 Accessory Adrenal Cortical Nodule**

LESION RATES

OVERALL (a)	26/50 (52%)	24/50 (48%)	18/50 (36%)	16/50 (32%)
POLY-3 RATE (b)	26/46.42	24/47.45	18/44.78	16/47.74
POLY-3 PERCENT (g)	56%	50.6%	40.2%	33.5%
TERMINAL (d)	23/36 (64%)	17/36 (47%)	14/35 (40%)	12/38 (32%)
FIRST INCIDENCE	599	591	637	676

STATISTICAL TESTS

POLY 3	P=0.010N**	P=0.372N	P=0.092N	P=0.020N*
POLY 1.5	P=0.013N*	P=0.394N	P=0.094N	P=0.025N*
POLY 6	P=0.008N**	P=0.341N	P=0.083N	P=0.015N*
COCH-ARM / FISHERS	P=0.017N*	P=0.421N	P=0.079N	P=0.034N*
MAX-ISO-POLY-3	P=0.016N*	P=0.298N	P=0.064N	P=0.013N*

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Adrenal Cortex
 Degeneration Fatty**

LESION RATES

OVERALL (a)	17/50 (34%)	17/50 (34%)	24/50 (48%)	15/50 (30%)
POLY-3 RATE (b)	17/47.98	17/48.30	24/46.88	15/48.88
POLY-3 PERCENT (g)	35.4%	35.2%	51.2%	30.7%
TERMINAL (d)	10/36 (28%)	9/36 (25%)	14/35 (40%)	9/38 (24%)
FIRST INCIDENCE	477	587	428	546

STATISTICAL TESTS

POLY 3	P=0.402N	P=0.575N	P=0.088	P=0.390N
POLY 1.5	P=0.415N	P=0.579N	P=0.088	P=0.401N
POLY 6	P=0.385N	P=0.568N	P=0.093	P=0.376N
COCH-ARM / FISHERS	P=0.431N	P=0.583N	P=0.111	P=0.415N
MAX-ISO-POLY-3	P=0.256N	P=0.489N	P=0.061	P=0.312N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Adrenal Cortex
 Hyperplasia Focal**

LESION RATES

OVERALL (a)	7/50 (14%)	12/50 (24%)	14/50 (28%)	6/50 (12%)
POLY-3 RATE (b)	7/46.02	12/46.94	14/44.31	6/47.42
POLY-3 PERCENT (g)	15.2%	25.6%	31.6%	12.7%
TERMINAL (d)	4/36 (11%)	10/36 (28%)	12/35 (34%)	5/38 (13%)
FIRST INCIDENCE	687	501	647	676

STATISTICAL TESTS

POLY 3	P=0.315N	P=0.162	P=0.053	P=0.477N
POLY 1.5	P=0.329N	P=0.160	P=0.055	P=0.486N
POLY 6	P=0.298N	P=0.163	P=0.052	P=0.466N
COCH-ARM / FISHERS	P=0.347N	P=0.154	P=0.070	P=0.500N
MAX-ISO-POLY-3	P=0.139N	P=0.109	P=0.033*	P=0.362N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Adrenal Cortex
 Hypertrophy Focal**

LESION RATES

OVERALL (a)	0/50 (0%)	4/50 (8%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/45.68	4/45.80	1/43.97	1/47.21
POLY-3 PERCENT (g)	0%	8.7%	2.3%	2.1%
TERMINAL (d)	0/36 (0%)	4/36 (11%)	1/35 (3%)	1/38 (3%)
FIRST INCIDENCE	---	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.544N	P=0.060	P=0.492	P=0.507
POLY 1.5	P=0.550N	P=0.061	P=0.493	P=0.504
POLY 6	P=0.537N	P=0.060	P=0.493	P=0.510
COCH-ARM / FISHERS	P=0.556N	P=0.059	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.189	P=0.020*	P=0.158	P=0.167

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Adrenal Medulla
 Hyperplasia**

LESION RATES

OVERALL (a)	14/50 (28%)	16/49 (33%)	10/50 (20%)	15/50 (30%)
POLY-3 RATE (b)	14/46.78	16/46.50	10/44.44	15/48.29
POLY-3 PERCENT (g)	29.9%	34.4%	22.5%	31.1%
TERMINAL (d)	10/36 (28%)	10/36 (28%)	9/35 (26%)	9/38 (24%)
FIRST INCIDENCE	600	623	591	591

STATISTICAL TESTS

POLY 3	P=0.498N	P=0.405	P=0.285N	P=0.541
POLY 1.5	P=0.511N	P=0.397	P=0.277N	P=0.524
POLY 6	P=0.481N	P=0.416	P=0.292N	P=0.563
COCH-ARM / FISHERS	P=0.523N	P=0.388	P=0.241N	P=0.500
MAX-ISO-POLY-3	P=0.466N	P=0.322	P=0.217N	P=0.451

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Bone Marrow
 Hyperplasia**

LESION RATES

OVERALL (a)	5/48 (10%)	7/50 (14%)	9/50 (18%)	6/49 (12%)
POLY-3 RATE (b)	5/45.22	7/45.80	9/44.90	6/47.10
POLY-3 PERCENT (g)	11.1%	15.3%	20.1%	12.7%
TERMINAL (d)	1/36 (3%)	7/36 (19%)	8/35 (23%)	5/38 (13%)
FIRST INCIDENCE	477	729 (T)	310	546

STATISTICAL TESTS

POLY 3	P=0.494	P=0.388	P=0.187	P=0.528
POLY 1.5	P=0.482	P=0.397	P=0.195	P=0.523
POLY 6	P=0.508	P=0.374	P=0.179	P=0.535
COCH-ARM / FISHERS	P=0.468	P=0.409	P=0.217	P=0.515
MAX-ISO-POLY-3	P=0.388	P=0.278	P=0.123	P=0.402

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Bone Marrow
 Infiltration Cellular Histiocyte**

LESION RATES

OVERALL (a)	1/48 (2%)	1/50 (2%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	1/43.88	1/45.80	0/43.97	0/46.52
POLY-3 PERCENT (g)	2.3%	2.2%	0%	0%
TERMINAL (d)	1/36 (3%)	1/36 (3%)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---	---

STATISTICAL TESTS

POLY 3	P=0.234N	P=0.751N	P=0.500N	P=0.488N
POLY 1.5	P=0.234N	P=0.751N	P=0.499N	P=0.491N
POLY 6	P=0.232N	P=0.752N	P=0.499N	P=0.484N
COCH-ARM / FISHERS	P=0.232N	P=0.742N	P=0.490N	P=0.495N
MAX-ISO-POLY-3	P=0.250N	P=0.487N	P=0.161N	P=0.157N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Bone Marrow
 Myelofibrosis**

LESION RATES

OVERALL (a)	1/48 (2%)	1/50 (2%)	2/50 (4%)	0/49 (0%)
POLY-3 RATE (b)	1/44.28	1/45.83	2/44.21	0/46.52
POLY-3 PERCENT (g)	2.3%	2.2%	4.5%	0%
TERMINAL (d)	0/36 (0%)	0/36 (0%)	1/35 (3%)	0/38 (0%)
FIRST INCIDENCE	613	721	667	---

STATISTICAL TESTS

POLY 3	P=0.352N	P=0.753N	P=0.499	P=0.490N
POLY 1.5	P=0.357N	P=0.752N	P=0.501	P=0.492N
POLY 6	P=0.347N	P=0.755N	P=0.499	P=0.487N
COCH-ARM / FISHERS	P=0.362N	P=0.742N	P=0.515	P=0.495N
MAX-ISO-POLY-3	P=0.275N	P=0.489N	P=0.282	P=0.157N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Bone: Femur
 Osteopetrosis**

LESION RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/45.76	0/45.80	0/43.97	0/47.21
POLY-3 PERCENT (g)	4.4%	0%	0%	0%
TERMINAL (d)	1/36 (3%)	0/36 (0%)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	710	---	---	---

STATISTICAL TESTS

POLY 3	P=0.115N	P=0.237N	P=0.246N	P=0.230N
POLY 1.5	P=0.115N	P=0.237N	P=0.245N	P=0.233N
POLY 6	P=0.115N	P=0.237N	P=0.246N	P=0.227N
COCH-ARM / FISHERS	P=0.115N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.032N*	P=0.076N	P=0.085N	P=0.076N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Brain
 Compression**

LESION RATES

OVERALL (a)	3/50 (6%)	4/50 (8%)	1/50 (2%)	6/50 (12%)
POLY-3 RATE (b)	3/46.23	4/47.45	1/43.97	6/47.58
POLY-3 PERCENT (g)	6.5%	8.4%	2.3%	12.6%
TERMINAL (d)	1/36 (3%)	0/36 (0%)	1/35 (3%)	3/38 (8%)
FIRST INCIDENCE	599	587	729 (T)	682

STATISTICAL TESTS

POLY 3	P=0.202	P=0.514	P=0.323N	P=0.257
POLY 1.5	P=0.200	P=0.508	P=0.320N	P=0.251
POLY 6	P=0.205	P=0.521	P=0.325N	P=0.264
COCH-ARM / FISHERS	P=0.200	P=0.500	P=0.309N	P=0.243
MAX-ISO-POLY-3	P=0.172	P=0.362	P=0.173N	P=0.161

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Brain
 Hemorrhage**

LESION RATES

OVERALL (a)	5/50 (10%)	18/50 (36%)	6/50 (12%)	13/50 (26%)
POLY-3 RATE (b)	5/45.68	18/48.05	6/44.21	13/47.36
POLY-3 PERCENT (g)	11%	37.5%	13.6%	27.5%
TERMINAL (d)	5/36 (14%)	12/36 (33%)	5/35 (14%)	11/38 (29%)
FIRST INCIDENCE	729 (T)	501	667	710

STATISTICAL TESTS

POLY 3	P=0.202	P=0.002**	P=0.477	P=0.038*
POLY 1.5	P=0.192	P=0.002**	P=0.478	P=0.035*
POLY 6	P=0.216	P=0.003**	P=0.482	P=0.041*
COCH-ARM / FISHERS	P=0.189	P=0.002**	P=0.500	P=0.033*
MAX-ISO-POLY-3	P=0.042*	P<0.001**	P=0.354	P=0.022*

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Brain
 Necrosis**

LESION RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/45.90	0/45.80	1/44.28	0/47.21
POLY-3 PERCENT (g)	2.2%	0%	2.3%	0%
TERMINAL (d)	0/36 (0%)	0/36 (0%)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	672	---	646	---

STATISTICAL TESTS

POLY 3	P=0.401N	P=0.500N	P=0.753	P=0.494N
POLY 1.5	P=0.403N	P=0.500N	P=0.753	P=0.497N
POLY 6	P=0.398N	P=0.502N	P=0.754	P=0.492N
COCH-ARM / FISHERS	P=0.405N	P=0.500N	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.255N	P=0.159N	P=0.489	P=0.159N

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 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Eye
 Cataract**

LESION RATES

OVERALL (a)	37/48 (77%)	26/48 (54%)	24/48 (50%)	26/49 (53%)
POLY-3 RATE (b)	37/45.25	26/44.42	24/42.88	26/47.33
POLY-3 PERCENT (g)	81.8%	58.5%	56%	54.9%
TERMINAL (d)	31/35 (89%)	23/34 (68%)	22/34 (65%)	22/38 (58%)
FIRST INCIDENCE	600	623	647	638

STATISTICAL TESTS

POLY 3	P=0.009N**	P=0.010N**	P=0.005N**	P=0.003N**
POLY 1.5	P=0.014N*	P=0.011N*	P=0.006N**	P=0.005N**
POLY 6	P=0.005N**	P=0.009N**	P=0.004N**	P=0.002N**
COCH-ARM / FISHERS	P=0.024N*	P=0.015N*	P=0.005N**	P=0.011N*
MAX-ISO-POLY-3	P=0.004N**	P=0.005N**	P=0.003N**	P=0.002N**

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Eye
 Edema

LESION RATES

OVERALL (a)	0/48 (0%)	2/48 (4%)	1/48 (2%)	3/49 (6%)
POLY-3 RATE (b)	0/43.80	2/44.12	1/42.85	3/46.52
POLY-3 PERCENT (g)	0%	4.5%	2.3%	6.5%
TERMINAL (d)	0/35 (0%)	1/34 (3%)	0/34 (0%)	3/38 (8%)
FIRST INCIDENCE	---	638	647	729 (T)

STATISTICAL TESTS

POLY 3	P=0.115	P=0.239	P=0.496	P=0.130
POLY 1.5	P=0.112	P=0.238	P=0.495	P=0.127
POLY 6	P=0.120	P=0.239	P=0.498	P=0.134
COCH-ARM / FISHERS	P=0.108	P=0.247	P=0.500	P=0.125
MAX-ISO-POLY-3	P=0.075	P=0.077	P=0.158	P=0.046*

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Eye: Bilateral
 Cataract

LESION RATES

OVERALL (a)	19/48 (40%)	10/48 (21%)	6/48 (13%)	6/49 (12%)
POLY-3 RATE (b)	19/44.31	10/43.83	6/42.55	6/46.52
POLY-3 PERCENT (g)	42.9%	22.8%	14.1%	12.9%
TERMINAL (d)	17/35 (49%)	9/34 (27%)	6/34 (18%)	6/38 (16%)
FIRST INCIDENCE	601	721	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P<0.001N**	P=0.034N*	P=0.002N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.035N*	P=0.002N**	P<0.001N**
POLY 6	P<0.001N**	P=0.035N*	P=0.002N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.037N*	P=0.002N**	P=0.002N**
MAX-ISO-POLY-3	P<0.001N**	P=0.021N*	P<0.001N**	P<0.001N**

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Eye: Retina
 Degeneration

LESION RATES

OVERALL (a)	7/48 (15%)	4/48 (8%)	3/48 (6%)	5/49 (10%)
POLY-3 RATE (b)	7/43.80	4/43.80	3/43.18	5/46.52
POLY-3 PERCENT (g)	16%	9.1%	7%	10.8%
TERMINAL (d)	7/35 (20%)	4/34 (12%)	1/34 (3%)	5/38 (13%)
FIRST INCIDENCE	729 (T)	729 (T)	638	729 (T)

STATISTICAL TESTS

POLY 3	P=0.325N	P=0.260N	P=0.162N	P=0.337N
POLY 1.5	P=0.335N	P=0.260N	P=0.166N	P=0.349N
POLY 6	P=0.312N	P=0.261N	P=0.154N	P=0.322N
COCH-ARM / FISHERS	P=0.344N	P=0.262N	P=0.158N	P=0.365N
MAX-ISO-POLY-3	P=0.232N	P=0.168N	P=0.095N	P=0.239N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Harderian Gland
 Hyperplasia Focal**

LESION RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	1/45.68	2/45.80	1/43.97	3/47.29
POLY-3 PERCENT (g)	2.2%	4.4%	2.3%	6.3%
TERMINAL (d)	1/36 (3%)	2/36 (6%)	1/35 (3%)	2/38 (5%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	710

STATISTICAL TESTS

POLY 3	P=0.248	P=0.501	P=0.752	P=0.318
POLY 1.5	P=0.243	P=0.501	P=0.753	P=0.313
POLY 6	P=0.254	P=0.500	P=0.753	P=0.325
COCH-ARM / FISHERS	P=0.237	P=0.500	P=0.753N	P=0.309
MAX-ISO-POLY-3	P=0.244	P=0.282	P=0.489	P=0.167

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Harderian Gland
 Inflammation Chronic**

LESION RATES

OVERALL (a)	3/50 (6%)	2/50 (4%)	2/50 (4%)	4/50 (8%)
POLY-3 RATE (b)	3/45.80	2/45.80	2/44.90	4/47.90
POLY-3 PERCENT (g)	6.6%	4.4%	4.5%	8.4%
TERMINAL (d)	2/36 (6%)	2/36 (6%)	1/35 (3%)	2/38 (5%)
FIRST INCIDENCE	699	729 (T)	310	546

STATISTICAL TESTS

POLY 3	P=0.376	P=0.500N	P=0.509N	P=0.524
POLY 1.5	P=0.368	P=0.500N	P=0.509N	P=0.514
POLY 6	P=0.388	P=0.502N	P=0.508N	P=0.537
COCH-ARM / FISHERS	P=0.357	P=0.500N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.418	P=0.324N	P=0.333N	P=0.372

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Heart
 Cardiomyopathy**

LESION RATES

OVERALL (a)	48/50 (96%)	45/50 (90%)	45/50 (90%)	42/50 (84%)
POLY-3 RATE (b)	48/49.74	45/49.08	45/48.13	42/49.30
POLY-3 PERCENT (g)	96.5%	91.7%	93.5%	85.2%
TERMINAL (d)	35/36 (97%)	34/36 (94%)	33/35 (94%)	33/38 (87%)
FIRST INCIDENCE	477	501	310	546

STATISTICAL TESTS

POLY 3	P=0.030N*	P=0.265N	P=0.410N	P=0.046N*
POLY 1.5	P=0.033N*	P=0.241N	P=0.366N	P=0.046N*
POLY 6	P=0.027N*	P=0.310N	P=0.458N	P=0.049N*
COCH-ARM / FISHERS	P=0.040N*	P=0.218N	P=0.218N	P=0.046N*
MAX-ISO-POLY-3	P=0.023N*	P=0.141N	P=0.239N	P=0.021N*

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Heart
 Thrombosis**

LESION RATES

OVERALL (a)	3/50 (6%)	4/50 (8%)	7/50 (14%)	2/50 (4%)
POLY-3 RATE (b)	3/46.63	4/46.46	7/45.40	2/47.36
POLY-3 PERCENT (g)	6.4%	8.6%	15.4%	4.2%
TERMINAL (d)	0/36 (0%)	1/36 (3%)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	600	638	637	711

STATISTICAL TESTS

POLY 3	P=0.417N	P=0.498	P=0.147	P=0.493N
POLY 1.5	P=0.422N	P=0.499	P=0.146	P=0.496N
POLY 6	P=0.411N	P=0.496	P=0.151	P=0.490N
COCH-ARM / FISHERS	P=0.430N	P=0.500	P=0.159	P=0.500N
MAX-ISO-POLY-3	P=0.249N	P=0.346	P=0.086	P=0.319N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Heart: Valve
 Hyperplasia

LESION RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	3/50 (6%)	3/50 (6%)
POLY-3 RATE (b)	1/46.07	1/46.26	3/44.94	3/47.47
POLY-3 PERCENT (g)	2.2%	2.2%	6.7%	6.3%
TERMINAL (d)	0/36 (0%)	0/36 (0%)	0/35 (0%)	1/38 (3%)
FIRST INCIDENCE	619	591	637	682

STATISTICAL TESTS

POLY 3	P=0.175	P=0.760N	P=0.296	P=0.316
POLY 1.5	P=0.171	P=0.760N	P=0.296	P=0.312
POLY 6	P=0.181	P=0.760N	P=0.301	P=0.322
COCH-ARM / FISHERS	P=0.165	P=0.753N	P=0.309	P=0.309
MAX-ISO-POLY-3	P=0.250	P=0.498N	P=0.150	P=0.166

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Islets, Pancreatic
 Hyperplasia**

LESION RATES

OVERALL (a)	2/50 (4%)	2/50 (4%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	2/45.80	2/45.80	3/44.14	0/47.21
POLY-3 PERCENT (g)	4.4%	4.4%	6.8%	0%
TERMINAL (d)	1/36 (3%)	2/36 (6%)	2/35 (6%)	0/38 (0%)
FIRST INCIDENCE	699	729 (T)	687	---

STATISTICAL TESTS

POLY 3	P=0.189N	P=0.694	P=0.483	P=0.230N
POLY 1.5	P=0.193N	P=0.693N	P=0.485	P=0.233N
POLY 6	P=0.183N	P=0.693	P=0.485	P=0.227N
COCH-ARM / FISHERS	P=0.199N	P=0.691N	P=0.500	P=0.247N
MAX-ISO-POLY-3	P=0.157N	P=0.499	P=0.312	P=0.076N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney
 Infarct**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/48 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.68	0/45.80	0/42.61	0/47.21
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/36 (0%)	0/36 (0%)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney
 Inflammation**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/48 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/45.68	0/45.80	0/42.61	2/47.21
POLY-3 PERCENT (g)	0%	0%	0%	4.2%
TERMINAL (d)	0/36 (0%)	0/36 (0%)	0/35 (0%)	2/38 (5%)
FIRST INCIDENCE	---	---	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.047*	(e)	(e)	P=0.245
POLY 1.5	P=0.047*	(e)	(e)	P=0.242
POLY 6	P=0.048*	(e)	(e)	P=0.248
COCH-ARM / FISHERS	P=0.047*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.039*	(e)	(e)	P=0.083

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney
 Mineralization**

LESION RATES

OVERALL (a)	13/50 (26%)	11/50 (22%)	7/48 (15%)	20/50 (40%)
POLY-3 RATE (b)	13/49.01	11/47.68	7/43.34	20/49.82
POLY-3 PERCENT (g)	26.5%	23.1%	16.2%	40.1%
TERMINAL (d)	3/36 (8%)	4/36 (11%)	5/35 (14%)	10/38 (26%)
FIRST INCIDENCE	477	623	604	546

STATISTICAL TESTS

POLY 3	P=0.053	P=0.438N	P=0.170N	P=0.110
POLY 1.5	P=0.050*	P=0.426N	P=0.158N	P=0.106
POLY 6	P=0.056	P=0.452N	P=0.182N	P=0.117
COCH-ARM / FISHERS	P=0.052	P=0.408N	P=0.125N	P=0.101
MAX-ISO-POLY-3	P=0.030*	P=0.349N	P=0.126N	P=0.077

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney
 Nephropathy**

LESION RATES

OVERALL (a)	46/50 (92%)	47/50 (94%)	42/48 (88%)	46/50 (92%)
POLY-3 RATE (b)	46/49.27	47/49.40	42/45.47	46/49.93
POLY-3 PERCENT (g)	93.4%	95.2%	92.4%	92.1%
TERMINAL (d)	35/36 (97%)	35/36 (97%)	34/35 (97%)	35/38 (92%)
FIRST INCIDENCE	477	501	428	546

STATISTICAL TESTS

POLY 3	P=0.409N	P=0.523	P=0.588N	P=0.561N
POLY 1.5	P=0.453N	P=0.512	P=0.552N	P=0.600N
POLY 6	P=0.333N	P=0.539	P=0.596N	P=0.499N
COCH-ARM / FISHERS	P=0.480N	P=0.500	P=0.344N	P=0.643N
MAX-ISO-POLY-3	P=0.524N	P=0.341	P=0.421N	P=0.402N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney
 Vacuolization Cytoplasmic**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/48 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.68	0/45.80	0/42.61	0/47.21
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/36 (0%)	0/36 (0%)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney: Renal Tubule
 Accumulation, Hyaline Droplet**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/48 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.68	0/45.80	0/42.61	0/47.21
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/36 (0%)	0/36 (0%)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney: Renal Tubule
 Hyperplasia**

LESION RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	0/48 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/45.68	2/45.80	0/42.61	0/47.21
POLY-3 PERCENT (g)	2.2%	4.4%	0%	0%
TERMINAL (d)	1/36 (3%)	2/36 (6%)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---	---

STATISTICAL TESTS

POLY 3	P=0.188N	P=0.501	P=0.514N	P=0.493N
POLY 1.5	P=0.189N	P=0.501	P=0.514N	P=0.496N
POLY 6	P=0.185N	P=0.500	P=0.512N	P=0.490N
COCH-ARM / FISHERS	P=0.190N	P=0.500	P=0.510N	P=0.500N
MAX-ISO-POLY-3	P=0.175N	P=0.282	P=0.173N	P=0.159N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney: Renal Tubule
 Necrosis**

LESION RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/48 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/46.12	0/45.80	0/42.61	0/47.21
POLY-3 PERCENT (g)	2.2%	0%	0%	0%
TERMINAL (d)	0/36 (0%)	0/36 (0%)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	600	---	---	---

STATISTICAL TESTS

POLY 3	P=0.311N	P=0.501N	P=0.516N	P=0.495N
POLY 1.5	P=0.310N	P=0.501N	P=0.515N	P=0.497N
POLY 6	P=0.311N	P=0.503N	P=0.515N	P=0.493N
COCH-ARM / FISHERS	P=0.307N	P=0.500N	P=0.510N	P=0.500N
MAX-ISO-POLY-3	P=0.125N	P=0.160N	P=0.175N	P=0.159N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney: Renal Tubule
 Pigmentation**

LESION RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	2/48 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/45.68	1/45.83	2/42.61	0/47.21
POLY-3 PERCENT (g)	0%	2.2%	4.7%	0%
TERMINAL (d)	0/36 (0%)	0/36 (0%)	2/35 (6%)	0/38 (0%)
FIRST INCIDENCE	---	721	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.603N	P=0.501	P=0.222	(e)
POLY 1.5	P=0.609N	P=0.500	P=0.222	(e)
POLY 6	P=0.596N	P=0.501	P=0.224	(e)
COCH-ARM / FISHERS	P=0.617N	P=0.500	P=0.237	(e)
MAX-ISO-POLY-3	P=0.325N	P=0.159	P=0.073	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney: Transitional Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	25/50 (50%)	10/50 (20%)	6/48 (13%)	18/50 (36%)
POLY-3 RATE (b)	25/47.57	10/46.67	6/43.41	18/47.86
POLY-3 PERCENT (g)	52.6%	21.4%	13.8%	37.6%
TERMINAL (d)	18/36 (50%)	7/36 (19%)	4/35 (11%)	13/38 (34%)
FIRST INCIDENCE	599	591	591	638

STATISTICAL TESTS

POLY 3	P=0.179N	P<0.001N**	P<0.001N**	P=0.101N
POLY 1.5	P=0.185N	P<0.001N**	P<0.001N**	P=0.105N
POLY 6	P=0.171N	P<0.001N**	P<0.001N**	P=0.098N
COCH-ARM / FISHERS	P=0.199N	P=0.002N**	P<0.001N**	P=0.113N
MAX-ISO-POLY-3	P=0.002N**	P<0.001N**	P<0.001N**	P=0.069N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Liver
 Angiectasis**

LESION RATES

OVERALL (a)	3/50 (6%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	3/45.68	0/45.80	0/43.97	1/47.21
POLY-3 PERCENT (g)	6.6%	0%	0%	2.1%
TERMINAL (d)	3/36 (8%)	0/36 (0%)	0/35 (0%)	1/38 (3%)
FIRST INCIDENCE	729 (T)	---	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.248N	P=0.118N	P=0.126N	P=0.294N
POLY 1.5	P=0.248N	P=0.118N	P=0.125N	P=0.299N
POLY 6	P=0.247N	P=0.118N	P=0.125N	P=0.287N
COCH-ARM / FISHERS	P=0.247N	P=0.121N	P=0.121N	P=0.309N
MAX-ISO-POLY-3	P=0.042N*	P=0.038N*	P=0.044N*	P=0.150N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Basophilic Focus

LESION RATES

OVERALL (a)	33/50 (66%)	36/50 (72%)	32/50 (64%)	34/50 (68%)
POLY-3 RATE (b)	33/47.07	36/47.07	32/45.34	34/47.47
POLY-3 PERCENT (g)	70.1%	76.5%	70.6%	71.6%
TERMINAL (d)	29/36 (81%)	33/36 (92%)	30/35 (86%)	31/38 (82%)
FIRST INCIDENCE	591	587	428	702

STATISTICAL TESTS

POLY 3	P=0.520N	P=0.313	P=0.574	P=0.526
POLY 1.5	P=0.527N	P=0.324	P=0.587	P=0.516
POLY 6	P=0.509N	P=0.288	P=0.559	P=0.538
COCH-ARM / FISHERS	P=0.531N	P=0.333	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.588	P=0.232	P=0.479	P=0.432

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Clear Cell Focus

LESION RATES

OVERALL (a)	29/50 (58%)	29/50 (58%)	31/50 (62%)	33/50 (66%)
POLY-3 RATE (b)	29/45.68	29/45.80	31/43.97	33/47.79
POLY-3 PERCENT (g)	63.5%	63.3%	70.5%	69.1%
TERMINAL (d)	29/36 (81%)	29/36 (81%)	31/35 (89%)	32/38 (84%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	546

STATISTICAL TESTS

POLY 3	P=0.268	P=0.583N	P=0.307	P=0.358
POLY 1.5	P=0.234	P=0.580N	P=0.326	P=0.318
POLY 6	P=0.323	P=0.592N	P=0.298	P=0.415
COCH-ARM / FISHERS	P=0.202	P=0.580N	P=0.419	P=0.268
MAX-ISO-POLY-3	P=0.406	P=0.493N	P=0.234	P=0.282

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Degeneration Cystic

LESION RATES

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.68	2/45.80	0/43.97	0/47.21
POLY-3 PERCENT (g)	0%	4.4%	0%	0%
TERMINAL (d)	0/36 (0%)	2/36 (6%)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	---	729 (T)	---	---

STATISTICAL TESTS

POLY 3	P=0.401N	P=0.238	(e)	(e)
POLY 1.5	P=0.403N	P=0.238	(e)	(e)
POLY 6	P=0.398N	P=0.237	(e)	(e)
COCH-ARM / FISHERS	P=0.405N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.252N	P=0.076	(e)	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Eosinophilic Focus

LESION RATES

OVERALL (a)	12/50 (24%)	7/50 (14%)	10/50 (20%)	19/50 (38%)
POLY-3 RATE (b)	12/45.68	7/45.80	10/43.97	19/47.42
POLY-3 PERCENT (g)	26.3%	15.3%	22.7%	40.1%
TERMINAL (d)	12/36 (33%)	7/36 (19%)	10/35 (29%)	18/38 (47%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	676

STATISTICAL TESTS

POLY 3	P=0.023*	P=0.148N	P=0.443N	P=0.114
POLY 1.5	P=0.021*	P=0.151N	P=0.440N	P=0.106
POLY 6	P=0.025*	P=0.147N	P=0.440N	P=0.125
COCH-ARM / FISHERS	P=0.022*	P=0.154N	P=0.405N	P=0.097
MAX-ISO-POLY-3	P=0.024*	P=0.097N	P=0.351N	P=0.080

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Liver
 Hematopoietic Cell Proliferation**

LESION RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/46.40	0/45.80	0/43.97	0/47.21
POLY-3 PERCENT (g)	2.2%	0%	0%	0%
TERMINAL (d)	0/36 (0%)	0/36 (0%)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	477	---	---	---

STATISTICAL TESTS

POLY 3	P=0.309N	P=0.503N	P=0.511N	P=0.497N
POLY 1.5	P=0.309N	P=0.502N	P=0.509N	P=0.498N
POLY 6	P=0.309N	P=0.504N	P=0.511N	P=0.494N
COCH-ARM / FISHERS	P=0.306N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.124N	P=0.162N	P=0.172N	P=0.159N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Hepatodiaphragmatic Nodule

LESION RATES

OVERALL (a)	4/50 (8%)	4/50 (8%)	6/50 (12%)	3/50 (6%)
POLY-3 RATE (b)	4/46.12	4/46.43	6/46.69	3/47.79
POLY-3 PERCENT (g)	8.7%	8.6%	12.9%	6.3%
TERMINAL (d)	3/36 (8%)	2/36 (6%)	3/35 (9%)	2/38 (5%)
FIRST INCIDENCE	600	638	86	546

STATISTICAL TESTS

POLY 3	P=0.424N	P=0.640N	P=0.377	P=0.481N
POLY 1.5	P=0.434N	P=0.641N	P=0.375	P=0.488N
POLY 6	P=0.412N	P=0.638N	P=0.380	P=0.471N
COCH-ARM / FISHERS	P=0.449N	P=0.643N	P=0.370	P=0.500N
MAX-ISO-POLY-3	P=0.428N	P=0.495N	P=0.261	P=0.333N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Infarct

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/45.68	0/45.80	0/43.97	2/47.29
POLY-3 PERCENT (g)	0%	0%	0%	4.2%
TERMINAL (d)	0/36 (0%)	0/36 (0%)	0/35 (0%)	1/38 (3%)
FIRST INCIDENCE	---	---	---	710

STATISTICAL TESTS

POLY 3	P=0.047*	(e)	(e)	P=0.245
POLY 1.5	P=0.046*	(e)	(e)	P=0.242
POLY 6	P=0.048*	(e)	(e)	P=0.249
COCH-ARM / FISHERS	P=0.046*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.039*	(e)	(e)	P=0.083

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Infiltration Cellular Mixed Cell

LESION RATES

OVERALL (a)	31/50 (62%)	32/50 (64%)	27/50 (54%)	15/50 (30%)
POLY-3 RATE (b)	31/46.20	32/46.94	27/44.77	15/47.50
POLY-3 PERCENT (g)	67.1%	68.2%	60.3%	31.6%
TERMINAL (d)	29/36 (81%)	29/36 (81%)	26/35 (74%)	13/38 (34%)
FIRST INCIDENCE	599	591	428	682

STATISTICAL TESTS

POLY 3	P<0.001N**	P=0.546	P=0.318N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.526	P=0.320N	P<0.001N**
POLY 6	P<0.001N**	P=0.573	P=0.310N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.500	P=0.272N	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.453	P=0.246N	P<0.001N**

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Mixed Cell Focus

LESION RATES

OVERALL (a)	9/50 (18%)	5/50 (10%)	7/50 (14%)	5/50 (10%)
POLY-3 RATE (b)	9/46.13	5/45.80	7/44.90	5/47.21
POLY-3 PERCENT (g)	19.5%	10.9%	15.6%	10.6%
TERMINAL (d)	8/36 (22%)	5/36 (14%)	6/35 (17%)	5/38 (13%)
FIRST INCIDENCE	599	729 (T)	310	729 (T)

STATISTICAL TESTS

POLY 3	P=0.202N	P=0.196N	P=0.415N	P=0.179N
POLY 1.5	P=0.209N	P=0.195N	P=0.413N	P=0.185N
POLY 6	P=0.193N	P=0.198N	P=0.415N	P=0.172N
COCH-ARM / FISHERS	P=0.217N	P=0.194N	P=0.393N	P=0.194N
MAX-ISO-POLY-3	P=0.173N	P=0.127N	P=0.315N	P=0.116N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Necrosis Focal

LESION RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/45.68	0/45.80	0/43.97	1/47.68
POLY-3 PERCENT (g)	2.2%	0%	0%	2.1%
TERMINAL (d)	1/36 (3%)	0/36 (0%)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	729 (T)	---	---	591

STATISTICAL TESTS

POLY 3	P=0.600	P=0.500N	P=0.508N	P=0.751N
POLY 1.5	P=0.597	P=0.500N	P=0.507N	P=0.755N
POLY 6	P=0.604	P=0.500N	P=0.507N	P=0.746N
COCH-ARM / FISHERS	P=0.595	P=0.500N	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.406N	P=0.159N	P=0.168N	P=0.487N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Liver: Bile Duct
 Hyperplasia**

LESION RATES

OVERALL (a)	50/50 (100%)	48/50 (96%)	44/50 (88%)	17/50 (34%)
POLY-3 RATE (b)	50/50.00	48/49.62	44/47.25	17/48.91
POLY-3 PERCENT (g)	100%	96.7%	93.1%	34.8%
TERMINAL (d)	36/36 (100%)	35/36 (97%)	33/35 (94%)	10/38 (26%)
FIRST INCIDENCE	477	501	549	546

STATISTICAL TESTS

POLY 3	P<0.001N**	P=0.295N	P=0.082N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.265N	P=0.052N	P<0.001N**
POLY 6	P<0.001N**	P=0.355N	P=0.106N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.247N	P=0.013N*	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.082N	P=0.027N*	P<0.001N**

TDMS No. 20008 - 03
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Milk thistle extract
CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
Time Report Requested: 11:00:55
First Dose M/F: 03/04/03 / 03/04/03
Lab: SRI

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver: Hepatocyte
Vacuolization Cytoplasmic

LESION RATES

OVERALL (a)	8/50 (16%)	9/50 (18%)	9/50 (18%)	4/50 (8%)
POLY-3 RATE (b)	8/46.67	9/47.85	9/46.35	4/48.01
POLY-3 PERCENT (g)	17.1%	18.8%	19.4%	8.3%
TERMINAL (d)	3/36 (8%)	1/36 (3%)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	619	591	591	638

STATISTICAL TESTS

POLY 3	P=0.116N	P=0.522	P=0.494	P=0.164N
POLY 1.5	P=0.121N	P=0.513	P=0.484	P=0.169N
POLY 6	P=0.110N	P=0.535	P=0.514	P=0.158N
COCH-ARM / FISHERS	P=0.128N	P=0.500	P=0.500	P=0.178N
MAX-ISO-POLY-3	P=0.145N	P=0.416	P=0.387	P=0.102N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver: Hepatocyte
 Vacuolization Cytoplasmic Focal

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.68	0/45.80	0/43.97	0/47.21
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/36 (0%)	0/36 (0%)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung
 Congestion**

LESION RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/46.15	2/46.27	0/43.97	0/47.21
POLY-3 PERCENT (g)	2.2%	4.3%	0%	0%
TERMINAL (d)	0/36 (0%)	1/36 (3%)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	591	587	---	---

STATISTICAL TESTS

POLY 3	P=0.188N	P=0.501	P=0.510N	P=0.495N
POLY 1.5	P=0.189N	P=0.501	P=0.508N	P=0.497N
POLY 6	P=0.187N	P=0.501	P=0.510N	P=0.493N
COCH-ARM / FISHERS	P=0.188N	P=0.500	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.173N	P=0.282	P=0.171N	P=0.159N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung
 Hemorrhage**

LESION RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	1/46.15	2/46.01	4/43.97	0/47.21
POLY-3 PERCENT (g)	2.2%	4.4%	9.1%	0%
TERMINAL (d)	0/36 (0%)	1/36 (3%)	4/35 (11%)	0/38 (0%)
FIRST INCIDENCE	591	672	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.358N	P=0.499	P=0.164	P=0.495N
POLY 1.5	P=0.364N	P=0.500	P=0.167	P=0.497N
POLY 6	P=0.351N	P=0.498	P=0.163	P=0.493N
COCH-ARM / FISHERS	P=0.373N	P=0.500	P=0.181	P=0.500N
MAX-ISO-POLY-3	P=0.153N	P=0.280	P=0.080	P=0.159N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung
 Infiltration Cellular Histiocyte**

LESION RATES

OVERALL (a)	34/50 (68%)	48/50 (96%)	43/50 (86%)	39/50 (78%)
POLY-3 RATE (b)	34/48.49	48/49.31	43/48.28	39/48.70
POLY-3 PERCENT (g)	70.1%	97.3%	89.1%	80.1%
TERMINAL (d)	25/36 (69%)	36/36 (100%)	31/35 (89%)	31/38 (82%)
FIRST INCIDENCE	477	501	86	638

STATISTICAL TESTS

POLY 3	P=0.385	P<0.001**	P=0.015*	P=0.178
POLY 1.5	P=0.386	P<0.001**	P=0.017*	P=0.179
POLY 6	P=0.393	P<0.001**	P=0.016*	P=0.181
COCH-ARM / FISHERS	P=0.402	P<0.001**	P=0.028*	P=0.184
MAX-ISO-POLY-3	P=0.005**	P<0.001**	P=0.008**	P=0.123

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung
 Inflammation Chronic**

LESION RATES

OVERALL (a)	3/50 (6%)	1/50 (2%)	2/50 (4%)	6/50 (12%)
POLY-3 RATE (b)	3/45.68	1/45.80	2/43.97	6/47.21
POLY-3 PERCENT (g)	6.6%	2.2%	4.6%	12.7%
TERMINAL (d)	3/36 (8%)	1/36 (3%)	2/35 (6%)	6/38 (16%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.082	P=0.304N	P=0.517N	P=0.259
POLY 1.5	P=0.080	P=0.305N	P=0.516N	P=0.252
POLY 6	P=0.085	P=0.304N	P=0.516N	P=0.267
COCH-ARM / FISHERS	P=0.079	P=0.309N	P=0.500N	P=0.243
MAX-ISO-POLY-3	P=0.083	P=0.154N	P=0.342N	P=0.163

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung
 Metaplasia Osseous**

LESION RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)	4/50 (8%)
POLY-3 RATE (b)	1/46.07	2/46.20	0/43.97	4/47.65
POLY-3 PERCENT (g)	2.2%	4.3%	0%	8.4%
TERMINAL (d)	0/36 (0%)	0/36 (0%)	0/35 (0%)	2/38 (5%)
FIRST INCIDENCE	619	647	---	638

STATISTICAL TESTS

POLY 3	P=0.110	P=0.501	P=0.509N	P=0.189
POLY 1.5	P=0.109	P=0.501	P=0.508N	P=0.185
POLY 6	P=0.113	P=0.501	P=0.510N	P=0.195
COCH-ARM / FISHERS	P=0.108	P=0.500	P=0.500N	P=0.181
MAX-ISO-POLY-3	P=0.091	P=0.282	P=0.170N	P=0.094

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung: Alveolar Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	17/50 (34%)	18/50 (36%)	17/50 (34%)	13/50 (26%)
POLY-3 RATE (b)	17/47.30	18/48.02	17/44.74	13/47.89
POLY-3 PERCENT (g)	35.9%	37.5%	38%	27.1%
TERMINAL (d)	13/36 (36%)	13/36 (36%)	15/35 (43%)	9/38 (24%)
FIRST INCIDENCE	477	501	604	638

STATISTICAL TESTS

POLY 3	P=0.179N	P=0.522	P=0.505	P=0.241N
POLY 1.5	P=0.184N	P=0.513	P=0.519	P=0.249N
POLY 6	P=0.168N	P=0.534	P=0.498	P=0.228N
COCH-ARM / FISHERS	P=0.186N	P=0.500	P=0.583N	P=0.257N
MAX-ISO-POLY-3	P=0.245N	P=0.436	P=0.419	P=0.179N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Lymph Node, Mesenteric Hemorrhage

LESION RATES

OVERALL (a)	3/50 (6%)	4/50 (8%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	3/46.59	4/45.80	1/44.40	3/47.21
POLY-3 PERCENT (g)	6.4%	8.7%	2.3%	6.4%
TERMINAL (d)	1/36 (3%)	4/36 (11%)	0/35 (0%)	3/38 (8%)
FIRST INCIDENCE	591	729 (T)	604	729 (T)

STATISTICAL TESTS

POLY 3	P=0.477N	P=0.491	P=0.323N	P=0.656N
POLY 1.5	P=0.479N	P=0.495	P=0.320N	P=0.658N
POLY 6	P=0.474N	P=0.483	P=0.324N	P=0.654N
COCH-ARM / FISHERS	P=0.479N	P=0.500	P=0.309N	P=0.661N
MAX-ISO-POLY-3	P=0.413N	P=0.340	P=0.172N	P=0.493N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lymph Node, Mesenteric
 Hyperplasia Lymphoid**

LESION RATES

OVERALL (a)	15/50 (30%)	31/50 (62%)	23/50 (46%)	20/50 (40%)
POLY-3 RATE (b)	15/47.49	31/47.61	23/44.88	20/48.05
POLY-3 PERCENT (g)	31.6%	65.1%	51.3%	41.6%
TERMINAL (d)	10/36 (28%)	27/36 (75%)	21/35 (60%)	17/38 (45%)
FIRST INCIDENCE	477	501	549	546

STATISTICAL TESTS

POLY 3	P=0.505	P<0.001**	P=0.040*	P=0.209
POLY 1.5	P=0.495	P<0.001**	P=0.047*	P=0.206
POLY 6	P=0.520	P<0.001**	P=0.035*	P=0.214
COCH-ARM / FISHERS	P=0.490	P<0.001**	P=0.074	P=0.201
MAX-ISO-POLY-3	P=0.024*	P<0.001**	P=0.028*	P=0.155

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lymph Node, Mesenteric
 Pigmentation**

LESION RATES

OVERALL (a)	45/50 (90%)	27/50 (54%)	17/50 (34%)	9/50 (18%)
POLY-3 RATE (b)	45/50.00	27/47.05	17/44.88	9/47.80
POLY-3 PERCENT (g)	90%	57.4%	37.9%	18.8%
TERMINAL (d)	31/36 (86%)	23/36 (64%)	15/35 (43%)	6/38 (16%)
FIRST INCIDENCE	477	591	549	638

STATISTICAL TESTS

POLY 3	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Lymph Node: Mediastinal Hemorrhage

LESION RATES

OVERALL (a)	2/10 (20%)	1/11 (9%)	3/18 (17%)	0/6 (0%)
POLY-3 RATE (b)	2/9.04	1/9.75	3/15.03	0/4.51
POLY-3 PERCENT (g)	22.1%	10.3%	20%	0%
TERMINAL (d)	1/4 (25%)	1/5 (20%)	0/6 (0%)	0/1 (0%)
FIRST INCIDENCE	599	729 (T)	428	---

STATISTICAL TESTS

POLY 3	P=0.350N	P=0.473N	P=0.650N	P=0.399N
POLY 1.5	P=0.332N	P=0.469N	P=0.643N	P=0.377N
POLY 6	P=0.372N	P=0.478N	P=0.658N	P=0.430N
COCH-ARM / FISHERS	P=0.299N	P=0.462N	P=0.601N	P=0.375N
MAX-ISO-POLY-3	P=0.323N	P=0.251N	P=0.454N	P=0.193N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lymph Node: Mediastinal
 Hyperplasia Lymphoid**

LESION RATES

OVERALL (a)	2/10 (20%)	2/11 (18%)	4/18 (22%)	0/6 (0%)
POLY-3 RATE (b)	2/9.11	2/9.75	4/14.60	0/4.51
POLY-3 PERCENT (g)	21.9%	20.5%	27.4%	0%
TERMINAL (d)	0/4 (0%)	2/5 (40%)	2/6 (33%)	0/1 (0%)
FIRST INCIDENCE	599	729 (T)	428	---

STATISTICAL TESTS

POLY 3	P=0.383N	P=0.681N	P=0.574	P=0.401N
POLY 1.5	P=0.351N	P=0.674N	P=0.589	P=0.378N
POLY 6	P=0.431N	P=0.693N	P=0.553	P=0.435N
COCH-ARM / FISHERS	P=0.302N	P=0.669N	P=0.723N	P=0.375N
MAX-ISO-POLY-3	P=0.334N	P=0.470N	P=0.391	P=0.196N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lymph Node: Mediastinal
 Pigmentation**

LESION RATES

OVERALL (a)	1/10 (10%)	1/11 (9%)	2/18 (11%)	0/6 (0%)
POLY-3 RATE (b)	1/8.60	1/10.08	2/14.60	0/4.51
POLY-3 PERCENT (g)	11.6%	9.9%	13.7%	0%
TERMINAL (d)	1/4 (25%)	0/5 (0%)	0/6 (0%)	0/1 (0%)
FIRST INCIDENCE	729 (T)	638	428	---

STATISTICAL TESTS

POLY 3	P=0.487N	P=0.727N	P=0.687	P=0.625N
POLY 1.5	P=0.473N	P=0.733N	P=0.686	P=0.614N
POLY 6	P=0.505N	P=0.717N	P=0.690	P=0.641N
COCH-ARM / FISHERS	P=0.447N	P=0.738N	P=0.751N	P=0.625N
MAX-ISO-POLY-3	P=0.473N	P=0.456N	P=0.449	P=0.273N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Mammary Gland
 Hyperplasia**

LESION RATES

OVERALL (a)	17/49 (35%)	18/49 (37%)	13/48 (27%)	13/49 (27%)
POLY-3 RATE (b)	17/47.00	18/48.30	13/44.64	13/47.64
POLY-3 PERCENT (g)	36.2%	37.3%	29.1%	27.3%
TERMINAL (d)	10/35 (29%)	8/36 (22%)	8/34 (24%)	7/38 (18%)
FIRST INCIDENCE	477	501	591	546

STATISTICAL TESTS

POLY 3	P=0.154N	P=0.540	P=0.310N	P=0.240N
POLY 1.5	P=0.157N	P=0.522	P=0.311N	P=0.247N
POLY 6	P=0.149N	P=0.566	P=0.303N	P=0.229N
COCH-ARM / FISHERS	P=0.157N	P=0.500	P=0.277N	P=0.256N
MAX-ISO-POLY-3	P=0.248N	P=0.455	P=0.242N	P=0.178N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Mammary Gland
 Hyperplasia Focal**

LESION RATES

OVERALL (a)	0/49 (0%)	0/49 (0%)	0/48 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/44.68	0/45.11	0/42.77	0/46.32
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/35 (0%)	0/36 (0%)	0/34 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Mammary Gland: Duct
 Ectasia**

LESION RATES

OVERALL (a)	8/49 (16%)	12/49 (24%)	4/48 (8%)	14/49 (29%)
POLY-3 RATE (b)	8/44.79	12/46.54	4/42.77	14/47.35
POLY-3 PERCENT (g)	17.9%	25.8%	9.4%	29.6%
TERMINAL (d)	7/35 (20%)	8/36 (22%)	4/34 (12%)	8/38 (21%)
FIRST INCIDENCE	702	587	729 (T)	638

STATISTICAL TESTS

POLY 3	P=0.166	P=0.254	P=0.199N	P=0.141
POLY 1.5	P=0.155	P=0.242	P=0.200N	P=0.128
POLY 6	P=0.183	P=0.271	P=0.195N	P=0.162
COCH-ARM / FISHERS	P=0.149	P=0.226	P=0.188N	P=0.113
MAX-ISO-POLY-3	P=0.136	P=0.185	P=0.128N	P=0.099

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Mesentery
 Accessory Spleen

LESION RATES

OVERALL (a)	0/3 (0%)	0/2 (0%)	1/6 (17%)	2/6 (33%)
POLY-3 RATE (b)	0/3.00	0/2.00	1/5.57	2/5.82
POLY-3 PERCENT (g)	0%	0%	18%	34.4%
TERMINAL (d)	0/3 (0%)	0/2 (0%)	0/4 (0%)	1/3 (33%)
FIRST INCIDENCE	---	---	647	714

STATISTICAL TESTS

POLY 3	P=0.169	(e)	P=0.622	P=0.384
POLY 1.5	P=0.173	(e)	P=0.627	P=0.389
POLY 6	P=0.161	(e)	P=0.614	P=0.375
COCH-ARM / FISHERS	P=0.161	(e)	P=0.667	P=0.417
MAX-ISO-POLY-3	P=0.239	(e)	P=0.260	P=0.165

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Mesentery: Fat
 Necrosis

LESION RATES

OVERALL (a)	3/3 (100%)	1/2 (50%)	3/6 (50%)	4/6 (67%)
POLY-3 RATE (b)	3/3.00	1/2.00	3/5.70	4/5.94
POLY-3 PERCENT (g)	100%	50%	52.6%	67.4%
TERMINAL (d)	3/3 (100%)	1/2 (50%)	2/4 (50%)	2/3 (67%)
FIRST INCIDENCE	729 (T)	729 (T)	604	702

STATISTICAL TESTS

POLY 3	P=0.421N	P=0.412N	P=0.242N	P=0.401N
POLY 1.5	P=0.422N	P=0.412N	P=0.232N	P=0.397N
POLY 6	P=0.422N	P=0.412N	P=0.263N	P=0.409N
COCH-ARM / FISHERS	P=0.420N	P=0.400N	P=0.238N	P=0.417N
MAX-ISO-POLY-3	P=0.242N	P=0.110N	P=0.092N	P=0.174N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Nose
 Foreign Body

LESION RATES

OVERALL (a)	10/50 (20%)	8/50 (16%)	7/50 (14%)	5/50 (10%)
POLY-3 RATE (b)	10/45.68	8/45.90	7/44.34	5/47.21
POLY-3 PERCENT (g)	21.9%	17.4%	15.8%	10.6%
TERMINAL (d)	10/36 (28%)	7/36 (19%)	4/35 (11%)	5/38 (13%)
FIRST INCIDENCE	729 (T)	702	647	729 (T)

STATISTICAL TESTS

POLY 3	P=0.089N	P=0.392N	P=0.319N	P=0.114N
POLY 1.5	P=0.095N	P=0.394N	P=0.321N	P=0.121N
POLY 6	P=0.082N	P=0.390N	P=0.310N	P=0.106N
COCH-ARM / FISHERS	P=0.102N	P=0.398N	P=0.298N	P=0.131N
MAX-ISO-POLY-3	P=0.113N	P=0.297N	P=0.234N	P=0.071N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Nose
 Inflammation Chronic**

LESION RATES

OVERALL (a)	16/50 (32%)	15/50 (30%)	6/50 (12%)	9/50 (18%)
POLY-3 RATE (b)	16/46.66	15/46.97	6/44.61	9/47.21
POLY-3 PERCENT (g)	34.3%	31.9%	13.5%	19.1%
TERMINAL (d)	13/36 (36%)	11/36 (31%)	3/35 (9%)	9/38 (24%)
FIRST INCIDENCE	591	591	646	729 (T)

STATISTICAL TESTS

POLY 3	P=0.027N*	P=0.491N	P=0.016N*	P=0.073N
POLY 1.5	P=0.028N*	P=0.495N	P=0.016N*	P=0.077N
POLY 6	P=0.026N*	P=0.487N	P=0.016N*	P=0.070N
COCH-ARM / FISHERS	P=0.030N*	P=0.500N	P=0.014N*	P=0.083N
MAX-ISO-POLY-3	P=0.031N*	P=0.403N	P=0.010N**	P=0.046N*

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Nose
 Thrombosis**

LESION RATES

OVERALL (a)	3/50 (6%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	3/46.63	1/46.10	0/43.97	0/47.21
POLY-3 PERCENT (g)	6.4%	2.2%	0%	0%
TERMINAL (d)	0/36 (0%)	0/36 (0%)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	600	647	---	---

STATISTICAL TESTS

POLY 3	P=0.043N*	P=0.309N	P=0.130N	P=0.117N
POLY 1.5	P=0.043N*	P=0.308N	P=0.127N	P=0.117N
POLY 6	P=0.043N*	P=0.313N	P=0.132N	P=0.116N
COCH-ARM / FISHERS	P=0.044N*	P=0.309N	P=0.121N	P=0.121N
MAX-ISO-POLY-3	P=0.023N*	P=0.159N	P=0.047N*	P=0.038N*

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Nose: Goblet Cell
 Hyperplasia**

LESION RATES

OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/45.68	2/46.11	1/44.08	1/47.52
POLY-3 PERCENT (g)	0%	4.3%	2.3%	2.1%
TERMINAL (d)	0/36 (0%)	1/36 (3%)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	---	643	702	645

STATISTICAL TESTS

POLY 3	P=0.518	P=0.239	P=0.493	P=0.508
POLY 1.5	P=0.510	P=0.239	P=0.493	P=0.505
POLY 6	P=0.528	P=0.240	P=0.494	P=0.512
COCH-ARM / FISHERS	P=0.500	P=0.247	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.278	P=0.078	P=0.158	P=0.168

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Nose: Respiratory Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	6/50 (12%)	6/50 (12%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	6/46.70	6/46.26	0/43.97	1/47.21
POLY-3 PERCENT (g)	12.9%	13%	0%	2.1%
TERMINAL (d)	3/36 (8%)	5/36 (14%)	0/35 (0%)	1/38 (3%)
FIRST INCIDENCE	591	591	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.010N**	P=0.614	P=0.019N*	P=0.054N
POLY 1.5	P=0.010N**	P=0.617	P=0.018N*	P=0.055N
POLY 6	P=0.010N**	P=0.608	P=0.019N*	P=0.053N
COCH-ARM / FISHERS	P=0.011N*	P=0.620N	P=0.013N*	P=0.056N
MAX-ISO-POLY-3	P=0.015N*	P=0.492	P=0.007N**	P=0.023N*

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pancreas
 Atrophy**

LESION RATES

OVERALL (a)	42/50 (84%)	36/50 (72%)	35/50 (70%)	30/50 (60%)
POLY-3 RATE (b)	42/48.79	36/48.22	35/47.27	30/48.99
POLY-3 PERCENT (g)	86.1%	74.7%	74.1%	61.2%
TERMINAL (d)	33/36 (92%)	28/36 (78%)	25/35 (71%)	23/38 (61%)
FIRST INCIDENCE	477	591	310	546

STATISTICAL TESTS

POLY 3	P=0.003N**	P=0.114N	P=0.103N	P=0.003N**
POLY 1.5	P=0.004N**	P=0.114N	P=0.104N	P=0.004N**
POLY 6	P=0.002N**	P=0.112N	P=0.093N	P=0.003N**
COCH-ARM / FISHERS	P=0.007N**	P=0.114N	P=0.077N	P=0.007N**
MAX-ISO-POLY-3	P=0.003N**	P=0.071N	P=0.066N	P=0.002N**

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pancreas: Acinus
 Hyperplasia Focal**

LESION RATES

OVERALL (a)	5/50 (10%)	4/50 (8%)	8/50 (16%)	9/50 (18%)
POLY-3 RATE (b)	5/45.68	4/45.80	8/44.01	9/47.21
POLY-3 PERCENT (g)	11%	8.7%	18.2%	19.1%
TERMINAL (d)	5/36 (14%)	4/36 (11%)	7/35 (20%)	9/38 (24%)
FIRST INCIDENCE	729 (T)	729 (T)	721	729 (T)

STATISTICAL TESTS

POLY 3	P=0.098	P=0.498N	P=0.251	P=0.211
POLY 1.5	P=0.093	P=0.499N	P=0.254	P=0.204
POLY 6	P=0.104	P=0.499N	P=0.252	P=0.220
COCH-ARM / FISHERS	P=0.088	P=0.500N	P=0.277	P=0.194
MAX-ISO-POLY-3	P=0.155	P=0.361N	P=0.170	P=0.141

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pancreas: Duct
 Ectasia**

LESION RATES

OVERALL (a)	24/50 (48%)	27/50 (54%)	19/50 (38%)	27/50 (54%)
POLY-3 RATE (b)	24/46.89	27/47.99	19/45.24	27/49.06
POLY-3 PERCENT (g)	51.2%	56.3%	42%	55%
TERMINAL (d)	20/36 (56%)	19/36 (53%)	14/35 (40%)	19/38 (50%)
FIRST INCIDENCE	477	591	591	546

STATISTICAL TESTS

POLY 3	P=0.481	P=0.385	P=0.248N	P=0.431
POLY 1.5	P=0.447	P=0.365	P=0.249N	P=0.391
POLY 6	P=0.532	P=0.419	P=0.232N	P=0.491
COCH-ARM / FISHERS	P=0.415	P=0.345	P=0.210N	P=0.345
MAX-ISO-POLY-3	P=0.495	P=0.310	P=0.190N	P=0.354

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pituitary Gland: Pars Distalis
 Angiectasis**

LESION RATES

OVERALL (a)	2/50 (4%)	4/50 (8%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/45.80	4/45.80	1/43.97	0/47.21
POLY-3 PERCENT (g)	4.4%	8.7%	2.3%	0%
TERMINAL (d)	1/36 (3%)	4/36 (11%)	1/35 (3%)	0/38 (0%)
FIRST INCIDENCE	699	729 (T)	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.081N	P=0.337	P=0.514N	P=0.230N
POLY 1.5	P=0.083N	P=0.338	P=0.512N	P=0.233N
POLY 6	P=0.079N	P=0.335	P=0.514N	P=0.227N
COCH-ARM / FISHERS	P=0.086N	P=0.339	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.078N	P=0.201	P=0.296N	P=0.076N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pituitary Gland: Pars Distalis
 Cyst**

LESION RATES

OVERALL (a)	6/50 (12%)	2/50 (4%)	5/50 (10%)	5/50 (10%)
POLY-3 RATE (b)	6/45.75	2/45.80	5/44.01	5/47.79
POLY-3 PERCENT (g)	13.1%	4.4%	11.4%	10.5%
TERMINAL (d)	5/36 (14%)	2/36 (6%)	4/35 (11%)	4/38 (11%)
FIRST INCIDENCE	711	729 (T)	721	546

STATISTICAL TESTS

POLY 3	P=0.560	P=0.132N	P=0.527N	P=0.470N
POLY 1.5	P=0.548	P=0.133N	P=0.524N	P=0.482N
POLY 6	P=0.562N	P=0.132N	P=0.526N	P=0.455N
COCH-ARM / FISHERS	P=0.533	P=0.134N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.389N	P=0.068N	P=0.400N	P=0.348N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pituitary Gland: Pars Distalis
 Hyperplasia**

LESION RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)	5/50 (10%)
POLY-3 RATE (b)	1/45.68	1/45.80	2/43.97	5/48.12
POLY-3 PERCENT (g)	2.2%	2.2%	4.6%	10.4%
TERMINAL (d)	1/36 (3%)	1/36 (3%)	2/35 (6%)	3/38 (8%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	546

STATISTICAL TESTS

POLY 3	P=0.032*	P=0.760N	P=0.487	P=0.114
POLY 1.5	P=0.030*	P=0.760N	P=0.488	P=0.109
POLY 6	P=0.034*	P=0.760N	P=0.488	P=0.121
COCH-ARM / FISHERS	P=0.029*	P=0.753N	P=0.500	P=0.102
MAX-ISO-POLY-3	P=0.048*	P=0.499N	P=0.273	P=0.056

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pituitary Gland: Pars Distalis
 Hyperplasia Focal**

LESION RATES

OVERALL (a)	11/50 (22%)	14/50 (28%)	19/50 (38%)	15/50 (30%)
POLY-3 RATE (b)	11/46.79	14/46.83	19/45.92	15/47.29
POLY-3 PERCENT (g)	23.5%	29.9%	41.4%	31.7%
TERMINAL (d)	9/36 (25%)	10/36 (28%)	14/35 (40%)	14/38 (37%)
FIRST INCIDENCE	477	501	310	711

STATISTICAL TESTS

POLY 3	P=0.214	P=0.321	P=0.050*	P=0.254
POLY 1.5	P=0.210	P=0.322	P=0.051	P=0.251
POLY 6	P=0.221	P=0.320	P=0.052	P=0.259
COCH-ARM / FISHERS	P=0.208	P=0.322	P=0.063	P=0.247
MAX-ISO-POLY-3	P=0.137	P=0.243	P=0.032*	P=0.188

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pituitary Gland: Pars Distalis
 Hypertrophy**

LESION RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/45.68	1/45.80	1/43.97	0/47.21
POLY-3 PERCENT (g)	0%	2.2%	2.3%	0%
TERMINAL (d)	0/36 (0%)	1/36 (3%)	1/35 (3%)	0/38 (0%)
FIRST INCIDENCE	---	729 (T)	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.586N	P=0.500	P=0.492	(e)
POLY 1.5	P=0.590N	P=0.500	P=0.493	(e)
POLY 6	P=0.582N	P=0.500	P=0.493	(e)
COCH-ARM / FISHERS	P=0.595N	P=0.500	P=0.500	(e)
MAX-ISO-POLY-3	P=0.403N	P=0.159	P=0.158	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pituitary Gland: Pars Intermedia
 Angiectasis**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.68	0/45.80	0/43.97	0/47.21
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/36 (0%)	0/36 (0%)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pituitary Gland: Pars Intermedia
 Cyst**

LESION RATES

OVERALL (a)	2/50 (4%)	4/50 (8%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	2/46.47	4/46.44	1/44.27	2/47.79
POLY-3 PERCENT (g)	4.3%	8.6%	2.3%	4.2%
TERMINAL (d)	0/36 (0%)	1/36 (3%)	0/35 (0%)	1/38 (3%)
FIRST INCIDENCE	613	643	647	546

STATISTICAL TESTS

POLY 3	P=0.425N	P=0.337	P=0.517N	P=0.684N
POLY 1.5	P=0.428N	P=0.338	P=0.514N	P=0.687N
POLY 6	P=0.420N	P=0.336	P=0.518N	P=0.680N
COCH-ARM / FISHERS	P=0.431N	P=0.339	P=0.500N	P=0.691N
MAX-ISO-POLY-3	P=0.383N	P=0.201	P=0.299N	P=0.488N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Pituitary Gland: Rathke's Cleft Hemorrhage

LESION RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/45.76	0/45.80	2/43.97	0/47.21
POLY-3 PERCENT (g)	4.4%	0%	4.6%	0%
TERMINAL (d)	1/36 (3%)	0/36 (0%)	2/35 (6%)	0/38 (0%)
FIRST INCIDENCE	710	---	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.240N	P=0.237N	P=0.680	P=0.230N
POLY 1.5	P=0.243N	P=0.237N	P=0.681	P=0.233N
POLY 6	P=0.235N	P=0.237N	P=0.680	P=0.227N
COCH-ARM / FISHERS	P=0.247N	P=0.247N	P=0.691N	P=0.247N
MAX-ISO-POLY-3	P=0.120N	P=0.076N	P=0.483	P=0.076N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Preputial Gland
 Hyperplasia**

LESION RATES

OVERALL (a)	3/50 (6%)	6/49 (12%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	3/46.12	6/45.27	0/43.97	2/47.79
POLY-3 PERCENT (g)	6.5%	13.3%	0%	4.2%
TERMINAL (d)	2/36 (6%)	6/36 (17%)	0/35 (0%)	1/38 (3%)
FIRST INCIDENCE	601	729 (T)	---	546

STATISTICAL TESTS

POLY 3	P=0.176N	P=0.233	P=0.127N	P=0.484N
POLY 1.5	P=0.179N	P=0.233	P=0.126N	P=0.490N
POLY 6	P=0.171N	P=0.231	P=0.128N	P=0.476N
COCH-ARM / FISHERS	P=0.184N	P=0.233	P=0.121N	P=0.500N
MAX-ISO-POLY-3	P=0.091N	P=0.141	P=0.045N*	P=0.313N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Preputial Gland
 Inflammation Chronic**

LESION RATES

OVERALL (a)	39/50 (78%)	37/49 (76%)	40/50 (80%)	40/50 (80%)
POLY-3 RATE (b)	39/48.08	37/47.62	40/48.53	40/49.08
POLY-3 PERCENT (g)	81.1%	77.7%	82.4%	81.5%
TERMINAL (d)	31/36 (86%)	29/36 (81%)	30/35 (86%)	34/38 (90%)
FIRST INCIDENCE	599	501	310	546

STATISTICAL TESTS

POLY 3	P=0.459	P=0.434N	P=0.539	P=0.586
POLY 1.5	P=0.428	P=0.448N	P=0.494	P=0.553
POLY 6	P=0.494	P=0.431N	P=0.598	P=0.603N
COCH-ARM / FISHERS	P=0.390	P=0.478N	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.587	P=0.334N	P=0.431	P=0.479

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Prostate
 Inflammation Chronic**

LESION RATES

OVERALL (a)	19/50 (38%)	17/50 (34%)	13/50 (26%)	16/50 (32%)
POLY-3 RATE (b)	19/47.82	17/47.46	13/44.87	16/47.58
POLY-3 PERCENT (g)	39.7%	35.8%	29%	33.6%
TERMINAL (d)	13/36 (36%)	12/36 (33%)	11/35 (31%)	13/38 (34%)
FIRST INCIDENCE	477	587	591	682

STATISTICAL TESTS

POLY 3	P=0.288N	P=0.427N	P=0.191N	P=0.342N
POLY 1.5	P=0.287N	P=0.424N	P=0.180N	P=0.341N
POLY 6	P=0.289N	P=0.432N	P=0.199N	P=0.343N
COCH-ARM / FISHERS	P=0.279N	P=0.418N	P=0.142N	P=0.338N
MAX-ISO-POLY-3	P=0.312N	P=0.346N	P=0.144N	P=0.269N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Prostate: Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	9/50 (18%)	8/50 (16%)	8/50 (16%)	7/50 (14%)
POLY-3 RATE (b)	9/47.19	8/47.00	8/44.87	7/47.40
POLY-3 PERCENT (g)	19.1%	17%	17.8%	14.8%
TERMINAL (d)	6/36 (17%)	4/36 (11%)	6/35 (17%)	5/38 (13%)
FIRST INCIDENCE	477	587	591	702

STATISTICAL TESTS

POLY 3	P=0.347N	P=0.504N	P=0.546N	P=0.389N
POLY 1.5	P=0.350N	P=0.503N	P=0.538N	P=0.391N
POLY 6	P=0.343N	P=0.504N	P=0.548N	P=0.385N
COCH-ARM / FISHERS	P=0.348N	P=0.500N	P=0.500N	P=0.393N
MAX-ISO-POLY-3	P=0.464N	P=0.397N	P=0.439N	P=0.290N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Salivary Glands
 Atrophy**

LESION RATES

OVERALL (a)	7/48 (15%)	7/50 (14%)	4/50 (8%)	9/50 (18%)
POLY-3 RATE (b)	7/44.60	7/45.80	4/44.27	9/47.68
POLY-3 PERCENT (g)	15.7%	15.3%	9%	18.9%
TERMINAL (d)	4/35 (11%)	7/36 (19%)	3/35 (9%)	8/38 (21%)
FIRST INCIDENCE	591	729 (T)	647	591

STATISTICAL TESTS

POLY 3	P=0.392	P=0.593N	P=0.265N	P=0.449
POLY 1.5	P=0.384	P=0.587N	P=0.260N	P=0.441
POLY 6	P=0.402	P=0.605N	P=0.267N	P=0.457
COCH-ARM / FISHERS	P=0.375	P=0.581N	P=0.239N	P=0.428
MAX-ISO-POLY-3	P=0.374	P=0.478N	P=0.174N	P=0.346

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Skin
 Cyst Epithelial Inclusion**

LESION RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	1/45.79	2/46.12	2/43.97	2/47.29
POLY-3 PERCENT (g)	2.2%	4.3%	4.6%	4.2%
TERMINAL (d)	0/36 (0%)	1/36 (3%)	2/35 (6%)	1/38 (3%)
FIRST INCIDENCE	702	638	729 (T)	710

STATISTICAL TESTS

POLY 3	P=0.438	P=0.503	P=0.486	P=0.511
POLY 1.5	P=0.431	P=0.502	P=0.488	P=0.507
POLY 6	P=0.446	P=0.503	P=0.486	P=0.517
COCH-ARM / FISHERS	P=0.423	P=0.500	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.470	P=0.283	P=0.272	P=0.293

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Skin
 Hyperkeratosis**

LESION RATES

OVERALL (a)	4/50 (8%)	3/50 (6%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	4/45.75	3/46.41	1/43.97	0/47.21
POLY-3 PERCENT (g)	8.7%	6.5%	2.3%	0%
TERMINAL (d)	3/36 (8%)	1/36 (3%)	1/35 (3%)	0/38 (0%)
FIRST INCIDENCE	711	643	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.024N*	P=0.492N	P=0.191N	P=0.056N
POLY 1.5	P=0.025N*	P=0.495N	P=0.190N	P=0.058N
POLY 6	P=0.023N*	P=0.488N	P=0.190N	P=0.054N
COCH-ARM / FISHERS	P=0.025N*	P=0.500N	P=0.181N	P=0.059N
MAX-ISO-POLY-3	P=0.030N*	P=0.341N	P=0.095N	P=0.019N*

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Skin
 Inflammation Chronic**

LESION RATES

OVERALL (a)	4/50 (8%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	4/45.68	0/45.80	0/43.97	0/47.21
POLY-3 PERCENT (g)	8.8%	0%	0%	0%
TERMINAL (d)	4/36 (11%)	0/36 (0%)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	729 (T)	---	---	---

STATISTICAL TESTS

POLY 3	P=0.018N*	P=0.060N	P=0.065N	P=0.056N
POLY 1.5	P=0.018N*	P=0.060N	P=0.065N	P=0.058N
POLY 6	P=0.018N*	P=0.060N	P=0.065N	P=0.054N
COCH-ARM / FISHERS	P=0.020N*	P=0.059N	P=0.059N	P=0.059N
MAX-ISO-POLY-3	P=0.003N**	P=0.019N*	P=0.023N*	P=0.019N*

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Skin: Epidermis
 Hyperplasia**

LESION RATES

OVERALL (a)	3/50 (6%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	3/45.68	2/46.10	1/43.97	0/47.21
POLY-3 PERCENT (g)	6.6%	4.3%	2.3%	0%
TERMINAL (d)	3/36 (8%)	1/36 (3%)	1/35 (3%)	0/38 (0%)
FIRST INCIDENCE	729 (T)	647	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.060N	P=0.496N	P=0.319N	P=0.113N
POLY 1.5	P=0.061N	P=0.498N	P=0.318N	P=0.115N
POLY 6	P=0.058N	P=0.494N	P=0.318N	P=0.110N
COCH-ARM / FISHERS	P=0.062N	P=0.500N	P=0.309N	P=0.121N
MAX-ISO-POLY-3	P=0.060N	P=0.321N	P=0.168N	P=0.038N*

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Spleen
 Fibrosis**

LESION RATES

OVERALL (a)	4/50 (8%)	3/50 (6%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	4/46.29	3/45.80	2/43.97	2/47.54
POLY-3 PERCENT (g)	8.6%	6.6%	4.6%	4.2%
TERMINAL (d)	2/36 (6%)	3/36 (8%)	2/35 (6%)	1/38 (3%)
FIRST INCIDENCE	619	729 (T)	729 (T)	638

STATISTICAL TESTS

POLY 3	P=0.241N	P=0.506N	P=0.361N	P=0.325N
POLY 1.5	P=0.245N	P=0.503N	P=0.357N	P=0.330N
POLY 6	P=0.235N	P=0.512N	P=0.364N	P=0.319N
COCH-ARM / FISHERS	P=0.248N	P=0.500N	P=0.339N	P=0.339N
MAX-ISO-POLY-3	P=0.298N	P=0.353N	P=0.225N	P=0.195N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Spleen
 Hematopoietic Cell Proliferation**

LESION RATES

OVERALL (a)	4/50 (8%)	0/50 (0%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	4/47.03	0/45.80	3/45.69	2/47.79
POLY-3 PERCENT (g)	8.5%	0%	6.6%	4.2%
TERMINAL (d)	0/36 (0%)	0/36 (0%)	1/35 (3%)	1/38 (3%)
FIRST INCIDENCE	477	---	310	546

STATISTICAL TESTS

POLY 3	P=0.418N	P=0.064N	P=0.516N	P=0.330N
POLY 1.5	P=0.424N	P=0.062N	P=0.513N	P=0.333N
POLY 6	P=0.410N	P=0.066N	P=0.519N	P=0.326N
COCH-ARM / FISHERS	P=0.431N	P=0.059N	P=0.500N	P=0.339N
MAX-ISO-POLY-3	P=0.212N	P=0.022N*	P=0.364N	P=0.197N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Spleen
 Pigmentation**

LESION RATES

OVERALL (a)	44/50 (88%)	45/50 (90%)	42/50 (84%)	45/50 (90%)
POLY-3 RATE (b)	44/48.95	45/49.06	42/48.10	45/49.56
POLY-3 PERCENT (g)	89.9%	91.7%	87.3%	90.8%
TERMINAL (d)	35/36 (97%)	34/36 (94%)	32/35 (91%)	36/38 (95%)
FIRST INCIDENCE	477	501	310	546

STATISTICAL TESTS

POLY 3	P=0.565	P=0.514	P=0.467N	P=0.578
POLY 1.5	P=0.528	P=0.507	P=0.471N	P=0.541
POLY 6	P=0.518N	P=0.533	P=0.453N	P=0.643
COCH-ARM / FISHERS	P=0.500	P=0.500	P=0.387N	P=0.500
MAX-ISO-POLY-3	P=0.599N	P=0.367	P=0.338N	P=0.435

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Spleen: Lymphoid Follicle
 Hyperplasia**

LESION RATES

OVERALL (a)	5/50 (10%)	6/50 (12%)	6/50 (12%)	7/50 (14%)
POLY-3 RATE (b)	5/46.58	6/45.80	6/43.97	7/47.79
POLY-3 PERCENT (g)	10.7%	13.1%	13.6%	14.7%
TERMINAL (d)	2/36 (6%)	6/36 (17%)	6/35 (17%)	6/38 (16%)
FIRST INCIDENCE	477	729 (T)	729 (T)	546

STATISTICAL TESTS

POLY 3	P=0.350	P=0.488	P=0.460	P=0.398
POLY 1.5	P=0.340	P=0.493	P=0.468	P=0.390
POLY 6	P=0.362	P=0.481	P=0.455	P=0.407
COCH-ARM / FISHERS	P=0.329	P=0.500	P=0.500	P=0.380
MAX-ISO-POLY-3	P=0.461	P=0.364	P=0.340	P=0.288

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Stomach, Forestomach
 Edema**

LESION RATES

OVERALL (a)	2/50 (4%)	4/50 (8%)	5/50 (10%)	3/50 (6%)
POLY-3 RATE (b)	2/46.23	4/46.47	5/45.08	3/48.01
POLY-3 PERCENT (g)	4.3%	8.6%	11.1%	6.3%
TERMINAL (d)	0/36 (0%)	0/36 (0%)	0/35 (0%)	1/38 (3%)
FIRST INCIDENCE	619	647	604	591

STATISTICAL TESTS

POLY 3	P=0.491	P=0.340	P=0.206	P=0.517
POLY 1.5	P=0.479	P=0.339	P=0.205	P=0.510
POLY 6	P=0.506	P=0.340	P=0.210	P=0.526
COCH-ARM / FISHERS	P=0.463	P=0.339	P=0.218	P=0.500
MAX-ISO-POLY-3	P=0.356	P=0.203	P=0.115	P=0.342

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Stomach, Forestomach
 Ulcer**

LESION RATES

OVERALL (a)	3/50 (6%)	4/50 (8%)	4/50 (8%)	3/50 (6%)
POLY-3 RATE (b)	3/46.31	4/46.55	4/45.00	3/48.01
POLY-3 PERCENT (g)	6.5%	8.6%	8.9%	6.3%
TERMINAL (d)	0/36 (0%)	0/36 (0%)	0/35 (0%)	1/38 (3%)
FIRST INCIDENCE	619	643	604	591

STATISTICAL TESTS

POLY 3	P=0.517N	P=0.503	P=0.484	P=0.645N
POLY 1.5	P=0.526N	P=0.502	P=0.484	P=0.652N
POLY 6	P=0.506N	P=0.504	P=0.489	P=0.638N
COCH-ARM / FISHERS	P=0.537N	P=0.500	P=0.500	P=0.661N
MAX-ISO-POLY-3	P=0.592N	P=0.350	P=0.335	P=0.481N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Stomach, Forestomach: Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	3/50 (6%)	6/50 (12%)	7/50 (14%)	5/50 (10%)
POLY-3 RATE (b)	3/46.36	6/46.86	7/45.80	5/48.36
POLY-3 PERCENT (g)	6.5%	12.8%	15.3%	10.3%
TERMINAL (d)	0/36 (0%)	0/36 (0%)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	600	643	604	638

STATISTICAL TESTS

POLY 3	P=0.398	P=0.247	P=0.152	P=0.380
POLY 1.5	P=0.382	P=0.246	P=0.149	P=0.370
POLY 6	P=0.419	P=0.250	P=0.161	P=0.394
COCH-ARM / FISHERS	P=0.363	P=0.243	P=0.159	P=0.357
MAX-ISO-POLY-3	P=0.275	P=0.152	P=0.088	P=0.256

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Stomach, Glandular
 Edema**

LESION RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	2/49 (4%)	1/50 (2%)
POLY-3 RATE (b)	1/46.07	2/45.93	2/44.08	1/47.54
POLY-3 PERCENT (g)	2.2%	4.4%	4.5%	2.1%
TERMINAL (d)	0/36 (0%)	0/36 (0%)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	619	702	646	638

STATISTICAL TESTS

POLY 3	P=0.544N	P=0.499	P=0.485	P=0.753N
POLY 1.5	P=0.549N	P=0.500	P=0.484	P=0.756N
POLY 6	P=0.536N	P=0.498	P=0.489	P=0.750N
COCH-ARM / FISHERS	P=0.556N	P=0.500	P=0.492	P=0.753N
MAX-ISO-POLY-3	P=0.534N	P=0.280	P=0.271	P=0.490N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Stomach, Glandular
 Erosion**

LESION RATES

OVERALL (a)	3/50 (6%)	3/50 (6%)	3/49 (6%)	2/50 (4%)
POLY-3 RATE (b)	3/45.80	3/46.38	3/44.87	2/47.29
POLY-3 PERCENT (g)	6.6%	6.5%	6.7%	4.2%
TERMINAL (d)	2/36 (6%)	0/36 (0%)	1/35 (3%)	1/38 (3%)
FIRST INCIDENCE	699	643	86	711

STATISTICAL TESTS

POLY 3	P=0.385N	P=0.657N	P=0.653	P=0.485N
POLY 1.5	P=0.391N	P=0.659N	P=0.650	P=0.491N
POLY 6	P=0.377N	P=0.654N	P=0.659	P=0.478N
COCH-ARM / FISHERS	P=0.398N	P=0.661N	P=0.651	P=0.500N
MAX-ISO-POLY-3	P=0.511N	P=0.493N	P=0.489	P=0.314N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Stomach, Glandular
 Ulcer**

LESION RATES

OVERALL (a)	4/50 (8%)	1/50 (2%)	4/49 (8%)	3/50 (6%)
POLY-3 RATE (b)	4/47.11	1/46.10	4/44.32	3/47.95
POLY-3 PERCENT (g)	8.5%	2.2%	9%	6.3%
TERMINAL (d)	0/36 (0%)	0/36 (0%)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	600	647	637	638

STATISTICAL TESTS

POLY 3	P=0.567N	P=0.185N	P=0.609	P=0.490N
POLY 1.5	P=0.574N	P=0.183N	P=0.612	P=0.494N
POLY 6	P=0.558N	P=0.191N	P=0.610	P=0.486N
COCH-ARM / FISHERS	P=0.578	P=0.181N	P=0.631	P=0.500N
MAX-ISO-POLY-3	P=0.474N	P=0.090N	P=0.464	P=0.340N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Testes: Germinal Epithelium
 Atrophy

LESION RATES

OVERALL (a)	6/50 (12%)	8/50 (16%)	11/50 (22%)	7/50 (14%)
POLY-3 RATE (b)	6/45.95	8/46.64	11/45.34	7/47.62
POLY-3 PERCENT (g)	13.1%	17.2%	24.3%	14.7%
TERMINAL (d)	4/36 (11%)	6/36 (17%)	8/35 (23%)	5/38 (13%)
FIRST INCIDENCE	687	591	428	638

STATISTICAL TESTS

POLY 3	P=0.484	P=0.398	P=0.133	P=0.527
POLY 1.5	P=0.468	P=0.394	P=0.132	P=0.516
POLY 6	P=0.504	P=0.401	P=0.138	P=0.542
COCH-ARM / FISHERS	P=0.448	P=0.387	P=0.143	P=0.500
MAX-ISO-POLY-3	P=0.345	P=0.294	P=0.085	P=0.409

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Testes: Interstitial Cell
 Hyperplasia

LESION RATES

OVERALL (a)	3/50 (6%)	4/50 (8%)	5/50 (10%)	5/50 (10%)
POLY-3 RATE (b)	3/46.13	4/46.95	5/45.34	5/48.69
POLY-3 PERCENT (g)	6.5%	8.5%	11%	10.3%
TERMINAL (d)	2/36 (6%)	1/36 (3%)	2/35 (6%)	0/38 (0%)
FIRST INCIDENCE	599	591	428	546

STATISTICAL TESTS

POLY 3	P=0.321	P=0.510	P=0.347	P=0.387
POLY 1.5	P=0.307	P=0.506	P=0.345	P=0.374
POLY 6	P=0.341	P=0.515	P=0.352	P=0.404
COCH-ARM / FISHERS	P=0.289	P=0.500	P=0.357	P=0.357
MAX-ISO-POLY-3	P=0.400	P=0.357	P=0.225	P=0.262

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Thymus
 Cyst**

LESION RATES

OVERALL (a)	1/41 (2%)	1/42 (2%)	0/46 (0%)	0/42 (0%)
POLY-3 RATE (b)	1/37.45	1/39.71	0/39.97	0/39.49
POLY-3 PERCENT (g)	2.7%	2.5%	0%	0%
TERMINAL (d)	1/30 (3%)	0/33 (0%)	0/31 (0%)	0/32 (0%)
FIRST INCIDENCE	729 (T)	638	---	---

STATISTICAL TESTS

POLY 3	P=0.231N	P=0.747N	P=0.487N	P=0.489N
POLY 1.5	P=0.231N	P=0.751N	P=0.485N	P=0.492N
POLY 6	P=0.231N	P=0.743N	P=0.488N	P=0.487N
COCH-ARM / FISHERS	P=0.228N	P=0.747N	P=0.471N	P=0.494N
MAX-ISO-POLY-3	P=0.247N	P=0.483N	P=0.150N	P=0.157N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Thymus
 Hemorrhage**

LESION RATES

OVERALL (a)	0/41 (0%)	0/42 (0%)	0/46 (0%)	0/42 (0%)
POLY-3 RATE (b)	0/37.45	0/39.38	0/39.97	0/39.49
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/30 (0%)	0/33 (0%)	0/31 (0%)	0/32 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Thyroid Gland
 Degeneration Cystic**

LESION RATES

OVERALL (a)	6/48 (13%)	7/49 (14%)	5/50 (10%)	4/49 (8%)
POLY-3 RATE (b)	6/44.16	7/46.27	5/44.58	4/47.65
POLY-3 PERCENT (g)	13.6%	15.1%	11.2%	8.4%
TERMINAL (d)	5/35 (14%)	2/36 (6%)	3/35 (9%)	1/38 (3%)
FIRST INCIDENCE	613	647	646	546

STATISTICAL TESTS

POLY 3	P=0.209N	P=0.536	P=0.493N	P=0.323N
POLY 1.5	P=0.221N	P=0.527	P=0.493N	P=0.337N
POLY 6	P=0.195N	P=0.549	P=0.488N	P=0.305N
COCH-ARM / FISHERS	P=0.234N	P=0.516	P=0.471N	P=0.357N
MAX-ISO-POLY-3	P=0.318N	P=0.417	P=0.368N	P=0.222N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Thyroid Gland
 Ultimobranchial Cyst**

LESION RATES

OVERALL (a)	1/48 (2%)	2/49 (4%)	2/50 (4%)	4/49 (8%)
POLY-3 RATE (b)	1/44.22	2/45.38	2/43.97	4/46.68
POLY-3 PERCENT (g)	2.3%	4.4%	4.6%	8.6%
TERMINAL (d)	0/35 (0%)	1/36 (3%)	2/35 (6%)	4/38 (11%)
FIRST INCIDENCE	591	702	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.124	P=0.509	P=0.498	P=0.196
POLY 1.5	P=0.121	P=0.508	P=0.501	P=0.191
POLY 6	P=0.127	P=0.509	P=0.497	P=0.201
COCH-ARM / FISHERS	P=0.116	P=0.508	P=0.515	P=0.187
MAX-ISO-POLY-3	P=0.138	P=0.290	P=0.281	P=0.098

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Thyroid Gland: C-Cell
 Hyperplasia**

LESION RATES

OVERALL (a)	9/48 (19%)	25/49 (51%)	15/50 (30%)	16/49 (33%)
POLY-3 RATE (b)	9/43.76	25/46.51	15/44.01	16/46.83
POLY-3 PERCENT (g)	20.6%	53.8%	34.1%	34.2%
TERMINAL (d)	9/35 (26%)	20/36 (56%)	14/35 (40%)	14/38 (37%)
FIRST INCIDENCE	729 (T)	591	721	710

STATISTICAL TESTS

POLY 3	P=0.413	P<0.001**	P=0.116	P=0.111
POLY 1.5	P=0.385	P<0.001**	P=0.120	P=0.102
POLY 6	P=0.453	P<0.001**	P=0.116	P=0.124
COCH-ARM / FISHERS	P=0.356	P<0.001**	P=0.145	P=0.091
MAX-ISO-POLY-3	P=0.033*	P<0.001**	P=0.077	P=0.078

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Thyroid Gland: Follicular Cell
 Hyperplasia Focal**

LESION RATES

OVERALL (a)	0/48 (0%)	4/49 (8%)	2/50 (4%)	0/49 (0%)
POLY-3 RATE (b)	0/43.76	4/45.60	2/43.97	0/46.68
POLY-3 PERCENT (g)	0%	8.8%	4.6%	0%
TERMINAL (d)	0/35 (0%)	3/36 (8%)	2/35 (6%)	0/38 (0%)
FIRST INCIDENCE	---	638	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.307N	P=0.065	P=0.238	(e)
POLY 1.5	P=0.316N	P=0.065	P=0.239	(e)
POLY 6	P=0.295N	P=0.067	P=0.239	(e)
COCH-ARM / FISHERS	P=0.330N	P=0.061	P=0.258	(e)
MAX-ISO-POLY-3	P=0.189N	P=0.023*	P=0.078	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Urinary Bladder: Transitional Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/46.07	2/46.37	0/43.97	0/47.21
POLY-3 PERCENT (g)	2.2%	4.3%	0%	0%
TERMINAL (d)	0/36 (0%)	0/36 (0%)	0/35 (0%)	0/38 (0%)
FIRST INCIDENCE	619	591	---	---

STATISTICAL TESTS

POLY 3	P=0.187N	P=0.502	P=0.509N	P=0.495N
POLY 1.5	P=0.188N	P=0.501	P=0.508N	P=0.497N
POLY 6	P=0.186N	P=0.503	P=0.510N	P=0.493N
COCH-ARM / FISHERS	P=0.188N	P=0.500	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.173N	P=0.283	P=0.170N	P=0.159N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Adrenal Cortex
 Accessory Adrenal Cortical Nodule**

LESION RATES

OVERALL (a)	7/48 (15%)	15/48 (31%)	11/49 (22%)	7/50 (14%)
POLY-3 RATE (b)	7/44.90	15/44.25	11/45.01	7/47.25
POLY-3 PERCENT (g)	15.6%	33.9%	24.4%	14.8%
TERMINAL (d)	3/38 (8%)	12/35 (34%)	7/34 (21%)	5/37 (14%)
FIRST INCIDENCE	575	618	484	619

STATISTICAL TESTS

POLY 3	P=0.261N	P=0.037*	P=0.217	P=0.574N
POLY 1.5	P=0.255N	P=0.042*	P=0.224	P=0.567N
POLY 6	P=0.284N	P=0.030*	P=0.202	P=0.593N
COCH-ARM / FISHERS	P=0.276N	P=0.044*	P=0.232	P=0.581N
MAX-ISO-POLY-3	P=0.203N	P=0.022*	P=0.148	P=0.459N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Adrenal Cortex
 Degeneration Fatty**

LESION RATES

OVERALL (a)	16/48 (33%)	17/48 (35%)	24/49 (49%)	22/50 (44%)
POLY-3 RATE (b)	16/45.33	17/44.42	24/44.96	22/47.34
POLY-3 PERCENT (g)	35.3%	38.3%	53.4%	46.5%
TERMINAL (d)	10/38 (26%)	13/35 (37%)	17/34 (50%)	17/37 (46%)
FIRST INCIDENCE	434	599	484	638

STATISTICAL TESTS

POLY 3	P=0.122	P=0.471	P=0.062	P=0.188
POLY 1.5	P=0.130	P=0.496	P=0.070	P=0.201
POLY 6	P=0.103	P=0.431	P=0.053	P=0.161
COCH-ARM / FISHERS	P=0.123	P=0.500	P=0.087	P=0.191
MAX-ISO-POLY-3	P=0.123	P=0.385	P=0.041*	P=0.139

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Adrenal Cortex
 Hyperplasia Focal**

LESION RATES

OVERALL (a)	21/48 (44%)	21/48 (44%)	21/49 (43%)	29/50 (58%)
POLY-3 RATE (b)	21/43.73	21/44.49	21/43.18	29/47.01
POLY-3 PERCENT (g)	48%	47.2%	48.6%	61.7%
TERMINAL (d)	21/38 (55%)	19/35 (54%)	20/34 (59%)	26/37 (70%)
FIRST INCIDENCE	729 (T)	459	703	638

STATISTICAL TESTS

POLY 3	P=0.081	P=0.555N	P=0.563	P=0.131
POLY 1.5	P=0.084	P=0.546N	P=0.580N	P=0.136
POLY 6	P=0.069	P=0.584N	P=0.524	P=0.112
COCH-ARM / FISHERS	P=0.077	P=0.581N	P=0.546N	P=0.113
MAX-ISO-POLY-3	P=0.127	P=0.468N	P=0.476	P=0.096

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Adrenal Cortex
 Hypertrophy Focal**

LESION RATES

OVERALL (a)	2/48 (4%)	3/48 (6%)	1/49 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/43.73	3/43.81	1/43.08	1/46.85
POLY-3 PERCENT (g)	4.6%	6.9%	2.3%	2.1%
TERMINAL (d)	2/38 (5%)	2/35 (6%)	1/34 (3%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	592	729 (T)	667

STATISTICAL TESTS

POLY 3	P=0.260N	P=0.501	P=0.505N	P=0.476N
POLY 1.5	P=0.259N	P=0.505	P=0.500N	P=0.476N
POLY 6	P=0.264N	P=0.491	P=0.514N	P=0.481N
COCH-ARM / FISHERS	P=0.265N	P=0.500	P=0.492N	P=0.485N
MAX-ISO-POLY-3	P=0.317N	P=0.324	P=0.287N	P=0.265N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Adrenal Medulla
 Hyperplasia**

LESION RATES

OVERALL (a)	4/48 (8%)	10/48 (21%)	3/48 (6%)	6/50 (12%)
POLY-3 RATE (b)	4/43.73	10/43.34	3/42.15	6/46.89
POLY-3 PERCENT (g)	9.2%	23.1%	7.1%	12.8%
TERMINAL (d)	4/38 (11%)	10/35 (29%)	3/34 (9%)	3/37 (8%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	693

STATISTICAL TESTS

POLY 3	P=0.495N	P=0.068	P=0.520N	P=0.414
POLY 1.5	P=0.494N	P=0.073	P=0.511N	P=0.414
POLY 6	P=0.505N	P=0.060	P=0.533N	P=0.406
COCH-ARM / FISHERS	P=0.513N	P=0.073	P=0.500N	P=0.397
MAX-ISO-POLY-3	P=0.326N	P=0.037*	P=0.368N	P=0.296

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Bone Marrow
 Hyperplasia**

LESION RATES

OVERALL (a)	5/49 (10%)	5/50 (10%)	8/50 (16%)	1/50 (2%)
POLY-3 RATE (b)	5/45.18	5/46.29	8/45.65	1/47.20
POLY-3 PERCENT (g)	11.1%	10.8%	17.5%	2.1%
TERMINAL (d)	4/38 (11%)	2/36 (6%)	2/34 (6%)	0/37 (0%)
FIRST INCIDENCE	623	477	477	546

STATISTICAL TESTS

POLY 3	P=0.101N	P=0.615N	P=0.282	P=0.092N
POLY 1.5	P=0.102N	P=0.610N	P=0.284	P=0.092N
POLY 6	P=0.104N	P=0.624N	P=0.281	P=0.094N
COCH-ARM / FISHERS	P=0.113N	P=0.617N	P=0.290	P=0.098N
MAX-ISO-POLY-3	P=0.065N	P=0.483N	P=0.191	P=0.042N*

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Bone Marrow
 Infiltration Cellular Histiocyte**

LESION RATES

OVERALL (a)	0/49 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.81	0/44.93	2/44.82	0/46.62
POLY-3 PERCENT (g)	0%	0%	4.5%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	1/34 (3%)	0/37 (0%)
FIRST INCIDENCE	---	---	451	---

STATISTICAL TESTS

POLY 3	P=0.614	(e)	P=0.237	(e)
POLY 1.5	P=0.612	(e)	P=0.239	(e)
POLY 6	P=0.611	(e)	P=0.234	(e)
COCH-ARM / FISHERS	P=0.598	(e)	P=0.253	(e)
MAX-ISO-POLY-3	P=0.256	(e)	P=0.077	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Bone Marrow
 Myelofibrosis**

LESION RATES

OVERALL (a)	0/49 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.81	0/44.93	1/44.26	0/46.62
POLY-3 PERCENT (g)	0%	0%	2.3%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	676	---

STATISTICAL TESTS

POLY 3	P=0.708	(e)	P=0.498	(e)
POLY 1.5	P=0.707	(e)	P=0.500	(e)
POLY 6	P=0.706	(e)	P=0.495	(e)
COCH-ARM / FISHERS	P=0.697	(e)	P=0.505	(e)
MAX-ISO-POLY-3	P=0.390	(e)	P=0.160	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Bone: Femur
 Osteopetrosis**

LESION RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/45.18	1/45.18	1/44.77	2/47.03
POLY-3 PERCENT (g)	2.2%	2.2%	2.2%	4.3%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	687	660	484	619

STATISTICAL TESTS

POLY 3	P=0.365	P=0.761N	P=0.759	P=0.514
POLY 1.5	P=0.363	P=0.758N	P=0.760	P=0.512
POLY 6	P=0.366	P=0.756	P=0.756	P=0.512
COCH-ARM / FISHERS	P=0.351	P=0.753N	P=0.753N	P=0.500
MAX-ISO-POLY-3	P=0.448	P=0.499N	P=0.497	P=0.296

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Brain
 Compression**

LESION RATES

OVERALL (a)	5/50 (10%)	9/50 (18%)	12/50 (24%)	10/50 (20%)
POLY-3 RATE (b)	5/45.99	9/46.11	12/44.24	10/47.81
POLY-3 PERCENT (g)	10.9%	19.5%	27.1%	20.9%
TERMINAL (d)	2/38 (5%)	6/36 (17%)	10/34 (29%)	5/37 (14%)
FIRST INCIDENCE	575	592	703	619

STATISTICAL TESTS

POLY 3	P=0.153	P=0.193	P=0.042*	P=0.148
POLY 1.5	P=0.150	P=0.199	P=0.046*	P=0.146
POLY 6	P=0.153	P=0.183	P=0.036*	P=0.146
COCH-ARM / FISHERS	P=0.131	P=0.194	P=0.054	P=0.131
MAX-ISO-POLY-3	P=0.089	P=0.125	P=0.025*	P=0.096

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Brain
 Hemorrhage**

LESION RATES

OVERALL (a)	4/50 (8%)	7/50 (14%)	8/50 (16%)	14/50 (28%)
POLY-3 RATE (b)	4/45.60	7/45.32	8/45.00	14/47.65
POLY-3 PERCENT (g)	8.8%	15.5%	17.8%	29.4%
TERMINAL (d)	2/38 (5%)	6/36 (17%)	6/34 (18%)	9/37 (24%)
FIRST INCIDENCE	575	618	484	619

STATISTICAL TESTS

POLY 3	P=0.005**	P=0.257	P=0.170	P=0.010**
POLY 1.5	P=0.005**	P=0.265	P=0.174	P=0.010**
POLY 6	P=0.005**	P=0.243	P=0.163	P=0.010**
COCH-ARM / FISHERS	P=0.005**	P=0.262	P=0.178	P=0.009**
MAX-ISO-POLY-3	P=0.007**	P=0.166	P=0.104	P=0.006**

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Brain
 Necrosis**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/45.02	0/44.93	2/44.79	1/47.02
POLY-3 PERCENT (g)	0%	0%	4.5%	2.1%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	567	613

STATISTICAL TESTS

POLY 3	P=0.264	(e)	P=0.236	P=0.509
POLY 1.5	P=0.260	(e)	P=0.237	P=0.507
POLY 6	P=0.266	(e)	P=0.235	P=0.508
COCH-ARM / FISHERS	P=0.246	(e)	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.179	(e)	P=0.076	P=0.169

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Clitoral Gland
 Cyst**

LESION RATES

OVERALL (a)	0/50 (0%)	2/49 (4%)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	0/45.02	2/44.34	4/44.08	0/46.62
POLY-3 PERCENT (g)	0%	4.5%	9.1%	0%
TERMINAL (d)	0/38 (0%)	2/36 (6%)	3/34 (9%)	0/37 (0%)
FIRST INCIDENCE	---	729 (T)	725	---

STATISTICAL TESTS

POLY 3	P=0.531N	P=0.234	P=0.057	(e)
POLY 1.5	P=0.533N	P=0.236	P=0.059	(e)
POLY 6	P=0.535N	P=0.230	P=0.056	(e)
COCH-ARM / FISHERS	P=0.553N	P=0.242	P=0.059	(e)
MAX-ISO-POLY-3	P=0.183N	P=0.075	P=0.019*	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Clitoral Gland
 Hyperplasia**

LESION RATES

OVERALL (a)	7/50 (14%)	3/49 (6%)	9/50 (18%)	7/50 (14%)
POLY-3 RATE (b)	7/45.18	3/44.73	9/45.02	7/47.00
POLY-3 PERCENT (g)	15.5%	6.7%	20%	14.9%
TERMINAL (d)	6/38 (16%)	2/36 (6%)	6/34 (18%)	6/37 (16%)
FIRST INCIDENCE	687	619	477	619

STATISTICAL TESTS

POLY 3	P=0.396	P=0.161N	P=0.389	P=0.583N
POLY 1.5	P=0.390	P=0.159N	P=0.391	P=0.586N
POLY 6	P=0.396	P=0.166N	P=0.383	P=0.588N
COCH-ARM / FISHERS	P=0.367	P=0.167N	P=0.393	P=0.613N
MAX-ISO-POLY-3	P=0.321	P=0.092N	P=0.290	P=0.468N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Clitoral Gland
 Inflammation Chronic**

LESION RATES

OVERALL (a)	5/50 (10%)	6/49 (12%)	6/50 (12%)	6/50 (12%)
POLY-3 RATE (b)	5/45.02	6/45.12	6/44.30	6/46.62
POLY-3 PERCENT (g)	11.1%	13.3%	13.6%	12.9%
TERMINAL (d)	5/38 (13%)	4/36 (11%)	5/34 (15%)	6/37 (16%)
FIRST INCIDENCE	729 (T)	619	667	729 (T)

STATISTICAL TESTS

POLY 3	P=0.483	P=0.502	P=0.489	P=0.524
POLY 1.5	P=0.481	P=0.501	P=0.493	P=0.522
POLY 6	P=0.476	P=0.499	P=0.482	P=0.518
COCH-ARM / FISHERS	P=0.460	P=0.486	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.599	P=0.375	P=0.364	P=0.398

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Eye
 Cataract**

LESION RATES

OVERALL (a)	0/48 (0%)	6/48 (13%)	3/49 (6%)	4/50 (8%)
POLY-3 RATE (b)	0/43.73	6/44.47	3/43.24	4/47.14
POLY-3 PERCENT (g)	0%	13.5%	6.9%	8.5%
TERMINAL (d)	0/38 (0%)	3/36 (8%)	2/34 (6%)	2/37 (5%)
FIRST INCIDENCE	---	618	687	619

STATISTICAL TESTS

POLY 3	P=0.239	P=0.016*	P=0.116	P=0.070
POLY 1.5	P=0.239	P=0.016*	P=0.119	P=0.070
POLY 6	P=0.233	P=0.015*	P=0.113	P=0.069
COCH-ARM / FISHERS	P=0.224	P=0.013*	P=0.125	P=0.064
MAX-ISO-POLY-3	P=0.063	P=0.005**	P=0.039*	P=0.026*

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Eye
 Edema

LESION RATES

OVERALL (a)	1/48 (2%)	4/48 (8%)	3/49 (6%)	4/50 (8%)
POLY-3 RATE (b)	1/43.89	4/44.08	3/43.24	4/47.39
POLY-3 PERCENT (g)	2.3%	9.1%	6.9%	8.4%
TERMINAL (d)	0/38 (0%)	2/36 (6%)	2/34 (6%)	2/37 (5%)
FIRST INCIDENCE	687	619	687	619

STATISTICAL TESTS

POLY 3	P=0.245	P=0.180	P=0.300	P=0.203
POLY 1.5	P=0.244	P=0.183	P=0.306	P=0.202
POLY 6	P=0.240	P=0.174	P=0.291	P=0.199
COCH-ARM / FISHERS	P=0.228	P=0.181	P=0.316	P=0.194
MAX-ISO-POLY-3	P=0.201	P=0.085	P=0.153	P=0.104

TDMS No. 20008 - 03
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Milk thistle extract
CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
Time Report Requested: 11:00:55
First Dose M/F: 03/04/03 / 03/04/03
Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Eye: Bilateral
Cataract

LESION RATES

OVERALL (a)	0/48 (0%)	0/48 (0%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.73	0/43.68	0/43.08	0/46.62
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---

.....
STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

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TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Eye: Retina
 Degeneration

LESION RATES

OVERALL (a)	1/48 (2%)	5/48 (10%)	3/49 (6%)	3/50 (6%)
POLY-3 RATE (b)	1/43.73	5/44.08	3/43.24	3/47.00
POLY-3 PERCENT (g)	2.3%	11.3%	6.9%	6.4%
TERMINAL (d)	1/38 (3%)	3/36 (8%)	2/34 (6%)	2/37 (5%)
FIRST INCIDENCE	729 (T)	619	687	619

STATISTICAL TESTS

POLY 3	P=0.463	P=0.103	P=0.301	P=0.332
POLY 1.5	P=0.463	P=0.105	P=0.306	P=0.331
POLY 6	P=0.455	P=0.099	P=0.293	P=0.327
COCH-ARM / FISHERS	P=0.444	P=0.102	P=0.316	P=0.324
MAX-ISO-POLY-3	P=0.219	P=0.046*	P=0.154	P=0.179

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Harderian Gland
 Hyperplasia Focal**

LESION RATES

OVERALL (a)	1/50 (2%)	2/49 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/45.02	2/44.34	0/44.06	1/46.62
POLY-3 PERCENT (g)	2.2%	4.5%	0%	2.2%
TERMINAL (d)	1/38 (3%)	2/36 (6%)	0/34 (0%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.494N	P=0.495	P=0.504N	P=0.753N
POLY 1.5	P=0.494N	P=0.497	P=0.502N	P=0.753N
POLY 6	P=0.496N	P=0.489	P=0.507N	P=0.755N
COCH-ARM / FISHERS	P=0.498N	P=0.492	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.381N	P=0.276	P=0.164N	P=0.489N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Harderian Gland
 Inflammation Chronic**

LESION RATES

OVERALL (a)	12/50 (24%)	7/49 (14%)	10/50 (20%)	12/50 (24%)
POLY-3 RATE (b)	12/45.28	7/44.34	10/45.05	12/47.82
POLY-3 PERCENT (g)	26.5%	15.8%	22.2%	25.1%
TERMINAL (d)	11/38 (29%)	7/36 (19%)	7/34 (21%)	9/37 (24%)
FIRST INCIDENCE	660	729 (T)	477	546

STATISTICAL TESTS

POLY 3	P=0.458	P=0.162N	P=0.409N	P=0.532N
POLY 1.5	P=0.441	P=0.157N	P=0.406N	P=0.545N
POLY 6	P=0.470	P=0.174N	P=0.416N	P=0.530N
COCH-ARM / FISHERS	P=0.402	P=0.166N	P=0.405N	P=0.592N
MAX-ISO-POLY-3	P=0.436N	P=0.107N	P=0.318N	P=0.438N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Heart
 Cardiomyopathy**

LESION RATES

OVERALL (a)	32/50 (64%)	33/50 (66%)	28/50 (56%)	34/50 (68%)
POLY-3 RATE (b)	32/46.40	33/47.51	28/46.05	34/48.63
POLY-3 PERCENT (g)	69%	69.5%	60.8%	69.9%
TERMINAL (d)	27/38 (71%)	26/36 (72%)	21/34 (62%)	26/37 (70%)
FIRST INCIDENCE	575	459	477	546

STATISTICAL TESTS

POLY 3	P=0.539	P=0.569	P=0.270N	P=0.549
POLY 1.5	P=0.514	P=0.569	P=0.265N	P=0.524
POLY 6	P=0.544N	P=0.543	P=0.285N	P=0.548
COCH-ARM / FISHERS	P=0.431	P=0.500	P=0.270N	P=0.417
MAX-ISO-POLY-3	P=0.552N	P=0.478	P=0.203N	P=0.459

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Heart
 Thrombosis**

LESION RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/45.02	1/45.14	2/44.85	1/46.72
POLY-3 PERCENT (g)	0%	2.2%	4.5%	2.1%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	---	672	567	703

STATISTICAL TESTS

POLY 3	P=0.386	P=0.501	P=0.236	P=0.507
POLY 1.5	P=0.383	P=0.502	P=0.237	P=0.507
POLY 6	P=0.384	P=0.497	P=0.236	P=0.506
COCH-ARM / FISHERS	P=0.366	P=0.500	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.236	P=0.159	P=0.076	P=0.168

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Heart: Valve
 Hyperplasia

LESION RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/45.35	1/44.93	0/44.06	0/46.62
POLY-3 PERCENT (g)	2.2%	2.2%	0%	0%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	637	729 (T)	---	---

STATISTICAL TESTS

POLY 3	P=0.237N	P=0.759	P=0.506N	P=0.495N
POLY 1.5	P=0.236N	P=0.759N	P=0.503N	P=0.494N
POLY 6	P=0.238N	P=0.753	P=0.510N	P=0.497N
COCH-ARM / FISHERS	P=0.236N	P=0.753N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.253N	P=0.496	P=0.166N	P=0.159N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Islets, Pancreatic
 Hyperplasia**

LESION RATES

OVERALL (a)	1/48 (2%)	0/48 (0%)	0/49 (0%)	0/49 (0%)
POLY-3 RATE (b)	1/43.73	0/43.68	0/43.08	0/45.86
POLY-3 PERCENT (g)	2.3%	0%	0%	0%
TERMINAL (d)	1/38 (3%)	0/36 (0%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	---	---	---

STATISTICAL TESTS

POLY 3	P=0.307N	P=0.500N	P=0.503N	P=0.490N
POLY 1.5	P=0.308N	P=0.498N	P=0.500N	P=0.490N
POLY 6	P=0.305N	P=0.505N	P=0.508N	P=0.493N
COCH-ARM / FISHERS	P=0.303N	P=0.500N	P=0.495N	P=0.495N
MAX-ISO-POLY-3	P=0.122N	P=0.159N	P=0.164N	P=0.157N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney
 Infarct**

LESION RATES

OVERALL (a)	0/48 (0%)	3/49 (6%)	2/49 (4%)	1/48 (2%)
POLY-3 RATE (b)	0/43.73	3/44.34	2/43.28	1/45.00
POLY-3 PERCENT (g)	0%	6.8%	4.6%	2.2%
TERMINAL (d)	0/38 (0%)	3/36 (8%)	1/34 (3%)	1/37 (3%)
FIRST INCIDENCE	---	729 (T)	676	729 (T)

STATISTICAL TESTS

POLY 3	P=0.571	P=0.121	P=0.235	P=0.506
POLY 1.5	P=0.571	P=0.124	P=0.238	P=0.506
POLY 6	P=0.563	P=0.116	P=0.230	P=0.503
COCH-ARM / FISHERS	P=0.554	P=0.125	P=0.253	P=0.500
MAX-ISO-POLY-3	P=0.194	P=0.039*	P=0.077	P=0.166

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney
 Inflammation**

LESION RATES

OVERALL (a)	0/48 (0%)	1/49 (2%)	0/49 (0%)	0/48 (0%)
POLY-3 RATE (b)	0/43.73	1/44.34	0/43.08	0/45.00
POLY-3 PERCENT (g)	0%	2.3%	0%	0%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	---	729 (T)	---	---

STATISTICAL TESTS

POLY 3	P=0.570N	P=0.503	(e)	(e)
POLY 1.5	P=0.567N	P=0.506	(e)	(e)
POLY 6	P=0.575N	P=0.498	(e)	(e)
COCH-ARM / FISHERS	P=0.568N	P=0.505	(e)	(e)
MAX-ISO-POLY-3	P=0.388N	P=0.161	(e)	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney
 Mineralization**

LESION RATES

OVERALL (a)	21/48 (44%)	28/49 (57%)	30/49 (61%)	26/48 (54%)
POLY-3 RATE (b)	21/44.31	28/46.15	30/44.58	26/45.90
POLY-3 PERCENT (g)	47.4%	60.7%	67.3%	56.6%
TERMINAL (d)	19/38 (50%)	23/36 (64%)	23/34 (68%)	21/37 (57%)
FIRST INCIDENCE	575	459	567	638

STATISTICAL TESTS

POLY 3	P=0.277	P=0.142	P=0.042*	P=0.250
POLY 1.5	P=0.273	P=0.149	P=0.048*	P=0.248
POLY 6	P=0.268	P=0.124	P=0.036*	P=0.239
COCH-ARM / FISHERS	P=0.231	P=0.132	P=0.064	P=0.207
MAX-ISO-POLY-3	P=0.126	P=0.102	P=0.026*	P=0.192

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney
 Nephropathy**

LESION RATES

OVERALL (a)	36/48 (75%)	45/49 (92%)	43/49 (88%)	42/48 (88%)
POLY-3 RATE (b)	36/44.13	45/47.56	43/46.27	42/47.27
POLY-3 PERCENT (g)	81.6%	94.6%	92.9%	88.9%
TERMINAL (d)	33/38 (87%)	35/36 (97%)	33/34 (97%)	33/37 (89%)
FIRST INCIDENCE	687	459	477	546

STATISTICAL TESTS

POLY 3	P=0.321	P=0.039*	P=0.080	P=0.237
POLY 1.5	P=0.254	P=0.036*	P=0.076	P=0.189
POLY 6	P=0.376	P=0.038*	P=0.082	P=0.274
COCH-ARM / FISHERS	P=0.136	P=0.024*	P=0.087	P=0.095
MAX-ISO-POLY-3	P=0.067	P=0.020*	P=0.043*	P=0.161

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney
 Vacuolization Cytoplasmic**

LESION RATES

OVERALL (a)	2/48 (4%)	0/49 (0%)	0/49 (0%)	0/48 (0%)
POLY-3 RATE (b)	2/44.28	0/44.34	0/43.08	0/45.00
POLY-3 PERCENT (g)	4.5%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	618	---	---	---

STATISTICAL TESTS

POLY 3	P=0.113N	P=0.237N	P=0.243N	P=0.234N
POLY 1.5	P=0.114N	P=0.233N	P=0.238N	P=0.232N
POLY 6	P=0.111N	P=0.245N	P=0.251N	P=0.238N
COCH-ARM / FISHERS	P=0.114N	P=0.242N	P=0.242N	P=0.247N
MAX-ISO-POLY-3	P=0.032N*	P=0.077N	P=0.083N	P=0.076N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney: Renal Tubule
 Accumulation, Hyaline Droplet**

LESION RATES

OVERALL (a)	1/48 (2%)	4/49 (8%)	6/49 (12%)	1/48 (2%)
POLY-3 RATE (b)	1/43.73	4/44.60	6/43.18	1/45.00
POLY-3 PERCENT (g)	2.3%	9%	13.9%	2.2%
TERMINAL (d)	1/38 (3%)	3/36 (8%)	5/34 (15%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	660	703	729 (T)

STATISTICAL TESTS

POLY 3	P=0.479N	P=0.184	P=0.053	P=0.754N
POLY 1.5	P=0.480N	P=0.188	P=0.056	P=0.754N
POLY 6	P=0.487N	P=0.178	P=0.050*	P=0.757N
COCH-ARM / FISHERS	P=0.502N	P=0.187	P=0.059	P=0.753N
MAX-ISO-POLY-3	P=0.200N	P=0.088	P=0.023*	P=0.491N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney: Renal Tubule
 Hyperplasia**

LESION RATES

OVERALL (a)	0/48 (0%)	0/49 (0%)	0/49 (0%)	1/48 (2%)
POLY-3 RATE (b)	0/43.73	0/44.34	0/43.08	1/45.00
POLY-3 PERCENT (g)	0%	0%	0%	2.2%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/34 (0%)	1/37 (3%)
FIRST INCIDENCE	---	---	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.202	(e)	(e)	P=0.506
POLY 1.5	P=0.201	(e)	(e)	P=0.506
POLY 6	P=0.201	(e)	(e)	P=0.503
COCH-ARM / FISHERS	P=0.197	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.132	(e)	(e)	P=0.166

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney: Renal Tubule
 Necrosis**

LESION RATES

OVERALL (a)	0/48 (0%)	0/49 (0%)	2/49 (4%)	1/48 (2%)
POLY-3 RATE (b)	0/43.73	0/44.34	2/44.27	1/45.30
POLY-3 PERCENT (g)	0%	0%	4.5%	2.2%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	507	647

STATISTICAL TESTS

POLY 3	P=0.259	(e)	P=0.240	P=0.507
POLY 1.5	P=0.256	(e)	P=0.241	P=0.506
POLY 6	P=0.259	(e)	P=0.237	P=0.506
COCH-ARM / FISHERS	P=0.244	(e)	P=0.253	P=0.500
MAX-ISO-POLY-3	P=0.179	(e)	P=0.077	P=0.168

TDMS No. 20008 - 03
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Milk thistle extract
CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
Time Report Requested: 11:00:55
First Dose M/F: 03/04/03 / 03/04/03
Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney: Renal Tubule
Pigmentation**

LESION RATES

OVERALL (a)	0/48 (0%)	0/49 (0%)	0/49 (0%)	0/48 (0%)
POLY-3 RATE (b)	0/43.73	0/44.34	0/43.08	0/45.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney: Transitional Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	3/48 (6%)	3/49 (6%)	4/49 (8%)	4/48 (8%)
POLY-3 RATE (b)	3/43.73	3/44.34	4/44.27	4/45.36
POLY-3 PERCENT (g)	6.9%	6.8%	9%	8.8%
TERMINAL (d)	3/38 (8%)	3/36 (8%)	2/34 (6%)	2/37 (5%)
FIRST INCIDENCE	729 (T)	729 (T)	507	638

STATISTICAL TESTS

POLY 3	P=0.411	P=0.656N	P=0.507	P=0.520
POLY 1.5	P=0.406	P=0.649N	P=0.509	P=0.518
POLY 6	P=0.411	P=0.657	P=0.500	P=0.516
COCH-ARM / FISHERS	P=0.386	P=0.651N	P=0.512	P=0.500
MAX-ISO-POLY-3	P=0.565	P=0.492N	P=0.353	P=0.368

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Angiectasis

LESION RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	1/49 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/45.41	2/44.93	1/43.08	0/46.62
POLY-3 PERCENT (g)	2.2%	4.5%	2.3%	0%
TERMINAL (d)	0/38 (0%)	2/36 (6%)	1/34 (3%)	0/37 (0%)
FIRST INCIDENCE	618	729 (T)	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.244N	P=0.496	P=0.749	P=0.495N
POLY 1.5	P=0.243N	P=0.501	P=0.752	P=0.495N
POLY 6	P=0.247N	P=0.487	P=0.744	P=0.498N
COCH-ARM / FISHERS	P=0.248N	P=0.500	P=0.747	P=0.500N
MAX-ISO-POLY-3	P=0.229N	P=0.278	P=0.485	P=0.159N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Basophilic Focus

LESION RATES

OVERALL (a)	44/50 (88%)	44/50 (88%)	44/49 (90%)	43/50 (86%)
POLY-3 RATE (b)	44/46.64	44/47.94	44/46.50	43/48.69
POLY-3 PERCENT (g)	94.3%	91.8%	94.6%	88.3%
TERMINAL (d)	38/38 (100%)	36/36 (100%)	34/34 (100%)	36/37 (97%)
FIRST INCIDENCE	575	477	451	546

STATISTICAL TESTS

POLY 3	P=0.174N	P=0.462N	P=0.676	P=0.228N
POLY 1.5	P=0.238N	P=0.476N	P=0.615	P=0.283N
POLY 6	P=0.134N	P=0.514N	P=0.720	P=0.208N
COCH-ARM / FISHERS	P=0.440N	P=0.620N	P=0.514	P=0.500N
MAX-ISO-POLY-3	P=0.181N	P=0.291N	P=0.471	P=0.131N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Clear Cell Focus

LESION RATES

OVERALL (a)	9/50 (18%)	10/50 (20%)	17/49 (35%)	21/50 (42%)
POLY-3 RATE (b)	9/45.02	10/45.18	17/43.08	21/46.62
POLY-3 PERCENT (g)	20%	22.1%	39.5%	45.1%
TERMINAL (d)	9/38 (24%)	9/36 (25%)	17/34 (50%)	21/37 (57%)
FIRST INCIDENCE	729 (T)	660	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.002**	P=0.504	P=0.035*	P=0.008**
POLY 1.5	P=0.002**	P=0.511	P=0.040*	P=0.008**
POLY 6	P<0.001**	P=0.487	P=0.030*	P=0.007**
COCH-ARM / FISHERS	P=0.002**	P=0.500	P=0.048*	P=0.008**
MAX-ISO-POLY-3	P=0.003**	P=0.400	P=0.022*	P=0.005**

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Degeneration Cystic

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.02	0/44.93	0/43.08	0/46.62
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Eosinophilic Focus

LESION RATES

OVERALL (a)	5/50 (10%)	13/50 (26%)	11/49 (22%)	11/50 (22%)
POLY-3 RATE (b)	5/45.02	13/46.00	11/43.15	11/46.65
POLY-3 PERCENT (g)	11.1%	28.3%	25.5%	23.6%
TERMINAL (d)	5/38 (13%)	9/36 (25%)	10/34 (29%)	10/37 (27%)
FIRST INCIDENCE	729 (T)	592	711	721

STATISTICAL TESTS

POLY 3	P=0.189	P=0.034*	P=0.068	P=0.096
POLY 1.5	P=0.188	P=0.035*	P=0.072	P=0.095
POLY 6	P=0.180	P=0.033*	P=0.063	P=0.091
COCH-ARM / FISHERS	P=0.168	P=0.033*	P=0.079	P=0.086
MAX-ISO-POLY-3	P=0.072	P=0.020*	P=0.040*	P=0.059

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Liver
 Hematopoietic Cell Proliferation**

LESION RATES

OVERALL (a)	0/50 (0%)	2/50 (4%)	1/49 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/45.02	2/45.70	1/43.18	0/46.62
POLY-3 PERCENT (g)	0%	4.4%	2.3%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	---	619	703	---

STATISTICAL TESTS

POLY 3	P=0.450N	P=0.241	P=0.492	(e)
POLY 1.5	P=0.450N	P=0.241	P=0.493	(e)
POLY 6	P=0.453N	P=0.238	P=0.489	(e)
COCH-ARM / FISHERS	P=0.462N	P=0.247	P=0.495	(e)
MAX-ISO-POLY-3	P=0.330N	P=0.079	P=0.157	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Hepatodiaphragmatic Nodule

LESION RATES

OVERALL (a)	6/50 (12%)	5/50 (10%)	4/49 (8%)	5/50 (10%)
POLY-3 RATE (b)	6/45.81	5/46.11	4/43.08	5/46.86
POLY-3 PERCENT (g)	13.1%	10.8%	9.3%	10.7%
TERMINAL (d)	5/38 (13%)	2/36 (6%)	4/34 (12%)	3/37 (8%)
FIRST INCIDENCE	434	459	729 (T)	674

STATISTICAL TESTS

POLY 3	P=0.430N	P=0.495N	P=0.409N	P=0.484N
POLY 1.5	P=0.430N	P=0.491N	P=0.399N	P=0.484N
POLY 6	P=0.433N	P=0.505N	P=0.421N	P=0.490N
COCH-ARM / FISHERS	P=0.438N	P=0.500N	P=0.383N	P=0.500N
MAX-ISO-POLY-3	P=0.508N	P=0.370N	P=0.291N	P=0.360N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Infarct

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.02	0/44.93	0/43.08	0/46.62
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Infiltration Cellular Mixed Cell

LESION RATES

OVERALL (a)	37/50 (74%)	34/50 (68%)	36/49 (73%)	39/50 (78%)
POLY-3 RATE (b)	37/47.81	34/46.83	36/45.34	39/48.74
POLY-3 PERCENT (g)	77.4%	72.6%	79.4%	80%
TERMINAL (d)	31/38 (82%)	28/36 (78%)	28/34 (82%)	31/37 (84%)
FIRST INCIDENCE	200	592	451	546

STATISTICAL TESTS

POLY 3	P=0.324	P=0.378N	P=0.506	P=0.472
POLY 1.5	P=0.301	P=0.356N	P=0.528	P=0.450
POLY 6	P=0.345	P=0.411N	P=0.482	P=0.488
COCH-ARM / FISHERS	P=0.269	P=0.330N	P=0.567N	P=0.408
MAX-ISO-POLY-3	P=0.436	P=0.292N	P=0.403	P=0.372

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Mixed Cell Focus

LESION RATES

OVERALL (a)	3/50 (6%)	6/50 (12%)	11/49 (22%)	10/50 (20%)
POLY-3 RATE (b)	3/45.09	6/44.93	11/43.31	10/46.85
POLY-3 PERCENT (g)	6.7%	13.4%	25.4%	21.4%
TERMINAL (d)	2/38 (5%)	6/36 (17%)	9/34 (27%)	9/37 (24%)
FIRST INCIDENCE	710	729 (T)	687	667

STATISTICAL TESTS

POLY 3	P=0.031*	P=0.240	P=0.015*	P=0.040*
POLY 1.5	P=0.030*	P=0.246	P=0.016*	P=0.040*
POLY 6	P=0.030*	P=0.228	P=0.014*	P=0.039*
COCH-ARM / FISHERS	P=0.026*	P=0.243	P=0.018*	P=0.036*
MAX-ISO-POLY-3	P=0.024*	P=0.145	P=0.007**	P=0.022*

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Necrosis Focal

LESION RATES

OVERALL (a)	3/50 (6%)	2/50 (4%)	0/49 (0%)	1/50 (2%)
POLY-3 RATE (b)	3/45.02	2/45.31	0/43.08	1/46.83
POLY-3 PERCENT (g)	6.7%	4.4%	0%	2.1%
TERMINAL (d)	3/38 (8%)	1/36 (3%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	619	---	674

STATISTICAL TESTS

POLY 3	P=0.162N	P=0.497N	P=0.127N	P=0.291N
POLY 1.5	P=0.163N	P=0.494N	P=0.125N	P=0.293N
POLY 6	P=0.162N	P=0.504N	P=0.129N	P=0.293N
COCH-ARM / FISHERS	P=0.164N	P=0.500N	P=0.125N	P=0.309N
MAX-ISO-POLY-3	P=0.112N	P=0.321N	P=0.044N*	P=0.149N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Liver: Bile Duct
 Hyperplasia**

LESION RATES

OVERALL (a)	37/50 (74%)	10/50 (20%)	10/49 (20%)	8/50 (16%)
POLY-3 RATE (b)	37/46.51	10/45.71	10/43.81	8/46.75
POLY-3 PERCENT (g)	79.6%	21.9%	22.8%	17.1%
TERMINAL (d)	31/38 (82%)	8/36 (22%)	8/34 (24%)	6/37 (16%)
FIRST INCIDENCE	575	459	567	703

STATISTICAL TESTS

POLY 3	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P<0.001N**	P<0.001N**	P<0.001N**

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver: Hepatocyte
 Vacuolization Cytoplasmic

LESION RATES

OVERALL (a)	8/50 (16%)	9/50 (18%)	8/49 (16%)	6/50 (12%)
POLY-3 RATE (b)	8/47.13	9/47.42	8/44.05	6/47.41
POLY-3 PERCENT (g)	17%	19%	18.2%	12.7%
TERMINAL (d)	1/38 (3%)	2/36 (6%)	2/34 (6%)	1/37 (3%)
FIRST INCIDENCE	434	477	660	638

STATISTICAL TESTS

POLY 3	P=0.290N	P=0.505	P=0.550	P=0.382N
POLY 1.5	P=0.284N	P=0.511	P=0.566	P=0.376N
POLY 6	P=0.305N	P=0.492	P=0.532	P=0.398N
COCH-ARM / FISHERS	P=0.289N	P=0.500	P=0.590	P=0.387N
MAX-ISO-POLY-3	P=0.391N	P=0.399	P=0.441	P=0.279N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver: Hepatocyte
 Vacuolization Cytoplasmic Focal

LESION RATES

OVERALL (a)	0/50 (0%)	2/50 (4%)	1/49 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/45.02	2/44.94	1/43.18	1/46.62
POLY-3 PERCENT (g)	0%	4.5%	2.3%	2.2%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	0/34 (0%)	1/37 (3%)
FIRST INCIDENCE	---	725	703	729 (T)

STATISTICAL TESTS

POLY 3	P=0.515	P=0.237	P=0.492	P=0.507
POLY 1.5	P=0.514	P=0.239	P=0.493	P=0.506
POLY 6	P=0.511	P=0.232	P=0.489	P=0.505
COCH-ARM / FISHERS	P=0.499	P=0.247	P=0.495	P=0.500
MAX-ISO-POLY-3	P=0.276	P=0.076	P=0.157	P=0.167

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung
 Congestion**

LESION RATES

OVERALL (a)	0/50 (0%)	2/50 (4%)	1/49 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/45.02	2/45.65	1/44.08	0/46.62
POLY-3 PERCENT (g)	0%	4.4%	2.3%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	---	618	80	---

STATISTICAL TESTS

POLY 3	P=0.449N	P=0.240	P=0.496	(e)
POLY 1.5	P=0.450N	P=0.241	P=0.497	(e)
POLY 6	P=0.453N	P=0.238	P=0.493	(e)
COCH-ARM / FISHERS	P=0.462N	P=0.247	P=0.495	(e)
MAX-ISO-POLY-3	P=0.332N	P=0.079	P=0.157	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung
 Hemorrhage**

LESION RATES

OVERALL (a)	3/50 (6%)	4/50 (8%)	2/49 (4%)	6/50 (12%)
POLY-3 RATE (b)	3/45.79	4/45.37	2/43.08	6/46.83
POLY-3 PERCENT (g)	6.6%	8.8%	4.6%	12.8%
TERMINAL (d)	1/38 (3%)	3/36 (8%)	2/34 (6%)	5/37 (14%)
FIRST INCIDENCE	575	599	729 (T)	674

STATISTICAL TESTS

POLY 3	P=0.201	P=0.495	P=0.528N	P=0.253
POLY 1.5	P=0.201	P=0.503	P=0.520N	P=0.255
POLY 6	P=0.196	P=0.481	P=0.539N	P=0.245
COCH-ARM / FISHERS	P=0.194	P=0.500	P=0.510N	P=0.243
MAX-ISO-POLY-3	P=0.222	P=0.343	P=0.352N	P=0.158

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung
 Infiltration Cellular Histiocyte**

LESION RATES

OVERALL (a)	45/50 (90%)	44/50 (88%)	45/49 (92%)	45/50 (90%)
POLY-3 RATE (b)	45/47.88	44/48.28	45/47.77	45/49.00
POLY-3 PERCENT (g)	94%	91.1%	94.2%	91.8%
TERMINAL (d)	37/38 (97%)	34/36 (94%)	32/34 (94%)	36/37 (97%)
FIRST INCIDENCE	302	477	451	546

STATISTICAL TESTS

POLY 3	P=0.479N	P=0.438N	P=0.657	P=0.494N
POLY 1.5	P=0.507N	P=0.423N	P=0.590	P=0.506N
POLY 6	P=0.498N	P=0.499N	P=0.663N	P=0.542N
COCH-ARM / FISHERS	P=0.502	P=0.500N	P=0.513	P=0.630N
MAX-ISO-POLY-3	P=0.529N	P=0.283N	P=0.479	P=0.331N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung
 Inflammation Chronic**

LESION RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	2/49 (4%)	10/50 (20%)
POLY-3 RATE (b)	1/45.02	0/44.93	2/43.08	10/46.65
POLY-3 PERCENT (g)	2.2%	0%	4.6%	21.4%
TERMINAL (d)	1/38 (3%)	0/36 (0%)	2/34 (6%)	9/37 (24%)
FIRST INCIDENCE	729 (T)	---	729 (T)	721

STATISTICAL TESTS

POLY 3	P<0.001**	P=0.500N	P=0.485	P=0.005**
POLY 1.5	P<0.001**	P=0.498N	P=0.488	P=0.005**
POLY 6	P<0.001**	P=0.505N	P=0.479	P=0.004**
COCH-ARM / FISHERS	P<0.001**	P=0.500N	P=0.492	P=0.004**
MAX-ISO-POLY-3	P<0.001**	P=0.159N	P=0.271	P=0.002**

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung
 Metaplasia Osseous**

LESION RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	0/49 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/45.09	1/44.93	0/43.08	1/46.62
POLY-3 PERCENT (g)	2.2%	2.2%	0%	2.2%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	0/34 (0%)	1/37 (3%)
FIRST INCIDENCE	710	729 (T)	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.614N	P=0.760	P=0.509N	P=0.753N
POLY 1.5	P=0.615N	P=0.759N	P=0.507N	P=0.754N
POLY 6	P=0.615N	P=0.755	P=0.512N	P=0.756N
COCH-ARM / FISHERS	P=0.616N	P=0.753N	P=0.505N	P=0.753N
MAX-ISO-POLY-3	P=0.541N	P=0.498	P=0.169N	P=0.490N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung: Alveolar Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	25/50 (50%)	25/50 (50%)	29/49 (59%)	25/50 (50%)
POLY-3 RATE (b)	25/45.18	25/47.30	29/45.16	25/48.54
POLY-3 PERCENT (g)	55.3%	52.9%	64.2%	51.5%
TERMINAL (d)	24/38 (63%)	20/36 (56%)	23/34 (68%)	19/37 (51%)
FIRST INCIDENCE	687	477	451	546

STATISTICAL TESTS

POLY 3	P=0.441N	P=0.488N	P=0.255	P=0.434N
POLY 1.5	P=0.483N	P=0.507N	P=0.248	P=0.474N
POLY 6	P=0.406N	P=0.478N	P=0.257	P=0.403N
COCH-ARM / FISHERS	P=0.495	P=0.579N	P=0.237	P=0.579N
MAX-ISO-POLY-3	P=0.461N	P=0.404N	P=0.191	P=0.358N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Lymph Node, Mesenteric Hemorrhage

LESION RATES

OVERALL (a)	3/49 (6%)	4/48 (8%)	3/50 (6%)	5/50 (10%)
POLY-3 RATE (b)	3/44.39	4/44.54	3/44.30	5/46.62
POLY-3 PERCENT (g)	6.8%	9%	6.8%	10.7%
TERMINAL (d)	3/38 (8%)	3/36 (8%)	2/34 (6%)	5/37 (14%)
FIRST INCIDENCE	729 (T)	599	667	729 (T)

STATISTICAL TESTS

POLY 3	P=0.336	P=0.502	P=0.661	P=0.384
POLY 1.5	P=0.337	P=0.502	P=0.659N	P=0.384
POLY 6	P=0.329	P=0.496	P=0.655	P=0.376
COCH-ARM / FISHERS	P=0.325	P=0.488	P=0.651N	P=0.369
MAX-ISO-POLY-3	P=0.406	P=0.349	P=0.498	P=0.258

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lymph Node, Mesenteric
 Hyperplasia Lymphoid**

LESION RATES

OVERALL (a)	1/49 (2%)	9/48 (19%)	5/50 (10%)	2/50 (4%)
POLY-3 RATE (b)	1/44.39	9/45.34	5/44.78	2/46.85
POLY-3 PERCENT (g)	2.3%	19.9%	11.2%	4.3%
TERMINAL (d)	1/38 (3%)	6/36 (17%)	4/34 (12%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	592	477	667

STATISTICAL TESTS

POLY 3	P=0.333N	P=0.009**	P=0.103	P=0.519
POLY 1.5	P=0.335N	P=0.008**	P=0.105	P=0.518
POLY 6	P=0.341N	P=0.009**	P=0.100	P=0.516
COCH-ARM / FISHERS	P=0.364N	P=0.007**	P=0.107	P=0.508
MAX-ISO-POLY-3	P=0.096	P=0.003**	P=0.045*	P=0.300

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lymph Node, Mesenteric
 Pigmentation**

LESION RATES

OVERALL (a)	47/49 (96%)	39/48 (81%)	29/50 (58%)	18/50 (36%)
POLY-3 RATE (b)	47/48.98	39/46.50	29/46.56	18/47.00
POLY-3 PERCENT (g)	96%	83.9%	62.3%	38.3%
TERMINAL (d)	37/38 (97%)	31/36 (86%)	22/34 (65%)	17/37 (46%)
FIRST INCIDENCE	200	477	451	619

STATISTICAL TESTS

POLY 3	P<0.001N**	P=0.042N*	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.031N*	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P=0.067N	P<0.001N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.023N*	P<0.001N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.020N*	P<0.001N**	P<0.001N**

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Lymph Node: Mediastinal Hemorrhage

LESION RATES

OVERALL (a)	2/9 (22%)	2/8 (25%)	2/5 (40%)	1/8 (13%)
POLY-3 RATE (b)	2/8.65	2/7.12	2/3.83	1/6.42
POLY-3 PERCENT (g)	23.1%	28.1%	52.2%	15.6%
TERMINAL (d)	1/6 (17%)	1/4 (25%)	0/0 (0%)	1/2 (50%)
FIRST INCIDENCE	618	477	80	729 (T)

STATISTICAL TESTS

POLY 3	P=0.520N	P=0.632	P=0.369	P=0.607N
POLY 1.5	P=0.475N	P=0.644	P=0.410	P=0.576N
POLY 6	P=0.599N	P=0.613	P=0.316	P=0.659N
COCH-ARM / FISHERS	P=0.427N	P=0.665	P=0.455	P=0.547N
MAX-ISO-POLY-3	P=0.457N	P=0.419	P=0.218	P=0.378N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lymph Node: Mediastinal
 Hyperplasia Lymphoid**

LESION RATES

OVERALL (a)	3/9 (33%)	3/8 (38%)	0/5 (0%)	0/8 (0%)
POLY-3 RATE (b)	3/8.26	3/7.51	0/2.60	0/6.42
POLY-3 PERCENT (g)	36.3%	40%	0%	0%
TERMINAL (d)	3/6 (50%)	1/4 (25%)	0/0 (0%)	0/2 (0%)
FIRST INCIDENCE	729 (T)	477	---	---

STATISTICAL TESTS

POLY 3	P=0.056N	P=0.638	P=0.384N	P=0.135N
POLY 1.5	P=0.046N*	P=0.630	P=0.334N	P=0.123N
POLY 6	P=0.081N	P=0.653	P=0.458N	P=0.161N
COCH-ARM / FISHERS	P=0.039N*	P=0.627	P=0.231N	P=0.124N
MAX-ISO-POLY-3	P=0.083N	P=0.443	P=0.228N	P=0.051N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lymph Node: Mediastinal
 Pigmentation**

LESION RATES

OVERALL (a)	4/9 (44%)	0/8 (0%)	0/5 (0%)	1/8 (13%)
POLY-3 RATE (b)	4/8.65	0/6.40	0/2.60	1/6.42
POLY-3 PERCENT (g)	46.2%	0%	0%	15.6%
TERMINAL (d)	3/6 (50%)	0/4 (0%)	0/0 (0%)	1/2 (50%)
FIRST INCIDENCE	618	---	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.152N	P=0.064N	P=0.296N	P=0.244N
POLY 1.5	P=0.141N	P=0.053N	P=0.235N	P=0.211N
POLY 6	P=0.183N	P=0.080N	P=0.390N	P=0.309N
COCH-ARM / FISHERS	P=0.147N	P=0.053N	P=0.126N	P=0.183N
MAX-ISO-POLY-3	P=0.046N*	P=0.026N*	P=0.187N	P=0.131N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Mammary Gland
 Hyperplasia**

LESION RATES

OVERALL (a)	20/50 (40%)	17/50 (34%)	24/50 (48%)	23/50 (46%)
POLY-3 RATE (b)	20/46.53	17/46.54	24/45.75	23/48.94
POLY-3 PERCENT (g)	43%	36.5%	52.5%	47%
TERMINAL (d)	15/38 (40%)	12/36 (33%)	17/34 (50%)	14/37 (38%)
FIRST INCIDENCE	575	599	567	613

STATISTICAL TESTS

POLY 3	P=0.257	P=0.336N	P=0.240	P=0.425
POLY 1.5	P=0.238	P=0.323N	P=0.252	P=0.408
POLY 6	P=0.275	P=0.362N	P=0.227	P=0.434
COCH-ARM / FISHERS	P=0.192	P=0.339N	P=0.273	P=0.343
MAX-ISO-POLY-3	P=0.272	P=0.262N	P=0.182	P=0.350

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Mammary Gland
 Hyperplasia Focal**

LESION RATES

OVERALL (a)	20/50 (40%)	26/50 (52%)	11/50 (22%)	20/50 (40%)
POLY-3 RATE (b)	20/45.88	26/46.22	11/44.64	20/47.73
POLY-3 PERCENT (g)	43.6%	56.3%	24.6%	41.9%
TERMINAL (d)	18/38 (47%)	22/36 (61%)	7/34 (21%)	16/37 (43%)
FIRST INCIDENCE	434	618	647	619

STATISTICAL TESTS

POLY 3	P=0.233N	P=0.153	P=0.044N*	P=0.518N
POLY 1.5	P=0.245N	P=0.163	P=0.042N*	P=0.529N
POLY 6	P=0.226N	P=0.141	P=0.045N*	P=0.513N
COCH-ARM / FISHERS	P=0.286N	P=0.158	P=0.041N*	P=0.581N
MAX-ISO-POLY-3	P=0.080N	P=0.109	P=0.028N*	P=0.434N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Mammary Gland: Duct
 Ectasia**

LESION RATES

OVERALL (a)	44/50 (88%)	37/50 (74%)	36/50 (72%)	40/50 (80%)
POLY-3 RATE (b)	44/47.93	37/47.91	36/46.69	40/49.42
POLY-3 PERCENT (g)	91.8%	77.2%	77.1%	80.9%
TERMINAL (d)	35/38 (92%)	28/36 (78%)	26/34 (77%)	28/37 (76%)
FIRST INCIDENCE	434	592	477	613

STATISTICAL TESTS

POLY 3	P=0.178N	P=0.039N*	P=0.039N*	P=0.099N
POLY 1.5	P=0.200N	P=0.036N*	P=0.034N*	P=0.111N
POLY 6	P=0.164N	P=0.049N*	P=0.049N*	P=0.097N
COCH-ARM / FISHERS	P=0.290N	P=0.062N	P=0.039N*	P=0.207N
MAX-ISO-POLY-3	P=0.064N	P=0.020N*	P=0.021N*	P=0.059N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Mesentery
 Accessory Spleen

LESION RATES

OVERALL (a)	1/10 (10%)	1/10 (10%)	0/4 (0%)	2/8 (25%)
POLY-3 RATE (b)	1/8.72	1/9.60	0/4.00	2/7.46
POLY-3 PERCENT (g)	11.5%	10.4%	0%	26.8%
TERMINAL (d)	1/7 (14%)	0/7 (0%)	0/4 (0%)	1/5 (20%)
FIRST INCIDENCE	729 (T)	722	---	674

STATISTICAL TESTS

POLY 3	P=0.289	P=0.740N	P=0.657N	P=0.442
POLY 1.5	P=0.287	P=0.748N	P=0.665N	P=0.435
POLY 6	P=0.288	P=0.732N	P=0.646N	P=0.445
COCH-ARM / FISHERS	P=0.272	P=0.763N	P=0.714N	P=0.412
MAX-ISO-POLY-3	P=0.264	P=0.473N	P=0.275N	P=0.227

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Mesentery: Fat
 Necrosis**

LESION RATES

OVERALL (a)	8/10 (80%)	8/10 (80%)	4/4 (100%)	6/8 (75%)
POLY-3 RATE (b)	8/9.84	8/9.58	4/4.00	6/7.79
POLY-3 PERCENT (g)	81.3%	83.5%	100%	77%
TERMINAL (d)	6/7 (86%)	7/7 (100%)	4/4 (100%)	4/5 (80%)
FIRST INCIDENCE	434	725	729 (T)	647

STATISTICAL TESTS

POLY 3	P=0.549N	P=0.681	P=0.479	P=0.641N
POLY 1.5	P=0.545N	P=0.691	P=0.466	P=0.630N
POLY 6	P=0.558N	P=0.668	P=0.503	P=0.661N
COCH-ARM / FISHERS	P=0.544N	P=0.709N	P=0.495	P=0.618N
MAX-ISO-POLY-3	P=0.523N	P=0.450	P=0.219	P=0.417N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Nose
 Foreign Body

LESION RATES

OVERALL (a)	0/50 (0%)	3/50 (6%)	1/49 (2%)	4/50 (8%)
POLY-3 RATE (b)	0/45.02	3/45.68	1/43.08	4/46.95
POLY-3 PERCENT (g)	0%	6.6%	2.3%	8.5%
TERMINAL (d)	0/38 (0%)	2/36 (6%)	1/34 (3%)	3/37 (8%)
FIRST INCIDENCE	---	459	729 (T)	638

STATISTICAL TESTS

POLY 3	P=0.077	P=0.121	P=0.491	P=0.066
POLY 1.5	P=0.076	P=0.122	P=0.493	P=0.065
POLY 6	P=0.076	P=0.118	P=0.488	P=0.065
COCH-ARM / FISHERS	P=0.072	P=0.121	P=0.495	P=0.059
MAX-ISO-POLY-3	P=0.038*	P=0.040*	P=0.157	P=0.024*

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Nose
 Inflammation Chronic**

LESION RATES

OVERALL (a)	7/50 (14%)	9/50 (18%)	7/49 (14%)	8/50 (16%)
POLY-3 RATE (b)	7/45.91	9/45.68	7/43.18	8/46.95
POLY-3 PERCENT (g)	15.3%	19.7%	16.2%	17%
TERMINAL (d)	3/38 (8%)	8/36 (22%)	6/34 (18%)	7/37 (19%)
FIRST INCIDENCE	618	459	703	638

STATISTICAL TESTS

POLY 3	P=0.530	P=0.388	P=0.566	P=0.519
POLY 1.5	P=0.531	P=0.400	P=0.580	P=0.521
POLY 6	P=0.518	P=0.361	P=0.544	P=0.503
COCH-ARM / FISHERS	P=0.511	P=0.393	P=0.597	P=0.500
MAX-ISO-POLY-3	P=0.594	P=0.289	P=0.450	P=0.407

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Nose
 Thrombosis**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.02	0/44.93	0/43.08	0/46.62
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Nose: Goblet Cell
 Hyperplasia**

LESION RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	1/49 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/45.02	1/45.14	1/43.18	0/46.62
POLY-3 PERCENT (g)	2.2%	2.2%	2.3%	0%
TERMINAL (d)	1/38 (3%)	0/36 (0%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	672	703	---

STATISTICAL TESTS

POLY 3	P=0.307N	P=0.760N	P=0.751	P=0.493N
POLY 1.5	P=0.308N	P=0.758N	P=0.753	P=0.494N
POLY 6	P=0.308N	P=0.758	P=0.749	P=0.495N
COCH-ARM / FISHERS	P=0.312N	P=0.753N	P=0.747	P=0.500N
MAX-ISO-POLY-3	P=0.331N	P=0.498N	P=0.488	P=0.158N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Nose: Respiratory Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	2/50 (4%)	5/50 (10%)	1/49 (2%)	2/50 (4%)
POLY-3 RATE (b)	2/45.02	5/45.68	1/43.08	2/46.62
POLY-3 PERCENT (g)	4.4%	11%	2.3%	4.3%
TERMINAL (d)	2/38 (5%)	4/36 (11%)	1/34 (3%)	2/37 (5%)
FIRST INCIDENCE	729 (T)	459	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.360N	P=0.222	P=0.515N	P=0.681N
POLY 1.5	P=0.361N	P=0.224	P=0.512N	P=0.682N
POLY 6	P=0.364N	P=0.215	P=0.521N	P=0.685N
COCH-ARM / FISHERS	P=0.372N	P=0.218	P=0.508N	P=0.691N
MAX-ISO-POLY-3	P=0.295N	P=0.125	P=0.296N	P=0.485N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Ovary
 Cyst

LESION RATES

OVERALL (a)	9/50 (18%)	8/49 (16%)	19/50 (38%)	10/50 (20%)
POLY-3 RATE (b)	9/45.02	8/45.83	19/46.00	10/46.98
POLY-3 PERCENT (g)	20%	17.5%	41.3%	21.3%
TERMINAL (d)	9/38 (24%)	4/36 (11%)	14/34 (41%)	7/37 (19%)
FIRST INCIDENCE	729 (T)	599	484	647

STATISTICAL TESTS

POLY 3	P=0.349	P=0.484N	P=0.022*	P=0.541
POLY 1.5	P=0.344	P=0.491N	P=0.021*	P=0.535
POLY 6	P=0.342	P=0.478N	P=0.022*	P=0.539
COCH-ARM / FISHERS	P=0.312	P=0.518N	P=0.022*	P=0.500
MAX-ISO-POLY-3	P=0.134	P=0.379N	P=0.013*	P=0.439

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Ovary: Granulosa Cell
 Hyperplasia**

LESION RATES

OVERALL (a)	1/50 (2%)	2/49 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/45.02	2/44.34	0/44.06	0/46.62
POLY-3 PERCENT (g)	2.2%	4.5%	0%	0%
TERMINAL (d)	1/38 (3%)	2/36 (6%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---	---

STATISTICAL TESTS

POLY 3	P=0.184N	P=0.495	P=0.504N	P=0.493N
POLY 1.5	P=0.184N	P=0.497	P=0.502N	P=0.494N
POLY 6	P=0.186N	P=0.489	P=0.507N	P=0.495N
COCH-ARM / FISHERS	P=0.187N	P=0.492	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.170N	P=0.276	P=0.164N	P=0.158N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pancreas
 Atrophy**

LESION RATES

OVERALL (a)	23/48 (48%)	19/48 (40%)	25/49 (51%)	26/49 (53%)
POLY-3 RATE (b)	23/46.44	19/45.90	25/45.88	26/47.43
POLY-3 PERCENT (g)	49.5%	41.4%	54.5%	54.8%
TERMINAL (d)	16/38 (42%)	13/36 (36%)	18/34 (53%)	20/37 (54%)
FIRST INCIDENCE	302	459	477	546

STATISTICAL TESTS

POLY 3	P=0.214	P=0.282N	P=0.394	P=0.380
POLY 1.5	P=0.222	P=0.266N	P=0.417	P=0.394
POLY 6	P=0.198	P=0.314N	P=0.361	P=0.350
COCH-ARM / FISHERS	P=0.217	P=0.269N	P=0.459	P=0.381
MAX-ISO-POLY-3	P=0.293	P=0.218N	P=0.319	P=0.305

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pancreas: Acinus
 Hyperplasia Focal**

LESION RATES

OVERALL (a)	2/48 (4%)	1/48 (2%)	2/49 (4%)	1/49 (2%)
POLY-3 RATE (b)	2/43.73	1/43.68	2/43.08	1/45.86
POLY-3 PERCENT (g)	4.6%	2.3%	4.6%	2.2%
TERMINAL (d)	2/38 (5%)	1/36 (3%)	2/34 (6%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.428N	P=0.500N	P=0.689	P=0.483N
POLY 1.5	P=0.429N	P=0.497N	P=0.693N	P=0.483N
POLY 6	P=0.430N	P=0.508N	P=0.680	P=0.489N
COCH-ARM / FISHERS	P=0.436N	P=0.500N	P=0.684N	P=0.492N
MAX-ISO-POLY-3	P=0.434N	P=0.281N	P=0.493	P=0.270N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pancreas: Duct
 Ectasia**

LESION RATES

OVERALL (a)	14/48 (29%)	14/48 (29%)	16/49 (33%)	17/49 (35%)
POLY-3 RATE (b)	14/44.28	14/44.28	16/44.65	17/46.77
POLY-3 PERCENT (g)	31.6%	31.6%	35.8%	36.4%
TERMINAL (d)	12/38 (32%)	12/36 (33%)	12/34 (35%)	14/37 (38%)
FIRST INCIDENCE	618	619	484	546

STATISTICAL TESTS

POLY 3	P=0.325	P=0.590N	P=0.422	P=0.400
POLY 1.5	P=0.320	P=0.577N	P=0.432	P=0.398
POLY 6	P=0.314	P=0.565	P=0.403	P=0.383
COCH-ARM / FISHERS	P=0.284	P=0.589N	P=0.440	P=0.357
MAX-ISO-POLY-3	P=0.509	P=0.499N	P=0.337	P=0.321

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pituitary Gland: Pars Distalis
 Angiectasis**

LESION RATES

OVERALL (a)	10/50 (20%)	6/50 (12%)	5/50 (10%)	7/50 (14%)
POLY-3 RATE (b)	10/45.98	6/45.31	5/44.06	7/47.16
POLY-3 PERCENT (g)	21.8%	13.2%	11.4%	14.8%
TERMINAL (d)	6/38 (16%)	5/36 (14%)	5/34 (15%)	4/37 (11%)
FIRST INCIDENCE	623	619	729 (T)	647

STATISTICAL TESTS

POLY 3	P=0.274N	P=0.214N	P=0.148N	P=0.277N
POLY 1.5	P=0.277N	P=0.204N	P=0.140N	P=0.276N
POLY 6	P=0.276N	P=0.234N	P=0.163N	P=0.288N
COCH-ARM / FISHERS	P=0.291N	P=0.207N	P=0.131N	P=0.298N
MAX-ISO-POLY-3	P=0.201N	P=0.144N	P=0.097N	P=0.198N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pituitary Gland: Pars Distalis
 Cyst**

LESION RATES

OVERALL (a)	12/50 (24%)	19/50 (38%)	20/50 (40%)	14/50 (28%)
POLY-3 RATE (b)	12/45.44	19/46.97	20/47.08	14/47.33
POLY-3 PERCENT (g)	26.4%	40.5%	42.5%	29.6%
TERMINAL (d)	10/38 (26%)	12/36 (33%)	11/34 (32%)	11/37 (30%)
FIRST INCIDENCE	660	477	484	546

STATISTICAL TESTS

POLY 3	P=0.533N	P=0.111	P=0.078	P=0.457
POLY 1.5	P=0.541N	P=0.111	P=0.072	P=0.451
POLY 6	P=0.542	P=0.108	P=0.085	P=0.447
COCH-ARM / FISHERS	P=0.490	P=0.097	P=0.066	P=0.410
MAX-ISO-POLY-3	P=0.217	P=0.078	P=0.053	P=0.369

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pituitary Gland: Pars Distalis
 Hyperplasia**

LESION RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/45.02	2/45.31	1/44.06	2/46.62
POLY-3 PERCENT (g)	2.2%	4.4%	2.3%	4.3%
TERMINAL (d)	1/38 (3%)	1/36 (3%)	1/34 (3%)	2/37 (5%)
FIRST INCIDENCE	729 (T)	619	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.458	P=0.502	P=0.756	P=0.512
POLY 1.5	P=0.456	P=0.505	P=0.758	P=0.511
POLY 6	P=0.455	P=0.497	P=0.753	P=0.509
COCH-ARM / FISHERS	P=0.444	P=0.500	P=0.753N	P=0.500
MAX-ISO-POLY-3	P=0.471	P=0.283	P=0.493	P=0.294

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pituitary Gland: Pars Distalis
 Hyperplasia Focal**

LESION RATES

OVERALL (a)	12/50 (24%)	9/50 (18%)	5/50 (10%)	8/50 (16%)
POLY-3 RATE (b)	12/45.18	9/44.94	5/44.26	8/47.44
POLY-3 PERCENT (g)	26.6%	20%	11.3%	16.9%
TERMINAL (d)	11/38 (29%)	8/36 (22%)	4/34 (12%)	5/37 (14%)
FIRST INCIDENCE	687	725	676	546

STATISTICAL TESTS

POLY 3	P=0.144N	P=0.314N	P=0.056N	P=0.189N
POLY 1.5	P=0.151N	P=0.304N	P=0.055N	P=0.196N
POLY 6	P=0.139N	P=0.336N	P=0.059N	P=0.188N
COCH-ARM / FISHERS	P=0.170N	P=0.312N	P=0.054N	P=0.227N
MAX-ISO-POLY-3	P=0.102N	P=0.233N	P=0.033N*	P=0.134N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pituitary Gland: Pars Distalis
 Hypertrophy**

LESION RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	2/45.28	0/44.93	4/44.06	0/46.62
POLY-3 PERCENT (g)	4.4%	0%	9.1%	0%
TERMINAL (d)	1/38 (3%)	0/36 (0%)	4/34 (12%)	0/37 (0%)
FIRST INCIDENCE	660	---	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.319N	P=0.239N	P=0.325	P=0.231N
POLY 1.5	P=0.322N	P=0.236N	P=0.330	P=0.231N
POLY 6	P=0.319N	P=0.245N	P=0.316	P=0.234N
COCH-ARM / FISHERS	P=0.337N	P=0.247N	P=0.339	P=0.247N
MAX-ISO-POLY-3	P=0.183N	P=0.078N	P=0.194	P=0.076N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pituitary Gland: Pars Intermedia
 Angiectasis**

LESION RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/45.02	1/44.93	0/44.06	2/46.72
POLY-3 PERCENT (g)	2.2%	2.2%	0%	4.3%
TERMINAL (d)	1/38 (3%)	1/36 (3%)	0/34 (0%)	1/37 (3%)
FIRST INCIDENCE	729 (T)	729 (T)	---	703

STATISTICAL TESTS

POLY 3	P=0.375	P=0.760	P=0.504N	P=0.513
POLY 1.5	P=0.373	P=0.759N	P=0.502N	P=0.512
POLY 6	P=0.374	P=0.756	P=0.507N	P=0.511
COCH-ARM / FISHERS	P=0.366	P=0.753N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.299	P=0.499	P=0.164N	P=0.295

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pituitary Gland: Pars Intermedia
 Cyst**

LESION RATES

OVERALL (a)	2/50 (4%)	2/50 (4%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/45.34	2/45.18	2/44.59	0/46.62
POLY-3 PERCENT (g)	4.4%	4.4%	4.5%	0%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	1/34 (3%)	0/37 (0%)
FIRST INCIDENCE	687	660	567	---

STATISTICAL TESTS

POLY 3	P=0.157N	P=0.693	P=0.688	P=0.231N
POLY 1.5	P=0.158N	P=0.691N	P=0.690	P=0.231N
POLY 6	P=0.159N	P=0.684	P=0.683	P=0.234N
COCH-ARM / FISHERS	P=0.163N	P=0.691N	P=0.691N	P=0.247N
MAX-ISO-POLY-3	P=0.191N	P=0.498	P=0.492	P=0.076N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Pituitary Gland: Rathke's Cleft Hemorrhage

LESION RATES

OVERALL (a)	2/50 (4%)	2/50 (4%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/45.39	2/45.18	2/44.53	1/46.62
POLY-3 PERCENT (g)	4.4%	4.4%	4.5%	2.2%
TERMINAL (d)	1/38 (3%)	1/36 (3%)	0/34 (0%)	1/37 (3%)
FIRST INCIDENCE	623	660	647	729 (T)

STATISTICAL TESTS

POLY 3	P=0.364N	P=0.692	P=0.687	P=0.491N
POLY 1.5	P=0.365N	P=0.691N	P=0.690	P=0.490N
POLY 6	P=0.367N	P=0.684	P=0.683	P=0.496N
COCH-ARM / FISHERS	P=0.373N	P=0.691N	P=0.691N	P=0.500N
MAX-ISO-POLY-3	P=0.460N	P=0.497	P=0.491	P=0.275N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Salivary Glands
 Atrophy**

LESION RATES

OVERALL (a)	12/50 (24%)	10/50 (20%)	13/50 (26%)	16/50 (32%)
POLY-3 RATE (b)	12/45.18	10/45.79	13/45.13	16/47.64
POLY-3 PERCENT (g)	26.6%	21.8%	28.8%	33.6%
TERMINAL (d)	11/38 (29%)	7/36 (19%)	10/34 (29%)	13/37 (35%)
FIRST INCIDENCE	687	618	451	546

STATISTICAL TESTS

POLY 3	P=0.175	P=0.390N	P=0.499	P=0.305
POLY 1.5	P=0.167	P=0.387N	P=0.501	P=0.294
POLY 6	P=0.178	P=0.399N	P=0.491	P=0.305
COCH-ARM / FISHERS	P=0.142	P=0.405N	P=0.500	P=0.252
MAX-ISO-POLY-3	P=0.259	P=0.301N	P=0.404	P=0.237

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Skin
 Cyst Epithelial Inclusion**

LESION RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/45.02	1/44.93	1/44.16	1/46.85
POLY-3 PERCENT (g)	2.2%	2.2%	2.3%	2.1%
TERMINAL (d)	1/38 (3%)	1/36 (3%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	703	667

STATISTICAL TESTS

POLY 3	P=0.624N	P=0.760	P=0.756	P=0.752N
POLY 1.5	P=0.626N	P=0.759N	P=0.758	P=0.753N
POLY 6	P=0.624N	P=0.756	P=0.754	P=0.753N
COCH-ARM / FISHERS	P=0.634	P=0.753N	P=0.753N	P=0.753N
MAX-ISO-POLY-3	P=0.735N	P=0.499	P=0.494	P=0.488N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Skin
 Hyperkeratosis**

LESION RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/45.02	0/44.93	0/44.06	2/46.62
POLY-3 PERCENT (g)	2.2%	0%	0%	4.3%
TERMINAL (d)	1/38 (3%)	0/36 (0%)	0/34 (0%)	2/37 (5%)
FIRST INCIDENCE	729 (T)	---	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.250	P=0.500N	P=0.504N	P=0.512
POLY 1.5	P=0.248	P=0.498N	P=0.502N	P=0.511
POLY 6	P=0.251	P=0.505N	P=0.507N	P=0.509
COCH-ARM / FISHERS	P=0.246	P=0.500N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.150	P=0.159N	P=0.164N	P=0.294

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Skin
 Inflammation Chronic**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.02	0/44.93	0/44.06	0/46.62
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Skin: Epidermis
 Hyperplasia**

LESION RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/45.02	0/44.93	0/44.06	2/46.62
POLY-3 PERCENT (g)	2.2%	0%	0%	4.3%
TERMINAL (d)	1/38 (3%)	0/36 (0%)	0/34 (0%)	2/37 (5%)
FIRST INCIDENCE	729 (T)	---	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.250	P=0.500N	P=0.504N	P=0.512
POLY 1.5	P=0.248	P=0.498N	P=0.502N	P=0.511
POLY 6	P=0.251	P=0.505N	P=0.507N	P=0.509
COCH-ARM / FISHERS	P=0.246	P=0.500N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.150	P=0.159N	P=0.164N	P=0.294

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Spleen
 Fibrosis**

LESION RATES

OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	1/49 (2%)
POLY-3 RATE (b)	0/44.39	0/44.93	0/44.06	1/46.25
POLY-3 PERCENT (g)	0%	0%	0%	2.2%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	619

STATISTICAL TESTS

POLY 3	P=0.204	(e)	(e)	P=0.508
POLY 1.5	P=0.202	(e)	(e)	P=0.507
POLY 6	P=0.204	(e)	(e)	P=0.507
COCH-ARM / FISHERS	P=0.197	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.136	(e)	(e)	P=0.169

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Spleen
 Hematopoietic Cell Proliferation**

LESION RATES

OVERALL (a)	5/49 (10%)	5/50 (10%)	7/50 (14%)	2/49 (4%)
POLY-3 RATE (b)	5/45.40	5/47.13	7/45.65	2/46.44
POLY-3 PERCENT (g)	11%	10.6%	15.3%	4.3%
TERMINAL (d)	3/38 (8%)	0/36 (0%)	1/34 (3%)	1/37 (3%)
FIRST INCIDENCE	302	477	477	546

STATISTICAL TESTS

POLY 3	P=0.187N	P=0.606N	P=0.383	P=0.207N
POLY 1.5	P=0.188N	P=0.607N	P=0.385	P=0.208N
POLY 6	P=0.190N	P=0.608N	P=0.382	P=0.210N
COCH-ARM / FISHERS	P=0.197N	P=0.617N	P=0.394	P=0.218N
MAX-ISO-POLY-3	P=0.168N	P=0.474N	P=0.273	P=0.116N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Spleen
 Pigmentation**

LESION RATES

OVERALL (a)	43/49 (88%)	42/50 (84%)	37/50 (74%)	42/49 (86%)
POLY-3 RATE (b)	43/46.72	42/48.33	37/45.95	42/47.63
POLY-3 PERCENT (g)	92%	86.9%	80.5%	88.2%
TERMINAL (d)	37/38 (97%)	33/36 (92%)	32/34 (94%)	36/37 (97%)
FIRST INCIDENCE	302	477	451	546

STATISTICAL TESTS

POLY 3	P=0.349N	P=0.305N	P=0.077N	P=0.381N
POLY 1.5	P=0.353N	P=0.313N	P=0.067N	P=0.390N
POLY 6	P=0.383N	P=0.319N	P=0.107N	P=0.419N
COCH-ARM / FISHERS	P=0.420N	P=0.403N	P=0.068N	P=0.500N
MAX-ISO-POLY-3	P=0.191N	P=0.197N	P=0.041N*	P=0.253N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Spleen: Lymphoid Follicle
 Hyperplasia**

LESION RATES

OVERALL (a)	2/49 (4%)	5/50 (10%)	7/50 (14%)	1/49 (2%)
POLY-3 RATE (b)	2/44.39	5/47.26	7/45.42	1/46.44
POLY-3 PERCENT (g)	4.5%	10.6%	15.4%	2.2%
TERMINAL (d)	2/38 (5%)	0/36 (0%)	2/34 (6%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	477	477	546

STATISTICAL TESTS

POLY 3	P=0.312N	P=0.242	P=0.084	P=0.484N
POLY 1.5	P=0.316N	P=0.239	P=0.084	P=0.487N
POLY 6	P=0.315N	P=0.243	P=0.083	P=0.486N
COCH-ARM / FISHERS	P=0.343N	P=0.226	P=0.085	P=0.500N
MAX-ISO-POLY-3	P=0.132N	P=0.144	P=0.042*	P=0.272N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Stomach, Forestomach
 Edema**

LESION RATES

OVERALL (a)	2/49 (4%)	1/48 (2%)	1/49 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/44.78	1/43.68	1/43.18	1/46.92
POLY-3 PERCENT (g)	4.5%	2.3%	2.3%	2.1%
TERMINAL (d)	1/38 (3%)	1/36 (3%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	618	729 (T)	703	647

STATISTICAL TESTS

POLY 3	P=0.396N	P=0.509N	P=0.513N	P=0.484N
POLY 1.5	P=0.397N	P=0.505N	P=0.507N	P=0.483N
POLY 6	P=0.398N	P=0.517N	P=0.521N	P=0.489N
COCH-ARM / FISHERS	P=0.401N	P=0.508N	P=0.500N	P=0.492N
MAX-ISO-POLY-3	P=0.408N	P=0.289N	P=0.294N	P=0.271N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Stomach, Forestomach
 Ulcer**

LESION RATES

OVERALL (a)	1/49 (2%)	1/48 (2%)	0/49 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/44.78	1/43.68	0/43.08	1/46.95
POLY-3 PERCENT (g)	2.2%	2.3%	0%	2.1%
TERMINAL (d)	0/38 (0%)	1/36 (3%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	618	729 (T)	---	638

STATISTICAL TESTS

POLY 3	P=0.608N	P=0.755	P=0.508N	P=0.750N
POLY 1.5	P=0.607N	P=0.758	P=0.504N	P=0.750N
POLY 6	P=0.610N	P=0.750	P=0.513N	P=0.753N
COCH-ARM / FISHERS	P=0.609N	P=0.747	P=0.500N	P=0.747N
MAX-ISO-POLY-3	P=0.534N	P=0.492	P=0.168N	P=0.486N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Stomach, Forestomach: Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	3/49 (6%)	5/48 (10%)	2/49 (4%)	1/50 (2%)
POLY-3 RATE (b)	3/44.56	5/44.28	2/43.42	1/46.95
POLY-3 PERCENT (g)	6.7%	11.3%	4.6%	2.1%
TERMINAL (d)	2/38 (5%)	3/36 (8%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	687	619	667	638

STATISTICAL TESTS

POLY 3	P=0.121N	P=0.353	P=0.512N	P=0.287N
POLY 1.5	P=0.121N	P=0.355	P=0.507N	P=0.287N
POLY 6	P=0.124N	P=0.347	P=0.519N	P=0.291N
COCH-ARM / FISHERS	P=0.129N	P=0.346	P=0.500N	P=0.301N
MAX-ISO-POLY-3	P=0.140N	P=0.229	P=0.336N	P=0.146N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Stomach, Glandular
 Edema**

LESION RATES

OVERALL (a)	0/49 (0%)	2/47 (4%)	0/49 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/44.39	2/44.03	0/43.08	0/45.86
POLY-3 PERCENT (g)	0%	4.5%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	---	619	---	---

STATISTICAL TESTS

POLY 3	P=0.394N	P=0.235	(e)	(e)
POLY 1.5	P=0.394N	P=0.235	(e)	(e)
POLY 6	P=0.397N	P=0.235	(e)	(e)
COCH-ARM / FISHERS	P=0.403N	P=0.237	(e)	(e)
MAX-ISO-POLY-3	P=0.251N	P=0.076	(e)	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Stomach, Glandular
 Erosion**

LESION RATES

OVERALL (a)	7/49 (14%)	2/47 (4%)	2/49 (4%)	1/49 (2%)
POLY-3 RATE (b)	7/46.09	2/43.66	2/43.57	1/46.16
POLY-3 PERCENT (g)	15.2%	4.6%	4.6%	2.2%
TERMINAL (d)	2/38 (5%)	0/36 (0%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	434	672	660	647

STATISTICAL TESTS

POLY 3	P=0.020N*	P=0.092N	P=0.093N	P=0.030N*
POLY 1.5	P=0.020N*	P=0.088N	P=0.087N	P=0.029N*
POLY 6	P=0.020N*	P=0.099N	P=0.100N	P=0.032N*
COCH-ARM / FISHERS	P=0.021N*	P=0.090N	P=0.080N	P=0.030N*
MAX-ISO-POLY-3	P=0.008N**	P=0.049N*	P=0.051N	P=0.012N*

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Stomach, Glandular
 Ulcer**

LESION RATES

OVERALL (a)	2/49 (4%)	1/47 (2%)	1/49 (2%)	3/49 (6%)
POLY-3 RATE (b)	2/44.49	1/43.81	1/43.31	3/46.59
POLY-3 PERCENT (g)	4.5%	2.3%	2.3%	6.4%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	710	619	667	638

STATISTICAL TESTS

POLY 3	P=0.340	P=0.505N	P=0.509N	P=0.521
POLY 1.5	P=0.338	P=0.505N	P=0.505N	P=0.517
POLY 6	P=0.341	P=0.508N	P=0.515N	P=0.521
COCH-ARM / FISHERS	P=0.330	P=0.516N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.335	P=0.286N	P=0.291N	P=0.346

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Thymus
 Cyst**

LESION RATES

OVERALL (a)	0/50 (0%)	0/49 (0%)	2/48 (4%)	1/49 (2%)
POLY-3 RATE (b)	0/45.02	0/43.93	2/42.15	1/45.85
POLY-3 PERCENT (g)	0%	0%	4.8%	2.2%
TERMINAL (d)	0/38 (0%)	0/35 (0%)	1/33 (3%)	1/37 (3%)
FIRST INCIDENCE	---	---	711	729 (T)

STATISTICAL TESTS

POLY 3	P=0.259	(e)	P=0.223	P=0.504
POLY 1.5	P=0.256	(e)	P=0.225	P=0.503
POLY 6	P=0.260	(e)	P=0.219	P=0.503
COCH-ARM / FISHERS	P=0.243	(e)	P=0.237	P=0.495
MAX-ISO-POLY-3	P=0.167	(e)	P=0.073	P=0.164

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

Date Report Requested: 10/09/2008
 Time Report Requested: 11:00:55
 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Thymus
 Hemorrhage**

LESION RATES

OVERALL (a)	17/50 (34%)	15/49 (31%)	13/48 (27%)	14/49 (29%)
POLY-3 RATE (b)	17/45.53	15/44.32	13/42.08	14/46.20
POLY-3 PERCENT (g)	37.3%	33.9%	30.9%	30.3%
TERMINAL (d)	16/38 (42%)	14/35 (40%)	13/33 (39%)	12/37 (32%)
FIRST INCIDENCE	575	618	729 (T)	674

STATISTICAL TESTS

POLY 3	P=0.270N	P=0.450N	P=0.341N	P=0.311N
POLY 1.5	P=0.280N	P=0.433N	P=0.323N	P=0.317N
POLY 6	P=0.266N	P=0.482N	P=0.367N	P=0.315N
COCH-ARM / FISHERS	P=0.313N	P=0.442N	P=0.301N	P=0.358N
MAX-ISO-POLY-3	P=0.383N	P=0.364N	P=0.268N	P=0.241N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
 CAS Number: 84604-20-6

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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Thyroid Gland
 Degeneration Cystic**

LESION RATES

OVERALL (a)	2/47 (4%)	8/49 (16%)	5/49 (10%)	4/50 (8%)
POLY-3 RATE (b)	2/43.59	8/45.54	5/43.08	4/46.78
POLY-3 PERCENT (g)	4.6%	17.6%	11.6%	8.6%
TERMINAL (d)	1/38 (3%)	4/36 (11%)	5/34 (15%)	1/37 (3%)
FIRST INCIDENCE	710	618	729 (T)	703

STATISTICAL TESTS

POLY 3	P=0.558	P=0.052	P=0.211	P=0.370
POLY 1.5	P=0.565	P=0.054	P=0.220	P=0.374
POLY 6	P=0.539	P=0.049*	P=0.199	P=0.361
COCH-ARM / FISHERS	P=0.553	P=0.053	P=0.235	P=0.369
MAX-ISO-POLY-3	P=0.178	P=0.026*	P=0.119	P=0.231

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Thyroid Gland
 Ultimobranchial Cyst**

LESION RATES

OVERALL (a)	1/47 (2%)	1/49 (2%)	3/49 (6%)	0/50 (0%)
POLY-3 RATE (b)	1/43.52	1/44.34	3/43.80	0/46.62
POLY-3 PERCENT (g)	2.3%	2.3%	6.9%	0%
TERMINAL (d)	1/38 (3%)	1/36 (3%)	2/34 (6%)	0/37 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	477	---

STATISTICAL TESTS

POLY 3	P=0.385N	P=0.756N	P=0.307	P=0.486N
POLY 1.5	P=0.384N	P=0.752N	P=0.313	P=0.485N
POLY 6	P=0.391N	P=0.758	P=0.299	P=0.491N
COCH-ARM / FISHERS	P=0.392N	P=0.742N	P=0.324	P=0.485N
MAX-ISO-POLY-3	P=0.225N	P=0.494N	P=0.157	P=0.155N

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Thyroid Gland: C-Cell
 Hyperplasia**

LESION RATES

OVERALL (a)	18/47 (38%)	17/49 (35%)	20/49 (41%)	21/50 (42%)
POLY-3 RATE (b)	18/43.61	17/44.82	20/43.97	21/47.65
POLY-3 PERCENT (g)	41.3%	37.9%	45.5%	44.1%
TERMINAL (d)	16/38 (42%)	15/36 (42%)	17/34 (50%)	17/37 (46%)
FIRST INCIDENCE	710	660	567	619

STATISTICAL TESTS

POLY 3	P=0.362	P=0.458N	P=0.428	P=0.477
POLY 1.5	P=0.355	P=0.437N	P=0.450	P=0.476
POLY 6	P=0.358	P=0.493N	P=0.400	P=0.463
COCH-ARM / FISHERS	P=0.318	P=0.438N	P=0.483	P=0.435
MAX-ISO-POLY-3	P=0.497	P=0.372N	P=0.345	P=0.395

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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 First Dose M/F: 03/04/03 / 03/04/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Thyroid Gland: Follicular Cell
 Hyperplasia Focal**

LESION RATES

OVERALL (a)	0/47 (0%)	3/49 (6%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.52	3/44.34	0/43.08	0/46.62
POLY-3 PERCENT (g)	0%	6.8%	0%	0%
TERMINAL (d)	0/38 (0%)	3/36 (8%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	---	729 (T)	---	---

STATISTICAL TESTS

POLY 3	P=0.302N	P=0.122	(e)	(e)
POLY 1.5	P=0.296N	P=0.126	(e)	(e)
POLY 6	P=0.312N	P=0.116	(e)	(e)
COCH-ARM / FISHERS	P=0.299N	P=0.129	(e)	(e)
MAX-ISO-POLY-3	P=0.163N	P=0.039*	(e)	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Urinary Bladder: Transitional Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/45.02	0/44.34	0/44.06	0/46.62
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/38 (0%)	0/36 (0%)	0/34 (0%)	0/37 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20008 - 03
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344/N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Uterus
 Hyperplasia Cystic**

LESION RATES

OVERALL (a)	32/50 (64%)	30/49 (61%)	33/50 (66%)	31/50 (62%)
POLY-3 RATE (b)	32/46.97	30/46.91	33/48.35	31/48.59
POLY-3 PERCENT (g)	68.1%	64%	68.3%	63.8%
TERMINAL (d)	24/38 (63%)	23/36 (64%)	21/34 (62%)	24/37 (65%)
FIRST INCIDENCE	575	477	451	546

STATISTICAL TESTS

POLY 3	P=0.412N	P=0.417N	P=0.582	P=0.408N
POLY 1.5	P=0.424N	P=0.411N	P=0.557	P=0.415N
POLY 6	P=0.426N	P=0.451N	P=0.585N	P=0.434N
COCH-ARM / FISHERS	P=0.501N	P=0.469N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.524N	P=0.334N	P=0.494	P=0.329N

TDMS No. 20008 - 03
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

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LEGEND

- (a) Number of tumor-bearing animals/number of animals examined at site.
 - (b) Number of tumor-bearing animals/Poly-3 number
 - (d) Observed incidence at terminal kill.
 - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group. The life table analysis regards tumors in animals dying prior to terminal kill as being (directly or indirectly) the cause of death.
 - (e) Value of Statistic cannot be computed.
 - (g) Poly-3 adjusted lifetime tumor incidence.
 - (I) Interim sacrifice
 - (T) Terminal sacrifice
 - # Tumor rates based on numbers of animals necropsied.
 - * To the right of any statistical result, indicates significance at ($P \leq 0.05$).
 - ** To the right of any statistical result, indicates significance at ($P \leq 0.01$).
 - N Indicates a negative trend for all tests
- Logistic regression is an alternative method for analyzing the incidence of non-fatal tumors.
The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

*** END OF REPORT ***