

TDMS No. 20008 - 04
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Milk thistle extract
CAS Number: 84604-20-6

Date Report Requested: 09/30/2008
Time Report Requested: 13:13:48
First Dose M/F: 03/25/03 / 03/25/03
Lab: SRI

F1_M3

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 MICE

Organ

Adrenal Cortex
Harderian Gland
Heart

Kidney

Kidney: Renal Tubule
Liver

Liver: Hepatocyte
Lung: Alveolar Epithelium
Lymph Node, Mesenteric
Preputial Gland
Spleen
Urinary Bladder

FEMALE MICE

Organ

Adrenal Cortex
Adrenal Cortex: Capsule
Bone
Clitoral Gland
Kidney

Liver

Morphology

Accessory Adrenal Cortical Nodule
Hyperplasia Focal
Cardiomyopathy
Thrombosis
Infarct
Infiltration Cellular Lymphocyte
Metaplasia Osseous
Nephropathy
Hyperplasia
Angiectasis
Clear Cell Focus
Hematopoietic Cell Proliferation
Mixed Cell Focus
Vacuolization Cytoplasmic
Hyperplasia
Hemorrhage
Cyst
Hematopoietic Cell Proliferation
Calculus Gross Observation

Morphology

Hypertrophy Focal
Hyperplasia
Fibro-osseous Lesion
Inflammation Chronic
Infarct
Infiltration Cellular Lymphocyte
Metaplasia Osseous
Hematopoietic Cell Proliferation
Infiltration Cellular Mixed Cell

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

Lung	Necrosis Focal
	Hemorrhage
	Inflammation Chronic
Lymph Node, Mandibular	Ectasia
	Pigmentation
Lymph Node: Iliac	Hyperplasia Lymphoid
Lymph Node: Renal	Hyperplasia Lymphoid
Pituitary Gland: Pars Distalis	Cyst
	Hyperplasia Focal
Salivary Glands	Atrophy
Spleen	Hematopoietic Cell Proliferation
Thymus	Atrophy
	Hyperplasia Lymphoid
Thyroid Gland: Follicle	Degeneration Focal
Thyroid Gland: Follicular Cell	Hyperplasia
Uterus	Angiectasis

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 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)	7/50 (14%)	7/50 (14%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	7/47.69	7/48.82	4/47.94	2/49.86
POLY-3 PERCENT (g)	14.7%	14.3%	8.3%	4%
TERMINAL (d)	7/45 (16%)	6/46 (13%)	4/43 (9%)	2/49 (4%)
FIRST INCIDENCE	729 (T)	642	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.034N*	P=0.595N	P=0.259N	P=0.069N
POLY 1.5	P=0.036N*	P=0.600N	P=0.258N	P=0.073N
POLY 6	P=0.033N*	P=0.590N	P=0.264N	P=0.067N
COCH-ARM / FISHERS	P=0.040N*	P=0.613N	P=0.262N	P=0.080N
MAX-ISO-POLY-3	P=0.052N	P=0.480N	P=0.168N	P=0.036N*

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Adrenal Cortex
 Hyperplasia Focal**

LESION RATES

OVERALL (a)	4/50 (8%)	8/50 (16%)	6/50 (12%)	8/50 (16%)
POLY-3 RATE (b)	4/47.69	8/48.50	6/47.94	8/49.86
POLY-3 PERCENT (g)	8.4%	16.5%	12.5%	16.1%
TERMINAL (d)	4/45 (9%)	8/46 (17%)	6/43 (14%)	8/49 (16%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.246	P=0.186	P=0.373	P=0.200
POLY 1.5	P=0.236	P=0.184	P=0.374	P=0.193
POLY 6	P=0.254	P=0.186	P=0.367	P=0.207
COCH-ARM / FISHERS	P=0.217	P=0.178	P=0.370	P=0.178
MAX-ISO-POLY-3	P=0.224	P=0.117	P=0.257	P=0.131

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Adrenal Cortex
 Hypertrophy Focal**

LESION RATES

OVERALL (a)	13/50 (26%)	13/50 (26%)	12/50 (24%)	9/50 (18%)
POLY-3 RATE (b)	13/47.69	13/48.50	12/48.20	9/50.00
POLY-3 PERCENT (g)	27.3%	26.8%	24.9%	18%
TERMINAL (d)	13/45 (29%)	13/46 (28%)	11/43 (26%)	8/49 (16%)
FIRST INCIDENCE	729 (T)	729 (T)	657	693

STATISTICAL TESTS

POLY 3	P=0.144N	P=0.571N	P=0.488N	P=0.198N
POLY 1.5	P=0.155N	P=0.576N	P=0.489N	P=0.210N
POLY 6	P=0.134N	P=0.569N	P=0.494N	P=0.187N
COCH-ARM / FISHERS	P=0.176N	P=0.590N	P=0.500N	P=0.235N
MAX-ISO-POLY-3	P=0.232N	P=0.479N	P=0.395N	P=0.143N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Adrenal Cortex: Capsule
 Hyperplasia**

LESION RATES

OVERALL (a)	2/50 (4%)	2/50 (4%)	3/50 (6%)	5/50 (10%)
POLY-3 RATE (b)	2/47.69	2/48.50	3/47.94	5/49.86
POLY-3 PERCENT (g)	4.2%	4.1%	6.3%	10%
TERMINAL (d)	2/45 (4%)	2/46 (4%)	3/43 (7%)	5/49 (10%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.125	P=0.687N	P=0.502	P=0.235
POLY 1.5	P=0.121	P=0.689N	P=0.503	P=0.229
POLY 6	P=0.128	P=0.687N	P=0.498	P=0.241
COCH-ARM / FISHERS	P=0.114	P=0.691N	P=0.500	P=0.218
MAX-ISO-POLY-3	P=0.192	P=0.492N	P=0.327	P=0.138

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Adrenal Medulla
 Hyperplasia**

LESION RATES

OVERALL (a)	0/49 (0%)	1/50 (2%)	0/49 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/46.69	1/48.50	0/47.18	0/48.86
POLY-3 PERCENT (g)	0%	2.1%	0%	0%
TERMINAL (d)	0/44 (0%)	1/46 (2%)	0/43 (0%)	0/48 (0%)
FIRST INCIDENCE	---	729 (T)	---	---

STATISTICAL TESTS

POLY 3	P=0.564N	P=0.508	(e)	(e)
POLY 1.5	P=0.565N	P=0.507	(e)	(e)
POLY 6	P=0.563N	P=0.508	(e)	(e)
COCH-ARM / FISHERS	P=0.568N	P=0.505	(e)	(e)
MAX-ISO-POLY-3	P=0.393N	P=0.167	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Bone Marrow
 Hyperplasia**

LESION RATES

OVERALL (a)	13/49 (27%)	14/49 (29%)	13/49 (27%)	17/50 (34%)
POLY-3 RATE (b)	13/49.00	14/49.00	13/47.92	17/50.00
POLY-3 PERCENT (g)	26.5%	28.6%	27.1%	34%
TERMINAL (d)	9/45 (20%)	11/46 (24%)	9/43 (21%)	16/49 (33%)
FIRST INCIDENCE	389	437	657	693

STATISTICAL TESTS

POLY 3	P=0.241	P=0.500	P=0.564	P=0.279
POLY 1.5	P=0.242	P=0.500	P=0.574	P=0.279
POLY 6	P=0.240	P=0.500	P=0.554	P=0.279
COCH-ARM / FISHERS	P=0.242	P=0.500	P=0.590N	P=0.278
MAX-ISO-POLY-3	P=0.338	P=0.409	P=0.473	P=0.212

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Bone
 Fibro-osseous Lesion**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/47.69	0/48.50	0/47.94	0/48.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/45 (0%)	0/46 (0%)	0/43 (0%)	0/48 (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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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Eye
 Inflammation Chronic**

LESION RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/47.69	0/48.50	0/47.94	0/49.86
POLY-3 PERCENT (g)	2.1%	0%	0%	0%
TERMINAL (d)	1/45 (2%)	0/46 (0%)	0/43 (0%)	0/49 (0%)
FIRST INCIDENCE	729 (T)	---	---	---

STATISTICAL TESTS

POLY 3	P=0.312N	P=0.497N	P=0.499N	P=0.491N
POLY 1.5	P=0.310N	P=0.498N	P=0.499N	P=0.494N
POLY 6	P=0.313N	P=0.496N	P=0.501N	P=0.489N
COCH-ARM / FISHERS	P=0.306N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.124N	P=0.159N	P=0.159N	P=0.159N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Eye: Cornea
 Hyperplasia

LESION RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/47.69	0/48.50	0/47.94	0/49.86
POLY-3 PERCENT (g)	2.1%	0%	0%	0%
TERMINAL (d)	1/45 (2%)	0/46 (0%)	0/43 (0%)	0/49 (0%)
FIRST INCIDENCE	729 (T)	---	---	---

STATISTICAL TESTS

POLY 3	P=0.312N	P=0.497N	P=0.499N	P=0.491N
POLY 1.5	P=0.310N	P=0.498N	P=0.499N	P=0.494N
POLY 6	P=0.313N	P=0.496N	P=0.501N	P=0.489N
COCH-ARM / FISHERS	P=0.306N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.124N	P=0.159N	P=0.159N	P=0.159N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Harderian Gland
 Hyperplasia Focal**

LESION RATES

OVERALL (a)	3/50 (6%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	3/47.69	2/48.50	0/47.94	1/49.86
POLY-3 PERCENT (g)	6.3%	4.1%	0%	2%
TERMINAL (d)	3/45 (7%)	2/46 (4%)	0/43 (0%)	1/49 (2%)
FIRST INCIDENCE	729 (T)	729 (T)	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.160N	P=0.492N	P=0.118N	P=0.290N
POLY 1.5	P=0.161N	P=0.494N	P=0.118N	P=0.295N
POLY 6	P=0.159N	P=0.492N	P=0.120N	P=0.286N
COCH-ARM / FISHERS	P=0.163N	P=0.500N	P=0.121N	P=0.309N
MAX-ISO-POLY-3	P=0.110N	P=0.319N	P=0.038N*	P=0.149N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Heart
 Cardiomyopathy**

LESION RATES

OVERALL (a)	4/50 (8%)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	4/49.01	1/48.50	0/47.94	2/50.00
POLY-3 PERCENT (g)	8.2%	2.1%	0%	4%
TERMINAL (d)	2/45 (4%)	1/46 (2%)	0/43 (0%)	1/49 (2%)
FIRST INCIDENCE	389	729 (T)	---	693

STATISTICAL TESTS

POLY 3	P=0.277N	P=0.183N	P=0.064N	P=0.329N
POLY 1.5	P=0.277N	P=0.181N	P=0.062N	P=0.332N
POLY 6	P=0.276N	P=0.185N	P=0.066N	P=0.326N
COCH-ARM / FISHERS	P=0.279N	P=0.181N	P=0.059N	P=0.339N
MAX-ISO-POLY-3	P=0.079N	P=0.087N	P=0.022N*	P=0.197N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Heart
 Mineralization**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.69	0/48.50	0/47.94	0/49.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/45 (0%)	0/46 (0%)	0/43 (0%)	0/49 (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 - 04
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Heart
 Thrombosis**

LESION RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/49.01	0/48.50	0/47.94	0/49.86
POLY-3 PERCENT (g)	4.1%	0%	0%	0%
TERMINAL (d)	0/45 (0%)	0/46 (0%)	0/43 (0%)	0/49 (0%)
FIRST INCIDENCE	389	---	---	---

STATISTICAL TESTS

POLY 3	P=0.114N	P=0.240N	P=0.242N	P=0.234N
POLY 1.5	P=0.114N	P=0.239N	P=0.240N	P=0.235N
POLY 6	P=0.114N	P=0.241N	P=0.246N	P=0.233N
COCH-ARM / FISHERS	P=0.115N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.033N*	P=0.078N	P=0.081N	P=0.076N

TDMS No. 20008 - 04
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 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney
 Cyst**

LESION RATES

OVERALL (a)	8/50 (16%)	10/50 (20%)	5/50 (10%)	7/50 (14%)
POLY-3 RATE (b)	8/47.69	10/48.50	5/47.94	7/49.86
POLY-3 PERCENT (g)	16.8%	20.6%	10.4%	14%
TERMINAL (d)	8/45 (18%)	10/46 (22%)	5/43 (12%)	7/49 (14%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.291N	P=0.413	P=0.273N	P=0.463N
POLY 1.5	P=0.301N	P=0.409	P=0.272N	P=0.475N
POLY 6	P=0.283N	P=0.414	P=0.279N	P=0.453N
COCH-ARM / FISHERS	P=0.320N	P=0.398	P=0.277N	P=0.500N
MAX-ISO-POLY-3	P=0.315N	P=0.317	P=0.185N	P=0.357N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney
 Infarct**

LESION RATES

OVERALL (a)	4/50 (8%)	3/50 (6%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	4/48.17	3/48.50	0/47.94	2/49.86
POLY-3 PERCENT (g)	8.3%	6.2%	0%	4%
TERMINAL (d)	3/45 (7%)	3/46 (7%)	0/43 (0%)	2/49 (4%)
FIRST INCIDENCE	588	729 (T)	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.189N	P=0.496N	P=0.061N	P=0.322N
POLY 1.5	P=0.190N	P=0.496N	P=0.060N	P=0.327N
POLY 6	P=0.188N	P=0.499N	P=0.063N	P=0.319N
COCH-ARM / FISHERS	P=0.194N	P=0.500N	P=0.059N	P=0.339N
MAX-ISO-POLY-3	P=0.114N	P=0.345N	P=0.020N*	P=0.193N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney
 Infiltration Cellular Lymphocyte**

LESION RATES

OVERALL (a)	3/50 (6%)	2/50 (4%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	3/47.69	2/48.50	3/47.94	0/49.86
POLY-3 PERCENT (g)	6.3%	4.1%	6.3%	0%
TERMINAL (d)	3/45 (7%)	2/46 (4%)	3/43 (7%)	0/49 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.103N	P=0.492N	P=0.660N	P=0.111N
POLY 1.5	P=0.106N	P=0.494N	P=0.659N	P=0.114N
POLY 6	P=0.100N	P=0.492N	P=0.660	P=0.109N
COCH-ARM / FISHERS	P=0.111N	P=0.500N	P=0.661N	P=0.121N
MAX-ISO-POLY-3	P=0.098N	P=0.319N	P=0.497N	P=0.038N*

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney
 Metaplasia Osseous**

LESION RATES

OVERALL (a)	0/50 (0%)	3/50 (6%)	5/50 (10%)	0/50 (0%)
POLY-3 RATE (b)	0/47.69	3/48.82	5/47.94	0/49.86
POLY-3 PERCENT (g)	0%	6.2%	10.4%	0%
TERMINAL (d)	0/45 (0%)	2/46 (4%)	5/43 (12%)	0/49 (0%)
FIRST INCIDENCE	---	642	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.467N	P=0.123	P=0.031*	(e)
POLY 1.5	P=0.478N	P=0.122	P=0.031*	(e)
POLY 6	P=0.458N	P=0.124	P=0.030*	(e)
COCH-ARM / FISHERS	P=0.500N	P=0.121	P=0.028*	(e)
MAX-ISO-POLY-3	P=0.135N	P=0.042*	P=0.010**	(e)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney
 Nephropathy**

LESION RATES

OVERALL (a)	45/50 (90%)	49/50 (98%)	47/50 (94%)	49/50 (98%)
POLY-3 RATE (b)	45/49.01	49/49.68	47/49.86	49/50.00
POLY-3 PERCENT (g)	91.8%	98.6%	94.3%	98%
TERMINAL (d)	43/45 (96%)	46/46 (100%)	41/43 (95%)	48/49 (98%)
FIRST INCIDENCE	389	437	460	693

STATISTICAL TESTS

POLY 3	P=0.187	P=0.117	P=0.466	P=0.164
POLY 1.5	P=0.155	P=0.113	P=0.427	P=0.136
POLY 6	P=0.225	P=0.111	P=0.497	P=0.196
COCH-ARM / FISHERS	P=0.114	P=0.102	P=0.357	P=0.102
MAX-ISO-POLY-3	P=0.093	P=0.046*	P=0.313	P=0.075

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 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)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/48.17	0/48.50	0/47.94	0/49.86
POLY-3 PERCENT (g)	2.1%	0%	0%	0%
TERMINAL (d)	0/45 (0%)	0/46 (0%)	0/43 (0%)	0/49 (0%)
FIRST INCIDENCE	588	---	---	---

STATISTICAL TESTS

POLY 3	P=0.310N	P=0.499N	P=0.501N	P=0.493N
POLY 1.5	P=0.309N	P=0.499N	P=0.500N	P=0.495N
POLY 6	P=0.311N	P=0.499N	P=0.504N	P=0.492N
COCH-ARM / FISHERS	P=0.306N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.124N	P=0.159N	P=0.160N	P=0.159N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney: Renal Tubule
 Hyperplasia**

LESION RATES

OVERALL (a)	5/50 (10%)	1/50 (2%)	1/50 (2%)	4/50 (8%)
POLY-3 RATE (b)	5/47.69	1/48.50	1/47.94	4/49.86
POLY-3 PERCENT (g)	10.5%	2.1%	2.1%	8%
TERMINAL (d)	5/45 (11%)	1/46 (2%)	1/43 (2%)	4/49 (8%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.556N	P=0.098N	P=0.101N	P=0.472N
POLY 1.5	P=0.559N	P=0.099N	P=0.100N	P=0.482N
POLY 6	P=0.554N	P=0.098N	P=0.103N	P=0.465N
COCH-ARM / FISHERS	P=0.562N	P=0.102N	P=0.102N	P=0.500N
MAX-ISO-POLY-3	P=0.142N	P=0.044N*	P=0.045N*	P=0.341N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney: Renal Tubule
 Necrosis**

LESION RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.69	1/48.82	0/47.94	0/49.86
POLY-3 PERCENT (g)	0%	2.1%	0%	0%
TERMINAL (d)	0/45 (0%)	0/46 (0%)	0/43 (0%)	0/49 (0%)
FIRST INCIDENCE	---	642	---	---

STATISTICAL TESTS

POLY 3	P=0.562N	P=0.505	(e)	(e)
POLY 1.5	P=0.564N	P=0.503	(e)	(e)
POLY 6	P=0.562N	P=0.506	(e)	(e)
COCH-ARM / FISHERS	P=0.567N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.392N	P=0.165	(e)	(e)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Angiectasis

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/47.69	0/48.50	0/47.94	2/49.86
POLY-3 PERCENT (g)	0%	0%	0%	4%
TERMINAL (d)	0/45 (0%)	0/46 (0%)	0/43 (0%)	2/49 (4%)
FIRST INCIDENCE	---	---	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.047*	(e)	(e)	P=0.247
POLY 1.5	P=0.046*	(e)	(e)	P=0.244
POLY 6	P=0.048*	(e)	(e)	P=0.250
COCH-ARM / FISHERS	P=0.046*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.041*	(e)	(e)	P=0.086

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Clear Cell Focus

LESION RATES

OVERALL (a)	7/50 (14%)	3/50 (6%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	7/47.69	3/48.50	3/47.94	0/49.86
POLY-3 PERCENT (g)	14.7%	6.2%	6.3%	0%
TERMINAL (d)	7/45 (16%)	3/46 (7%)	3/43 (7%)	0/49 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.005N**	P=0.151N	P=0.156N	P=0.006N**
POLY 1.5	P=0.006N**	P=0.153N	P=0.156N	P=0.007N**
POLY 6	P=0.005N**	P=0.151N	P=0.160N	P=0.006N**
COCH-ARM / FISHERS	P=0.007N**	P=0.159N	P=0.159N	P=0.006N**
MAX-ISO-POLY-3	P=0.003N**	P=0.088N	P=0.090N	P=0.002N**

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Eosinophilic Focus

LESION RATES

OVERALL (a)	2/50 (4%)	1/50 (2%)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	2/47.69	1/48.50	4/47.94	1/49.86
POLY-3 PERCENT (g)	4.2%	2.1%	8.3%	2%
TERMINAL (d)	2/45 (4%)	1/46 (2%)	4/43 (9%)	1/49 (2%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.479N	P=0.494N	P=0.340	P=0.485N
POLY 1.5	P=0.486N	P=0.496N	P=0.341	P=0.490N
POLY 6	P=0.473N	P=0.494N	P=0.335	P=0.480N
COCH-ARM / FISHERS	P=0.500N	P=0.500N	P=0.339	P=0.500N
MAX-ISO-POLY-3	P=0.394N	P=0.278N	P=0.204	P=0.272N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Liver
 Hematopoietic Cell Proliferation**

LESION RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/48.17	0/48.50	0/47.94	0/49.86
POLY-3 PERCENT (g)	4.2%	0%	0%	0%
TERMINAL (d)	1/45 (2%)	0/46 (0%)	0/43 (0%)	0/49 (0%)
FIRST INCIDENCE	588	---	---	---

STATISTICAL TESTS

POLY 3	P=0.115N	P=0.236N	P=0.238N	P=0.230N
POLY 1.5	P=0.115N	P=0.236N	P=0.237N	P=0.232N
POLY 6	P=0.115N	P=0.237N	P=0.242N	P=0.228N
COCH-ARM / FISHERS	P=0.115N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.033N*	P=0.076N	P=0.077N	P=0.076N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Infiltration Cellular Lymphocyte

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.69	0/48.50	0/47.94	0/49.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/45 (0%)	0/46 (0%)	0/43 (0%)	0/49 (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 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Infiltration Cellular Mixed Cell

LESION RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/47.69	0/48.50	1/47.94	0/49.86
POLY-3 PERCENT (g)	2.1%	0%	2.1%	0%
TERMINAL (d)	1/45 (2%)	0/46 (0%)	1/43 (2%)	0/49 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.401N	P=0.497N	P=0.759N	P=0.491N
POLY 1.5	P=0.403N	P=0.498N	P=0.759N	P=0.494N
POLY 6	P=0.399N	P=0.496N	P=0.759	P=0.489N
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=0.498N	P=0.159N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Mixed Cell Focus

LESION RATES

OVERALL (a)	10/50 (20%)	7/50 (14%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	10/47.69	7/48.50	0/47.94	3/49.86
POLY-3 PERCENT (g)	21%	14.4%	0%	6%
TERMINAL (d)	10/45 (22%)	7/46 (15%)	0/43 (0%)	3/49 (6%)
FIRST INCIDENCE	729 (T)	729 (T)	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.006N**	P=0.284N	P<0.001N**	P=0.029N*
POLY 1.5	P=0.007N**	P=0.288N	P<0.001N**	P=0.031N*
POLY 6	P=0.006N**	P=0.283N	P<0.001N**	P=0.027N*
COCH-ARM / FISHERS	P=0.008N**	P=0.298N	P<0.001N**	P=0.036N*
MAX-ISO-POLY-3	P=0.003N**	P=0.204N	P<0.001N**	P=0.016N*

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Necrosis Focal

LESION RATES

OVERALL (a)	2/50 (4%)	3/50 (6%)	5/50 (10%)	0/50 (0%)
POLY-3 RATE (b)	2/48.17	3/48.50	5/48.00	0/49.86
POLY-3 PERCENT (g)	4.2%	6.2%	10.4%	0%
TERMINAL (d)	1/45 (2%)	3/46 (7%)	4/43 (9%)	0/49 (0%)
FIRST INCIDENCE	588	729 (T)	712	---

STATISTICAL TESTS

POLY 3	P=0.203N	P=0.503	P=0.215	P=0.230N
POLY 1.5	P=0.208N	P=0.503	P=0.218	P=0.232N
POLY 6	P=0.199N	P=0.501	P=0.210	P=0.228N
COCH-ARM / FISHERS	P=0.221N	P=0.500	P=0.218	P=0.247N
MAX-ISO-POLY-3	P=0.097N	P=0.328	P=0.120	P=0.076N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver: Centrilobular
 Necrosis

LESION RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/48.49	2/49.34	1/48.20	0/49.86
POLY-3 PERCENT (g)	2.1%	4.1%	2.1%	0%
TERMINAL (d)	0/45 (0%)	0/46 (0%)	0/43 (0%)	0/49 (0%)
FIRST INCIDENCE	427	437	657	---

STATISTICAL TESTS

POLY 3	P=0.242N	P=0.506	P=0.759	P=0.494N
POLY 1.5	P=0.244N	P=0.504	P=0.760	P=0.496N
POLY 6	P=0.240N	P=0.507	P=0.757	P=0.493N
COCH-ARM / FISHERS	P=0.247N	P=0.500	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.234N	P=0.288	P=0.498	P=0.159N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver: Hepatocyte
 Vacuolization Cytoplasmic

LESION RATES

OVERALL (a)	7/50 (14%)	4/50 (8%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	7/47.69	4/49.29	1/47.94	0/49.86
POLY-3 PERCENT (g)	14.7%	8.1%	2.1%	0%
TERMINAL (d)	7/45 (16%)	3/46 (7%)	1/43 (2%)	0/49 (0%)
FIRST INCIDENCE	729 (T)	437	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.002N**	P=0.243N	P=0.030N*	P=0.006N**
POLY 1.5	P=0.002N**	P=0.249N	P=0.030N*	P=0.007N**
POLY 6	P=0.002N**	P=0.241N	P=0.031N*	P=0.006N**
COCH-ARM / FISHERS	P=0.002N**	P=0.262N	P=0.030N*	P=0.006N**
MAX-ISO-POLY-3	P=0.002N**	P=0.159N	P=0.012N*	P=0.002N**

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Lung
 Foreign Body

LESION RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/47.69	0/48.50	1/48.08	0/49.86
POLY-3 PERCENT (g)	4.2%	0%	2.1%	0%
TERMINAL (d)	2/45 (4%)	0/46 (0%)	0/43 (0%)	0/49 (0%)
FIRST INCIDENCE	729 (T)	---	693	---

STATISTICAL TESTS

POLY 3	P=0.186N	P=0.234N	P=0.497N	P=0.228N
POLY 1.5	P=0.187N	P=0.235N	P=0.497N	P=0.231N
POLY 6	P=0.185N	P=0.233N	P=0.500N	P=0.225N
COCH-ARM / FISHERS	P=0.188N	P=0.247N	P=0.500N	P=0.247N
MAX-ISO-POLY-3	P=0.078N	P=0.076N	P=0.279N	P=0.076N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Lung
 Hemorrhage

LESION RATES

OVERALL (a)	3/50 (6%)	3/50 (6%)	3/50 (6%)	3/50 (6%)
POLY-3 RATE (b)	3/47.69	3/48.50	3/48.68	3/49.86
POLY-3 PERCENT (g)	6.3%	6.2%	6.2%	6%
TERMINAL (d)	3/45 (7%)	3/46 (7%)	2/43 (5%)	3/49 (6%)
FIRST INCIDENCE	729 (T)	729 (T)	460	729 (T)

STATISTICAL TESTS

POLY 3	P=0.559N	P=0.654N	P=0.652N	P=0.641N
POLY 1.5	P=0.566N	P=0.656N	P=0.654N	P=0.648N
POLY 6	P=0.553N	P=0.654N	P=0.655N	P=0.635N
COCH-ARM / FISHERS	P=0.580	P=0.661N	P=0.661N	P=0.661N
MAX-ISO-POLY-3	P=0.724N	P=0.491N	P=0.489N	P=0.477N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung
 Infiltration Cellular Histiocyte**

LESION RATES

OVERALL (a)	6/50 (12%)	6/50 (12%)	4/50 (8%)	4/50 (8%)
POLY-3 RATE (b)	6/47.69	6/48.85	4/47.94	4/49.86
POLY-3 PERCENT (g)	12.6%	12.3%	8.3%	8%
TERMINAL (d)	6/45 (13%)	5/46 (11%)	4/43 (9%)	4/49 (8%)
FIRST INCIDENCE	729 (T)	633	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.244N	P=0.603N	P=0.367N	P=0.343N
POLY 1.5	P=0.250N	P=0.609N	P=0.366N	P=0.352N
POLY 6	P=0.239N	P=0.599N	P=0.373N	P=0.335N
COCH-ARM / FISHERS	P=0.262N	P=0.620N	P=0.370N	P=0.370N
MAX-ISO-POLY-3	P=0.381N	P=0.482N	P=0.252N	P=0.236N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung
 Infiltration Cellular Lymphocyte**

LESION RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/47.69	2/48.50	0/47.94	0/49.86
POLY-3 PERCENT (g)	2.1%	4.1%	0%	0%
TERMINAL (d)	1/45 (2%)	2/46 (4%)	0/43 (0%)	0/49 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---	---

STATISTICAL TESTS

POLY 3	P=0.183N	P=0.506	P=0.499N	P=0.491N
POLY 1.5	P=0.185N	P=0.504	P=0.499N	P=0.494N
POLY 6	P=0.182N	P=0.506	P=0.501N	P=0.489N
COCH-ARM / FISHERS	P=0.188N	P=0.500	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.176N	P=0.287	P=0.159N	P=0.159N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung
 Inflammation Chronic**

LESION RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/47.69	1/48.50	1/47.94	0/49.86
POLY-3 PERCENT (g)	0%	2.1%	2.1%	0%
TERMINAL (d)	0/45 (0%)	1/46 (2%)	1/43 (2%)	0/49 (0%)
FIRST INCIDENCE	---	729 (T)	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.582N	P=0.503	P=0.501	(e)
POLY 1.5	P=0.586N	P=0.502	P=0.501	(e)
POLY 6	P=0.579N	P=0.504	P=0.499	(e)
COCH-ARM / FISHERS	P=0.595N	P=0.500	P=0.500	(e)
MAX-ISO-POLY-3	P=0.410N	P=0.163	P=0.160	(e)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung: Alveolar Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	2/50 (4%)	7/50 (14%)	3/50 (6%)	5/50 (10%)
POLY-3 RATE (b)	2/47.69	7/48.50	3/47.94	5/49.86
POLY-3 PERCENT (g)	4.2%	14.4%	6.3%	10%
TERMINAL (d)	2/45 (4%)	7/46 (15%)	3/43 (7%)	5/49 (10%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.379	P=0.084	P=0.502	P=0.235
POLY 1.5	P=0.369	P=0.083	P=0.503	P=0.229
POLY 6	P=0.387	P=0.084	P=0.498	P=0.241
COCH-ARM / FISHERS	P=0.350	P=0.080	P=0.500	P=0.218
MAX-ISO-POLY-3	P=0.241	P=0.042*	P=0.327	P=0.138

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Lymph Node, Mandibular
 Ectasia

LESION RATES

OVERALL (a)	0/48 (0%)	0/45 (0%)	0/49 (0%)	0/47 (0%)
POLY-3 RATE (b)	0/45.69	0/43.85	0/46.94	0/46.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/43 (0%)	0/42 (0%)	0/42 (0%)	0/46 (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 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lymph Node, Mandibular
 Hyperplasia Lymphoid**

LESION RATES

OVERALL (a)	3/48 (6%)	2/45 (4%)	1/49 (2%)	1/47 (2%)
POLY-3 RATE (b)	3/45.69	2/43.85	1/46.94	1/46.86
POLY-3 PERCENT (g)	6.6%	4.6%	2.1%	2.1%
TERMINAL (d)	3/43 (7%)	2/42 (5%)	1/42 (2%)	1/46 (2%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.192N	P=0.519N	P=0.296N	P=0.297N
POLY 1.5	P=0.194N	P=0.522N	P=0.295N	P=0.302N
POLY 6	P=0.190N	P=0.516N	P=0.299N	P=0.292N
COCH-ARM / FISHERS	P=0.198N	P=0.531N	P=0.301N	P=0.316N
MAX-ISO-POLY-3	P=0.222N	P=0.341N	P=0.149N	P=0.152N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lymph Node, Mandibular
 Pigmentation**

LESION RATES

OVERALL (a)	0/48 (0%)	0/45 (0%)	1/49 (2%)	2/47 (4%)
POLY-3 RATE (b)	0/45.69	0/43.85	1/46.94	2/46.86
POLY-3 PERCENT (g)	0%	0%	2.1%	4.3%
TERMINAL (d)	0/43 (0%)	0/42 (0%)	1/42 (2%)	2/46 (4%)
FIRST INCIDENCE	---	---	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.075	(e)	P=0.505	P=0.243
POLY 1.5	P=0.073	(e)	P=0.506	P=0.240
POLY 6	P=0.076	(e)	P=0.503	P=0.246
COCH-ARM / FISHERS	P=0.070	(e)	P=0.505	P=0.242
MAX-ISO-POLY-3	P=0.087	(e)	P=0.164	P=0.082

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lymph Node, Mesenteric
 Atrophy**

LESION RATES

OVERALL (a)	1/47 (2%)	1/44 (2%)	0/48 (0%)	1/48 (2%)
POLY-3 RATE (b)	1/46.34	1/43.60	0/46.18	1/47.86
POLY-3 PERCENT (g)	2.2%	2.3%	0%	2.1%
TERMINAL (d)	1/44 (2%)	0/41 (0%)	0/42 (0%)	1/47 (2%)
FIRST INCIDENCE	729 (T)	437	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.604N	P=0.747	P=0.501N	P=0.753N
POLY 1.5	P=0.604N	P=0.746	P=0.499N	P=0.754N
POLY 6	P=0.604N	P=0.747	P=0.503N	P=0.752N
COCH-ARM / FISHERS	P=0.604N	P=0.736	P=0.495N	P=0.747N
MAX-ISO-POLY-3	P=0.525N	P=0.482	P=0.161N	P=0.490N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lymph Node, Mesenteric
 Hematopoietic Cell Proliferation**

LESION RATES

OVERALL (a)	2/47 (4%)	3/44 (7%)	2/48 (4%)	1/48 (2%)
POLY-3 RATE (b)	2/46.34	3/42.82	2/46.32	1/47.86
POLY-3 PERCENT (g)	4.3%	7%	4.3%	2.1%
TERMINAL (d)	2/44 (5%)	3/41 (7%)	1/42 (2%)	1/47 (2%)
FIRST INCIDENCE	729 (T)	729 (T)	693	729 (T)

STATISTICAL TESTS

POLY 3	P=0.294N	P=0.464	P=0.693	P=0.489N
POLY 1.5	P=0.295N	P=0.466	P=0.691N	P=0.490N
POLY 6	P=0.291N	P=0.463	P=0.690	P=0.486N
COCH-ARM / FISHERS	P=0.296N	P=0.468	P=0.684N	P=0.492N
MAX-ISO-POLY-3	P=0.331N	P=0.297	P=0.499	P=0.273N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Lymph Node, Mesenteric Hemorrhage

LESION RATES

OVERALL (a)	0/47 (0%)	3/44 (7%)	1/48 (2%)	1/48 (2%)
POLY-3 RATE (b)	0/46.34	3/42.82	1/46.18	1/47.86
POLY-3 PERCENT (g)	0%	7%	2.2%	2.1%
TERMINAL (d)	0/44 (0%)	3/41 (7%)	1/42 (2%)	1/47 (2%)
FIRST INCIDENCE	---	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.610	P=0.105	P=0.499	P=0.506
POLY 1.5	P=0.608	P=0.105	P=0.501	P=0.505
POLY 6	P=0.612	P=0.105	P=0.497	P=0.508
COCH-ARM / FISHERS	P=0.605	P=0.109	P=0.505	P=0.505
MAX-ISO-POLY-3	P=0.223	P=0.035*	P=0.160	P=0.165

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lymph Node, Mesenteric
 Hyperplasia Lymphoid**

LESION RATES

OVERALL (a)	2/47 (4%)	3/44 (7%)	4/48 (8%)	1/48 (2%)
POLY-3 RATE (b)	2/46.34	3/42.82	4/46.32	1/47.86
POLY-3 PERCENT (g)	4.3%	7%	8.6%	2.1%
TERMINAL (d)	2/44 (5%)	3/41 (7%)	3/42 (7%)	1/47 (2%)
FIRST INCIDENCE	729 (T)	729 (T)	693	729 (T)

STATISTICAL TESTS

POLY 3	P=0.344N	P=0.464	P=0.337	P=0.489N
POLY 1.5	P=0.347N	P=0.466	P=0.341	P=0.490N
POLY 6	P=0.340N	P=0.463	P=0.333	P=0.486N
COCH-ARM / FISHERS	P=0.351N	P=0.468	P=0.349	P=0.492N
MAX-ISO-POLY-3	P=0.270N	P=0.297	P=0.202	P=0.273N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Lymph Node: Iliac
 Hyperplasia Lymphoid

LESION RATES

OVERALL (a)	0/2 (0%)	0/1 (0%)	0/2 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/2.00	0/0.68	0/1.47	0/0.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/2 (0%)	0/0 (0%)	0/0 (0%)	0/0 (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 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Lymph Node: Renal
 Hyperplasia Lymphoid

LESION RATES

OVERALL (a)	0/2 (0%)	0/1 (0%)	0/2 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/2.00	0/0.68	0/1.47	0/0.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/2 (0%)	0/0 (0%)	0/0 (0%)	0/0 (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 - 04
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
Time Report Requested: 13:13:48
First Dose M/F: 03/25/03 / 03/25/03
Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Mammary Gland
Hyperplasia**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.69	0/48.50	0/47.94	0/49.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/45 (0%)	0/46 (0%)	0/43 (0%)	0/49 (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 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Mesentery: Fat
 Necrosis

LESION RATES

OVERALL (a)	1/2 (50%)	2/3 (67%)	2/3 (67%)	1/3 (33%)
POLY-3 RATE (b)	1/2.00	2/3.00	2/2.73	1/3.00
POLY-3 PERCENT (g)	50%	66.7%	73.2%	33.3%
TERMINAL (d)	1/2 (50%)	2/3 (67%)	2/2 (100%)	0/2 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	693

STATISTICAL TESTS

POLY 3	P=0.436N	P=0.670	P=0.646	P=0.670N
POLY 1.5	P=0.437N	P=0.670	P=0.658	P=0.670N
POLY 6	P=0.436N	P=0.670	P=0.621	P=0.670N
COCH-ARM / FISHERS	P=0.424N	P=0.700	P=0.700	P=0.700N
MAX-ISO-POLY-3	P=0.470N	P=0.393	P=0.340	P=0.393N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Nose
 Inflammation Chronic**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.69	0/48.50	0/47.94	0/49.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/45 (0%)	0/46 (0%)	0/43 (0%)	0/49 (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 - 04
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
Time Report Requested: 13:13:48
First Dose M/F: 03/25/03 / 03/25/03
Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pancreas
Atrophy**

LESION RATES

OVERALL (a)	0/49 (0%)	0/49 (0%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.81	0/47.82	0/47.18	0/49.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/45 (0%)	0/46 (0%)	0/43 (0%)	0/49 (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 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pancreas
 Cyst**

LESION RATES

OVERALL (a)	0/49 (0%)	0/49 (0%)	1/49 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/46.81	0/47.82	1/47.45	1/49.86
POLY-3 PERCENT (g)	0%	0%	2.1%	2%
TERMINAL (d)	0/45 (0%)	0/46 (0%)	0/43 (0%)	1/49 (2%)
FIRST INCIDENCE	---	---	657	729 (T)

STATISTICAL TESTS

POLY 3	P=0.251	(e)	P=0.503	P=0.513
POLY 1.5	P=0.248	(e)	P=0.502	P=0.510
POLY 6	P=0.254	(e)	P=0.502	P=0.515
COCH-ARM / FISHERS	P=0.240	(e)	P=0.500	P=0.505
MAX-ISO-POLY-3	P=0.270	(e)	P=0.162	P=0.173

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pancreas: Acinus
 Cytoplasmic Alteration**

LESION RATES

OVERALL (a)	1/49 (2%)	1/49 (2%)	2/49 (4%)	4/50 (8%)
POLY-3 RATE (b)	1/46.81	1/47.82	2/47.32	4/50.00
POLY-3 PERCENT (g)	2.1%	2.1%	4.2%	8%
TERMINAL (d)	1/45 (2%)	1/46 (2%)	1/43 (2%)	3/49 (6%)
FIRST INCIDENCE	729 (T)	729 (T)	693	693

STATISTICAL TESTS

POLY 3	P=0.082	P=0.756N	P=0.504	P=0.200
POLY 1.5	P=0.080	P=0.757N	P=0.503	P=0.195
POLY 6	P=0.084	P=0.755N	P=0.502	P=0.204
COCH-ARM / FISHERS	P=0.075	P=0.753N	P=0.500	P=0.187
MAX-ISO-POLY-3	P=0.125	P=0.493N	P=0.285	P=0.103

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Parathyroid Gland
 Cyst**

LESION RATES

OVERALL (a)	0/50 (0%)	2/50 (4%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/47.69	2/48.50	2/47.94	1/49.86
POLY-3 PERCENT (g)	0%	4.1%	4.2%	2%
TERMINAL (d)	0/45 (0%)	2/46 (4%)	2/43 (5%)	1/49 (2%)
FIRST INCIDENCE	---	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.494	P=0.241	P=0.238	P=0.509
POLY 1.5	P=0.486	P=0.240	P=0.239	P=0.506
POLY 6	P=0.501	P=0.241	P=0.236	P=0.511
COCH-ARM / FISHERS	P=0.469	P=0.247	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.240	P=0.080	P=0.077	P=0.170

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pituitary Gland: Pars Distalis
 Cyst**

LESION RATES

OVERALL (a)	2/48 (4%)	3/48 (6%)	2/47 (4%)	3/50 (6%)
POLY-3 RATE (b)	2/45.76	3/47.34	2/45.25	3/49.86
POLY-3 PERCENT (g)	4.4%	6.3%	4.4%	6%
TERMINAL (d)	2/44 (5%)	3/46 (7%)	2/42 (5%)	3/49 (6%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.496	P=0.515	P=0.690	P=0.539
POLY 1.5	P=0.489	P=0.511	P=0.689	P=0.532
POLY 6	P=0.501	P=0.518	P=0.687	P=0.544
COCH-ARM / FISHERS	P=0.476	P=0.500	P=0.684	P=0.520
MAX-ISO-POLY-3	P=0.575	P=0.340	P=0.495	P=0.364

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 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)	2/48 (4%)	0/48 (0%)	1/47 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/45.76	0/47.34	1/45.25	0/49.86
POLY-3 PERCENT (g)	4.4%	0%	2.2%	0%
TERMINAL (d)	2/44 (5%)	0/46 (0%)	1/42 (2%)	0/49 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.183N	P=0.230N	P=0.504N	P=0.219N
POLY 1.5	P=0.183N	P=0.232N	P=0.504N	P=0.222N
POLY 6	P=0.183N	P=0.229N	P=0.506N	P=0.216N
COCH-ARM / FISHERS	P=0.183N	P=0.247N	P=0.508N	P=0.237N
MAX-ISO-POLY-3	P=0.077N	P=0.076N	P=0.284N	P=0.074N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Preputial Gland
 Cyst**

LESION RATES

OVERALL (a)	19/50 (38%)	28/50 (56%)	26/50 (52%)	20/49 (41%)
POLY-3 RATE (b)	19/47.69	28/49.16	26/48.33	20/49.00
POLY-3 PERCENT (g)	39.8%	57%	53.8%	40.8%
TERMINAL (d)	19/45 (42%)	26/46 (57%)	24/43 (56%)	19/48 (40%)
FIRST INCIDENCE	729 (T)	633	638	693

STATISTICAL TESTS

POLY 3	P=0.383N	P=0.068	P=0.120	P=0.543
POLY 1.5	P=0.413N	P=0.062	P=0.120	P=0.517
POLY 6	P=0.357N	P=0.074	P=0.115	P=0.567
COCH-ARM / FISHERS	P=0.473N	P=0.054	P=0.114	P=0.468
MAX-ISO-POLY-3	P=0.241	P=0.047*	P=0.085	P=0.461

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Preputial Gland
 Inflammation Chronic**

LESION RATES

OVERALL (a)	12/50 (24%)	12/50 (24%)	17/50 (34%)	14/49 (29%)
POLY-3 RATE (b)	12/47.69	12/49.29	17/48.41	14/49.00
POLY-3 PERCENT (g)	25.2%	24.4%	35.1%	28.6%
TERMINAL (d)	12/45 (27%)	11/46 (24%)	15/43 (35%)	13/48 (27%)
FIRST INCIDENCE	729 (T)	437	638	693

STATISTICAL TESTS

POLY 3	P=0.329	P=0.556N	P=0.200	P=0.441
POLY 1.5	P=0.313	P=0.567N	P=0.199	P=0.423
POLY 6	P=0.347	P=0.551N	P=0.197	P=0.459
COCH-ARM / FISHERS	P=0.282	P=0.592N	P=0.189	P=0.387
MAX-ISO-POLY-3	P=0.364	P=0.463N	P=0.145	P=0.355

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Salivary Glands
 Atrophy**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/47.69	0/48.50	0/47.94	1/49.86
POLY-3 PERCENT (g)	0%	0%	0%	2%
TERMINAL (d)	0/45 (0%)	0/46 (0%)	0/43 (0%)	1/49 (2%)
FIRST INCIDENCE	---	---	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.204	(e)	(e)	P=0.509
POLY 1.5	P=0.202	(e)	(e)	P=0.506
POLY 6	P=0.206	(e)	(e)	P=0.511
COCH-ARM / FISHERS	P=0.198	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.139	(e)	(e)	P=0.170

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Salivary Glands
 Infiltration Cellular Lymphocyte**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/47.69	0/48.50	1/47.94	0/49.86
POLY-3 PERCENT (g)	0%	0%	2.1%	0%
TERMINAL (d)	0/45 (0%)	0/46 (0%)	1/43 (2%)	0/49 (0%)
FIRST INCIDENCE	---	---	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.711	(e)	P=0.501	(e)
POLY 1.5	P=0.705	(e)	P=0.501	(e)
POLY 6	P=0.716	(e)	P=0.499	(e)
COCH-ARM / FISHERS	P=0.694	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.396	(e)	P=0.160	(e)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Skin
 Edema

LESION RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/47.69	0/48.50	0/47.94	0/49.86
POLY-3 PERCENT (g)	2.1%	0%	0%	0%
TERMINAL (d)	1/45 (2%)	0/46 (0%)	0/43 (0%)	0/49 (0%)
FIRST INCIDENCE	729 (T)	---	---	---

STATISTICAL TESTS

POLY 3	P=0.312N	P=0.497N	P=0.499N	P=0.491N
POLY 1.5	P=0.310N	P=0.498N	P=0.499N	P=0.494N
POLY 6	P=0.313N	P=0.496N	P=0.501N	P=0.489N
COCH-ARM / FISHERS	P=0.306N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.124N	P=0.159N	P=0.159N	P=0.159N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Spleen
 Hematopoietic Cell Proliferation**

LESION RATES

OVERALL (a)	16/50 (32%)	11/50 (22%)	12/49 (24%)	4/50 (8%)
POLY-3 RATE (b)	16/49.15	11/48.90	12/48.11	4/49.86
POLY-3 PERCENT (g)	32.6%	22.5%	24.9%	8%
TERMINAL (d)	12/45 (27%)	9/46 (20%)	8/43 (19%)	4/49 (8%)
FIRST INCIDENCE	427	633	638	729 (T)

STATISTICAL TESTS

POLY 3	P=0.003N**	P=0.188N	P=0.274N	P=0.002N**
POLY 1.5	P=0.003N**	P=0.185N	P=0.272N	P=0.002N**
POLY 6	P=0.003N**	P=0.192N	P=0.278N	P=0.002N**
COCH-ARM / FISHERS	P=0.004N**	P=0.184N	P=0.272N	P=0.003N**
MAX-ISO-POLY-3	P=0.002N**	P=0.134N	P=0.207N	P<0.001N**

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Spleen: Lymphoid Follicle
 Atrophy**

LESION RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	0/49 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/48.54	1/48.50	0/47.18	2/49.86
POLY-3 PERCENT (g)	2.1%	2.1%	0%	4%
TERMINAL (d)	0/45 (0%)	1/46 (2%)	0/43 (0%)	2/49 (4%)
FIRST INCIDENCE	389	729 (T)	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.372	P=0.760	P=0.506N	P=0.509
POLY 1.5	P=0.370	P=0.760	P=0.505N	P=0.506
POLY 6	P=0.375	P=0.760	P=0.507N	P=0.513
COCH-ARM / FISHERS	P=0.366	P=0.753N	P=0.505N	P=0.500
MAX-ISO-POLY-3	P=0.295	P=0.499	P=0.164N	P=0.291

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Spleen: Lymphoid Follicle
 Hyperplasia**

LESION RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)	3/49 (6%)	2/50 (4%)
POLY-3 RATE (b)	2/47.69	0/48.50	3/47.18	2/49.86
POLY-3 PERCENT (g)	4.2%	0%	6.4%	4%
TERMINAL (d)	2/45 (4%)	0/46 (0%)	3/43 (7%)	2/49 (4%)
FIRST INCIDENCE	729 (T)	---	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.440	P=0.234N	P=0.495	P=0.677N
POLY 1.5	P=0.434	P=0.235N	P=0.495	P=0.683N
POLY 6	P=0.446	P=0.233N	P=0.492	P=0.673N
COCH-ARM / FISHERS	P=0.422	P=0.247N	P=0.490	P=0.691N
MAX-ISO-POLY-3	P=0.346	P=0.076N	P=0.320	P=0.481N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Stomach, Forestomach: Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/47.69	1/48.50	0/47.94	1/49.86
POLY-3 PERCENT (g)	0%	2.1%	0%	2%
TERMINAL (d)	0/45 (0%)	1/46 (2%)	0/43 (0%)	1/49 (2%)
FIRST INCIDENCE	---	729 (T)	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.418	P=0.503	(e)	P=0.509
POLY 1.5	P=0.414	P=0.502	(e)	P=0.506
POLY 6	P=0.421	P=0.504	(e)	P=0.511
COCH-ARM / FISHERS	P=0.405	P=0.500	(e)	P=0.500
MAX-ISO-POLY-3	P=0.273	P=0.163	(e)	P=0.170

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Stomach, Glandular
 Cyst**

LESION RATES

OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.81	0/48.50	0/47.94	0/49.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/45 (0%)	0/46 (0%)	0/43 (0%)	0/49 (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 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Stomach, Glandular
 Erosion**

LESION RATES

OVERALL (a)	2/49 (4%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	2/47.68	1/49.29	1/48.00	0/49.86
POLY-3 PERCENT (g)	4.2%	2%	2.1%	0%
TERMINAL (d)	0/45 (0%)	0/46 (0%)	0/43 (0%)	0/49 (0%)
FIRST INCIDENCE	427	437	712	---

STATISTICAL TESTS

POLY 3	P=0.149N	P=0.488N	P=0.498N	P=0.228N
POLY 1.5	P=0.150N	P=0.489N	P=0.495N	P=0.229N
POLY 6	P=0.148N	P=0.489N	P=0.503N	P=0.226N
COCH-ARM / FISHERS	P=0.150N	P=0.492N	P=0.492N	P=0.242N
MAX-ISO-POLY-3	P=0.119N	P=0.273N	P=0.279N	P=0.075N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Testes: Germinal Epithelium
 Atrophy

LESION RATES

OVERALL (a)	2/50 (4%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/47.69	1/48.50	0/47.94	1/49.86
POLY-3 PERCENT (g)	4.2%	2.1%	0%	2%
TERMINAL (d)	2/45 (4%)	1/46 (2%)	0/43 (0%)	1/49 (2%)
FIRST INCIDENCE	729 (T)	729 (T)	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.365N	P=0.494N	P=0.236N	P=0.485N
POLY 1.5	P=0.366N	P=0.496N	P=0.236N	P=0.490N
POLY 6	P=0.364N	P=0.494N	P=0.238N	P=0.480N
COCH-ARM / FISHERS	P=0.366N	P=0.500N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.227N	P=0.278N	P=0.076N	P=0.272N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Thymus
 Atrophy**

LESION RATES

OVERALL (a)	4/45 (9%)	5/46 (11%)	5/49 (10%)	1/40 (3%)
POLY-3 RATE (b)	4/45.00	5/46.00	5/47.92	1/40.00
POLY-3 PERCENT (g)	8.9%	10.9%	10.4%	2.5%
TERMINAL (d)	2/43 (5%)	1/42 (2%)	0/42 (0%)	0/39 (0%)
FIRST INCIDENCE	389	437	657	693

STATISTICAL TESTS

POLY 3	P=0.159N	P=0.514	P=0.539	P=0.216N
POLY 1.5	P=0.159N	P=0.514	P=0.544	P=0.216N
POLY 6	P=0.160N	P=0.514	P=0.534	P=0.216N
COCH-ARM / FISHERS	P=0.157N	P=0.514	P=0.555	P=0.219N
MAX-ISO-POLY-3	P=0.176N	P=0.376	P=0.400	P=0.112N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Thymus
 Cyst**

LESION RATES

OVERALL (a)	4/45 (9%)	2/46 (4%)	4/49 (8%)	6/40 (15%)
POLY-3 RATE (b)	4/43.35	2/44.50	4/46.94	6/39.86
POLY-3 PERCENT (g)	9.2%	4.5%	8.5%	15.1%
TERMINAL (d)	4/43 (9%)	2/42 (5%)	4/42 (10%)	6/39 (15%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.146	P=0.325N	P=0.599N	P=0.317
POLY 1.5	P=0.144	P=0.325N	P=0.595N	P=0.312
POLY 6	P=0.148	P=0.329N	P=0.609N	P=0.319
COCH-ARM / FISHERS	P=0.137	P=0.328N	P=0.594N	P=0.296
MAX-ISO-POLY-3	P=0.157	P=0.193N	P=0.453N	P=0.212

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

	Males			
DOSE	0 PPM	12500 PPM	25000 PPM	50000 PPM

Thymus
 Hyperplasia Lymphoid

LESION RATES

OVERALL (a)	0/45 (0%)	0/46 (0%)	0/49 (0%)	0/40 (0%)
POLY-3 RATE (b)	0/43.35	0/44.50	0/46.94	0/39.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/43 (0%)	0/42 (0%)	0/42 (0%)	0/39 (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 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Thyroid Gland: Follicle
 Degeneration Focal**

LESION RATES

OVERALL (a)	6/48 (13%)	11/49 (22%)	3/50 (6%)	6/50 (12%)
POLY-3 RATE (b)	6/46.66	11/48.60	3/47.94	6/50.00
POLY-3 PERCENT (g)	12.9%	22.6%	6.3%	12%
TERMINAL (d)	6/45 (13%)	10/46 (22%)	3/43 (7%)	5/49 (10%)
FIRST INCIDENCE	729 (T)	437	729 (T)	693

STATISTICAL TESTS

POLY 3	P=0.266N	P=0.165	P=0.229N	P=0.571N
POLY 1.5	P=0.271N	P=0.161	P=0.226N	P=0.578N
POLY 6	P=0.261N	P=0.167	P=0.236N	P=0.564N
COCH-ARM / FISHERS	P=0.282N	P=0.154	P=0.223N	P=0.591N
MAX-ISO-POLY-3	P=0.175N	P=0.110	P=0.138N	P=0.449N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Thyroid Gland: Follicular Cell
 Hyperplasia**

LESION RATES

OVERALL (a)	0/48 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/46.66	0/47.82	0/47.94	0/49.86
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/45 (0%)	0/46 (0%)	0/43 (0%)	0/49 (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 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Urinary Bladder
 Calculus Gross Observation**

LESION RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/47.69	0/48.50	0/47.18	0/49.86
POLY-3 PERCENT (g)	4.2%	0%	0%	0%
TERMINAL (d)	2/45 (4%)	0/46 (0%)	0/43 (0%)	0/49 (0%)
FIRST INCIDENCE	729 (T)	---	---	---

STATISTICAL TESTS

POLY 3	P=0.117N	P=0.234N	P=0.240N	P=0.228N
POLY 1.5	P=0.116N	P=0.235N	P=0.240N	P=0.231N
POLY 6	P=0.117N	P=0.233N	P=0.241N	P=0.225N
COCH-ARM / FISHERS	P=0.116N	P=0.247N	P=0.253N	P=0.247N
MAX-ISO-POLY-3	P=0.033N*	P=0.076N	P=0.077N	P=0.076N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Urinary Bladder
 Infiltration Cellular Lymphocyte**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	1/49 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/47.69	0/48.50	1/47.18	0/49.86
POLY-3 PERCENT (g)	0%	0%	2.1%	0%
TERMINAL (d)	0/45 (0%)	0/46 (0%)	1/43 (2%)	0/49 (0%)
FIRST INCIDENCE	---	---	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.710	(e)	P=0.498	(e)
POLY 1.5	P=0.704	(e)	P=0.498	(e)
POLY 6	P=0.715	(e)	P=0.497	(e)
COCH-ARM / FISHERS	P=0.694	(e)	P=0.495	(e)
MAX-ISO-POLY-3	P=0.394	(e)	P=0.157	(e)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 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)	5/50 (10%)	6/50 (12%)	7/50 (14%)	7/50 (14%)
POLY-3 RATE (b)	5/47.01	6/47.07	7/47.98	7/48.25
POLY-3 PERCENT (g)	10.6%	12.8%	14.6%	14.5%
TERMINAL (d)	5/40 (13%)	5/43 (12%)	7/42 (17%)	6/45 (13%)
FIRST INCIDENCE	729 (T)	649	729 (T)	721

STATISTICAL TESTS

POLY 3	P=0.342	P=0.501	P=0.394	P=0.398
POLY 1.5	P=0.329	P=0.496	P=0.389	P=0.386
POLY 6	P=0.358	P=0.515	P=0.398	P=0.416
COCH-ARM / FISHERS	P=0.319	P=0.500	P=0.380	P=0.380
MAX-ISO-POLY-3	P=0.289	P=0.374	P=0.284	P=0.288

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Adrenal Cortex
 Hyperplasia Focal**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.01	0/46.78	0/47.98	0/48.22
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/40 (0%)	0/43 (0%)	0/42 (0%)	0/45 (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 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Adrenal Cortex
 Hypertrophy Focal**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/47.01	0/46.78	0/47.98	2/48.22
POLY-3 PERCENT (g)	0%	0%	0%	4.2%
TERMINAL (d)	0/40 (0%)	0/43 (0%)	0/42 (0%)	2/45 (4%)
FIRST INCIDENCE	---	---	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.047*	(e)	(e)	P=0.243
POLY 1.5	P=0.046*	(e)	(e)	P=0.239
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=0.024*	(e)	(e)	P=0.081

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Adrenal Cortex: Capsule
 Hyperplasia**

LESION RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/47.01	0/46.78	0/47.98	0/48.22
POLY-3 PERCENT (g)	4.3%	0%	0%	0%
TERMINAL (d)	2/40 (5%)	0/43 (0%)	0/42 (0%)	0/45 (0%)
FIRST INCIDENCE	729 (T)	---	---	---

STATISTICAL TESTS

POLY 3	P=0.113N	P=0.238N	P=0.233N	P=0.232N
POLY 1.5	P=0.113N	P=0.239N	P=0.235N	P=0.235N
POLY 6	P=0.115N	P=0.235N	P=0.231N	P=0.226N
COCH-ARM / FISHERS	P=0.115N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.021N*	P=0.076N	P=0.075N	P=0.075N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Adrenal Medulla
 Hyperplasia**

LESION RATES

OVERALL (a)	2/49 (4%)	3/49 (6%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/46.56	3/45.78	0/47.98	1/48.22
POLY-3 PERCENT (g)	4.3%	6.6%	0%	2.1%
TERMINAL (d)	2/40 (5%)	3/42 (7%)	0/42 (0%)	1/45 (2%)
FIRST INCIDENCE	729 (T)	729 (T)	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.232N	P=0.492	P=0.231N	P=0.488N
POLY 1.5	P=0.234N	P=0.493	P=0.231N	P=0.492N
POLY 6	P=0.229N	P=0.497	P=0.230N	P=0.481N
COCH-ARM / FISHERS	P=0.235N	P=0.500	P=0.242N	P=0.492N
MAX-ISO-POLY-3	P=0.114N	P=0.317	P=0.074N	P=0.272N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Bone Marrow
 Hyperplasia**

LESION RATES

OVERALL (a)	19/50 (38%)	21/50 (42%)	24/50 (48%)	18/50 (36%)
POLY-3 RATE (b)	19/48.60	21/49.13	24/49.23	18/48.99
POLY-3 PERCENT (g)	39.1%	42.7%	48.8%	36.7%
TERMINAL (d)	12/40 (30%)	15/43 (35%)	18/42 (43%)	15/45 (33%)
FIRST INCIDENCE	549	406	659	632

STATISTICAL TESTS

POLY 3	P=0.431N	P=0.436	P=0.224	P=0.488N
POLY 1.5	P=0.445N	P=0.425	P=0.219	P=0.502N
POLY 6	P=0.411N	P=0.457	P=0.230	P=0.467N
COCH-ARM / FISHERS	P=0.442N	P=0.419	P=0.210	P=0.500N
MAX-ISO-POLY-3	P=0.249N	P=0.356	P=0.170	P=0.404N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Bone
 Fibro-osseous Lesion**

LESION RATES

OVERALL (a)	8/50 (16%)	15/50 (30%)	19/50 (38%)	17/50 (34%)
POLY-3 RATE (b)	8/47.01	15/46.78	19/48.75	17/48.38
POLY-3 PERCENT (g)	17%	32.1%	39%	35.1%
TERMINAL (d)	8/40 (20%)	15/43 (35%)	17/42 (41%)	16/45 (36%)
FIRST INCIDENCE	729 (T)	729 (T)	602	688

STATISTICAL TESTS

POLY 3	P=0.049*	P=0.071	P=0.013*	P=0.035*
POLY 1.5	P=0.042*	P=0.071	P=0.012*	P=0.032*
POLY 6	P=0.059	P=0.076	P=0.015*	P=0.042*
COCH-ARM / FISHERS	P=0.040*	P=0.077	P=0.012*	P=0.032*
MAX-ISO-POLY-3	P=0.017*	P=0.044*	P=0.008**	P=0.022*

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Clitoral Gland
 Inflammation Chronic**

LESION RATES

OVERALL (a)	0/47 (0%)	3/47 (6%)	0/49 (0%)	2/47 (4%)
POLY-3 RATE (b)	0/44.01	3/44.00	0/46.98	2/46.20
POLY-3 PERCENT (g)	0%	6.8%	0%	4.3%
TERMINAL (d)	0/37 (0%)	1/40 (3%)	0/41 (0%)	2/43 (5%)
FIRST INCIDENCE	---	675	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.369	P=0.118	(e)	P=0.248
POLY 1.5	P=0.361	P=0.117	(e)	P=0.244
POLY 6	P=0.379	P=0.122	(e)	P=0.254
COCH-ARM / FISHERS	P=0.352	P=0.121	(e)	P=0.247
MAX-ISO-POLY-3	P=0.107	P=0.038*	(e)	P=0.086

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Eye
 Inflammation Chronic**

LESION RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/47.01	0/46.78	2/47.98	0/48.22
POLY-3 PERCENT (g)	2.1%	0%	4.2%	0%
TERMINAL (d)	1/40 (3%)	0/43 (0%)	2/42 (5%)	0/45 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.452N	P=0.501N	P=0.507	P=0.495N
POLY 1.5	P=0.456N	P=0.502N	P=0.504	P=0.498N
POLY 6	P=0.446N	P=0.498N	P=0.509	P=0.490N
COCH-ARM / FISHERS	P=0.461N	P=0.500N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.204N	P=0.159N	P=0.288	P=0.158N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Eye: Cornea
 Hyperplasia

LESION RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	1/47.01	0/46.78	2/47.98	0/48.22
POLY-3 PERCENT (g)	2.1%	0%	4.2%	0%
TERMINAL (d)	1/40 (3%)	0/43 (0%)	2/42 (5%)	0/45 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.452N	P=0.501N	P=0.507	P=0.495N
POLY 1.5	P=0.456N	P=0.502N	P=0.504	P=0.498N
POLY 6	P=0.446N	P=0.498N	P=0.509	P=0.490N
COCH-ARM / FISHERS	P=0.461N	P=0.500N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.204N	P=0.159N	P=0.288	P=0.158N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Harderian Gland
 Hyperplasia Focal**

LESION RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.01	1/46.78	0/47.98	0/48.22
POLY-3 PERCENT (g)	0%	2.1%	0%	0%
TERMINAL (d)	0/40 (0%)	1/43 (2%)	0/42 (0%)	0/45 (0%)
FIRST INCIDENCE	---	729 (T)	---	---

STATISTICAL TESTS

POLY 3	P=0.565N	P=0.499	(e)	(e)
POLY 1.5	P=0.567N	P=0.498	(e)	(e)
POLY 6	P=0.562N	P=0.502	(e)	(e)
COCH-ARM / FISHERS	P=0.567N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.239N	P=0.158	(e)	(e)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Heart
 Cardiomyopathy**

LESION RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.01	1/46.80	0/47.98	0/48.22
POLY-3 PERCENT (g)	0%	2.1%	0%	0%
TERMINAL (d)	0/40 (0%)	0/43 (0%)	0/42 (0%)	0/45 (0%)
FIRST INCIDENCE	---	725	---	---

STATISTICAL TESTS

POLY 3	P=0.565N	P=0.499	(e)	(e)
POLY 1.5	P=0.567N	P=0.498	(e)	(e)
POLY 6	P=0.562N	P=0.502	(e)	(e)
COCH-ARM / FISHERS	P=0.567N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.239N	P=0.158	(e)	(e)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Heart
 Mineralization**

LESION RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/47.37	2/47.02	0/47.98	0/48.22
POLY-3 PERCENT (g)	2.1%	4.3%	0%	0%
TERMINAL (d)	0/40 (0%)	1/43 (2%)	0/42 (0%)	0/45 (0%)
FIRST INCIDENCE	629	664	---	---

STATISTICAL TESTS

POLY 3	P=0.186N	P=0.497	P=0.497N	P=0.496N
POLY 1.5	P=0.188N	P=0.496	P=0.498N	P=0.499N
POLY 6	P=0.183N	P=0.502	P=0.497N	P=0.493N
COCH-ARM / FISHERS	P=0.188N	P=0.500	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.107N	P=0.279	P=0.158N	P=0.158N

TDMS No. 20008 - 04
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
Time Report Requested: 13:13:48
First Dose M/F: 03/25/03 / 03/25/03
Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Heart
Thrombosis**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.01	0/46.78	0/47.98	0/48.22
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/40 (0%)	0/43 (0%)	0/42 (0%)	0/45 (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 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney
 Cyst**

LESION RATES

OVERALL (a)	0/50 (0%)	1/49 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/47.01	1/45.78	1/47.98	1/48.22
POLY-3 PERCENT (g)	0%	2.2%	2.1%	2.1%
TERMINAL (d)	0/40 (0%)	1/42 (2%)	1/42 (2%)	1/45 (2%)
FIRST INCIDENCE	---	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.397	P=0.495	P=0.504	P=0.505
POLY 1.5	P=0.391	P=0.494	P=0.503	P=0.502
POLY 6	P=0.406	P=0.498	P=0.505	P=0.510
COCH-ARM / FISHERS	P=0.386	P=0.495	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.208	P=0.157	P=0.163	P=0.164

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney
 Infarct**

LESION RATES

OVERALL (a)	2/50 (4%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/47.01	0/45.78	0/47.98	0/48.22
POLY-3 PERCENT (g)	4.3%	0%	0%	0%
TERMINAL (d)	2/40 (5%)	0/42 (0%)	0/42 (0%)	0/45 (0%)
FIRST INCIDENCE	729 (T)	---	---	---

STATISTICAL TESTS

POLY 3	P=0.113N	P=0.243N	P=0.233N	P=0.232N
POLY 1.5	P=0.112N	P=0.244N	P=0.235N	P=0.235N
POLY 6	P=0.114N	P=0.240N	P=0.231N	P=0.226N
COCH-ARM / FISHERS	P=0.115N	P=0.253N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.022N*	P=0.080N	P=0.075N	P=0.075N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney
 Infiltration Cellular Lymphocyte**

LESION RATES

OVERALL (a)	4/50 (8%)	2/49 (4%)	2/50 (4%)	11/50 (22%)
POLY-3 RATE (b)	4/47.11	2/45.78	2/47.98	11/48.22
POLY-3 PERCENT (g)	8.5%	4.4%	4.2%	22.8%
TERMINAL (d)	3/40 (8%)	2/42 (5%)	2/42 (5%)	11/45 (24%)
FIRST INCIDENCE	705	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.005**	P=0.351N	P=0.329N	P=0.049*
POLY 1.5	P=0.005**	P=0.352N	P=0.332N	P=0.046*
POLY 6	P=0.005**	P=0.345N	P=0.327N	P=0.054
COCH-ARM / FISHERS	P=0.005**	P=0.349N	P=0.339N	P=0.045*
MAX-ISO-POLY-3	P=0.002**	P=0.212N	P=0.196N	P=0.027*

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney
 Metaplasia Osseous**

LESION RATES

OVERALL (a)	4/50 (8%)	0/49 (0%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	4/47.11	0/45.78	0/47.98	3/48.22
POLY-3 PERCENT (g)	8.5%	0%	0%	6.2%
TERMINAL (d)	3/40 (8%)	0/42 (0%)	0/42 (0%)	3/45 (7%)
FIRST INCIDENCE	705	---	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.570N	P=0.064N	P=0.058N	P=0.487N
POLY 1.5	P=0.571N	P=0.065N	P=0.059N	P=0.496N
POLY 6	P=0.572N	P=0.062N	P=0.057N	P=0.475N
COCH-ARM / FISHERS	P=0.575N	P=0.061N	P=0.059N	P=0.500N
MAX-ISO-POLY-3	P=0.050N*	P=0.021N*	P=0.019N*	P=0.336N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney
 Nephropathy**

LESION RATES

OVERALL (a)	10/50 (20%)	7/49 (14%)	13/50 (26%)	10/50 (20%)
POLY-3 RATE (b)	10/48.15	7/46.28	13/48.81	10/48.25
POLY-3 PERCENT (g)	20.8%	15.1%	26.6%	20.7%
TERMINAL (d)	6/40 (15%)	5/42 (12%)	10/42 (24%)	9/45 (20%)
FIRST INCIDENCE	549	649	637	721

STATISTICAL TESTS

POLY 3	P=0.424	P=0.329N	P=0.331	P=0.596N
POLY 1.5	P=0.416	P=0.328N	P=0.326	P=0.594
POLY 6	P=0.433	P=0.321N	P=0.335	P=0.586N
COCH-ARM / FISHERS	P=0.413	P=0.314N	P=0.318	P=0.598N
MAX-ISO-POLY-3	P=0.246	P=0.242N	P=0.251	P=0.496N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 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)	2/50 (4%)	1/49 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/47.11	1/46.07	0/47.98	1/48.48
POLY-3 PERCENT (g)	4.3%	2.2%	0%	2.1%
TERMINAL (d)	0/40 (0%)	0/42 (0%)	0/42 (0%)	0/45 (0%)
FIRST INCIDENCE	705	649	---	659

STATISTICAL TESTS

POLY 3	P=0.362N	P=0.508N	P=0.233N	P=0.490N
POLY 1.5	P=0.363N	P=0.510N	P=0.235N	P=0.496N
POLY 6	P=0.361N	P=0.502N	P=0.232N	P=0.481N
COCH-ARM / FISHERS	P=0.365N	P=0.508N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.141N	P=0.288N	P=0.075N	P=0.274N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney: Renal Tubule
 Hyperplasia**

LESION RATES

OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.01	0/45.78	0/47.98	0/48.22
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/40 (0%)	0/42 (0%)	0/42 (0%)	0/45 (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 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Kidney: Renal Tubule
 Necrosis**

LESION RATES

OVERALL (a)	0/50 (0%)	2/49 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.01	2/46.28	0/47.98	0/48.22
POLY-3 PERCENT (g)	0%	4.3%	0%	0%
TERMINAL (d)	0/40 (0%)	0/42 (0%)	0/42 (0%)	0/45 (0%)
FIRST INCIDENCE	---	649	---	---

STATISTICAL TESTS

POLY 3	P=0.397N	P=0.234	(e)	(e)
POLY 1.5	P=0.402N	P=0.232	(e)	(e)
POLY 6	P=0.390N	P=0.239	(e)	(e)
COCH-ARM / FISHERS	P=0.404N	P=0.242	(e)	(e)
MAX-ISO-POLY-3	P=0.154N	P=0.074	(e)	(e)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 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%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/47.01	2/46.99	0/47.98	0/48.22
POLY-3 PERCENT (g)	2.1%	4.3%	0%	0%
TERMINAL (d)	1/40 (3%)	1/43 (2%)	0/42 (0%)	0/45 (0%)
FIRST INCIDENCE	729 (T)	675	---	---

STATISTICAL TESTS

POLY 3	P=0.185N	P=0.500	P=0.496N	P=0.495N
POLY 1.5	P=0.187N	P=0.498	P=0.497N	P=0.498N
POLY 6	P=0.181N	P=0.506	P=0.495N	P=0.490N
COCH-ARM / FISHERS	P=0.188N	P=0.500	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.107N	P=0.280	P=0.158N	P=0.158N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Clear Cell Focus

LESION RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/47.01	1/46.78	1/47.98	1/48.22
POLY-3 PERCENT (g)	0%	2.1%	2.1%	2.1%
TERMINAL (d)	0/40 (0%)	1/43 (2%)	1/42 (2%)	1/45 (2%)
FIRST INCIDENCE	---	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.395	P=0.499	P=0.504	P=0.505
POLY 1.5	P=0.389	P=0.498	P=0.503	P=0.502
POLY 6	P=0.404	P=0.502	P=0.505	P=0.510
COCH-ARM / FISHERS	P=0.384	P=0.500	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.209	P=0.158	P=0.163	P=0.164

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Eosinophilic Focus

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.01	0/46.78	0/47.98	0/48.22
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/40 (0%)	0/43 (0%)	0/42 (0%)	0/45 (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 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Liver
 Hematopoietic Cell Proliferation**

LESION RATES

OVERALL (a)	1/50 (2%)	4/50 (8%)	1/50 (2%)	6/50 (12%)
POLY-3 RATE (b)	1/47.01	4/47.79	1/48.23	6/48.86
POLY-3 PERCENT (g)	2.1%	8.4%	2.1%	12.3%
TERMINAL (d)	1/40 (3%)	2/43 (5%)	0/42 (0%)	3/45 (7%)
FIRST INCIDENCE	729 (T)	450	661	632

STATISTICAL TESTS

POLY 3	P=0.058	P=0.184	P=0.755N	P=0.063
POLY 1.5	P=0.055	P=0.181	P=0.757N	P=0.059
POLY 6	P=0.062	P=0.191	P=0.752N	P=0.069
COCH-ARM / FISHERS	P=0.054	P=0.181	P=0.753N	P=0.056
MAX-ISO-POLY-3	P=0.021*	P=0.088	P=0.491N	P=0.029*

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Infiltration Cellular Lymphocyte

LESION RATES

OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/47.01	2/46.78	1/47.98	0/48.22
POLY-3 PERCENT (g)	0%	4.3%	2.1%	0%
TERMINAL (d)	0/40 (0%)	2/43 (5%)	1/42 (2%)	0/45 (0%)
FIRST INCIDENCE	---	729 (T)	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.452N	P=0.236	P=0.504	(e)
POLY 1.5	P=0.458N	P=0.235	P=0.503	(e)
POLY 6	P=0.443N	P=0.239	P=0.505	(e)
COCH-ARM / FISHERS	P=0.461N	P=0.247	P=0.500	(e)
MAX-ISO-POLY-3	P=0.204N	P=0.075	P=0.163	(e)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Infiltration Cellular Mixed Cell

LESION RATES

OVERALL (a)	0/50 (0%)	3/50 (6%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/47.01	3/46.78	2/47.98	0/48.22
POLY-3 PERCENT (g)	0%	6.4%	4.2%	0%
TERMINAL (d)	0/40 (0%)	3/43 (7%)	2/42 (5%)	0/45 (0%)
FIRST INCIDENCE	---	729 (T)	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.396N	P=0.118	P=0.242	(e)
POLY 1.5	P=0.405N	P=0.117	P=0.240	(e)
POLY 6	P=0.384N	P=0.121	P=0.243	(e)
COCH-ARM / FISHERS	P=0.409N	P=0.121	P=0.247	(e)
MAX-ISO-POLY-3	P=0.142N	P=0.038*	P=0.080	(e)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver
 Mixed Cell Focus

LESION RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/47.01	1/46.78	1/47.98	0/48.22
POLY-3 PERCENT (g)	2.1%	2.1%	2.1%	0%
TERMINAL (d)	1/40 (3%)	1/43 (2%)	1/42 (2%)	0/45 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.306N	P=0.759	P=0.756N	P=0.495N
POLY 1.5	P=0.310N	P=0.758	P=0.758N	P=0.498N
POLY 6	P=0.302N	P=0.758N	P=0.755N	P=0.490N
COCH-ARM / FISHERS	P=0.311N	P=0.753N	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.206N	P=0.497	P=0.493N	P=0.158N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 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%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	3/47.37	1/46.78	0/47.98	0/48.22
POLY-3 PERCENT (g)	6.3%	2.1%	0%	0%
TERMINAL (d)	2/40 (5%)	1/43 (2%)	0/42 (0%)	0/45 (0%)
FIRST INCIDENCE	629	729 (T)	---	---

STATISTICAL TESTS

POLY 3	P=0.042N*	P=0.310N	P=0.117N	P=0.116N
POLY 1.5	P=0.042N*	P=0.310N	P=0.117N	P=0.118N
POLY 6	P=0.042N*	P=0.306N	P=0.116N	P=0.112N
COCH-ARM / FISHERS	P=0.044N*	P=0.309N	P=0.121N	P=0.121N
MAX-ISO-POLY-3	P=0.015N*	P=0.159N	P=0.038N*	P=0.038N*

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver: Centrilobular
 Necrosis

LESION RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/47.02	1/46.99	0/47.98	1/48.57
POLY-3 PERCENT (g)	2.1%	2.1%	0%	2.1%
TERMINAL (d)	0/40 (0%)	0/43 (0%)	0/42 (0%)	0/45 (0%)
FIRST INCIDENCE	728	675	---	632

STATISTICAL TESTS

POLY 3	P=0.612N	P=0.760	P=0.496N	P=0.753N
POLY 1.5	P=0.613N	P=0.759	P=0.497N	P=0.758N
POLY 6	P=0.610N	P=0.757N	P=0.495N	P=0.747N
COCH-ARM / FISHERS	P=0.616N	P=0.753N	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.335N	P=0.498	P=0.158N	P=0.489N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Liver: Hepatocyte
 Vacuolization Cytoplasmic

LESION RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	1/47.56	1/46.99	3/48.42	0/48.22
POLY-3 PERCENT (g)	2.1%	2.1%	6.2%	0%
TERMINAL (d)	0/40 (0%)	0/43 (0%)	2/42 (5%)	0/45 (0%)
FIRST INCIDENCE	560	675	602	---

STATISTICAL TESTS

POLY 3	P=0.401N	P=0.758	P=0.312	P=0.497N
POLY 1.5	P=0.406N	P=0.757	P=0.310	P=0.500N
POLY 6	P=0.394N	P=0.760N	P=0.314	P=0.494N
COCH-ARM / FISHERS	P=0.409N	P=0.753N	P=0.309	P=0.500N
MAX-ISO-POLY-3	P=0.142N	P=0.495	P=0.161	P=0.158N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Lung
 Foreign Body

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.01	0/46.78	0/47.98	0/48.22
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/40 (0%)	0/43 (0%)	0/42 (0%)	0/45 (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 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung
 Hemorrhage**

LESION RATES

OVERALL (a)	2/50 (4%)	4/50 (8%)	2/50 (4%)	7/50 (14%)
POLY-3 RATE (b)	2/47.01	4/46.78	2/48.31	7/49.20
POLY-3 PERCENT (g)	4.3%	8.6%	4.1%	14.2%
TERMINAL (d)	2/40 (5%)	4/43 (9%)	1/42 (2%)	6/45 (13%)
FIRST INCIDENCE	729 (T)	729 (T)	637	196

STATISTICAL TESTS

POLY 3	P=0.064	P=0.335	P=0.684N	P=0.091
POLY 1.5	P=0.060	P=0.333	P=0.688N	P=0.086
POLY 6	P=0.067	P=0.342	P=0.680N	P=0.097
COCH-ARM / FISHERS	P=0.056	P=0.339	P=0.691N	P=0.080
MAX-ISO-POLY-3	P=0.037*	P=0.199	P=0.487N	P=0.049*

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung
 Infiltration Cellular Histiocyte**

LESION RATES

OVERALL (a)	1/50 (2%)	4/50 (8%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/47.01	4/47.54	1/48.24	1/48.22
POLY-3 PERCENT (g)	2.1%	8.4%	2.1%	2.1%
TERMINAL (d)	1/40 (3%)	3/43 (7%)	0/42 (0%)	1/45 (2%)
FIRST INCIDENCE	729 (T)	450	659	729 (T)

STATISTICAL TESTS

POLY 3	P=0.361N	P=0.182	P=0.755N	P=0.755N
POLY 1.5	P=0.368N	P=0.180	P=0.757N	P=0.758N
POLY 6	P=0.351N	P=0.188	P=0.752N	P=0.749N
COCH-ARM / FISHERS	P=0.373N	P=0.181	P=0.753N	P=0.753N
MAX-ISO-POLY-3	P=0.204N	P=0.086	P=0.491N	P=0.491N

TDMS No. 20008 - 04
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
Time Report Requested: 13:13:48
First Dose M/F: 03/25/03 / 03/25/03
Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung
Infiltration Cellular Lymphocyte**

LESION RATES

OVERALL (a)	3/50 (6%)	1/50 (2%)	6/50 (12%)	5/50 (10%)
POLY-3 RATE (b)	3/47.18	1/46.78	6/47.98	5/48.22
POLY-3 PERCENT (g)	6.4%	2.1%	12.5%	10.4%
TERMINAL (d)	2/40 (5%)	1/43 (2%)	6/42 (14%)	5/45 (11%)
FIRST INCIDENCE	685	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.159	P=0.309N	P=0.251	P=0.369
POLY 1.5	P=0.153	P=0.309N	P=0.248	P=0.361
POLY 6	P=0.166	P=0.304N	P=0.252	P=0.380
COCH-ARM / FISHERS	P=0.148	P=0.309N	P=0.243	P=0.357
MAX-ISO-POLY-3	P=0.098	P=0.157N	P=0.155	P=0.243

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung
 Inflammation Chronic**

LESION RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/47.11	0/46.78	0/47.98	0/48.22
POLY-3 PERCENT (g)	4.3%	0%	0%	0%
TERMINAL (d)	1/40 (3%)	0/43 (0%)	0/42 (0%)	0/45 (0%)
FIRST INCIDENCE	705	---	---	---

STATISTICAL TESTS

POLY 3	P=0.113N	P=0.239N	P=0.233N	P=0.232N
POLY 1.5	P=0.113N	P=0.240N	P=0.235N	P=0.236N
POLY 6	P=0.115N	P=0.236N	P=0.232N	P=0.227N
COCH-ARM / FISHERS	P=0.115N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.021N*	P=0.077N	P=0.075N	P=0.075N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lung: Alveolar Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	1/50 (2%)	3/50 (6%)	3/50 (6%)	1/50 (2%)
POLY-3 RATE (b)	1/47.01	3/46.78	3/47.98	1/48.22
POLY-3 PERCENT (g)	2.1%	6.4%	6.3%	2.1%
TERMINAL (d)	1/40 (3%)	3/43 (7%)	3/42 (7%)	1/45 (2%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.485N	P=0.304	P=0.313	P=0.755N
POLY 1.5	P=0.494N	P=0.302	P=0.310	P=0.758N
POLY 6	P=0.473N	P=0.309	P=0.315	P=0.749N
COCH-ARM / FISHERS	P=0.500N	P=0.309	P=0.309	P=0.753N
MAX-ISO-POLY-3	P=0.246N	P=0.153	P=0.161	P=0.491N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lymph Node, Mandibular
 Ectasia**

LESION RATES

OVERALL (a)	2/48 (4%)	0/49 (0%)	0/46 (0%)	0/47 (0%)
POLY-3 RATE (b)	2/45.61	0/45.78	0/44.69	0/45.99
POLY-3 PERCENT (g)	4.4%	0%	0%	0%
TERMINAL (d)	2/40 (5%)	0/42 (0%)	0/41 (0%)	0/45 (0%)
FIRST INCIDENCE	729 (T)	---	---	---

STATISTICAL TESTS

POLY 3	P=0.115N	P=0.236N	P=0.242N	P=0.235N
POLY 1.5	P=0.115N	P=0.236N	P=0.244N	P=0.240N
POLY 6	P=0.117N	P=0.234N	P=0.239N	P=0.229N
COCH-ARM / FISHERS	P=0.118N	P=0.242N	P=0.258N	P=0.253N
MAX-ISO-POLY-3	P=0.022N*	P=0.076N	P=0.078N	P=0.076N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lymph Node, Mandibular
 Hyperplasia Lymphoid**

LESION RATES

OVERALL (a)	4/48 (8%)	3/49 (6%)	1/46 (2%)	3/47 (6%)
POLY-3 RATE (b)	4/45.61	3/45.78	1/44.69	3/46.02
POLY-3 PERCENT (g)	8.8%	6.6%	2.2%	6.5%
TERMINAL (d)	4/40 (10%)	3/42 (7%)	1/41 (2%)	2/45 (4%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	721

STATISTICAL TESTS

POLY 3	P=0.399N	P=0.498N	P=0.185N	P=0.495N
POLY 1.5	P=0.406N	P=0.497N	P=0.188N	P=0.506N
POLY 6	P=0.390N	P=0.493N	P=0.181N	P=0.478N
COCH-ARM / FISHERS	P=0.413N	P=0.488N	P=0.194N	P=0.512N
MAX-ISO-POLY-3	P=0.193N	P=0.344N	P=0.087N	P=0.343N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lymph Node, Mandibular
 Pigmentation**

LESION RATES

OVERALL (a)	2/48 (4%)	4/49 (8%)	1/46 (2%)	7/47 (15%)
POLY-3 RATE (b)	2/45.61	4/46.02	1/44.69	7/45.99
POLY-3 PERCENT (g)	4.4%	8.7%	2.2%	15.2%
TERMINAL (d)	2/40 (5%)	3/42 (7%)	1/41 (2%)	7/45 (16%)
FIRST INCIDENCE	729 (T)	664	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.053	P=0.341	P=0.507N	P=0.081
POLY 1.5	P=0.051	P=0.341	P=0.510N	P=0.076
POLY 6	P=0.057	P=0.348	P=0.503N	P=0.088
COCH-ARM / FISHERS	P=0.050*	P=0.349	P=0.516N	P=0.074
MAX-ISO-POLY-3	P=0.025*	P=0.203	P=0.286N	P=0.041*

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lymph Node, Mesenteric
 Atrophy**

LESION RATES

OVERALL (a)	2/49 (4%)	0/47 (0%)	1/49 (2%)	2/50 (4%)
POLY-3 RATE (b)	2/47.00	0/44.85	1/47.24	2/48.51
POLY-3 PERCENT (g)	4.3%	0%	2.1%	4.1%
TERMINAL (d)	0/40 (0%)	0/42 (0%)	0/41 (0%)	0/45 (0%)
FIRST INCIDENCE	560	---	659	659

STATISTICAL TESTS

POLY 3	P=0.486	P=0.248N	P=0.498N	P=0.682N
POLY 1.5	P=0.483	P=0.248N	P=0.499N	P=0.686N
POLY 6	P=0.489	P=0.245N	P=0.499N	P=0.676N
COCH-ARM / FISHERS	P=0.481	P=0.258N	P=0.500N	P=0.684N
MAX-ISO-POLY-3	P=0.262N	P=0.083N	P=0.279N	P=0.485N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lymph Node, Mesenteric
 Hematopoietic Cell Proliferation**

LESION RATES

OVERALL (a)	2/49 (4%)	2/47 (4%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/46.06	2/44.85	0/46.98	0/48.22
POLY-3 PERCENT (g)	4.3%	4.5%	0%	0%
TERMINAL (d)	2/40 (5%)	2/42 (5%)	0/41 (0%)	0/45 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	---	---

STATISTICAL TESTS

POLY 3	P=0.081N	P=0.684	P=0.233N	P=0.227N
POLY 1.5	P=0.082N	P=0.680	P=0.235N	P=0.231N
POLY 6	P=0.080N	P=0.692	P=0.232N	P=0.222N
COCH-ARM / FISHERS	P=0.083N	P=0.676	P=0.247N	P=0.242N
MAX-ISO-POLY-3	P=0.073N	P=0.488	P=0.075N	P=0.074N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Lymph Node, Mesenteric Hemorrhage

LESION RATES

OVERALL (a)	1/49 (2%)	0/47 (0%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/46.06	0/44.85	0/46.98	0/48.22
POLY-3 PERCENT (g)	2.2%	0%	0%	0%
TERMINAL (d)	1/40 (3%)	0/42 (0%)	0/41 (0%)	0/45 (0%)
FIRST INCIDENCE	729 (T)	---	---	---

STATISTICAL TESTS

POLY 3	P=0.306N	P=0.505N	P=0.496N	P=0.491N
POLY 1.5	P=0.303N	P=0.507N	P=0.498N	P=0.494N
POLY 6	P=0.310N	P=0.501N	P=0.495N	P=0.486N
COCH-ARM / FISHERS	P=0.302N	P=0.510N	P=0.500N	P=0.495N
MAX-ISO-POLY-3	P=0.078N	P=0.162N	P=0.158N	P=0.157N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Lymph Node, Mesenteric
 Hyperplasia Lymphoid**

LESION RATES

OVERALL (a)	3/49 (6%)	5/47 (11%)	2/49 (4%)	1/50 (2%)
POLY-3 RATE (b)	3/46.06	5/44.85	2/46.98	1/48.22
POLY-3 PERCENT (g)	6.5%	11.2%	4.3%	2.1%
TERMINAL (d)	3/40 (8%)	5/42 (12%)	2/41 (5%)	1/45 (2%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.120N	P=0.342	P=0.491N	P=0.289N
POLY 1.5	P=0.125N	P=0.336	P=0.494N	P=0.295N
POLY 6	P=0.114N	P=0.353	P=0.489N	P=0.281N
COCH-ARM / FISHERS	P=0.128N	P=0.334	P=0.500N	P=0.301N
MAX-ISO-POLY-3	P=0.086N	P=0.219	P=0.316N	P=0.147N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Lymph Node: Iliac
 Hyperplasia Lymphoid

LESION RATES

OVERALL (a)	0/10 (0%)	1/4 (25%)	3/6 (50%)	1/4 (25%)
POLY-3 RATE (b)	0/8.84	1/3.71	3/5.84	1/4.00
POLY-3 PERCENT (g)	0%	27%	51.4%	25%
TERMINAL (d)	0/6 (0%)	1/3 (33%)	3/5 (60%)	1/4 (25%)
FIRST INCIDENCE	---	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.154	P=0.313	P=0.019*	P=0.328
POLY 1.5	P=0.132	P=0.310	P=0.017*	P=0.318
POLY 6	P=0.191	P=0.317	P=0.023*	P=0.345
COCH-ARM / FISHERS	P=0.121	P=0.286	P=0.036*	P=0.286
MAX-ISO-POLY-3	P=0.067	P=0.076	P=0.004**	P=0.078

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Lymph Node: Renal
 Hyperplasia Lymphoid

LESION RATES

OVERALL (a)	0/10 (0%)	1/4 (25%)	3/6 (50%)	0/4 (0%)
POLY-3 RATE (b)	0/8.84	1/3.71	3/5.84	0/4.00
POLY-3 PERCENT (g)	0%	27%	51.4%	0%
TERMINAL (d)	0/6 (0%)	1/3 (33%)	3/5 (60%)	0/4 (0%)
FIRST INCIDENCE	---	729 (T)	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.482	P=0.313	P=0.019*	(e)
POLY 1.5	P=0.439	P=0.310	P=0.017*	(e)
POLY 6	P=0.549	P=0.317	P=0.023*	(e)
COCH-ARM / FISHERS	P=0.399	P=0.286	P=0.036*	(e)
MAX-ISO-POLY-3	P=0.096	P=0.076	P=0.004**	(e)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Mammary Gland
 Hyperplasia**

LESION RATES

OVERALL (a)	5/50 (10%)	5/50 (10%)	5/50 (10%)	4/50 (8%)
POLY-3 RATE (b)	5/48.34	5/47.33	5/48.47	4/48.64
POLY-3 PERCENT (g)	10.3%	10.6%	10.3%	8.2%
TERMINAL (d)	1/40 (3%)	2/43 (5%)	2/42 (5%)	2/45 (4%)
FIRST INCIDENCE	549	649	674	659

STATISTICAL TESTS

POLY 3	P=0.411N	P=0.617	P=0.628N	P=0.496N
POLY 1.5	P=0.417N	P=0.618	P=0.628N	P=0.502N
POLY 6	P=0.403N	P=0.622	P=0.629N	P=0.487N
COCH-ARM / FISHERS	P=0.419N	P=0.630N	P=0.630N	P=0.500N
MAX-ISO-POLY-3	P=0.355N	P=0.484	P=0.497N	P=0.358N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Mesentery: Fat
 Necrosis

LESION RATES

OVERALL (a)	3/5 (60%)	2/2 (100%)	0/1 (0%)	3/3 (100%)
POLY-3 RATE (b)	3/4.07	2/2.00	0/1.00	3/3.00
POLY-3 PERCENT (g)	73.7%	100%	0%	100%
TERMINAL (d)	2/2 (100%)	2/2 (100%)	0/1 (0%)	3/3 (100%)
FIRST INCIDENCE	685	729 (T)	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.438	P=0.655	P=0.401N	P=0.548
POLY 1.5	P=0.348	P=0.542	P=0.453N	P=0.429
POLY 6	P=0.650	P=0.890	P=0.291N	P=0.831
COCH-ARM / FISHERS	P=0.290	P=0.476	P=0.500N	P=0.357
MAX-ISO-POLY-3	P=0.087	P=0.195	P=0.095N	P=0.121

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Nose
 Inflammation Chronic**

LESION RATES

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/47.01	2/46.78	0/47.98	1/48.22
POLY-3 PERCENT (g)	0%	4.3%	0%	2.1%
TERMINAL (d)	0/40 (0%)	2/43 (5%)	0/42 (0%)	1/45 (2%)
FIRST INCIDENCE	---	729 (T)	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.548	P=0.236	(e)	P=0.505
POLY 1.5	P=0.542	P=0.235	(e)	P=0.502
POLY 6	P=0.557	P=0.239	(e)	P=0.510
COCH-ARM / FISHERS	P=0.539	P=0.247	(e)	P=0.500
MAX-ISO-POLY-3	P=0.208	P=0.075	(e)	P=0.164

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Ovary
 Angiectasis**

LESION RATES

OVERALL (a)	1/46 (2%)	3/50 (6%)	3/48 (6%)	4/49 (8%)
POLY-3 RATE (b)	1/43.50	3/46.78	3/46.35	4/47.22
POLY-3 PERCENT (g)	2.3%	6.4%	6.5%	8.5%
TERMINAL (d)	1/38 (3%)	3/43 (7%)	3/42 (7%)	4/44 (9%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.181	P=0.332	P=0.328	P=0.205
POLY 1.5	P=0.176	P=0.331	P=0.326	P=0.200
POLY 6	P=0.188	P=0.335	P=0.331	P=0.211
COCH-ARM / FISHERS	P=0.171	P=0.341	P=0.325	P=0.201
MAX-ISO-POLY-3	P=0.114	P=0.176	P=0.175	P=0.104

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Ovary
 Cyst**

LESION RATES

OVERALL (a)	16/46 (35%)	10/50 (20%)	19/48 (40%)	19/49 (39%)
POLY-3 RATE (b)	16/44.05	10/47.02	19/46.35	19/47.38
POLY-3 PERCENT (g)	36.3%	21.3%	41%	40.1%
TERMINAL (d)	15/38 (40%)	9/43 (21%)	19/42 (45%)	18/44 (41%)
FIRST INCIDENCE	560	664	729 (T)	688

STATISTICAL TESTS

POLY 3	P=0.173	P=0.086N	P=0.405	P=0.438
POLY 1.5	P=0.164	P=0.086N	P=0.402	P=0.424
POLY 6	P=0.185	P=0.081N	P=0.406	P=0.462
COCH-ARM / FISHERS	P=0.160	P=0.081N	P=0.395	P=0.425
MAX-ISO-POLY-3	P=0.115	P=0.056N	P=0.325	P=0.356

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Ovary
 Hemorrhage**

LESION RATES

OVERALL (a)	8/46 (17%)	12/50 (24%)	10/48 (21%)	10/49 (20%)
POLY-3 RATE (b)	8/43.50	12/46.80	10/46.35	10/47.22
POLY-3 PERCENT (g)	18.4%	25.6%	21.6%	21.2%
TERMINAL (d)	7/38 (18%)	11/43 (26%)	10/42 (24%)	10/44 (23%)
FIRST INCIDENCE	728	725	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.521	P=0.283	P=0.455	P=0.473
POLY 1.5	P=0.505	P=0.282	P=0.448	P=0.460
POLY 6	P=0.541	P=0.291	P=0.461	P=0.491
COCH-ARM / FISHERS	P=0.494	P=0.294	P=0.436	P=0.456
MAX-ISO-POLY-3	P=0.309	P=0.207	P=0.354	P=0.371

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Ovary: Interstitial Cell
 Hyperplasia**

LESION RATES

OVERALL (a)	0/46 (0%)	1/50 (2%)	1/48 (2%)	2/49 (4%)
POLY-3 RATE (b)	0/43.50	1/46.78	1/46.35	2/47.22
POLY-3 PERCENT (g)	0%	2.1%	2.2%	4.2%
TERMINAL (d)	0/38 (0%)	1/43 (2%)	1/42 (2%)	2/44 (5%)
FIRST INCIDENCE	---	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.166	P=0.515	P=0.513	P=0.256
POLY 1.5	P=0.162	P=0.514	P=0.511	P=0.253
POLY 6	P=0.170	P=0.517	P=0.514	P=0.260
COCH-ARM / FISHERS	P=0.159	P=0.521	P=0.511	P=0.263
MAX-ISO-POLY-3	P=0.089	P=0.171	P=0.172	P=0.090

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pancreas
 Atrophy**

LESION RATES

OVERALL (a)	2/49 (4%)	1/48 (2%)	1/49 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/46.32	1/45.81	1/47.22	1/48.22
POLY-3 PERCENT (g)	4.3%	2.2%	2.1%	2.1%
TERMINAL (d)	2/40 (5%)	0/42 (0%)	1/42 (2%)	1/45 (2%)
FIRST INCIDENCE	729 (T)	675	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.397N	P=0.504N	P=0.493N	P=0.486N
POLY 1.5	P=0.400N	P=0.507N	P=0.496N	P=0.491N
POLY 6	P=0.395N	P=0.498N	P=0.491N	P=0.479N
COCH-ARM / FISHERS	P=0.401N	P=0.508N	P=0.500N	P=0.492N
MAX-ISO-POLY-3	P=0.254N	P=0.283N	P=0.276N	P=0.271N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pancreas
 Cyst**

LESION RATES

OVERALL (a)	2/49 (4%)	0/48 (0%)	1/49 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/46.32	0/45.61	1/47.22	1/48.22
POLY-3 PERCENT (g)	4.3%	0%	2.1%	2.1%
TERMINAL (d)	2/40 (5%)	0/42 (0%)	1/42 (2%)	1/45 (2%)
FIRST INCIDENCE	729 (T)	---	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.489N	P=0.241N	P=0.493N	P=0.486N
POLY 1.5	P=0.490N	P=0.242N	P=0.496N	P=0.491N
POLY 6	P=0.488N	P=0.238N	P=0.491N	P=0.479N
COCH-ARM / FISHERS	P=0.492N	P=0.253N	P=0.500N	P=0.492N
MAX-ISO-POLY-3	P=0.170N	P=0.078N	P=0.276N	P=0.271N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pancreas: Acinus
 Cytoplasmic Alteration**

LESION RATES

OVERALL (a)	2/49 (4%)	3/48 (6%)	1/49 (2%)	2/50 (4%)
POLY-3 RATE (b)	2/47.26	3/46.47	1/47.22	2/48.64
POLY-3 PERCENT (g)	4.2%	6.5%	2.1%	4.1%
TERMINAL (d)	0/40 (0%)	2/42 (5%)	1/42 (2%)	0/45 (0%)
FIRST INCIDENCE	560	371	729 (T)	659

STATISTICAL TESTS

POLY 3	P=0.486N	P=0.492	P=0.500N	P=0.683N
POLY 1.5	P=0.489N	P=0.491	P=0.500N	P=0.687N
POLY 6	P=0.481N	P=0.495	P=0.502N	P=0.678N
COCH-ARM / FISHERS	P=0.488N	P=0.490	P=0.500N	P=0.684N
MAX-ISO-POLY-3	P=0.297N	P=0.316	P=0.281N	P=0.487N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Parathyroid Gland
 Cyst**

LESION RATES

OVERALL (a)	1/48 (2%)	1/48 (2%)	0/48 (0%)	1/48 (2%)
POLY-3 RATE (b)	1/45.37	1/45.02	0/46.22	1/46.22
POLY-3 PERCENT (g)	2.2%	2.2%	0%	2.2%
TERMINAL (d)	1/39 (3%)	1/42 (2%)	0/41 (0%)	1/43 (2%)
FIRST INCIDENCE	729 (T)	729 (T)	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.612N	P=0.759	P=0.496N	P=0.756N
POLY 1.5	P=0.614N	P=0.758	P=0.498N	P=0.759N
POLY 6	P=0.611N	P=0.759N	P=0.495N	P=0.752N
COCH-ARM / FISHERS	P=0.616N	P=0.753N	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.335N	P=0.496	P=0.158N	P=0.493N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Pituitary Gland: Pars Distalis
 Cyst**

LESION RATES

OVERALL (a)	0/49 (0%)	3/49 (6%)	2/48 (4%)	0/48 (0%)
POLY-3 RATE (b)	0/46.37	3/45.78	2/46.22	0/46.22
POLY-3 PERCENT (g)	0%	6.6%	4.3%	0%
TERMINAL (d)	0/40 (0%)	3/42 (7%)	2/41 (5%)	0/43 (0%)
FIRST INCIDENCE	---	729 (T)	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.408N	P=0.116	P=0.236	(e)
POLY 1.5	P=0.415N	P=0.116	P=0.235	(e)
POLY 6	P=0.398N	P=0.118	P=0.237	(e)
COCH-ARM / FISHERS	P=0.417N	P=0.121	P=0.242	(e)
MAX-ISO-POLY-3	P=0.141	P=0.038*	P=0.076	(e)

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
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 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 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)	5/49 (10%)	1/49 (2%)	1/48 (2%)	5/48 (10%)
POLY-3 RATE (b)	5/46.37	1/45.78	1/46.22	5/46.22
POLY-3 PERCENT (g)	10.8%	2.2%	2.2%	10.8%
TERMINAL (d)	5/40 (13%)	1/42 (2%)	1/41 (2%)	5/43 (12%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.418	P=0.104N	P=0.102N	P=0.628
POLY 1.5	P=0.413	P=0.105N	P=0.104N	P=0.619
POLY 6	P=0.422	P=0.102N	P=0.101N	P=0.620N
COCH-ARM / FISHERS	P=0.408	P=0.102N	P=0.107N	P=0.617
MAX-ISO-POLY-3	P=0.129	P=0.047N*	P=0.046N*	P=0.496

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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 MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Salivary Glands
 Atrophy**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/47.01	0/46.78	0/47.22	2/48.38
POLY-3 PERCENT (g)	0%	0%	0%	4.1%
TERMINAL (d)	0/40 (0%)	0/43 (0%)	0/42 (0%)	1/45 (2%)
FIRST INCIDENCE	---	---	---	688

STATISTICAL TESTS

POLY 3	P=0.047*	(e)	(e)	P=0.244
POLY 1.5	P=0.046*	(e)	(e)	P=0.240
POLY 6	P=0.048*	(e)	(e)	P=0.250
COCH-ARM / FISHERS	P=0.047*	(e)	(e)	P=0.247
MAX-ISO-POLY-3	P=0.025*	(e)	(e)	P=0.081

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

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 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Salivary Glands
 Infiltration Cellular Lymphocyte**

LESION RATES

OVERALL (a)	7/50 (14%)	8/50 (16%)	8/49 (16%)	4/50 (8%)
POLY-3 RATE (b)	7/47.06	8/46.78	8/47.22	4/48.38
POLY-3 PERCENT (g)	14.9%	17.1%	16.9%	8.3%
TERMINAL (d)	6/40 (15%)	8/43 (19%)	8/42 (19%)	3/45 (7%)
FIRST INCIDENCE	717	729 (T)	729 (T)	688

STATISTICAL TESTS

POLY 3	P=0.173N	P=0.495	P=0.503	P=0.246N
POLY 1.5	P=0.184N	P=0.492	P=0.495	P=0.256N
POLY 6	P=0.159N	P=0.507	P=0.510	P=0.231N
COCH-ARM / FISHERS	P=0.193N	P=0.500	P=0.483	P=0.262N
MAX-ISO-POLY-3	P=0.133N	P=0.383	P=0.391	P=0.160N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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 MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Skin
 Edema

LESION RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/47.51	0/46.78	1/47.98	1/48.57
POLY-3 PERCENT (g)	4.2%	0%	2.1%	2.1%
TERMINAL (d)	0/40 (0%)	0/43 (0%)	1/42 (2%)	0/45 (0%)
FIRST INCIDENCE	582	---	729 (T)	632

STATISTICAL TESTS

POLY 3	P=0.493N	P=0.241N	P=0.497N	P=0.492N
POLY 1.5	P=0.496N	P=0.241N	P=0.498N	P=0.498N
POLY 6	P=0.491N	P=0.239N	P=0.496N	P=0.484N
COCH-ARM / FISHERS	P=0.500N	P=0.247N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.171N	P=0.079N	P=0.278N	P=0.276N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
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 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Spleen
 Hematopoietic Cell Proliferation**

LESION RATES

OVERALL (a)	20/50 (40%)	17/48 (35%)	17/49 (35%)	11/50 (22%)
POLY-3 RATE (b)	20/47.16	17/46.84	17/47.51	11/49.02
POLY-3 PERCENT (g)	42.4%	36.3%	35.8%	22.4%
TERMINAL (d)	17/40 (43%)	13/42 (31%)	15/42 (36%)	7/45 (16%)
FIRST INCIDENCE	705	450	688	632

STATISTICAL TESTS

POLY 3	P=0.023N*	P=0.347N	P=0.326N	P=0.028N*
POLY 1.5	P=0.028N*	P=0.373N	P=0.343N	P=0.035N*
POLY 6	P=0.018N*	P=0.308N	P=0.308N	P=0.021N*
COCH-ARM / FISHERS	P=0.032N*	P=0.398N	P=0.368N	P=0.041N*
MAX-ISO-POLY-3	P=0.021N*	P=0.274N	P=0.256N	P=0.018N*

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Spleen: Lymphoid Follicle
 Atrophy**

LESION RATES

OVERALL (a)	1/50 (2%)	0/48 (0%)	1/49 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/47.59	0/45.61	1/47.48	0/48.22
POLY-3 PERCENT (g)	2.1%	0%	2.1%	0%
TERMINAL (d)	0/40 (0%)	0/42 (0%)	0/42 (0%)	0/45 (0%)
FIRST INCIDENCE	549	---	659	---

STATISTICAL TESTS

POLY 3	P=0.401N	P=0.508N	P=0.760	P=0.497N
POLY 1.5	P=0.403N	P=0.509N	P=0.758	P=0.500N
POLY 6	P=0.400N	P=0.506N	P=0.759N	P=0.494N
COCH-ARM / FISHERS	P=0.403N	P=0.510N	P=0.747	P=0.500N
MAX-ISO-POLY-3	P=0.160N	P=0.166N	P=0.498	P=0.158N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Spleen: Lymphoid Follicle
 Hyperplasia**

LESION RATES

OVERALL (a)	6/50 (12%)	9/48 (19%)	8/49 (16%)	6/50 (12%)
POLY-3 RATE (b)	6/47.11	9/45.61	8/47.22	6/48.22
POLY-3 PERCENT (g)	12.7%	19.7%	16.9%	12.4%
TERMINAL (d)	5/40 (13%)	9/42 (21%)	8/42 (19%)	6/45 (13%)
FIRST INCIDENCE	705	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.427N	P=0.264	P=0.389	P=0.604N
POLY 1.5	P=0.442N	P=0.259	P=0.382	P=0.615N
POLY 6	P=0.409N	P=0.275	P=0.394	P=0.588N
COCH-ARM / FISHERS	P=0.450N	P=0.259	P=0.371	P=0.620N
MAX-ISO-POLY-3	P=0.297N	P=0.182	P=0.285	P=0.481N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Stomach, Forestomach: Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	2/50 (4%)	2/50 (4%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	2/47.54	2/46.78	3/47.98	0/48.22
POLY-3 PERCENT (g)	4.2%	4.3%	6.3%	0%
TERMINAL (d)	0/40 (0%)	2/43 (5%)	3/42 (7%)	0/45 (0%)
FIRST INCIDENCE	629	729 (T)	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.193N	P=0.688	P=0.504	P=0.234N
POLY 1.5	P=0.197N	P=0.688	P=0.503	P=0.237N
POLY 6	P=0.188N	P=0.690	P=0.503	P=0.231N
COCH-ARM / FISHERS	P=0.199N	P=0.691N	P=0.500	P=0.247N
MAX-ISO-POLY-3	P=0.101N	P=0.492	P=0.327	P=0.075N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Stomach, Glandular
 Cyst**

LESION RATES

OVERALL (a)	4/50 (8%)	4/48 (8%)	2/50 (4%)	4/50 (8%)
POLY-3 RATE (b)	4/47.01	4/45.61	2/47.98	4/48.22
POLY-3 PERCENT (g)	8.5%	8.8%	4.2%	8.3%
TERMINAL (d)	4/40 (10%)	4/42 (10%)	2/42 (5%)	4/45 (9%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.518N	P=0.626	P=0.328N	P=0.629N
POLY 1.5	P=0.524N	P=0.621	P=0.332N	P=0.638N
POLY 6	P=0.509N	P=0.636	P=0.325N	P=0.616N
COCH-ARM / FISHERS	P=0.529N	P=0.619	P=0.339N	P=0.643N
MAX-ISO-POLY-3	P=0.329N	P=0.480	P=0.195N	P=0.483N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Stomach, Glandular
 Erosion**

LESION RATES

OVERALL (a)	2/50 (4%)	1/48 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/47.19	1/45.81	0/47.98	1/48.57
POLY-3 PERCENT (g)	4.2%	2.2%	0%	2.1%
TERMINAL (d)	0/40 (0%)	0/42 (0%)	0/42 (0%)	0/45 (0%)
FIRST INCIDENCE	685	675	---	632

STATISTICAL TESTS

POLY 3	P=0.361N	P=0.510N	P=0.234N	P=0.490N
POLY 1.5	P=0.362N	P=0.513N	P=0.235N	P=0.496N
POLY 6	P=0.361N	P=0.504N	P=0.233N	P=0.481N
COCH-ARM / FISHERS	P=0.363N	P=0.515N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.142N	P=0.289N	P=0.075N	P=0.274N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
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 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Thymus
 Atrophy**

LESION RATES

OVERALL (a)	6/49 (12%)	1/47 (2%)	5/46 (11%)	3/49 (6%)
POLY-3 RATE (b)	6/48.03	1/44.23	5/45.20	3/47.86
POLY-3 PERCENT (g)	12.5%	2.3%	11.1%	6.3%
TERMINAL (d)	0/40 (0%)	0/41 (0%)	3/41 (7%)	0/44 (0%)
FIRST INCIDENCE	560	675	602	632

STATISTICAL TESTS

POLY 3	P=0.328N	P=0.071N	P=0.542N	P=0.245N
POLY 1.5	P=0.333N	P=0.069N	P=0.543N	P=0.247N
POLY 6	P=0.322N	P=0.071N	P=0.542N	P=0.240N
COCH-ARM / FISHERS	P=0.339N	P=0.062N	P=0.545N	P=0.243N
MAX-ISO-POLY-3	P=0.130N	P=0.035N*	P=0.414N	P=0.149N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

Thymus
 Cyst

LESION RATES

OVERALL (a)	0/49 (0%)	0/47 (0%)	0/46 (0%)	0/49 (0%)
POLY-3 RATE (b)	0/46.59	0/44.02	0/44.61	0/47.22
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/40 (0%)	0/41 (0%)	0/41 (0%)	0/44 (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 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Thymus
 Hyperplasia Lymphoid**

LESION RATES

OVERALL (a)	9/49 (18%)	5/47 (11%)	6/46 (13%)	0/49 (0%)
POLY-3 RATE (b)	9/46.59	5/44.02	6/44.86	0/47.22
POLY-3 PERCENT (g)	19.3%	11.4%	13.4%	0%
TERMINAL (d)	9/40 (23%)	5/41 (12%)	5/41 (12%)	0/44 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	661	---

STATISTICAL TESTS

POLY 3	P=0.003N**	P=0.225N	P=0.315N	P=0.002N**
POLY 1.5	P=0.003N**	P=0.226N	P=0.323N	P=0.002N**
POLY 6	P=0.002N**	P=0.217N	P=0.303N	P<0.001N**
COCH-ARM / FISHERS	P=0.003N**	P=0.217N	P=0.335N	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.151N	P=0.223N	P<0.001N**

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Thyroid Gland: Follicle
 Degeneration Focal**

LESION RATES

OVERALL (a)	25/50 (50%)	19/48 (40%)	20/49 (41%)	13/50 (26%)
POLY-3 RATE (b)	25/48.45	19/46.87	20/47.61	13/48.57
POLY-3 PERCENT (g)	51.6%	40.5%	42%	26.8%
TERMINAL (d)	21/40 (53%)	16/42 (38%)	18/42 (43%)	12/45 (27%)
FIRST INCIDENCE	549	450	659	632

STATISTICAL TESTS

POLY 3	P=0.010N**	P=0.190N	P=0.230N	P=0.009N**
POLY 1.5	P=0.011N*	P=0.199N	P=0.233N	P=0.010N**
POLY 6	P=0.009N**	P=0.171N	P=0.227N	P=0.008N**
COCH-ARM / FISHERS	P=0.011N*	P=0.202N	P=0.237N	P=0.011N*
MAX-ISO-POLY-3	P=0.006N**	P=0.140N	P=0.173N	P=0.005N**

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Thyroid Gland: Follicular Cell
 Hyperplasia**

LESION RATES

OVERALL (a)	0/50 (0%)	0/48 (0%)	0/49 (0%)	3/50 (6%)
POLY-3 RATE (b)	0/47.01	0/45.61	0/47.22	3/48.22
POLY-3 PERCENT (g)	0%	0%	0%	6.2%
TERMINAL (d)	0/40 (0%)	0/42 (0%)	0/42 (0%)	3/45 (7%)
FIRST INCIDENCE	---	---	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.012*	(e)	(e)	P=0.124
POLY 1.5	P=0.012*	(e)	(e)	P=0.121
POLY 6	P=0.012*	(e)	(e)	P=0.128
COCH-ARM / FISHERS	P=0.013*	(e)	(e)	P=0.121
MAX-ISO-POLY-3	P=0.008**	(e)	(e)	P=0.042*

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 09/30/2008
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 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Urinary Bladder
 Calculus Gross Observation**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/47.01	0/46.78	0/47.98	0/48.22
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/40 (0%)	0/43 (0%)	0/42 (0%)	0/45 (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 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Urinary Bladder
 Infiltration Cellular Lymphocyte**

LESION RATES

OVERALL (a)	2/50 (4%)	3/50 (6%)	5/50 (10%)	3/50 (6%)
POLY-3 RATE (b)	2/47.01	3/46.78	5/47.98	3/48.25
POLY-3 PERCENT (g)	4.3%	6.4%	10.4%	6.2%
TERMINAL (d)	2/40 (5%)	3/43 (7%)	5/42 (12%)	2/45 (4%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	721

STATISTICAL TESTS

POLY 3	P=0.425	P=0.498	P=0.225	P=0.512
POLY 1.5	P=0.413	P=0.496	P=0.222	P=0.504
POLY 6	P=0.441	P=0.505	P=0.227	P=0.523
COCH-ARM / FISHERS	P=0.404	P=0.500	P=0.218	P=0.500
MAX-ISO-POLY-3	P=0.220	P=0.321	P=0.127	P=0.335

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Uterus
 Angiectasis**

LESION RATES

OVERALL (a)	1/50 (2%)	3/50 (6%)	0/50 (0%)	6/50 (12%)
POLY-3 RATE (b)	1/47.01	3/46.99	0/47.98	6/48.38
POLY-3 PERCENT (g)	2.1%	6.4%	0%	12.4%
TERMINAL (d)	1/40 (3%)	2/43 (5%)	0/42 (0%)	5/45 (11%)
FIRST INCIDENCE	729 (T)	675	---	688

STATISTICAL TESTS

POLY 3	P=0.031*	P=0.305	P=0.496N	P=0.061
POLY 1.5	P=0.030*	P=0.303	P=0.497N	P=0.058
POLY 6	P=0.033*	P=0.312	P=0.495N	P=0.066
COCH-ARM / FISHERS	P=0.031*	P=0.309	P=0.500N	P=0.056
MAX-ISO-POLY-3	P=0.012*	P=0.154	P=0.158N	P=0.027*

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Uterus
 Hyperplasia Cystic**

LESION RATES

OVERALL (a)	47/50 (94%)	46/50 (92%)	46/50 (92%)	44/50 (88%)
POLY-3 RATE (b)	47/49.12	46/49.24	46/49.51	44/48.38
POLY-3 PERCENT (g)	95.7%	93.4%	92.9%	91%
TERMINAL (d)	39/40 (98%)	40/43 (93%)	41/42 (98%)	43/45 (96%)
FIRST INCIDENCE	549	371	602	688

STATISTICAL TESTS

POLY 3	P=0.226N	P=0.479N	P=0.432N	P=0.285N
POLY 1.5	P=0.231N	P=0.501N	P=0.460N	P=0.293N
POLY 6	P=0.221N	P=0.421N	P=0.408N	P=0.265N
COCH-ARM / FISHERS	P=0.184N	P=0.500N	P=0.500N	P=0.243N
MAX-ISO-POLY-3	P=0.166N	P=0.300N	P=0.262N	P=0.159N

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Milk thistle extract
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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Uterus
 Inflammation Chronic**

LESION RATES

OVERALL (a)	0/50 (0%)	2/50 (4%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/47.01	2/46.78	2/47.98	1/48.22
POLY-3 PERCENT (g)	0%	4.3%	4.2%	2.1%
TERMINAL (d)	0/40 (0%)	2/43 (5%)	2/42 (5%)	1/45 (2%)
FIRST INCIDENCE	---	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.484	P=0.236	P=0.242	P=0.505
POLY 1.5	P=0.475	P=0.235	P=0.240	P=0.502
POLY 6	P=0.497	P=0.239	P=0.243	P=0.510
COCH-ARM / FISHERS	P=0.469	P=0.247	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.146	P=0.075	P=0.080	P=0.164

TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	12500 PPM	25000 PPM	50000 PPM

**Uterus
 Metaplasia**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	0/47.01	0/46.78	2/47.98	2/48.22
POLY-3 PERCENT (g)	0%	0%	4.2%	4.2%
TERMINAL (d)	0/40 (0%)	0/43 (0%)	2/42 (5%)	2/45 (4%)
FIRST INCIDENCE	---	---	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.091	(e)	P=0.242	P=0.243
POLY 1.5	P=0.088	(e)	P=0.240	P=0.239
POLY 6	P=0.094	(e)	P=0.243	P=0.249
COCH-ARM / FISHERS	P=0.086	(e)	P=0.247	P=0.247
MAX-ISO-POLY-3	P=0.080	(e)	P=0.080	P=0.081

TDMS No. 20008 - 04
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Milk thistle extract
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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 ***