

Experiment Number: 91005-03
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Methylene blue trihydrate

CAS Number: 7220-79-3

Date Report Requested: 10/15/2014

Time Report Requested: 18:02:43

First Dose M/F: NA / NA

Lab: BAT

C Number:	C91005B
Lock Date:	05/12/1994
Cage Range:	All
Date Range:	All
Reasons For Removal:	All
Removal Date Range:	All
Treatment Groups:	All
Study Gender:	Both
PWG Approval Date	NONE

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SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF METHYLENE BLUE TRIHYDRATE

MALE RAT

Organ

Bone Marrow

Kidney

Liver

Liver: Centrilobular

Lung

Spleen

Spleen: Capsule

Spleen: Lymph Follic

FEMALE RAT

Organ

Bone Marrow

Liver

Spleen

Spleen: Capsule

Spleen: Lymph Follic

Morphology

Hyperplasia

Vacuolization Cytoplasmic Diffuse

Hepatodiaphragmatic Nodule

Vacuolization Cytoplasmic

Cyst

Inflammation Chronic Diffuse

Congestion

Hematopoietic Cell Proliferation

Fibrosis

Depletion Cellular

Morphology

Hyperplasia

Hepatodiaphragmatic Nodule

Congestion

Hematopoietic Cell Proliferation

Fibrosis

Depletion Cellular

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
LAST REMOVAL AT 11 WEEKS**

DOSE	MALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Adrenal Cortex					
Vacuolization Cytoplasmic Focal					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.46	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	92(T)
STATISTICAL TESTS					
POLY 3	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.289	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.159
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS

DOSE	MALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Bone Marrow					
Hyperplasia					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/10 (0%)	8/10 (80%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/9.46	8/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	80%	100%	100%
TERMINAL (d)	0/10 (0%)	0/9 (0%)	8/10 (80%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	---	92(T)	92(T)	92(T)
STATISTICAL TESTS					
POLY 3	P=0.000**	(e)	P=0.000**	P=NA	P=NA
POLY 1.5	P=0.000**	(e)	P=0.000**	P=NA	P=NA
POLY 6	P=0.000**	(e)	P=0.000**	P=NA	P=NA
COCH-ARM / FISHERS	P=0.000**	(e)	P=0.000**	P=0.000**	P=0.000**
MAX-ISO-POLY-3	P=0.000**	(e)	P=0.000**	(e)	(e)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	MALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Heart					
Inflammation Chronic Diffuse					
LESION RATES					
OVERALL(a)	1/10 (10%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	1/10.00	0/0.46	0/0.00	0/0.00	3/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	30%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
FIRST INCIDENCE	92(T)	---	---	---	92(T)
STATISTICAL TESTS					
POLY 3	(e)	P=0.932N	(e)	(e)	P=0.292
POLY 1.5	(e)	P=0.925N	(e)	(e)	P=0.292
POLY 6	(e)	P=0.939N	(e)	(e)	P=0.292
COCH-ARM / FISHERS	P=0.178	P=0.909N	(e)	(e)	P=0.291
MAX-ISO-POLY-3	(e)	P=0.459N	(e)	(e)	P=0.138
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

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 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	MALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Heart					
Inflammation Chronic Focal					
LESION RATES					
OVERALL(a)	5/10 (50%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	5/10.00	0/0.46	0/0.00	0/0.00	3/10.00
POLY-3 PERCENT (g)	50%	0%	0%	0%	30%
TERMINAL (d)	5/10 (50%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
FIRST INCIDENCE	92(T)	---	---	---	92(T)
STATISTICAL TESTS					
POLY 3	(e)	P=0.709N	(e)	(e)	P=0.329N
POLY 1.5	(e)	P=0.641N	(e)	(e)	P=0.329N
POLY 6	(e)	P=0.778N	(e)	(e)	P=0.329N
COCH-ARM / FISHERS	P=0.291N	P=0.545N	(e)	(e)	P=0.325N
MAX-ISO-POLY-3	(e)	P=0.379N	(e)	(e)	P=0.189N
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	MALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Kidney					
Nephropathy					
LESION RATES					
OVERALL(a)	4/10 (40%)	1/1 (100%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	4/10.00	1/1.00	0/0.00	0/0.00	3/10.00
POLY-3 PERCENT (g)	40%	100%	0%	0%	30%
TERMINAL (d)	4/10 (40%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
FIRST INCIDENCE	92(T)	71	---	---	92(T)
STATISTICAL TESTS					
POLY 3	(e)	P=0.463	(e)	(e)	P=0.500N
POLY 1.5	(e)	P=0.463	(e)	(e)	P=0.500N
POLY 6	(e)	P=0.463	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.331N	P=0.455	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	P=0.206	(e)	(e)	P=0.327N
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	MALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Kidney					
Vacuolization Cytoplasmic Diffuse					
LESION RATES					
OVERALL(a)	0/10 (0%)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	1/1.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	100%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	71	---	---	---
STATISTICAL TESTS					
POLY 3	(e)	P=0.091	(e)	(e)	(e)
POLY 1.5	(e)	P=0.091	(e)	(e)	(e)
POLY 6	(e)	P=0.091	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.412N	P=0.091	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	P=0.000**	(e)	(e)	(e)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

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 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	MALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Liver					
Hepatodiaphragmatic Nodule					
LESION RATES					
OVERALL(a)	2/10 (20%)	1/2 (50%)	0/0 (0%)	2/2 (100%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	1/1.46	0/0.00	2/2.00	0/10.00
POLY-3 PERCENT (g)	20%	68.5%	0%	100%	0%
TERMINAL (d)	2/10 (20%)	1/1 (100%)	0/0 (0%)	2/2 (100%)	0/10 (0%)
FIRST INCIDENCE	92(T)	92(T)	---	92(T)	---
STATISTICAL TESTS					
POLY 3	(e)	P=0.419	(e)	P=0.053	P=0.227N
POLY 1.5	(e)	P=0.453	(e)	P=0.053	P=0.227N
POLY 6	(e)	P=0.379	(e)	P=0.053	P=0.227N
COCH-ARM / FISHERS	P=0.149N	P=0.455	(e)	P=0.091	P=0.237N
MAX-ISO-POLY-3	(e)	P=0.213	(e)	P=0.023*	P=0.067N
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

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Species/Strain: Rat/F 344/N

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Time Report Requested: 18:02:43

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
LAST REMOVAL AT 11 WEEKS

DOSE	MALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Liver: Centrilobular					
Vacuolization Cytoplasmic					
LESION RATES					
OVERALL(a)	8/10 (80%)	1/2 (50%)	0/0 (0%)	0/2 (0%)	10/10 (100%)
POLY-3 RATE (b)	8/10.00	1/2.00	0/0.00	0/2.00	10/10.00
POLY-3 PERCENT (g)	80%	50%	0%	0%	100%
TERMINAL (d)	8/10 (80%)	0/1 (0%)	0/0 (0%)	0/2 (0%)	10/10 (100%)
FIRST INCIDENCE	92(T)	71	---	---	92(T)
STATISTICAL TESTS					
POLY 3	(e)	P=0.500N	(e)	P=0.053N	P=0.227
POLY 1.5	(e)	P=0.500N	(e)	P=0.053N	P=0.227
POLY 6	(e)	P=0.500N	(e)	P=0.053N	P=0.227
COCH-ARM / FISHERS	P=0.149	P=0.455N	(e)	P=0.091N	P=0.237
MAX-ISO-POLY-3	(e)	P=0.256N	(e)	P=0.023N*	P=0.067
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

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 Route: GAVAGE
 Species/Strain: Rat/F 344/N

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	MALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Lung					
Cyst					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/1 (0%)	1/1 (100%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.46	1/1.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	100%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	92(T)	---	---
STATISTICAL TESTS					
POLY 3	(e)	(e)	P=0.091	(e)	(e)
POLY 1.5	(e)	(e)	P=0.091	(e)	(e)
POLY 6	(e)	(e)	P=0.091	(e)	(e)
COCH-ARM / FISHERS	P=0.524N	(e)	P=0.091	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	P=0.000**	(e)	(e)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

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First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
LAST REMOVAL AT 11 WEEKS**

DOSE	MALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Lung					
Hemorrhage Acute Diffuse					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/1 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.46	0/1.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---
STATISTICAL TESTS					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	MALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Lung					
Inflammation Chronic Diffuse					
LESION RATES					
OVERALL(a)	5/10 (50%)	0/1 (0%)	0/1 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	5/10.00	0/0.46	0/1.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	50%	0%	0%	0%	10%
TERMINAL (d)	5/10 (50%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	92(T)	---	---	---	92(T)
STATISTICAL TESTS					
POLY 3	(e)	P=0.709N	P=0.536N	(e)	P=0.061N
POLY 1.5	(e)	P=0.641N	P=0.536N	(e)	P=0.061N
POLY 6	(e)	P=0.778N	P=0.536N	(e)	P=0.061N
COCH-ARM / FISHERS	P=0.060N	P=0.545N	P=0.545N	(e)	P=0.070N
MAX-ISO-POLY-3	(e)	P=0.379N	P=0.251N	(e)	P=0.020N*
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	MALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Lung					
Inflammation Focal					
LESION RATES					
OVERALL(a)	2/10 (20%)	0/1 (0%)	0/1 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	0/0.46	0/1.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	92(T)	---	---	---	---
STATISTICAL TESTS					
POLY 3	(e)	P=0.844N	P=0.786N	(e)	P=0.227N
POLY 1.5	(e)	P=0.822N	P=0.786N	(e)	P=0.227N
POLY 6	(e)	P=0.866N	P=0.786N	(e)	P=0.227N
COCH-ARM / FISHERS	P=0.145N	P=0.818N	P=0.818N	(e)	P=0.237N
MAX-ISO-POLY-3	(e)	P=0.439N	P=0.369N	(e)	P=0.067N
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	MALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Lung: Alveolus					
Infiltration Cellular					
LESION RATES					
OVERALL(a)	1/10 (10%)	0/1 (0%)	0/1 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.46	0/1.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/1 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	92(T)	---	---	---	---
STATISTICAL TESTS					
POLY 3	(e)	P=0.932N	P=0.913N	(e)	P=0.500N
POLY 1.5	(e)	P=0.925N	P=0.913N	(e)	P=0.500N
POLY 6	(e)	P=0.939N	P=0.913N	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.320N	P=0.909N	P=0.909N	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	P=0.459N	P=0.411N	(e)	P=0.159N
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS

DOSE	MALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Lymph Node: Mediastinal					
Hyperplasia Lymphoid Diffuse					
LESION RATES					
OVERALL(a)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	1/1.00	0/0.00	0/0.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	100%	0%	0%	0%	0%
TERMINAL (d)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	92(T)	---	---	---	---
STATISTICAL TESTS					
POLY 3	(e)	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	MALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Mesentery					
Inflammation Chronic Focal					
LESION RATES					
OVERALL(a)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/1.00	0/0.00	0/0.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---	---
STATISTICAL TESTS					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	MALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Mesentery: Fat					
Inflammation Chronic Focal					
LESION RATES					
OVERALL(a)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	1/1.00	0/0.00	0/0.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	100%	0%	0%	0%	0%
TERMINAL (d)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	92(T)	---	---	---	---
STATISTICAL TESTS					
POLY 3	(e)	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Methylene blue trihydrate

CAS Number: 7220-79-3

Date Report Requested: 10/15/2014

Time Report Requested: 18:02:43

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
LAST REMOVAL AT 11 WEEKS**

DOSE	MALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Nose					
Inflammation Chronic					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.46	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---
STATISTICAL TESTS					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	MALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Prostate					
Inflammation Chronic					
LESION RATES					
OVERALL(a)	3/10 (30%)	1/1 (100%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	3/10.00	1/1.00	0/0.00	0/0.00	3/10.00
POLY-3 PERCENT (g)	30%	100%	0%	0%	30%
TERMINAL (d)	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
FIRST INCIDENCE	92(T)	71	---	---	92(T)
STATISTICAL TESTS					
POLY 3	(e)	P=0.384	(e)	(e)	P=0.678
POLY 1.5	(e)	P=0.384	(e)	(e)	P=0.678
POLY 6	(e)	P=0.384	(e)	(e)	P=0.678
COCH-ARM / FISHERS	P=1.000N	P=0.364	(e)	(e)	P=0.686N
MAX-ISO-POLY-3	(e)	P=0.153	(e)	(e)	P=1.000
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	MALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Spleen					
Congestion					
LESION RATES					
OVERALL(a)	0/10 (0%)	9/10 (90%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	9/9.46	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	95.1%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	9/9 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	92(T)	92(T)	92(T)	92(T)
STATISTICAL TESTS					
POLY 3	P=0.000**	P=0.000**	P=NA	P=NA	P=NA
POLY 1.5	P=0.000**	P=0.000**	P=NA	P=NA	P=NA
POLY 6	P=0.000**	P=0.000**	P=NA	P=NA	P=NA
COCH-ARM / FISHERS	P=0.000**	P=0.000**	P=0.000**	P=0.000**	P=0.000**
MAX-ISO-POLY-3	P=0.000**	P=0.000**	(e)	(e)	(e)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	MALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Spleen					
Hematopoietic Cell Proliferation					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/10 (0%)	10/10 (100%)	9/10 (90%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/9.46	10/10.00	9/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	100%	90%	100%
TERMINAL (d)	0/10 (0%)	0/9 (0%)	10/10 (100%)	9/10 (90%)	10/10 (100%)
FIRST INCIDENCE	---	---	92(T)	92(T)	92(T)
STATISTICAL TESTS					
POLY 3	P=0.000**	(e)	P=NA	P=0.000**	P=NA
POLY 1.5	P=0.000**	(e)	P=NA	P=0.000**	P=NA
POLY 6	P=0.000**	(e)	P=NA	P=0.000**	P=NA
COCH-ARM / FISHERS	P=0.000**	(e)	P=0.000**	P=0.000**	P=0.000**
MAX-ISO-POLY-3	P=0.000**	(e)	(e)	P=0.000**	(e)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	MALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Spleen: Capsule					
Fibrosis					
LESION RATES					
OVERALL(a)	1/10 (10%)	2/10 (20%)	0/10 (0%)	1/10 (10%)	9/10 (90%)
POLY-3 RATE (b)	1/10.00	2/9.46	0/10.00	1/10.00	9/10.00
POLY-3 PERCENT (g)	10%	21.1%	0%	10%	90%
TERMINAL (d)	1/10 (10%)	2/9 (22%)	0/10 (0%)	1/10 (10%)	9/10 (90%)
FIRST INCIDENCE	92(T)	92(T)	---	92(T)	92(T)
STATISTICAL TESTS					
POLY 3	P=0.000**	P=0.480	P=0.500N	P=0.760	P=0.000**
POLY 1.5	P=0.000**	P=0.488	P=0.500N	P=0.760	P=0.000**
POLY 6	P=0.000**	P=0.470	P=0.500N	P=0.760	P=0.000**
COCH-ARM / FISHERS	P=0.000**	P=0.500	P=0.500N	P=0.763N	P<0.001**
MAX-ISO-POLY-3	P=0.000**	P=0.262	P=0.159N	P=1.000	P=0.000**
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	MALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Spleen: Lymph Follic Depletion Cellular					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	5/10 (50%)
POLY-3 RATE (b)	0/10.00	0/9.46	0/10.00	2/10.00	5/10.00
POLY-3 PERCENT (g)	0%	0%	0%	20%	50%
TERMINAL (d)	0/10 (0%)	0/9 (0%)	0/10 (0%)	2/10 (20%)	5/10 (50%)
FIRST INCIDENCE	---	---	---	92(T)	92(T)
STATISTICAL TESTS					
POLY 3	P=0.000**	(e)	(e)	P=0.227	P=0.008**
POLY 1.5	P=0.000**	(e)	(e)	P=0.227	P=0.008**
POLY 6	P=0.000**	(e)	(e)	P=0.227	P=0.008**
COCH-ARM / FISHERS	P=0.000**	(e)	(e)	P=0.237	P=0.016*
MAX-ISO-POLY-3	P=0.000**	(e)	(e)	P=0.067	P<0.001**
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Methylene blue trihydrate

CAS Number: 7220-79-3

Date Report Requested: 10/15/2014

Time Report Requested: 18:02:43

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
LAST REMOVAL AT 11 WEEKS

DOSE	MALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Stomach, Glandular					
Mineralization					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.46	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	92(T)
STATISTICAL TESTS					
POLY 3	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.289	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.159
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	FEMALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Adrenal Cortex					
Vacuolization Cytoplasmic Focal					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/6.51
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---
STATISTICAL TESTS					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	FEMALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Bone Marrow					
Hyperplasia					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/10 (0%)	4/10 (40%)	9/10 (90%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	4/10.00	9/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	40%	90%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	4/10 (40%)	8/9 (89%)	6/6 (100%)
FIRST INCIDENCE	---	---	92(T)	14	14
STATISTICAL TESTS					
POLY 3	P=0.000**	(e)	P=0.033*	P=0.000**	P=NA
POLY 1.5	P=0.000**	(e)	P=0.033*	P=0.000**	P=NA
POLY 6	P=0.000**	(e)	P=0.033*	P=0.000**	P=NA
COCH-ARM / FISHERS	P=0.000**	(e)	P=0.043*	P=0.000**	P=0.000**
MAX-ISO-POLY-3	P=0.000**	(e)	P=0.007**	P=0.000**	(e)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS

DOSE	FEMALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Heart					
Inflammation Chronic Diffuse					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/6.51
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---
STATISTICAL TESTS					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	FEMALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Heart					
Inflammation Chronic Focal					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	1/6.51
POLY-3 PERCENT (g)	0%	0%	0%	0%	15.4%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/6 (17%)
FIRST INCIDENCE	---	---	---	---	92(T)
STATISTICAL TESTS					
POLY 3	(e)	(e)	(e)	(e)	P=0.417
POLY 1.5	(e)	(e)	(e)	(e)	P=0.431
POLY 6	(e)	(e)	(e)	(e)	P=0.408
COCH-ARM / FISHERS	P=0.300	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.155
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	FEMALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Kidney					
Nephropathy					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/6.51
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---
STATISTICAL TESTS					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	FEMALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Kidney					
Vacuolization Cytoplasmic Diffuse					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/6.51
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---
STATISTICAL TESTS					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	FEMALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Liver					
Hepatodiaphragmatic Nodule					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/2 (50%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	1/1.00	1/6.51
POLY-3 PERCENT (g)	0%	0%	0%	100%	15.4%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/1 (100%)	1/6 (17%)
FIRST INCIDENCE	---	---	---	92(T)	92(T)
STATISTICAL TESTS					
POLY 3	(e)	(e)	(e)	P=0.063	P=0.417
POLY 1.5	(e)	(e)	(e)	P=0.066	P=0.431
POLY 6	(e)	(e)	(e)	P=0.063	P=0.408
COCH-ARM / FISHERS	P=0.349	(e)	(e)	P=0.167	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.007**	P=0.155
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	FEMALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Liver: Centrilobular					
Vacuolization Cytoplasmic					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/2 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/1.00	2/7.51
POLY-3 PERCENT (g)	0%	0%	0%	0%	26.6%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	1/6 (17%)
FIRST INCIDENCE	---	---	---	---	14
STATISTICAL TESTS					
POLY 3	(e)	(e)	(e)	(e)	P=0.163
POLY 1.5	(e)	(e)	(e)	(e)	P=0.175
POLY 6	(e)	(e)	(e)	(e)	P=0.155
COCH-ARM / FISHERS	P=0.122	(e)	(e)	(e)	P=0.237
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.061
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS

DOSE	FEMALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Lung					
Cyst					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/6.51
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---
STATISTICAL TESTS					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Methylene blue trihydrate

CAS Number: 7220-79-3

Date Report Requested: 10/15/2014

Time Report Requested: 18:02:43

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
LAST REMOVAL AT 11 WEEKS

DOSE	FEMALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Lung					
Hemorrhage Acute Diffuse					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	1/7.51
POLY-3 PERCENT (g)	0%	0%	0%	0%	13.3%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	14
STATISTICAL TESTS					
POLY 3	(e)	(e)	(e)	(e)	P=0.443
POLY 1.5	(e)	(e)	(e)	(e)	P=0.455
POLY 6	(e)	(e)	(e)	(e)	P=0.436
COCH-ARM / FISHERS	P=0.300	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.156
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS

DOSE	FEMALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Lung					
Inflammation Chronic Diffuse					
LESION RATES					
OVERALL(a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/6.51
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	92(T)	---	---	---	---
STATISTICAL TESTS					
POLY 3	(e)	(e)	(e)	P=0.943N	P=0.582N
POLY 1.5	(e)	(e)	(e)	P=0.942N	P=0.567N
POLY 6	(e)	(e)	(e)	P=0.943N	P=0.590N
COCH-ARM / FISHERS	P=0.300N	(e)	(e)	P=0.909N	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.500N	P=0.258N
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS

DOSE	FEMALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Lung					
Inflammation Focal					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/6.51
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---
STATISTICAL TESTS					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	FEMALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Lung: Alveolus					
Infiltration Cellular					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/6.51
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---
STATISTICAL TESTS					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	FEMALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Lymph Node: Mediastinal					
Hyperplasia Lymphoid Diffuse					
LESION RATES					
OVERALL(a)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---	---
STATISTICAL TESTS					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Methylene blue trihydrate

CAS Number: 7220-79-3

Date Report Requested: 10/15/2014

Time Report Requested: 18:02:43

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
LAST REMOVAL AT 11 WEEKS

DOSE	FEMALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Mesentery					
Inflammation Chronic Focal					
LESION RATES					
OVERALL(a)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	1/1.00	0/0.00	0/0.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	100%	0%	0%	0%	0%
TERMINAL (d)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	92(T)	---	---	---	---
STATISTICAL TESTS					
POLY 3	(e)	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS

DOSE	FEMALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Mesentery: Fat					
Inflammation Chronic Focal					
LESION RATES					
OVERALL(a)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
POLY-3 RATE (b)	0/1.00	0/0.00	0/0.00	0/0.00	0/0.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/1 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	---	---	---
STATISTICAL TESTS					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	FEMALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Nose					
Inflammation Chronic					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	1/6.51
POLY-3 PERCENT (g)	0%	0%	0%	0%	15.4%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/6 (17%)
FIRST INCIDENCE	---	---	---	---	92(T)
STATISTICAL TESTS					
POLY 3	(e)	(e)	(e)	(e)	P=0.417
POLY 1.5	(e)	(e)	(e)	(e)	P=0.431
POLY 6	(e)	(e)	(e)	(e)	P=0.408
COCH-ARM / FISHERS	P=0.300	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P=0.155
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	FEMALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Ovary: Periovarn Tiss					
Cyst					
LESION RATES					
OVERALL(a)	2/10 (20%)	0/0 (0%)	1/1 (100%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	0/0.00	1/1.00	0/0.00	0/6.51
POLY-3 PERCENT (g)	20%	0%	100%	0%	0%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	1/1 (100%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	92(T)	---	92(T)	---	---
STATISTICAL TESTS					
POLY 3	(e)	(e)	P=0.286	P=0.882N	P=0.337N
POLY 1.5	(e)	(e)	P=0.286	P=0.878N	P=0.315N
POLY 6	(e)	(e)	P=0.286	P=0.882N	P=0.350N
COCH-ARM / FISHERS	P=0.105N	(e)	P=0.273	P=0.818N	P=0.237N
MAX-ISO-POLY-3	(e)	(e)	P=0.090	P=0.500N	P=0.167N
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	FEMALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Spleen					
Congestion					
LESION RATES					
OVERALL(a)	0/10 (0%)	9/10 (90%)	10/10 (100%)	9/10 (90%)	9/10 (90%)
POLY-3 RATE (b)	0/10.00	9/10.00	10/10.00	9/9.00	9/9.46
POLY-3 PERCENT (g)	0%	90%	100%	100%	95.1%
TERMINAL (d)	0/10 (0%)	9/10 (90%)	10/10 (100%)	9/9 (100%)	6/6 (100%)
FIRST INCIDENCE	---	92(T)	92(T)	92(T)	14
STATISTICAL TESTS					
POLY 3	P=0.000**	P=0.000**	P=NA	P=0.000**	P=0.000**
POLY 1.5	P=0.000**	P=0.000**	P=NA	P=0.000**	P=0.000**
POLY 6	P=0.000**	P=0.000**	P=NA	P=0.000**	P=0.000**
COCH-ARM / FISHERS	P=0.003**	P=0.000**	P=0.000**	P=0.000**	P=0.000**
MAX-ISO-POLY-3	P=0.000**	P=0.000**	(e)	P=0.000**	P=0.000**
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	FEMALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Spleen					
Hematopoietic Cell Proliferation					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/10 (0%)	8/10 (80%)	9/10 (90%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	8/10.00	9/9.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	80%	100%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	8/10 (80%)	9/9 (100%)	6/6 (100%)
FIRST INCIDENCE	---	---	92(T)	92(T)	14
STATISTICAL TESTS					
POLY 3	P=0.000**	(e)	P=0.000**	P=0.000**	P=NA
POLY 1.5	P=0.000**	(e)	P=0.000**	P=0.000**	P=NA
POLY 6	P=0.000**	(e)	P=0.000**	P=0.000**	P=NA
COCH-ARM / FISHERS	P=0.000**	(e)	P=0.000**	P=0.000**	P=0.000**
MAX-ISO-POLY-3	P=0.000**	(e)	P=0.000**	P=0.000**	(e)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	FEMALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Spleen: Capsule					
Fibrosis					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)	7/10 (70%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	3/9.00	7/9.46
POLY-3 PERCENT (g)	0%	0%	0%	33.3%	74%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/9 (33%)	4/6 (67%)
FIRST INCIDENCE	---	---	---	92(T)	14
STATISTICAL TESTS					
POLY 3	P=0.000**	(e)	(e)	P=0.076	P=0.000**
POLY 1.5	P=0.000**	(e)	(e)	P=0.077	P=0.000**
POLY 6	P=0.000**	(e)	(e)	P=0.076	P=0.000**
COCH-ARM / FISHERS	P=0.000**	(e)	(e)	P=0.105	P=0.002**
MAX-ISO-POLY-3	P=0.000**	(e)	(e)	P=0.023*	P=0.000**
HISTCONT SAME RTE					
HISTCONT ALL RTEs					
CURR VS HC SAME RTE					
CURR VS HC ALL RTEs					

Experiment Number: 91005-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Methylene blue trihydrate

CAS Number: 7220-79-3

Date Report Requested: 10/15/2014

Time Report Requested: 18:02:43

First Dose M/F: NA / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
LAST REMOVAL AT 11 WEEKS

DOSE	FEMALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Spleen: Lymph Follic Depletion Cellular					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	9/10 (90%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	1/9.00	9/9.00
POLY-3 PERCENT (g)	0%	0%	0%	11.1%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/9 (11%)	6/6 (100%)
FIRST INCIDENCE	---	---	---	92(T)	27
STATISTICAL TESTS					
POLY 3	P=0.000**	(e)	(e)	P=0.479	P=0.000**
POLY 1.5	P=0.000**	(e)	(e)	P=0.480	P=0.000**
POLY 6	P=0.000**	(e)	(e)	P=0.479	P=0.000**
COCH-ARM / FISHERS	P=0.000**	(e)	(e)	P=0.500	P=0.000**
MAX-ISO-POLY-3	P=0.000**	(e)	(e)	P=0.158	P=0.000**
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Methylene blue trihydrate
 CAS Number: 7220-79-3

Date Report Requested: 10/15/2014
 Time Report Requested: 18:02:43
 First Dose M/F: NA / NA
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
 LAST REMOVAL AT 11 WEEKS**

DOSE	FEMALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Stomach, Glandular Mineralization					
LESION RATES					
OVERALL(a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/6.51
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/6 (0%)
FIRST INCIDENCE	---	---	---	---	---
STATISTICAL TESTS					
POLY 3	(n)	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Methylene blue trihydrate

CAS Number: 7220-79-3

Date Report Requested: 10/15/2014

Time Report Requested: 18:02:43

First Dose M/F: NA / NA

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RAT(F 344/N)
LAST REMOVAL AT 11 WEEKS**

DOSE	FEMALE				
	0 MG/KG	25 MG/KG	50 MG/KG	100 MG/KG	200 MG/KG
Uterus					
Dilatation					
LESION RATES					
OVERALL(a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/1 (0%)	1/10 (10%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	0/0.00	1/6.51
POLY-3 PERCENT (g)	20%	0%	0%	0%	15.4%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/6 (17%)
FIRST INCIDENCE	92(T)	---	---	---	92(T)
STATISTICAL TESTS					
POLY 3	(e)	(e)	(e)	P=0.882N	P=0.647N
POLY 1.5	(e)	(e)	(e)	P=0.878N	P=0.622N
POLY 6	(e)	(e)	(e)	P=0.882N	P=0.661N
COCH-ARM / FISHERS	P=0.375N	(e)	(e)	P=0.818N	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.500N	P=0.427N
HISTCONT SAME RTE					
HISTCONT ALL RTES					
CURR VS HC SAME RTE					
CURR VS HC ALL RTES					

Experiment Number: 91005-03

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: Rat/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Methylene blue trihydrate

CAS Number: 7220-79-3

Date Report Requested: 10/15/2014

Time Report Requested: 18:02:43

First Dose M/F: NA / NA

Lab: BAT

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.
 - (e) Value of statistic cannot be computed.
 - (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.
 - (g) Poly-3 adjusted lifetime tumor incidence.
 - (n) No statistics are calculated if all dose groups have fewer than two tumors.
 - (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
- The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

**** END OF REPORT ****