

Experiment Number: 91069 - 01
Test Type: 28-DAY
Route: GAVAGE
Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)
CAS Number: 50892-23-4

Date Report Requested: 02/06/2018
Time Report Requested: 12:39:53
First Dose M/F: 01/26/12 / 01/27/12
Lab: BAT

Wyeth_Final 1

NTP Study Number: C91069
Lock Date: 04/25/2016
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 3.0.2.3_002
PWG Approval Date: NONE

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF WYETH 14,643 (WY)

MALE RATS

Organ

Liver: Hepatocyte

Morphology

Cytoplasmic Alteration

Hypertrophy

FEMALE RATS

Organ

Liver: Hepatocyte

Morphology

Cytoplasmic Alteration

Hypertrophy

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
Adrenal Cortex				
Mineral				
<hr/>				
LESION RATES				
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	29 (T)	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158N

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
Adrenal Cortex				
Vacuolization Cytoplasmic				
<hr/>				
LESION RATES				
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	29 (T)	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158N

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
Epididymis				
Inflammation Chronic				
<hr/>				
LESION RATES				
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	29 (T)	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(e)	(e)	P=0.500N	P=0.500N
POLY 1.5	(e)	(e)	P=0.500N	P=0.500N
POLY 6	(e)	(e)	P=0.500N	P=0.500N
COCH-ARM / FISHERS	P=0.267N	(e)	P=0.500N	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	P=0.158N	P=0.158N

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
<hr/>				
Epididymis: Duct Exfoliated Germ Cell				
<hr/>				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	29 (T)
<hr/>				
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.267	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
Esophagus Inflammation				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
Esophagus: Muscularis Degeneration				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
Esophagus: Muscularis Inflammation Chronic				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
<hr/>				
Heart				
Cardiomyopathy				
<hr/>				
LESION RATES				
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	29 (T)	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158N

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
Heart				
Infiltration Cellular Mixed Cell				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
Kidney				
Nephropathy Chronic Progressive				
LESION RATES				
OVERALL (a)	6/10 (60%)	4/10 (40%)	8/10 (80%)	7/10 (70%)
POLY-3 RATE (b)	6/10.00	4/10.00	8/10.00	7/10.00
POLY-3 PERCENT (g)	60%	40%	80%	70%
TERMINAL (d)	6/10 (60%)	4/10 (40%)	8/10 (80%)	7/10 (70%)
FIRST INCIDENCE	29 (T)	29 (T)	29 (T)	29 (T)
STATISTICAL TESTS				
POLY 3	P=0.237	P=0.333N	P=0.318	P=0.500
POLY 1.5	P=0.237	P=0.333N	P=0.318	P=0.500
POLY 6	P=0.237	P=0.333N	P=0.318	P=0.500
COCH-ARM / FISHERS	P=0.236	P=0.328N	P=0.314	P=0.500
MAX-ISO-POLY-3	P=0.124	P=0.193N	P=0.172	P=0.325

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
<hr/>				
Liver				
Hepatodiaphragmatic Nodule				
<hr/>				
LESION RATES				
OVERALL (a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	29 (T)	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.306N	P=0.500N	P=0.500N	P=0.500N
POLY 1.5	P=0.306N	P=0.500N	P=0.500N	P=0.500N
POLY 6	P=0.306N	P=0.500N	P=0.500N	P=0.500N
COCH-ARM / FISHERS	P=0.304N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.078N	P=0.158N	P=0.158N	P=0.158N

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
Liver				
Infiltration Cellular Mixed Cell				
LESION RATES				
OVERALL (a)	1/10 (10%)	2/10 (20%)	2/10 (20%)	4/10 (40%)
POLY-3 RATE (b)	1/10.00	2/10.00	2/10.00	4/10.00
POLY-3 PERCENT (g)	10%	20%	20%	40%
TERMINAL (d)	1/10 (10%)	2/10 (20%)	2/10 (20%)	4/10 (40%)
FIRST INCIDENCE	29 (T)	29 (T)	29 (T)	29 (T)
STATISTICAL TESTS				
POLY 3	P=0.093	P=0.500	P=0.500	P=0.148
POLY 1.5	P=0.093	P=0.500	P=0.500	P=0.148
POLY 6	P=0.093	P=0.500	P=0.500	P=0.148
COCH-ARM / FISHERS	P=0.089	P=0.500	P=0.500	P=0.152
MAX-ISO-POLY-3	P=0.057	P=0.274	P=0.274	P=0.058

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
<hr/>				
Liver				
Inflammation Chronic				
<hr/>				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
<hr/>				
Liver Necrosis				
<hr/>				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
<hr/>				
Liver				
Necrosis Focal				
<hr/>				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
Liver: Hepatocyte Cytoplasmic Alteration				
LESION RATES				
OVERALL (a)	0/10 (0%)	9/10 (90%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	9/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	90%	100%	100%
TERMINAL (d)	0/10 (0%)	9/10 (90%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	29 (T)	29 (T)	29 (T)
STATISTICAL TESTS				
POLY 3	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	(e)	(e)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
<hr/>				
Liver: Hepatocyte Hypertrophy				
<hr/>				
LESION RATES				
OVERALL (a)	0/10 (0%)	5/10 (50%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	5/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	50%	100%	100%
TERMINAL (d)	0/10 (0%)	5/10 (50%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	29 (T)	29 (T)	29 (T)
<hr/>				
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.008**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.008**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.008**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.016*	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	(e)	(e)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
Lung				
Infiltration Cellular				
<hr/>				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	29 (T)
<hr/>				
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.304	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
Lung				
Infiltration Cellular Histiocyte				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
Lung				
Inflammation Chronic				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
Lung: Alveolar Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
Lung: Alveolar Epithelium Hypertrophy				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
Pancreas				
Inflammation Chronic				
<hr/>				
LESION RATES				
OVERALL (a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	29 (T)	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.306N	P=0.500N	P=0.500N	P=0.500N
POLY 1.5	P=0.306N	P=0.500N	P=0.500N	P=0.500N
POLY 6	P=0.306N	P=0.500N	P=0.500N	P=0.500N
COCH-ARM / FISHERS	P=0.304N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.078N	P=0.158N	P=0.158N	P=0.158N

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
Pancreas: Acinar Cell Atrophy				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	29 (T)
STATISTICAL TESTS				
POLY 3	P=0.199	(e)	(e)	P=0.500
POLY 1.5	P=0.199	(e)	(e)	P=0.500
POLY 6	P=0.199	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.196	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.078	(e)	(e)	P=0.158

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M
Stomach, Glandular Mineral				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	29 (T)
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.304	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Males			
	0mg/kg/d M	6.25mg/kg/d M	12.5mg/kg/d M	25mg/kg/d M

Testes: Germinal Epithelium
Degeneration

LESION RATES

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	29 (T)

STATISTICAL TESTS

POLY 3	P=0.199	(e)	(e)	P=0.500
POLY 1.5	P=0.199	(e)	(e)	P=0.500
POLY 6	P=0.199	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.196	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.078	(e)	(e)	P=0.158

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
Adrenal Cortex				
Mineral				
<hr/>				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
Adrenal Cortex				
Vacuolization Cytoplasmic				
<hr/>				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
Esophagus Inflammation				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	29 (T)
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.304	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
Esophagus: Muscularis Degeneration				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	29 (T)
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.304	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
Esophagus: Muscularis Inflammation Chronic				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	29 (T)
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.304	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
<hr/>				
Heart				
Cardiomyopathy				
<hr/>				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
Heart				
Infiltration Cellular Mixed Cell				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	29 (T)
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.304	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F

Kidney
Nephropathy Chronic Progressive

LESION RATES

OVERALL (a)	5/10 (50%)	3/10 (30%)	3/10 (30%)	6/10 (60%)
POLY-3 RATE (b)	5/10.00	3/10.00	3/10.00	6/10.00
POLY-3 PERCENT (g)	50%	30%	30%	60%
TERMINAL (d)	5/10 (50%)	3/10 (30%)	3/10 (30%)	6/10 (60%)
FIRST INCIDENCE	29 (T)	29 (T)	29 (T)	29 (T)

STATISTICAL TESTS

POLY 3	P=0.316	P=0.329N	P=0.329N	P=0.500
POLY 1.5	P=0.316	P=0.329N	P=0.329N	P=0.500
POLY 6	P=0.316	P=0.329N	P=0.329N	P=0.500
COCH-ARM / FISHERS	P=0.313	P=0.325N	P=0.325N	P=0.500
MAX-ISO-POLY-3	P=0.149	P=0.188N	P=0.188N	P=0.332

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
<hr/>				
Liver				
Hepatodiaphragmatic Nodule				
<hr/>				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
<hr/>				
Liver				
Infiltration Cellular Mixed Cell				
<hr/>				
LESION RATES				
OVERALL (a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	29 (T)	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.306N	P=0.500N	P=0.500N	P=0.500N
POLY 1.5	P=0.306N	P=0.500N	P=0.500N	P=0.500N
POLY 6	P=0.306N	P=0.500N	P=0.500N	P=0.500N
COCH-ARM / FISHERS	P=0.304N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.078N	P=0.158N	P=0.158N	P=0.158N

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
Liver				
Inflammation Chronic				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	1/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	10%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	---	---	29 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.694	(e)	P=0.500	(e)
POLY 1.5	P=0.694	(e)	P=0.500	(e)
POLY 6	P=0.694	(e)	P=0.500	(e)
COCH-ARM / FISHERS	P=0.696	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.239	(e)	P=0.158	(e)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
<hr/>				
Liver Necrosis				
<hr/>				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	1/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	10%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	---	---	29 (T)	---
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.694	(e)	P=0.500	(e)
POLY 1.5	P=0.694	(e)	P=0.500	(e)
POLY 6	P=0.694	(e)	P=0.500	(e)
COCH-ARM / FISHERS	P=0.696	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.239	(e)	P=0.158	(e)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
<hr/>				
Liver				
Necrosis Focal				
<hr/>				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	29 (T)
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.199	(e)	(e)	P=0.500
POLY 1.5	P=0.199	(e)	(e)	P=0.500
POLY 6	P=0.199	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.196	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.078	(e)	(e)	P=0.158

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
<hr/>				
Liver: Hepatocyte Cytoplasmic Alteration				
<hr/>				
LESION RATES				
OVERALL (a)	0/10 (0%)	7/10 (70%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	7/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	70%	100%	100%
TERMINAL (d)	0/10 (0%)	7/10 (70%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	29 (T)	29 (T)	29 (T)
<hr/>				
STATISTICAL TESTS				
POLY 3	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.002**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	(e)	(e)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
Liver: Hepatocyte Hypertrophy				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/10 (0%)	2/10 (20%)	8/10 (80%)
POLY-3 RATE (b)	0/10.00	0/10.00	2/10.00	8/10.00
POLY-3 PERCENT (g)	0%	0%	20%	80%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	2/10 (20%)	8/10 (80%)
FIRST INCIDENCE	---	---	29 (T)	29 (T)
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P=0.227	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.227	P<0.001**
POLY 6	P<0.001**	(e)	P=0.227	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.237	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.066	P<0.001**

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
<hr/>				
Lung Infiltration Cellular				
<hr/>				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
<hr/>				
Lung				
Infiltration Cellular Histiocyte				
<hr/>				
LESION RATES				
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	29 (T)	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158N

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
<hr/>				
Lung				
Inflammation Chronic				
<hr/>				
LESION RATES				
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	29 (T)	---	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158N

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
Lung: Alveolar Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	29 (T)
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.304	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
Lung: Alveolar Epithelium Hypertrophy				
LESION RATES				
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	29 (T)	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158N

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
<hr/>				
Ovary Cyst				
<hr/>				
LESION RATES				
OVERALL (a)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	1/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	10%	0%	0%
TERMINAL (d)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	29 (T)	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.567N	P=0.500	(e)	(e)
POLY 1.5	P=0.567N	P=0.500	(e)	(e)
POLY 6	P=0.567N	P=0.500	(e)	(e)
COCH-ARM / FISHERS	P=0.568N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.239N	P=0.158	(e)	(e)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
<hr/>				
Ovary				
Hematocyst				
<hr/>				
LESION RATES				
OVERALL (a)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	1/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	10%	0%	0%
TERMINAL (d)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	29 (T)	---	---
<hr/>				
STATISTICAL TESTS				
POLY 3	P=0.567N	P=0.500	(e)	(e)
POLY 1.5	P=0.567N	P=0.500	(e)	(e)
POLY 6	P=0.567N	P=0.500	(e)	(e)
COCH-ARM / FISHERS	P=0.568N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.239N	P=0.158	(e)	(e)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
Pancreas				
Inflammation Chronic				
LESION RATES				
OVERALL (a)	1/10 (10%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00	1/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	10%	0%
TERMINAL (d)	1/10 (10%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	29 (T)	---	29 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.406N	P=0.500N	P=0.760	P=0.500N
POLY 1.5	P=0.406N	P=0.500N	P=0.760	P=0.500N
POLY 6	P=0.406N	P=0.500N	P=0.760	P=0.500N
COCH-ARM / FISHERS	P=0.403N	P=0.500N	P=0.763N	P=0.500N
MAX-ISO-POLY-3	P=0.158N	P=0.158N	P=1.000	P=0.158N

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
Pancreas: Acinar Cell Atrophy				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
Stomach, Glandular				
Mineral				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---
STATISTICAL TESTS				
POLY 3	(n)	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
<hr/>				
Uterus Cyst				
<hr/>				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	29 (T)
<hr/>				
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.304	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(HSD)
TERMINAL SACRIFICE AT 5 WEEKS**

DOSE	Females			
	0mg/kg/d F	6.25mg/kg/d F	12.5mg/kg/d F	25mg/kg/d F
Uterus				
Dilation				
<hr/>				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	2/10.00
POLY-3 PERCENT (g)	0%	0%	0%	20%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
FIRST INCIDENCE	---	---	---	29 (T)
<hr/>				
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	P=0.227
POLY 1.5	(e)	(e)	(e)	P=0.227
POLY 6	(e)	(e)	(e)	P=0.227
COCH-ARM / FISHERS	P=0.132	(e)	(e)	P=0.237
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.066

Experiment Number: 91069 - 01

Test Type: 28-DAY

Route: GAVAGE

Species/Strain: RATS/HSD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Wyeth 14,643 (WY)

CAS Number: 50892-23-4

Date Report Requested: 02/06/2018

Time Report Requested: 12:39:53

First Dose M/F: 01/26/12 / 01/27/12

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 ***