

**TDMS No.** 20515 - 02

**Test Type:** 90-DAY

**Route:** RESPIRATORY EXPOSURE WHOLE BODY

**Species/Strain:** MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

Metal working fluids (CIMSTAR 3800)

**CAS Number:** CIMSTAR3800

**Date Report Requested:** 10/21/2008

**Time Report Requested:** 07:18:30

**First Dose M/F:** 06/12/06 / 06/12/06

**Lab:** BNW

F1\_M3

**C Number:** C20515  
**Lock Date:** 04/04/2007  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 2.0.0

TDMS No. 20515 - 02

Test Type: 90-DAY

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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CAS Number: CIMSTAR3800

Date Report Requested: 10/21/2008

Time Report Requested: 07:18:30

First Dose M/F: 06/12/06 / 06/12/06

Lab: BNW

**SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF Metal working fluids (CIMSTAR 3800)**

**MALE MICE**

**Organ**

Larynx

Larynx: Epiglottis

Larynx: Squamous Epithelium

Lung: Arteriole

Lung: Bronchiole

Lung: Perivascular

Nose: Olfactory Epithelium

Nose: Respiratory Epithelium

**Morphology**

Inflammation Chronic

Metaplasia

Dysplasia

Hyperplasia

Hypertrophy

Hyperplasia

Inflammation Chronic

Accumulation, Hyaline Droplet

Accumulation, Hyaline Droplet

**FEMALE MICE**

**Organ**

Larynx

Larynx: Epiglottis

Larynx: Squamous Epithelium

Lung: Arteriole

Lung: Bronchiole

Lung: Perivascular

Nose: Olfactory Epithelium

Nose: Respiratory Epithelium

**Morphology**

Inflammation Chronic

Metaplasia

Dysplasia

Hyperplasia

Hypertrophy

Hyperplasia

Inflammation Chronic

Accumulation, Hyaline Droplet

Accumulation, Hyaline Droplet

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3

**Kidney: Renal Tubule  
Regeneration**

**LESION RATES**

OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	2/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	20%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
FIRST INCIDENCE	95 (T)	---	---	---	---	95 (T)

**STATISTICAL TESTS**

POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.377	(e)	(e)	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.274

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3

**Larynx  
Inflammation Chronic**

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	4/10 (40%)	6/10 (60%)	10/10 (100%)	9/10 (90%)
POLY-3 RATE (b)	0/10.00	0/10.00	4/10.00	6/10.00	10/10.00	9/10.00
POLY-3 PERCENT (g)	0%	0%	40%	60%	100%	90%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	4/10 (40%)	6/10 (60%)	10/10 (100%)	9/10 (90%)
FIRST INCIDENCE	---	---	95 (T)	95 (T)	95 (T)	95 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001**	(e)	P=0.033*	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.033*	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	(e)	P=0.033*	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.043*	P=0.005**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.007**	P<0.001**	P<0.001**	P<0.001**

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3

**Larynx  
Metaplasia**

**LESION RATES**

OVERALL (a)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	10/10.00	10/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	100%	100%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	95 (T)	95 (T)	95 (T)	95 (T)	95 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001**	P<0.001**	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**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	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**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3

**Larynx: Epiglottis  
Dysplasia**

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	6/10 (60%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	6/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	60%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	6/10 (60%)
FIRST INCIDENCE	---	---	---	---	---	95 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001**	(e)	(e)	(e)	(e)	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	(e)	(e)	P<0.001**
POLY 6	P<0.001**	(e)	(e)	(e)	(e)	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	(e)	P=0.005**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	P<0.001**

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3

**Larynx: Squamous Epithelium  
Hyperplasia**

**LESION RATES**

OVERALL (a)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	7/10 (70%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	1/10.00	0/10.00	0/10.00	7/10.00	10/10.00
POLY-3 PERCENT (g)	0%	10%	0%	0%	70%	100%
TERMINAL (d)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	7/10 (70%)	10/10 (100%)
FIRST INCIDENCE	---	95 (T)	---	---	95 (T)	95 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001**	P=0.500	(e)	(e)	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.500	(e)	(e)	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.500	(e)	(e)	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500	(e)	(e)	P=0.002**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.158	(e)	(e)	P<0.001**	P<0.001**

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3

**Lung: Arteriole Hypertrophy**

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	3/10 (30%)	4/10 (40%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	2/10.00	3/10.00	4/10.00
POLY-3 PERCENT (g)	0%	0%	0%	20%	30%	40%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	3/10 (30%)	4/10 (40%)
FIRST INCIDENCE	---	---	---	95 (T)	95 (T)	95 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001**	(e)	(e)	P=0.227	P=0.095	P=0.033*
POLY 1.5	P<0.001**	(e)	(e)	P=0.227	P=0.095	P=0.033*
POLY 6	P<0.001**	(e)	(e)	P=0.227	P=0.095	P=0.033*
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.237	P=0.105	P=0.043*
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P=0.066	P=0.025*	P=0.007**



**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3

**Lung: Bronchiole  
Hyperplasia**

**LESION RATES**

OVERALL (a)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	10/10.00	10/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	100%	100%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	95 (T)	95 (T)	95 (T)	95 (T)	95 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001**	P<0.001**	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**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	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**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3

**Lung: Perivascular  
Inflammation Chronic**

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)	4/10 (40%)	6/10 (60%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	3/10.00	4/10.00	6/10.00
POLY-3 PERCENT (g)	0%	0%	0%	30%	40%	60%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	3/10 (30%)	4/10 (40%)	6/10 (60%)
FIRST INCIDENCE	---	---	---	95 (T)	95 (T)	95 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001**	(e)	(e)	P=0.095	P=0.033*	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	P=0.095	P=0.033*	P<0.001**
POLY 6	P<0.001**	(e)	(e)	P=0.095	P=0.033*	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.105	P=0.043*	P=0.005**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P=0.025*	P=0.007**	P<0.001**

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3

**Nose: Olfactory Epithelium  
Accumulation, Hyaline Droplet**

**LESION RATES**

OVERALL (a)	0/10 (0%)	7/10 (70%)	4/10 (40%)	10/10 (100%)	10/10 (100%)	9/10 (90%)
POLY-3 RATE (b)	0/10.00	7/10.00	4/10.00	10/10.00	10/10.00	9/10.00
POLY-3 PERCENT (g)	0%	70%	40%	100%	100%	90%
TERMINAL (d)	0/10 (0%)	7/10 (70%)	4/10 (40%)	10/10 (100%)	10/10 (100%)	9/10 (90%)
FIRST INCIDENCE	---	95 (T)	95 (T)	95 (T)	95 (T)	95 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001**	P<0.001**	P=0.033*	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P=0.033*	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P=0.033*	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.002**	P=0.043*	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P=0.007**	P<0.001**	P<0.001**	P<0.001**

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3

**Nose: Respiratory Epithelium  
Accumulation, Hyaline Droplet**

**LESION RATES**

OVERALL (a)	0/10 (0%)	8/10 (80%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	8/10.00	10/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	80%	100%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	8/10 (80%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	95 (T)	95 (T)	95 (T)	95 (T)	95 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001**	P<0.001**	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**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	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**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3

**Kidney: Renal Tubule  
Regeneration**

**LESION RATES**

OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	96 (T)	---	---	---	---	---

**STATISTICAL TESTS**

POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.304N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.158N

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3

**Larynx  
Inflammation Chronic**

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	1/10 (10%)	9/10 (90%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	1/10.00	9/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	10%	90%	100%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	1/10 (10%)	9/10 (90%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	---	96 (T)	96 (T)	96 (T)	96 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001**	(e)	P=0.500	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.500	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	(e)	P=0.500	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.500	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.158	P<0.001**	P<0.001**	P<0.001**

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3

**Larynx  
Metaplasia**

**LESION RATES**

OVERALL (a)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	10/10.00	10/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	100%	100%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	96 (T)	96 (T)	96 (T)	96 (T)	96 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001**	P<0.001**	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**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	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**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3

**Larynx: Epiglottis  
Dysplasia**

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	7/10 (70%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	2/10.00	7/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	20%	70%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	7/10 (70%)
FIRST INCIDENCE	---	---	---	---	96 (T)	96 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001**	(e)	(e)	(e)	P=0.227	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	(e)	P=0.227	P<0.001**
POLY 6	P<0.001**	(e)	(e)	(e)	P=0.227	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	(e)	P=0.237	P=0.002**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	P=0.066	P<0.001**



**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3

**Larynx: Squamous Epithelium  
Hyperplasia**

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	1/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	0%	10%	100%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	---	---	96 (T)	96 (T)	96 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001**	(e)	(e)	P=0.500	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	(e)	(e)	P=0.500	P<0.001**	P<0.001**
POLY 6	P<0.001**	(e)	(e)	P=0.500	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	(e)	P=0.500	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	P=0.158	P<0.001**	P<0.001**

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3

**Lung: Arteriole Hypertrophy**

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	4/10 (40%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	2/10.00	4/10.00	2/10.00
POLY-3 PERCENT (g)	0%	0%	0%	20%	40%	20%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	4/10 (40%)	2/10 (20%)
FIRST INCIDENCE	---	---	---	96 (T)	96 (T)	96 (T)

**STATISTICAL TESTS**

POLY 3	P=0.026*	(e)	(e)	P=0.227	P=0.033*	P=0.227
POLY 1.5	P=0.026*	(e)	(e)	P=0.227	P=0.033*	P=0.227
POLY 6	P=0.026*	(e)	(e)	P=0.227	P=0.033*	P=0.227
COCH-ARM / FISHERS	P=0.033*	(e)	(e)	P=0.237	P=0.043*	P=0.237
MAX-ISO-POLY-3	P=0.018*	(e)	(e)	P=0.066	P=0.007**	P=0.066

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3

**Lung: Bronchiole  
Hyperplasia**

**LESION RATES**

OVERALL (a)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	10/10.00	10/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	100%	100%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	96 (T)	96 (T)	96 (T)	96 (T)	96 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001**	P<0.001**	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**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	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**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3

**Lung: Perivascular  
Inflammation Chronic**

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	1/10 (10%)	6/10 (60%)	8/10 (80%)	3/10 (30%)
POLY-3 RATE (b)	0/10.00	0/10.00	1/10.00	6/10.00	8/10.00	3/10.00
POLY-3 PERCENT (g)	0%	0%	10%	60%	80%	30%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	1/10 (10%)	6/10 (60%)	8/10 (80%)	3/10 (30%)
FIRST INCIDENCE	---	---	96 (T)	96 (T)	96 (T)	96 (T)

**STATISTICAL TESTS**

POLY 3	P=0.004**	(e)	P=0.500	P<0.001**	P<0.001**	P=0.095
POLY 1.5	P=0.004**	(e)	P=0.500	P<0.001**	P<0.001**	P=0.095
POLY 6	P=0.004**	(e)	P=0.500	P<0.001**	P<0.001**	P=0.095
COCH-ARM / FISHERS	P=0.018*	(e)	P=0.500	P=0.005**	P<0.001**	P=0.105
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.158	P<0.001**	P<0.001**	P=0.025*

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3

**Nose: Olfactory Epithelium  
Accumulation, Hyaline Droplet**

**LESION RATES**

OVERALL (a)	0/10 (0%)	7/10 (70%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	7/10.00	10/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	70%	100%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	7/10 (70%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	96 (T)	96 (T)	96 (T)	96 (T)	96 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001**	P<0.001**	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**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	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**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	0 mg/m3	25 mg/m3	50 mg/m3	100 mg/m3	200 mg/m3	400 mg/m3

**Nose: Respiratory Epithelium  
Accumulation, Hyaline Droplet**

**LESION RATES**

OVERALL (a)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	10/10.00	10/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	100%	100%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	96 (T)	96 (T)	96 (T)	96 (T)	96 (T)

**STATISTICAL TESTS**

POLY 3	P<0.001**	P<0.001**	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**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	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**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**

**LEGEND**

- (a) Number of tumor-bearing animals/number of animals examined at site.
  - (b) Number of tumor-bearing animals/Poly-3 number
  - (d) Observed incidence at terminal kill.
  - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group. The life table analysis regards tumors in animals dying prior to terminal kill as being (directly or indirectly) the cause of death.
  - (e) Value of Statistic cannot be computed.
  - (g) Poly-3 adjusted lifetime tumor incidence.
  - (I) Interim sacrifice
  - (T) Terminal sacrifice
  - # Tumor rates based on numbers of animals necropsied.
  - \* To the right of any statistical result, indicates significance at ( $P \leq 0.05$ ).
  - \*\* To the right of any statistical result, indicates significance at ( $P \leq 0.01$ ).
  - N Indicates a negative trend for all tests
- Logistic regression is an alternative method for analyzing the incidence of non-fatal tumors.  
The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

\*\*\* END OF REPORT \*\*\*