

Experiment Number: 20701 - 02
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Nanoscale material (Fullerene-C60 1 micron)
CAS Number: 99685-96-8

Date Report Requested: 02/22/2013
Time Report Requested: 07:59:02
First Dose M/F: 11/05/07 / 11/05/07
Lab: BNW

F2_Rev.1_M3

NTP Study Number: C20701
Lock Date: 02/24/2009
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 3.0.1.1_001
PWG Approval Date: NONE

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SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF NANOSCALE MATERIAL (FULLERENE-C60 1 MICRON)

MALE MICE

Organ

Kidney: Renal Tubule
Larynx
Lung

Lymph Node, Bronchial
Stomach, Forestomach

FEMALE MICE

Organ

Harderian Gland
Larynx
Lung

Lymph Node, Bronchial

Morphology

Necrosis
Metaplasia
Infiltration Cellular Histiocyte
Inflammation Chronic
Pigmentation
Pigmentation
Hyperplasia
Ulcer

Morphology

Inflammation Acute
Metaplasia
Infiltration Cellular Histiocyte
Inflammation Chronic
Pigmentation
Pigmentation

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
<hr/>				
Eye: Cornea Necrosis				
<hr/>				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.36	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)

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 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Harderian Gland Inflammation Acute				
LESION RATES				
OVERALL (a)	7/10 (70%)	0/1 (0%)	0/0 (0%)	7/10 (70%)
POLY-3 RATE (b)	7/10.00	0/0.36	0/0.00	7/10.00
POLY-3 PERCENT (g)	70%	0%	0%	70%
TERMINAL (d)	7/10 (70%)	0/0 (0%)	0/0 (0%)	7/10 (70%)
FIRST INCIDENCE	89 (T)	---	---	89 (T)
STATISTICAL TESTS				
POLY 3	(e)	P=0.710N	(e)	P=0.678
POLY 1.5	(e)	P=0.591N	(e)	P=0.678
POLY 6	(e)	P=0.807N	(e)	P=0.678
COCH-ARM / FISHERS	P=0.486	P=0.364N	(e)	P=0.686N
MAX-ISO-POLY-3	(e)	P=0.355N	(e)	P=1.000

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Kidney Nephropathy				
LESION RATES				
OVERALL (a)	1/10 (10%)	2/10 (20%)	0/10 (0%)	2/10 (20%)
POLY-3 RATE (b)	1/10.00	2/9.36	0/10.00	2/10.00
POLY-3 PERCENT (g)	10%	21.4%	0%	20%
TERMINAL (d)	1/10 (10%)	2/9 (22%)	0/10 (0%)	2/10 (20%)
FIRST INCIDENCE	89 (T)	89 (T)	---	89 (T)
STATISTICAL TESTS				
POLY 3	P=0.539	P=0.476	P=0.500N	P=0.500
POLY 1.5	P=0.537	P=0.485	P=0.500N	P=0.500
POLY 6	P=0.540	P=0.467	P=0.500N	P=0.500
COCH-ARM / FISHERS	P=0.535	P=0.500	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.253	P=0.260	P=0.158N	P=0.274

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Kidney: Papilla				
Infiltration Cellular Polymorphonuclear				
LESION RATES				
OVERALL (a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/9.36	0/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%
TERMINAL (d)	1/10 (10%)	0/9 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	89 (T)	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.350N	P=0.513N	P=0.500N	P=0.500N
POLY 1.5	P=0.354N	P=0.508N	P=0.500N	P=0.500N
POLY 6	P=0.346N	P=0.518N	P=0.500N	P=0.500N
COCH-ARM / FISHERS	P=0.359N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.078N	P=0.175N	P=0.158N	P=0.158N

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 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Kidney: Renal Tubule Necrosis				
LESION RATES				
OVERALL (a)	1/10 (10%)	0/10 (0%)	1/10 (10%)	3/10 (30%)
POLY-3 RATE (b)	1/10.00	0/9.36	1/10.00	3/10.00
POLY-3 PERCENT (g)	10%	0%	10%	30%
TERMINAL (d)	1/10 (10%)	0/9 (0%)	1/10 (10%)	3/10 (30%)
FIRST INCIDENCE	89 (T)	---	89 (T)	89 (T)
STATISTICAL TESTS				
POLY 3	P=0.067	P=0.513N	P=0.760	P=0.292
POLY 1.5	P=0.064	P=0.508N	P=0.760	P=0.292
POLY 6	P=0.069	P=0.518N	P=0.760	P=0.292
COCH-ARM / FISHERS	P=0.062	P=0.500N	P=0.763N	P=0.291
MAX-ISO-POLY-3	P=0.046*	P=0.175N	P=1.000	P=0.136

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 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Larynx				
Metaplasia				
LESION RATES				
OVERALL (a)	1/10 (10%)	0/9 (0%)	5/10 (50%)	9/10 (90%)
POLY-3 RATE (b)	1/10.00	0/8.36	5/10.00	9/10.00
POLY-3 PERCENT (g)	10%	0%	50%	90%
TERMINAL (d)	1/10 (10%)	0/8 (0%)	5/10 (50%)	9/10 (90%)
FIRST INCIDENCE	89 (T)	---	89 (T)	89 (T)
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.536N	P=0.061	P<0.001**
POLY 1.5	P<0.001**	P=0.530N	P=0.061	P<0.001**
POLY 6	P<0.001**	P=0.541N	P=0.061	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.526N	P=0.070	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.195N	P=0.020*	P<0.001**

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 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Larynx: Squamous Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	0/10 (0%)	1/9 (11%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	1/9.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	11.1%	0%	0%
TERMINAL (d)	0/10 (0%)	0/8 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	63	---	---
STATISTICAL TESTS				
POLY 3	P=0.420N	P=0.479	(e)	(e)
POLY 1.5	P=0.420N	P=0.479	(e)	(e)
POLY 6	P=0.420N	P=0.479	(e)	(e)
COCH-ARM / FISHERS	P=0.419N	P=0.474	(e)	(e)
MAX-ISO-POLY-3	P=0.230N	P=0.150	(e)	(e)

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 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Liver				
Inflammation Granulomatous				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.36	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	---	---	---	89 (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=0.288	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158

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 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Liver				
Necrosis				
LESION RATES				
OVERALL (a)	1/10 (10%)	0/1 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.36	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	89 (T)	---	---	---
STATISTICAL TESTS				
POLY 3	(e)	P=0.935N	(e)	P=0.500N
POLY 1.5	(e)	P=0.928N	(e)	P=0.500N
POLY 6	(e)	P=0.941N	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.318N	P=0.909N	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	P=0.466N	(e)	P=0.158N

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 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Lung Hemorrhage				
LESION RATES				
OVERALL (a)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	1/9.36	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	10.7%	0%	0%
TERMINAL (d)	0/10 (0%)	1/9 (11%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	89 (T)	---	---
STATISTICAL TESTS				
POLY 3	P=0.438N	P=0.487	(e)	(e)
POLY 1.5	P=0.434N	P=0.492	(e)	(e)
POLY 6	P=0.442N	P=0.482	(e)	(e)
COCH-ARM / FISHERS	P=0.427N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.232N	P=0.158	(e)	(e)

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 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Lung				
Infiltration Cellular Histiocyte				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/10 (0%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/9.36	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	100%	100%
TERMINAL (d)	0/10 (0%)	0/9 (0%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	---	89 (T)	89 (T)
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	(e)	P<0.001**	P<0.001**
POLY 6	P<0.001**	(e)	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Lung Inflammation Chronic				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/10 (0%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/9.36	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	100%	100%
TERMINAL (d)	0/10 (0%)	0/9 (0%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	---	89 (T)	89 (T)
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	(e)	P<0.001**	P<0.001**
POLY 6	P<0.001**	(e)	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Lung Pigmentation				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/10 (0%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/9.36	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	100%	100%
TERMINAL (d)	0/10 (0%)	0/9 (0%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	---	89 (T)	89 (T)
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	(e)	P<0.001**	P<0.001**
POLY 6	P<0.001**	(e)	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)

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 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Lymph Node, Bronchial Pigmentation				
LESION RATES				
OVERALL (a)	2/6 (33%)	1/4 (25%)	2/5 (40%)	9/9 (100%)
POLY-3 RATE (b)	2/6.00	1/4.00	2/5.00	9/9.00
POLY-3 PERCENT (g)	33.3%	25%	40%	100%
TERMINAL (d)	2/6 (33%)	1/4 (25%)	2/5 (40%)	9/9 (100%)
FIRST INCIDENCE	89 (T)	89 (T)	89 (T)	89 (T)
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.648N	P=0.642	P<0.001**
POLY 1.5	P<0.001**	P=0.648N	P=0.642	P<0.001**
POLY 6	P<0.001**	P=0.648N	P=0.642	P<0.001**
COCH-ARM / FISHERS	P=0.002**	P=0.667N	P=0.652	P=0.011*
MAX-ISO-POLY-3	P<0.001**	P=0.406N	P=0.419	P<0.001**

Experiment Number: 20701 - 02
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Nanoscale material (Fullerene-C60 1 micron)
CAS Number: 99685-96-8

Date Report Requested: 02/22/2013
Time Report Requested: 07:59:02
First Dose M/F: 11/05/07 / 11/05/07
Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Mammary Gland Inflammation Acute				
LESION RATES				
OVERALL (a)	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
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (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: 20701 - 02
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Nanoscale material (Fullerene-C60 1 micron)
 CAS Number: 99685-96-8

Date Report Requested: 02/22/2013
 Time Report Requested: 07:59:02
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Nose: Olfactory Epithelium Accumulation, Hyaline Droplet				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.36	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	---	---	---	89 (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=0.288	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158

Experiment Number: 20701 - 02
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Nanoscale material (Fullerene-C60 1 micron)
 CAS Number: 99685-96-8

Date Report Requested: 02/22/2013
 Time Report Requested: 07:59:02
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Nose: Respiratory Epithelium Accumulation, Hyaline Droplet				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/1 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.36	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	---	---	---	89 (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=0.288	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158

Experiment Number: 20701 - 02
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Nanoscale material (Fullerene-C60 1 micron)
 CAS Number: 99685-96-8

Date Report Requested: 02/22/2013
 Time Report Requested: 07:59:02
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Stomach, Forestomach Hyperplasia				
LESION RATES				
OVERALL (a)	0/10 (0%)	1/1 (100%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	1/1.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	100%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	63	---	---
STATISTICAL TESTS				
POLY 3	(e)	P=0.091	(e)	(e)
POLY 1.5	(e)	P=0.091	(e)	(e)
POLY 6	(e)	P=0.091	(e)	(e)
COCH-ARM / FISHERS	P=0.371N	P=0.091	(e)	(e)
MAX-ISO-POLY-3	(e)	P<0.001**	(e)	(e)

Experiment Number: 20701 - 02
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Nanoscale material (Fullerene-C60 1 micron)
 CAS Number: 99685-96-8

Date Report Requested: 02/22/2013
 Time Report Requested: 07:59:02
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Stomach, Forestomach Ulcer				
LESION RATES				
OVERALL (a)	0/10 (0%)	1/1 (100%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	1/1.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	100%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	63	---	---
STATISTICAL TESTS				
POLY 3	(e)	P=0.091	(e)	(e)
POLY 1.5	(e)	P=0.091	(e)	(e)
POLY 6	(e)	P=0.091	(e)	(e)
COCH-ARM / FISHERS	P=0.371N	P=0.091	(e)	(e)
MAX-ISO-POLY-3	(e)	P<0.001**	(e)	(e)

Experiment Number: 20701 - 02
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Nanoscale material (Fullerene-C60 1 micron)
 CAS Number: 99685-96-8

Date Report Requested: 02/22/2013
 Time Report Requested: 07:59:02
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Testes: Germinal Epithelium Degeneration				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/9.36	1/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	10%	0%
TERMINAL (d)	0/10 (0%)	0/9 (0%)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	---	---	89 (T)	---
STATISTICAL TESTS				
POLY 3	P=0.650	(e)	P=0.500	(e)
POLY 1.5	P=0.646	(e)	P=0.500	(e)
POLY 6	P=0.654	(e)	P=0.500	(e)
COCH-ARM / FISHERS	P=0.641	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.239	(e)	P=0.158	(e)

Experiment Number: 20701 - 02
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Nanoscale material (Fullerene-C60 1 micron)
 CAS Number: 99685-96-8

Date Report Requested: 02/22/2013
 Time Report Requested: 07:59:02
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Eye: Cornea				
Necrosis				
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	89 (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: 20701 - 02
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Nanoscale material (Fullerene-C60 1 micron)
 CAS Number: 99685-96-8

Date Report Requested: 02/22/2013
 Time Report Requested: 07:59:02
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Harderian Gland Inflammation Acute				
LESION RATES				
OVERALL (a)	3/10 (30%)	0/0 (0%)	0/0 (0%)	7/10 (70%)
POLY-3 RATE (b)	3/10.00	0/0.00	0/0.00	7/10.00
POLY-3 PERCENT (g)	30%	0%	0%	70%
TERMINAL (d)	3/10 (30%)	0/0 (0%)	0/0 (0%)	7/10 (70%)
FIRST INCIDENCE	89 (T)	---	---	89 (T)
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	P=0.082
POLY 1.5	(e)	(e)	(e)	P=0.082
POLY 6	(e)	(e)	(e)	P=0.082
COCH-ARM / FISHERS	P=0.059	(e)	(e)	P=0.089
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.032*

Experiment Number: 20701 - 02
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Nanoscale material (Fullerene-C60 1 micron)
 CAS Number: 99685-96-8

Date Report Requested: 02/22/2013
 Time Report Requested: 07:59:02
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Kidney Nephropathy				
LESION RATES				
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	10%	0%	0%	10%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	89 (T)	---	---	89 (T)
STATISTICAL TESTS				
POLY 3	(e)	(e)	(e)	P=0.760
POLY 1.5	(e)	(e)	(e)	P=0.760
POLY 6	(e)	(e)	(e)	P=0.760
COCH-ARM / FISHERS	P=0.645	(e)	(e)	P=0.763N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=1.000

Experiment Number: 20701 - 02
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Nanoscale material (Fullerene-C60 1 micron)
 CAS Number: 99685-96-8

Date Report Requested: 02/22/2013
 Time Report Requested: 07:59:02
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Kidney: Papilla				
Infiltration Cellular Polymorphonuclear				
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: 20701 - 02
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Nanoscale material (Fullerene-C60 1 micron)
CAS Number: 99685-96-8

Date Report Requested: 02/22/2013
Time Report Requested: 07:59:02
First Dose M/F: 11/05/07 / 11/05/07
Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Kidney: Renal Tubule Necrosis				
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: 20701 - 02
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Nanoscale material (Fullerene-C60 1 micron)
 CAS Number: 99685-96-8

Date Report Requested: 02/22/2013
 Time Report Requested: 07:59:02
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Larynx Metaplasia				
LESION RATES				
OVERALL (a)	0/10 (0%)	1/8 (13%)	6/10 (60%)	9/10 (90%)
POLY-3 RATE (b)	0/10.00	1/8.00	6/10.00	9/10.00
POLY-3 PERCENT (g)	0%	12.5%	60%	90%
TERMINAL (d)	0/10 (0%)	1/8 (13%)	6/10 (60%)	9/10 (90%)
FIRST INCIDENCE	---	89 (T)	89 (T)	89 (T)
STATISTICAL TESTS				
POLY 3	P<0.001**	P=0.455	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.455	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.455	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.444	P=0.005**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.142	P<0.001**	P<0.001**

Experiment Number: 20701 - 02
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Nanoscale material (Fullerene-C60 1 micron)
 CAS Number: 99685-96-8

Date Report Requested: 02/22/2013
 Time Report Requested: 07:59:02
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Larynx: Squamous Epithelium Hyperplasia				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/8 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/8.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/8 (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: 20701 - 02
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Nanoscale material (Fullerene-C60 1 micron)
 CAS Number: 99685-96-8

Date Report Requested: 02/22/2013
 Time Report Requested: 07:59:02
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Liver				
Inflammation Granulomatous				
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: 20701 - 02
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Nanoscale material (Fullerene-C60 1 micron)
 CAS Number: 99685-96-8

Date Report Requested: 02/22/2013
 Time Report Requested: 07:59:02
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Liver Necrosis				
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	---	---	---	89 (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: 20701 - 02
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Nanoscale material (Fullerene-C60 1 micron)
 CAS Number: 99685-96-8

Date Report Requested: 02/22/2013
 Time Report Requested: 07:59:02
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Lung Hemorrhage				
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	89 (T)	---	---	---
STATISTICAL TESTS				
POLY 3	P=0.361N	P=0.500N	P=0.500N	P=0.500N
POLY 1.5	P=0.361N	P=0.500N	P=0.500N	P=0.500N
POLY 6	P=0.361N	P=0.500N	P=0.500N	P=0.500N
COCH-ARM / FISHERS	P=0.359N	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: 20701 - 02
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Nanoscale material (Fullerene-C60 1 micron)
 CAS Number: 99685-96-8

Date Report Requested: 02/22/2013
 Time Report Requested: 07:59:02
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Lung				
Infiltration Cellular Histiocyte				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/10 (0%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	100%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	---	89 (T)	89 (T)
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	(e)	P<0.001**	P<0.001**
POLY 6	P<0.001**	(e)	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P<0.001**	P<0.001**
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

Experiment Number: 20701 - 02
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Nanoscale material (Fullerene-C60 1 micron)
 CAS Number: 99685-96-8

Date Report Requested: 02/22/2013
 Time Report Requested: 07:59:02
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Lung Inflammation Chronic				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/10 (0%)	3/10 (30%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	3/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	30%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	3/10 (30%)	10/10 (100%)
FIRST INCIDENCE	---	---	89 (T)	89 (T)
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P=0.095	P<0.001**
POLY 1.5	P<0.001**	(e)	P=0.095	P<0.001**
POLY 6	P<0.001**	(e)	P=0.095	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.105	P<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.025*	(e)

Experiment Number: 20701 - 02
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Nanoscale material (Fullerene-C60 1 micron)
 CAS Number: 99685-96-8

Date Report Requested: 02/22/2013
 Time Report Requested: 07:59:02
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Lung Pigmentation				
LESION RATES				
OVERALL (a)	0/10 (0%)	0/10 (0%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	100%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	---	89 (T)	89 (T)
STATISTICAL TESTS				
POLY 3	P<0.001**	(e)	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	(e)	P<0.001**	P<0.001**
POLY 6	P<0.001**	(e)	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P<0.001**	P<0.001**
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

Experiment Number: 20701 - 02
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Nanoscale material (Fullerene-C60 1 micron)
 CAS Number: 99685-96-8

Date Report Requested: 02/22/2013
 Time Report Requested: 07:59:02
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Lymph Node, Bronchial Pigmentation				
LESION RATES				
OVERALL (a)	2/5 (40%)	3/6 (50%)	1/5 (20%)	6/6 (100%)
POLY-3 RATE (b)	2/5.00	3/6.00	1/5.00	6/6.00
POLY-3 PERCENT (g)	40%	50%	20%	100%
TERMINAL (d)	2/5 (40%)	3/6 (50%)	1/5 (20%)	6/6 (100%)
FIRST INCIDENCE	89 (T)	89 (T)	89 (T)	89 (T)
STATISTICAL TESTS				
POLY 3	P=0.029*	P=0.599	P=0.500N	P=0.030*
POLY 1.5	P=0.029*	P=0.599	P=0.500N	P=0.030*
POLY 6	P=0.029*	P=0.599	P=0.500N	P=0.030*
COCH-ARM / FISHERS	P=0.047*	P=0.608	P=0.500N	P=0.061
MAX-ISO-POLY-3	P=0.012*	P=0.384	P=0.263N	P=0.005**

Experiment Number: 20701 - 02
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Nanoscale material (Fullerene-C60 1 micron)
 CAS Number: 99685-96-8

Date Report Requested: 02/22/2013
 Time Report Requested: 07:59:02
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Mammary Gland Inflammation Acute				
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	---	---	---	89 (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: 20701 - 02
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Nanoscale material (Fullerene-C60 1 micron)
 CAS Number: 99685-96-8

Date Report Requested: 02/22/2013
 Time Report Requested: 07:59:02
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Nose: Olfactory Epithelium Accumulation, Hyaline Droplet				
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	---	---	---	89 (T)
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: 20701 - 02
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Nanoscale material (Fullerene-C60 1 micron)
 CAS Number: 99685-96-8

Date Report Requested: 02/22/2013
 Time Report Requested: 07:59:02
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Nose: Respiratory Epithelium Accumulation, Hyaline Droplet				
LESION RATES				
OVERALL (a)	5/10 (50%)	0/0 (0%)	0/0 (0%)	4/10 (40%)
POLY-3 RATE (b)	5/10.00	0/0.00	0/0.00	4/10.00
POLY-3 PERCENT (g)	50%	0%	0%	40%
TERMINAL (d)	5/10 (50%)	0/0 (0%)	0/0 (0%)	4/10 (40%)
FIRST INCIDENCE	89 (T)	---	---	89 (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=0.411N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.332N

Experiment Number: 20701 - 02
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Nanoscale material (Fullerene-C60 1 micron)
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 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Stomach, Forestomach 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: 20701 - 02
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: MICE/B6C3F1

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females			
	0 mg/m3	2 mg/m3	15 mg/m3	30 mg/m3
Stomach, Forestomach Ulcer				
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: 20701 - 02
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Nanoscale material (Fullerene-C60 1 micron)
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LEGEND

- (a) Number of tumor-bearing animals/number of animals examined at site.
 - (b) Number of tumor-bearing animals/Poly-3 number
 - (d) Observed incidence at terminal kill.
 - (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 ***