

**Experiment Number:** 20407 - 02  
**Test Type:** 90-DAY  
**Route:** RESPIRATORY EXPOSURE NASAL  
**Species/Strain:** MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
Nanoscale material (Fullerene-C60 50 nanometers)  
**CAS Number:** 99685-96-8

**Date Report Requested:** 02/05/2013  
**Time Report Requested:** 07:58:33  
**First Dose M/F:** 11/05/07 / 11/05/07  
**Lab:** BNW

F2\_M3

**NTP Study Number:** C20407  
**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 50 NANOMETERS)**

**MALE MICE**

**Organ**

Lung

Lymph Node, Bronchial

**FEMALE MICE**

**Organ**

Lung

**Morphology**

Infiltration Cellular Histiocyte

Pigmentation

Pigmentation

**Morphology**

Infiltration Cellular Histiocyte

Pigmentation

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

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DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
<b>Heart</b>			
<b>Infiltration Cellular Mixed Cell</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/10 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	90 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	P=0.500
POLY 6	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.385	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	P=0.158

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

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DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
<hr/>			
Intestine Large, Rectum Parasite Metazoan			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	90 (T)	---	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.385N	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	P=0.158N

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

DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
<b>Kidney</b>			
<b>Casts Protein</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/10 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	90 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	P=0.500
POLY 6	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.385	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	P=0.158

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

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DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
<b>Kidney</b>			
<b>Inflammation Chronic</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---
<b>STATISTICAL TESTS</b>			
POLY 3	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)

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

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DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
<b>Kidney: Renal Tubule Regeneration</b>			
<b>LESION RATES</b>			
OVERALL (a)	4/10 (40%)	0/0 (0%)	2/10 (20%)
POLY-3 RATE (b)	4/10.00	0/0.00	2/10.00
POLY-3 PERCENT (g)	40%	0%	20%
TERMINAL (d)	4/10 (40%)	0/0 (0%)	2/10 (20%)
FIRST INCIDENCE	90 (T)	---	90 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	P=0.318N
POLY 1.5	(e)	(e)	P=0.318N
POLY 6	(e)	(e)	P=0.318N
COCH-ARM / FISHERS	P=0.265N	(e)	P=0.314N
MAX-ISO-POLY-3	(e)	(e)	P=0.172N

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

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DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
<hr/>			
Liver			
Eosinophilic Focus			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)

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

DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Lung Hemorrhage			
<b>LESION RATES</b>			
OVERALL (a)	0/10 (0%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	1/10.00	0/10.00
POLY-3 PERCENT (g)	0%	10%	0%
TERMINAL (d)	0/10 (0%)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	---	90 (T)	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.695N	P=0.500	(e)
POLY 1.5	P=0.695N	P=0.500	(e)
POLY 6	P=0.695N	P=0.500	(e)
COCH-ARM / FISHERS	P=0.698N	P=0.500	(e)
MAX-ISO-POLY-3	P=0.270N	P=0.158	(e)

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

DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
<b>Lung</b>			
<b>Infiltration Cellular Histiocyte</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/10 (10%)	2/10 (20%)	7/10 (70%)
POLY-3 RATE (b)	1/10.00	2/10.00	7/10.00
POLY-3 PERCENT (g)	10%	20%	70%
TERMINAL (d)	1/10 (10%)	2/10 (20%)	7/10 (70%)
FIRST INCIDENCE	90 (T)	90 (T)	90 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001**	P=0.500	P=0.003**
POLY 1.5	P<0.001**	P=0.500	P=0.003**
POLY 6	P<0.001**	P=0.500	P=0.003**
COCH-ARM / FISHERS	P=0.003**	P=0.500	P=0.010**
MAX-ISO-POLY-3	P<0.001**	P=0.274	P<0.001**

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

DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
<b>Lung Inflammation Chronic</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	90 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.305	(e)	P=0.500
POLY 1.5	P=0.305	(e)	P=0.500
POLY 6	P=0.305	(e)	P=0.500
COCH-ARM / FISHERS	P=0.302	(e)	P=0.500
MAX-ISO-POLY-3	P=0.109	(e)	P=0.158

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 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
<b>Lung Pigmentation</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/10 (0%)	0/10 (0%)	7/10 (70%)
POLY-3 RATE (b)	0/10.00	0/10.00	7/10.00
POLY-3 PERCENT (g)	0%	0%	70%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	7/10 (70%)
FIRST INCIDENCE	---	---	90 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001**	(e)	P<0.001**
POLY 1.5	P<0.001**	(e)	P<0.001**
POLY 6	P<0.001**	(e)	P<0.001**
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.002**
MAX-ISO-POLY-3	P<0.001**	(e)	P<0.001**

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TERMINAL SACRIFICE AT 13 WEEKS**

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DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
<hr/>			
Lung: Artery			
Inflammation Chronic			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)

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TERMINAL SACRIFICE AT 13 WEEKS**

---

DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3

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Lung: Perivascular  
Infiltration Cellular Mixed Cell

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**LESION RATES**

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

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**STATISTICAL TESTS**

POLY 3	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)

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 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
<b>Lymph Node, Bronchial Pigmentation</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/9 (0%)	2/7 (29%)	5/7 (71%)
POLY-3 RATE (b)	0/9.00	2/7.00	5/7.00
POLY-3 PERCENT (g)	0%	28.6%	71.4%
TERMINAL (d)	0/9 (0%)	2/7 (29%)	5/7 (71%)
FIRST INCIDENCE	---	90 (T)	90 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001**	P=0.162	P<0.001**
POLY 1.5	P<0.001**	P=0.162	P<0.001**
POLY 6	P<0.001**	P=0.162	P<0.001**
COCH-ARM / FISHERS	P=0.004**	P=0.175	P=0.005**
MAX-ISO-POLY-3	P<0.001**	P=0.047*	P<0.001**

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 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
<b>Testes: Germinal Epithelium Degeneration</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/10 (20%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	1/10.00	0/10.00
POLY-3 PERCENT (g)	20%	10%	0%
TERMINAL (d)	2/10 (20%)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	90 (T)	90 (T)	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.180N	P=0.500N	P=0.227N
POLY 1.5	P=0.180N	P=0.500N	P=0.227N
POLY 6	P=0.180N	P=0.500N	P=0.227N
COCH-ARM / FISHERS	P=0.176N	P=0.500N	P=0.237N
MAX-ISO-POLY-3	P=0.070N	P=0.274N	P=0.066N



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

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DOSE	Females		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3

---

Heart  
Infiltration Cellular Mixed Cell

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**LESION RATES**

OVERALL (a)	1/10 (10%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	90 (T)	---	---

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**STATISTICAL TESTS**

POLY 3	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.385N	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	P=0.159N

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Experiment Number: 20407 - 02  
Test Type: 90-DAY  
Route: RESPIRATORY EXPOSURE NASAL  
Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
Nanoscale material (Fullerene-C60 50 nanometers)  
CAS Number: 99685-96-8

Date Report Requested: 02/05/2013  
Time Report Requested: 07:58:33  
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**

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DOSE	Females		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
<hr/>			
Intestine Large, Rectum Parasite Metazoan			
<hr/>			
<b>LESION RATES</b>			
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---
<hr/>			
<b>STATISTICAL TESTS</b>			
POLY 3	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)

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Experiment Number: 20407 - 02  
 Test Type: 90-DAY  
 Route: RESPIRATORY EXPOSURE NASAL  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Nanoscale material (Fullerene-C60 50 nanometers)  
 CAS Number: 99685-96-8

Date Report Requested: 02/05/2013  
 Time Report Requested: 07:58:33  
 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	0.5 mg/m3	2.0 mg/m3
<b>Kidney</b>			
<b>Casts Protein</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/10 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	90 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	P=0.500
POLY 6	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.385	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	P=0.159

Experiment Number: 20407 - 02  
Test Type: 90-DAY  
Route: RESPIRATORY EXPOSURE NASAL  
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Nanoscale material (Fullerene-C60 50 nanometers)  
CAS Number: 99685-96-8

Date Report Requested: 02/05/2013  
Time Report Requested: 07:58:33  
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**

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DOSE	Females		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
<b>Kidney Inflammation Chronic</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/10 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	90 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	P=0.500
POLY 6	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.385	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	P=0.159

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Experiment Number: 20407 - 02  
 Test Type: 90-DAY  
 Route: RESPIRATORY EXPOSURE NASAL  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Nanoscale material (Fullerene-C60 50 nanometers)  
 CAS Number: 99685-96-8

Date Report Requested: 02/05/2013  
 Time Report Requested: 07:58:33  
 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	0.5 mg/m3	2.0 mg/m3
<b>Kidney: Renal Tubule Regeneration</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/10 (20%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	2/10.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	20%	0%	10%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	90 (T)	---	90 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.429N	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	P=0.275N

Experiment Number: 20407 - 02  
 Test Type: 90-DAY  
 Route: RESPIRATORY EXPOSURE NASAL  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Nanoscale material (Fullerene-C60 50 nanometers)  
 CAS Number: 99685-96-8

Date Report Requested: 02/05/2013  
 Time Report Requested: 07:58:33  
 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	0.5 mg/m3	2.0 mg/m3
<b>Liver</b>			
<b>Eosinophilic Focus</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/10 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	90 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	P=0.500
POLY 6	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.385	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	P=0.159

Experiment Number: 20407 - 02  
 Test Type: 90-DAY  
 Route: RESPIRATORY EXPOSURE NASAL  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Nanoscale material (Fullerene-C60 50 nanometers)  
 CAS Number: 99685-96-8

Date Report Requested: 02/05/2013  
 Time Report Requested: 07:58:33  
 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	0.5 mg/m3	2.0 mg/m3
Lung Hemorrhage			
<b>LESION RATES</b>			
OVERALL (a)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	90 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.305	(e)	P=0.500
POLY 1.5	P=0.305	(e)	P=0.500
POLY 6	P=0.305	(e)	P=0.500
COCH-ARM / FISHERS	P=0.302	(e)	P=0.500
MAX-ISO-POLY-3	P=0.156	(e)	P=0.159

Experiment Number: 20407 - 02  
 Test Type: 90-DAY  
 Route: RESPIRATORY EXPOSURE NASAL  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Nanoscale material (Fullerene-C60 50 nanometers)  
 CAS Number: 99685-96-8

Date Report Requested: 02/05/2013  
 Time Report Requested: 07:58:33  
 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	0.5 mg/m3	2.0 mg/m3
<b>Lung</b>			
<b>Infiltration Cellular Histiocyte</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/10 (20%)	1/10 (10%)	5/10 (50%)
POLY-3 RATE (b)	2/10.00	1/10.00	5/10.00
POLY-3 PERCENT (g)	20%	10%	50%
TERMINAL (d)	2/10 (20%)	1/10 (10%)	5/10 (50%)
FIRST INCIDENCE	90 (T)	90 (T)	90 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.065	P=0.500N	P=0.174
POLY 1.5	P=0.065	P=0.500N	P=0.174
POLY 6	P=0.065	P=0.500N	P=0.174
COCH-ARM / FISHERS	P=0.070	P=0.500N	P=0.175
MAX-ISO-POLY-3	P=0.048*	P=0.275N	P=0.080



Experiment Number: 20407 - 02  
 Test Type: 90-DAY  
 Route: RESPIRATORY EXPOSURE NASAL  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Nanoscale material (Fullerene-C60 50 nanometers)  
 CAS Number: 99685-96-8

Date Report Requested: 02/05/2013  
 Time Report Requested: 07:58:33  
 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	0.5 mg/m3	2.0 mg/m3
<b>Lung Inflammation Chronic</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---
<b>STATISTICAL TESTS</b>			
POLY 3	(n)	(n)	(n)
POLY 1.5	(n)	(n)	(n)
POLY 6	(n)	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)	(n)

Experiment Number: 20407 - 02  
 Test Type: 90-DAY  
 Route: RESPIRATORY EXPOSURE NASAL  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Nanoscale material (Fullerene-C60 50 nanometers)  
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Date Report Requested: 02/05/2013  
 Time Report Requested: 07:58:33  
 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	0.5 mg/m3	2.0 mg/m3
<b>Lung Pigmentation</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/10 (0%)	0/10 (0%)	5/10 (50%)
POLY-3 RATE (b)	0/10.00	0/10.00	5/10.00
POLY-3 PERCENT (g)	0%	0%	50%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	5/10 (50%)
FIRST INCIDENCE	---	---	90 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P<0.001**	(e)	P=0.008**
POLY 1.5	P<0.001**	(e)	P=0.008**
POLY 6	P<0.001**	(e)	P=0.008**
COCH-ARM / FISHERS	P=0.002**	(e)	P=0.016*
MAX-ISO-POLY-3	P<0.001**	(e)	P<0.001**

Experiment Number: 20407 - 02  
 Test Type: 90-DAY  
 Route: RESPIRATORY EXPOSURE NASAL  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Nanoscale material (Fullerene-C60 50 nanometers)  
 CAS Number: 99685-96-8

Date Report Requested: 02/05/2013  
 Time Report Requested: 07:58:33  
 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	0.5 mg/m3	2.0 mg/m3
<b>Lung: Artery Inflammation Chronic</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/10 (0%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	1/10.00	0/10.00
POLY-3 PERCENT (g)	0%	10%	0%
TERMINAL (d)	0/10 (0%)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	---	90 (T)	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.695N	P=0.500	(e)
POLY 1.5	P=0.695N	P=0.500	(e)
POLY 6	P=0.695N	P=0.500	(e)
COCH-ARM / FISHERS	P=0.698N	P=0.500	(e)
MAX-ISO-POLY-3	P=0.378N	P=0.159	(e)

Experiment Number: 20407 - 02  
 Test Type: 90-DAY  
 Route: RESPIRATORY EXPOSURE NASAL  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Nanoscale material (Fullerene-C60 50 nanometers)  
 CAS Number: 99685-96-8

Date Report Requested: 02/05/2013  
 Time Report Requested: 07:58:33  
 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	0.5 mg/m3	2.0 mg/m3
<b>Lung: Perivascular Infiltration Cellular Mixed Cell</b>			
<b>LESION RATES</b>			
OVERALL (a)	1/10 (10%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%
TERMINAL (d)	1/10 (10%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	90 (T)	---	---
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.433N	P=0.500N	P=0.500N
POLY 1.5	P=0.433N	P=0.500N	P=0.500N
POLY 6	P=0.433N	P=0.500N	P=0.500N
COCH-ARM / FISHERS	P=0.431N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.156N	P=0.159N	P=0.159N

Experiment Number: 20407 - 02  
 Test Type: 90-DAY  
 Route: RESPIRATORY EXPOSURE NASAL  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Nanoscale material (Fullerene-C60 50 nanometers)  
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Date Report Requested: 02/05/2013  
 Time Report Requested: 07:58:33  
 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	0.5 mg/m3	2.0 mg/m3
<b>Lymph Node, Bronchial Pigmentation</b>			
<b>LESION RATES</b>			
OVERALL (a)	2/10 (20%)	3/7 (43%)	4/10 (40%)
POLY-3 RATE (b)	2/10.00	3/7.00	4/10.00
POLY-3 PERCENT (g)	20%	42.9%	40%
TERMINAL (d)	2/10 (20%)	3/7 (43%)	4/10 (40%)
FIRST INCIDENCE	90 (T)	90 (T)	90 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.327	P=0.322	P=0.318
POLY 1.5	P=0.327	P=0.322	P=0.318
POLY 6	P=0.327	P=0.322	P=0.318
COCH-ARM / FISHERS	P=0.322	P=0.314	P=0.314
MAX-ISO-POLY-3	P=0.235	P=0.182	P=0.172

Experiment Number: 20407 - 02  
 Test Type: 90-DAY  
 Route: RESPIRATORY EXPOSURE NASAL  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Nanoscale material (Fullerene-C60 50 nanometers)  
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Date Report Requested: 02/05/2013  
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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	0.5 mg/m3	2.0 mg/m3
<b>Ovary</b>			
<b>Infiltration Cellular Histiocyte</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/10 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	90 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	P=0.500
POLY 6	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.385	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	P=0.159

Experiment Number: 20407 - 02  
 Test Type: 90-DAY  
 Route: RESPIRATORY EXPOSURE NASAL  
 Species/Strain: MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Nanoscale material (Fullerene-C60 50 nanometers)  
 CAS Number: 99685-96-8

Date Report Requested: 02/05/2013  
 Time Report Requested: 07:58:33  
 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	0.5 mg/m3	2.0 mg/m3
<b>Ovary Pigmentation</b>			
<b>LESION RATES</b>			
OVERALL (a)	0/10 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	90 (T)
<b>STATISTICAL TESTS</b>			
POLY 3	(e)	(e)	P=0.500
POLY 1.5	(e)	(e)	P=0.500
POLY 6	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.385	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	P=0.159

**Experiment Number:** 20407 - 02  
**Test Type:** 90-DAY  
**Route:** RESPIRATORY EXPOSURE NASAL  
**Species/Strain:** MICE/B6C3F1

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
Nanoscale material (Fullerene-C60 50 nanometers)  
**CAS Number:** 99685-96-8

**Date Report Requested:** 02/05/2013  
**Time Report Requested:** 07:58:33  
**First Dose M/F:** 11/05/07 / 11/05/07  
**Lab:** BNW

## **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 \*\*\*