

Experiment Number: 20407 - 01
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: RATS/Wistar Han

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: 07:56:27
First Dose M/F: 11/05/07 / 11/05/07
Lab: BNW

F2_RE

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 RATS

Organ

Epididymis
Harderian Gland
Kidney
Lung
Lymph Node, Bronchial
Lymph Node, Mediastinal
Prostate
Testes: Germinal Epithelium

Morphology

Hypospermia
Inflammation Chronic
Nephropathy
Pigmentation
Pigmentation
Pigmentation
Inflammation Chronic
Degeneration

FEMALE RATS

Organ

Lung

Lymph Node, Bronchial
Lymph Node, Mediastinal

Morphology

Infiltration Cellular Histiocyte
Pigmentation
Pigmentation
Pigmentation

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Adrenal Cortex			
Accessory Adrenal Cortical Nodule			
LESION RATES			
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)
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=0.429N	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	P=0.274N

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TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
<hr/>			
Epididymis			
Hypospermia			
<hr/>			
LESION RATES			
OVERALL (a)	0/10 (0%)	0/10 (0%)	2/10 (20%)
POLY-3 RATE (b)	0/10.00	0/10.00	2/10.00
POLY-3 PERCENT (g)	0%	0%	20%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	2/10 (20%)
FIRST INCIDENCE	---	---	90 (T)
<hr/>			
STATISTICAL TESTS			
POLY 3	P=0.081	(e)	P=0.227
POLY 1.5	P=0.081	(e)	P=0.227
POLY 6	P=0.081	(e)	P=0.227
COCH-ARM / FISHERS	P=0.086	(e)	P=0.237
MAX-ISO-POLY-3	P=0.033*	(e)	P=0.066

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TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Harderian Gland Inflammation Chronic			
LESION RATES			
OVERALL (a)	0/10 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	0/10.00	0/0.00	3/10.00
POLY-3 PERCENT (g)	0%	0%	30%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	3/10 (30%)
FIRST INCIDENCE	---	---	90 (T)
STATISTICAL TESTS			
POLY 3	(e)	(e)	P=0.095
POLY 1.5	(e)	(e)	P=0.095
POLY 6	(e)	(e)	P=0.095
COCH-ARM / FISHERS	P=0.076	(e)	P=0.105
MAX-ISO-POLY-3	(e)	(e)	P=0.025*

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
<hr/>			
Heart Cardiomyopathy			
<hr/>			
LESION RATES			
OVERALL (a)	1/10 (10%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	10%	0%	10%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	90 (T)	---	90 (T)
<hr/>			
STATISTICAL TESTS			
POLY 3	(e)	(e)	P=0.760
POLY 1.5	(e)	(e)	P=0.760
POLY 6	(e)	(e)	P=0.760
COCH-ARM / FISHERS	P=0.703	(e)	P=0.763N
MAX-ISO-POLY-3	(e)	(e)	P=1.000

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 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Kidney Infarct			
LESION RATES			
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)
STATISTICAL TESTS			
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
Kidney			
Nephropathy			
LESION RATES			
OVERALL (a)	1/10 (10%)	1/10 (10%)	6/10 (60%)
POLY-3 RATE (b)	1/10.00	1/10.00	6/10.00
POLY-3 PERCENT (g)	10%	10%	60%
TERMINAL (d)	1/10 (10%)	1/10 (10%)	6/10 (60%)
FIRST INCIDENCE	90 (T)	90 (T)	90 (T)
STATISTICAL TESTS			
POLY 3	P=0.003**	P=0.760	P=0.018*
POLY 1.5	P=0.003**	P=0.760	P=0.018*
POLY 6	P=0.003**	P=0.760	P=0.018*
COCH-ARM / FISHERS	P=0.007**	P=0.763N	P=0.029*
MAX-ISO-POLY-3	P=0.002**	P=1.000	P=0.004**

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TERMINAL SACRIFICE AT 13 WEEKS**

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

**Kidney: Bilateral, Pelvis
Dilatation**

LESION RATES			
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)

STATISTICAL TESTS			
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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DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Kidney: Medulla Inflammation Chronic			
LESION RATES			
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)
STATISTICAL TESTS			
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
Kidney: Pelvis Dilatation			
LESION RATES			
OVERALL (a)	0/10 (0%)	2/10 (20%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	2/10.00	1/10.00
POLY-3 PERCENT (g)	0%	20%	10%
TERMINAL (d)	0/10 (0%)	2/10 (20%)	1/10 (10%)
FIRST INCIDENCE	---	90 (T)	90 (T)
STATISTICAL TESTS			
POLY 3	P=0.541	P=0.227	P=0.500
POLY 1.5	P=0.541	P=0.227	P=0.500
POLY 6	P=0.541	P=0.227	P=0.500
COCH-ARM / FISHERS	P=0.541	P=0.237	P=0.500
MAX-ISO-POLY-3	P=0.134	P=0.066	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
Lung			
Infiltration Cellular Histiocyte			
LESION RATES			
OVERALL (a)	1/10 (10%)	1/10 (10%)	3/10 (30%)
POLY-3 RATE (b)	1/10.00	1/10.00	3/10.00
POLY-3 PERCENT (g)	10%	10%	30%
TERMINAL (d)	1/10 (10%)	1/10 (10%)	3/10 (30%)
FIRST INCIDENCE	90 (T)	90 (T)	90 (T)
STATISTICAL TESTS			
POLY 3	P=0.185	P=0.760	P=0.292
POLY 1.5	P=0.185	P=0.760	P=0.292
POLY 6	P=0.185	P=0.760	P=0.292
COCH-ARM / FISHERS	P=0.180	P=0.763N	P=0.291
MAX-ISO-POLY-3	P=0.119	P=1.000	P=0.136

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 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Lung			
Metaplasia Osseous			
LESION RATES			
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)	---	---
STATISTICAL TESTS			
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=0.109N	P=0.158N	P=0.158N

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 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Lung Pigmentation			
LESION RATES			
OVERALL (a)	0/10 (0%)	0/10 (0%)	3/10 (30%)
POLY-3 RATE (b)	0/10.00	0/10.00	3/10.00
POLY-3 PERCENT (g)	0%	0%	30%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	3/10 (30%)
FIRST INCIDENCE	---	---	90 (T)
STATISTICAL TESTS			
POLY 3	P=0.017*	(e)	P=0.095
POLY 1.5	P=0.017*	(e)	P=0.095
POLY 6	P=0.017*	(e)	P=0.095
COCH-ARM / FISHERS	P=0.025*	(e)	P=0.105
MAX-ISO-POLY-3	P=0.008**	(e)	P=0.025*

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 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Lymph Node, Bronchial Pigmentation			
LESION RATES			
OVERALL (a)	0/10 (0%)	3/9 (33%)	4/10 (40%)
POLY-3 RATE (b)	0/10.00	3/9.00	4/10.00
POLY-3 PERCENT (g)	0%	33.3%	40%
TERMINAL (d)	0/10 (0%)	3/9 (33%)	4/10 (40%)
FIRST INCIDENCE	---	90 (T)	90 (T)
STATISTICAL TESTS			
POLY 3	P=0.061	P=0.074	P=0.033*
POLY 1.5	P=0.061	P=0.074	P=0.033*
POLY 6	P=0.061	P=0.074	P=0.033*
COCH-ARM / FISHERS	P=0.068	P=0.087	P=0.043*
MAX-ISO-POLY-3	P=0.015*	P=0.019*	P=0.007**

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TERMINAL SACRIFICE AT 13 WEEKS**

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

Lymph Node, Mediastinal Pigmentation

LESION RATES

OVERALL (a)	1/10 (10%)	6/8 (75%)	2/10 (20%)
POLY-3 RATE (b)	1/10.00	6/8.00	2/10.00
POLY-3 PERCENT (g)	10%	75%	20%
TERMINAL (d)	1/10 (10%)	6/8 (75%)	2/10 (20%)
FIRST INCIDENCE	90 (T)	90 (T)	90 (T)

STATISTICAL TESTS

POLY 3	P=0.553N	P=0.002**	P=0.500
POLY 1.5	P=0.553N	P=0.002**	P=0.500
POLY 6	P=0.553N	P=0.002**	P=0.500
COCH-ARM / FISHERS	P=0.545N	P=0.009**	P=0.500
MAX-ISO-POLY-3	P=0.027*	P<0.001**	P=0.274

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

Pancreas: Acinus
Atrophy

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)	---	---

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=0.158N

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 Time Report Requested: 07:56:27
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Pituitary Gland Cyst			
LESION RATES			
OVERALL (a)	2/10 (20%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	20%	0%	0%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	90 (T)	---	---
STATISTICAL TESTS			
POLY 3	(e)	(e)	P=0.227N
POLY 1.5	(e)	(e)	P=0.227N
POLY 6	(e)	(e)	P=0.227N
COCH-ARM / FISHERS	P=0.169N	(e)	P=0.237N
MAX-ISO-POLY-3	(e)	(e)	P=0.066N

Experiment Number: 20407 - 01
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: RATS/Wistar Han

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 13 WEEKS**

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

Pituitary Gland: Pars Distalis
Hyperplasia

LESION RATES

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)

STATISTICAL TESTS

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

Experiment Number: 20407 - 01
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: RATS/Wistar Han

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

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First Dose M/F: 11/05/07 / 11/05/07
Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Preputial Gland Inflammation Chronic			
LESION RATES			
OVERALL (a)	2/10 (20%)	0/0 (0%)	2/10 (20%)
POLY-3 RATE (b)	2/10.00	0/0.00	2/10.00
POLY-3 PERCENT (g)	20%	0%	20%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	2/10 (20%)
FIRST INCIDENCE	90 (T)	---	90 (T)
STATISTICAL TESTS			
POLY 3	(e)	(e)	P=0.702
POLY 1.5	(e)	(e)	P=0.702
POLY 6	(e)	(e)	P=0.702
COCH-ARM / FISHERS	P=0.655	(e)	P=0.709N
MAX-ISO-POLY-3	(e)	(e)	P=1.000

Experiment Number: 20407 - 01
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: RATS/Wistar Han

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

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First Dose M/F: 11/05/07 / 11/05/07
Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Prostate Inflammation Chronic			
LESION RATES			
OVERALL (a)	0/10 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	0/10.00	0/0.00	3/10.00
POLY-3 PERCENT (g)	0%	0%	30%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	3/10 (30%)
FIRST INCIDENCE	---	---	90 (T)
STATISTICAL TESTS			
POLY 3	(e)	(e)	P=0.095
POLY 1.5	(e)	(e)	P=0.095
POLY 6	(e)	(e)	P=0.095
COCH-ARM / FISHERS	P=0.076	(e)	P=0.105
MAX-ISO-POLY-3	(e)	(e)	P=0.025*

Experiment Number: 20407 - 01
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: RATS/Wistar Han

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

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Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 13 WEEKS**

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

Stomach, Forestomach
Hyperplasia

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)	---	---

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=0.158N

Experiment Number: 20407 - 01
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: RATS/Wistar Han

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: 07:56:27
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Testes: Germinal Epithelium Degeneration			
LESION RATES			
OVERALL (a)	0/10 (0%)	0/10 (0%)	3/10 (30%)
POLY-3 RATE (b)	0/10.00	0/10.00	3/10.00
POLY-3 PERCENT (g)	0%	0%	30%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	3/10 (30%)
FIRST INCIDENCE	---	---	90 (T)
STATISTICAL TESTS			
POLY 3	P=0.017*	(e)	P=0.095
POLY 1.5	P=0.017*	(e)	P=0.095
POLY 6	P=0.017*	(e)	P=0.095
COCH-ARM / FISHERS	P=0.025*	(e)	P=0.105
MAX-ISO-POLY-3	P=0.008**	(e)	P=0.025*

Experiment Number: 20407 - 01
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: RATS/Wistar Han

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: 07:56:27
First Dose M/F: 11/05/07 / 11/05/07
Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Thymus Cyst			
LESION RATES			
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	---	---	---
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)

Experiment Number: 20407 - 01
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: RATS/Wistar Han

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
<hr/>			
Thymus Hemorrhage			
<hr/>			
LESION RATES			
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)
<hr/>			
STATISTICAL TESTS			
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

Experiment Number: 20407 - 01
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: RATS/Wistar Han

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Males		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Urinary Bladder Inflammation Chronic			
LESION RATES			
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)
STATISTICAL TESTS			
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

Experiment Number: 20407 - 01
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: RATS/Wistar Han

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Adrenal Cortex			
Accessory Adrenal Cortical Nodule			
LESION RATES			
OVERALL (a)	2/10 (20%)	0/0 (0%)	2/10 (20%)
POLY-3 RATE (b)	2/10.00	0/0.00	2/10.00
POLY-3 PERCENT (g)	20%	0%	20%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	2/10 (20%)
FIRST INCIDENCE	90 (T)	---	90 (T)
STATISTICAL TESTS			
POLY 3	(e)	(e)	P=0.702
POLY 1.5	(e)	(e)	P=0.702
POLY 6	(e)	(e)	P=0.702
COCH-ARM / FISHERS	P=0.655	(e)	P=0.709N
MAX-ISO-POLY-3	(e)	(e)	P=1.000

Experiment Number: 20407 - 01
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: RATS/Wistar Han

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Clitoral Gland Inflammation Chronic			
LESION RATES			
OVERALL (a)	4/10 (40%)	0/0 (0%)	4/10 (40%)
POLY-3 RATE (b)	4/10.00	0/0.00	4/10.00
POLY-3 PERCENT (g)	40%	0%	40%
TERMINAL (d)	4/10 (40%)	0/0 (0%)	4/10 (40%)
FIRST INCIDENCE	90 (T)	---	90 (T)
STATISTICAL TESTS			
POLY 3	(e)	(e)	P=0.667
POLY 1.5	(e)	(e)	P=0.667
POLY 6	(e)	(e)	P=0.667
COCH-ARM / FISHERS	P=0.628	(e)	P=0.675N
MAX-ISO-POLY-3	(e)	(e)	P=1.000

Experiment Number: 20407 - 01
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: RATS/Wistar Han

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Harderian Gland Inflammation Chronic			
LESION RATES			
OVERALL (a)	2/10 (20%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	20%	0%	0%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	90 (T)	---	---
STATISTICAL TESTS			
POLY 3	(e)	(e)	P=0.227N
POLY 1.5	(e)	(e)	P=0.227N
POLY 6	(e)	(e)	P=0.227N
COCH-ARM / FISHERS	P=0.169N	(e)	P=0.237N
MAX-ISO-POLY-3	(e)	(e)	P=0.066N

Experiment Number: 20407 - 01
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: RATS/Wistar Han

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Heart			
Cardiomyopathy			
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)	---	---
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=0.158N

Experiment Number: 20407 - 01
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: RATS/Wistar Han

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

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Kidney Infarct			
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	---	---	---
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)

Experiment Number: 20407 - 01
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: RATS/Wistar Han

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Kidney Nephropathy			
LESION RATES			
OVERALL (a)	2/10 (20%)	3/10 (30%)	2/10 (20%)
POLY-3 RATE (b)	2/10.00	3/10.00	2/10.00
POLY-3 PERCENT (g)	20%	30%	20%
TERMINAL (d)	2/10 (20%)	3/10 (30%)	2/10 (20%)
FIRST INCIDENCE	90 (T)	90 (T)	90 (T)
STATISTICAL TESTS			
POLY 3	P=0.583N	P=0.500	P=0.702
POLY 1.5	P=0.583N	P=0.500	P=0.702
POLY 6	P=0.583N	P=0.500	P=0.702
COCH-ARM / FISHERS	P=0.587N	P=0.500	P=0.709N
MAX-ISO-POLY-3	P=0.398N	P=0.310	P=1.000

Experiment Number: 20407 - 01
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: RATS/Wistar Han

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Kidney: Bilateral, Pelvis Dilatation			
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	---	---	---
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)

Experiment Number: 20407 - 01
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: RATS/Wistar Han

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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First Dose M/F: 11/05/07 / 11/05/07
Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 13 WEEKS**

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

**Kidney: Medulla
Inflammation Chronic**

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	---	---	---

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)

Experiment Number: 20407 - 01
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: RATS/Wistar Han

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: 07:56:27
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Kidney: Pelvis Dilatation			
LESION RATES			
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)
STATISTICAL TESTS			
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

Experiment Number: 20407 - 01
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: RATS/Wistar Han

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: 07:56:27
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Lung			
Infiltration Cellular Histiocyte			
LESION RATES			
OVERALL (a)	2/10 (20%)	1/10 (10%)	8/10 (80%)
POLY-3 RATE (b)	2/10.00	1/10.00	8/10.00
POLY-3 PERCENT (g)	20%	10%	80%
TERMINAL (d)	2/10 (20%)	1/10 (10%)	8/10 (80%)
FIRST INCIDENCE	90 (T)	90 (T)	90 (T)
STATISTICAL TESTS			
POLY 3	P<0.001**	P=0.500N	P=0.004**
POLY 1.5	P<0.001**	P=0.500N	P=0.004**
POLY 6	P<0.001**	P=0.500N	P=0.004**
COCH-ARM / FISHERS	P=0.002**	P=0.500N	P=0.012*
MAX-ISO-POLY-3	P<0.001**	P=0.274N	P<0.001**

Experiment Number: 20407 - 01
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: RATS/Wistar Han

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: 07:56:27
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Lung			
Metaplasia Osseous			
LESION RATES			
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)	---
STATISTICAL TESTS			
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

Experiment Number: 20407 - 01
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: RATS/Wistar Han

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: 07:56:27
First Dose M/F: 11/05/07 / 11/05/07
Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
<hr/>			
Lung Pigmentation			
<hr/>			
LESION RATES			
OVERALL (a)	0/10 (0%)	0/10 (0%)	8/10 (80%)
POLY-3 RATE (b)	0/10.00	0/10.00	8/10.00
POLY-3 PERCENT (g)	0%	0%	80%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	8/10 (80%)
FIRST INCIDENCE	---	---	90 (T)
<hr/>			
STATISTICAL TESTS			
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<0.001**
MAX-ISO-POLY-3	P<0.001**	(e)	P<0.001**

Experiment Number: 20407 - 01
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: RATS/Wistar Han

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: 07:56:27
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Lymph Node, Bronchial Pigmentation			
LESION RATES			
OVERALL (a)	0/10 (0%)	1/10 (10%)	5/10 (50%)
POLY-3 RATE (b)	0/10.00	1/10.00	5/10.00
POLY-3 PERCENT (g)	0%	10%	50%
TERMINAL (d)	0/10 (0%)	1/10 (10%)	5/10 (50%)
FIRST INCIDENCE	---	90 (T)	90 (T)
STATISTICAL TESTS			
POLY 3	P=0.002**	P=0.500	P=0.008**
POLY 1.5	P=0.002**	P=0.500	P=0.008**
POLY 6	P=0.002**	P=0.500	P=0.008**
COCH-ARM / FISHERS	P=0.005**	P=0.500	P=0.016*
MAX-ISO-POLY-3	P<0.001**	P=0.158	P<0.001**

Experiment Number: 20407 - 01
 Test Type: 90-DAY
 Route: RESPIRATORY EXPOSURE NASAL
 Species/Strain: RATS/Wistar Han

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: 07:56:27
 First Dose M/F: 11/05/07 / 11/05/07
 Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
 TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Lymph Node, Mediastinal Pigmentation			
LESION RATES			
OVERALL (a)	0/8 (0%)	7/8 (88%)	9/10 (90%)
POLY-3 RATE (b)	0/8.00	7/8.00	9/10.00
POLY-3 PERCENT (g)	0%	87.5%	90%
TERMINAL (d)	0/8 (0%)	7/8 (88%)	9/10 (90%)
FIRST INCIDENCE	---	90 (T)	90 (T)
STATISTICAL TESTS			
POLY 3	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P=0.002**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**

Experiment Number: 20407 - 01
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: RATS/Wistar Han

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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First Dose M/F: 11/05/07 / 11/05/07
Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Ovary Cyst			
LESION RATES			
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)
STATISTICAL TESTS			
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

Experiment Number: 20407 - 01
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: RATS/Wistar Han

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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First Dose M/F: 11/05/07 / 11/05/07
Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 13 WEEKS**

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

Ovary: Bilateral
Cyst

LESION RATES

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)

STATISTICAL TESTS

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

Experiment Number: 20407 - 01
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: RATS/Wistar Han

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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First Dose M/F: 11/05/07 / 11/05/07
Lab: BNW

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 13 WEEKS**

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

Pancreas: Acinus
Atrophy

LESION RATES

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	---	---	---

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)

Experiment Number: 20407 - 01
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: RATS/Wistar Han

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Pituitary Gland Cyst			
LESION RATES			
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	---	---	---
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)

Experiment Number: 20407 - 01
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: RATS/Wistar Han

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 13 WEEKS**

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

Pituitary Gland: Pars Distalis
Hyperplasia

LESION RATES

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)

STATISTICAL TESTS

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

Experiment Number: 20407 - 01
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: RATS/Wistar Han

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Stomach, Forestomach Hyperplasia			
LESION RATES			
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	---	---	---
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)

Experiment Number: 20407 - 01
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: RATS/Wistar Han

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
<hr/>			
Thymus Cyst			
<hr/>			
LESION RATES			
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)
<hr/>			
STATISTICAL TESTS			
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

Experiment Number: 20407 - 01
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: RATS/Wistar Han

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
<hr/>			
Thymus Hemorrhage			
<hr/>			
LESION RATES			
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/>			
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)

Experiment Number: 20407 - 01
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: RATS/Wistar Han

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(Wistar Han)
TERMINAL SACRIFICE AT 13 WEEKS**

DOSE	Females		
	0 mg/m3	0.5 mg/m3	2.0 mg/m3
Urinary Bladder Inflammation Chronic			
LESION RATES			
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	---	---	---
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)

Experiment Number: 20407 - 01
Test Type: 90-DAY
Route: RESPIRATORY EXPOSURE NASAL
Species/Strain: RATS/Wistar Han

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