

**TDMS No.** 20226 - 01  
**Test Type:** 26-WEEK  
**Route:** DOSED FEED  
**Species/Strain:** RATS/SD

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

Chitosan  
**CAS Number:** 9012-76-4

**Date Report Requested:** 05/28/2009  
**Time Report Requested:** 08:46:11  
**First Dose M/F:** 08/31/06 / 09/01/06  
**Lab:** BAT

F1\_R8

**C Number:** C20226  
**Lock Date:** 05/07/2008  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 2.1.0

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**SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF CHITOSAN**

**MALE RATS**

**Organ**

Kidney: Pelvis  
Liver  
Prostate

**FEMALE RATS**

**Organ**

Kidney  
Liver: Periportal

**Morphology**

Dilatation  
Hematopoietic Cell Proliferation  
Inflammation

**Morphology**

Nephropathy  
Fatty Change

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)  
TERMINAL SACRIFICE AT 25 WEEKS

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DOSE	Males			
	0 %	1 %	3 %	9 %
<b>Harderian Gland Infiltration Cellular Lymphocyte</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	20%	0%	0%	10%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	169 (T)	---	---	169 (T)
<b>STATISTICAL TESTS</b>				
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=0.417N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.274N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)**  
**TERMINAL SACRIFICE AT 25 WEEKS**

DOSE	Males			
	0 %	1 %	3 %	9 %
<b>Heart</b>				
<b>Cardiomyopathy</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	5/10 (50%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
<b>POLY-3 RATE (b)</b>	5/10.00	0/0.00	0/0.00	3/10.00
<b>POLY-3 PERCENT (g)</b>	50%	0%	0%	30%
<b>TERMINAL (d)</b>	5/10 (50%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
<b>FIRST INCIDENCE</b>	169 (T)	---	---	169 (T)
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	(e)	(e)	(e)	P=0.329N
<b>POLY 1.5</b>	(e)	(e)	(e)	P=0.329N
<b>POLY 6</b>	(e)	(e)	(e)	P=0.329N
<b>COCH-ARM / FISHERS</b>	P=0.271N	(e)	(e)	P=0.325N
<b>MAX-ISO-POLY-3</b>	(e)	(e)	(e)	P=0.188N

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)  
TERMINAL SACRIFICE AT 25 WEEKS

---

DOSE	Males			
	0 %	1 %	3 %	9 %
<b>Kidney Mineralization</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/10 (20%)	4/10 (40%)	3/10 (30%)	5/10 (50%)
POLY-3 RATE (b)	2/10.00	4/10.00	3/10.00	5/10.00
POLY-3 PERCENT (g)	20%	40%	30%	50%
TERMINAL (d)	2/10 (20%)	4/10 (40%)	3/10 (30%)	5/10 (50%)
FIRST INCIDENCE	169 (T)	169 (T)	169 (T)	169 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.189	P=0.318	P=0.500	P=0.174
POLY 1.5	P=0.189	P=0.318	P=0.500	P=0.174
POLY 6	P=0.189	P=0.318	P=0.500	P=0.174
COCH-ARM / FISHERS	P=0.184	P=0.314	P=0.500	P=0.175
MAX-ISO-POLY-3	P=0.084	P=0.172	P=0.310	P=0.079

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)**  
**TERMINAL SACRIFICE AT 25 WEEKS**

DOSE	Males			
	0 %	1 %	3 %	9 %
<b>Kidney</b>				
<b>Nephropathy</b>				
<b>LESION RATES</b>				
OVERALL (a)	9/10 (90%)	9/10 (90%)	9/10 (90%)	9/10 (90%)
POLY-3 RATE (b)	9/10.00	9/10.00	9/10.00	9/10.00
POLY-3 PERCENT (g)	90%	90%	90%	90%
TERMINAL (d)	9/10 (90%)	9/10 (90%)	9/10 (90%)	9/10 (90%)
FIRST INCIDENCE	169 (T)	169 (T)	169 (T)	169 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.666	P=0.760	P=0.760	P=0.760
POLY 1.5	P=0.666	P=0.760	P=0.760	P=0.760
POLY 6	P=0.666	P=0.760	P=0.760	P=0.760
COCH-ARM / FISHERS	P=0.675	P=0.763N	P=0.763N	P=0.763N
MAX-ISO-POLY-3	P=1.000	P=1.000	P=1.000	P=1.000

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)**  
**TERMINAL SACRIFICE AT 25 WEEKS**

DOSE	Males			
	0 %	1 %	3 %	9 %
<b>Kidney: Pelvis Dilatation</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/10 (20%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	0/10.00	1/10.00	0/10.00
POLY-3 PERCENT (g)	20%	0%	10%	0%
TERMINAL (d)	2/10 (20%)	0/10 (0%)	1/10 (10%)	0/10 (0%)
FIRST INCIDENCE	169 (T)	---	169 (T)	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.260N	P=0.227N	P=0.500N	P=0.227N
POLY 1.5	P=0.260N	P=0.227N	P=0.500N	P=0.227N
POLY 6	P=0.260N	P=0.227N	P=0.500N	P=0.227N
COCH-ARM / FISHERS	P=0.260N	P=0.237N	P=0.500N	P=0.237N
MAX-ISO-POLY-3	P=0.045N*	P=0.066N	P=0.274N	P=0.066N

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**TERMINAL SACRIFICE AT 25 WEEKS**

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DOSE	Males			
	0 %	1 %	3 %	9 %
<b>Liver</b>				
<b>Hematopoietic Cell Proliferation</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/10 (20%)	3/10 (30%)	3/10 (30%)	6/10 (60%)
POLY-3 RATE (b)	2/10.00	3/10.00	3/10.00	6/10.00
POLY-3 PERCENT (g)	20%	30%	30%	60%
TERMINAL (d)	2/10 (20%)	3/10 (30%)	3/10 (30%)	6/10 (60%)
FIRST INCIDENCE	169 (T)	169 (T)	169 (T)	169 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.048*	P=0.500	P=0.500	P=0.077
POLY 1.5	P=0.048*	P=0.500	P=0.500	P=0.077
POLY 6	P=0.048*	P=0.500	P=0.500	P=0.077
COCH-ARM / FISHERS	P=0.048*	P=0.500	P=0.500	P=0.085
MAX-ISO-POLY-3	P=0.030*	P=0.310	P=0.310	P=0.029*

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TERMINAL SACRIFICE AT 25 WEEKS

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DOSE	Males			
	0 %	1 %	3 %	9 %
<hr/>				
Liver				
Inflammation Chronic				
<hr/>				
<b>LESION RATES</b>				
OVERALL (a)	10/10 (100%)	10/10 (100%)	10/10 (100%)	9/10 (90%)
POLY-3 RATE (b)	10/10.00	10/10.00	10/10.00	9/10.00
POLY-3 PERCENT (g)	100%	100%	100%	90%
TERMINAL (d)	10/10 (100%)	10/10 (100%)	10/10 (100%)	9/10 (90%)
FIRST INCIDENCE	169 (T)	169 (T)	169 (T)	169 (T)
<hr/>				
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.215N	(e)	(e)	P=0.500N
POLY 1.5	P=0.215N	(e)	(e)	P=0.500N
POLY 6	P=0.215N	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.213N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	P=0.078N	(e)	(e)	P=0.158N

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**TERMINAL SACRIFICE AT 25 WEEKS**

DOSE	Males			
	0 %	1 %	3 %	9 %
<b>Liver: Periportal Fatty Change</b>				
<b>LESION RATES</b>				
OVERALL (a)	6/10 (60%)	3/10 (30%)	6/10 (60%)	3/10 (30%)
POLY-3 RATE (b)	6/10.00	3/10.00	6/10.00	3/10.00
POLY-3 PERCENT (g)	60%	30%	60%	30%
TERMINAL (d)	6/10 (60%)	3/10 (30%)	6/10 (60%)	3/10 (30%)
FIRST INCIDENCE	169 (T)	169 (T)	169 (T)	169 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.248N	P=0.186N	P=0.667	P=0.186N
POLY 1.5	P=0.248N	P=0.186N	P=0.667	P=0.186N
POLY 6	P=0.248N	P=0.186N	P=0.667	P=0.186N
COCH-ARM / FISHERS	P=0.247N	P=0.185N	P=0.675N	P=0.185N
MAX-ISO-POLY-3	P=0.089N	P=0.089N	P=1.000	P=0.089N

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**TERMINAL SACRIFICE AT 25 WEEKS**

DOSE	Males			
	0 %	1 %	3 %	9 %
<b>Lung Hemorrhage</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	169 (T)	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	P=0.227N
POLY 1.5	(e)	(e)	(e)	P=0.227N
POLY 6	(e)	(e)	(e)	P=0.227N
COCH-ARM / FISHERS	P=0.160N	(e)	(e)	P=0.237N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.066N

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**TERMINAL SACRIFICE AT 25 WEEKS**

DOSE	Males			
	0 %	1 %	3 %	9 %
<b>Lung</b>				
<b>Inflammation Chronic</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	4/10 (40%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	4/10.00
POLY-3 PERCENT (g)	20%	0%	0%	40%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	4/10 (40%)
FIRST INCIDENCE	169 (T)	---	---	169 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	P=0.318
POLY 1.5	(e)	(e)	(e)	P=0.318
POLY 6	(e)	(e)	(e)	P=0.318
COCH-ARM / FISHERS	P=0.258	(e)	(e)	P=0.314
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.172

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**TERMINAL SACRIFICE AT 25 WEEKS**

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DOSE	Males			
	0 %	1 %	3 %	9 %
<b>Lung: Alveolus</b>				
<b>Infiltration Cellular Histiocyte</b>				
<hr/>				
<b>LESION RATES</b>				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---
<hr/>				
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

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**TERMINAL SACRIFICE AT 25 WEEKS**

DOSE	Males			
	0 %	1 %	3 %	9 %
<b>Lymph Node, Mandibular Infiltration Cellular Plasma Cell</b>				
<b>LESION RATES</b>				
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	2/10.00
POLY-3 PERCENT (g)	10%	0%	0%	20%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
FIRST INCIDENCE	169 (T)	---	---	169 (T)
<b>STATISTICAL TESTS</b>				
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=0.417	(e)	(e)	P=0.500
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.274

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**TERMINAL SACRIFICE AT 25 WEEKS**

DOSE	Males			
	0 %	1 %	3 %	9 %
<b>Pancreas Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	20%	0%	0%	10%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	169 (T)	---	---	169 (T)
<b>STATISTICAL TESTS</b>				
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=0.417N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.274N

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**TERMINAL SACRIFICE AT 25 WEEKS**

DOSE	Males			
	0 %	1 %	3 %	9 %
<b>Preputial Gland Inflammation Chronic</b>				
<b>LESION RATES</b>				
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	---	---	---	169 (T)
<b>STATISTICAL TESTS</b>				
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=0.160	(e)	(e)	P=0.237
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.066



TDMS No. 20226 - 01  
 Test Type: 26-WEEK  
 Route: DOSED FEED  
 Species/Strain: RATS/SD

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Chitosan  
 CAS Number: 9012-76-4

Date Report Requested: 05/28/2009  
 Time Report Requested: 08:46:11  
 First Dose M/F: 08/31/06 / 09/01/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)**  
**TERMINAL SACRIFICE AT 25 WEEKS**

DOSE	Males			
	0 %	1 %	3 %	9 %
<b>Prostate Inflammation</b>				
<b>LESION RATES</b>				
OVERALL (a)	8/10 (80%)	9/10 (90%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	8/10.00	9/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	80%	90%	100%	100%
TERMINAL (d)	8/10 (80%)	9/10 (90%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	169 (T)	169 (T)	169 (T)	169 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.162	P=0.500	P=0.227	P=0.227
POLY 1.5	P=0.162	P=0.500	P=0.227	P=0.227
POLY 6	P=0.162	P=0.500	P=0.227	P=0.227
COCH-ARM / FISHERS	P=0.161	P=0.500	P=0.237	P=0.237
MAX-ISO-POLY-3	P=0.045*	P=0.274	P=0.066	P=0.066

TDMS No. 20226 - 01  
 Test Type: 26-WEEK  
 Route: DOSED FEED  
 Species/Strain: RATS/SD

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Chitosan  
 CAS Number: 9012-76-4

Date Report Requested: 05/28/2009  
 Time Report Requested: 08:46:11  
 First Dose M/F: 08/31/06 / 09/01/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)**  
**TERMINAL SACRIFICE AT 25 WEEKS**

DOSE	Males			
	0 %	1 %	3 %	9 %
<b>Spleen</b>				
<b>Hematopoietic Cell Proliferation</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	5/10 (50%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
<b>POLY-3 RATE (b)</b>	5/10.00	0/0.00	0/0.00	2/10.00
<b>POLY-3 PERCENT (g)</b>	50%	0%	0%	20%
<b>TERMINAL (d)</b>	5/10 (50%)	0/0 (0%)	0/0 (0%)	2/10 (20%)
<b>FIRST INCIDENCE</b>	169 (T)	---	---	169 (T)
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	(e)	(e)	(e)	P=0.174N
<b>POLY 1.5</b>	(e)	(e)	(e)	P=0.174N
<b>POLY 6</b>	(e)	(e)	(e)	P=0.174N
<b>COCH-ARM / FISHERS</b>	P=0.137N	(e)	(e)	P=0.175N
<b>MAX-ISO-POLY-3</b>	(e)	(e)	(e)	P=0.079N

TDMS No. 20226 - 01  
 Test Type: 26-WEEK  
 Route: DOSED FEED  
 Species/Strain: RATS/SD

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Chitosan  
 CAS Number: 9012-76-4

Date Report Requested: 05/28/2009  
 Time Report Requested: 08:46:11  
 First Dose M/F: 08/31/06 / 09/01/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)**  
**TERMINAL SACRIFICE AT 25 WEEKS**

DOSE	Males			
	0 %	1 %	3 %	9 %
<b>Stomach, Forestomach: Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
OVERALL (a)	3/10 (30%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	3/10.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	30%	0%	0%	10%
TERMINAL (d)	3/10 (30%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	169 (T)	---	---	169 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	P=0.292N
POLY 1.5	(e)	(e)	(e)	P=0.292N
POLY 6	(e)	(e)	(e)	P=0.292N
COCH-ARM / FISHERS	P=0.228N	(e)	(e)	P=0.291N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.136N

TDMS No. 20226 - 01  
Test Type: 26-WEEK  
Route: DOSED FEED  
Species/Strain: RATS/SD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Chitosan  
CAS Number: 9012-76-4

Date Report Requested: 05/28/2009  
Time Report Requested: 08:46:11  
First Dose M/F: 08/31/06 / 09/01/06  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)  
TERMINAL SACRIFICE AT 25 WEEKS

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DOSE	Females			
	0 %	1 %	3 %	9 %
<b>Clitoral Gland Inflammation Chronic</b>				
<b>LESION RATES</b>				
OVERALL (a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	169 (T)	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	P=0.227N
POLY 1.5	(e)	(e)	(e)	P=0.227N
POLY 6	(e)	(e)	(e)	P=0.227N
COCH-ARM / FISHERS	P=0.160N	(e)	(e)	P=0.237N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.066N

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TDMS No. 20226 - 01  
 Test Type: 26-WEEK  
 Route: DOSED FEED  
 Species/Strain: RATS/SD

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Chitosan  
 CAS Number: 9012-76-4

Date Report Requested: 05/28/2009  
 Time Report Requested: 08:46:11  
 First Dose M/F: 08/31/06 / 09/01/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)**  
**TERMINAL SACRIFICE AT 25 WEEKS**

DOSE	Females			
	0 %	1 %	3 %	9 %
<b>Harderian Gland</b>				
<b>Infiltration Cellular Lymphocyte</b>				
<b>LESION RATES</b>				
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	169 (T)	---	---	169 (T)
<b>STATISTICAL TESTS</b>				
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=0.690	(e)	(e)	P=0.763N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=1.000

TDMS No. 20226 - 01  
 Test Type: 26-WEEK  
 Route: DOSED FEED  
 Species/Strain: RATS/SD

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Chitosan  
 CAS Number: 9012-76-4

Date Report Requested: 05/28/2009  
 Time Report Requested: 08:46:11  
 First Dose M/F: 08/31/06 / 09/01/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)**  
**TERMINAL SACRIFICE AT 25 WEEKS**

DOSE	Females			
	0 %	1 %	3 %	9 %
<b>Heart</b>				
<b>Cardiomyopathy</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
<b>POLY-3 RATE (b)</b>	1/10.00	0/0.00	0/0.00	0/10.00
<b>POLY-3 PERCENT (g)</b>	10%	0%	0%	0%
<b>TERMINAL (d)</b>	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
<b>FIRST INCIDENCE</b>	169 (T)	---	---	---
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	(e)	(e)	(e)	P=0.500N
<b>POLY 1.5</b>	(e)	(e)	(e)	P=0.500N
<b>POLY 6</b>	(e)	(e)	(e)	P=0.500N
<b>COCH-ARM / FISHERS</b>	P=0.366N	(e)	(e)	P=0.500N
<b>MAX-ISO-POLY-3</b>	(e)	(e)	(e)	P=0.158N

TDMS No. 20226 - 01  
 Test Type: 26-WEEK  
 Route: DOSED FEED  
 Species/Strain: RATS/SD

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Chitosan  
 CAS Number: 9012-76-4

Date Report Requested: 05/28/2009  
 Time Report Requested: 08:46:11  
 First Dose M/F: 08/31/06 / 09/01/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)**  
**TERMINAL SACRIFICE AT 25 WEEKS**

DOSE	Females			
	0 %	1 %	3 %	9 %
<b>Kidney Mineralization</b>				
<b>LESION RATES</b>				
OVERALL (a)	8/10 (80%)	8/10 (80%)	5/10 (50%)	6/10 (60%)
POLY-3 RATE (b)	8/10.00	8/10.00	5/10.00	6/10.00
POLY-3 PERCENT (g)	80%	80%	50%	60%
TERMINAL (d)	8/10 (80%)	8/10 (80%)	5/10 (50%)	6/10 (60%)
FIRST INCIDENCE	169 (T)	169 (T)	169 (T)	169 (T)
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.230N	P=0.702	P=0.174N	P=0.318N
POLY 1.5	P=0.230N	P=0.702	P=0.174N	P=0.318N
POLY 6	P=0.230N	P=0.702	P=0.174N	P=0.318N
COCH-ARM / FISHERS	P=0.227N	P=0.709N	P=0.175N	P=0.314N
MAX-ISO-POLY-3	P=0.118N	P=1.000	P=0.079N	P=0.172N

TDMS No. 20226 - 01  
 Test Type: 26-WEEK  
 Route: DOSED FEED  
 Species/Strain: RATS/SD

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Chitosan  
 CAS Number: 9012-76-4

Date Report Requested: 05/28/2009  
 Time Report Requested: 08:46:11  
 First Dose M/F: 08/31/06 / 09/01/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)**  
**TERMINAL SACRIFICE AT 25 WEEKS**

DOSE	Females			
	0 %	1 %	3 %	9 %
<b>Kidney</b>				
<b>Nephropathy</b>				
<b>LESION RATES</b>				
OVERALL (a)	5/10 (50%)	6/10 (60%)	5/10 (50%)	0/10 (0%)
POLY-3 RATE (b)	5/10.00	6/10.00	5/10.00	0/10.00
POLY-3 PERCENT (g)	50%	60%	50%	0%
TERMINAL (d)	5/10 (50%)	6/10 (60%)	5/10 (50%)	0/10 (0%)
FIRST INCIDENCE	169 (T)	169 (T)	169 (T)	---
<b>STATISTICAL TESTS</b>				
POLY 3	P=0.003N**	P=0.500	P=0.664	P=0.008N**
POLY 1.5	P=0.003N**	P=0.500	P=0.664	P=0.008N**
POLY 6	P=0.003N**	P=0.500	P=0.664	P=0.008N**
COCH-ARM / FISHERS	P=0.005N**	P=0.500	P=0.672N	P=0.016N*
MAX-ISO-POLY-3	P=0.002N**	P=0.332	P=1.000	P<0.001N**



TDMS No. 20226 - 01  
Test Type: 26-WEEK  
Route: DOSED FEED  
Species/Strain: RATS/SD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Chitosan  
CAS Number: 9012-76-4

Date Report Requested: 05/28/2009  
Time Report Requested: 08:46:11  
First Dose M/F: 08/31/06 / 09/01/06  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)  
TERMINAL SACRIFICE AT 25 WEEKS

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DOSE	Females			
	0 %	1 %	3 %	9 %
<b>Kidney: Pelvis Dilatation</b>				
<b>LESION RATES</b>				
OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

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TDMS No. 20226 - 01  
 Test Type: 26-WEEK  
 Route: DOSED FEED  
 Species/Strain: RATS/SD

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Chitosan  
 CAS Number: 9012-76-4

Date Report Requested: 05/28/2009  
 Time Report Requested: 08:46:11  
 First Dose M/F: 08/31/06 / 09/01/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)**  
**TERMINAL SACRIFICE AT 25 WEEKS**

DOSE	Females			
	0 %	1 %	3 %	9 %
<b>Liver</b>				
<b>Hematopoietic Cell Proliferation</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	1/10 (10%)	1/10 (10%)	2/10 (20%)	1/10 (10%)
<b>POLY-3 RATE (b)</b>	1/10.00	1/10.00	2/10.00	1/10.00
<b>POLY-3 PERCENT (g)</b>	10%	10%	20%	10%
<b>TERMINAL (d)</b>	1/10 (10%)	1/10 (10%)	2/10 (20%)	1/10 (10%)
<b>FIRST INCIDENCE</b>	169 (T)	169 (T)	169 (T)	169 (T)
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.641N	P=0.760	P=0.500	P=0.760
<b>POLY 1.5</b>	P=0.641N	P=0.760	P=0.500	P=0.760
<b>POLY 6</b>	P=0.641N	P=0.760	P=0.500	P=0.760
<b>COCH-ARM / FISHERS</b>	P=0.647N	P=0.763N	P=0.500	P=0.763N
<b>MAX-ISO-POLY-3</b>	P=0.371	P=1.000	P=0.274	P=1.000

TDMS No. 20226 - 01  
 Test Type: 26-WEEK  
 Route: DOSED FEED  
 Species/Strain: RATS/SD

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Chitosan  
 CAS Number: 9012-76-4

Date Report Requested: 05/28/2009  
 Time Report Requested: 08:46:11  
 First Dose M/F: 08/31/06 / 09/01/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)**  
**TERMINAL SACRIFICE AT 25 WEEKS**

DOSE	Females			
	0 %	1 %	3 %	9 %
<b>Liver</b>				
<b>Inflammation Chronic</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	9/10 (90%)	9/10 (90%)	9/10 (90%)	10/10 (100%)
<b>POLY-3 RATE (b)</b>	9/10.00	9/10.00	9/10.00	10/10.00
<b>POLY-3 PERCENT (g)</b>	90%	90%	90%	100%
<b>TERMINAL (d)</b>	9/10 (90%)	9/10 (90%)	9/10 (90%)	10/10 (100%)
<b>FIRST INCIDENCE</b>	169 (T)	169 (T)	169 (T)	169 (T)
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	P=0.325	P=0.760	P=0.760	P=0.500
<b>POLY 1.5</b>	P=0.325	P=0.760	P=0.760	P=0.500
<b>POLY 6</b>	P=0.325	P=0.760	P=0.760	P=0.500
<b>COCH-ARM / FISHERS</b>	P=0.318	P=0.763N	P=0.763N	P=0.500
<b>MAX-ISO-POLY-3</b>	P=0.206	P=1.000	P=1.000	P=0.158

TDMS No. 20226 - 01  
 Test Type: 26-WEEK  
 Route: DOSED FEED  
 Species/Strain: RATS/SD

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Chitosan  
 CAS Number: 9012-76-4

Date Report Requested: 05/28/2009  
 Time Report Requested: 08:46:11  
 First Dose M/F: 08/31/06 / 09/01/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)**  
**TERMINAL SACRIFICE AT 25 WEEKS**

DOSE	Females			
	0 %	1 %	3 %	9 %
<b>Liver: Periportal Fatty Change</b>				
<b>LESION RATES</b>				
OVERALL (a)	7/10 (70%)	4/10 (40%)	4/10 (40%)	0/10 (0%)
POLY-3 RATE (b)	7/10.00	4/10.00	4/10.00	0/10.00
POLY-3 PERCENT (g)	70%	40%	40%	0%
TERMINAL (d)	7/10 (70%)	4/10 (40%)	4/10 (40%)	0/10 (0%)
FIRST INCIDENCE	169 (T)	169 (T)	169 (T)	---
<b>STATISTICAL TESTS</b>				
POLY 3	P<0.001N**	P=0.186N	P=0.186N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.186N	P=0.186N	P<0.001N**
POLY 6	P<0.001N**	P=0.186N	P=0.186N	P<0.001N**
COCH-ARM / FISHERS	P=0.003N**	P=0.185N	P=0.185N	P=0.002N**
MAX-ISO-POLY-3	P<0.001N**	P=0.089N	P=0.089N	P<0.001N**

TDMS No. 20226 - 01  
Test Type: 26-WEEK  
Route: DOSED FEED  
Species/Strain: RATS/SD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Chitosan  
CAS Number: 9012-76-4

Date Report Requested: 05/28/2009  
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First Dose M/F: 08/31/06 / 09/01/06  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)  
TERMINAL SACRIFICE AT 25 WEEKS

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DOSE	Females			
	0 %	1 %	3 %	9 %
<hr/>				
Lung Hemorrhage				
<hr/>				
<b>LESION RATES</b>				
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---
<hr/>				
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

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TDMS No. 20226 - 01  
 Test Type: 26-WEEK  
 Route: DOSED FEED  
 Species/Strain: RATS/SD

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Chitosan  
 CAS Number: 9012-76-4

Date Report Requested: 05/28/2009  
 Time Report Requested: 08:46:11  
 First Dose M/F: 08/31/06 / 09/01/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)**  
**TERMINAL SACRIFICE AT 25 WEEKS**

DOSE	Females			
	0 %	1 %	3 %	9 %
<b>Lung</b>				
<b>Inflammation Chronic</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 20226 - 01  
 Test Type: 26-WEEK  
 Route: DOSED FEED  
 Species/Strain: RATS/SD

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Chitosan  
 CAS Number: 9012-76-4

Date Report Requested: 05/28/2009  
 Time Report Requested: 08:46:11  
 First Dose M/F: 08/31/06 / 09/01/06  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)**  
**TERMINAL SACRIFICE AT 25 WEEKS**

DOSE	Females			
	0 %	1 %	3 %	9 %
<b>Lung: Alveolus</b>				
<b>Infiltration Cellular Histiocyte</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
<b>POLY-3 RATE (b)</b>	2/10.00	0/0.00	0/0.00	0/10.00
<b>POLY-3 PERCENT (g)</b>	20%	0%	0%	0%
<b>TERMINAL (d)</b>	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
<b>FIRST INCIDENCE</b>	169 (T)	---	---	---
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	(e)	(e)	(e)	P=0.227N
<b>POLY 1.5</b>	(e)	(e)	(e)	P=0.227N
<b>POLY 6</b>	(e)	(e)	(e)	P=0.227N
<b>COCH-ARM / FISHERS</b>	P=0.160N	(e)	(e)	P=0.237N
<b>MAX-ISO-POLY-3</b>	(e)	(e)	(e)	P=0.066N

TDMS No. 20226 - 01  
Test Type: 26-WEEK  
Route: DOSED FEED  
Species/Strain: RATS/SD

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
Chitosan  
CAS Number: 9012-76-4

Date Report Requested: 05/28/2009  
Time Report Requested: 08:46:11  
First Dose M/F: 08/31/06 / 09/01/06  
Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)  
TERMINAL SACRIFICE AT 25 WEEKS

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DOSE	Females			
	0 %	1 %	3 %	9 %
<b>Lymph Node, Mandibular Infiltration Cellular Plasma Cell</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

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TDMS No. 20226 - 01  
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**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Chitosan  
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)**  
**TERMINAL SACRIFICE AT 25 WEEKS**

DOSE	Females			
	0 %	1 %	3 %	9 %
<b>Pancreas Inflammation</b>				
<b>LESION RATES</b>				
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	169 (T)	---	---	---
<b>STATISTICAL TESTS</b>				
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=0.366N	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	P=0.158N

TDMS No. 20226 - 01  
 Test Type: 26-WEEK  
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 Species/Strain: RATS/SD

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
 Chitosan  
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)**  
**TERMINAL SACRIFICE AT 25 WEEKS**

DOSE	Females			
	0 %	1 %	3 %	9 %
<b>Spleen</b>				
<b>Hematopoietic Cell Proliferation</b>				
<b>LESION RATES</b>				
<b>OVERALL (a)</b>	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
<b>POLY-3 RATE (b)</b>	1/10.00	0/0.00	0/0.00	0/10.00
<b>POLY-3 PERCENT (g)</b>	10%	0%	0%	0%
<b>TERMINAL (d)</b>	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
<b>FIRST INCIDENCE</b>	169 (T)	---	---	---
<b>STATISTICAL TESTS</b>				
<b>POLY 3</b>	(e)	(e)	(e)	P=0.500N
<b>POLY 1.5</b>	(e)	(e)	(e)	P=0.500N
<b>POLY 6</b>	(e)	(e)	(e)	P=0.500N
<b>COCH-ARM / FISHERS</b>	P=0.366N	(e)	(e)	P=0.500N
<b>MAX-ISO-POLY-3</b>	(e)	(e)	(e)	P=0.158N

TDMS No. 20226 - 01  
Test Type: 26-WEEK  
Route: DOSED FEED  
Species/Strain: RATS/SD

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(SD)  
TERMINAL SACRIFICE AT 25 WEEKS

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DOSE	Females			
	0 %	1 %	3 %	9 %
<b>Stomach, Forestomach: Epithelium Hyperplasia</b>				
<b>LESION RATES</b>				
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	---	---	---	---
<b>STATISTICAL TESTS</b>				
POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

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TDMS No. 20226 - 01  
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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.  
(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 \*\*\*