

**APPENDIX 3 (response #3)**

(Dow Corning Reference 152 "Life-Time Carcinogenicity Study with TX-1208..." critical tables.)

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Report No.: 1998-10000-44643  
Title: A Life-time Implant Study with Dow Corning® Q7-2159A  
in Rats.  
Study No.: 7088  
Test Article: Q7-2159A  
Study Director: Paal C. Klykken, Ph.D.  
Sponsor: Dow Corning Corporation  
Sponsor Representative: Patrick W. Langvardt, M.S.  
Toxicology Laboratory Manager  
Testing Facility: Dow Corning Corporation  
Health and Environmental Sciences  
Midland, MI  
Study Completion Date: 06/30/98  
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Table I

Materials and Methods of the Life-time Implant Study  
with Dow Corning® Q7-2159A Gel in Rats.

**Study Laboratory**  
Dow Corning Corporation  
Health and Environmental Sciences  
2200 W Salzburg Road  
Midland, MI 48686-0994

**Method of animal distribution**  
Animals randomized to groups and  
randomly assigned to cases using  
the Xybrion Path/Tox System®

**Strain and Species**  
CD(Sprague-Dawley) rats

**Animals per cage**  
one

**Animal Source**  
Charles River Breeding Labs, Inc.  
Shaver Road  
Bldg. PO1  
Portage, MI 49081

**Animal identification**  
Ear tag

**Time held before study**  
22 days

**Diet**  
Certified Rodent Chow 5002  
(available *ad libitum*)  
Ralston Purina Company  
P.O. Box 548  
Richmond, IN

**Average age at study start**  
6 to 8 weeks

**Water**  
Tap Water (automatic system, available  
*ad libitum*)  
Bay Metro Water Treatment Plant  
2691 N. Euclid Road  
Bay City, MI

**Method of dose administration**  
Blunt dissection followed by test  
material implantation

**Implantation sites**  
Subcutaneous

**Cages**  
Suspended stainless steel wire bottom cage  
Suburban Surgical Company  
275 12th Street  
Wheeling, IL

**Test and Control materials**  
Dow Corning® Q7-2159A Gel  
Low density polyethylene-disks

**Absorbent Pellets**  
Bed O'Cobs (Alfa'Cobs) pellets  
The Anderson Corporation  
P.O. Box 119  
Maumee, OH

**Dates of implantation**  
October 31, 1990 through  
November 13, 1992

**Duration of exposure**  
Life-time (104 weeks)

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Table 1 (continued)

Materials and Methods of the Life-time Implant Study  
with Dow Corning® Q7-2159A Gel in Rats.

<b>Dates of terminal necropsy</b> October 28, 1992 through November 10, 1992	<b>Animal room environment</b> Temperature: 68°-73° F. Relative Humidity: 30%-83% Fluorescent Light: 12 hrs/day Room Air Changes: 7-17/hr
<b>Average age at necropsy</b> 110 to 112 weeks	
<b>Doses</b> Group 1: sham control Group 2: 4 x 0.2 ml of gel Group 3: 4 x 0.9 ml of gel Group 4: 4 x 4.0 ml of gel Group 5: 2 x 0.5 cm of PE Group 6: 2 x 1.0 cm of PE Group 7: 2 x 2.0 cm of PE	<b>Size of study groups</b>  n=100/group

**Type and frequency of observations**

<u>Environmental conditions</u> daily	<u>Clinical observations</u> each regular working day
<u>Body Weights*</u> day of implantation, 2 weeks post-implantation, biweekly beginning week 7	<u>Food consumption*</u> 2 weeks post-implantation, biweekly beginning week 7
<u>Mass palpations</u> weeks 7, 29, 41, 49, 53, and biweekly thereafter	

\* During the first 4½ weeks of study, the body weight and food consumption schedule could not be strictly adhered to.

**Final Necropsy**

Organ weights  
adrenal glands, brain, kidneys, and liver

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Table 1 (continued)

Materials and Methods of the Life-time Implant Study  
with Dow Corning® Q7-2159A Gel in Rats.

**Histopathology**

adrenal glands	aorta	bone-	bone marrow-
brain	cecum	femur	femur
cervix	colon	sternum	sternum
duodenum	esophagus	eyes	harderian glands
heart	ileum	jejunum	kidneys
larynx	liver	lungs	lymph nodes-
mammary gland	muscle, skeletal	nerves-	mandibular
ovary	oviduct	optic	mediastinal
pancreas	parathyroid gland	sciatic	mesenteric
pituitary gland	rectum	salivary gland-	skin/subcutaneous(sc)
spinal cord	spleen	mandibular	stomach
sc implant sites	thymus	thyroid gland	trachea
urinary bladder	uterus	vagina	

**Clinical Pathology**

Hematology

hematocrit, hemoglobin, platelet count, red blood cell count, and total white blood cell count and differential

Clinical chemistry

alanine aminotransferase, albumin, albumin/globulin ratio, aspartate aminotransferase, blood urea nitrogen, calcium, chloride, creatinine, direct bilirubin, gamma glutamyl transferase, globulin, glucose, phosphorus, potassium, sodium, total bilirubin, and total protein

Urinalysis

bilirubin, blood, glucose, ketones, microscopic evaluation, pH, protein, refractive index, urobilinogen, and volume

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Table 2  
Body Weights (grams) of Silicone Gel Animals

All Animals

Dose	Weeks 1-15		Weeks 16-30		Weeks 31-60		>Week 60	
	Mean ± s.e.	n	Mean ± s.e.	n	Mean ± s.e.	n	Mean ± s.e.	n
Sham	243.0 ± 2.3	100	316.2 ± 3.9	99	389.2 ± 5.4	99	467.2 ± 8.6	91
Low	241.9 ± 1.9	100	310.2 ± 3.3	99	378.5 ± 5.5	99	453.6 ± 8.0	92
Mid	243.4 ± 2.0	100	312.5 ± 3.4	100	387.0 ± 5.6	100	469.2 ± 8.7	94
High	† 256.1 ± 1.9	100	322.6 ± 3.1	100	393.3 ± 5.3	100	481.6 ± 8.2	97

Animals without SST

Dose	Weeks 1-15		Weeks 16-30		Weeks 31-60		>Week 60	
	Mean ± s.e.	n	Mean ± s.e.	n	Mean ± s.e.	n	Mean ± s.e.	n
Sham	243.0 ± 2.3	100	316.2 ± 3.9	99	389.2 ± 5.4	99	467.2 ± 8.6	91
Low	242.0 ± 1.9	98	310.5 ± 3.3	97	378.9 ± 5.6	97	453.6 ± 8.2	90
Mid	243.5 ± 2.1	98	312.5 ± 3.4	98	387.1 ± 5.7	98	469.4 ± 8.8	92
High	† 252.3 ± 2.1	57	318.3 ± 3.6	57	386.5 ± 6.3	57	466.1 ± 10.2	55

Animals with SST\*

Dose	Weeks 1-15		Weeks 16-30		Weeks 31-60		>Week 60	
	Mean ± s.e.	n	Mean ± s.e.	n	Mean ± s.e.	n	Mean ± s.e.	n
Sham	243.0 ± 2.3	100	316.2 ± 3.9	99	389.2 ± 5.4	99	467.2 ± 8.6	91
Low	235.5 ± 12.1	2	296.9 ± 13.4	2	360.6 ± 15.8	2	456.0 ± 41.9	2
Mid	239.2 ± 3.5	2	312.4 ± 18.6	2	383.6 ± 30.1	2	461.2 ± 61.6	2
High	† 261.2 ± 3.4	43	328.3 ± 5.2	43	402.5 ± 8.9	43	501.8 ± 12.9	42

\* statistics for control group animals, all of which were free of SST, are included for comparison.

Female Sprague Dawley rats were implanted subcutaneously with three dose levels of mammary silicone gel. The implantation procedure was performed on sham control animals but no test material was introduced into the animals. Body weights were recorded on the day of surgery, two weeks after surgery, and biweekly beginning on week 7. Animals exhibiting SST were identified and analyses were performed with and without data from these animals. Period specific averages (1-15 weeks, 16-30 weeks, 31-60 weeks, and >60 weeks) were evaluated by ANOVA followed by Dunnett's multiple comparison procedure. † p<0.05 relative to sham control group

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Table 3  
Body Weights (grams) of Polyethylene Animals

All Animals

Dose	Weeks 1-15		Weeks 16-30		Weeks 31-60		>Week 60	
	Mean ± s.e.	n	Mean ± s.e.	n	Mean ± s.e.	n	Mean ± s.e.	n
Sham	243.0 ± 2.3	100	316.2 ± 3.9	99	389.2 ± 5.4	99	467.2 ± 8.6	91
Low	245.9 ± 2.0	100	316.6 ± 3.5	100	392.1 ± 6.0	100	463.1 ± 9.3	92
Mid	245.6 ± 2.2	100	319.5 ± 3.8	100	399.3 ± 6.2	100	494.1 ± 10.2	93
High	243.4 ± 2.3	100	311.4 ± 3.8	99	382.7 ± 6.7	99	468.0 ± 10.5	88

Animals without SST

Dose	Weeks 1-15		Weeks 16-30		Weeks 31-60		>Week 60	
	Mean ± s.e.	n	Mean ± s.e.	n	Mean ± s.e.	n	Mean ± s.e.	n
Sham	243.0 ± 2.3	100	316.2 ± 3.9	99	389.2 ± 5.4	99	467.2 ± 8.6	91
Low	246.2 ± 2.0	99	316.8 ± 3.5	99	392.5 ± 6.1	99	463.9 ± 9.4	91
Mid	245.3 ± 2.6	81	320.0 ± 4.5	81	399.4 ± 7.2	81	493.3 ± 12.1	74
High	245.1 ± 2.9	48	313.5 ± 4.7	47	383.0 ± 8.0	47	450.0 ± 11.4	42

Animals with SST\*

Dose	Weeks 1-15		Weeks 16-30		Weeks 31-60		>Week 60	
	Mean ± s.e.	n	Mean ± s.e.	n	Mean ± s.e.	n	Mean ± s.e.	n
Sham	243.0 ± 2.3	100	316.2 ± 3.9	99	389.2 ± 5.4	99	467.2 ± 8.6	91
Low	224.5 ± 0.0	1	296.6 ± 0.0	1	353.9 ± 0.0	1	425.6 ± 0.0	1
Mid	246.9 ± 4.1	19	317.2 ± 6.1	19	399.2 ± 11.3	19	497.3 ± 17.8	19
High	241.7 ± 3.6	52	309.5 ± 5.8	52	382.4 ± 10.5	52	484.4 ± 16.9	46

\* statistics for control group animals, all of which were free of SST, are included for comparison.

Female Sprague Dawley rats were implanted subcutaneously with three dose levels of low density polyethylene. The implantation procedure was performed on sham control animals but no test material was introduced into the animals. Body weights were recorded on the day of surgery, two weeks after surgery, and bi-weekly beginning on week 7. Animals exhibiting SST were identified and analyses were performed with and without data from these animals. Period specific averages (1-15 weeks, 16-30 weeks, 31-60 weeks, and >60 weeks) were evaluated by ANOVA followed by Dunnett's multiple comparison procedure. § p<0.05 relative to sham control group

\*



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**Table 4**  
Food Consumption (grams/day) of Silicone Gel Animals

**All Animals**

Dose	Weeks 1-15		Weeks 16-30		Weeks 31-60		>Week 60	
	Mean ± s.e.	n	Mean ± s.e.	n	Mean ± s.e.	n	Mean ± s.e.	n
Sham	21.7 ± 0.2	100	20.7 ± 0.2	99	23.0 ± 0.2	99	24.5 ± 0.3	91
Low	21.0 ± 0.2	100	20.2 ± 0.2	99	22.3 ± 0.3	99	23.6 ± 0.4	92
Mid	21.3 ± 0.2	100	20.4 ± 0.2	100	22.7 ± 0.3	100	24.2 ± 0.3	94
High	21.3 ± 0.2	100	20.3 ± 0.2	100	22.4 ± 0.3	100	24.2 ± 0.3	96

**Animals without SST**

Dose	Weeks 1-15		Weeks 16-30		Weeks 31-60		>Week 60	
	Mean ± s.e.	n	Mean ± s.e.	n	Mean ± s.e.	n	Mean ± s.e.	n
Sham	21.7 ± 0.2	100	20.7 ± 0.2	99	23.0 ± 0.2	99	24.5 ± 0.3	91
Low	21.0 ± 0.2	98	20.3 ± 0.2	97	22.3 ± 0.3	97	23.6 ± 0.4	90
Mid	21.3 ± 0.2	98	20.4 ± 0.2	98	22.6 ± 0.3	98	24.2 ± 0.3	92
High	21.1 ± 0.3	57	20.2 ± 0.3	57	22.1 ± 0.3	57	23.8 ± 0.4	55

**Animals with SST<sup>a</sup>**

Dose	Weeks 1-15		Weeks 16-30		Weeks 31-60		>Week 60	
	Mean ± s.e.	n	Mean ± s.e.	n	Mean ± s.e.	n	Mean ± s.e.	n
Sham	21.7 ± 0.2	100	20.7 ± 0.2	99	23.0 ± 0.2	99	24.5 ± 0.3	91
Low	19.4 ± 0.8	2	18.0 ± 0.5	2	20.0 ± 0.5	2	21.2 ± 1.0	2
Mid	20.4 ± 0.6	2	20.6 ± 1.5	2	23.6 ± 0.7	2	24.9 ± 1.7	2
High	21.7 ± 0.3	43	20.6 ± 0.3	43	22.9 ± 0.4	43	24.7 ± 0.5	42

<sup>a</sup> statistics for control group animals, all of which were free of SST, are included for comparison.

Female Sprague Dawley rats were implanted subcutaneously with three dose levels of mammary silicone gel. The implantation procedure was performed on sham control animals but no test material was introduced into the animals. Food consumption was determined two weeks after surgery and biweekly beginning on week 7. Animals exhibiting SST were identified and analyses were performed with and without data from these animals. Period specific averages (1-15 weeks, 16-30 weeks, 31-60 weeks, and >60 weeks) were evaluated by ANOVA followed by Dunnett's multiple comparison procedure. † p≤0.05 relative to sham control group

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DC Report No. - 1998-10000-44643  
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Food Consumption (grams/day) of Polyethylene Animals

## All Animals

Dose	Weeks 1-15		Weeks 16-30		Weeks 31-60		> Week 60	
	Mean ± s.e.	n	Mean ± s.e.	n	Mean ± s.e.	n	Mean ± s.e.	n
Sham	21.7 ± 0.2	100	20.7 ± 0.2	99	23.0 ± 0.2	99	24.5 ± 0.3	91
Low	21.5 ± 0.2	100	20.6 ± 0.2	100	22.9 ± 0.3	100	24.1 ± 0.4	92
Mid	21.7 ± 0.2	100	20.6 ± 0.2	100	23.0 ± 0.2	100	24.6 ± 0.3	93
High	21.2 ± 0.2	100	20.2 ± 0.2	99	22.4 ± 0.3	99	23.8 ± 0.4	88

## Animals without SST

Dose	Weeks 1-15		Weeks 16-30		Weeks 31-60		> Week 60	
	Mean ± s.e.	n	Mean ± s.e.	n	Mean ± s.e.	n	Mean ± s.e.	n
Sham	21.7 ± 0.2	100	20.7 ± 0.2	99	23.0 ± 0.2	99	24.5 ± 0.3	91
Low	21.5 ± 0.2	99	20.6 ± 0.2	99	22.9 ± 0.3	99	24.1 ± 0.4	91
Mid	21.8 ± 0.2	81	20.7 ± 0.2	81	23.0 ± 0.3	81	24.7 ± 0.4	74
High	21.4 ± 0.3	48	20.5 ± 0.3	47	22.4 ± 0.4	47	23.5 ± 0.4	42

## Animals with SST\*

Dose	Weeks 1-15		Weeks 16-30		Weeks 31-60		> Week 60	
	Mean ± s.e.	n	Mean ± s.e.	n	Mean ± s.e.	n	Mean ± s.e.	n
Sham	21.7 ± 0.2	100	20.7 ± 0.2	99	23.0 ± 0.2	99	24.5 ± 0.3	91
Low	23.0 ± 0.0	1	21.8 ± 0.0	1	22.8 ± 0.0	1	22.8 ± 0.0	1
Mid	21.1 ± 0.4	19	20.3 ± 0.4	19	22.7 ± 0.5	19	24.0 ± 0.7	19
High	20.9 ± 0.3	52	20.0 ± 0.3	52	22.4 ± 0.4	52	24.1 ± 0.7	46

\* statistics for control group animals, all of which were free of SST, are included for comparison.

Female Sprague Dawley rats were implanted subcutaneously with three dose levels of low density polyethylene. The implantation procedure was performed on sham control animals but no test material was introduced into the animals. Food consumption was determined two weeks after surgery and biweekly beginning on week 7. Animals exhibiting SST were identified and analyses were performed with and without data from these animals. Period specific averages (1-15 weeks, 16-30 weeks, 31-60 weeks, and > 60 weeks) were evaluated by ANOVA followed by Dunnett's multiple comparison procedure. § p≤0.05 relative to sham control group

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TABLE 6  
SUMMARY: Incidence of NEOPLASTIC Microscopic Findings for All Treated Animals

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 100	M Gel 100	H Gel 100	L PE 100	M PE 100	H PE 100
	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
ALL SITES.							
NON-SARCOMATOUS TUMORS <sup>2</sup>	# Ex 100 93 (93)	100 97 (97)	100 99 <sup>1</sup> (99)	100 84 <sup>2</sup> (84)	100 91 (91)	100 92 (92)	100 81 <sup>3</sup> (81)
ADRENAL CORTEX	# Ex 100	100	100	100	100	100	98
ADENOMA, UNILATERAL <sup>1</sup>	0 (0)	0 (0)	1 (1)	2 (2)	2 (2)	0 (0)	1 (1)
CARCINOMA, UNILATERAL	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)
CARCINOMA OR ADENOMA <sup>1</sup>	0 (0)	0 (0)	1 (1)	2 (2)	2 (2)	2 (2)	1 (1)
ADRENAL MEDULLA	# Ex 100	100	98	97	98	99	96
PHEOCHROMOCYTOMA, UNILATERAL	4 (4)	4 (4)	3 (3)	3 (3)	4 (4)	0 (0)	2 (2)
PHEOCHROMOCYTOMA, BILATERAL	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
PHEOCHROMOCYTOMA, MAL., UNILAT	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
PHEOCHROMOCYTOMA, BENIGN	4 (4)	5 (5)	4 (4)	3 (3)	4 (4)	0 (0)	2 (2)
PHEOCHROMOCYTOMA, MAL. OR BEN.	5 (5)	5 (5)	4 (4)	3 (3)	4 (4)	0 (0)	2 (2)
AORTA	# Ex 100	100	100	100	100	100	100
BRAIN	# Ex 100	99	100	100	100	100	100
ASTROCYTOMA	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
ASTROCYTOMA, MALIGNANT	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)
GLIOMA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
OLIGODENDROGLIOMA	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
GRANULAR CELL TUMOR	0 (0)	2 (2)	0 (0)	0 (0)	1 (1)	1 (1)	1 (1)
ASTROCYTOMA, MAL. OR BEN. <sup>1</sup>	3 (3)	1 (1)	0 (0)	0 (0)	0 (0)	2 (2)	1 (1)
GLIAL TUMORS (ASTRO. AND GLIOMAS) <sup>2</sup>	5 (5)	1 (1)	0 <sup>2</sup> (0)	1 (1)	0 <sup>2</sup> (0)	2 (2)	1 (1)
OLIGODENDROGLIOMA OR GLIOMA	2 (2)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
CECUM	# Ex 87	92	89	84	87	82	88
ADENOCARCINOMA	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
CERVIX	# Ex 98	97	97	100	99	100	99
ENDOMETRIAL STROMAL POLYP	1 (1)	1 (1)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
ENDOMETRIAL STROMAL SARCOMA	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)
FIBROMA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
ENDO. STROMAL SARCOMA OR POLYP	1 (1)	1 (1)	3 (3)	0 (0)	0 (0)	0 (0)	1 (1)
CLITORAL GLAND	# Ex 4	3	2	1	3	5	3
COLON	# Ex 90	95	90	89	91	88	90
DUODENUM	# Ex 89	94	92	90	94	94	95
ESOPHAGUS	# Ex 100	100	100	100	100	100	100
EYES	# Ex 99	98	100	98	99	100	100
FEMUR - BONE	# Ex 99	97	97	98	97	96	97
FEMUR - BONE MARROW	# Ex 99	96	97	98	97	96	97
FOOTPAD	# Ex 17	20	14	14	19	15	10
FORESTOMACH	# Ex 100	100	100	8	100	99	100
SQUAMOUS CELL PAPILLOMA	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)	1 (1)
HARDERIAN GLAND	# Ex 100	100	100	99	100	100	100

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TABLE 6 (continued)  
SUMMARY: Incidence of NEOPLASTIC Microscopic Findings for All Treated Animals

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 100	M Gel 100	H Gel 100	L PE 100	M PE 100	H PE 100
HEART	# Ex 100	# (%) 100	# (%) 100	# (%) 100	# (%) 100	# (%) 100	# (%) 100
ILEUM	# Ex 88	# (%) 88	# (%) 88	# (%) 83	# (%) 84	# (%) 83	# (%) 83
IMPLANT 1 - CAPSULE	# Ex 97	# (%) 97	# (%) 94	# (%) 100	# (%) 58	# (%) 86	# (%) 94
SARCOMA <sup>112</sup>	0 (0)	1 (1)	0 (0)	10 <sup>12</sup> (10)	0 (0)	11 <sup>12</sup> (13)	29 <sup>12</sup> (31)
OSTEOSARCOMA <sup>12</sup>	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
SARCOMA OR OSTEOSARCOMA <sup>112</sup>	0 (0)	1 (1)	0 (0)	10 <sup>12</sup> (10)	0 (0)	11 <sup>12</sup> (13)	32 <sup>12</sup> (34)
IMPLANT 1 - EXTRACAPSULAR	# Ex 97	# (%) 98	# (%) 97	# (%) 100	# (%) 87	# (%) 100	# (%) 97
IMPLANT 2 - CAPSULE	# Ex 96	# (%) 100	# (%) 99	# (%) 99	# (%) 70	# (%) 86	# (%) 96
SARCOMA <sup>112</sup>	0 (0)	0 (0)	0 (0)	13 <sup>12</sup> (13)	1 (1)	5 <sup>12</sup> (7)	22 <sup>12</sup> (23)
OSTEOSARCOMA <sup>12</sup>	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	2 (2)
SARCOMA OR OSTEOSARCOMA <sup>112</sup>	0 (0)	0 (0)	0 (0)	13 <sup>12</sup> (13)	1 (1)	7 <sup>12</sup> (8)	24 <sup>12</sup> (25)
IMPLANT 2 - EXTRACAPSULAR	# Ex 96	# (%) 100	# (%) 99	# (%) 100	# (%) 89	# (%) 99	# (%) 96
IMPLANT 3 - CAPSULE	# Ex 97	# (%) 94	# (%) 99	# (%) 98	# (%) 0	# (%) 0	# (%) 0
SARCOMA <sup>12</sup>	0 (0)	0 (0)	0 (0)	12 <sup>12</sup> (12)	0 (0)	0 (0)	0 (0)
SARCOMA OR OSTEOSARCOMA <sup>12</sup>	0 (0)	0 (0)	0 (0)	12 <sup>12</sup> (12)	0 (0)	0 (0)	0 (0)
IMPLANT 3 - EXTRACAPSULAR	# Ex 97	# (%) 98	# (%) 99	# (%) 99	# (%) 0	# (%) 0	# (%) 0
IMPLANT 4 - CAPSULE	# Ex 96	# (%) 97	# (%) 96	# (%) 99	# (%) 0	# (%) 0	# (%) 0
SARCOMA <sup>12</sup>	0 (0)	0 (0)	1 (1)	10 <sup>12</sup> (10)	0 (0)	0 (0)	0 (0)
SARCOMA OR OSTEOSARCOMA <sup>12</sup>	0 (0)	0 (0)	1 (1)	10 <sup>12</sup> (10)	0 (0)	0 (0)	0 (0)
IMPLANT 4 - EXTRACAPSULAR	# Ex 96	# (%) 99	# (%) 98	# (%) 99	# (%) 0	# (%) 0	# (%) 0
IMPLANT SITE, NOS	# Ex 98	# (%) 100	# (%) 100	# (%) 100	# (%) 95	# (%) 100	# (%) 100
SARCOMA	0 (0)	1 (1)	1 (1)	2 (2)	0 (0)	1 (1)	0 (0)
SARCOMA OR OSTEOSARCOMA	0 (0)	1 (1)	1 (1)	2 (2)	0 (0)	1 (1)	0 (0)
IMPLANT SITES, ALL	# Ex 98	# (%) 100	# (%) 100	# (%) 100	# (%) 95	# (%) 100	# (%) 100
SARCOMA <sup>112</sup>	0 (0)	2 (2)	2 (2)	40 <sup>12</sup> (40)	1 (1)	17 <sup>12</sup> (17)	47 <sup>12</sup> (47)
OSTEOSARCOMA <sup>12</sup>	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	5 <sup>12</sup> (5)
SARCOMA OR OSTEOSARCOMA <sup>112</sup>	0 (0)	2 (2)	2 (2)	40 <sup>12</sup> (40)	1 (1)	18 <sup>12</sup> (18)	52 <sup>12</sup> (52)
JEJUNUM	# Ex 89	# (%) 92	# (%) 90	# (%) 85	# (%) 89	# (%) 89	# (%) 92
ADENOCARCINOMA	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
KIDNEYS	# Ex 99	# (%) 100	# (%) 100	# (%) 99	# (%) 100	# (%) 100	# (%) 100
TUBULAR CELL ADENOMA	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)
TUBULAR CELL CARCINOMA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
LIPOMA	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)
LIPOSARCOMA	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	2 (2)
LIPOSARCOMA OR LIPOMA	1 (1)	0 (0)	1 (1)	0 (0)	1 (1)	1 (1)	2 (2)
TUB. CELL CARCINOMA OR ADENOMA	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	2 (2)	0 (0)
LARYNX	# Ex 97	# (%) 98	# (%) 98	# (%) 99	# (%) 99	# (%) 99	# (%) 100
LIVER	# Ex 99	# (%) 100	# (%) 100	# (%) 100	# (%) 100	# (%) 100	# (%) 100
HEPATOCELLULAR ADENOMA	1 (1)	1 (1)	1 (1)	1 (1)	0 (0)	0 (0)	1 (1)
HEPATOCELLULAR ADENOMA, MULT.	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
HEPATOCELLULAR CARCINOMA	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)	1 (1)
HEMANGIOSARCOMA	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
HEPATO. CARCINOMA OR ADENOMA	1 (1)	1 (1)	1 (1)	2 (2)	0 (0)	1 (1)	3 (3)



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TABLE 6 (continued)  
SUMMARY: Incidence of NEOPLASTIC Microscopic Findings for All Treated Animals

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 100	M Gel 100	H Gel 100	L PE 100	M PE 100	H PE 100
LUNGS	# Ex 100	# (%) 100	# (%) 100	# (%) 100	# (%) 100	# (%) 100	# (%) 100
ALVEOLAR/BRONCHIOLAR ADENOMA	0 (0)	2 (2)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
LYMPH NODE, MANDIBULAR	# Ex 85	94	94	91	95	88	94
LYMPH NODE, MEDIASTINAL	# Ex 86	91	91	88	93	94	90
LYMPH NODE, MESENTERIC	# Ex 98	98	98	98	96	96	100
LYMPH NODE, OTHER	# Ex 26	37	29	31	30	30	22
MAMMARY GLAND	# Ex 100	100	100	100	100	99	100
ADENOMA	2 (2)	3 (3)	1 (1)	0 (0)	0 (0)	2 (2)	0 (0)
FIBROADENOMA	20 (20)	22 (22)	18 (18)	11 (11)	18 (18)	17 (17)	18 (18)
FIBROADENOMA, MULTIPLE	9 (9)	10 (10)	4 (4)	6 (6)	6 (6)	7 (7)	4 (4)
ADENOCARCINOMA	11 (11)	10 (10)	13 (13)	7 (7)	12 (12)	12 (12)	8 (8)
ADENOCARCINOMA, MULTIPLE	2 (2)	4 (4)	1 (1)	4 (4)	3 (3)	3 (3)	4 (4)
FIBROSARCOMA IN FIBROADENOMA	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
CARCINOMA IN SITU	2 (2)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
ADENOCARCINOMA IN FIBROADENOMA	1 (1)	1 (1)	1 (1)	1 (1)	0 (0)	1 (1)	0 (0)
BENIGN EPITHELIAL TUMORS <sup>1</sup>	30 (30)	34 (34)	23 (23)	17 <sup>2</sup> (17)	24 (24)	25 (25)	22 (22)
MALIGNANT EPITHELIAL TUMORS	16 (16)	16 (16)	15 (15)	15 (15)	15 (15)	16 (16)	12 (12)
MAL. AND BEN. EPITHELIAL TUMORS <sup>1</sup>	42 (42)	45 (45)	30 (30)	27 <sup>2</sup> (27)	34 (34)	38 (38)	29 (29)
OPTIC NERVE	# Ex 99	98	99	97	99	100	100
OVARIES	# Ex 99	100	100	100	100	100	100
GRANULOSA-THECA CL TUMOR, BGN.	1 (1)	0 (0)	1 (1)	1 (1)	1 (1)	0 (0)	1 (1)
GRANULOSA-THECA CL TUMOR, MAL.	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
HEMANGIOMA	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
GRAN.-THECA CL TUMOR, MAL. OR BEN.	1 (1)	0 (0)	2 (2)	1 (1)	1 (1)	0 (0)	1 (1)
OVIDUCTS	# Ex 98	99	98	100	99	99	100
PANCREAS	# Ex 99	100	100	98	100	100	100
PANCREATIC ISLETS	# Ex 99	99	100	98	99	100	100
CARCINOMA	4 (4)	2 (2)	5 (5)	0 (0)	6 (6)	3 (3)	0 (0)
ADENOMA	3 (3)	1 (1)	3 (3)	2 (2)	5 (5)	3 (3)	2 (2)
ADENOMA, MULT	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	2 (2)	0 (0)
ADENOMA OR ADENOMA, MULT.	4 (4)	1 (1)	3 (3)	3 (3)	5 (5)	5 (5)	2 (2)
CARCINOMA OR ADENOMA	8 (8)	3 (3)	8 (8)	3 (3)	11 (11)	7 (7)	2 (2)
PARATHYROID	# Ex 98	99	97	93	96	95	98
ADENOMA, UNILATERAL	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)
PITUITARY	# Ex 100	98	98	99	99	100	100
ADENOMA	77 (77)	72 (73)	78 (80)	70 (71)	75 (76)	77 (77)	67 (67)
ADENOMA, PARS INTERMEDIA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
CARCINOMA	7 (7)	14 (14)	8 (8)	3 (3)	8 (8)	5 (5)	6 (6)
CARCINOMA OR ADENOMA <sup>1*</sup>	84 (84)	86 (88)	86 (88)	73 <sup>2</sup> (74)	83 (84)	82 (82)	73 (73)
RECTUM	# Ex 89	93	91	92	93	94	97
SALIVARY GLAND	# Ex 96	100	100	100	100	98	99
ADENOCARCINOMA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

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TABLE 6 (continued)  
SUMMARY: Incidence of NEOPLASTIC Macroscopic Findings for All Treated Animals

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 100	M Gel 100	H Gel 100	L PE 100	M PE 100	H PE 100
<b>SCIATIC NERVE</b>	# Ex 97	97	98	99	98	97	97
SCHWANNOMA, MAL.	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
<b>SKELETAL MUSCLE</b>	# Ex 99	100	99	99	99	100	99
<b>SKIN/SUBCUTIS</b>	# Ex 100	100	100	100	100	100	100
SQUAMOUS CELL PAPILLOMA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
SQUAMOUS CELL CARCINOMA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FIBROMA	2 (2)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
FIBROMA, MULT	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FIBROSARCOMA	2 (2)	2 (2)	1 (1)	3 (3)	0 (0)	1 (1)	0 (0)
LIPOMA	1 (1)	0 (0)	1 (1)	2 (2)	0 (0)	2 (2)	2 (2)
HEMANGIOMA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
OSTEOSARCOMA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
SARCOMA, MULT	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
SARCOMA*	1 (1)	0 (0)	0 (0)	4 (4)	0 (0)	2 (2)	0 (0)
FIBROMA OR FIBROMA, MULT.	2 (2)	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
FIBROSARCOMA OR FIBROMA*	4 (4)	3 (3)	1 (1)	3 (3)	1 (1)	1 (1)	0 (0)
SARCOMA OR OSTEOSARCOMA*	1 (1)	0 (0)	0 (0)	4 (4)	0 (0)	3 (3)	1 (1)
<b>SPINAL CORD</b>	# Ex 99	100	100	99	100	100	100
<b>SPLEEN</b>	# Ex 99	100	100	99	100	100	100
HEMANGIOSARCOMA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
<b>STERNUM - BONE</b>	# Ex 99	99	98	100	100	100	100
<b>STERNUM - BONE MARROW</b>	# Ex 99	98	98	100	100	100	100
<b>STOMACH</b>	# Ex 96	98	100	96	99	99	99
<b>SYSTEMIC DISEASES</b>	# Ex 100	100	100	100	100	100	100
LYMPHOCYTIC LYMPHOMA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
LYMPHOBLASTIC LYMPHOMA	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
MONONUCLEAR CELL LEUKEMIA	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)	1 (1)
GRANULOCYTIC LEUKEMIA	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
LYMPHOMA NOS	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
HISTIOCYTIC SARCOMA	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
<b>TAIL</b>	# Ex 18	14	15	20	16	16	16
<b>THYMUS</b>	# Ex 82	95	82	78	86	85	81
THYMOMA	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
THYMIC LYMPHOMA	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)
<b>THYROID</b>	# Ex 98	97	98	99	99	99	98
FOLL. CELL ADENOMA, UNILAT.	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)	1 (1)	0 (0)
FOLL. CELL CARCINOMA, UNILAT.	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)	1 (1)
C-CELL ADENOMA, UNILATERAL	10 (10)	13 (13)	10 (10)	5 (5)	6 (6)	9 (9)	0 (0)
C-CELL ADENOMA, BILATERAL	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
C-CELL CARCINOMA, UNILAT.	2 (2)	3 (3)	0 (0)	2 (2)	0 (0)	1 (1)	0 (0)
C-CELL ADENOMA, UNILAT. AND BILAT.	10 (10)	13 (13)	11 (11)	5 (5)	7 (7)	9 (9)	0 (0)
C-CELL CARCINOMA OR ADENOMA*	12 (12)	15 (15)	11 (11)	7 (7)	7 (7)	10 (10)	0 (0)
FOLL. CELL CARCINOMA OR ADENOMA	0 (0)	0 (0)	3 (3)	1 (1)	0 (0)	1 (1)	1 (1)
<b>TRACHEA</b>	# Ex 99	100	100	99	100	100	100
<b>URINARY BLADDER</b>	# Ex 98	97	100	96	98	98	99



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TABLE 6 (Continued)  
SUMMARY: Incidence of NEOPLASTIC Microscopic Findings for All Treated Animals

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 100	M Gel 100	H Gel 100	L PE 100	M PE 100	H PE 100
<b>UTERUS</b>	# Ex 98	99	100	100	99	100	100
ENDOMETRIAL STROMAL POLYP	4 (4)	5 (5)	6 (6)	5 (5)	4 (4)	2 (2)	5 (5)
ENDOMETRIAL STROMAL SARCOMA	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)
ADENOCARCINOMA	0 (0)	1 (1)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
LEIOMYOSARCOMA <sup>†</sup>	0 (0)	0 (0)	0 (0)	2 (2)	1 (1)	0 (0)	0 (0)
ENDOMETRIAL STROM. POLYP, MULT FIBROMA	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
ENDO. STROM. POLYP OR MULT. ENDO. STROMAL SARCOMA OR POLYP	4 (4)	5 (5)	6 (6)	5 (5)	5 (5)	2 (2)	5 (5)
	4 (4)	5 (5)	7 (7)	5 (5)	5 (5)	3 (3)	5 (5)
<b>UTERUS AND CERVIX</b>	98	99	100	100			
ENDO. STROMAL SARCOMA OR POLYP	5 (5)	6 (6)	10 (10)	5 (5)	5 (5)	3 (3)	6 (6)
LEIOMYOSARCOMA <sup>†</sup>	0 (0)	0 (0)	0 (0)	2 (2)	1 (1)	0 (0)	0 (0)
<b>VAGINA</b>	# Ex 98	99	99	98	99	100	99
FIBROMA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
SQUAMOUS CELL CARCINOMA	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>OTHER TISSUES AND LESIONS:</b>							
ZYMBALETS GLAND: CARCINOMA	1 (1)	1 (1)	0 (0)	2 (2)	1 (1)	1 (1)	0 (0)
ABD WALL: LIPOMA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
ABD WALL: FIBROSARCOMA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)

Legend - Table 6

Female Sprague Dawley rats were implanted subcutaneously with three dose levels of either mammary silicone gel or low density polyethylene. The implantation procedure was performed on sham control animals but no test material was introduced into the animals. Forty-six specified tissues and organs were collected from all animals for histopathology. The incidence of neoplastic lesions was calculated as the ratio of the number of animals bearing lesions at a site to the number of animals examined histologically (# Ex) and are reported as percents (%). Neoplastic lesions of the same histogenetic type within the same organ or tissue were grouped for analyses. A statistical analysis of tumor incidence was only performed if there were at least 2 observations in one of the experimental groups within a potential analysis. Silicone gel and PE groups were analyzed independently of one another.

Logistic regression analysis was the primary statistical method used to assess lesion incidence among treated and control groups. The life table test was applied to provide an appropriate approach for analyzing the incidence of rapidly lethal lesions (e.g. solid state tumors). In addition, the Fisher exact test and the Cochran-Armitage trend test were utilized although they are procedures which do not adjust for intercurrent mortality.

† Silicone gel group is significantly different from sham control group at p<0.05. § Polyethylene group is significantly different from sham control group at p<0.05. A symbol immediately after the lesion indicates a significant increasing trend for the silicone gel groups (†) or the polyethylene groups (§) at p<0.05 (one-sided). Significance using a two-sided evaluation at p<0.05 is identified by ‡ (silicone gel) or ¶ (PE) according to the same scheme.



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TABLE 7  
 SUMMARY: Incidence of NEOPLASTIC Microscopic Findings for Treated Animals Without Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 98	M Gel 98	H Gel 57	L PE 99	M PE 81	H PE 48
ALL SITES	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
NON-SARCOMATOUS TUMORS	# Ex 100 93 (93)	98 95 (97)	98 97 (99)	57 51 (89)	99 90 (91)	81 76 (94)	48 43 (90)
ADRENAL CORTEX	# Ex 100	98	98	57	99	81	48
ADENOMA, UNILATERAL	0 (0)	0 (0)	1 (1)	0 (0)	2 (2)	0 (0)	0 (0)
CARCINOMA, UNILATERAL	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)
CARCINOMA OR ADENOMA	0 (0)	0 (0)	1 (1)	0 (0)	2 (2)	2 (2)	0 (0)
ADRENAL MEDULLA	# Ex 100	98	96	55	97	80	48
PHEOCHROMOCYTOMA, UNILATERAL	4 (4)	4 (4)	3 (3)	1 (2)	4 (4)	0 (0)	1 (2)
PHEOCHROMOCYTOMA, BILATERAL	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
PHEOCHROMOCYTOMA, MAL., UNILAT	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
PHEOCHROMOCYTOMA, BENIGN	4 (4)	5 (5)	4 (4)	1 (1)	4 (4)	0 (0)	1 (2)
PHEOCHROMOCYTOMA, MAL. OR BEN.	5 (5)	5 (5)	4 (4)	1 (1)	4 (4)	0 (0)	1 (2)
AORTA	# Ex 100	98	98	57	99	81	48
BRAIN	# Ex 100	97	98	57	99	81	48
ASTROCYTOMA	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
ASTROCYTOMA, MALIGNANT	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
GLIOMA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
OLIGODENDROGLIOMA	1 (1)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
GRANULAR CELL TUMOR	0 (0)	2 (2)	0 (0)	0 (0)	1 (1)	1 (1)	1 (2)
ASTROCYTOMA, MAL. OR BEN.	3 (3)	1 (1)	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)
GLIAL TUMORS (ATRO. OR GLIAL)	5 (5)	1 (1)	0 (0)	1 (2)	0 (0)	2 (2)	0 (0)
OLIGODENDROGLIOMA OR GLIOMA	2 (2)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
CECUM	# Ex 87	90	88	50	86	68	44
ADENOCARCINOMA	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
CERVIX	# Ex 98	95	95	57	98	81	48
ENDOMETRIAL STROMAL POLYP	1 (1)	1 (1)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
ENDOMETRIAL STROMAL SARCOMA	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
FIBROMA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
ENDO. STROMAL SARCOMA OR POLYP	1 (1)	1 (1)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)
CLITORAL GLAND	# Ex 4	3	2	0	3	3	1
COLON	# Ex 90	93	89	51	90	71	43
DUODENUM	# Ex 89	92	91	51	93	76	45
ESOPHAGUS	# Ex 100	98	98	57	99	81	48
EYES	# Ex 99	96	98	56	98	81	48
FEMUR - BONE	# Ex 99	95	95	56	96	78	47
FEMUR - BONE MARROW	# Ex 99	94	95	56	96	78	47
FOOTPAD	# Ex 17	20	14	6	19	14	4
FORESTOMACH	# Ex 100	98	98	56	99	80	48
SQUAMOUS CELL PAPILLOMA	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)
HARDERIAN GLAND	# Ex 100	98	98	56	99	81	48





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TABLE 7 (continued)  
SUMMARY: Incidence of NEOPLASTIC Microscopic Findings for Treated Animals Without Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 98	M Gel 98	H Gel 57	L PE 99	M PE 81	H PE 48
HEART	# Ex 100	# (%) 98	# (%) 98	# (%) 57	# (%) 99	# (%) 81	# (%) 48
ILEUM	# Ex 88	# (%) 86	# (%) 87	# (%) 49	# (%) 83	# (%) 68	# (%) 42
IMPLANT 1 - CAPSULE	# Ex 97	# (%) 95	# (%) 92	# (%) 57	# (%) 38	# (%) 70	# (%) 47
IMPLANT 1 - EXTRACAPSULAR	# Ex 97	# (%) 96	# (%) 95	# (%) 57	# (%) 86	# (%) 81	# (%) 47
IMPLANT 2 - CAPSULE	# Ex 96	# (%) 98	# (%) 97	# (%) 56	# (%) 69	# (%) 71	# (%) 47
IMPLANT 2 - EXTRACAPSULAR	# Ex 96	# (%) 98	# (%) 97	# (%) 57	# (%) 88	# (%) 80	# (%) 47
IMPLANT 3 - CAPSULE	# Ex 97	# (%) 93	# (%) 97	# (%) 55	# (%) 0	# (%) 0	# (%) 0
IMPLANT 3 - EXTRACAPSULAR	# Ex 97	# (%) 96	# (%) 97	# (%) 56	# (%) 0	# (%) 0	# (%) 0
IMPLANT 4 - CAPSULE	# Ex 96	# (%) 95	# (%) 94	# (%) 57	# (%) 0	# (%) 0	# (%) 0
IMPLANT 4 - EXTRACAPSULAR	# Ex 96	# (%) 97	# (%) 96	# (%) 57	# (%) 0	# (%) 0	# (%) 0
IMPLANT SITE, NOS	# Ex 98	# (%) 98	# (%) 98	# (%) 57	# (%) 94	# (%) 81	# (%) 48
JEJUNUM	# Ex 89	# (%) 90	# (%) 89	# (%) 49	# (%) 88	# (%) 72	# (%) 44
ADENOCARCINOMA	0 (0)	0 (0)	0 (0)	1 (2)	1 (1)	0 (0)	0 (0)
KIDNEYS	# Ex 99	# (%) 98	# (%) 98	# (%) 57	# (%) 99	# (%) 81	# (%) 48
TUBULAR CELL ADENOMA	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)
TUBULAR CELL CARCINOMA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
LIPOMA	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
LIPOSARCOMA	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
TUB. CELL CARCINOMA OR ADENOMA	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	2 (2)	0 (0)
LARYNX	# Ex 97	# (%) 96	# (%) 96	# (%) 57	# (%) 98	# (%) 80	# (%) 48
LIVER	# Ex 99	# (%) 98	# (%) 98	# (%) 57	# (%) 99	# (%) 81	# (%) 48
HEPATOCELLULAR ADENOMA	1 (1)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	1 (2)
HEPATOCELLULAR CARCINOMA	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	1 (1)	1 (2)
HEMANGIOSARCOMA	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
HEPATOCELLULAR CARC. OR ADEN.	1 (1)	1 (1)	1 (1)	1 (1)	0 (0)	1 (1)	2 (4)
LUNGS	# Ex 100	# (%) 98	# (%) 98	# (%) 57	# (%) 99	# (%) 81	# (%) 48
ALVEOLAR/BRONCHIOLAR ADENOMA	0 (0)	2 (2)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
LYMPH NODE, MANDIBULAR	# Ex 85	# (%) 92	# (%) 92	# (%) 53	# (%) 94	# (%) 73	# (%) 45
LYMPH NODE, MEDIASTINAL	# Ex 86	# (%) 89	# (%) 89	# (%) 49	# (%) 92	# (%) 76	# (%) 43
LYMPH NODE, MESENTERIC	# Ex 98	# (%) 96	# (%) 97	# (%) 56	# (%) 95	# (%) 79	# (%) 48
LYMPH NODE, OTHER	# Ex 26	# (%) 36	# (%) 28	# (%) 23	# (%) 30	# (%) 26	# (%) 8
MAMMARY GLAND	# Ex 100	# (%) 98	# (%) 98	# (%) 57	# (%) 99	# (%) 81	# (%) 48
ADENOMA	2 (2)	3 (3)	1 (1)	0 (0)	0 (0)	2 (2)	0 (0)
FIBROADENOMA	20 (20)	21 (21)	17 (17)	8 (14)	17 (17)	12 (15)	11 (23)
FIBROADENOMA, MULTIPLE	9 (9)	10 (10)	4 (4)	2 (4)	6 (6)	7 (9)	2 (4)
ADENOCARCINOMA	11 (11)	10 (10)	12 (12)	6 (10)	11 (11)	12 (15)	4 (8)
ADENOCARCINOMA, MULTIPLE	2 (2)	4 (4)	1 (1)	1 (2)	3 (3)	2 (2)	2 (4)
CARCINOMA IN SITU	2 (2)	1 (1)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)

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TABLE 7 (continued)  
SUMMARY: Incidence of NEOPLASTIC Microscopic Findings for Treated Animals Without Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 98	M Gel 98	H Gel 57	L PE 99	M PE 81	H PE 48
MAMMARY GLAND	# Ex 100	98	98	57	99	81	48
ADENOCARCINOMA IN FIBROADENOMA	1 (1)	1 (1)	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)
BENIGN EPITHELIAL TUMORS <sup>1</sup>	30 (30)	33 (34)	22 (22)	10 (18)	23 (23)	20 (25)	13 (27)
MALIGNANT EPITHELIAL TUMORS	16 (16)	16 (16)	14 (14)	8 (14)	14 (14)	15 (19)	6 (13)
BEN. AND MAL. EPITHELIAL TUMORS <sup>1</sup>	42 (42)	44 (45)	29 (30)	17 (30)	33 (33)	32 (40)	16 (33)
OPTIC NERVE	# Ex 99	97	97	56	98	81	48
OVARIES	# Ex 99	98	98	57	99	81	48
GRANULOSA-THECA CL TUMOR, BGN.	1 (1)	0 (0)	0 (0)	1 (2)	1 (1)	0 (0)	0 (0)
GRANULOSA-THECA CL TUMOR, MAL.	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
OVIDUCTS	# Ex 98	97	97	57	98	80	48
PANCREAS	# Ex 99	98	98	56	99	81	48
PANCREATIC ISLETS	# Ex 99	97	98	56	98	81	48
CARCINOMA	4 (4)	2 (2)	5 (5)	0 (0)	6 (6)	3 (4)	0 (0)
ADENOMA	3 (3)	1 (1)	3 (3)	0 (0)	4 (4)	3 (4)	1 (2)
ADENOMA, MULT	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)
ADENOMA OR ADENOMA MULT.	4 (4)	1 (1)	3 (3)	0 (0)	4 (4)	5 (6)	1 (2)
CARCINOMA OR ADENOMA	8 (8)	3 (3)	8 (8)	0 (0)	10 (10)	7 (9)	1 (2)
PARATHYROID	# Ex 98	97	95	54	96	77	48
ADENOMA, UNILATERAL	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
PITUITARY	# Ex 100	97	96	57	98	81	48
ADENOMA	77 (77)	72 (74)	77 (80)	45 (79)	74 (76)	63 (78)	37 (77)
ADENOMA, PARS INTERMEDIA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
CARCINOMA	7 (7)	14 (14)	7 (7)	1 (2)	8 (8)	5 (6)	2 (4)
CARCINOMA OR ADENOMA	84 (84)	86 (89)	84 (88)	46 (81)	82 (84)	68 (84)	39 (81)
RECTUM	# Ex 89	91	90	51	92	76	47
SALIVARY GLAND	# Ex 96	98	98	57	99	79	48
SCIATIC NERVE	# Ex 97	95	96	57	97	79	47
SCHWANNOMA, MAL.	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
SKELETAL MUSCLE	# Ex 99	98	97	57	98	81	47
SKIN/SUBCUTIS	# Ex 100	98	98	57	99	81	48
SQUAMOUS CELL PAPILLOMA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
SQUAMOUS CELL CARCINOMA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FIBROMA	2 (2)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
FIBROMA, MULT	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FIBROSARCOMA	2 (2)	2 (2)	1 (1)	2 (4)	0 (0)	1 (1)	0 (0)
LIPOMA	1 (1)	0 (0)	1 (1)	2 (4)	0 (0)	2 (2)	0 (0)
HEMANGIOMA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
OSTEOSARCOMA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
SARCOMA	1 (1)	0 (0)	0 (0)	1 (2)	0 (0)	1 (1)	0 (0)
FIBROMA OR FIBROMA, MULT.	2 (2)	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
FIBROSARCOMA OR FIBROMA	4 (4)	3 (3)	1 (1)	2 (4)	1 (1)	1 (1)	0 (0)
SPINAL CORD	# Ex 99	98	98	57	99	81	48
SPLEEN	# Ex 99	98	98	57	99	81	48



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TABLE 7 (continued)  
SUMMARY: Incidence of NEOPLASTIC Microscopic Findings for Treated Animals Without Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 98	M Gel 98	H Gel 57	L PE 99	M PE 81	H PE 48
<b>STERNUM - BONE</b>	# Ex 99	# (%) 97	# (%) 96	# (%) 57	# (%) 99	# (%) 81	# (%) 48
STERNUM - BONE MARROW	# Ex 99	96	96	57	99	81	48
<b>STOMACH</b>	# Ex 96	96	98	54	98	80	48
<b>SYSTEMIC DISEASES</b>	# Ex 100	98	98	57	99	81	48
LYMPHOBLASTIC LYMPHOMA	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
MONONUCLEAR CELL LEUKEMIA	0 (0)	0 (0)	0 (0)	1 (2)	1 (1)	0 (0)	0 (0)
GRANULOCYTTIC LEUKEMIA	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
LYMPHOMA NOS	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
HISTIOCYTTIC SARCOMA	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
<b>TAIL</b>	# Ex 18	14	15	11	16	16	9
<b>THYMUS</b>	# Ex 82	93	81	48	85	69	41
THYMOMA	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
THYMIC LYMPHOMA	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (2)
<b>THYROID</b>	# Ex 98	95	96	56	98	80	48
FOLL. CELL ADENOMA, UNILAT.	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
FOLL. CELL CARCINOMA, UNILAT.	0 (0)	0 (0)	1 (1)	1 (2)	0 (0)	0 (0)	1 (2)
C-CELL ADENOMA, UNILATERAL	10 (10)	13 (14)	9 (9)	3 (5)	6 (6)	9 (11)	0 (0)
C-CELL ADENOMA, BILATERAL	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
C-CELL CARCINOMA, UNILAT.	2 (2)	3 (3)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
C-CELL ADENOMA, UNILAT. AND BILAT.	10 (10)	13 (14)	10 (10)	3 (5)	7 (7)	9 (11)	0 (0)
C-CELL CARCINOMA OR ADENOMA	12 (12)	15 (16)	10 (10)	4 (7)	7 (7)	9 (11)	0 (0)
FOLL. CELL CARCINOMA OR ADENOMA	0 (0)	0 (0)	3 (3)	1 (2)	0 (0)	0 (0)	1 (2)
<b>TRACHEA</b>	# Ex 99	98	98	57	99	81	48
<b>URINARY BLADDER</b>	# Ex 98	95	98	54	97	79	47
<b>UTERUS</b>	# Ex 98	97	98	57	98	81	48
ENDOMETRIAL STROMAL POLYP	4 (4)	4 (4)	6 (6)	4 (7)	4 (4)	1 (1)	3 (6)
ENDOMETRIAL STROMAL SARCOMA	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
ADENOCARCINOMA	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
LEIOMYOSARCOMA	0 (0)	0 (0)	0 (0)	1 (2)	1 (1)	0 (0)	0 (0)
ENDOMETRIAL STROM. POLYP, MULT	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
FIBROMA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
ENDO. STROM. SARCOMA OR POLYP	4 (4)	4 (4)	7 (7)	4 (7)	5 (5)	1 (1)	3 (6)
ENDO. STROM. POLYP AND MULT.	4 (4)	4 (4)	6 (6)	4 (7)	5 (5)	1 (1)	3 (6)
<b>UTERUS AND CERVIX</b>	98	97	98	57	98	81	48
ENDO. STROM. SARCOMA OR POLYP	5 (5)	5 (5)	10 (10)	4 (7)	5 (5)	1 (1)	3 (6)
<b>VAGINA</b>	# Ex 98	97	97	56	98	81	48
FIBROMA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
SQUAMOUS CELL CARCINOMA	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>OTHER TISSUES AND LESIONS:</b>							
ZYMBALS GLAND: CARCINOMA	1 (1)	1 (1)	0 (0)	2 (3)	1 (1)	1 (1)	0 (0)
ABD WALL: LIPOMA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
ABD WALL: FIBROSARCOMA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)

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## Legend - Table 7

Female Sprague Dawley rats were implanted subcutaneously with three dose levels of either mammary silicone gel or low density polyethylene. The implantation procedure was performed on sham control animals but no test material was introduced into the animals. Forty-six specified tissues and organs were collected from all animals for histopathology. Animals exhibiting SST were censored, and the incidence of neoplastic lesions was calculated as the ratio of the number of animals bearing lesions at a site to the number of animals examined histologically (# Ex) and are reported as percents (%). Neoplastic lesions of the same histogenetic type within the same organ or tissue were grouped for analyses. A statistical analysis of tumor incidence was only performed if there were at least 2 observations in one of the experimental groups within a potential analysis. Silicone gel and PE groups were analyzed independently of one another.

Logistic regression analysis was the primary statistical method used to assess lesion incidence among treated and control groups. The life table test was applied to provide an appropriate approach for analyzing the incidence of rapidly lethal lesions (e.g. solid state tumors). In addition, the Fisher exact test and the Cochran-Armitage trend test were utilized although they are procedures which do not adjust for intercurrent mortality.

† Silicone gel group is significantly different from sham control group at  $p \leq 0.05$ . § Polyethylene group is significantly different from sham control group at  $p \leq 0.05$ . A statistical symbol immediately after the lesion indicates a significant trend for the silicone gel groups (†) or the polyethylene groups (§) at  $p \leq 0.05$  (one-side). Significance using a two-sided evaluation at  $p \leq 0.05$  is identified by ‡ (silicone gel) or ¶ (PE) according to the same scheme.

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TABLE 8  
SUMMARY: Incidence of NEOPLASTIC Microscopic Findings for Treated Animals With Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 2	M Gel 2	H Gel 43	L PE 1	M PE 19	H PE 52
ADRENAL CORTEX	# Ex 100	2	2	43	1	19	50
ADENOMA, UNILATERAL*	0 (0)	0 (0)	0 (0)	2 <sup>1</sup> (5)	0 (0)	0 (0)	1 (2)
CARCINOMA OR ADENOMA <sup>†</sup>	0 (0)	0 (0)	0 (0)	2 <sup>1</sup> (5)	0 (0)	0 (0)	1 (2)
ADRENAL MEDULLA	# Ex 100	2	2	42	1	19	48
PHEOCHROMOCYTOMA, UNILATERAL	4 (4)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	1 (2)
PHEOCHROMOCYTOMA, MAL., UNILAT	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
PHEOCHROMOCYTOMA, MAL. OR BEN.	5 (5)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)	1 (2)
AORTA	# Ex 100	2	2	43	1	19	52
BRAIN	# Ex 100	2	2	43	1	19	52
ASTROCYTOMA	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ASTROCYTOMA, MALIGNANT	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
GLIOMA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
OLIGODENDROGLIOMA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ASTROCYTOMA, MAL. OR BEN.	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
GLIAL TUMORS (ASTRO. AND GLIOMAS)	5 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
OLIGENDENDROGLIOMA OR GLIOMA	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
CECUM	# Ex 87	2	1	34	1	14	44
CERVIX	# Ex 98	2	2	43	1	19	51
ENDOMETRIAL STROMAL POLYP	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ENDOMETRIAL STROMAL SARCOMA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
CLITORAL GLAND	# Ex 4	0	0	1	0	2	2
COLON	# Ex 90	2	1	38	1	17	47
DUODENUM	# Ex 89	2	1	39	1	18	50
ESOPHAGUS	# Ex 100	2	2	43	1	19	52
EYES	# Ex 99	2	2	42	1	19	52
FEMUR - BONE	# Ex 99	2	2	42	1	18	50
FEMUR - BONE MARROW	# Ex 99	2	2	42	1	18	50
FOOTPAD	# Ex 17	0	0	8	0	1	6
FORESTOMACH	# Ex 100	2	2	42	1	19	52
SQUAMOUS CELL PAPILOMA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
HARDERIAN GLAND	# Ex 100	2	2	43	1	19	52
HEART	# Ex 100	2	2	43	1	19	52
ILEUM	# Ex 88	2	1	34	1	15	41
IMPLANT I - CAPSULE	# Ex 97	2	2	43	0	16	47
SARCOMA <sup>††</sup>	0 (0)	1 <sup>†</sup> (50)	0 (0)	10 <sup>†</sup> (23)	0 (0)	11 <sup>†</sup> (69)	29 <sup>†</sup> (62)
OSTEOSARCOMA <sup>†</sup>	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 <sup>†</sup> (6)
SARCOMA OR OSTEOSARCOMA <sup>††</sup>	0 (0)	1 <sup>†</sup> (50)	0 (0)	10 <sup>†</sup> (23)	0 (0)	11 <sup>†</sup> (69)	32 <sup>†</sup> (68)
IMPLANT I - EXTRACAPSULAR	# Ex 97	2	2	43	1	19	50



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DC Report Number - 1998-10000-44643  
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TABLE 2 (continued)  
SUMMARY: Incidence of NEOPLASTIC Microscopic Findings for Treated Animals With Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 2	M Gel 2	H Gel 43	L PE 1	M PE 19	H PE 52
IMPLANT 2 - CAPSULE	# Ex 96	2	2	43	1	15	49
SARCOMA <sup>11</sup>	0 (0)	0 (0)	0 (0)	13 <sup>†</sup> (30)	1 <sup>†</sup> (100)	6 <sup>†</sup> (40)	22 <sup>†</sup> (45)
OSTEOSARCOMA <sup>1</sup>	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (7)	2 (4)
SARCOMA OR OSTEOSARCOMA <sup>11</sup>	0 (0)	0 (0)	0 (0)	13 <sup>†</sup> (30)	1 <sup>†</sup> (100)	7 <sup>†</sup> (47)	24 <sup>†</sup> (49)
IMPLANT 2 - EXTRACAPSULAR	# Ex 96	2	2	43	1	19	49
IMPLANT 3 - CAPSULE	# Ex 97	1	2	43	0	0	0
SARCOMA <sup>1</sup>	0 (0)	0 (0)	0 (0)	12 <sup>†</sup> (28)	0 (0)	0 (0)	0 (0)
SARCOMA OR OSTEOSARCOMA <sup>1</sup>	0 (0)	0 (0)	0 (0)	12 <sup>†</sup> (28)	0 (0)	0 (0)	0 (0)
IMPLANT 3 - EXTRACAPSULAR	# Ex 97	2	2	43	0	0	0
IMPLANT 4 - CAPSULE	# Ex 96	2	2	42	0	0	0
SARCOMA <sup>1</sup>	0 (0)	0 (0)	1 <sup>†</sup> (50)	10 <sup>†</sup> (24)	0 (0)	0 (0)	0 (0)
SARCOMA OR OSTEOSARCOMA <sup>1</sup>	0 (0)	0 (0)	1 <sup>†</sup> (50)	10 <sup>†</sup> (24)	0 (0)	0 (0)	0 (0)
IMPLANT 4 - EXTRACAPSULAR	# Ex 96	2	2	42	0	0	0
IMPLANT SITE, NOS	# Ex 98	2	2	43	1	19	52
SARCOMA <sup>1</sup>	0 (0)	1 <sup>†</sup> (50)	1 <sup>†</sup> (50)	2 (5)	0 (0)	1 (5)	0 (0)
SARCOMA OR OSTEOSARCOMA <sup>1</sup>	0 (0)	1 <sup>†</sup> (50)	1 <sup>†</sup> (50)	2 (5)	0 (0)	1 (5)	0 (0)
IMPLANT SITES, ALL	98	2	2	43	1	19	52
SARCOMA <sup>11</sup>	0 (0)	2 <sup>†</sup> (100)	2 <sup>†</sup> (100)	40 <sup>†</sup> (93)	1 <sup>†</sup> (100)	17 <sup>†</sup> (89)	47 <sup>†</sup> (90)
OSTEOSARCOMA <sup>1</sup>	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	5 <sup>†</sup> (10)
SARCOMA OR OSTEOSARCOMA <sup>11</sup>	0 (0)	2 <sup>†</sup> (100)	2 <sup>†</sup> (100)	40 <sup>†</sup> (93)	1 <sup>†</sup> (100)	18 <sup>†</sup> (95)	52 <sup>†</sup> (100)
JEJUNUM	# Ex 89	2	1	36	1	17	48
KIDNEYS	# Ex 99	2	2	42	1	19	52
TUBULAR CELL CARCINOMA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
LIPOMA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
LIPOSARCOMA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (4)
LIPOSARCOMA OR SARCOMA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	2 (4)
LARYNX	# Ex 97	2	2	42	1	19	52
LIVER	# Ex 99	2	2	43	1	19	52
HEPATOCELLULAR ADENOMA	1 (1)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
HEPATOCELLULAR ADENOMA, MULT.	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
LUNGS	# Ex 100	2	2	43	1	19	52
LYMPH NODE, MANDEBULAR	# Ex 85	2	2	38	1	15	49
LYMPH NODE, MEDIASTINAL	# Ex 86	2	2	39	1	18	47
LYMPH NODE, MESENTERIC	# Ex 98	2	1	42	1	17	52
LYMPH NODE, OTHER	# Ex 26	1	1	8	0	4	14
MAMMARY GLAND	# Ex 100	2	2	43	1	18	52
ADENOMA	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FIBROADENOMA	20 (20)	1 (50)	1 (50)	3 (7)	1 (100)	5 (28)	7 (13)
FIBROADENOMA, MULTIPLE	9 (9)	0 (0)	0 (0)	4 (9)	0 (0)	0 (0)	2 (4)
ADENOCARCINOMA	11 (11)	0 (0)	1 (50)	1 (2)	1 (100)	0 (0)	4 (8)
ADENOCARCINOMA, MULTIPLE	2 (2)	0 (0)	0 (0)	3 (7)	0 (0)	1 (6)	2 (4)



Study Number - 7008

DC Report Number - 1958-10000-44543  
Security - Internal

TABLE 8 (continued)  
SUMMARY: Incidence of NEOPLASTIC Microscopic Findings for Treated Animals With Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 2	M Gel 2	H Gel 43	L PE 1	M PE 19	H PE 52
<b>MAMMARY GLAND</b>	# Ex 100	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
FIBROSARCOMA IN FIBROADENOMA	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
CARCINOMA IN SITU	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ADENOCARCINOMA IN FIBROADENOMA	1 (1)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
BENIGN EPITHELIAL TUMORS	30 (30)	1 (50)	1 (50)	7 (16)	1 (100)	5 (26)	9 (17)
MALIGNANT EPITHELIAL TUMORS	16 (16)	0 (0)	1 (50)	5 (12)	1 (100)	1 (6)	6 (12)
BEN. OR MAL. EPITHELIAL TUMORS	42 (42)	1 (50)	1 (50)	10 (23)	1 (100)	6 (33)	13 (25)
<b>OPTIC NERVE</b>	# Ex 99	1	2	41	1	19	52
<b>OVARIES</b>	# Ex 99	2	2	43	1	19	52
GRANULOSA-THECA CL TUMOR, BGN.	1 (1)	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	1 (2)
HEMANGIOMA	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
<b>OVIDUCTS</b>	# Ex 98	2	1	43	1	19	52
<b>PANCREAS</b>	# Ex 99	2	2	42	1	19	52
<b>PANCREATIC ISLETS</b>	# Ex 99	2	2	42	1	19	52
CARCINOMA	4 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ADENOMA	3 (3)	0 (0)	0 (0)	2 (5)	1 (100)	0 (0)	1 (2)
ADENOMA, MULT	1 (1)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
ADENOMA AND ADENOMA, MULT.	4 (4)	0 (0)	0 (0)	3 (7)	1 (100)	0 (0)	1 (2)
CARCINOMA OR ADENOMA	8 (8)	0 (0)	0 (0)	3 (7)	1 (100)	0 (0)	1 (2)
<b>PARATHYROID</b>	# Ex 98	2	2	39	6	18	50
ADENOMA, UNILATERAL	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
<b>PITUITARY</b>	# Ex 100	1	2	42	1	19	52
ADENOMA	77 (77)	0 (0)	1 (50)	25 (60)	1 (100)	14 (74)	30 (58)
CARCINOMA	7 (7)	0 (0)	1 (50)	2 (5)	0 (0)	0 (0)	4 (8)
CARCINOMA OR ADENOMA	84 (84)	0 (0)	2 (100)	27 (64)	1 (100)	14 (74)	34 (65)
<b>RECTUM</b>	# Ex 89	2	1	41	1	18	50
<b>SALIVARY GLAND</b>	# Ex 96	2	2	43	1	19	51
ADENOCARCINOMA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
<b>SCIATIC NERVE</b>	# Ex 97	2	2	42	1	18	50
<b>SKELETAL MUSCLE</b>	# Ex 99	2	2	42	1	19	52
<b>SKIN/SUBCUTIS</b>	# Ex 100	2	2	43	1	19	52
SQUAMOUS CELL CARCINOMA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FIBROMA	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FIBROSARCOMA	2 (2)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
LIPOMA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (4)
HEMANGIOMA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
SARCOMA, MULT	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
SARCOMA*	1 (1)	0 (0)	0 (0)	3* (7)	0 (0)	1 (5)	0 (0)
FIBROSARCOMA OR FIBROMA	4 (4)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
SARCOMA OR OSTEOSARCOMA*	1 (1)	0 (0)	0 (0)	3* (7)	0 (0)	2† (11)	0 (0)
<b>SPINAL CORD</b>	# Ex 99	2	2	42	1	19	52
<b>SPLEEN</b>	# Ex 99	2	2	43	1	19	52
HEMANGIOSARCOMA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)



Study Number - 7088

DC Report Number - 1998-10000-44643  
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TABLE 8 (continued)  
SUMMARY: Incidence of NEOPLASTIC Microscopic Findings for Treated Animals With Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 2	M Gel 2	H Gel 43	L PE 1	M PE 19	H PE 52
STERNUM - BONE	# Ex 99	# (%) 2	# (%) 2	# (%) 43	# (%) 1	# (%) 19	# (%) 52
STERNUM - BONE MARROW	# Ex 99	2	2	43	1	19	52
STOMACH	# Ex 96	2	2	42	1	19	51
SYSTEMIC DISEASES	# Ex 100	2	2	43	1	19	52
LYMPHOCYTIC LYMPHOMA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
MONONUCLEAR CELL LEUKEMIA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
TAIL	# Ex 18	0	0	9	0	0	7
THYMUS	# Ex 82	2	1	30	1	16	40
THYMOMA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)
THYROID	# Ex 98	2	2	43	1	19	50
FOLL. CELL ADENOMA, UNILAT.	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
C-CELL ADENOMA, UNILATERAL	10 (10)	0 (0)	1 (50)	2 (5)	0 (0)	0 (0)	0 (0)
C-CELL CARCINOMA, UNILAT.	2 (2)	0 (0)	0 (0)	1 (2)	0 (0)	1 (5)	0 (0)
C-CELL CARCINOMA OR ADENOMA	12 (12)	0 (0)	1 (50)	3 (7)	0 (0)	1 (5)	0 (0)
TRACHEA	# Ex 99	2	2	42	1	19	52
URINARY BLADDER	# Ex 98	2	2	42	1	19	52
UTERUS	# Ex 98	2	2	43	1	19	52
ENDOMETRIAL STROMAL POLYP	4 (4)	1* (50)	0 (0)	1 (2)	0 (0)	1 (5)	2 (4)
ENDOMETRIAL STROMAL SARCOMA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
ADENOCARCINOMA	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
LEIOMYSARCOMA	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
ENDO. STROM. SARCOMA OR POLYP	4 (4)	1* (50)	0 (0)	1 (2)	0 (0)	2 (11)	2 (4)
UTERUS AND CERVIX	98	2	2	43			
ENDO. STROM. SARCOMA OR POLYP	5 (5)	1* (50)	0 (0)	1 (2)	0 (0)	2 (11)	3 (6)
VAGINA	# Ex 98	2	2	42	1	19	51
FIBROMA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
OTHER TISSUES AND LESIONS:							
ZYMBALS GLAND: CARCINOMA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

\*



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## Legend - Table 8

Female Sprague Dawley rats were implanted subcutaneously with three dose levels of either mammary silicone gel or low density polyethylene. The implantation procedure was performed on sham control animals but no test material was introduced into the animals. Forty-six specified tissues and organs were collected from all animals for histopathology. Animals exhibiting SST were identified, and the incidence of neoplastic lesions was calculated as the ratio of the number of animals bearing lesions at a site to the number of animals examined histologically (# Ex) and are reported as percents (%). Neoplastic lesions of the same histogenetic type within the same organ or tissue were grouped for analyses. A statistical analysis of tumor incidence was only performed if there were at least 2 observations in one of the experimental groups within a potential analysis. Silicone gel and PE groups were analyzed independently of one another.

Logistic regression analysis was the primary statistical method used to assess lesion incidence among treated and control groups. The life table test was applied to provide an appropriate approach for analyzing the incidence of rapidly lethal lesions (e.g. solid state tumors). In addition, the Fisher exact test and the Cochran-Armitage trend test were utilized although they are procedures which do not adjust for intercurrent mortality.

† Silicone gel group is significantly different from sham control group at  $p \leq 0.05$ . § Polyethylene group is significantly different from sham control group at  $p \leq 0.05$ . A statistical symbol immediately after the lesion indicates a significant trend for the silicone gel groups (†) or the polyethylene groups (§) at  $p \leq 0.05$ .

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Study Number - 7088

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TABLE 9  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for All Treated Animals

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 100	M Gel 100	H Gel 100	L PE 100	M PE 100	H PE 100
ADRENAL CORTEX	# Ex 100	100	100	100	100	100	98
HYPERPLASIA	5 (5)	4 (4)	5 (5)	1 (1)	2 (2)	4 (4)	5 (5)
HYPERTROPHY	8 (8)	5 (5)	2 (2)	4 (4)	5 (5)	3 (3)	3 (3)
HEMORRHAGIC CYST/CYST(S)	90 (90)	93 (93)	90 (90)	84 (84)	88 (88)	85 (85)	76 (78)
THROMBUS/THROMBOSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
FATTY CHANGE	3 (3)	7 (7)	6 (6)	3 (3)	3 (3)	1 (1)	3 (3)
DEGENERATION	19 (19)	21 (21)	18 (18)	16 (16)	22 (22)	16 (16)	17 (17)
CONGESTION	3 (3)	5 (5)	3 (3)	4 (4)	2 (2)	7 (7)	4 (4)
HEMORRHAGE	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)
EXTRAMEDULLARY HEMATOPOIESIS <sup>1</sup>	0 (0)	2 (2)	3 (3)	10 <sup>1</sup> (10)	0 (0)	7 <sup>1</sup> (7)	9 <sup>1</sup> (9)
ATROPHY	1 (1)	1 (1)	0 (0)	1 (1)	1 (1)	5 (5)	2 (2)
FIBROSIS	1 (1)	2 (2)	1 (1)	3 (3)	0 (0)	1 (1)	1 (1)
NECROSIS	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
INFLAMMATION, CHRONIC	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
ADRENAL MEDULLA	# Ex 100	100	98	97	98	99	96
HYPERPLASIA	17 (17)	5 (5)	8 (8)	7 (7)	9 (9)	13 (13)	7 (7)
AORTA	# Ex 100	100	100	100	100	100	100
DEGENERATION	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
MINERALIZATION	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
BRAIN	# Ex 100	99	100	100	100	100	100
GLIOSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
MALACIA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	2 (2)
COMPRESSION	51 (51)	43 (43)	48 (48)	39 (39)	54 (54)	52 (52)	39 (39)
HYDROCEPHALUS <sup>1</sup>	16 (16)	9 (9)	7 (7)	6 (6)	6 (6)	19 (19)	21 (21)
HEMORRHAGE	4 (4)	6 (6)	4 (4)	3 (3)	5 (5)	9 (9)	5 (5)
CONGESTION	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)
THROMBUS/THROMBOSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
MINERALIZATION	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
CECUM	# Ex 87	92	89	84	87	82	88
EROSION	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
ULCER	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
ULCER, MULT	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
INFLAMMATION, ACUTE	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)
INFLAMMATION, CHRONIC	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
INFLAMMATION, GRANULOMATOUS	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FIBROSIS	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
CONGESTION	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
HEMORRHAGE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
EDEMA	1 (1)	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
CERVIX	# Ex 98	97	97	100	99	100	99
PROLIFERATIVE FASCICULITIS <sup>1</sup>	1 (1)	3 (3)	3 (3)	6 <sup>1</sup> (6)	2 (2)	3 (3)	1 (1)
INTUSSUSCEPTION	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
FIBROSIS	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)
SQUAMOUS METAPLASIA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
EPITHELIAL DYSPLASIA	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
STROMAL HYPERPLASIA	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)
INFLAMMATION, ACUTE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC	1 (1)	3 (3)	2 (2)	0 (0)	0 (0)	0 (0)	1 (1)
INFLAMMATION, CHRONIC ACTIVE	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)
EKUDATE <sup>1</sup>	1 (1)	2 (2)	3 (3)	1 (1)	0 (0)	1 (1)	4 (4)
EPITHELIAL HYPERPLASIA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
CYSTS(S) <sup>1</sup>	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)



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Study Number - 7088

DC Report Number - 1998-10000-44643  
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TABLE 9 (continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for All Treated Animals

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 100	M Gel 100	H Gel 100	L PE 100	M PE 100	H PE 100
<b>CLITORAL GLAND</b>	# Ex 4	# (%) 3	# (%) 2	# (%) 1	# (%) 3	# (%) 5	# (%) 3
CYSTIC DUCTS	3 (75)	3 (100)	1 (50)	0 (0)	1 (33)	3 (60)	2 (67)
INFLAMMATION, CHRONIC	0 (0)	1 (33)	0 (0)	0 (0)	0 (0)	1 (20)	1 (33)
<b>COLON</b>	# Ex 90	# (%) 95	# (%) 90	# (%) 89	# (%) 91	# (%) 88	# (%) 90
NECROSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
EPITHELIAL HYPERPLASIA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ULCER, MULT	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
INFLAMMATION, ACUTE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
INFLAMMATION, CHRONIC	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
INFLAMMATION, CHRONIC ACTIVE	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
EDEMA	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
DIVERTICULUM	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
<b>DUODENUM</b>	# Ex 89	# (%) 94	# (%) 92	# (%) 90	# (%) 94	# (%) 94	# (%) 95
EROSION, MULT	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
CONGESTION	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
<b>ESOPHAGUS</b>	# Ex 100	# (%) 100	# (%) 100	# (%) 100	# (%) 100	# (%) 100	# (%) 100
INGESTA	3 (3)	1 (1)	1 (1)	3 (3)	5 (5)	0 (0)	2 (2)
<b>EYES</b>	# Ex 99	# (%) 98	# (%) 100	# (%) 98	# (%) 99	# (%) 100	# (%) 100
CORNEA, EPITHELIAL HYPERPLASIA	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)
CORNEA, EDEMA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
CORNEA, MINERALIZATION <sup>1</sup>	4 (4)	12 <sup>2</sup> (12)	12 <sup>2</sup> (12)	9 (9)	8 (8)	5 (5)	10 <sup>1</sup> (10)
CORNEA, VASCULARIZATION	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
CORNEA, ULCER	0 (0)	1 (1)	0 (0)	0 (0)	2 (2)	1 (1)	1 (1)
CORNEA, INFLAMMATION ACUTE	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	3 (3)	0 (0)
CORNEA, INFLAMMATION CHRONIC	2 (2)	0 (0)	2 (2)	2 (2)	3 (3)	0 (0)	0 (0)
CORNEA, INFLAM CHRONIC ACTIVE	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)
CORNEA, INFLAM GRANULOMATOUS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
IRIDOCYCLITIS	0 (0)	3 (3)	1 (1)	1 (1)	1 (1)	1 (1)	2 (2)
CATARACT	3 (3)	0 (0)	3 (3)	0 (0)	2 (2)	0 (0)	0 (0)
PANOPTHALMITIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
RETINA, DEGENERATION	2 (2)	1 (1)	1 (1)	2 (2)	0 (0)	1 (1)	0 (0)
RETINA, HEMORRHAGE	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
ANTERIOR UVEITIS	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
PHTHISIS BULBI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
<b>FEMUR - BONE</b>	# Ex 99	# (%) 97	# (%) 97	# (%) 98	# (%) 97	# (%) 96	# (%) 97
BONE-CYST	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FIBROUS OSTEOID <sup>2</sup> STROPHY	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)
EXOSTOSES	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
OSTEOSCLEROSIS	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
SYNOVITIS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>FEMUR - BONE MARROW</b>	# Ex 99	# (%) 96	# (%) 97	# (%) 98	# (%) 97	# (%) 96	# (%) 97
HYPERPLASIA, MYELOID <sup>1</sup>	10 (10)	12 (13)	6 (6)	20 <sup>2</sup> (20)	9 (9)	18 <sup>1</sup> (19)	22 <sup>1</sup> (23)
HYPERPLASIA, NOS	3 (3)	4 (4)	4 (4)	2 (2)	3 (3)	5 (5)	4 (4)
FIBROSIS	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)
CYST(S)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
CONGESTION	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
<b>FOOTPAD</b>	# Ex 17	# (%) 20	# (%) 14	# (%) 14	# (%) 19	# (%) 15	# (%) 10
CYST(S)/INCLUSION CYST(S)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (7)	0 (0)
ULCER, MULT	0 (0)	0 (0)	0 (0)	1 (7)	0 (0)	0 (0)	0 (0)
SQUAMOUS CELL HYPERPLASIA	0 (0)	3 (15)	0 (0)	0 (0)	1 (5)	1 (7)	0 (0)



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TABLE 9 (continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for All Treated Animals

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 100	M Gel 100	H Gel 100	L PE 100	M PE 100	H PE 100
<b>FOOTPAD</b>	# Ex 17	# (%) 20	# (%) 14	# (%) 14	# (%) 19	# (%) 15	# (%) 10
HYPERKERATOSIS	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ULCER	16 (94)	14 (70)	12 (86)	13 (93)	17 (89)	14 (93)	8 (80)
INFLAMMATION, CHRONIC ACTIVE	1 (6)	5 (25)	3 (21)	1 (7)	1 (5)	1 (7)	1 (10)
ABSCESS <sup>1</sup>	0 (0)	3 (15)	1 (7)	0 (0)	1 (5)	1 (7)	2 (20)
PROLIFERATIVE CHONDROPATHY	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>FORESTOMACH</b>	# Ex 100	# (%) 100	# (%) 100	# (%) 98	# (%) 100	# (%) 99	# (%) 100
SQUAMOUS CELL HYPERPLASIA	3 (3)	7 (7)	7 (7)	0 (0)	5 (5)	4 (4)	2 (2)
EROSION	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)
ULCER	3 (3)	3 (3)	5 (5)	3 (3)	3 (3)	5 (5)	4 (4)
ULCER, MULT <sup>1</sup>	0 (0)	1 (1)	1 (1)	2 (2)	1 (1)	0 (0)	1 (1)
PERFORATING ULCER	1 (1)	1 (1)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)
INFLAMMATION, ACUTE	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)	1 (1)	1 (1)
INFLAMMATION, CHRONIC ACTIVE	7 (7)	5 (5)	3 (3)	3 (3)	5 (5)	3 (3)	3 (3)
EDEMA <sup>1</sup>	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
FIBROSIS	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
INCLUSION CYST(S) <sup>1</sup>	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)
VESICLES	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
<b>HARDERIAN GLAND</b>	# Ex 100	# (%) 100	# (%) 100	# (%) 99	# (%) 100	# (%) 100	# (%) 100
ATROPHY	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
INFLAMMATION, CHRONIC	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC ACTIVE	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FIBROSIS	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
<b>HEART</b>	# Ex 100	# (%) 100	# (%) 100	# (%) 100	# (%) 100	# (%) 100	# (%) 100
CARDIOMYOPATHY <sup>1</sup>	74 (74)	73 (73)	78 (78)	68 (68)	70 (70)	72 (72)	72 (72)
MINERALIZATION	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
ATRIAL THROMBOSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
ENDOCARDIAL HYPERPLASIA	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
PERICARDITIS	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
NECROSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
<b>ILEUM</b>	# Ex 88	# (%) 88	# (%) 88	# (%) 83	# (%) 84	# (%) 83	# (%) 83
EROSION, MULT	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>IMPLANT 1 - CAPSULE</b>	# Ex 97	# (%) 97	# (%) 94	# (%) 100	# (%) 58	# (%) 86	# (%) 94
FIBROSIS <sup>11</sup>	0 (0)	97 <sup>1</sup> (100)	94 <sup>1</sup> (100)	95 <sup>1</sup> (95)	58 <sup>1</sup> (100)	75 <sup>1</sup> (87)	70 <sup>1</sup> (74)
HYPERPLASIA, FIBROBLASTIC <sup>11</sup>	0 (0)	3 (3)	6 <sup>1</sup> (6)	22 <sup>1</sup> (22)	3 (5)	5 <sup>1</sup> (6)	17 <sup>1</sup> (18)
INGROWTH <sup>1</sup>	0 (0)	4 (4)	3 (3)	5 <sup>1</sup> (5)	0 (0)	0 (0)	0 (0)
COMPARTMENTALIZATION <sup>1</sup>	0 (0)	2 (2)	5 <sup>1</sup> (5)	10 <sup>1</sup> (10)	1 (2)	2 (2)	1 (1)
IMPLANT MATERIAL <sup>1</sup>	0 (0)	12 <sup>1</sup> (12)	30 <sup>1</sup> (32)	49 <sup>1</sup> (49)	3 (5)	0 (0)	1 (1)
INFLAMMATION, CHRONIC <sup>11</sup>	0 (0)	4 (4)	9 <sup>1</sup> (10)	21 <sup>1</sup> (21)	20 <sup>1</sup> (34)	19 <sup>1</sup> (22)	11 <sup>1</sup> (12)
INFLAMMATION, CHRONIC ACTIVE	0 (0)	0 (0)	0 (0)	2 (2)	1 (2)	1 (1)	2 (2)
INFLAMMATION, GRANULOMATOUS <sup>1</sup>	0 (0)	0 (0)	0 (0)	3 (3)	19 <sup>1</sup> (33)	11 <sup>1</sup> (13)	4 <sup>1</sup> (4)
MINERALIZATION	0 (0)	2 <sup>1</sup> (3)	27 <sup>1</sup> (29)	3 (3)	0 (0)	1 (1)	0 (0)
DEGENERATION <sup>11</sup>	0 (0)	4 (4)	9 <sup>1</sup> (10)	18 <sup>1</sup> (18)	0 (0)	9 <sup>1</sup> (10)	2 (2)
PIGMENT <sup>1</sup>	0 (0)	1 (1)	1 (1)	6 <sup>1</sup> (6)	9 <sup>1</sup> (16)	19 <sup>1</sup> (22)	2 (2)
ABSCESS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
PLANT MATERIAL	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
HEMORRHAGE	0 (0)	1 (1)	2 (2)	2 (2)	1 (2)	3 (3)	1 (1)
OSSEOUS METAPLASIA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

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TABLE 9 (continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for All Treated Animals

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 100	M Gel 100	H Gel 100	L PE 100	M PE 100	H PE 100
<b>IMPLANT 1 - EXTRACAPSULAR</b>	# Ex 97	98	97	100	87	100	97
IMPLANT MATERIAL*	0 (0)	60 <sup>a</sup> (61)	70 <sup>a</sup> (72)	66 <sup>a</sup> (66)	1 (1)	1 (1)	1 (1)
FIBROSIS*	1 (1)	54 <sup>a</sup> (55)	46 <sup>a</sup> (47)	53 <sup>a</sup> (55)	5 (6)	2 (2)	0 (0)
INFLAMMATION, ACUTE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC*	0 (0)	16 <sup>a</sup> (16)	20 <sup>a</sup> (21)	20 <sup>a</sup> (20)	4 <sup>a</sup> (5)	2 (2)	0 (0)
INFLAMMATION, GRANULOMATOUS	0 (0)	0 (0)	2 (2)	1 (1)	0 (0)	0 (0)	0 (0)
MINERALIZATION	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
ULCER-SKIN*	0 (0)	0 (0)	1 (1)	1 (1)	1 (1)	0 (0)	3 (3)
PIGMENT	0 (0)	1 (1)	2 (2)	2 (2)	7 <sup>a</sup> (8)	1 (1)	0 (0)
DERMIS-FIBROSIS*	2 (2)	0 (0)	0 (0)	0 (0)	2 (2)	4 (4)	7 <sup>a</sup> (7)
ABSCESS-SKIN	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
SQUAMOUS CELL HYPERPL-SKIN	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)	2 (2)
EROSION-SKIN	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
HEMORRHAGE	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
<b>IMPLANT 2 - CAPSULE</b>	# Ex 96	100	99	99	70	86	96
FIBROSIS*	0 (0)	100 <sup>a</sup> (100)	99 <sup>a</sup> (100)	92 <sup>a</sup> (93)	69 <sup>a</sup> (99)	80 <sup>a</sup> (93)	73 <sup>a</sup> (76)
HYPERPLASIA, FIBROBLASTIC*	0 (0)	1 (1)	0 (0)	10 <sup>a</sup> (10)	8 <sup>a</sup> (11)	10 <sup>a</sup> (12)	22 <sup>a</sup> (23)
INGROWTH*	0 (0)	6 <sup>a</sup> (6)	1 (1)	6 <sup>a</sup> (6)	0 (0)	0 (0)	0 (0)
COMPARTMENTALIZATION	0 (0)	8 <sup>a</sup> (8)	2 (2)	4 <sup>a</sup> (4)	0 (0)	0 (0)	0 (0)
IMPLANT MATERIAL*	0 (0)	18 <sup>a</sup> (18)	30 <sup>a</sup> (30)	36 <sup>a</sup> (36)	0 (0)	1 (1)	0 (0)
INFLAMMATION, CHRONIC*	0 (0)	2 (2)	5 <sup>a</sup> (5)	12 <sup>a</sup> (12)	29 <sup>a</sup> (41)	19 <sup>a</sup> (22)	13 <sup>a</sup> (14)
INFLAMMATION, CHRONIC ACTIVE*	0 (0)	0 (0)	0 (0)	3 (3)	0 <sup>a</sup> (0)	0 (0)	3 (3)
INFLAMMATION, GRANULOMATOUS*	0 (0)	0 (0)	0 (0)	3 (3)	14 <sup>a</sup> (20)	7 <sup>a</sup> (8)	6 <sup>a</sup> (6)
MINERALIZATION	0 (0)	21 <sup>a</sup> (21)	19 <sup>a</sup> (19)	3 (3)	1 (1)	0 (0)	0 (0)
DEGENERATION*	0 (0)	2 (2)	0 (0)	8 <sup>a</sup> (8)	0 (0)	2 (2)	2 (2)
PIGMENT*	0 (0)	0 (0)	0 (0)	0 (0)	8 <sup>a</sup> (11)	7 <sup>a</sup> (8)	7 <sup>a</sup> (7)
HEMORRHAGE	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)
OSSEOUS METAPLASIA	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
<b>IMPLANT 2 - EXTRACAPSULAR</b>	# Ex 96	100	99	100	89	99	96
DERMIS-FIBROSIS	7 (7)	2 (2)	1 (1)	0 (0)	0 (0)	3 (3)	6 (6)
IMPLANT MATERIAL*	0 (0)	63 <sup>a</sup> (63)	66 <sup>a</sup> (67)	53 <sup>a</sup> (53)	1 (1)	1 (1)	0 (0)
FIBROSIS*	0 (0)	59 <sup>a</sup> (59)	48 <sup>a</sup> (48)	38 <sup>a</sup> (38)	1 (1)	0 (0)	0 (0)
INFLAMMATION, ACUTE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
INFLAMMATION, CHRONIC*	0 (0)	15 <sup>a</sup> (15)	11 <sup>a</sup> (11)	8 <sup>a</sup> (8)	0 (0)	2 (2)	0 (0)
INFLAMMATION, CHRONIC ACTIVE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
INFLAMMATION, GRANULOMATOUS*	0 (0)	0 (0)	1 (1)	3 (3)	2 (2)	1 (1)	0 (0)
PIGMENT	0 (0)	0 (0)	0 (0)	0 (0)	5 <sup>a</sup> (6)	0 (0)	0 (0)
EROSION-SKIN	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
HYPERKERATOSIS-SKIN	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
ULCER-SKIN*	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	4 <sup>a</sup> (4)
SQUAMOUS CELL HYPERPL-SKIN	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
ULCER, MULT-SKIN	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
<b>IMPLANT 3 - CAPSULE</b>	# Ex 97	94	99	98	0	0	0
FIBROSIS*	0 (0)	94 <sup>a</sup> (100)	99 <sup>a</sup> (100)	93 <sup>a</sup> (95)	0 (0)	0 (0)	0 (0)
HYPERPLASIA, FIBROBLASTIC*	0 (0)	0 (0)	3 (3)	19 <sup>a</sup> (19)	0 (0)	0 (0)	0 (0)
INGROWTH	0 (0)	11 <sup>a</sup> (12)	6 <sup>a</sup> (6)	3 <sup>a</sup> (3)	0 (0)	0 (0)	0 (0)
COMPARTMENTALIZATION*	0 (0)	9 <sup>a</sup> (10)	4 (4)	11 <sup>a</sup> (11)	0 (0)	0 (0)	0 (0)
IMPLANT MATERIAL*	0 (0)	25 <sup>a</sup> (27)	44 <sup>a</sup> (44)	58 <sup>a</sup> (59)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC*	0 (0)	9 <sup>a</sup> (10)	12 <sup>a</sup> (12)	23 <sup>a</sup> (23)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC ACTIVE	0 (0)	2 (2)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
INFLAMMATION, GRANULOMATOUS*	0 (0)	0 (0)	1 (1)	2 (2)	0 (0)	0 (0)	0 (0)
MINERALIZATION	0 (0)	35 <sup>a</sup> (37)	23 <sup>a</sup> (23)	1 (1)	0 (0)	0 (0)	0 (0)
DEGENERATION*	0 (0)	5 <sup>a</sup> (5)	8 <sup>a</sup> (8)	23 <sup>a</sup> (23)	0 (0)	0 (0)	0 (0)
PIGMENT*	0 (0)	0 (0)	1 (1)	7 <sup>a</sup> (7)	0 (0)	0 (0)	0 (0)
HEMORRHAGE	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)



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TABLE 9 (continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for All Treated Animals

GROUP:	Sham	L Gel	M Gel	H Gel	L PE	M PE	H PE
NUMBER OF ANIMALS:	100	100	100	100	100	100	100
<b>IMPLANT 3 - EXTRACAPSULAR</b>	# Ex 97	98	99	99	0	0	0
DERMIS-FIBROSIS	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
IMPLANT MATERIAL*	0 (0)	59 <sup>†</sup> (60)	76 <sup>†</sup> (77)	68 <sup>†</sup> (69)	0 (0)	0 (0)	0 (0)
FIBROSIS*	0 (0)	46 <sup>†</sup> (47)	60 <sup>†</sup> (61)	47 <sup>†</sup> (47)	0 (0)	0 (0)	0 (0)
INFLAMMATION, ACUTE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC*	1 (1)	27 <sup>†</sup> (28)	22 <sup>†</sup> (22)	25 <sup>†</sup> (25)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC ACTIVE	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, GRANULOMATOUS	0 (0)	3 (3)	3 (3)	3 (3)	0 (0)	0 (0)	0 (0)
DERMIS-FIBROSIS	2 (2)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
SQUAMOUS CELL HYPERPL-SKIN	1 (1)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
MYOPATHY-MUSCLE	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
<b>IMPLANT 4 - CAPSULE</b>	# Ex 96	97	96	99	0	0	0
FIBROSIS*	0 (0)	97 <sup>†</sup> (100)	96 <sup>†</sup> (100)	90 <sup>†</sup> (91)	0 (0)	0 (0)	0 (0)
HYPERPLASIA, FIBROBLASTIC*	0 (0)	0 (0)	0 (0)	10 <sup>†</sup> (10)	0 (0)	0 (0)	0 (0)
INGROWTH	0 (0)	4 (4)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
COMPARTMENTALIZATION	0 (0)	5 <sup>†</sup> (5)	2 (2)	1 (1)	0 (0)	0 (0)	0 (0)
IMPLANT MATERIAL*	0 (0)	14 <sup>†</sup> (14)	28 <sup>†</sup> (29)	35 <sup>†</sup> (35)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC*	0 (0)	1 (1)	3 <sup>†</sup> (3)	12 <sup>†</sup> (12)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC ACTIVE*	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)
INFLAMMATION, GRANULOMATOUS*	0 (0)	0 (0)	0 (0)	3 (3)	0 (0)	0 (0)	0 (0)
MINERALIZATION	0 (0)	14 <sup>†</sup> (14)	15 <sup>†</sup> (16)	0 (0)	0 (0)	0 (0)	0 (0)
DEGENERATION*	0 (0)	1 (1)	0 (0)	9 <sup>†</sup> (9)	0 (0)	0 (0)	0 (0)
PIGMENT	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
<b>IMPLANT 4 - EXTRACAPSULAR</b>	# Ex 96	99	98	99	0	0	0
DERMIS-FIBROSIS	3 (3)	7 (7)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
IMPLANT MATERIAL*	0 (0)	50 <sup>†</sup> (51)	63 <sup>†</sup> (64)	46 <sup>†</sup> (46)	0 (0)	0 (0)	0 (0)
FIBROSIS*	0 (0)	43 <sup>†</sup> (43)	53 <sup>†</sup> (54)	37 <sup>†</sup> (37)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC*	0 (0)	13 <sup>†</sup> (13)	12 <sup>†</sup> (12)	8 <sup>†</sup> (8)	0 (0)	0 (0)	0 (0)
INFLAMMATION, GRANULOMATOUS	0 (0)	2 (2)	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)
GRANULOMA	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
EDEMA	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
ULCER-SKIN	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
<b>IMPLANT SITE, NOS</b>	# Ex 98	100	100	100	95	100	100
ULCER	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
<b>JEJUNUM</b>	# Ex 89	92	90	85	89	89	92
PERFORATING ULCER	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
DIVERTICULUM	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
INTUSSUSCEPTION	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
<b>KIDNEYS</b>	# Ex 99	100	100	99	100	100	100
TUBULAR CELL HYPERPLASIA	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)
TRANSITIONAL CELL HYPERPLASIA	0 (0)	1 (1)	1 (1)	1 (1)	1 (1)	0 (0)	2 (2)
CHRONIC NEPHROPATHY	66 (67)	70 (70)	71 (71)	66 (67)	64 (64)	64 (64)	51 (51)
HYDRONEPHROSIS**	8 (8)	8 (8)	10 (10)	13 (13)	5 (5)	14 (14)	15 <sup>†</sup> (15)
CYST(S)	1 (1)	1 (1)	0 (0)	1 (1)	0 (0)	1 (1)	2 (2)
HYALINE DROPLETS**	0 (0)	5 <sup>†</sup> (5)	2 (2)	10 <sup>†</sup> (10)	0 (0)	5 <sup>†</sup> (5)	7 <sup>†</sup> (7)
MINERALIZATION	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)
MINERALIZATION-PELVIS*	29 (29)	28 (28)	32 (32)	35 (35)	34 (34)	30 (30)	39 <sup>†</sup> (39)
CALCUL*	0 (0)	0 (0)	2 (2)	5 <sup>†</sup> (5)	1 (1)	0 (0)	2 (2)
PYELITIS	4 (4)	3 (3)	1 (1)	0 (0)	0 (0)	2 (2)	0 (0)
PYELONEPHRITIS	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
INFLAMMATION, ACUTE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
CONGESTION	10 (10)	6 (6)	12 (12)	7 (7)	15 (15)	9 (9)	8 (8)

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TABLE 9 (Continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for All Treated Animals

GROUP: NUMBER OF ANIMALS:	Stam 100	L Gel 100	M Gel 100	H Gel 100	L PE 100	M PE 100	H PE 100
<b>KIDNEYS</b>	# Ex 99	# (%) 100	# (%) 100	# (%) 99	# (%) 100	# (%) 100	# (%) 100
HEMORRHAGE	0 (0)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
EXTRAMEDULLARY HEMATOPOIESIS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FIBRIN THROMBI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)
PROTEIN CASTS	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)
PIGMENT <sup>†</sup>	0 (0)	3 (3)	2 (2)	3 (3)	3 (3)	3 (3)	5 <sup>‡</sup> (5)
ADHESIONS	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)
FIBROSIS	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
HEMORRHAGE-PELVIS	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
VACUOLIZATION	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
FATTY CHANGE	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
DEGENERATION	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>LARYNX</b>	# Ex 97	# (%) 98	# (%) 98	# (%) 99	# (%) 99	# (%) 99	# (%) 100
HYPERPLASIA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, ACUTE	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	2 (2)	1 (1)
INFLAMMATION, CHRONIC	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
INFLAMMATION, CHRONIC ACTIVE	0 (0)	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	2 (2)
ULCER	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)
INGESTA	3 (3)	2 (2)	2 (2)	3 (3)	6 (6)	1 (1)	2 (2)
ULCER, MULT	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
EXUDATE	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)	1 (1)	0 (0)
HEMORRHAGE	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
ABSCESS	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
<b>LIVER</b>	# Ex 99	# (%) 100	# (%) 100	# (%) 100	# (%) 100	# (%) 100	# (%) 100
DIAPHRAGMATIC HERNIA	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
TIGROID BASOPHILIC FOCUS	8 (8)	12 (12)	13 (13)	5 (5)	9 (9)	6 (6)	10 (10)
TIGROID BASOPHILIC FOCUS, MULT	4 (4)	9 (9)	8 (8)	3 (3)	11 <sup>‡</sup> (11)	3 (3)	4 (4)
EOSINOPHILIC FOCUS	13 (13)	13 (13)	14 (14)	5 (5)	8 (8)	7 (7)	7 (7)
EOSINOPHILIC FOCUS, MULT	2 (2)	8 <sup>†</sup> (8)	4 (4)	4 (4)	4 (4)	2 (2)	2 (2)
CLEAR CELL FOCUS	0 (0)	2 (2)	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)
CLEAR CELL FOCUS, MULT	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
HOMOGENEOUS BASOPHILIC FOCUS	4 (4)	0 (0)	4 (4)	1 (1)	0 (0)	3 (3)	3 (3)
HOMOGENEOUS BASO FOCUS, MULT.	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
CYSTIC BILE DUCTS	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ANGIECTASIS <sup>††</sup>	3 (3)	4 (4)	2 (2)	8 <sup>†</sup> (8)	6 (6)	11 <sup>‡</sup> (11)	10 <sup>‡</sup> (10)
CYSTIC DEGENERATION	9 (9)	6 (6)	4 (4)	1 (1)	5 (5)	3 (3)	2 (2)
FATTY CHANGE, NOS	37 (37)	31 (31)	41 (41)	30 (30)	26 (26)	45 (45)	31 (31)
DEGENERATION, CENTRILOBULAR <sup>††</sup>	0 (0)	1 (1)	1 (1)	8 <sup>†</sup> (8)	1 (1)	7 <sup>‡</sup> (7)	19 <sup>‡</sup> (19)
HYPERTROPHY, NOS <sup>†</sup>	2 (2)	5 (5)	0 (0)	3 (3)	1 (1)	5 (5)	12 <sup>‡</sup> (12)
NECROSIS, NOS	10 (10)	2 (2)	10 (10)	6 (6)	5 (5)	9 (9)	2 (2)
NECROSIS, CENTRILOBULAR	0 (0)	1 (1)	1 (1)	0 (0)	1 (1)	1 (1)	0 (0)
INFLAMMATION, ACUTE	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
INFLAMMATION, GRANULOMATOUS	0 (0)	0 (0)	0 (0)	1 (1)	2 (2)	0 (0)	0 (0)
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
FIBROSIS	1 (1)	1 (1)	2 (2)	1 (1)	0 (0)	0 (0)	2 (2)
CONGESTION	10 (10)	9 (9)	19 (19)	11 (11)	17 (17)	19 <sup>‡</sup> (19)	10 (10)
HEMORRHAGE	2 (2)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
PIGMENT <sup>†</sup>	9 (9)	13 (13)	14 (14)	7 (7)	9 (9)	9 (9)	33 <sup>‡</sup> (33)
LEUKEMOID REACTION	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
EXTRAMEDULLARY HEMATOPOIESIS <sup>††</sup>	2 (2)	4 (4)	7 (7)	10 <sup>†</sup> (10)	3 (3)	6 (6)	15 <sup>‡</sup> (15)
BILE DUCT HYPERPLASIA	3 (3)	3 (3)	5 (5)	4 (4)	2 (2)	5 (5)	0 (0)
BILIARY CYST(S)	2 (2)	0 (0)	1 (1)	0 (0)	1 (1)	2 (2)	1 (1)
OVAL CELL HYPERPLASIA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)



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TABLE 9 (continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for All Treated Animals

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 100	M Gel 100	H Gel 100	L PE 100	M PE 100	H PE 100
<b>LIVER</b>	# Ex 99	100	100	100	100	100	100
VASCULAR ECTASIA <sup>a</sup>	11 (11)	14 (14)	16 (16)	8 (8)	13 (13)	17 (17)	17 <sup>a</sup> (17)
ABSCISS, MULTIPLE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
CAPSULAR FIBROSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
<b>LUNGS</b>	# Ex 100	100	100	100	100	100	100
ALVEOLAR EPITH. HYPERPLASIA	1 (1)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)
INTERSTITIAL PNEUMONIA	2 (2)	6 (6)	4 (4)	1 (1)	4 (4)	8 <sup>b</sup> (8)	4 (4)
BRONCHOPNEUMONIA	1 (1)	3 (3)	2 (2)	2 (2)	4 (4)	1 (1)	0 (0)
PLEURITIS	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
INFLAMMATION, ACUTE	1 (1)	0 (0)	0 (0)	0 (0)	2 (2)	1 (1)	2 (2)
INFLAMMATION, GRANULOMATOUS	4 (4)	1 (1)	4 (4)	2 (2)	5 (5)	0 (0)	0 (0)
INFLAMMATION, PYOGRANULOMATOUS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
CONGESTION	15 (15)	10 (10)	17 (17)	9 (9)	18 (18)	21 (21)	15 (15)
HEMORRHAGE	0 (0)	3 (3)	0 (0)	4 (4)	0 (0)	0 (0)	2 (2)
THROMBUS/THROMBOSIS	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
LEUKEMOID REACTION <sup>b</sup>	0 (0)	1 (1)	0 (0)	3 (3)	1 (1)	0 (0)	3 (3)
ABSCISS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
FIBRIN THROMBI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)
ADHESIONS	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
PIGMENT	3 (3)	1 (1)	6 (6)	0 (0)	0 (0)	4 (4)	1 (1)
HYPERPLASIA, LYMPHOID	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
HAMARTOMA	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
SQUAMOUS METAPLASIA	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
<b>LYMPH NODE, MANDIBULAR</b>	# Ex 85	94	94	91	95	88	94
HYPERPLASIA, LYMPHOID	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
PLASMACYTOSIS	0 (0)	2 (2)	0 (0)	1 (1)	2 (2)	5 <sup>c</sup> (5)	2 (2)
ECTASIA/CYST(S) <sup>d</sup>	1 (1)	1 (1)	2 (2)	4 (4)	2 (2)	2 (2)	1 (1)
ATROPHY	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
CONGESTION	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
HEMORRHAGE <sup>e</sup>	0 (0)	2 (2)	1 (1)	1 (1)	3 (3)	0 (0)	7 <sup>f</sup> (7)
INFLAMMATION, CHRONIC ACTIVE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
<b>LYMPH NODE, MEDIASTINAL</b>	# Ex 86	91	91	88	93	94	90
PIGMENT	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
HYPERPLASIA, LYMPHOID	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
PLASMACYTOSIS	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)	1 (1)	1 (1)
ECTASIA/CYST(S)	3 (3)	7 (8)	3 (3)	3 (3)	8 (9)	4 (4)	4 (4)
ATROPHY	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
CONGESTION	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
HEMORRHAGE	2 (2)	2 (2)	0 (0)	1 (1)	4 (4)	1 (1)	4 (4)
<b>LYMPH NODE, MESENTERIC</b>	# Ex 98	98	98	98	96	96	100
HYPERPLASIA, LYMPHOID	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)
PLASMACYTOSIS	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ECTASIA/CYST(S)	0 (0)	1 (1)	1 (1)	1 (1)	1 (1)	0 (0)	0 (0)
ATROPHY	3 (3)	1 (1)	1 (1)	1 (1)	0 (0)	1 (1)	0 (0)
HEMORRHAGE	0 (0)	3 (3)	0 (0)	1 (1)	2 (2)	0 (0)	2 (2)
SINUS HISTIOCYTOSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
<b>LYMPH NODE, OTHER</b>	# Ex 26	37	29	31	30	30	22
PIGMENT	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)
PLASMACYTOSIS	1 (4)	5 (14)	4 (14)	3 (10)	3 (10)	3 (10)	1 (5)
ECTASIA/CYST(S)	0 (0)	1 (3)	1 (3)	0 (0)	0 (0)	0 (0)	1 (5)
ATROPHY	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)





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TABLE 9 (continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for All Treated Animals

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 100	M Gel 100	H Gel 100	L PE 100	M PE 100	H PE 100
<b>LYMPH NODE, OTHER</b>	# Ex 26	# (%) 37	# (%) 29	# (%) 31	# (%) 30	# (%) 30	# (%) 22
HEMORRHAGE	0 (0)	0 (0)	1 (3)	0 (0)	1 (3)	0 (0)	1 (5)
FIBROSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)
ENCAP IMPLANT MAT, REGIONAL LN	0 (0)	1 (3)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)
<b>MAMMARY GLAND</b>	Ex 100	100	100	100	100	99	100
FIBROCYSTIC DISEASE	95 (95)	89 (89)	91 (91)	96 <sup>o</sup> (96)	89 (89)	89 (90)	92 (92)
HYPERPLASIA	3 (3)	8 (8)	4 (4)	3 (3)	10 <sup>d</sup> (10)	8 (8)	4 (4)
GALACTOCELE/CYST(S) <sup>f</sup>	6 (6)	15 <sup>g</sup> (15)	8 (8)	11 (11)	12 (12)	12 (12)	24 <sup>j</sup> (24)
INFLAMMATION, CHRONIC ACTIVE	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
ATYPICAL HYPERPLASIA	2 (2)	4 (4)	1 (1)	0 (0)	1 (1)	1 (1)	1 (1)
ABSCESS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ATROPHY	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FIBROSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
<b>OPTIC NERVE</b>	# Ex 99	98	99	97	99	100	100
<b>OVARIES</b>	# Ex 99	100	100	100	100	100	100
CYST(S)	27 (27)	19 (19)	23 (23)	25 (25)	21 (21)	21 (21)	23 (23)
LUTEALSTROMAL HYPERPLASIA	14 (14)	8 (8)	16 (16)	9 (9)	11 (11)	6 (6)	11 (11)
SERTOLI CELL HYPERPLASIA	7 (7)	8 (8)	4 (4)	3 (3)	4 (4)	6 (6)	7 (7)
CONGESTION	3 (3)	1 (1)	2 (2)	2 (2)	1 (1)	0 (0)	2 (2)
<b>OVIDUCTS</b>	# Ex 98	99	98	100	99	99	100
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
CYST(S)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
<b>PANCREAS</b>	# Ex 99	100	100	98	100	100	100
ATROPHY	7 (7)	6 (6)	6 (6)	8 (8)	5 (5)	5 (5)	5 (5)
FIBROSIS	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)
INFLAMMATION, CHRONIC	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
INFLAMMATION, CHRONIC ACTIVE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
FAT-NECROSIS	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
CYSTIC DUCTS	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)
<b>PANCREATIC ISLETS</b>	# Ex 99	99	100	98	99	100	100
HYPERPLASIA	2 (2)	1 (1)	2 (2)	1 (1)	3 (3)	5 (5)	1 (1)
<b>PARATHYROID</b>	# Ex 98	99	97	93	96	95	98
HYPERPLASIA <sup>h</sup>	0 (0)	0 (0)	0 (0)	3 (3)	2 (2)	1 (1)	0 (0)
<b>PITUITARY</b>	# Ex 100	98	98	99	99	100	100
HYPERPLASIA	7 (7)	3 (3)	3 (3)	4 (4)	8 (8)	3 (3)	5 (5)
CYST(S) <sup>i</sup>	3 (3)	5 (5)	6 (6)	8 <sup>o</sup> (8)	8 (8)	8 (8)	6 (6)
ANGIECTASIS <sup>l</sup>	4 (4)	4 (4)	5 (5)	9 (9)	6 (6)	7 (7)	13 <sup>j</sup> (13)
THROMBUS/THROMBOSIS	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
FIBROSIS	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>RECTUM</b>	# Ex 89	93	91	92	93	94	97
PROLIFERATIVE FASCICULITIS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
EROSION	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, ACUTE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
INFLAMMATION, CHRONIC ACTIVE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FIBROSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
EDEMA	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)	1 (1)	0 (0)

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TABLE 9 (continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for All Treated Animals

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 100	M Gel 100	H Gel 100	L PE 100	M PE 100	H PE 100
<b>SALIVARY GLAND</b>	# Ex 96	100	100	100	100	98	99
ATROPHY	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)	3 (3)	1 (1)
INFLAMMATION, ACUTE	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)	1 (1)	1 (1)
HEMORRHAGE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
ABSCESS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
<b>SCIATIC NERVE</b>	# Ex 97	97	98	99	98	97	97
DEGENERATION	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>SKELETAL MUSCLE</b>	# Ex 99	100	99	99	99	100	99
MYOPATHY	4 (4)	3 (3)	6 (6)	1 (1)	1 (1)	1 (1)	0 (0)
INFLAMMATION, CHRONIC ACTIVE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FIBROSIS	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ATROPHY	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>SKIN/SUBCUTIS</b>	# Ex 100	100	100	100	100	100	100
FAT NECROSIS	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
SQUAMOUS CELL HYPERPLASIA	2 (2)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
CYST(S)/INCLUSION CYST(S) <sup>1</sup>	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)	2 (2)
ULCER	5 (5)	7 (7)	5 (5)	3 (3)	1 (1)	1 (1)	5 (5)
ULCER, MULT	1 (1)	0 (0)	0 (0)	1 (1)	2 (2)	0 (0)	1 (1)
INFLAMMATION, CHRONIC <sup>1</sup>	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)	1 (1)	1 (1)
INFLAMMATION, CHRONIC ACTIVE	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)
ABSCESS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
FIBROSIS	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
EDEMA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
SCAB	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
DERMIS-FIBROSIS <sup>1</sup>	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	2 (2)
IMPLANT MATERIAL	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
EXUDATE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
<b>SPINAL CORD</b>	# Ex 99	100	100	99	100	100	100
GLIOSIS	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)
MALACIA	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
HEMORRHAGE	1 (1)	2 (2)	2 (2)	1 (1)	1 (1)	3 (3)	1 (1)
<b>SPLEEN</b>	# Ex 99	100	100	99	100	100	100
NECROSIS	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
EXTRAMEDULLARY HEMATOPOIESIS <sup>1</sup>	31 (31)	27 (27)	19 (19)	38 <sup>1</sup> (38)	27 (27)	38 (38)	48 <sup>1</sup> (48)
HEMOSIDERIN	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
CONGESTION	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
HEMORRHAGE	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
PERITONITIS	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
CYST-CAPSULE <sup>1</sup>	0 (0)	2 (2)	1 (1)	3 (3)	0 (0)	1 (1)	4 <sup>1</sup> (4)
FIBROSIS-CAPSULE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ACCESSORY SPLEEN	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
ATROPHY	3 (3)	0 (0)	0 (0)	3 (3)	0 (0)	0 (0)	1 (1)
<b>STERNUM - BONE</b>	# Ex 99	99	98	100	100	100	100
FIBROUS OSTEODYSTROPHY	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	2 (2)	1 (1)
DEGENERATION-CARTILAGE	12 (12)	18 (18)	12 (12)	6 (6)	10 (10)	17 (17)	13 (13)
ENDOSTOSES	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
OSTEOSCLEROSIS	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)

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TABLE 9 (continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for All Treated Animals

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 100	M Gel 100	H Gel 100	L PE 100	M PE 100	H PE 100
<b>STERNUM - BONE MARROW</b>	# Ex 99	98	98	100	100	100	100
HYPERPLASIA, MYELOID <sup>11</sup>	8 (8)	10 (10)	6 (6)	20 <sup>7</sup> (20)	9 (9)	17 <sup>2</sup> (17)	19 <sup>1</sup> (19)
HYPERPLASIA, NOS	2 (2)	4 (4)	5 (5)	2 (2)	2 (2)	6 (6)	3 (3)
CYST(S)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
CONGESTION	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
<b>STOMACH</b>	# Ex 96	98	100	96	99	99	99
EROSION	9 (9)	3 (3)	7 (7)	9 (9)	3 (3)	9 (9)	11 (11)
EROSION, MULT <sup>1</sup>	0 (0)	3 (3)	2 (2)	3 (3)	2 (2)	2 (2)	4 <sup>1</sup> (4)
ULCER	1 (1)	2 (2)	1 (1)	4 (4)	0 (0)	0 (0)	0 (0)
INFLAMMATION, ACUTE	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
INFLAMMATION, CHRONIC ACTIVE	0 (0)	2 (2)	0 (0)	1 (1)	0 (0)	1 (1)	1 (1)
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
CONGESTION	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)
HEMORRHAGE	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
MINERALIZATION	1 (1)	0 (0)	1 (1)	0 (0)	1 (1)	2 (2)	0 (0)
EDEMA	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)	1 (1)
FIBROSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)
<b>SYSTEMIC DISEASES</b>	# Ex 100	100	100	100	100	100	100
PERIARTERITIS	5 (5)	2 (2)	0 (0)	0 (0)	4 (4)	5 (5)	3 (3)
MINERALIZ. MULTIPLE ARTERIES	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
PERITONITIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
SEPTICEMIA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
<b>TAIL</b>	# Ex 18	14	15	20	16	16	16
ULCER, MULTIPLE	3 (17)	0 (0)	0 (0)	3 (15)	0 (0)	0 (0)	0 (0)
SQUAMOUS CELL HYPERPLASIA	1 (6)	1 (7)	2 (13)	0 (0)	0 (0)	0 (0)	1 (6)
HYPERKERATOSIS	4 (22)	5 (36)	4 (27)	7 (35)	3 (19)	2 (13)	1 (6)
CYST(S)/INCLUSION CYST(S) <sup>1</sup>	0 (0)	1 (7)	0 (0)	2 (10)	0 (0)	2 (13)	2 (13)
ULCER	6 (33)	2 (14)	5 (33)	5 (25)	8 (50)	5 (31)	5 (31)
INFLAMMATION, ACUTE	0 (0)	0 (0)	1 (7)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC	1 (6)	1 (7)	0 (0)	1 (5)	0 (0)	1 (6)	0 (0)
INFLAMMATION, CHRONIC ACTIVE <sup>1</sup>	0 (0)	2 (14)	6 <sup>1</sup> (40)	2 (10)	0 (0)	2 (13)	6 <sup>1</sup> (38)
ABSCESS	6 (33)	6 (43)	4 (27)	7 (35)	10 (63)	4 (25)	6 (38)
NECROSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (13)	0 (0)
EXUDATE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)
INFARCT	1 (6)	1 (7)	0 (0)	3 (15)	0 (0)	1 (6)	1 (6)
SCAB	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)	3 (19)	0 (0)
EXOSTOSES	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)
<b>THYMUS</b>	# Ex 82	95	82	78	86	85	81
FIBROSIS	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
ATROPHY <sup>1</sup>	25 (30)	47 <sup>1</sup> (49)	33 (40)	28 (36)	24 (28)	35 <sup>1</sup> (41)	34 <sup>1</sup> (42)
CYST(S) <sup>1</sup>	9 (11)	23 <sup>1</sup> (24)	17 (21)	10 (13)	8 (9)	5 (6)	16 <sup>1</sup> (20)
HEMORRHAGE	1 (1)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	2 (2)
HYPERPLASIA, EPITHELIAL	0 (0)	4 (4)	2 (2)	3 (4)	2 (2)	4 (5)	2 (2)
ECTOPIC PARATHYROID	0 (0)	0 (0)	1 (1)	1 (1)	1 (1)	0 (0)	0 (0)
ECTOPIC THYROID	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>THYROID</b>	# Ex 98	97	98	99	99	99	98
FOLL. CELL HYPERPLASIA	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
FOLLICULAR CYST(S)	1 (1)	4 (4)	1 (1)	0 (0)	3 (3)	1 (1)	0 (0)
C-CELL HYPERPLASIA	7 (7)	9 (9)	9 (9)	4 (4)	11 (11)	5 (5)	7 (7)
ULTIMOBRANCHIAL CYST(S)	15 (15)	16 (16)	12 (12)	5 (5)	17 (17)	10 (10)	12 (12)
HEMORRHAGE	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)

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TABLE 9 (Continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for All Treated Animals

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 100	M Gel 100	H Gel 100	L PE 100	M PE 100	H PE 100
<b>TRACHEA</b>	# Ex 99						
INFLAMMATION, CHRONIC ACTIVE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
ULCER	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
INGESTA	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
EXUDATE	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)
HEMORRHAGE	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
<b>URINARY BLADDER</b>	# Ex 98						
TRANSITIONAL CELL HYPERPLASIA	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
PROLIFERATIVE CYSTITIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
INFLAMMATION, ACUTE	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
INFLAMMATION, GRANULOMATOUS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
CALCULI	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
HEMORRHAGE	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
SQUAMOUS METAPLASIA	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>UTERUS</b>	# Ex 98						
CYSTIC ENDOMETRIAL HYPERPLASIA <sup>11</sup>	76 (78)	87 <sup>1</sup> (88)	94 <sup>1</sup> (94)	87 <sup>1</sup> (87)	92 <sup>2</sup> (93)	75 (75)	85 <sup>1</sup> (85)
SQUAMOUS METAPLASIA	1 (1)	3 (3)	0 (0)	1 (1)	4 (4)	1 (1)	0 (0)
INFLAMMATION, ACUTE	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
CONGESTION	1 (1)	1 (1)	1 (1)	1 (1)	1 (1)	0 (0)	0 (0)
HEMORRHAGE <sup>1</sup>	0 (0)	0 (0)	0 (0)	2 (2)	1 (1)	0 (0)	0 (0)
INTUSSUSCEPTION	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)	1 (1)
INFLAMMATION, SUPPURATIVE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
ATROPHY	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
<b>VAGINA</b>	# Ex 98						
PROLIFERATIVE FASCICULITIS	11 (11)	7 (7)	9 (9)	6 (6)	12 (12)	11 (11)	8 (8)
FIBROSIS	2 (2)	1 (1)	2 (2)	0 (0)	3 (3)	1 (1)	1 (1)
ULCER	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)
INFLAMMATION, ACUTE	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC <sup>3</sup>	1 (1)	1 (1)	3 (3)	2 (2)	1 (1)	2 (2)	6 <sup>4</sup> (6)
INFLAMMATION, CHRONIC ACTIVE	4 (4)	0 (0)	1 (1)	0 (0)	0 (0)	3 (3)	1 (1)
EXUDATE <sup>11</sup>	17 (17)	19 (19)	26 (26)	29 <sup>1</sup> (30)	11 (11)	26 (26)	22 (22)
EPITHELIAL HYPERPLASIA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
CYST(S)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
STROMAL HYPERPLASIA	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
<b>OTHER TISSUES AND LESIONS:</b>							
MESENTERY: STEATITIS	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
MESENTERY: FAT NECROSIS	1 (1)	5 (5)	3 (3)	3 (3)	8 <sup>1</sup> (8)	3 (3)	2 (2)
ADD FAT: HEMORRHAGE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
MESENTERY: ABSCESS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
EAR/PINNA: PROLIF CHONDROPATHY	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
MEDIAST: PLEURITIS <sup>1</sup>	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
MESENTERY: PERITONITIS	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
URETER: DILATATION	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
URETER: TRANSIT CELL HYPERPL	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
URETER: CALCULI	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
URETER: NORMAL	1 (1)	1 (1)	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)
MESENTERY: ACCESSORY SPLEEN	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
MESENTERY: INFLAM, CHRONIC	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
PINEAL GLAND: NORMAL <sup>1</sup>	1 (1)	3 (3)	2 (2)	3 (3)	3 (3)	1 (1)	4 (4)
PALATE: NECROTIZING ULCER	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
NASAL CAVITY: ULCER, MULT.	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

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TABLE 9 (continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for All Treated Animals

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 100	M Gel 100	H Gel 100	L PE 100	M PE 100	H PE 100
OTHER TISSUES AND LESIONS:							
	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
BONE: FRACTURE	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
TOOTH: FRACTURE	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FACIAL BONE: FRACTURE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
JOINTS: ARTHRITIS	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
DIAPHRAGM: NORMAL	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
ACCESSORY SEX GL: CHR ACT INFL	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)
URETHRA: NORMAL	0 (0)	0 (0)	0 (0)	0 (0)	5 <sup>†</sup> (5)	0 (0)	0 (0)
TOOTH: ABSCESS	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
ACCESSORY SEX GL: NORMAL	0 (0)	2 (2)	0 (0)	1 (1)	5 (5)	1 (1)	0 (0)
EAR: ABSCESS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
MENINGES: FIBROSIS	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)
OVARIAN BURSA: FIBROSIS	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
RENAL V.: THROMBUS/THROMBOSIS	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
BILE DUCT: DILATATION	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
MEDIASTINUM: ECTOPIC THYROID	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
JOINTS: ANKYLOSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
NERVES: DEGENERATION	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
URETER: CHRONIC INFLAM	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
MESENTERY: FIBROSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
TARSUS: HYPERKERATOSIS	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)

Legend - Table 9

Female Sprague Dawley rats were implanted subcutaneously with three dose levels of either mammary silicone gel or low density polyethylene. The implantation procedure was performed on sham control animals but no test material was introduced into the animals. Forty-six specified tissues and organs were collected from all animals for histopathology. The incidence of non-neoplastic lesions was calculated as the ratio of the number of animals bearing lesions at a site to the number of animals examined histologically (# Ex) and are reported as percents (%). A statistical analysis of lesion incidence was only performed if there were at least 2 observations in one of the experimental groups within a potential analysis. Silicone gel and PE groups were analyzed independently of one another.

Logistic regression analysis was the primary statistical method used to assess lesion incidence among treated and control groups. The life table test was applied to provide an appropriate approach for analyzing the incidence of rapidly lethal lesions (e.g. solid state tumors). In addition, the Fisher exact test and the Cochran-Armitage trend test were utilized although they are procedures which do not adjust for intercurrent mortality.

† Silicone gel group is significantly different from sham control group at p<0.05. § Polyethylene group is significantly different from sham control group at p<0.05. A statistical symbol immediately after the lesion indicates a significant trend for the silicone gel groups (†) or the polyethylene groups (§) at p<0.05.

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Study Number - 7088

DC Report Number - 1998-10000-44643  
Security - Internal

TABLE 10  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for Treated Animals Without Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 98	M Gel 98	H Gel 37	L PE 99	M PE 81	H PE 48
ADRENAL CORTEX	# Ex 100	98	98	37	99	81	48
HYPERPLASIA	5 (5)	4 (4)	5 (5)	1 (2)	2 (2)	3 (4)	3 (6)
HYPERTROPHY	8 (8)	5 (5)	2 (2)	2 (4)	5 (5)	3 (4)	0 (0)
HEMORRHAGIC CYST/CYST(S)	90 (90)	91 (93)	88 (90)	49 (86)	87 (88)	69 (85)	89 (81)
FATTY CHANGE	3 (3)	6 (6)	6 (6)	1 (2)	3 (3)	1 (1)	1 (2)
DEGENERATION	19 (19)	21 (21)	17 (17)	5 (9)	21 (22)	14 (17)	7 (15)
CONGESTION	3 (3)	5 (5)	3 (3)	1 (2)	2 (2)	6 (7)	2 (4)
HEMORRHAGE	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
EXTRAMEDULLARY HEMATOPOIESIS	0 (0)	1 (1)	3 (3)	0 (0)	0 (0)	1 (1)	0 (0)
ATROPHY	1 (1)	1 (1)	0 (0)	0 (0)	1 (1)	5 <sup>a</sup> (6)	0 (0)
FIBROSIS	1 (1)	2 (2)	1 (1)	1 (2)	0 (0)	1 (1)	0 (0)
NECROSIS	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
ADRENAL MEDULLA	# Ex 100	98	96	35	97	80	48
HYPERPLASIA	17 (17)	5 (5)	8 (8)	5 (9)	9 (9)	9 (11)	6 (13)
AORTA	# Ex 100	98	98	37	99	81	48
DEGENERATION	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
MINERALIZATION	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
BRAIN	# Ex 100	97	98	37	99	81	48
GLIOSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
MALACIA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	2 (4)
COMPRESSION	51 (51)	43 (44)	47 (48)	30 (53)	54 (55)	47 (58)	26 (54)
HYDROCEPHALUS <sup>1</sup>	16 (16)	9 (9)	7 (7)	5 (9)	6 (6)	16 (20)	14 <sup>a</sup> (29)
HEMORRHAGE	4 (4)	6 (6)	4 (4)	2 (4)	5 (5)	6 (7)	3 (6)
CONGESTION	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	1 (2)
THROMBUS/THROMBOSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
MINERALIZATION	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
CECUM	# Ex 37	90	88	30	86	68	44
EROSION	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
ULCER	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
ULCER, MULT	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
INFLAMMATION, ACUTE	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	1 (2)
INFLAMMATION, CHRONIC	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
INFLAMMATION, GRANULOMATOUS	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FIBROSIS	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
HEMORRHAGE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
EDEMA	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
CERVIX	# Ex 98	95	95	37	98	81	48
PROLIFERATIVE FASCICULITIS	1 (1)	3 (3)	3 (3)	3 (5)	1 (1)	2 (2)	1 (2)
INTUSSUSCEPTION	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
FIBROSIS	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
EPITHELIAL DYSPLASIA	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
STROMAL HYPERPLASIA	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (2)
INFLAMMATION, ACUTE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC	1 (1)	3 (3)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC ACTIVE	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	1 (2)
EXUDATE	1 (1)	2 (2)	3 (3)	1 (2)	0 (0)	1 (1)	2 (4)
EPITHELIAL HYPERPLASIA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
CYST(S)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)

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TABLE 10 (continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for Treated Animals Without Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 98	M Gel 98	H Gel 57	L PE 99	M PE 81	H PE 48
CLITORAL GLAND	# Ex 4	# (%) 3 (75)	# (%) 2 (100)	# (%) 1 (50)	# (%) 0 (0)	# (%) 1 (33)	# (%) 1 (100)
CYSTIC DUCTS	3 (75)	3 (100)	1 (50)	0 (0)	1 (33)	3 (100)	1 (100)
INFLAMMATION, CHRONIC	0 (0)	1 (33)	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)
COLON	# Ex 90	93	89	51	90	71	43
EPITHELIAL HYPERPLASIA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ULCER, MULT	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
INFLAMMATION, CHRONIC	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
INFLAMMATION, CHRONIC ACTIVE	0 (0)	1 (1)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
EDEMA	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
DIVERTICULUM	0 (0)	0 (0)	0 (0)	1 (2)	1 (1)	0 (0)	0 (0)
DUODENUM	# Ex 89	92	91	51	93	76	45
EROSION, MULT	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
CONGESTION	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
ESOPHAGUS	# Ex 100	98	98	57	99	81	48
INGESTA	3 (3)	1 (1)	1 (1)	0 (0)	5 (5)	0 (0)	2 (4)
EYES	# Ex 99	96	98	56	98	81	48
CORNEA, EPITHELIAL HYPERPLASIA	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)
CORNEA, EDEMA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
CORNEA, MINERALIZATION <sup>†</sup>	4 (4)	11 <sup>†</sup> (11)	12 <sup>†</sup> (12)	5 (9)	8 (8)	5 (6)	7 <sup>†</sup> (15)
CORNEA, VASCULARIZATION	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
CORNEA, ULCER	0 (0)	1 (1)	0 (0)	0 (0)	2 (2)	1 (1)	0 (0)
CORNEA, INFLAMMATION ACUTE	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)
CORNEA, INFLAMMATION CHRONIC	2 (2)	0 (0)	2 (2)	2 (4)	3 (3)	0 (0)	0 (0)
CORNEA, INFLAM CHRONIC ACTIVE	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)
CORNEA, INFLAM GRANULOMATOUS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
IRIDOCYCLITIS	0 (0)	3 (3)	1 (1)	0 (0)	1 (1)	1 (1)	0 (0)
CATARACT	3 (3)	0 (0)	2 (2)	0 (0)	2 (2)	0 (0)	0 (0)
PANOPTHALMITIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
RETINA, DEGENERATION	2 (2)	1 (1)	1 (1)	1 (2)	0 (0)	1 (1)	0 (0)
RETINA, HEMORRHAGE	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
ANTERIOR UVEITIS	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
PHTHESIS BULBI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
FEMUR - BONE	# Ex 99	95	95	56	96	78	47
BONE-CYST	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FIBROUS OSTEODYSTROPHY	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)
OSTEOSCLEROSIS	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
SYNOVITIS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FEMUR - BONE MARROW	# Ex 99	94	95	56	96	78	47
HYPERPLASIA, MYELOID	10 (10)	12 (13)	6 (6)	6 (11)	9 (9)	11 (14)	6 (13)
HYPERPLASIA, NOS	3 (3)	4 (4)	4 (4)	0 (0)	3 (3)	3 (4)	0 (0)
CONGESTION	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
FOOTPAD	# Ex 17	20	14	6	19	14	4
CYST(S)/INCLUSION CYST(S)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (7)	0 (0)
SQUAMOUS CELL HYPERPLASIA	0 (0)	3 (15)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
HYPERKERATOSIS	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ULCER	16 (94)	14 (70)	12 (86)	6 (100)	17 (89)	13 (93)	4 (100)
INFLAMMATION, CHRONIC ACTIVE	1 (6)	5 (25)	3 (21)	1 (17)	1 (5)	1 (7)	0 (0)
ABSCESS	0 (0)	3 (15)	1 (7)	0 (0)	1 (5)	1 (7)	0 (0)
PROLIFERATIVE CHONDROPATHY	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

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TABLE 10 (continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for Treated Animals Without Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 98	M Gel 98	H Gel 57	L PE 99	M PE 81	H PE 48
<b>FORESTOMACH</b>	# Ex 100	98	98	56	99	80	48
SQUAMOUS CELL HYPERPLASIA	3 (3)	7 (7)	7 (7)	0 (0)	3 (5)	3 (4)	2 (4)
EROSION	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	1 (2)
ULCER	3 (3)	2 (2)	5 (5)	3 (5)	3 (3)	5 (6)	2 (4)
ULCER, MULT'	0 (0)	1 (1)	1 (1)	2 (4)	1 (1)	0 (0)	1 (2)
PERFORATING ULCER	1 (1)	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
INFLAMMATION, ACUTE	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)	1 (1)	1 (2)
INFLAMMATION, CHRONIC ACTIVE	7 (7)	5 (5)	3 (3)	3 (5)	5 (5)	2 (3)	2 (4)
EDEMA <sup>1</sup>	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (4)
FIBROSIS	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
INCLUSION CYST(S)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
VESICLES	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>HARDERIAN GLAND</b>	# Ex 100	98	98	56	99	81	48
ATROPHY	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
INFLAMMATION, CHRONIC	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC ACTIVE	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FIBROSIS	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
<b>HEART</b>	# Ex 100	98	98	57	99	81	48
CARDIOMYOPATHY	74 (74)	73 (74)	76 (78)	41 (72)	68 (70)	60 (74)	36 (75)
MINERALIZATION	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
ATRIAL THROMBOSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
ENDOCARDIAL HYPERPLASIA	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
NECROSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
<b>ILEUM</b>	# Ex 88	86	87	49	83	68	42
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>IMPLANT I - CAPSULE</b>	# Ex 97	95	92	57	58	70	47
FIBROSIS <sup>10</sup>	0 (0)	95 <sup>1</sup> (100)	92 <sup>1</sup> (100)	57 <sup>1</sup> (100)	58 <sup>1</sup> (100)	70 <sup>1</sup> (100)	46 <sup>1</sup> (98)
HYPERPLASIA, FIBROBLASTIC <sup>10</sup>	0 (0)	2 (2)	6 <sup>1</sup> (7)	12 <sup>1</sup> (21)	3 (5)	5 <sup>1</sup> (7)	11 <sup>1</sup> (23)
INGROWTH	0 (0)	4 (4)	3 (3)	2 (4)	0 (0)	0 (0)	0 (0)
COMPARTMENTALIZATION <sup>10</sup>	0 (0)	2 (2)	5 <sup>1</sup> (5)	6 <sup>1</sup> (11)	1 (2)	2 (3)	0 (0)
IMPLANT MATERIAL <sup>10</sup>	0 (0)	12 <sup>1</sup> (13)	30 <sup>1</sup> (33)	32 <sup>1</sup> (56)	3 (5)	0 (0)	1 (2)
INFLAMMATION, CHRONIC <sup>10</sup>	0 (0)	4 (4)	9 <sup>1</sup> (10)	16 <sup>1</sup> (28)	20 (34)	18 (26)	7 (15)
INFLAMMATION, CHRONIC ACTIVE <sup>10</sup>	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	1 (1)	2 (4)
INFLAMMATION, GRANULOMATOUS <sup>10</sup>	0 (0)	0 (0)	0 (0)	3 <sup>1</sup> (5)	19 <sup>1</sup> (33)	11 <sup>1</sup> (16)	3 <sup>1</sup> (6)
MINERALIZATION	0 (0)	31 <sup>1</sup> (33)	26 <sup>1</sup> (28)	2 (4)	0 (0)	1 (1)	0 (0)
DEGENERATION <sup>10</sup>	0 (0)	4 (4)	9 <sup>1</sup> (10)	13 <sup>1</sup> (23)	0 (0)	9 <sup>1</sup> (13)	1 (2)
PIGMENT <sup>10</sup>	0 (0)	1 (1)	1 (1)	4 <sup>1</sup> (7)	9 <sup>1</sup> (16)	18 <sup>1</sup> (26)	1 (2)
ABSCESS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
PLANT MATERIAL	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
HEMORRHAGE	0 (0)	1 (1)	2 (2)	1 (2)	1 (2)	2 (3)	0 (0)
<b>IMPLANT I - EXTRACAPSULAR</b>	# Ex 97	96	95	57	86	81	47
IMPLANT MATERIAL <sup>10</sup>	0 (0)	59 <sup>1</sup> (61)	69 <sup>1</sup> (73)	39 <sup>1</sup> (68)	1 (1)	1 (1)	0 (0)
FIBROSIS <sup>10</sup>	1 (1)	54 <sup>1</sup> (56)	45 <sup>1</sup> (47)	34 <sup>1</sup> (60)	5 (6)	2 (2)	0 (0)
INFLAMMATION, ACUTE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC <sup>10</sup>	0 (0)	16 <sup>1</sup> (17)	19 <sup>1</sup> (20)	16 <sup>1</sup> (28)	4 <sup>1</sup> (5)	2 (2)	0 (0)
INFLAMMATION, GRANULOMATOUS	0 (0)	0 (0)	2 (2)	1 (2)	0 (0)	0 (0)	0 (0)
MINERALIZATION	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
ULCER-SKIN	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
PIGMENT	0 (0)	1 (1)	2 (2)	1 (2)	7 <sup>1</sup> (8)	1 (1)	0 (0)
DERMIS-FIBROSIS <sup>10</sup>	2 (2)	0 (0)	0 (0)	0 (0)	2 (2)	4 (5)	6 <sup>1</sup> (13)
ABSCESS-SKIN	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
SQUAMOUS CELL HYPERPL-SKIN	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)	1 (2)
HEMORRHAGE	0 (0)	0 (0)	1 (1)	1 (2)	0 (0)	0 (0)	0 (0)





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TABLE 10 (continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for Treated Animals Without Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 98	M Gel 98	H Gel 57	L PE 99	M PE 81	H PE 48
<b>IMPLANT 2 - CAPSULE</b>	# Ex 96	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
FIBROSIS <sup>1</sup>	0 (0)	98 <sup>1</sup> (100)	97 <sup>1</sup> (100)	56 <sup>1</sup> (100)	69 <sup>1</sup> (100)	71 <sup>1</sup> (100)	47 <sup>1</sup> (98)
HYPERPLASIA, FIBROBLASTIC <sup>1</sup>	0 (0)	1 (1)	0 (0)	6 <sup>1</sup> (11)	8 <sup>1</sup> (12)	10 <sup>1</sup> (14)	14 <sup>1</sup> (30)
INGROWTH	0 (0)	6 <sup>1</sup> (6)	1 (1)	3 <sup>1</sup> (5)	0 (0)	0 (0)	0 (0)
COMPARTMENTALIZATION	0 (0)	8 <sup>1</sup> (8)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
IMPLANT MATERIAL <sup>1</sup>	0 (0)	18 <sup>1</sup> (18)	30 <sup>1</sup> (31)	22 <sup>1</sup> (39)	0 (0)	1 (1)	0 (0)
INFLAMMATION, CHRONIC <sup>1</sup>	0 (0)	2 (2)	5 <sup>1</sup> (5)	7 <sup>1</sup> (13)	29 <sup>1</sup> (42)	18 <sup>1</sup> (25)	10 <sup>1</sup> (21)
INFLAMMATION, CHRONIC ACTIVE <sup>1</sup>	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)	0 (0)	2 (4)
INFLAMMATION, GRANULOMATOUS <sup>1</sup>	0 (0)	0 (0)	0 (0)	1 (2)	14 <sup>1</sup> (30)	7 <sup>1</sup> (10)	5 <sup>1</sup> (11)
MINERALIZATION	0 (0)	20 <sup>1</sup> (20)	19 <sup>1</sup> (20)	0 (0)	1 (1)	0 (0)	0 (0)
DEGENERATION <sup>1</sup>	0 (0)	2 (2)	0 (0)	5 <sup>1</sup> (9)	0 (0)	2 (3)	1 (2)
PIGMENT <sup>1</sup>	0 (0)	0 (0)	0 (0)	0 (0)	8 <sup>1</sup> (12)	6 <sup>1</sup> (8)	5 <sup>1</sup> (11)
HEMORRHAGE	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)
OSSEOUS METAPLASIA	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
<b>IMPLANT 2 - EXTRACAPSULAR</b>	# Ex 96	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
DERMIS-FIBROSIS	7 (7)	2 (2)	1 (1)	0 (0)	0 (0)	7 (9)	5 (11)
IMPLANT MATERIAL <sup>1</sup>	0 (0)	63 <sup>1</sup> (64)	64 <sup>1</sup> (66)	34 <sup>1</sup> (60)	1 (1)	1 (1)	0 (0)
FIBROSIS <sup>1</sup>	0 (0)	58 <sup>1</sup> (59)	46 <sup>1</sup> (47)	25 <sup>1</sup> (44)	1 (1)	0 (0)	0 (0)
INFLAMMATION, ACUTE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC <sup>1</sup>	0 (0)	15 <sup>1</sup> (15)	11 <sup>1</sup> (11)	7 <sup>1</sup> (12)	0 (0)	2 (3)	0 (0)
INFLAMMATION, CHRONIC ACTIVE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
INFLAMMATION, GRANULOMATOUS <sup>1</sup>	0 (0)	0 (0)	1 (1)	2 (4)	2 (2)	1 (1)	0 (0)
PIGMENT <sup>1</sup>	0 (0)	0 (0)	0 (0)	0 (0)	5 <sup>1</sup> (6)	0 (0)	0 (0)
HYPERKERATOSIS-SKIN	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
SQUAMOUS CELL HYPERPL-SKIN	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ULCER, MULT-SKIN	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
<b>IMPLANT 3 - CAPSULE</b>	# Ex 97	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
FIBROSIS <sup>1</sup>	0 (0)	93 <sup>1</sup> (100)	97 <sup>1</sup> (100)	55 <sup>1</sup> (100)	0 (0)	0 (0)	0 (0)
HYPERPLASIA, FIBROBLASTIC <sup>1</sup>	0 (0)	0 (0)	3 (3)	14 <sup>1</sup> (25)	0 (0)	0 (0)	0 (0)
INGROWTH	0 (0)	11 <sup>1</sup> (12)	6 <sup>1</sup> (6)	3 <sup>1</sup> (5)	0 (0)	0 (0)	0 (0)
COMPARTMENTALIZATION <sup>1</sup>	0 (0)	9 <sup>1</sup> (10)	4 (4)	9 <sup>1</sup> (16)	0 (0)	0 (0)	0 (0)
IMPLANT MATERIAL <sup>1</sup>	0 (0)	25 <sup>1</sup> (27)	44 <sup>1</sup> (45)	36 <sup>1</sup> (63)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC <sup>1</sup>	0 (0)	9 <sup>1</sup> (10)	12 <sup>1</sup> (12)	15 <sup>1</sup> (27)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC ACTIVE	0 (0)	2 (2)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
INFLAMMATION, GRANULOMATOUS <sup>1</sup>	0 (0)	0 (0)	1 (1)	2 (4)	0 (0)	0 (0)	0 (0)
MINERALIZATION	0 (0)	35 <sup>1</sup> (38)	22 <sup>1</sup> (23)	0 (0)	0 (0)	0 (0)	0 (0)
DEGENERATION <sup>1</sup>	0 (0)	5 <sup>1</sup> (5)	8 <sup>1</sup> (8)	14 <sup>1</sup> (25)	0 (0)	0 (0)	0 (0)
PIGMENT <sup>1</sup>	0 (0)	0 (0)	1 (1)	6 <sup>1</sup> (11)	0 (0)	0 (0)	0 (0)
HEMORRHAGE	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
<b>IMPLANT 3 - EXTRACAPSULAR</b>	# Ex 97	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
DERMIS-FIBROSIS	4 (4)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
IMPLANT MATERIAL <sup>1</sup>	0 (0)	59 <sup>1</sup> (61)	74 <sup>1</sup> (76)	38 <sup>1</sup> (68)	0 (0)	0 (0)	0 (0)
FIBROSIS <sup>1</sup>	0 (0)	46 <sup>1</sup> (48)	59 <sup>1</sup> (61)	28 <sup>1</sup> (50)	0 (0)	0 (0)	0 (0)
INFLAMMATION, ACUTE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC <sup>1</sup>	1 (1)	27 <sup>1</sup> (28)	22 <sup>1</sup> (23)	18 <sup>1</sup> (32)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC ACTIVE	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, GRANULOMATOUS <sup>1</sup>	0 (0)	3 (3)	3 (3)	3 <sup>1</sup> (5)	0 (0)	0 (0)	0 (0)
SQUAMOUS CELL HYPERPL-SKIN	1 (1)	1 (1)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
MYOPATHY-MUSCLE	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
<b>IMPLANT 4 - CAPSULE</b>	# Ex 96	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
FIBROSIS <sup>1</sup>	0 (0)	95 <sup>1</sup> (100)	94 <sup>1</sup> (100)	57 <sup>1</sup> (100)	0 (0)	0 (0)	0 (0)
HYPERPLASIA, FIBROBLASTIC <sup>1</sup>	0 (0)	0 (0)	0 (0)	9 <sup>1</sup> (16)	0 (0)	0 (0)	0 (0)
INGROWTH	0 (0)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
COMPARTMENTALIZATION	0 (0)	5 <sup>1</sup> (5)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)



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TABLE 10 (continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for Treated Animals Without Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 98	M Gel 98	H Gel 57	L PE 99	M PE 81	H PE 48
<b>IMPLANT 4 - CAPSULE</b>	# Ex 96	# 95	# 94	# 57	# 0	# 0	# 0
IMPLANT MATERIAL <sup>1</sup>	0 (0)	13 <sup>1</sup> (14)	28 <sup>1</sup> (30)	26 <sup>1</sup> (46)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC <sup>1</sup>	0 (0)	1 (1)	3 <sup>1</sup> (3)	12 <sup>1</sup> (21)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC ACTIVE	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
INFLAMMATION, GRANULOMATOUS	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
MINERALIZATION	0 (0)	13 <sup>1</sup> (14)	15 <sup>1</sup> (16)	0 (0)	0 (0)	0 (0)	0 (0)
DEGENERATION <sup>1</sup>	0 (0)	1 (1)	0 (0)	6 <sup>1</sup> (11)	0 (0)	0 (0)	0 (0)
PIGMENT	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
<b>IMPLANT 4 - EXTRACAPSULAR</b>	# Ex 96	# 97	# 96	# 57	# 0	# 0	# 0
DERMIS-FIBROSIS	3 (3)	7 (7)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
IMPLANT MATERIAL <sup>1</sup>	0 (0)	49 <sup>1</sup> (51)	62 <sup>1</sup> (65)	32 <sup>1</sup> (56)	0 (0)	0 (0)	0 (0)
FIBROSIS <sup>1</sup>	0 (0)	43 <sup>1</sup> (44)	52 <sup>1</sup> (54)	27 <sup>1</sup> (47)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC <sup>1</sup>	0 (0)	13 <sup>1</sup> (13)	12 <sup>1</sup> (13)	7 <sup>1</sup> (12)	0 (0)	0 (0)	0 (0)
INFLAMMATION, GRANULOMATOUS	0 (0)	2 (2)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
GRANULOMA	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
EDEMA	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
<b>IMPLANT 4 - NOS</b>	# Ex 98	# 98	# 98	# 57	# 94	# 81	# 48
<b>JEJUNUM</b>	# Ex 89	# 90	# 89	# 49	# 88	# 72	# 44
PERFORATING ULCER	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
DIVERTICULUM	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
INTUSSUSCEPTION	0 (0)	1 (1)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
<b>KIDNEYS</b>	# Ex 99	# 98	# 98	# 57	# 99	# 81	# 48
TUBULAR CELL HYPERPLASIA	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
TRANSITIONAL CELL HYPERPLASIA	0 (0)	1 (1)	1 (1)	0 (0)	1 (1)	0 (0)	1 (2)
CHRONIC NEPHROPATHY	66 (67)	69 (70)	69 (70)	39 (68)	64 (65)	50 (62)	28 (58)
HYDRONEPHROSIS <sup>1</sup>	8 (8)	8 (8)	10 (10)	6 (11)	5 (5)	14 <sup>1</sup> (17)	8 (17)
CYST(S)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	2 (4)
HYALINE DROPLETS	0 (0)	4 (4)	1 (1)	0 (0)	0 (0)	0 (0)	1 (2)
MINERALIZATION	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
MINERALIZATION-PELVIS	29 (29)	28 (29)	32 (33)	23 (40)	33 (33)	27 (33)	17 (35)
CALCULI <sup>1</sup>	0 (0)	0 (0)	2 (2)	3 <sup>1</sup> (5)	1 (1)	0 (0)	2 (4)
PYELITIS	4 (4)	3 (3)	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)
PYELONEPHRITIS	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
CONGESTION	10 (10)	6 (6)	11 (11)	5 (9)	15 (15)	6 (7)	4 (8)
HEMORRHAGE	0 (0)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
EXTRAMEDULLARY HEMATOPOIESIS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FIBRIN THROMBI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
PROTEIN CASTS	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
PIGMENT	0 (0)	3 (3)	2 (2)	2 (4)	3 (3)	0 (0)	1 (2)
ADHESIONS	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (2)
FIBROSIS	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
HEMORRHAGE-PELVIS	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
VACUOLIZATION	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
FATTY CHANGE	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
DEGENERATION	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>LARYNX</b>	# Ex 97	# 96	# 96	# 57	# 98	# 80	# 48
HYPERPLASIA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, ACUTE	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	1 (1)	1 (2)
INFLAMMATION, CHRONIC	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
INFLAMMATION, CHRONIC ACTIVE <sup>1</sup>	0 (0)	2 (2)	1 (1)	1 (2)	0 (0)	0 (0)	2 (4)
ULCER	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)

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TABLE 10 (continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for Treated Animals Without Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Stam 100	L Gel 98	M Gel 98	H Gel 57	L PE 99	M PE 81	H PE 48
LARYNX	# Ex 97	# (%) 96	# (%) 96	# (%) 57	# (%) 98	# (%) 80	# (%) 48
INGESTA	3 (3)	2 (2)	2 (2)	0 (0)	6 (6)	1 (1)	2 (4)
ULCER, MULT	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
EXUDATE	0 (0)	0 (0)	1 (1)	1 (2)	0 (0)	0 (0)	0 (0)
HEMORRHAGE	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
LIVER	# Ex 99	# (%) 98	# (%) 98	# (%) 57	# (%) 99	# (%) 81	# (%) 48
DIAPHRAGMATIC HERNIA	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
TIGROID BASOPHILIC FOCUS	8 (8)	12 (12)	13 (13)	2 (4)	9 (9)	5 (6)	6 (13)
TIGROID BASOPHILIC FOCUS, MULT	4 (4)	9 (9)	8 (8)	1 (2)	11 <sup>1</sup> (11)	3 (4)	4 (8)
EOSINOPHILIC FOCUS	13 (13)	13 (13)	14 (14)	1 (2)	8 (8)	7 (9)	2 (4)
EOSINOPHILIC FOCUS, MULT	2 (2)	8 <sup>1</sup> (8)	4 (4)	3 (5)	4 (4)	2 (2)	2 (4)
CLEAR CELL FOCUS	0 (0)	2 (2)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
CLEAR CELL FOCUS, MULT	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
HOMOGENEOUS BASOPHILIC FOCUS	4 (4)	0 (0)	4 (4)	1 (2)	0 (0)	2 (2)	3 (6)
HOMOGENEOUS BASO FOCUS, MULT.	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
CYSTIC BILE DUCTS	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ANGIECTASIS <sup>1</sup>	3 (3)	4 (4)	2 (2)	3 (5)	6 (6)	9 <sup>1</sup> (11)	6 <sup>1</sup> (13)
CYSTIC DEGENERATION	9 (9)	6 (6)	3 (3)	1 (2)	5 (5)	3 (4)	1 (2)
FATTY CHANGE, NOS	37 (37)	30 (31)	39 (40)	14 (25)	26 (26)	36 (44)	11 (23)
DEGENERATION, CENTRILOBULAR	0 (0)	1 (1)	1 (1)	2 (4)	1 (1)	1 (1)	1 (2)
HYPERTROPHY, NOS	2 (2)	5 (5)	0 (0)	0 (0)	1 (1)	2 (2)	1 (2)
NECROSIS, NOS	10 (10)	2 (2)	9 (9)	2 (4)	5 (5)	7 (9)	0 (0)
NECROSIS, CENTRILOBULAR	0 (0)	1 (1)	1 (1)	0 (0)	1 (1)	1 (1)	0 (0)
INFLAMMATION, ACUTE	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
INFLAMMATION, GRANULOMATOUS	0 (0)	0 (0)	0 (0)	1 (2)	2 (2)	0 (0)	0 (0)
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
FIBROSIS	1 (1)	1 (1)	2 (2)	1 (2)	0 (0)	0 (0)	0 (0)
CONGESTION	10 (10)	9 (9)	18 (18)	6 (11)	17 (17)	15 (19)	6 (13)
HEMORRHAGE	2 (2)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
PIGMENT	9 (9)	13 (13)	14 (14)	3 (5)	9 (9)	4 (5)	10 <sup>1</sup> (21)
EXTRAMEDULLARY HEMATOPOIESIS	2 (2)	4 (4)	7 (7)	1 (2)	3 (3)	2 (2)	1 (2)
BILE DUCT HYPERPLASIA	3 (3)	3 (3)	5 (5)	2 (4)	2 (2)	5 (6)	0 (0)
BILIARY CYST(S)	2 (2)	0 (0)	1 (1)	0 (0)	1 (1)	1 (1)	1 (2)
VASCULAR ECTASIA <sup>1</sup>	11 (11)	14 (14)	16 (16)	4 (7)	13 (13)	16 <sup>1</sup> (20)	11 <sup>1</sup> (23)
ABSCESS, MULTIPLE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
CAPSULAR FIBROSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
LUNGS	# Ex 100	# (%) 98	# (%) 98	# (%) 57	# (%) 99	# (%) 81	# (%) 48
ALVEOLAR EPITH. HYPERPLASIA	1 (1)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
INTERSTITIAL PNEUMONIA <sup>1</sup>	2 (2)	6 (6)	4 (4)	1 (2)	4 (4)	7 <sup>1</sup> (9)	3 (6)
BRONCHOPNEUMONIA	1 (1)	3 (3)	2 (2)	2 (4)	4 (4)	1 (1)	0 (0)
INFLAMMATION, ACUTE	1 (1)	0 (0)	0 (0)	0 (0)	2 (2)	1 (1)	1 (2)
INFLAMMATION, GRANULOMATOUS	4 (4)	1 (1)	4 (4)	1 (2)	5 (5)	0 (0)	0 (0)
INFLAMMATION, PYOGRANULOMATOUS <sup>1</sup>	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (4)
CONGESTION	15 (15)	10 (10)	16 (16)	6 (11)	13 (13)	16 (20)	9 (19)
HEMORRHAGE	0 (0)	2 (2)	0 (0)	1 (2)	0 (0)	0 (0)	1 (2)
THROMBUS/THROMBOSIS	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
LEUKEMOID REACTION	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
ABSCESS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
FIBRIN THROMBI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
ADHESIONS	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
PIGMENT	3 (3)	1 (1)	5 (5)	0 (0)	0 (0)	4 (5)	1 (2)
HYPERPLASIA, LYMPHOID	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
HAMARTOMA	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)

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TABLE 10 (continued)

SUMMARY: Incidences of NON-NEOPLASTIC Microscopic Findings for Treated Animals Without Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 98	M Gel 98	H Gel 57	L PE 99	M PE 81	H PE 48
<b>LYMPH NODE, MANDIBULAR</b>	# Ex 85	92	92	53	94	73	45
HYPERPLASIA, LYMPHOID	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
PLASMACYTOSIS	0 (0)	2 (2)	0 (0)	1 (2)	1 (1)	3 (4)	1 (2)
ECTASIA/CYST(S) <sup>1</sup>	1 (1)	1 (1)	2 (2)	4 (8)	2 (2)	2 (3)	1 (2)
ATROPHY	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
CONGESTION	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
HEMORRHAGE	0 (0)	1 (1)	1 (1)	0 (0)	3 (3)	0 (0)	2 (4)
<b>LYMPH NODE, MEDIASTINAL</b>	# Ex 86	89	89	49	92	76	43
HYPERPLASIA, LYMPHOID	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
PLASMACYTOSIS	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)	1 (1)	1 (2)
ECTASIA/CYST(S)	3 (3)	6 (7)	3 (3)	1 (2)	8 (9)	1 (1)	1 (2)
ATROPHY	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
CONGESTION	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
HEMORRHAGE	2 (2)	2 (2)	0 (0)	0 (0)	4 (4)	0 (0)	1 (2)
<b>LYMPH NODE, MESENTERIC</b>	# Ex 98	96	97	56	95	79	48
HYPERPLASIA, LYMPHOID	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
PLASMACYTOSIS	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ECTASIA/CYST(S)	0 (0)	1 (1)	1 (1)	1 (2)	1 (1)	0 (0)	0 (0)
ATROPHY	3 (3)	1 (1)	1 (1)	1 (2)	0 (0)	0 (0)	0 (0)
HEMORRHAGE	0 (0)	3 (3)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
SINUS HISTIOCYTOSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
<b>LYMPH NODE, OTHER</b>	# Ex 26	36	28	23	30	26	8
PIGMENT	0 (0)	0 (0)	1 (4)	0 (0)	0 (0)	0 (0)	0 (0)
PLASMACYTOSIS	1 (4)	5 (14)	4 (14)	2 (9)	3 (10)	3 (12)	0 (0)
ECTASIA/CYST(S)	0 (0)	1 (3)	1 (4)	0 (0)	0 (0)	0 (0)	1 (13)
ATROPHY	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)
HEMORRHAGE	0 (0)	0 (0)	1 (4)	0 (0)	1 (3)	0 (0)	0 (0)
FIBROSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ENCAP IMPLANT MAT, REGIONAL LN	0 (0)	1 (3)	1 (4)	0 (0)	0 (0)	0 (0)	0 (0)
<b>MAMMARY GLAND</b>	# Ex 100	98	98	57	99	81	48
FIBROCYSTIC DISEASE	25 (25)	27 (27)	29 (29)	14 (24)	28 (28)	23 (28)	11 (23)
HYPERPLASIA	3 (3)	8 (8)	4 (4)	2 (4)	10 (10)	6 (7)	1 (2)
GALACTOCELE/CYST(S) <sup>1</sup>	6 (6)	14 (14)	8 (8)	7 (12)	12 (12)	12 (15)	12 (25)
INFLAMMATION, CHRONIC ACTIVE	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
ATYPICAL HYPERPLASIA	2 (2)	4 (4)	1 (1)	0 (0)	1 (1)	1 (1)	1 (2)
ABSCESS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ATROPHY	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FIBROSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
<b>OPTIC NERVE</b>	# Ex 99	97	97	56	98	81	48
<b>OVARIES</b>	# Ex 99	98	98	57	99	81	48
CYST(S)	27 (27)	19 (19)	23 (23)	13 (23)	21 (21)	18 (22)	13 (27)
LUTEAL/STROMAL HYPERPLASIA	14 (14)	8 (8)	16 (16)	7 (12)	11 (11)	4 (5)	5 (10)
SERTOLI CELL HYPERPLASIA	7 (7)	8 (8)	4 (4)	2 (4)	4 (4)	5 (6)	3 (6)
CONGESTION	3 (3)	1 (1)	2 (2)	2 (4)	1 (1)	0 (0)	0 (0)
<b>OVIDUCTS</b>	# Ex 98	97	97	57	98	80	48
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
CYST(S)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)

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TABLE 10 (continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for Treated Animals Without Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 98	M Gel 98	H Gel 57	L PE 99	M PE 81	H PE 48
<b>PANCREAS</b>	# Ex 99	# 98	# 98	# 56	# 99	# 81	# 48
ATROPHY	7 (7)	6 (6)	6 (6)	5 (9)	5 (5)	4 (5)	2 (4)
FIBROSIS	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)
INFLAMMATION, CHRONIC	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
FAT-NECROSIS	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
CYSTIC DUCTS	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	1 (2)
<b>PANCREATIC ISLETS</b>	# Ex 99	# 97	# 98	# 56	# 98	# 81	# 48
HYPERPLASIA	2 (2)	1 (1)	2 (2)	0 (0)	3 (3)	4 (5)	0 (0)
<b>PARATHYROID</b>	# Ex 98	# 97	# 95	# 54	# 96	# 77	# 48
HYPERPLASIA <sup>1</sup>	0 (0)	0 (0)	0 (0)	2 (4)	2 (2)	1 (1)	0 (0)
<b>PITUITARY</b>	# Ex 100	# 97	# 96	# 57	# 98	# 81	# 48
HYPERPLASIA	7 (7)	2 (2)	3 (3)	1 (2)	8 (8)	2 (2)	1 (2)
CYST(S)	3 (3)	5 (5)	6 (6)	3 (5)	8 (8)	6 (7)	3 (6)
ANGIECTASIS	4 (4)	4 (4)	5 (5)	3 (9)	6 (6)	5 (6)	4 (8)
THROMBUS/THROMBOSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FIBROSIS	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>RECTUM</b>	# Ex 89	# 91	# 90	# 51	# 92	# 76	# 47
PROLIFERATIVE FASCICULITIS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
EROSION	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC ACTIVE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FIBROSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
EDEMA	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)	1 (1)	0 (0)
<b>SALIVARY GLAND</b>	# Ex 96	# 98	# 98	# 57	# 99	# 79	# 48
ATROPHY <sup>1</sup>	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)	3 (4)	1 (2)
INFLAMMATION, ACUTE	0 (0)	1 (1)	0 (0)	1 (2)	0 (0)	1 (1)	1 (2)
HEMORRHAGE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
ABSCESS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
<b>SCIATIC NERVE</b>	# Ex 97	# 95	# 96	# 57	# 97	# 79	# 47
DEGENERATION	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>SKELETAL MUSCLE</b>	# Ex 99	# 98	# 97	# 57	# 98	# 81	# 47
MYOPATHY	4 (4)	3 (3)	6 (6)	1 (2)	1 (1)	1 (1)	0 (0)
INFLAMMATION, CHRONIC ACTIVE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>SKIN/SUBCUTIS</b>	# Ex 100	# 98	# 98	# 57	# 99	# 81	# 48
FAT NECROSIS	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
SQUAMOUS CELL HYPERPLASIA	2 (2)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
CYST(S)/INCLUSION CYST(S)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
ULCER	5 (5)	7 (7)	4 (4)	1 (2)	1 (1)	1 (1)	1 (2)
ULCER, MULT	1 (1)	0 (0)	0 (0)	1 (2)	2 (2)	0 (0)	1 (2)
INFLAMMATION, CHRONIC	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC ACTIVE	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	1 (2)
ABSCESS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
FIBROSIS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
DERMIS-FIBROSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	1 (2)
EXUDATE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
<b>SPINAL CORD</b>	# Ex 99	# 98	# 98	# 57	# 99	# 81	# 48
GLIOSIS	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)
MALACIA	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
HEMORRHAGE	1 (1)	2 (2)	2 (2)	1 (2)	1 (1)	2 (2)	0 (0)



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TABLE 10 (continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for Treated Animals Without Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 98	M Gel 98	H Gel 57	L PE 99	M PE 81	H PE 48
<b>SPLEEN</b>	# Ex	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
NECROSIS	0	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
EXTRAMEDULLARY HEMATOPOIESIS	31	31 (31)	26 (27)	17 (17)	12 (12)	27 (27)	11 (23)
CONGESTION	0	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
HEMORRHAGE	0	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
ADHESIONS	1	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
CYST-CAPSULE <sup>1</sup>	0	0 (0)	2 (2)	1 (1)	2 (2)	0 (0)	1 (1)
FIBROSIS-CAPSULE	1	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ACCESSORY SPLEEN	0	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
ATROPHY	3	3 (3)	0 (0)	0 (0)	1 (2)	0 (0)	1 (2)
<b>STERNUM - BONE</b>	# Ex	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
FIBROUS OSTEODYSTROPHY	0	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	2 (2)
DEGENERATION-CARTILAGE	12	12 (12)	18 (19)	11 (11)	4 (7)	10 (10)	14 (17)
ENDOSTOSES	0	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
OSTEOSCLEROSIS	0	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
<b>STERNUM - BONE MARROW</b>	# Ex	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
HYPERPLASIA, MYELOID	8	8 (8)	10 (10)	6 (6)	6 (11)	9 (9)	5 (10)
HYPERPLASIA, NOS	2	2 (2)	4 (4)	5 (5)	0 (0)	2 (2)	4 (5)
CONGESTION	0	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
<b>STOMACH</b>	# Ex	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
EROSION	9	9 (9)	3 (3)	7 (7)	2 (4)	3 (3)	6 (8)
EROSION, MULT	0	0 (0)	2 (2)	2 (2)	1 (2)	2 (2)	1 (1)
ULCER	1	1 (1)	2 (2)	1 (1)	1 (2)	0 (0)	0 (0)
INFLAMMATION, CHRONIC ACTIVE	0	0 (0)	2 (2)	0 (0)	1 (2)	0 (0)	1 (1)
ADHESIONS	1	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
CONGESTION	1	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
HEMORRHAGE	0	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)
MINERALIZATION	1	1 (1)	0 (0)	1 (1)	0 (0)	1 (1)	2 (3)
EDEMA	0	0 (0)	0 (0)	1 (1)	1 (2)	0 (0)	1 (2)
FIBROSIS	0	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	1 (2)
<b>SYSTEMIC DISEASES</b>	# Ex	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
PERIARTERITIS	5	5 (5)	2 (2)	0 (0)	0 (0)	4 (4)	4 (5)
MINERALIZ. MULTIPLE ARTERIES	0	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)
<b>TAIL</b>	# Ex	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
ULCER, MULTIPLE	3	3 (17)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)
SQUAMOUS CELL HYPERPLASIA	1	1 (6)	1 (7)	2 (13)	0 (0)	0 (0)	1 (11)
HYPERKERATOSIS	4	4 (22)	5 (36)	4 (27)	4 (36)	3 (19)	0 (0)
CYST(S)/INCLUSION CYST(S) <sup>1</sup>	0	0 (0)	1 (7)	0 (0)	1 (9)	0 (0)	1 (11)
ULCER	6	6 (33)	2 (14)	5 (33)	2 (18)	8 (50)	5 (31)
INFLAMMATION, ACUTE	0	0 (0)	0 (0)	1 (7)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC	1	1 (6)	1 (7)	0 (0)	1 (9)	0 (0)	1 (6)
INFLAMMATION, CHRONIC ACTIVE <sup>11</sup>	0	0 (0)	2 (14)	6 (40)	2 (18)	0 (0)	2 (13)
ABSCESS	6	6 (33)	6 (43)	4 (27)	4 (36)	10 (63)	4 (25)
NECROSIS	0	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (13)
EXUDATE	0	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)
INFARCT	1	1 (6)	1 (7)	0 (0)	2 (18)	0 (0)	1 (6)
SCAB	0	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	3 (19)
EXOSTOSES	0	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (11)
<b>THYMUS</b>	# Ex	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
FIBROSIS	0	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
ATROPHY	25	25 (30)	47 (51)	32 (40)	9 (19)	24 (28)	27 (37)
CYST(S)	9	9 (11)	23 (25)	17 (21)	4 (8)	8 (9)	4 (5)



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TABLE 10 (continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for Treated Animals Without Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 98	M Gel 98	H Gel 57	L PE 99	M PE 81	H PE 48
<b>THYMUS</b>	# Ex 82	93	81	48	85	69	41
HEMORRHAGE	1 (1)	1 (1)	0 (0)	1 (2)	0 (0)	0 (0)	2 (5)
HYPERPLASIA, EPITHELIAL	0 (0)	4 (4)	2 (2)	2 (4)	2 (2)	4 (6)	1 (2)
ECTOPIC PARATHYROID	0 (0)	0 (0)	1 (1)	1 (2)	1 (1)	0 (0)	0 (0)
ECTOPIC THYROID	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>THYROID</b>	# Ex 98	95	96	56	98	80	48
FOLL. CELL HYPERPLASIA	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
FOLLICULAR CYST(S)	1 (1)	4 (4)	1 (1)	0 (0)	3 (3)	1 (1)	0 (0)
C-CELL HYPERPLASIA	7 (7)	9 (9)	9 (9)	1 (2)	11 (11)	5 (6)	1 (2)
ULTIMOBRANCHIAL CYST(S)	15 (15)	16 (17)	11 (11)	1 (2)	17 (17)	8 (10)	4 (8)
HEMORRHAGE	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
<b>TRACHEA</b>	# Ex 99	98	98	57	99	81	48
INFLAMMATION, CHRONIC ACTIVE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
ULCER	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
INGESTA	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
EXUDATE	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
HEMORRHAGE	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
<b>URINARY BLADDER</b>	# Ex 98	95	98	54	97	79	47
TRANSITIONAL CELL HYPERPLASIA	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
PROLIFERATIVE CYSTITIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
INFLAMMATION, ACUTE	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
INFLAMMATION, GRANULOMATOUS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
CALCULI	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
HEMORRHAGE	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
SQUAMOUS METAPLASIA	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>UTERUS</b>	# Ex 98	97	98	57	98	81	48
CYSTIC ENDOMETRIAL HYPERPLASIA*	76 (78)	83* (88)	92* (94)	50 (88)	91* (93)	60 (74)	40 (83)
SQUAMOUS METAPLASIA	1 (1)	3 (3)	0 (0)	1 (2)	4 (4)	1 (1)	0 (0)
INFLAMMATION, ACUTE	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
CONGESTION	1 (1)	1 (1)	1 (1)	1 (2)	1 (1)	0 (0)	0 (0)
HEMORRHAGE	0 (0)	0 (0)	0 (0)	1 (2)	1 (1)	0 (0)	0 (0)
INTUSSUSCEPTION	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
ATROPHY	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
<b>VAGINA</b>	# Ex 98	97	97	56	98	81	48
PROLIFERATIVE FASCICULITIS	11 (11)	7 (7)	8 (8)	5 (9)	12 (12)	10 (12)	6 (12)
FIBROSIS	2 (2)	1 (1)	2 (2)	0 (0)	3 (3)	0 (0)	1 (2)
ULCER	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
INFLAMMATION, ACUTE	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC*	1 (1)	1 (1)	3 (3)	2 (4)	1 (1)	2 (2)	3 (6)
INFLAMMATION, CHRONIC ACTIVE	4 (4)	0 (0)	1 (1)	0 (0)	0 (0)	3 (4)	0 (0)
EXUDATE*	17 (17)	19 (20)	25 (26)	16 (29)	11 (11)	22 (27)	14 (29)
EPITHELIAL HYPERPLASIA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
CYST(S)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
STROMAL HYPERPLASIA	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
<b>OTHER TISSUES AND LESIONS:</b>							
MESENTERY: STEATITIS	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
MESENTERY: FAT NECROSIS	1 (1)	5 (5)	3 (3)	1 (2)	8* (8)	2 (2)	1 (2)
ABD FAT: HEMORRHAGE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
MESENTERY: ABSCESS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
EAR/PINNA: PROLIF CHONDROPATHY	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)

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TABLE 10 (continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for Treated Animals Without Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 98	M Gel 98	H Gel 57	L PE 99	M PE 81	H PE 48
<b>OTHER TISSUES AND LESIONS:</b>							
MEDIAST: PLEURITIS	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
MESENTERY: PERITONITIS	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
URETER: DILATATION	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
URETER: TRANSIT CELL HYPERPL	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
URETER: CALCULI	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
URETER: NORMAL	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
MESENTERY: ACCESSORY SPLEEN	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
MESENTERY: INFLAM, CHRONIC	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
PINEAL GLAND: NORMAL	1 (1)	3 (3)	2 (2)	1 (2)	3 (3)	1 (1)	2 (4)
PALATE: NECROTIZING ULCER	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
NASAL CAVITY: ULCER, MULT.	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
BONE: FRACTURE	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
TOOTH: FRACTURE	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FACIAL BONE: FRACTURE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
JOINTS: ARTHRITIS	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
DIAPHRAGM: NORMAL	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
ACCESSORY SEX GL: CHR ACT INFL	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
URETHRA: NORMAL	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)	0 (0)	0 (0)
TOOTH: ABSCESS	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
ACCESSORY SEX GL: NORMAL	0 (0)	2 (2)	0 (0)	0 (0)	5 (5)	1 (1)	0 (0)
EAR: ABSCESS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
MENINGES: FIBROSIS	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)	0 (0)	0 (0)
OVARIAN BURSA: FIBROSIS	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
RENAL V.: THROMBUS/THROMBOSIS	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
BILE DUCT: DILATATION	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
MEDIASTINUM: ECTOPIC THYROID	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
JOINTS: ANKYLOSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (4)
URETER: CHRONIC INFLAM	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
MESENTERY: FIBROSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
TARSUS: HYPERKERATOSIS	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)

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## Legend - Table 10

Female Sprague Dawley rats were implanted subcutaneously with three dose levels of either mammary silicone gel or low density polyethylene. The implantation procedure was performed on sham control animals but no test material was introduced into the animals. Forty-six specified tissues and organs were collected from all animals for histopathology. Animals exhibiting SST were censored and the incidence of non-neoplastic lesions was calculated as the ratio of the number of animals bearing lesions at a site to the number of animals examined histologically (# Ex) and are reported as percents (%). A statistical analysis of lesion incidence was only performed if there were at least 2 observations in one of the experimental groups within a potential analysis. Silicone gel and PE groups were analyzed independently of one another.

Logistic regression analysis was the primary statistical method used to assess lesion incidence among treated and control groups. The life table test was applied to provide an appropriate approach for analyzing the incidence of rapidly lethal lesions (e.g. solid state tumors). In addition, the Fisher exact test and the Cochran-Armitage trend test were utilized although they are procedures which do not adjust for intercurrent mortality.

† Silicone gel group is significantly different from sham control group at  $p \leq 0.05$ . § Polyethylene group is significantly different from sham control group at  $p \leq 0.05$ . A statistical symbol immediately after the lesion indicates a significant trend for the silicone gel groups (†) or the polyethylene groups (§) at  $p \leq 0.05$ .

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TABLE 11  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for Treated Animals With Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 2	M Gel 2	H Gel 43	L PE 1	M PE 19	H PE 52
<b>ADRENAL CORTEX</b>	# Ex 100	# (%) 2 (2)	# (%) 2 (100)	# (%) 43 (100)	# (%) 1 (100)	# (%) 19 (100)	# (%) 50 (100)
HYPERPLASIA	5 (5)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	2 (4)
HYPERTROPHY	8 (8)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	3 (6)
HEMORRHAGIC CYST/CYST(S)	90 (90)	2 (100)	2 (100)	35 <sup>†</sup> (81)	1 (100)	16 (84)	37 <sup>†</sup> (74)
THROMBUS/THROMBOSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
FATTY CHANGE	3 (3)	1 <sup>†</sup> (50)	0 (0)	2 (5)	0 (0)	0 (0)	2 (4)
DEGENERATION <sup>†</sup>	19 (19)	0 (0)	1 (50)	11 <sup>†</sup> (26)	0 (0)	2 (11)	10 (20)
CONGESTION	3 (3)	0 (0)	0 (0)	3 (7)	0 (0)	1 (5)	2 (4)
HEMORRHAGE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
EXTRAMEDULLARY HEMATOPOIESIS <sup>††</sup>	0 (0)	1 <sup>†</sup> (50)	0 (0)	10 <sup>†</sup> (23)	0 (0)	6 <sup>†</sup> (32)	9 <sup>†</sup> (18)
ATROPHY	1 (1)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	2 (4)
FIBROSIS	1 (1)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	1 (2)
NECROSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
<b>ADRENAL MEDULLA</b>	# Ex 100	# (%) 2 (2)	# (%) 2 (100)	# (%) 42 (100)	# (%) 1 (100)	# (%) 19 (100)	# (%) 48 (100)
HYPERPLASIA	17 (17)	0 (0)	0 (0)	2 (5)	0 (0)	4 (21)	1 (2)
<b>AORTA</b>	# Ex 100	# (%) 2 (2)	# (%) 2 (100)	# (%) 43 (100)	# (%) 1 (100)	# (%) 19 (100)	# (%) 52 (100)
MINERALIZATION	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>BRAIN</b>	# Ex 100	# (%) 2 (2)	# (%) 2 (100)	# (%) 43 (100)	# (%) 1 (100)	# (%) 19 (100)	# (%) 52 (100)
MALACIA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
COMPRESSION	51 (51)	0 (0)	1 (50)	9 (21)	0 (0)	5 (26)	13 (25)
HYDROCEPHALUS	16 (16)	0 (0)	0 (0)	1 (2)	0 (0)	3 (16)	7 (13)
HEMORRHAGE	4 (4)	0 (0)	0 (0)	1 (2)	0 (0)	3 (16)	2 (4)
<b>CECUM</b>	# Ex 100	# (%) 2 (2)	# (%) 1 (50)	# (%) 34 (100)	# (%) 1 (100)	# (%) 14 (100)	# (%) 44 (100)
INFLAMMATION, CHRONIC	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
CONGESTION	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
EDEMA	1 (1)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>CERVIX</b>	# Ex 98	# (%) 2 (2)	# (%) 2 (100)	# (%) 43 (100)	# (%) 1 (100)	# (%) 19 (100)	# (%) 51 (100)
PROLIFERATIVE FASCICULITIS <sup>†</sup>	1 (1)	0 (0)	0 (0)	3 <sup>†</sup> (7)	1 (100)	1 (5)	0 (0)
FIBROSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
SQUAMOUS METAPLASIA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
INFLAMMATION, ACUTE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
INFLAMMATION, CHRONIC ACTIVE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
EXUDATE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (4)
CYSTS(S)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
<b>CLITORAL GLAND</b>	# Ex 4	# (%) 0 (0)	# (%) 0 (0)	# (%) 1 (100)	# (%) 0 (0)	# (%) 2 (100)	# (%) 2 (100)
CYSTIC DUCTS	3 (75)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (50)
INFLAMMATION, CHRONIC	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (50)	0 (0)
<b>COLON</b>	# Ex 90	# (%) 2 (2)	# (%) 1 (50)	# (%) 38 (100)	# (%) 1 (100)	# (%) 17 (100)	# (%) 47 (100)
NECROSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)
EPITHELIAL HYPERPLASIA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, ACUTE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>DUODENUM</b>	# Ex 89	# (%) 2 (2)	# (%) 1 (50)	# (%) 39 (100)	# (%) 1 (100)	# (%) 18 (100)	# (%) 50 (100)
<b>ESOPHAGUS</b>	# Ex 100	# (%) 2 (2)	# (%) 2 (100)	# (%) 43 (100)	# (%) 1 (100)	# (%) 19 (100)	# (%) 52 (100)
INGESTA	3 (3)	0 (0)	0 (0)	3 (7)	0 (0)	0 (0)	0 (0)
<b>EYES</b>	# Ex 99	# (%) 2 (2)	# (%) 2 (100)	# (%) 42 (100)	# (%) 1 (100)	# (%) 19 (100)	# (%) 52 (100)
CORNEA, EDEMA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
CORNEA, MINERALIZATION	4 (4)	1 <sup>†</sup> (50)	0 (0)	4 (10)	0 (0)	1 (5)	3 (6)

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TABLE II (continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for Treated Animals With Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 2	M Gel 2	H Gel 43	L PE 1	M PE 19	H PE 52
<b>EYES</b>	# Ex 99	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
CORNEA, ULCER	0 (0)	0 (0)	2 (0)	0 (0)	1 (0)	0 (0)	1 (2)
CORNEA, INFLAMMATION ACUTE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
CORNEA, INFLAMMATION CHRONIC	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
IRIDOCYCLITIS <sup>1</sup>	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	2 (4)
CATARACT	3 (3)	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)
RETINA, DEGENERATION	2 (2)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
<b>FEMUR - BONE</b>	# Ex 99	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
EXOSTOSES	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)	0 (0)
SYNOVITIS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>FEMUR - BONE MARROW</b>	# Ex 99	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
HYPERPLASIA, MYELOID <sup>11</sup>	10 (10)	0 (0)	0 (0)	14 <sup>1</sup> (33)	0 (0)	7 <sup>1</sup> (39)	16 <sup>1</sup> (32)
HYPERPLASIA, NOS <sup>1</sup>	3 (3)	0 (0)	0 (0)	2 (5)	0 (0)	2 (11)	4 (8)
FIBROSIS	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	1 (2)
CYST(S)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
<b>FOOTPAD</b>	# Ex 17	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
ULCER, MULT	0 (0)	0 (0)	0 (0)	1 (13)	0 (0)	0 (0)	0 (0)
HYPERKERATOSIS	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
SQUAMOUS CELL HYPERPLASIA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)
ULCER <sup>1</sup>	16 (94)	0 (0)	0 (0)	7 <sup>1</sup> (88)	0 (0)	1 (100)	4 (67)
INFLAMMATION, CHRONIC ACTIVE	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (17)
ABSCESS <sup>1</sup>	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 <sup>1</sup> (33)
<b>FORESTOMACH</b>	# Ex 100	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
SQUAMOUS CELL HYPERPLASIA	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
ULCER	3 (3)	1 <sup>1</sup> (30)	0 (0)	0 (0)	0 (0)	0 (0)	2 (4)
PERFORATING ULCER	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
INFLAMMATION, CHRONIC ACTIVE	7 (7)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	1 (2)
INCLUSION CYST(S)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
VESICLES	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
<b>HARDERIAN GLAND</b>	# Ex 100	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
INFLAMMATION, CHRONIC	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>HEART</b>	# Ex 100	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
CARDIOMYOPATHY <sup>11</sup>	74 (74)	0 (0)	2 (100)	27 <sup>1</sup> (63)	1 (100)	12 (63)	36 <sup>1</sup> (69)
PERICARDITIS	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
<b>ILEUM</b>	# Ex 88	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
EROSION, MULT	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (7)	0 (0)
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>IMPLANT 1 - CAPSULE</b>	# Ex 97	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
FIBROSIS <sup>11</sup>	0 (0)	2 <sup>1</sup> (100)	2 <sup>1</sup> (100)	38 <sup>1</sup> (88)	0 (0)	5 <sup>1</sup> (31)	24 <sup>1</sup> (51)
HYPERPLASIA, FIBROBLASTIC <sup>11</sup>	0 (0)	1 <sup>1</sup> (50)	0 (0)	10 <sup>1</sup> (23)	0 (0)	0 (0)	6 <sup>1</sup> (13)
INGROWTH <sup>1</sup>	0 (0)	0 (0)	0 (0)	3 <sup>1</sup> (7)	0 (0)	0 (0)	0 (0)
COMPARTMENTALIZATION <sup>1</sup>	0 (0)	0 (0)	0 (0)	4 <sup>1</sup> (9)	0 (0)	0 (0)	1 (2)
IMPLANT MATERIAL <sup>1</sup>	0 (0)	0 (0)	0 (0)	17 <sup>1</sup> (40)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC <sup>11</sup>	0 (0)	0 (0)	0 (0)	5 <sup>1</sup> (13)	0 (0)	1 (6)	4 <sup>1</sup> (9)
INFLAMMATION, CHRONIC ACTIVE <sup>1</sup>	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)
INFLAMMATION, GRANULOMATOUS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
MINERALIZATION	0 (0)	1 (50)	1 (50)	1 (2)	0 (0)	0 (0)	0 (0)
DEGENERATION <sup>1</sup>	0 (0)	0 (0)	0 (0)	5 <sup>1</sup> (12)	0 (0)	0 (0)	1 (2)
PIGMENT <sup>1</sup>	0 (0)	0 (0)	0 (0)	2 <sup>1</sup> (5)	0 (0)	1 (6)	1 (2)
HEMORRHAGE	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	1 (6)	1 (2)
OSSEOUS METAPLASIA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)

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TABLE II (continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for Treated Animals With Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 2	M Gel 2	H Gel 43	L PE 1	M PE 19	H PE 52
<b>IMPLANT 1 - EXTRACAPSULAR</b>	# Ex 97	2	2	43	1	19	50
IMPLANT MATERIAL <sup>1</sup>	0 (0)	1 <sup>1</sup> (50)	1 <sup>1</sup> (50)	27 <sup>1</sup> (63)	0 (0)	0 (0)	1 (2)
FIBROSIS <sup>1</sup>	1 (1)	0 (0)	1 <sup>1</sup> (50)	21 <sup>1</sup> (49)	0 (0)	0 (0)	0 (0)
INFLAMMATION, ACUTE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC <sup>1</sup>	0 (0)	0 (0)	1 <sup>1</sup> (50)	4 <sup>1</sup> (9)	0 (0)	0 (0)	0 (0)
ULCER-SKIN <sup>1</sup>	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	3 <sup>1</sup> (6)
PIGMENT	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
DERMIS-FIBROSIS	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
SQUAMOUS CELL HYPERPL-SKIN	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
EROSION-SKIN	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
<b>IMPLANT 2 - CAPSULE</b>	# Ex 96	2	2	43	1	15	49
FIBROSIS <sup>11</sup>	0 (0)	2 <sup>1</sup> (100)	2 <sup>1</sup> (100)	36 <sup>1</sup> (84)	0 (0)	9 <sup>1</sup> (60)	27 <sup>1</sup> (55)
HYPERPLASIA, FIBROBLASTIC <sup>11</sup>	0 (0)	0 (0)	0 (0)	4 <sup>1</sup> (9)	0 (0)	0 (0)	0 (0)
INGROWTH <sup>1</sup>	0 (0)	0 (0)	0 (0)	3 <sup>1</sup> (7)	0 (0)	0 (0)	0 (0)
COMPARTMENTALIZATION <sup>1</sup>	0 (0)	0 (0)	0 (0)	4 <sup>1</sup> (9)	0 (0)	0 (0)	0 (0)
IMPLANT MATERIAL <sup>1</sup>	0 (0)	0 (0)	0 (0)	14 <sup>1</sup> (33)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC <sup>11</sup>	0 (0)	0 (0)	0 (0)	5 <sup>1</sup> (12)	0 (0)	1 (7)	3 <sup>1</sup> (6)
INFLAMMATION, CHRONIC ACTIVE	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	1 (2)
INFLAMMATION, GRANULOMATOUS <sup>1</sup>	0 (0)	0 (0)	0 (0)	2 <sup>1</sup> (5)	0 (0)	0 (0)	1 (2)
MINERALIZATION <sup>1</sup>	0 (0)	1 <sup>1</sup> (50)	0 (0)	3 <sup>1</sup> (7)	0 (0)	0 (0)	0 (0)
DEGENERATION <sup>1</sup>	0 (0)	0 (0)	0 (0)	3 <sup>1</sup> (7)	0 (0)	0 (0)	1 (2)
PIGMENT <sup>1</sup>	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (7)	2 <sup>1</sup> (4)
<b>IMPLANT 2 - EXTRACAPSULAR</b>	# Ex 96	2	2	43	1	19	49
DERMIS-FIBROSIS	7 (7)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	1 (2)
IMPLANT MATERIAL <sup>1</sup>	0 (0)	0 (0)	2 <sup>1</sup> (100)	19 <sup>1</sup> (44)	0 (0)	0 (0)	0 (0)
FIBROSIS <sup>1</sup>	0 (0)	1 <sup>1</sup> (50)	2 <sup>1</sup> (100)	13 <sup>1</sup> (30)	0 (0)	0 (0)	0 (0)
INFLAMMATION, ACUTE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
INFLAMMATION, CHRONIC	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
INFLAMMATION, GRANULOMATOUS	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
EROSION-SKIN	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
ULCER-SKIN <sup>1</sup>	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	4 <sup>1</sup> (8)
SQUAMOUS CELL HYPERPL-SKIN	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
<b>IMPLANT 3 - CAPSULE</b>	# Ex 97	1	2	43	0	0	0
FIBROSIS <sup>1</sup>	0 (0)	1 <sup>1</sup> (100)	2 <sup>1</sup> (100)	38 <sup>1</sup> (88)	0 (0)	0 (0)	0 (0)
HYPERPLASIA, FIBROBLASTIC <sup>1</sup>	0 (0)	0 (0)	0 (0)	5 <sup>1</sup> (12)	0 (0)	0 (0)	0 (0)
INGROWTH <sup>1</sup>	0 (0)	0 (0)	0 (0)	2 <sup>1</sup> (5)	0 (0)	0 (0)	0 (0)
COMPARTMENTALIZATION <sup>1</sup>	0 (0)	0 (0)	0 (0)	2 <sup>1</sup> (5)	0 (0)	0 (0)	0 (0)
IMPLANT MATERIAL <sup>1</sup>	0 (0)	0 (0)	0 (0)	22 <sup>1</sup> (51)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC <sup>1</sup>	0 (0)	0 (0)	0 (0)	8 <sup>1</sup> (19)	0 (0)	0 (0)	0 (0)
MINERALIZATION	0 (0)	0 (0)	1 (50)	1 (2)	0 (0)	0 (0)	0 (0)
DEGENERATION <sup>1</sup>	0 (0)	0 (0)	0 (0)	9 <sup>1</sup> (21)	0 (0)	0 (0)	0 (0)
PIGMENT	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
<b>IMPLANT 3 - EXTRACAPSULAR</b>	# Ex 97	2	2	43	0	0	0
DERMIS-FIBROSIS	4 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
IMPLANT MATERIAL <sup>1</sup>	0 (0)	0 (0)	2 <sup>1</sup> (100)	30 <sup>1</sup> (70)	0 (0)	0 (0)	0 (0)
FIBROSIS <sup>1</sup>	0 (0)	0 (0)	1 <sup>1</sup> (50)	19 <sup>1</sup> (44)	0 (0)	0 (0)	0 (0)
INFLAMMATION, ACUTE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC <sup>1</sup>	1 (1)	0 (0)	0 (0)	7 <sup>1</sup> (16)	0 (0)	0 (0)	0 (0)
SQUAMOUS CELL HYPERPL-SKIN	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>IMPLANT 4 - CAPSULE</b>	# Ex 96	2	2	42	0	0	0
FIBROSIS <sup>1</sup>	0 (0)	2 <sup>1</sup> (100)	2 <sup>1</sup> (100)	33 <sup>1</sup> (79)	0 (0)	0 (0)	0 (0)
HYPERPLASIA, FIBROBLASTIC	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
INGROWTH	0 (0)	1 (50)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
COMPARTMENTALIZATION	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
IMPLANT MATERIAL <sup>1</sup>	0 (0)	1 <sup>1</sup> (50)	0 (0)	9 <sup>1</sup> (21)	0 (0)	0 (0)	0 (0)

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TABLE 11 (continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for Treated Animals With Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 2	M Gel 2	H Gel 43	L PE 1	M PE 19	H PE 52
<b>IMPLANT 4 - CAPSULE</b>	# Ex 96	2	2	42	0	0	0
INFLAMMATION, CHRONIC ACTIVE	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
INFLAMMATION, GRANULOMATOUS <sup>1</sup>	0 (0)	0 (0)	0 (0)	2 <sup>1</sup> (5)	0 (0)	0 (0)	0 (0)
MINERALIZATION	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
DEGENERATION <sup>1</sup>	0 (0)	0 (0)	0 (0)	3 <sup>1</sup> (7)	0 (0)	0 (0)	0 (0)
<b>IMPLANT 4 - EXTRACAPSULAR</b>	# Ex 96	2	2	42	0	0	0
DERMIS-FIBROSIS	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
IMPLANT MATERIAL <sup>1</sup>	0 (0)	1 <sup>1</sup> (50)	1 <sup>1</sup> (50)	14 <sup>1</sup> (33)	0 (0)	0 (0)	0 (0)
FIBROSIS <sup>1</sup>	0 (0)	0 (0)	1 <sup>1</sup> (50)	10 <sup>1</sup> (24)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
INFLAMMATION, GRANULOMATOUS	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
ULCER-SKIN	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
<b>IMPLANT SITE, NOS</b>	# Ex 98	2	2	43	1	19	52
ULCER	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
<b>JEJUNUM</b>	# Ex 89	2	1	36	1	17	48
PERFORATING ULCER	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>KIDNEYS</b>	# Ex 99	2	2	42	1	19	52
TUBULAR CELL HYPERPLASIA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
TRANSITIONAL CELL HYPERPLASIA	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	1 (2)
CHRONIC NEPHROPATHY <sup>1</sup>	66 (67)	1 (50)	2 (100)	27 <sup>1</sup> (64)	0 (0)	14 (74)	23 (44)
HYDRONEPHROSIS <sup>1</sup>	8 (8)	0 (0)	0 (0)	7 <sup>1</sup> (17)	0 (0)	0 (0)	7 (13)
CYST(S)	1 (1)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
HYALINE DROPLETS <sup>1</sup>	0 (0)	1 <sup>1</sup> (50)	1 <sup>1</sup> (50)	10 <sup>1</sup> (24)	0 (0)	5 <sup>1</sup> (26)	6 <sup>1</sup> (12)
MINERALIZATION	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
MINERALIZATION-PELVIS <sup>1</sup>	29 (29)	0 (0)	0 (0)	12 (28)	1 (100)	3 (16)	22 <sup>1</sup> (42)
CALCULI <sup>1</sup>	0 (0)	0 (0)	0 (0)	2 <sup>1</sup> (5)	0 (0)	0 (0)	0 (0)
PYELITIS	4 (4)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
PYELONEPHRITIS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, ACUTE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
CONGESTION	10 (10)	0 (0)	1 (50)	2 (5)	0 (0)	3 (16)	4 (8)
HEMORRHAGE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
EXTRAMEDULLARY HEMATOPOIESIS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FIBRIN THROMBI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
PROTEIN CASTS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
PIGMENT <sup>1</sup>	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	3 <sup>1</sup> (16)	4 <sup>1</sup> (8)
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FATTY CHANGE	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
<b>LARYNX</b>	# Ex 97	2	2	42	1	19	52
HYPERPLASIA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, ACUTE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
INFLAMMATION, CHRONIC <sup>1</sup>	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
ULCER	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
INGESTA	3 (3)	0 (0)	0 (0)	3 (7)	0 (0)	0 (0)	0 (0)
EXUDATE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
ABSCESS	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
<b>LIVER</b>	# Ex 99	2	2	43	1	19	52
TIGROID BASOPHILIC FOCUS	8 (8)	0 (0)	0 (0)	3 (7)	0 (0)	1 (5)	4 (8)
TIGROID BASOPHILIC FOCUS, MULT	4 (4)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)
EOSINOPHILIC FOCUS	13 (13)	0 (0)	0 (0)	4 (9)	0 (0)	0 (0)	5 (10)
EOSINOPHILIC FOCUS, MULT	2 (2)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
CLEAR CELL FOCUS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
HOMOGENEOUS BASOPHILIC FOCUS	4 (4)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
ANGIECTASIS <sup>1</sup>	3 (3)	0 (0)	0 (0)	5 <sup>1</sup> (12)	0 (0)	2 (11)	4 (8)



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TABLE 11 (continued)  
SUMMARY: Incidence of NON-NEDPLASTIC Microscopic Findings for Treated Animals With Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 2	M Gel 2	H Gel 43	L PE 1	M PE 19	H PE 52
<b>LIVER</b>	# Ex 99	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
CYSTIC DEGENERATION	9 (9)	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	1 (2)
FATTY CHANGE, NOS <sup>1</sup>	37 (37)	1 (50)	2 (100)	16 (37)	0 (0)	9 (47)	20 (38)
DEGENERATION, CENTRILOBULAR <sup>1</sup>	0 (0)	0 (0)	0 (0)	6 (14)	0 (0)	6 (32)	18 (35)
HYPERTROPHY, NOS <sup>1</sup>	2 (2)	0 (0)	0 (0)	3 (7)	0 (0)	3 (16)	11 (21)
NECROSIS, NOS	10 (10)	0 (0)	1 (50)	4 (9)	0 (0)	2 (10)	2 (4)
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FIBROSIS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (4)
CONGESTION	10 (10)	0 (0)	1 (50)	5 (12)	0 (0)	4 (21)	4 (8)
HEMORRHAGE	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
PIGMENT <sup>1</sup>	9 (9)	0 (0)	0 (0)	4 (9)	0 (0)	5 (26)	23 (44)
LEUKEMOID REACTION	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
EXTRAMEDULLARY HEMATOPOIESIS <sup>1</sup>	2 (2)	0 (0)	0 (0)	9 (21)	0 (0)	4 (21)	14 (27)
BILE DUCT HYPERPLASIA	3 (3)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)
BILIARY CYST(S)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
OVAL CELL HYPERPLASIA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
VASCULAR ECTASIA	11 (11)	0 (0)	0 (0)	4 (9)	0 (0)	1 (5)	6 (12)
<b>LUNGS</b>	# Ex 100	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
ALVEOLAR EPITH. HYPERPLASIA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
INTERSTITIAL PNEUMONIA	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	1 (2)
BRONCHOPNEUMONIA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
PLEURITIS	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
INFLAMMATION, ACUTE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
INFLAMMATION, GRANULOMATOUS	4 (4)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
CONGESTION	15 (15)	0 (0)	1 (50)	3 (7)	0 (0)	5 (26)	6 (12)
HEMORRHAGE <sup>1</sup>	0 (0)	1 (50)	0 (0)	3 (7)	0 (0)	0 (0)	1 (2)
THROMBUS/THROMBOSIS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
LEUKEMOID REACTION <sup>1</sup>	0 (0)	0 (0)	0 (0)	3 (7)	0 (0)	0 (0)	3 (6)
FIBRIN THROMBI	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
ADHESIONS	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
PIGMENT	3 (3)	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)
SQUAMOUS METAPLASIA	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
<b>LYMPH NODE, MANDIBULAR</b>	# Ex 85	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
PLASMACYTOSIS	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	2 (13)	1 (2)
ECTASIA/CYST(S)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ATROPHY	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
HEMORRHAGE <sup>1</sup>	0 (0)	1 (50)	0 (0)	1 (3)	0 (0)	0 (0)	5 (10)
INFLAMMATION, CHRONIC ACTIVE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
<b>LYMPH NODE, MEDIASTINAL</b>	# Ex 86	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
PIGMENT	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
HYPERPLASIA, LYMPHOID	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ECTASIA/CYST(S)	3 (3)	1 (50)	0 (0)	2 (5)	0 (0)	3 (17)	3 (6)
ATROPHY	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
HEMORRHAGE	2 (2)	0 (0)	0 (0)	1 (3)	0 (0)	1 (5)	3 (6)
<b>LYMPH NODE, MESENTERIC</b>	# Ex 98	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
HYPERPLASIA, LYMPHOID	1 (1)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
ATROPHY	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
HEMORRHAGE <sup>1</sup>	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	2 (4)
<b>LYMPH NODE, OTHER</b>	# Ex 26	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
PLASMACYTOSIS	1 (4)	0 (0)	0 (0)	1 (13)	0 (0)	0 (0)	1 (7)
HEMORRHAGE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (7)
FIBROSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (7)

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TABLE 11 (continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for Treated Animals With Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 2	M Gel 2	H Gel 43	L PE 1	M PE 19	H PE 52
<b>MAMMARY GLAND</b>	# Ex 100	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
FIBROCYSTIC DISEASE <sup>14</sup>	95 (95)	2 (100)	2 (100)	42 <sup>1</sup> (98)	1 (100)	16 (89)	48 <sup>1</sup> (92)
HYPERPLASIA	3 (3)	0 (0)	0 (0)	1 (2)	0 (0)	2 (11)	3 (6)
GALACTOCELE/CYST(S) <sup>1</sup>	6 (6)	1 <sup>1</sup> (50)	0 (0)	4 (9)	0 (0)	0 (0)	12 <sup>1</sup> (23)
ATYPICAL HYPERPLASIA	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ABSCCESS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ATROPHY	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>OPTIC NERVE</b>	# Ex 99	1	2	41	1	19	52
<b>OVARIES</b>	# Ex 99	2	2	43	1	19	52
CYST(S) <sup>1</sup>	27 (27)	0 (0)	0 (0)	12 <sup>1</sup> (28)	0 (0)	3 (16)	10 (19)
LUTEAL/STROMAL HYPERPLASIA	14 (14)	0 (0)	0 (0)	2 (3)	0 (0)	2 (11)	6 (12)
SERTOLI CELL HYPERPLASIA	7 (7)	0 (0)	0 (0)	1 (2)	0 (0)	1 (5)	4 (8)
CONGESTION	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (4)
<b>OVIDUCTS</b>	# Ex 98	2	1	43	1	19	52
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
CYST(S)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>PANCREAS</b>	# Ex 99	2	2	42	1	19	52
ATROPHY	7 (7)	0 (0)	0 (0)	3 (7)	0 (0)	1 (5)	3 (6)
FIBROSIS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC ACTIVE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
<b>PANCREATIC ISLETS</b>	# Ex 99	2	2	42	1	19	52
HYPERPLASIA	2 (2)	0 (0)	0 (0)	1 (2)	0 (0)	1 (5)	1 (2)
<b>PARATHYROID</b>	# Ex 98	2	2	39	0	18	50
HYPERPLASIA	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)
<b>PITUITARY</b>	# Ex 100	1	2	42	1	19	52
HYPERPLASIA	7 (7)	1 (100)	0 (0)	3 (7)	0 (0)	1 (5)	4 (8)
CYST(S) <sup>1</sup>	3 (3)	0 (0)	0 (0)	5 <sup>1</sup> (12)	0 (0)	2 (11)	3 (6)
ANGIECTASIS <sup>14</sup>	4 (4)	0 (0)	0 (0)	4 (10)	0 (0)	2 (11)	9 <sup>1</sup> (17)
THROMBOSIS/THROMBOSIS	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
<b>RECTUM</b>	# Ex 89	2	1	41	1	18	50
PROLIFERATIVE FASCICULITIS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, ACUTE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>SALIVARY GLAND</b>	# Ex 96	2	2	43	1	19	51
<b>SCIATIC NERVE</b>	# Ex 97	2	2	42	1	18	50
DEGENERATION	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>SKELETAL MUSCLE</b>	# Ex 99	2	2	42	1	19	52
MYOPATHY	4 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC ACTIVE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FIBROSIS	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ATROPHY	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>SKIN/SUBCUTIS</b>	# Ex 100	2	2	43	1	19	52
SQUAMOUS CELL HYPERPLASIA	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
CYST(S)/INCLUSION CYST(S) <sup>1</sup>	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	2 (4)
ULCER	5 (5)	0 (0)	1 (50)	2 (5)	0 (0)	0 (0)	4 (8)
ULCER, MULT	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	1 (5)	1 (2)
INFLAMMATION, CHRONIC ACTIVE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

\*

TABLE 11 (continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for Treated Animals With Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	SHAM 100	L Gel 2	M Gel 2	H Gel 43	L PE 1	M PE 19	H PE 52
<b>SKIN/SUBCUTIS</b>	# Ex 100	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
FIBROSIS	1 (1)	0 (0)	2 (100)	1 (2)	0 (0)	0 (0)	0 (0)
EDEMA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
SCAB	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
DERMIS-FIBROSIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
IMPLANT MATERIAL	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
<b>SPINAL CORD</b>	# Ex 99	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
MALACIA	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
HEMORRHAGE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	1 (2)
<b>SPLEEN</b>	# Ex 99	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
EXTRAMEDULLARY HEMATOPOIESIS <sup>1</sup>	31 (31)	1 <sup>1</sup> (50)	2 (100)	26 <sup>1</sup> (60)	0 (0)	14 <sup>1</sup> (74)	37 <sup>1</sup> (71)
HEMOSIDERIN	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
PERITONITIS	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
CYST-CAPSULE	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	1 (2)
FIBROSIS-CAPSULE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ATROPHY	3 (3)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)
<b>STERNUM - BONE DEGENERATION-CARTILAGE</b>	# Ex 99	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
DEGENERATION-CARTILAGE	12 (12)	0 (0)	1 (50)	2 (5)	0 (0)	3 (16)	5 (10)
<b>STERNUM - BONE MARROW HYPERPLASIA, MYELOID<sup>1</sup></b>	# Ex 99	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
HYPERPLASIA, MYELOID <sup>1</sup>	8 (8)	0 (0)	0 (0)	14 <sup>1</sup> (33)	0 (0)	8 <sup>1</sup> (42)	14 <sup>1</sup> (27)
HYPERPLASIA, NOS	2 (2)	0 (0)	0 (0)	2 (5)	0 (0)	2 <sup>1</sup> (11)	3 (6)
CYST(S)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
<b>STOMACH</b>	# Ex 96	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
EROSION <sup>1</sup>	9 (9)	0 (0)	0 (0)	7 <sup>1</sup> (17)	0 (0)	3 (16)	8 <sup>1</sup> (16)
EROSION, MULT <sup>1</sup>	0 (0)	1 <sup>1</sup> (50)	0 (0)	2 (5)	0 (0)	1 (5)	3 <sup>1</sup> (6)
ULCER <sup>1</sup>	1 (1)	0 (0)	0 (0)	3 <sup>1</sup> (7)	0 (0)	0 (0)	0 (0)
INFLAMMATION, ACUTE	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
ADHESIONS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
CONGESTION	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
MINERALIZATION	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>SYSTEMIC DISEASES</b>	# Ex 100	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
PERIARTERITIS	5 (5)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	1 (2)
PERITONITIS	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
SEPTICEMIA	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
<b>TAIL</b>	# Ex 18	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
ULCER	6 (33)	0 (0)	0 (0)	3 (33)	0 (0)	0 (0)	2 (29)
ULCER, MULTIPLE	3 (17)	0 (0)	0 (0)	2 (22)	0 (0)	0 (0)	0 (0)
SQUAMOUS CELL HYPERPLASIA	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)
CYST(S) INCLUSION CYST(S)	0 (0)	0 (0)	0 (0)	1 (11)	0 (0)	0 (0)	1 (14)
INFLAMMATION, CHRONIC	1 (6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC ACTIVE <sup>1</sup>	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 <sup>1</sup> (43)
ABSCESS	6 (33)	0 (0)	0 (0)	3 (33)	0 (0)	0 (0)	2 (29)
INFARCT	1 (6)	0 (0)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
<b>THYMUS</b>	# Ex 82	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
ATROPHY <sup>1</sup>	25 (30)	0 (0)	1 (100)	19 <sup>1</sup> (59)	0 (0)	8 <sup>1</sup> (50)	19 <sup>1</sup> (48)
CYST(S)	9 (11)	0 (0)	0 (0)	6 (20)	0 (0)	1 (6)	8 (20)
HEMORRHAGE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
HYPERPLASIA, EPITHELIAL	0 (0)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	1 (3)





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TABLE 11 (continued)  
SUMMARY: Incidence of NON-NEOPLASTIC Microscopic Findings for Treated Animals With Solid State Tumorigenesis

GROUP: NUMBER OF ANIMALS:	Sham 100	L Gel 2	M Gel 2	H Gel 43	L PE 1	M PE 19	H PE 52
<b>THYROID</b>	# Ex 98	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
FOLLICULAR CYST(S)	1 (1)	0 (0)	2 (100)	0 (0)	0 (0)	0 (0)	0 (0)
C-CELL HYPERPLASIA	7 (7)	0 (0)	0 (0)	3 (7)	0 (0)	0 (0)	6 (12)
ULTIMOBANCHIAL CYST(S)	15 (15)	0 (0)	1 (50)	4 (9)	0 (0)	2 (11)	8 (16)
<b>TRACHEA</b>	# Ex 99	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
INFLAMMATION, CHRONIC ACTIVE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
INGESTA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
EXUDATE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
<b>URINARY BLADDER</b>	# Ex 98	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
TRANSITIONAL CELL HYPERPLASIA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, ACUTE	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
<b>UTERUS</b>	# Ex 98	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
CYSTIC ENDOMETRIAL HYPERPLASIA <sup>11</sup>	76 (78)	2 <sup>1</sup> (100)	2 (100)	37 <sup>1</sup> (86)	1 (100)	15 (79)	45 <sup>1</sup> (87)
SQUAMOUS METAPLASIA	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INFLAMMATION, CHRONIC	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
CONGESTION	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
HEMORRHAGE	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
INTUSSUSCEPTION	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
INFLAMMATION, SUPPURATIVE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
<b>VAGINA</b>	# Ex 98	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
PROLIFERATIVE FASCICULITIS	11 (11)	0 (0)	1 (50)	1 (2)	0 (0)	1 (5)	2 (4)
FIBROSIS	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
ULCER	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
INFLAMMATION, CHRONIC <sup>1</sup>	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (6)
INFLAMMATION, CHRONIC ACTIVE	4 (4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
EXUDATE <sup>1</sup>	17 (17)	0 (0)	1 (50)	13 <sup>1</sup> (31)	0 (0)	4 (21)	8 (16)
<b>OTHER TISSUES AND LESIONS:</b>							
MESENTERY: STEATITIS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
MESENTERY: FAT NECROSIS	1 (1)	0 (0)	0 (0)	2 (5)	0 (0)	1 (5)	1 (2)
EAR/FINNA: PROLIF CHONDROPATHY	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (4)
MEDIAST: PLEURITIS <sup>1</sup>	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 <sup>1</sup> (6)
MESENTERY: PERITONITIS	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
URETER: NORMAL	1 (1)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)	0 (0)
MESENTERY: ACCESSORY SPLEEN	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
PINEAL GLAND: NORMAL <sup>1</sup>	1 (1)	0 (0)	0 (0)	2 <sup>1</sup> (5)	0 (0)	0 (0)	2 (4)
FACIAL BONE: FRACTURE	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ACCESSORY SEX GL: CHR ACT INFL	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
ACCESSORY SEX GL: NORMAL	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)
NERVES: DEGENERATION	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)

\*

## Legend - Table 11

Female Sprague Dawley rats were implanted subcutaneously with three dose levels of either mammary silicone gel or low density polyethylene. The implantation procedure was performed on sham control animals but no test material was introduced into the animals. Forty-six specified tissues and organs were collected from all animals for histopathology. Animals exhibiting SST were identified and the incidence of non-neoplastic lesions was calculated as the ratio of the number of animals bearing lesions at a site to the number of animals examined histologically (# Ex) and are reported as percents (%). A statistical analysis of lesion incidence was only performed if there were at least 2 observations in one of the experimental groups within a potential analysis. Silicone gel and PE groups were analyzed independently of one another.

Logistic regression analysis was the primary statistical method used to assess lesion incidence among treated and control groups. The life table test was applied to provide an appropriate approach for analyzing the incidence of rapidly lethal lesions (e.g. solid state tumors). In addition, the Fisher exact test and the Cochran-Armitage trend test were utilized although they are procedures which do not adjust for intercurrent mortality.

† Silicone gel group is significantly different from sham control group at  $p \leq 0.05$ . § Polyethylene group is significantly different from sham control group at  $p \leq 0.05$ . A statistical symbol immediately after the lesion indicates a significant trend for the silicone gel groups (†) or the polyethylene groups (§) at  $p \leq 0.05$ .

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Table 12: Organ Weights (grams)

A. All Animals

Organ	SHAM	L GEL	M GEL	H GEL	L PE	M PE	H PE
Brain	2.007 ± 0.015	2.024 ± 0.015	2.014 ± 0.014	2.003 ± 0.017	2.030 ± 0.017	2.021 ± 0.017	2.000 ± 0.018
Adrenal Glands	0.115 ± 0.007	0.142 ± 0.015	0.159 ± 0.021	0.112 ± 0.013	0.120 ± 0.008	0.175 ± 0.040	0.123 ± 0.012
Kidneys	3.215 ± 0.143	3.061 ± 0.076	3.075 ± 0.087	2.845 ± 0.080	2.897 ± 0.080	3.711 ± 0.597	3.002 ± 0.117
Liver	12.219 ± 0.448	11.740 ± 0.404	11.452 ± 0.353	11.251 ± 0.498	11.234 ± 0.381	11.592 ± 0.484	11.161 ± 0.393

B. Animals without Solid State Tumorigenesis

Organ	SHAM	L GEL	M GEL	H GEL	L PE	M PE	H PE
Brain	2.007 ± 0.015	2.024 ± 0.015	2.014 ± 0.015	2.016 ± 0.019	2.030 ± 0.017	2.028 ± 0.019	2.012 ± 0.022
Adrenal Glands	0.115 ± 0.007	0.142 ± 0.015	0.160 ± 0.021	0.123 ± 0.018	0.121 ± 0.008	0.182 ± 0.045	0.137 ± 0.019
Kidneys†	3.215 ± 0.143	3.061 ± 0.076	3.076 ± 0.089	2.777 ± 0.075	2.915 ± 0.080	3.837 ± 0.681	3.152 ± 0.179
Liver	12.219 ± 0.448	11.740 ± 0.404	11.406 ± 0.359	11.120 ± 0.540	11.323 ± 0.380	11.587 ± 0.516	10.957 ± 0.459

C. Animals with Solid State Tumorigenesis\*

Organ	SHAM	L GEL	M GEL	H GEL	L PE	M PE	H PE
Brain	2.007 ± 0.015	(f) ± (f)	2.016 ± (f)	1.969 ± 0.034	2.011 ± (f)	1.978 ± 0.040	1.981 ± 0.030
Adrenal Glands†	0.115 ± 0.007	(f) ± (f)	0.100 ± (f)	0.087 ± 0.007	0.087 ± (f)	0.124 ± 0.011	0.100 ± 0.007
Kidneys‡	3.215 ± 0.143	(f) ± (f)	3.020 ± (f)	3.026 ± 0.207	2.276 ± (f)	2.900 ± 0.597	2.770 ± 0.117
Liver	12.219 ± 0.448	(f) ± (f)	13.323 ± (f)	11.596 ± 1.176	8.011 ± (f)	11.627 ± 1.604	11.476 ± 0.722

\* statistics for control group animals, all of which were free of SST, are included for comparison.  
(f) No statistic calculated because insufficient measurements were available.

Legend - Table 12

Female Sprague Dawley rats were implanted subcutaneously with three dose levels of either mammary silicone gel or low density polyethylene. The implantation procedure was performed on sham control animals but no test material was introduced into the animals. Organ weights were collected from all animals surviving to scheduled necropsy. Animals exhibiting SST were identified and analyses were performed with and without data from these animals. Values represent group mean ± s.e. Based on an assessment of dose-related trend using Jonckheere's test, non-parametric multiple comparison methods (Shirley's or Dunn's) were used to assess treatment related effects.

† Silicone gel group is significantly different from sham control group at p≤0.05. § Polyethylene group is significantly different from sham control group at p≤0.05. A statistical symbol in the organ column indicates a significant trend for the silicone gel groups (†) or the polyethylene groups (§) at p≤0.05.

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Table 13: Organ To Body Weight Ratio

A. All Animals

Organ	SHAM	L GEL	M GEL	H GEL	L PE	M PE	H PE
Brain	4.78 ± 0.21	4.88 ± 0.18	4.63 ± 0.18	4.61 ± 0.24	4.78 ± 0.22	4.92 ± 0.30	4.98 ± 0.30
Adrenal Glands	0.27 ± 0.02	0.34 ± 0.04	0.37 ± 0.06	0.26 ± 0.04	0.28 ± 0.02	0.39 ± 0.07	0.32 ± 0.05
Kidneys	7.75 ± 0.59	7.26 ± 0.26	7.01 ± 0.32	6.47 ± 0.31	6.65 ± 0.24	9.95 ± 2.68	7.56 ± 0.64
Liver†	28.30 ± 1.22	27.40 ± 0.87	25.41 ± 0.64	24.80 ± 0.83	25.29 ± 0.64	26.60 ± 0.98	26.74 ± 1.07

B. Animals without Solid State Tumorigenesis

Organ	SHAM	L GEL	M GEL	H GEL	L PE	M PE	H PE
Brain	4.78 ± 0.21	4.88 ± 0.18	4.65 ± 0.18	4.65 ± 0.29	4.76 ± 0.22	4.92 ± 0.30	5.45 ± 0.41
Adrenal Glands	0.27 ± 0.02	0.34 ± 0.04	0.37 ± 0.06	0.29 ± 0.05	0.28 ± 0.02	0.41 ± 0.08	0.39 ± 0.07
Kidneys	7.75 ± 0.59	7.26 ± 0.26	7.05 ± 0.33	6.38 ± 0.40	6.66 ± 0.24	10.38 ± 3.06	8.45 ± 0.94
Liver†	28.30 ± 1.22	27.40 ± 0.87	25.43 ± 0.65	24.71 ± 1.01	25.38 ± 0.65	28.65 ± 1.07	28.77 ± 1.50

C. Animals with Solid State Tumorigenesis\*

Organ	SHAM	L GEL	M GEL	H GEL	L PE	M PE	H PE
Brain	4.78 ± 0.21	(f) ± (f)	3.70 ± (f)	4.49 ± 0.42	5.49 ± (f)	4.91 ± 1.22	4.24 ± 0.31
Adrenal Glands†	0.27 ± 0.02	(f) ± (f)	0.18 ± (f)	0.19 ± 0.01	0.24 ± (f)	0.31 ± 0.08	0.21 ± 0.01
Kidneys	7.75 ± 0.59	(f) ± (f)	5.55 ± (f)	6.69 ± 0.47	6.22 ± (f)	6.91 ± 1.27	5.84 ± 0.36
Liver†	28.30 ± 1.22	(f) ± (f)	24.47 ± (f)	23.04 ± 1.58	21.89 ± (f)	26.23 ± 2.60	23.60 ± 0.86

\* statistics for control group animals, all of which were free of SST, are included for comparison.  
(f) No statistic calculated because insufficient measurements were available.

Legend - Table 13

Female Sprague Dawley rats were implanted subcutaneously with three dose levels of either mammary silicone gel or low density polyethylene. The implantation procedure was performed on sham control animals but no test material was introduced into the animals. Organ weights were collected from all animals surviving to scheduled necropsy. Animals exhibiting SST were identified and analyses were performed with and without data from these animals. Values represent the mean ± s.e. of the individual ratios of organ weight (mg) to terminal body weight (grams). Based on an assessment of dose-related trend using Jonckheere's test, non-parametric multiple comparison methods (Shirley's or Dunn's) were used to assess treatment related effects.

† Silicone gel group is significantly different from sham control group at p ≤ 0.05. § Polyethylene group is significantly different from sham control group at p ≤ 0.05. A statistical symbol in the organ column indicates a significant trend for the silicone gel groups (†) or the polyethylene groups (§) at p ≤ 0.05.



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DC Report Number - 1998-10000-44643  
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## Legend - Table 14

Female Sprague Dawley rats were implanted subcutaneously with three dose levels of either mammary silicone gel or low density polyethylene. The implantation procedure was performed on sham control animals but no test material was introduced into the animals. Blood was collected from all animals surviving to scheduled necropsy and samples were subsequently prepared for hematological analysis. Animals exhibiting SST were identified and analyses were performed with and without data from these animals. Values represent the mean  $\pm$  s.e. Based on an assessment of dose-related trend using Jonckheere's test, non-parametric multiple comparison methods (Shirley's or Dunn's) were used to assess treatment related effects.

† Silicone gel group is significantly different from sham control group at  $p \leq 0.05$ . § Polyethylene group is significantly different from sham control group at  $p \leq 0.05$ . A statistical symbol in the parameter column indicates a significant trend for the silicone gel groups (†) or the polyethylene groups (§) at  $p \leq 0.05$ .

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Table 15: Clinical Chemistry

A. All Animals

Parameters	SHAM	L GEL	M GEL	H GEL	L PE	M PE	H PE
Albumin (g/dl)	3.59 ± 0.08	3.72 ± 0.07	3.60 ± 0.07	3.50 ± 0.11	3.66 ± 0.07	3.31 ± 0.14	3.60 ± 0.08
Globulin (g/dl)	3.64 ± 0.11	3.53 ± 0.07	3.45 ± 0.07	3.42 ± 0.11	3.44 ± 0.09	3.67 ± 0.18	3.49 ± 0.10
Albumin/Globulin ratio	1.02 ± 0.04	1.08 ± 0.03	1.06 ± 0.03	1.06 ± 0.05	1.09 ± 0.04	0.97 ± 0.06	1.06 ± 0.04
ALT (IU/L)	46.36 ± 5.21	46.38 ± 3.13	54.07 ± 4.60	48.04 ± 3.95	45.95 ± 5.51	54.06 ± 9.14	48.96 ± 7.47
AST (IU/L)	161.7 ± 9.9	174.1 ± 8.9	187.7 ± 13.4	183.3 ± 13.0	166.3 ± 8.3	177.4 ± 13.7	191.7 ± 19.6
Direct Bilirubin (mg/dl)	0.275 ± 0.048	0.238 ± 0.030	0.221 ± 0.019	0.364 ± 0.089	0.254 ± 0.033	0.259 ± 0.042	0.218 ± 0.037
Total Bilirubin (mg/dl)	0.247 ± 0.027	0.216 ± 0.014	0.214 ± 0.009	0.293 ± 0.058	0.216 ± 0.018	0.209 ± 0.013	0.271 ± 0.038
Urea Nitrogen (mg/dl)	19.11 ± 3.49	14.20 ± 0.67	14.33 ± 0.66	16.25 ± 0.79	14.30 ± 0.44	16.44 ± 0.92	15.68 ± 0.44
Calcium (mg/dl)	10.11 ± 0.12	10.16 ± 0.07	9.96 ± 0.07	10.18 ± 0.16	9.97 ± 0.07	9.94 ± 0.12	10.17 ± 0.13
Chloride (mmol/l)	103.7 ± 0.7	104.1 ± 0.5	104.2 ± 0.5	104.9 ± 0.6	103.8 ± 0.5	104.1 ± 0.7	103.8 ± 0.7
Creatinine (mg/dl)	0.822 ± 0.051	0.780 ± 0.017	0.748 ± 0.018	0.811 ± 0.021	0.803 ± 0.020	0.747 ± 0.017	0.793 ± 0.033
GGT (IU/L) <sup>a</sup>	10.94 ± 0.65	11.80 ± 0.88	13.67 ± 0.86	12.86 ± 1.07	12.32 ± 1.09	14.44 ± 1.50	11.75 ± 0.82
Phosphorus (mg/dl)	6.14 ± 0.27	5.78 ± 0.11	5.67 ± 0.11	6.01 ± 0.16	5.68 ± 0.13	5.94 ± 0.13	5.80 ± 0.17
Potassium (mmol/l)	3.87 ± 0.08	3.86 ± 0.08	3.94 ± 0.07	3.89 ± 0.11	3.79 ± 0.09	3.95 ± 0.10	3.96 ± 0.13
Serum Glucose (mg/dl)	102.1 ± 3.8	108.0 ± 3.7	109.0 ± 3.6	112.4 ± 3.1	104.3 ± 3.2	101.7 ± 3.2	105.1 ± 5.5
Sodium (mmol/l)	145.5 ± 0.9	145.1 ± 0.4	144.9 ± 0.5	144.8 ± 0.4	144.8 ± 0.3	145.3 ± 0.5	145.1 ± 0.6
Total Protein (g/dl)	7.24 ± 0.12	7.26 ± 0.09	7.05 ± 0.10	6.93 ± 0.14	7.09 ± 0.09	6.97 ± 0.15	7.09 ± 0.11

B. Animals without Solid State Tumorigenesis

Parameters	SHAM	L GEL	M GEL	H GEL	L PE	M PE	H PE
Albumin (g/dl)	3.59 ± 0.08	3.72 ± 0.07	3.60 ± 0.07	3.57 ± 0.15	3.66 ± 0.07	3.29 ± 0.15	3.61 ± 0.12
Globulin (g/dl)	3.64 ± 0.11	3.53 ± 0.07	3.45 ± 0.08	3.47 ± 0.12	3.44 ± 0.09	3.76 ± 0.20	3.65 ± 0.13
Albumin/Globulin ratio	1.02 ± 0.04	1.08 ± 0.03	1.06 ± 0.03	1.05 ± 0.06	1.09 ± 0.04	0.95 ± 0.06	1.01 ± 0.05
ALT (IU/L) <sup>a</sup>	46.36 ± 5.21	46.38 ± 3.13	54.46 ± 4.70	51.80 ± 4.61	46.42 ± 5.64	54.46 ± 10.35	52.00 ± 11.66
AST (IU/L)	161.7 ± 9.9	174.1 ± 8.9	187.8 ± 13.7	166.9 ± 10.2	165.8 ± 8.5	182.1 ± 15.2	174.0 ± 26.1
Direct Bilirubin (mg/dl)	0.275 ± 0.048	0.238 ± 0.030	0.220 ± 0.020	0.345 ± 0.106	0.256 ± 0.034	0.264 ± 0.047	0.253 ± 0.058
Total Bilirubin (mg/dl)	0.247 ± 0.027	0.216 ± 0.014	0.215 ± 0.010	0.275 ± 0.070	0.217 ± 0.018	0.214 ± 0.014	0.318 ± 0.094
Urea Nitrogen (mg/dl)	19.11 ± 3.49	14.20 ± 0.67	14.22 ± 0.66	16.05 ± 0.98	14.31 ± 0.45	16.32 ± 1.00	15.29 ± 1.17
Calcium (mg/dl)	10.11 ± 0.12	10.16 ± 0.07	9.96 ± 0.08	10.01 ± 0.14	9.97 ± 0.07	9.92 ± 0.14	10.14 ± 0.14
Chloride (mmol/l)	103.7 ± 0.7	104.1 ± 0.5	104.2 ± 0.5	104.6 ± 0.8	103.8 ± 0.5	103.9 ± 0.8	103.1 ± 0.8
Creatinine (mg/dl)	0.822 ± 0.051	0.780 ± 0.017	0.749 ± 0.018	0.815 ± 0.023	0.803 ± 0.021	0.757 ± 0.018	0.771 ± 0.049
GGT (IU/L) <sup>a</sup>	10.94 ± 0.65	11.80 ± 0.88	13.78 ± 0.87	13.00 ± 1.16	12.47 ± 1.11	13.00 ± 1.66	11.53 ± 0.80
Phosphorus (mg/dl)	6.14 ± 0.27	5.78 ± 0.11	5.67 ± 0.11	5.97 ± 0.19	5.69 ± 0.13	6.00 ± 0.14	5.98 ± 0.26
Potassium (mmol/l)	3.87 ± 0.08	3.86 ± 0.08	3.94 ± 0.07	3.89 ± 0.13	3.79 ± 0.09	3.96 ± 0.12	4.08 ± 0.20
Serum Glucose (mg/dl)	102.1 ± 3.8	108.0 ± 3.7	109.1 ± 3.7	113.8 ± 4.0	104.81 ± 3.25	99.18 ± 5.25	99.71 ± 7.45
Sodium (mmol/l)	145.5 ± 0.9	145.1 ± 0.4	144.9 ± 0.5	144.9 ± 0.5	144.8 ± 0.4	145.3 ± 0.6	145.1 ± 0.9
Total Protein (g/dl)	7.24 ± 0.12	7.26 ± 0.09	7.05 ± 0.10	7.04 ± 0.17	7.11 ± 0.09	7.05 ± 0.14	7.26 ± 0.15

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Table 15: Clinical Chemistry (continued)

C. Animals with Solid State Tumorigenesis<sup>a</sup>

Parameters	SHAM	L GEL	M GEL	H GEL	L PE	M PE	H PE
Albumin (g/dl)	3.59 ± 0.08	(d) ± (d)	3.60 ± (d)	3.35 ± 0.11	3.40 ± (d)	3.43 ± 0.42	3.59 ± 0.12
Globulin (g/dl)	3.64 ± 0.11	(d) ± (d)	3.40 ± (d)	3.70 ± 0.25	3.20 ± (d)	2.98 ± 0.29	3.25 ± 0.12
Albumin/Globulin ratio	1.02 ± 0.04	(d) ± (d)	1.06 ± (d)	1.07 ± 0.1	1.06 ± (d)	1.14 ± 0.04	1.12 ± 0.04
ALT (IU/L)	46.36 ± 5.21	(d) ± (d)	38.00 ± (d)	38.63 ± 6.95	29.00 ± (d)	51.25 ± 12.47	44.27 ± 6.63
AST (IU/L) <sup>†</sup>	161.7 ± 9.9	(d) ± (d)	185.0 ± (d)	224.3 ± 35.0	183.0 ± (d)	144.5 ± 19.8	219.0 ± 28.8
Direct Bilirubin (mg/dl)	0.275 ± 0.048	(d) ± (d)	0.300 ± (d)	0.413 ± 0.173	0.280 ± (d)	0.225 ± 0.048	0.164 ± 0.024
Total Bilirubin (mg/dl)	0.247 ± 0.027	(d) ± (d)	0.200 ± (d)	0.338 ± 0.113	0.200 ± (d)	0.175 ± 0.025	0.200 ± 0.019
Urea Nitrogen (mg/dl)	19.11 ± 3.49	(d) ± (d)	19.00 ± (d)	16.75 ± 1.32	14.00 ± (d)	17.25 ± 2.36	18.27 ± 1.18
Calcium (mg/dl)	10.11 ± 0.12	(d) ± (d)	9.90 ± (d)	10.60 ± 0.43	10.00 ± (d)	10.10 ± 0.25	10.22 ± 0.25
Chloride (mmol/l)	103.7 ± 0.7	(d) ± (d)	104.0 ± (d)	105.8 ± 1.1	104.0 ± (d)	105.8 ± 1.2	104.8 ± 1.3
Cholesterol (mg/dl)	0.822 ± 0.051	(d) ± (d)	0.700 ± (d)	0.800 ± 0.046	0.800 ± (d)	0.875 ± 0.048	0.827 ± 0.036
GGT (IU/L)	10.94 ± 0.65	(d) ± (d)	9.00 ± (d)	12.50 ± 2.34	7.00 ± (d)	10.50 ± 2.40	12.09 ± 1.74
Phosphorus (mg/dl)	6.14 ± 0.27	(d) ± (d)	5.40 ± (d)	6.11 ± 0.31	5.40 ± (d)	5.33 ± 0.14	5.54 ± 0.12
Potassium (mmol/l)	3.87 ± 0.08	(d) ± (d)	4.10 ± (d)	3.89 ± 0.21	3.70 ± (d)	3.89 ± 0.12	3.76 ± 0.11
Serum Glucose (mg/dl)	102.1 ± 3.8	(d) ± (d)	105.0 ± (d)	108.9 ± 4.3	85.00 ± (d)	119.50 ± 18.93	113.86 ± 7.53
Sodium (mmol/l)	145.5 ± 0.9	(d) ± (d)	144.0 ± (d)	144.5 ± 0.8	145.0 ± (d)	145.5 ± 1.2	145.2 ± 0.7
Total Protein (g/dl)	7.24 ± 0.12	(d) ± (d)	7.00 ± (d)	6.65 ± 0.23	6.60 ± (d)	6.40 ± 0.70	6.84 ± 0.16

<sup>a</sup> statistics for control group animals, all of which were free of SST, are included for comparison.

(d) No statistic calculated because insufficient measurements were available.

Legend - Table 15

Female Sprague Dawley rats were implanted subcutaneously with three dose levels of either mammary silicone gel or low density polyethylene. The implantation procedure was performed on sham control animals but no test material was introduced into the animals. Blood was collected from all animals surviving to scheduled necropsy and samples were subsequently prepared for serum chemistry analysis. Animals exhibiting SST were identified and analyses were performed with and without data from these animals. Values represent the mean ± s.e. Based on an assessment of dose-related trend using Jonckheere's test, non-parametric multiple comparison methods (Shirley's or Duan's) were used to assess treatment related effects.

† Silicone gel group is significantly different from sham control group at p≤0.05. § Polyethylene group is significantly different from sham control group at p≤0.05. A statistical symbol in the parameter column indicates a significant trend for the silicone gel groups (†) or the polyethylene groups (§) at p≤0.05.





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Table 16: Urine Analysis

A. All Animals

Parameters	SHAM	L GEL	M GEL	H GEL	L PE	M PE	H PE
Urine Glucose (mg/dl)	0.000 ± 0.000	0.000 ± 0.000	0.000 ± 0.000	0.000 ± 0.000	0.000 ± 0.000	0.031 ± 0.031	0.036 ± 0.036
Urine Ketones (mg/dl) <sup>a</sup>	0.108 ± 0.052	0.067 ± 0.038	0.000 ± 0.000	0.000 ± 0.000	0.081 ± 0.060	0.125 ± 0.074	0.143 ± 0.067
Urine Protein (mg/dl)	2.95 ± 0.20	3.00 ± 0.15	2.93 ± 0.20	2.76 ± 0.21	2.73 ± 0.21	2.72 ± 0.24	3.00 ± 0.19
Urine Bilirubin	0.081 ± 0.045	0.067 ± 0.038	0.048 ± 0.033	0.034 ± 0.034	0.081 ± 0.045	0.156 ± 0.091	0.071 ± 0.071
Blood in Urine	0.973 ± 0.256	0.622 ± 0.189	0.571 ± 0.178	0.863 ± 0.220	0.838 ± 0.214	0.844 ± 0.258	0.929 ± 0.281
Urine pH	5.91 ± 0.08	5.73 ± 0.07	6.05 ± 0.09	5.74 ± 0.11	5.78 ± 0.09	5.91 ± 0.11	5.88 ± 0.12
Urine Volume (ml)	14.22 ± 1.37	13.49 ± 1.08	12.76 ± 0.79	12.52 ± 1.01	13.24 ± 1.08	13.03 ± 1.11	11.64 ± 1.10
Urobilinogen (E.U./dl)	0.330 ± 0.049	0.307 ± 0.041	0.295 ± 0.040	0.393 ± 0.065	0.308 ± 0.046	0.358 ± 0.071	0.400 ± 0.067
Refractive Index (ND)	1.34 ± 0.00	1.34 ± 0.00	1.34 ± 0.00	1.34 ± 0.00	1.34 ± 0.00	1.34 ± 0.00	1.34 ± 0.00

B. Animals without Solid State Tumorigenesis

Parameters	SHAM	L GEL	M GEL	H GEL	L PE	M PE	H PE
Urine Glucose (mg/dl)	0.000 ± 0.000	0.000 ± 0.000	0.000 ± 0.000	0.000 ± 0.000	0.000 ± 0.000	0.036 ± 0.036	0.059 ± 0.059
Urine Ketones (mg/dl) <sup>a</sup>	0.108 ± 0.052	0.067 ± 0.038	0.000 ± 0.000	0.000 ± 0.000	0.083 ± 0.061	0.143 ± 0.085	0.176 ± 0.095
Urine Protein (mg/dl)	2.95 ± 0.20	3.00 ± 0.15	2.90 ± 0.20	2.52 ± 0.26	2.78 ± 0.21	2.79 ± 0.26	3.06 ± 0.28
Urine Bilirubin	0.081 ± 0.045	0.067 ± 0.038	0.049 ± 0.034	0.000 ± 0.000	0.083 ± 0.047	0.179 ± 0.104	0.118 ± 0.118
Blood in Urine	0.973 ± 0.256	0.622 ± 0.189	0.537 ± 0.178	0.762 ± 0.248	0.861 ± 0.219	0.821 ± 0.268	1.176 ± 0.385
Urine pH	5.91 ± 0.08	5.73 ± 0.07	6.06 ± 0.09	5.90 ± 0.13	5.81 ± 0.09	5.96 ± 0.12	5.91 ± 0.16
Urine Volume (ml)	14.22 ± 1.37	13.49 ± 1.08	12.78 ± 0.81	12.81 ± 1.09	13.31 ± 1.11	13.36 ± 1.23	10.18 ± 1.37
Urobilinogen (E.U./dl)	0.330 ± 0.049	0.307 ± 0.041	0.298 ± 0.041	0.390 ± 0.076	0.311 ± 0.047	0.350 ± 0.077	0.435 ± 0.091
Refractive Index (ND)	1.34 ± 0.00	1.34 ± 0.00	1.34 ± 0.00	1.34 ± 0.00	1.34 ± 0.00	1.34 ± 0.00	1.34 ± 0.00

C. Animals with Solid State Tumorigenesis<sup>a</sup>

Parameters	SHAM	L GEL	M GEL	H GEL	L PE	M PE	H PE
Urine Glucose (mg/dl)	0.000 ± 0.000	(f) ± (f)	0.000 ± (f)	0.000 ± 0.000	0.000 ± (f)	0.000 ± 0.000	0.000 ± 0.000
Urine Ketones (mg/dl)	0.108 ± 0.052	(f) ± (f)	0.000 ± (f)	0.000 ± 0.000	0.000 ± (f)	0.000 ± 0.000	0.091 ± 0.091
Urine Protein (mg/dl)	2.95 ± 0.20	(f) ± (f)	4.00 ± (f)	3.38 ± 0.26	1.00 ± (f)	2.25 ± 0.63	2.91 ± 0.25
Urine Bilirubin	0.081 ± 0.045	(f) ± (f)	0.000 ± (f)	0.125 ± 0.125	0.000 ± (f)	0.000 ± 0.000	0.000 ± 0.000
Blood in Urine	0.973 ± 0.256	(f) ± (f)	2.000 ± (f)	1.125 ± 0.479	0.000 ± (f)	1.000 ± 1.000	0.545 ± 0.350
Urine pH <sup>a</sup>	5.91 ± 0.08	(f) ± (f)	5.50 ± (f)	5.31 ± 0.13	5.00 ± (f)	5.50 ± 0.20	5.82 ± 0.17
Urine Volume (ml)	14.22 ± 1.37	(f) ± (f)	12.00 ± (f)	11.75 ± 2.36	11.00 ± (f)	10.75 ± 2.29	13.91 ± 1.68
Urobilinogen (E.U./dl)	0.330 ± 0.049	(f) ± (f)	0.200 ± (f)	0.400 ± 0.131	0.200 ± (f)	0.400 ± 0.200	0.345 ± 0.098
Refractive Index (ND)	1.34 ± 0.00	(f) ± (f)	1.34 ± (f)	1.34 ± 0.00	1.34 ± (f)	1.34 ± 0.00	1.34 ± 0.00

<sup>a</sup> statistics for control group animals, all of which were free of SST, are included for comparison.  
(f) No statistic calculated because insufficient measurements were available.

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## Legend - Table 16

Female Sprague Dawley rats were implanted subcutaneously with three dose levels of either mammary silicone gel or low density polyethylene. The implantation procedure was performed on sham control animals but no test material was introduced into the animals. Urine was collected from all animals surviving to scheduled necropsy the night prior to sacrifice. Animals exhibiting SST were identified and analyses were performed with and without data from these animals. Values represent the mean  $\pm$  s.e. Based on an assessment of dose-related trend using Jonckheere's test, non-parametric multiple comparison methods (Shirley's or Dunn's) were used to assess treatment related effects.

† Silicone gel group is significantly different from sham control group at  $p \leq 0.05$ . § Polyethylene group is significantly different from sham control group at  $p \leq 0.05$ . A statistical symbol in the parameter column indicates a significant trend for the silicone gel groups (†) or the polyethylene groups (§) at  $p \leq 0.05$ .

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Table 17

## Protocol Deviations

1. Surgical staples were inadvertently removed from the surgical sites of animal B8597 (Group 5 Low Dose Polyethylene) after four days which was prior to the seven day period specified in the study protocol. The animal was a replacement for an animal which had died following surgery and was in a group of animals scheduled to have surgical staples removed on that day. Early removal of the staples did not require re-stapling of the surgical sites and did not result in the loss of either of the two implants.

Date: 4/23/91

2. *Section of Protocol Deviated From:* 11.5: Urine Analysis Functions  
*Deviation:* Microscopic examination of urine performed. Not indicated in the protocol.  
*Reason for Deviation:* Inadvertent omission from the original protocol.

Date: 11/13/92

3. *Section of Protocol Deviated From:* 11.3: Serum Chemistry Functions  
*Deviation:* Due to limitations of Xybion System®, derived calculations for IBTL, AG, Glob do not appear in Xybion raw data, but do appear on summary tables.  
*Reason for Deviation:* Inherent limitation of the Xybion System® will not allow for entry of IBTL, AG, Glob into the Xybion® database. As such, the datasets and calculated results will not appear in Xybion® records, but will be included in the hardcopy study records (summary tables).

Date: 11/13/92

4. *Section of Protocol Deviated From:* Study Personnel  
*Deviation:* Mark Evans assumed the responsibilities of Study Pathologist as of January 25, 1993  
*Reason for Deviation:* The former Pathologist, Mark Zimmer, was no longer employed by Dow Corning and Mark Evans assumed most of his work responsibilities.

The change in personnel was described in a Memo to File dated January 25, 1993. Upon further consideration by Quality Assurance, it was decided that this Memo was inappropriate documentation for a change in study personnel and that documentation after the fact would need to be in the form of a Deviation.

Date: 12/16/93

5. *Section of Protocol Deviated From:* Diet Information  
*Deviation:* The diet used on this study was Purina Certified Rodent Chow #5002C  
*Reason for Deviation:* The diet was not adequately identified in the protocol as required by GLPs, Section 58.120 (T).

Date: 12/29/93

Table 17

Protocol Deviations

6. *Section of Protocol Deviated From:* Histopathology Instructions

*Deviation:* Following tissue collection sessions during final necropsy at Dow Corning, tissues were sent to American Histolabs (Gaithersburg, MD) for histological processing. Pathology was subsequently performed by Dr. Dawn Goodman of Pathco, Inc. (Ijamsville, MD) whom was designated as reading pathologist for this study.

*Reason for Deviation:* These institutions were better equipped and organized to perform histology and pathology on the large number of tissues in a timely fashion.

Date: 1/25/94

7. *Section of Protocol Deviated From:* Statistical Tests for Study

*Deviation:* Brain organ weight ratios were calculated and reported on Xybion

*Reason for Deviation:* Organ weight ratios were calculated using brain weights as brain weights are relatively stable values as compared to whole body weights. Consequently, a brain organ ratio is better indicative of any fluctuations or changes in organ weights.

Date: 1/25/94

8. *Section of Protocol Deviated From:* Statistical Tests for Study

*Deviation:* The statistical methods and comparisons utilized for this study were modified and conducted by Mr. Steven Seilkop, Analytical Sciences, Inc. (ASI), Durham, NC. A description of the statistical methods is attached.

*Reason for Deviation:* ASI was better equipped to conduct the analyses in a reasonable time frame considering the large volume and complexity of the data sets. In addition, an analysis such as this conducted by an experienced and reputable source allows for greater confidence in the results and conclusions. ASI's services vary from short-term expert statistical consulting to multiple person, long-term efforts. ASI is a recognized leader in the statistical analysis of toxicological data as is reflected by two, successive five year contracts with the National Institute of Environmental Health Sciences for whom they have performed analyses on carcinogenesis bioassays and animal toxicity studies.

Date: 9/14/94

9. The protocol is amended to a higher weight range to reflect the actual weight range at randomization. The age of the animals has not changed.

Date: 10/30/90

10. The protocol is amended to a higher weight range to reflect the actual weight range at randomization. The age of the animals has not changed.

The second part of this amendment is to change the leg that the anesthetic is injected into, from right to left, in section 14.2 "Administration of Test Substance". This is being done to match the leg which will used in moribund or humane sacrifices and the final necropsy. This will prevent the skeletal muscle sample which is taken, from the right leg according to the necropsy SOP, from having any scar tissue or other effects as a result of anesthetic administration.

Date: 10/30/90



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Table 17

Protocol Deviations

11. Reason: Modification to fit developing situation in and after surgery.

*Special Instructions:* Animals for this study will be evaluated by the Attending Veterinarian as to their suitability for the study. This will include a pre-study health screen on 10 animals selected from different parts of the animal room which includes gross necropsy, clinical chemistry and hematology, urinalysis, and a fecal examination for ova and parasites. During the gross necropsy, at least the following tissues will be collected for possible histopathologic evaluation: lung, liver, kidney, spleen, salivary gland and lymph node, and Hardarian gland. Serum samples will be retained for six months from the start of the surgery for possible use should a pre-existing infectious disease becomes suspect during this time period. In addition to the pre-study health screen, an ophthalmoscopic examination will be conducted. The report of these evaluations will be maintained as a part of the study record.

Approved animals will be randomized to groups and then assigned to cages using the XYBION Path/Tox System.

Prior to final necropsy, all surviving animals will again undergo an ophthalmoscopic examination.

The basic study design is presented below in tabular form. Group 1 is the sham control group and 4 sites will be created surgically to mirror the number of implants in the primary study groups (Groups 2 through 4). Groups 5 through 7 will be implanted with only 2 implants per animal. This is because of size constraints in recovery of implants. In addition to this difference, the total surface areas of the silicone gel and polyethylene groups overlap, but do not directly coincide. These differences will not affect the intended use of these groups since their purpose is to generate animals with operational solid state tumors.

STUDY DESIGN

Group/ Material	Number/ Size	Total		equivalent	
		Volume	Surface Area	Volume	Surface Area
1-Sham	4/0.0ml	0.0ml	0.0cm.sq	0.0ml	0.0cm.sq.
2-Gel	4/0.2ml	0.8ml	6.6cm.sq	100ml	825cm.sq.
3-Gel	4/0.9ml	3.6ml	18.0cm.sq	450ml	2,250cm.sq
4-Gel*	4/4.0ml	16.0ml	48.8cm.sq.	2,000ml	6,100cm.sq.
5-PE	2/0.5 cm diam.	-	0.79cm.sq	-	-
6-PE	2/1.0cm diam.	-	3.14cm.sq	-	-
7-PE	2/2.0cm diam	-	12.56cm.sq.	-	-

\* Equivalent doses calculated assuming a mature body weight in female rats of 400 grams and female humans of 50 kilograms.

During the conduct of the study, preservation of tumor histology will be a significant concern. Therefore, when there is evidence that a tumor is becoming necrotic or the tumor is approximately 10 cm in its largest dimension, the animal will be sacrificed. Animals may also be sacrificed for humane reasons during the course of the study.

*Administration of Test Substance:* Surgical implantation will occur over a ten working day period. The order of surgery will be by cage order, starting with cage 1 and proceeding to cage 700. The work will be divided into approximately 10 seventy animal days, though, some variation in the number of animals implanted in a given day is acceptable. Surgeons will implant the next available animal, without regard to the assigned treatment group.

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Table 17

## Protocol Deviations.

Animals from the Sham Operated Control group (group 1) will have 4 surgical sites opened and closed without the introduction of either test or control materials. Animals from the 3 gel treated groups (groups 2, 3 and 4) will have 4 surgical sites opened and the appropriate amount of gel introduced into each site before closure of the wound. Animals from the 3 polyethylene control groups (groups 5, 6 and 7) will have 2 surgical sites opened and the appropriate sized disk introduced into each site before closure of the wound.

Prior to implant placement or sham surgery, each animal will be anesthetized with 90 mg/kg body weight ketamine HCl and 10 mg/kg body weight xylazine, both given intramuscularly in the muscles of the left thigh. A bland ophthalmic ointment will be applied to the corneas to minimize drying. The dorsal thorax and abdomen of each animal is clipped free of hair and scrubbed with a povidone iodine scrub. A final application of a chlorhexidine gluconate solution will be applied to the animal when it is on the surgery table.

All implantation will be accomplished under anesthesia, using aseptic technique and in an area meeting appropriate standard of veterinary care. The animal will be draped with a sterile drape. Either 2 or 4 surgical incisions are made, depending upon the group. Each incision is made and the implantation completed separately. The incision is made with the point of a scalpel and extended up to approximately 2cm in length. Any bleeding is controlled by direct pressure. A subcutaneous pocket of the appropriate size for the implant is bluntly dissected to the ventro-lateral aspect of the incision and the implant introduced. The incision is then closed with surgical staples using care to avoid the loss of any implant or implant material.

Should it be necessary to replace an animal due to death or other untoward happening during the surgical period, this will be documented, and a replacement animal will be selected from the animals not originally selected during the randomization process. This replacement animal will be assigned the ear tag number of the animal which it is replacing. At the end of the surgical period, all remaining animals will be returned to the Animal Resources Department.

Surgical staples will be removed at any time from seven days after surgery (surgery is day 1) up to approximately fourteen days after implantation. The specific day will be recorded in the study records.

*Histopathology Instructions:* All tissues specified by this protocol will be examined microscopically for all animals. All tissues will be routinely processed, embedded in paraffin, sectioned and stained with hematoxylin and eosin. Special stains and/or recuts and rewets/reblocks will be performed at the discretion of the pathologist.

Every reasonable effort will be made to identify, collect and examine all tissues specified in this protocol. In the course of study conduct, occasional tissues may not be identified and this occurrence will be documented. An opinion as to the adequacy of the tissues available for evaluation, both in quantity and quality, will be addressed in writing by the pathologist.

*Additional Tissues:* Tissues not specified by protocol may be examined and collected to further define possible treatment-related effects at the discretion of the pathologist.

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*Tissue Preservation:* Tissues collected for standard light microscopy will be preserved in 10% buffered formalin in a ratio of approximately 10:1 formalin to tissue. Once collected, tissues will be gently swirled on a gyratory shaker for approximately four hours to improve fixation.

*Amendments to Protocol:* Any change in the approved protocol and the reason therefore will be documented, signed by the Study Director, dated, and maintained with the original hard copy of the protocol. Alterations may be authorized verbally by the Study Director, or Alternate when the Study Director is not available in a timely fashion. This authorization is to be followed by an appropriate formal protocol amendment. A copy of the change(s) shall be given to the quality Assurance Unit. Change(s) which may have an impact upon the conditions of animal care, use or treatment will be discussed with the Attending Veterinarian in advance, if possible, and followed by delivery of a copy of the change(s) for review.

Date: 11/8/90

- 12. The animals on this study are being moved from room 195 to room 194 effective today. This is being done to allow room 195 to undergo maintenance which had not be anticipated at the start of the study. This move will be permanent. No adverse effects have occurred from the paint problems which required the move, and no adverse effects are anticipated form the move.

Date: 3/1/91

- 13. This amendment to the protocol is being done to add language to the protocol in Section 4 to bring the protocol into compliance with current Animal Welfare Act regulations. No change in actual study conduct is intended or anticipated.

Date: 3/28/91

- 14. Reason: Changed lab organization (Study Director by memo from J. J. Clary).  
*Study Personnel:*

Study Director	Paal C. Klykken
Study Pathologist	Gary J. Sibert
Principal Investigator	Stefanie A. Hunter
Investigator	Sharon Mudgett
Alternate Study Director	Lawrence Ruhr

Date: 12/20/91

- 15. The responsible department has been changed from the Quality Assurance Unit to Sample Handling Unit.

Date: 5/7/92

A 04

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Table 17

Protocol Deviations

16. Reason: Gary Sibert is no longer with the company.

Study Personnel:

Study Pathologist	Mark Zimmer
Principal Investigator	Stefanie A. Hunter
Investigator	Sharon Mudgett
Alternate Study Director	Lawrence Ruhr

Approval date: Mon. 29-Oct-90

17. Reason: To add to list of current investigators.

Study Personnel:

Approval date: Mon. 29-Oct-90

Study Pathologist	Mark Zimmer
Principal Investigator	Stefanie A. Hunter
Investigator	Sharon Mudgett
Alternate Study Director	Lawrence Ruhr
Investigator	Terry Lassitter
Investigator	Steven Macalpine
Investigator	Joan A. Barnekow

Date: 6/2/92

18. Reason: Inadvertently entered the wrong text.

Study Personnel:

Approval date: Mon. 29-Oct-90

Study Pathologist	Mark Zimmer
Principal Investigator	Stefanie A. Hunter
Investigator	Sharon Mudgett
Alternate Study Director	Lawrence Ruhr
Investigator	Terry Lassitter
Investigator	Steven Macalpine
Investigator	Joan A. Barnekow

Date: 6/2/92

19. Reason: Added additional necropsy days per section 11.6.1 of protocol.

Proposed dates:

Study start date	Wed. 31-Oct-90
Study completion date	Tue. 31-Aug-93

Sacrifice Date:

Final sacrifice:	Mon. 02-Nov-92	No. of days: 5
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Table 17

Protocol Deviations

*Further Information:* Ten working days are presently scheduled for surgery and final necropsy.  
See section 11.6.1 for further information.

Date: 11/2/92

20. Reason: Added additional necropsy days per section 11.6.1 of protocol.

*Proposed Dates:*

Study start Date	Wed. 31-Oct-90
Study completion date	Tue. 31-Aug-93

*Sacrifice Date:*

Final sacrifice:	Mon. 09-Nov-92	No. of days: 2
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*Further Information:* Ten working days are presently scheduled for surgery and final necropsy. See section 11.6.1 for further information.

Date: 11/9/92

21. Reason: To incorporate a peer review of this study.

Date: 9/7/93

22. Michael Woolhiser is replacing Stefanie Nelson as principle investigator as Stefanie has started a new position elsewhere within the company

Date: 12/1/93

23. Reason: Personnel change

*Study Personnel:*

Approval date: Mon. 29-Oct-90

Study Director	Paal Klykken
Study Pathologist	Mark Zimmer
Principal Investigator	Michael R. Woolhiser
Investigator	Sharon Mudgett
Alternate Study Director	Lawrence Ruhr
Investigator	Terry Lassitter
Investigator	Steven Macalpine
Investigator	Stefanie A. Hunter

25. Deviation to protocol: Temperature and relative humidity (protocol specifies temperature range of 68 to 73°F, relative humidity range of 30 to 70% on the following occasions these ranges deviated from these specification).

A. On 2-20-95, relative humidity decreased to as low as 22% for approximately 7 hours due to a steam shut down in the building.

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Protocol Deviations

- B. On 2-21-91, relative humidity decreased to 21% for approximately 3 hours, due to a steam shut down in the building.
- C. On 5-26-91, relative humidity increased to 82% for 1 hour due to power outage caused by severe weather conditions.
- D. On 6-15-91, relative humidity increased to 72% for approximately 1 hour and the temperature increased to 73°F for approximately 1 hour, due to an air handler shut down in the building.
- E. On 6-28-91, temperature increased to 73°F for approximately 1 hour due to an air handler shut down in the building.
- F. On 9-12-91, temperature decreased to 66°F for approximately 4 hours.
- G. On 7-29-91, temperature increased to 73°F for approximately 2 hours, due to an air handler shutdown.
- H. On 10-13-92, relative humidity decreased to 27% for approximately 16 hours, due to a hole in the pneumatic actuator that opens the steam valve.

The deviations listed in this table are not expected to adversely impact on the integrity of the study.

- 26. The protocol is amended to delete protocol amendment 15.10 from the protocol amendments. The amendment contained an error that did not apply to the study.

Date: 5/14/98

- 27. The protocol is amended to a higher weight range to reflect the actual weight range at randomization referred to in protocol amendment 1.

Date: 5/14/98

- 28. The protocol is amended to revise the proposed study completion date from 8/31/93 to 6/15/98.

Date: 5/14/98

- 29. The protocol is amended to reflect that the HES Test Article Archives are now responsible for the storage of the reserve sample test and control articles.

Date: 5/14/98

- 30. *Section of Protocol Deviated From:* 11.3: Serum Chemistry Functions

*Deviation:* Due to limitations of equipment used in the analysis of total bilirubin and direct bilirubin, derived calculations for indirect bilirubin will not appear in the summary tables.

*Reason for Deviation:* A previous deviation stated that this data would be reported, however due to insufficient sensitivity of the instrumentation used to analyze the parameters for total

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Table 17

Protocol Deviations

bilirubin and direct bilirubin, values for indirect bilirubin can not be accurately derived and will not be reported.

Date: 5/14/98

31. *Section of Protocol Deviated From:* 6.2: Test Article

*Deviation:* Written documentation associated with loading of gel test material into syringes was inadvertently not included in study records.

*Reason for Deviation:* The protocol stated that these records would be retained.

Date: 5/14/98