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Office of Pollution Prevention and Toxics  
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Attn: TSCA Section 8(e)Coordinator  
U.S. Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Avenue, NW  
Washington, DC 20004



8EHQ-0510-17959A

Re: Supplemental TSCA Section 8(e) Submission; Final Report - A 28-Day Subchronic Oral Gavage Feasibility Study of Various Low Molecular Weight Silicone Oligomers in Rats.

Dear TSCA Section 8(e) Coordinator:

In accordance with the provisions of Section 8(e) of the Toxic Substances and Control Act (TSCA), as interpreted in the TSCA Section 8(e) Policy Statement and Guidance, Fed. Reg. 33129 (June 3, 2003) and other Agency guidance, the Dow Corning Corporation submits the following information as a supplemental submission to our November 19, 2009 TSCA Section 8(e) notification, 8EHQ-09-17732. Our initial notification reported the preliminary results from a reassessment of a 28-day oral toxicity study conducted with hexamethylcyclotrisiloxane and hexamethyldisiloxane in Sprague-Dawley rats that was identified during a scientific review of historical studies for which exposure gave rise to pigment accumulation in the liver. The submitted preliminary results are consistent with the final supplemental information report. This submission provides the final reports. Dow Corning has not made a determination at this time that any significant risk of injury to human health or the environment is presented by these findings.

**Chemical Substances**

541-05-9 Hexamethylcyclotrisiloxane  
107-46-0 Hexamethyldisiloxane



DCN: 8810000288

**Final Study Reports**

A 28-Day Subchronic Oral Gavage Feasibility Study of Various Low Molecular Weight Silicone Oligomers in Rats. Report Number: 1990-I0000-35105.

Supplemental Scientific Information for Report Number 1990-I0000-35105, A 28-Day Subchronic Oral Gavage Feasibility Study of Various Low Molecular Weight Silicone Oligomers in Rats. Report Number: 2010-I0000-62059.

**Summary**

Protoporphyrinosis was observed in the liver of male rats following 28 days (5 days/week) of administration of hexamethylcyclotrisiloxane (D3) or hexamethyldisiloxane (HMDS) by oral gavage at 1500 mg/kg/day.

**Attachment**

Enclosed please find copies of the final reports for these studies.

If you have any questions concerning this submission, please contact me at (989) 496-8046, [kathy.plotzke@dowcorning.com](mailto:kathy.plotzke@dowcorning.com), or at the address provided herein.

Sincerely,



Kathleen P. Plotzke, Ph.D.  
Director, Health and Environmental Sciences  
989-496-8046

**DOW CORNING CORPORATION  
HEALTH & ENVIRONMENTAL SCIENCES (HES)  
TECHNICAL REPORT**

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**Report Number:** 2010-10000-62059

**Title:** NON-REGULATED STUDY: Supplemental Scientific Information for Report Number 1990-10000-35105, A 28-Day Subchronic Oral Gavage Feasibility Study of Various Low Molecular Weight Silicone Oligomers in Rats.

**Study Number:**

**Test Articles:** Hexamethyldisiloxane, decamethyltetrasiloxane, dodecamethylpentasiloxane, methyltris(trimethylsiloxy)silane, tetrakis(trimethylsiloxy)silane, hexamethylcyclotrisiloxane, decamethylcyclopentasiloxane, dodecamethylcyclohexasiloxane, and tetramethyldisiloxanediol

**Study Leader:**

**Pathologist:**

**Sponsor:** Dow Corning Corporation  
2200 W. Salzburg Road  
Auburn, MI 48611

**HES Management:**

**Testing Facility:**

**Study Completion Date:** March 31, 2010

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## 1 ABSTRACT

The purpose of this histopathology review of liver tissue slides from the study described in report 1990-I0000-35105 was to determine if treatment related effects, such as liver protoporphyrin accumulation and periportal vacuolation or perilobular fatty change were present in this older study. The primary effects of interest were fatty vacuolation in periportal areas or perilobular fatty change (also sometimes called lipidosis, steatosis, or simply vacuolation) and the portal deposition of a deep reddish-brown pigment, which, viewed under polarized light, shows red birefringence and “maltese cross” patterns (protoporphyrin accumulation). The latter change has been consistently accompanied by bile duct proliferation (hyperplasia) and chronic inflammation (cholangitis, mononuclear cell infiltration). Brown pigment was observed in liver tissue in the 1990 study and this peer review of the slides was to further characterize whether the brown pigment was protoporphyrin accumulation. Observation of a maltese cross pattern in liver tissue with brown pigment under polarized light is indicative of protoporphyrin (Greaves 2007).

Typically in a histology peer review the peer review pathologist reaches a consensus with the study pathologist if there are differences in diagnosis. The 1990 study pathologist is no longer with Dow Corning, however, the peer review pathologist confirmed brown pigment in livers from male animals treated with hexamethylcyclotrisiloxane (D3) and hexamethyldisiloxane (HMDS). The 1990 study pathologist apparently did not examine the brown pigment under polarized light and made the diagnosis of bile stasis rather than protoporphyrin accumulation, the diagnosis of the peer review pathologist. In conclusion, the peer review pathologist’s diagnosis of protoporphyrin accumulation is the correct diagnosis. In addition, the peer review pathologist did not observe a clear increase in perilobular fatty change (periportal lipid vacuolation) in any of the treated groups, confirming the 1990 study pathologist’s results.

**2 APPROVAL SIGNATURES**

The report consists of pages 1 through 12, including Table 1.

Jeanne Y. Domradski March 31, 2010  
Date

Study Leader  
Health and Environmental Sciences

[Signature] Mar 31, 2010  
Date

Pathologist

Paul A. Bean 31 Mar 10  
Date

Team Leader, Toxicology  
Health and Environmental Sciences

**3 STUDY INFORMATION**

**Study Initiation Date:** Not Applicable

**Experimental Start Date:** Not applicable

**Experimental Termination Date:** Not applicable

**Study Completion Date:** March 31, 2010

**Study Number:**

**Study Title:** NON-REGULATED STUDY: Supplemental Scientific Information for Report Number 1990-10000-35105, A 28-Day Subchronic Oral Gavage Feasibility Study of Various Low Molecular Weight Silicone Oligomers in Rats.

**Testing Facility:**

**Study Leader:**

**Pathologist:**

**Team Leader, Toxicology:**

#### 4 INTRODUCTION / OBJECTIVE

The purpose of this histopathology review of liver tissue slides from the study described in report 1990-I0000-35105 was to determine if treatment related effects, such as liver protoporphyrin accumulation and periportal vacuolation, described in more recent studies with Si-based materials were present in this older study. The primary effects of interest were fatty vacuolation in periportal areas or perilobular fatty change (also sometimes called lipidosis, steatosis, or simply vacuolation) and the portal deposition of a deep reddish-brown pigment, which, viewed under polarized light, shows red birefringence and “maltese cross” patterns (protoporphyrin accumulation). The latter change has been consistently accompanied by bile duct proliferation (hyperplasia) and chronic inflammation (cholangitis, mononuclear cell infiltration). Brown pigment was observed in liver tissue in the 1990 study and this peer review of the slides was to further characterize whether the brown pigment was protoporphyrin accumulation. Observation of a maltese cross pattern in liver tissue with brown pigment under polarized light is indicative of protoporphyrin (Greaves 2007).

#### 5 MATERIALS AND METHODS

The study reported in 1990 tested nine materials, each at a single high dosage level given by repeated oral gavage for 28 days (5 days per week) to Sprague-Dawley rats, 6 animals/sex/test article. Articles were tested neat except where noted. The group numbers, test articles, and dosages were as follows:

Group	Test Article	Dosage (mg/kg/day)
I	Distilled Water	1500
II	Hexamethyldisiloxane (MM, HMDS)	1500
III	Decamethyltetrasiloxane (MD2M, L4)	1500
IV	Dodecamethylpentasiloxane (MD3M, L5)	1500
V	Methyltris(trimethylsiloxy)silane (M3T)	1500
VI	Tetrakis(trimethylsiloxy)silane (M4Q)	1500
VII	Decamethylcyclopentasiloxane (D5)	1500
VIII	Dodecamethylcyclohexasiloxane (D6)	1500
IX	Tetramethyldisiloxanediol (TMDSDO) (in water)	1000
X	Sesame Seed Oil	1500
XI	Hexamethylcyclotrisiloxane (D3) (in sesame oil)	1500

**Grading Scheme, Severity:**

Minimal (1): Tissue changes are minimally distinguishable from normal.

Mild (2): Tissues changes are readily distinguishable, but not expected to significantly affect organ function, clinical pathology parameters, or clinical signs.

Moderate (3): Tissue changes are easily appreciated and may have significant effects on organ function, clinical pathology parameters, or clinical signs.

Marked (4): Tissue changes are extensive and will markedly affect organ function, perhaps to the extent of organ failure. Severe lesions in vital organs may cause or contribute to the death of the animal.

**6 RESULTS AND DISCUSSION**

The slides, which are approaching twenty-years-old, were in generally good condition, although they had a somewhat washed-out appearance under the microscope, and fine detail, like vacuole morphology, was not easily evaluated. In-any-case, a clear increase in periportal lipid vacuolation or perilobular fatty change was not observed in any of the tested groups and probably could have been appreciated had it been present to a significant degree.

Dark brown pigment was observed in bile ducts from about half (4/6, 3/6, respectively) of the male rats in groups II (HMDS) and XI (D3) consistent with the 1990 study pathologist. The pigment under polarized light showed red birefringence and “Maltese cross” patterns and was accompanied by bile duct proliferation and chronic inflammation. In the reported study the brown pigmented material had been observed, but was called bile stasis with an attendant granulomatous cholangitis. It should be noted that bile stasis is a process, not a material; what would actually be seen in such a case is bile pigment (bile) that has accumulated due to intra- or extra-hepatic obstruction. A special stain (Hall’s) can positively identify bile. It did not appear that any special stains had been used to characterize the material. It can be inferred from the 1990 report that the authors hypothesized that the presumptive bile stasis was secondary to dosing accidents involving the lung. In short, the report authors’ entire interpretation was erroneous and followed misidentification of the brown pigment.

It should be noted that the pigment deposits in these old slides often appeared somewhat washed out, or, in some cases, the centers of the deposits were clear. None-the-less, the classical appearance of protoporphyrin pigment (red birefringence and Maltese cross patterns under polarized light) was observed clearly enough to make a confident diagnosis.

**7 CONCLUSIONS**

Typically in a histology peer review the peer review pathologist reaches a consensus with the study pathologist if there are differences in diagnosis. The 1990 study pathologist is no longer with Dow Corning, however, the peer review pathologist confirmed brown pigment in livers from male animals treated with hexamethylcyclotrisiloxane (D3) and hexamethyldisiloxane (HMDS). The 1990 study pathologist apparently did not examine the brown pigment under polarized light and made the diagnosis of bile stasis rather than protoporphyrin accumulation, the

diagnosis of the peer review pathologist. In conclusion, the peer review pathologist diagnosis of protoporphyrin accumulation is the correct diagnosis. In addition, the peer review pathologist did not observe a clear increase in perilobular fatty change (periportal lipid vacuolation) in any of the treated groups, confirming the 1990 study pathologist's results.

## **8 ARCHIVE**

A copy of the final report are archived at  
Sciences,

Health and Environmental

## **9 REFERENCES**

Greaves, P. (2007). *Histopathology of Preclinical Studies*. pp 490-492. Elsevier

**Table 1 – Peer Review - Individual Animal Liver Histopathology.**

Group	Test Article and Dosage	Acc. No.	Sex	PPA*	PPV**	Comment
I	Distilled Water (control)	91-0140	m	0	0	
		1500 mg/kg/day	91-0141	m	0	0
		91-0142	m	0	0	
		91-0143	m	0	0	
		91-0144	m	0	0	
		91-0145	m	0	0	
		91-0146	f	0	0	
		91-0147	f	0	0	
		91-0148	f	0	0	
		91-0149	f	0	0	
		91-0150	f	0	0	
	91-0151	f	0	0		
II	Hexamethyldisiloxane	91-0152	m	2	0	
		HMDS	91-0153	m	3	0
	1500 mg/kg/day	91-0154	m	1	0	
		91-0155	m	0	0	
		91-0156	m	4	0	
		91-0157	m	0	0	
		91-0158	f	0	0	heavy hemosiderin
		91-0159	f	0	0	
		91-0160	f	0	0	
		91-0161	f	0	0	
		91-0162	f	0	0	
	91-0163	f	0	0		
III	Decamethyltetrasiloxane	91-0164	m	0	0	
		L4	91-0165	m	0	0
	1500 mg/kg/day	91-0166	m	0	0	
		91-0167	m	0	0	
		91-0168	m	0	0	
		91-0169	m	0	0	
		91-0170	f	0	0	
		91-0171	f	0	0	heavy hemosiderin
		91-0172	f	0	0	
		91-0173	f	0	0	
		91-0174	f	0	2	
	91-0175	f	0	1		

Acc.No. = Accession number on slide (linked to animal number in study file); \*PPA = protoporphyrin accumulation accompanied by bile duct proliferation and chronic inflammation, severity grade; \*\*PPV = periportal vacuolation, severity grade; m = male, f = female

**Table 1 – Peer Review - Individual Animal Liver Histopathology (continued).**

Group	Test Article and Dosage	Acc. No.	Sex	PPA*	PPV**	Comment
IV	Dodecamethylpentasiloxane LS 1500 mg/kg/day	91-0176	m	0	0	
		91-0177	m	0	0	
		91-0178	m	0	0	
		91-0179	m	0	0	
		91-0180	m	0	0	
		91-0181	m	0	0	
		91-0182	f	0	0	heavy hemosiderin
		91-0183	f	0	0	
		91-0184	f	0	0	
		91-0185	f	0	0	
V	Methyltris(trimethylsiloxy)silane M3T 1500 mg/kg/day	91-0186	f	0	0	large altered focus
		91-0187	f	0	0	
		91-0188	m	0	0	
		91-0189	m	0	0	
		91-0190	m	0	0	
		91-0191	m	0	0	
		91-0192	m	0	0	
		91-0193	m	0	0	
		91-0194	f	0	0	
		91-0195	f	0	0	
VI	tetrakis(trimethylsiloxy)silane M4Q	91-0196	f	0	0	
		91-0197	f	0	0	
		91-0198	f	0	0	
		91-0199	f	0	0	
		91-0200	m	0	0	
		91-0201	m	0	0	
		91-0202	m	0	0	
		91-0203	m	0	1	
		91-0204	m	0	0	
		91-0205	m	0	0	
91-0206	f	0	0			
91-0207	f	0	0			
91-0208	f	0	0			
91-0209	f	0	0			
91-0210	f	0	0			
91-0211	f	0	0			

Acc.No. = Accession number on slide (linked to animal number in study file); \*PPA = protoporphyrin accumulation accompanied by bile duct proliferation and chronic inflammation, severity grade; \*\*PPV = periportal vacuolation, severity grade; m = male, f = female

**Table 1 – Peer Review - Individual Animal Liver Histopathology (continued).**

Group	Test Article and Dosage	Acc. No.	Sex	PPA*	PPV**	Comment
VII	Decamethylcyclopentasiloxane D5 1500 mg/kg/day	91-0212	m	0	0	
		91-0213	m	0	0	
		91-0214	m	0	0	
		91-0215	m	0	0	
		91-0216	m	0	0	
		91-0217	m	0	0	
		91-0218	f	0	0	
		91-0219	f	0	0	scattered vacuoles, grade 1
		91-0220	f	0	0	
		91-0221	f	0	0	
		91-0222	f	0	1	
		91-0223	f	0	1	scattered vacuoles, grade 2
		VIII	Dodecamethylcyclohexasiloxane D6 1500 mg/kg/day	91-0224	m	0
91-0225	m			0	0	
91-0226	m			0	0	
91-0227	m			0	0	
91-0228	m			0	0	
91-0229	m			0	0	
91-0230	f			0	0	
91-0231	f			0	0	
91-0232	f			0	0	
91-0233	f			0	0	
91-0234	f			0	0	
91-0235	f			0	0	
IX	Tetramethyldisiloxanediol TMDSO (in water) 1500 mg/kg/day			91-0236	m	0
		91-0237	m	0	0	
		91-0238	m	0	0	
		91-0239	m	0	0	
		91-0240	m	0	0	
		91-0241	m	0	0	
		91-0242	f	0	0	
		91-0243	f	0	0	
		91-0244	f	0	0	
		91-0245	f	0	0	
		91-0246	f	0	0	
		91-0247	f	0	0	scattered vacuoles, grade 1

Acc.No. = Accession number on slide (linked to animal number in study file); \*PPA = protoporphyrin accumulation accompanied by bile duct proliferation and chronic inflammation, severity grade; \*\*PPV = periportal vacuolation, severity grade; m = male, f = female



DOW CORNING CORPORATION  
Toxicology Department

A 28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY File No.:  
STUDY OF VARIOUS LOW MOLECULAR WEIGHT  
SILICONE OLIGOMERS IN RATS

Reference No.: TX-89-0200-08

Lot No.:

Document I.D.: 1990-I0000-35105

Authors:

GLP/QAU:

Submitted By:

Reported By:

Checked By:

Date: February 12, 1990

This summary of data and conclusions is based upon the samples received. Additional studies may be required as specific uses and formulations are developed or if process changes occur.

ABSTRACT

A twenty-eight day subchronic oral feasibility study was conducted with various low molecular weight silicone oligomers in laboratory rats. The oligomers examined in this study were hexamethyldisiloxane (MM), decamethyltetrasiloxane (MD<sub>2</sub>M), dodecamethylpentasiloxane, methyltris(trimethylsiloxy)silane, tetraakis(trimethylsiloxy)silane, hexamethylcyclo-trisiloxane (D<sub>3</sub>), decamethylcyclopentasiloxane (D<sub>5</sub>), dodecamethylcyclo-hexasiloxane and tetramethyldisiloxanediol (TMDSDO). Two control and nine treatment groups of six male and six female Sprague-Dawley rats were administered by oral gavage either distilled water, sesame oil or test material at dose levels of either 1,000 or 1,500 mg/kg of body weight/day. Animals were observed for signs of local or systemic toxicity, general appearance, behavioral abnormalities and mortality. Body weights and food consumption were determined weekly.

No treatment related deaths, overt signs of toxicity or changes in behavior were noted in any of the groups. Statistical comparison of mean body weight and food consumption data indicated no treatment related effects between the control and test groups, except in the case of the D<sub>3</sub> treated males which showed significant decreases in these parameters. Statistical comparison of organ weight data between control and test groups showed significant increases in the relative kidney weights of the male animals treated with MM, MD<sub>2</sub>M and TMDSDO and the absolute and relative liver weights of the male and female animals treated either with D<sub>3</sub> or TMDSDO. A statistically significant increase in absolute liver weight was also observed in female rats treated with D<sub>5</sub>. No gross pathological changes were observed in any of the organs of tissues of male and female rats in all control and test groups.

In conclusion, the results of this study suggest that an oral administration of D<sub>3</sub>, D<sub>5</sub> and TMDSDO may produce statistically significant increases in liver weight.

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Addendum added August 19, 1991. This consists of pages 64 - 66

I. INTRODUCTION

Current toxicological data indicates that octamethylcyclotetrasiloxane (D<sub>4</sub>) and decamethylcyclopentasiloxane (D<sub>5</sub>), both cyclic polydimethylsiloxane oligomers, are capable of producing a treatment related effect, specifically hepatomegaly. Siddiqui, et. al., (1989) have demonstrated that liver enlargement occurs within multiple species during inhalation studies of D<sub>4</sub>. Furthermore, an oral dosing study (Siddiqui, et. al., 1989) has shown that D<sub>5</sub> is able to exert an amplifying effect on the relative liver weight, while simultaneously resembling phenobarbital in its ability to induce the drug metabolizing enzymes. To further elucidate the treatment related effects, if any, of the polydimethylsiloxane oligomers, including those that are branched, cyclical or linear in structure, the following twenty-eight day oral gavage study was conducted.

II. MATERIALS AND METHODS

A. Materials

The test materials, exclusive of the sesame oil, were received from of the Environmental Chemistry Department, Dow Corning Corporation, Midland, MI. utilized common distillation practices, with the exception of decamethylcyclopentasiloxane and tetramethyldisiloxanediol, to purify technical grade materials. The decamethylcyclopentasiloxane utilized in this study was technical grade and the tetramethyldisiloxanediol was prepared by Analysis, for test material purity, was performed with a 5840A Hewlett-Packard gas chromatograph equipped with a flame ionization detector. The sesame oil used as a vehicle was purchased from The following table details all the test materials used in this study:

Material	TX Number	File Number	Reference or Lot Number	Purity	Source
1. Hexamethyldisiloxane <i>per addendum dated August 19, 1991</i> (MM)	89-0200-08	1010-13	8667-48	> 99 %	a. MAS
2. Decamethyltetrasiloxane (MD <sub>2</sub> M)	89-0200-08	4924-2	8667-49	> 99 %	a.
3. Dodecamethylpentasiloxane (MD <sub>3</sub> M)	89-0200-08	4002-2	8667-50	> 99 %	a.
4. Methyltris(trimethylsiloxy)silane (M <sub>3</sub> T)	89-0200-08	5287-2	8385-134	> 99 %	a.
5. Tetrakis(trimethylsiloxy)silane (M <sub>4</sub> Q)	89-0200-08	5286-2	8667-51	> 99 %	a.

6.	Hexamethylcyclotrisiloxane ( D <sub>3</sub> )	89-0200-08	1179-10	8667-46	> 98 %	a.
7.	Decamethylcyclopentasiloxane ( D <sub>5</sub> )	89-0200-08	3724-9	107864	> 98 %	a.
8.	Dodecamethylcyclohexasiloxane ( D <sub>6</sub> )	89-0200-08	4659-3	8667-47	> 99 %	a.
9.	Tetramethyldisiloxanediol ( TMDSDO )	89-0200-08	2987-2	8385-121	> 99 %	a.
10.	Sesame Oil	89-0200-08	N/A	08H31	N/A	b.

---

B. Experimental Animals

Seventy-five male and seventy-five female Charles River CD® (Sprague-Dawley) rats, approximately eight weeks of age, were obtained from

Upon arrival at the Health and Environmental Sciences building, all rats were given a thorough health examination by the attending veterinarian and found to be free of any outward signs of disease or sickness. The rats were housed individually in conventional design stainless steel, wire mesh bottom cages. All rats were quarantined for seven days prior to initiation of the study and housed in a room designed to be maintained at a temperature of  $20 \pm 3^{\circ}$  C, a relative humidity of  $50 \pm 20$  % and a 12-hour light/dark cycle. The animals were fed PURINA® rodent chow and fresh water ad libitum. Each animal was identified by an individually numbered metal ear tag. A color coded label was affixed to each cage identifying each animal by animal number, project number and dose level assignment.

C. Experimental Design

1. Group Assignment

One day prior to the start of the study, all approved animals were weighed and ordered consecutively by weight. Sixty-six male rats were selected from the middle body weight range and categorized into eleven weight groups. One animal from each weight group was randomly assigned to each of the eleven groups until each group had six animals. Male and female animals were randomized separately since they are biologically different. After all study groups were formed, the animals were ear tagged and placed into housing racks. A structural outline of the experimental design is given below:

Group Number	Number of Animals		Test Material	Dose Level (mg/kg/day)
	Male	Female		
I	6	6	N/A (Distilled Water)	1,500
II	6	6	MM	1,500
III	6	6	MD <sub>2</sub> M	1,500
IV	6	6	MD <sub>3</sub> M	1,500
V	6	6	M <sub>3</sub> T	1,500
VI	6	6	M <sub>4</sub> Q	1,500
VII	6	6	D <sub>5</sub>	1,500
VIII	6	6	D <sub>6</sub>	1,500
IX	6	6	TMDSDO	1,000
X	6	6	N/A (Sesame Oil)	1,500
XI	6	6	D <sub>3</sub>	1,500

## 2. Treatment Procedure

Dosages of the test and control materials were administered using 1 cc disposable glass syringes fitted with sixteen gauge ball tipped dosing needles. Two of the nine test materials, D<sub>3</sub> and TMDSDO, were administered in 25% suspensions of sesame oil and distilled water, respectively. For these suspensions 2.5 cc disposable plastic syringes fitted with either thirteen or fourteen gauge ball tipped dosing needles were used to deliver D<sub>3</sub> and TMDSDO, respectively. All animals were dosed daily, five days per week, four consecutive weeks. The control animals were treated identically as the test animals but were dosed with either distilled water or sesame oil. Dosages were adjusted once every week during the study period to reflect changes in body weights. Immediately after dosing, each animal was returned to its respective cage. Water and feed were provided ad libitum except for an approximate sixteen hour period prior to necropsy when the animals were fasted for urine collection.

D. Observations

All rats were observed twice daily on week days during the treatment period for signs of toxicity, general appearance, behavioral abnormalities, signs of local or systemic toxicity and mortality. Animals were also observed during weekends for mortality and to check the environmental conditions.

E. Body Weights and Food Consumption Measurements

Body weights of all study animals were recorded on the initial day of the study, weekly during the study periods and just prior to necropsy. Food consumption was measured weekly throughout the study period.

F. Urine Collection

Urine samples were collected from four male and four female animals randomly selected from each group. These animals were placed in metabolism cages and fasted for an overnight collection of urine. To preclude the potential evaporation of the test materials or their metabolite(s), the collection containers, which were identified by TX number, file number and animal number, were placed on dry ice. The collection containers were then submitted to the Environmental Chemistry Department for possible identification of metabolite(s). Results of the identification of any and all urinary metabolite(s) will be reported separately by the Environmental Chemistry Department.

G. Organ Weight Assessment

Animals that did not survive until terminal necropsy were refrigerated and necropsied as soon as possible upon the discovery of their demise. At the completion of the study all surviving animals were necropsied. The animals were first anesthetized with Ketamine HCl and exsanguinated by clipping the abdominal aorta. The liver, kidneys, testes or ovaries, brain, heart and spleen were weighed at necropsy. The lungs were removed intact and distended to their approximate normal inspiratory volume by tracheal infusion with formalin. All tissues and organs collected from each rat were fixed in 10% neutral buffered formalin for possible future microscopic examination.

#### H. Statistical Analysis

Statistical comparisons between distilled water control, Group I, and test groups, Groups II through IX, were carried out where applicable. In addition, statistical comparisons between sesame oil control, Group X, and test group XI, were conducted in an identical manner. Body weights, food consumption, and absolute and relative organ weights were analyzed by one-way analysis of variance. Group mean values were compared to control values using Dunnett's multiple t-test (Steel and Torrie, 1960) or where appropriate a non-parametric analysis of variance by ranks was used. The level of significance was  $P < 0.05$  (95% confidence level).

### III. RESULTS AND DISCUSSION

No overt signs of toxicity or behavioral changes were observed in the animals during the course of the study. Three animals died, due to dosing errors as revealed upon gross pathological examination, and were replaced by other animals only if the dosing error occurred within the first forty-eight hours of the study.

Group mean body weight data for all male and female rats are given in Tables I through IV. Individual animal data are reported in Appendices 1 to 4. The only statistically significant event was a decrease in body weight gains noted during the fourth week of the study in the male animals treated with  $D_3$  when compared to the sesame oil control group.

Group mean food consumption values are presented in Tables V through VIII and the individual animal data are reported in Appendices 5 to 8. Here again the only statistically significant event was a decrease in food consumption recorded in the male rats treated with  $D_3$  when compared to the sesame oil control group.

Group mean absolute and relative organ weights of the rats are reported in Tables IX through XII. The individual animal data are given in Appendices 9 to 12. The most pronounced statistically significant event, with regard to the organ weight assessment, occurred in the liver weights. Increases in the absolute and relative liver weights were seen in the male and female animals treated with  $D_3$  and TMDSO. The female animals treated with  $D_5$  also exhibited a statistically significant increase in mean absolute liver weights. In addition, statistically significant increases in the relative kidney weights were observed in the male rats treated with MM, MD<sub>2</sub>M and TMDSO. The only statistically significant decrease recorded, with regard to the organs examined in this study, occurred in the mean absolute heart weight of those animals treated with TMDSO.

In conclusion, the results of this study indicate that an oral administration of tetramethyldisiloxanediol, hexamethylcyclotrisiloxane and decamethylcyclopentasiloxane at the tested dose levels, during a period of twenty-eight days, produced treatment related increases in the liver weights of rats.

Any deviations from the protocol or standard laboratory practices, which occurred during the course of this study were evaluated and were not considered to have compromised the scientific validity or interpretation of the results.

IV. REFERENCES

1.

2.

3.

4. Steel, R. G. and Torrie, J. H., (1960). Principles and Procedures of Statistics, McGraw-Hill Book Company, Inc., New York, NY, pp. 101 - 105 and 111 - 112.

V. ACKNOWLEDGMENT

This author would particularly like to recognize the time and efforts of collaborating investigator, \_\_\_\_\_ was invaluable in helping to accomplish the seemingly endless and detailed aspects of this study. Also, this author wishes to thank all the personnel in the Animal Resources Department who assisted with the animal handling facets of this study.

VI. Signature of Authors

This report constitutes pages 1-12, Tables I-XIII, and Appendices 1-12.

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**QUALITY ASSURANCE STATEMENT**

This report represents data generated by the Toxicology Department, Dow Corning Corporation, Midland, Michigan. This study was conducted according to the Food and Drug Administration; Good Laboratory Practice Regulations 21 CFR Part 58 Friday September 4, 1987. The results reported accurately reflect the data generated. All raw data is located at

Study Initiated: June 12, 1989

Study Completed: February 8, 1990

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Experimental Termination: July 12, 1989

Study Audited: June 14, 1989 and July 12, 1989

Report Issued: February 12, 1990

*Charles A. Hunter*

Quality Assurance  
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*February 9, 1990*  
Report Audit Date:

*Forrest Starb* *2/12/90*  
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Date

Study Director

TABLE I

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
GROUP MEAN BODY WEIGHT DATA.  
MALE RATS.

TABLE OF MEANS, STANDARD DEVIATIONS, AND SAMPLE SIZES.

DOSE 1500M G/KG	DAY1	DAY8	DAY15	DAY22	DAY28
=====					
CONTROL	277. 11.	330. 23.	366. 32.	403. 39.	426. 44.
N=	6	6	6	6	6
MM	279. 9.	331. 10.	375. 15.	409. 22.	430. 26.
N=	6	6	6	6	6
	278. 9.	332. 27.	371. 36.	410. 44.	425. 45.
N=	6	6	6	6	6
	278. 9.	335. 18.	374. 27.	410. 36.	436. 38.
N=	6	6	6	6	6
	278. 8.	322. 17.	359. 23.	397. 27.	418. 27.
N=	6	6	5	5	5
	277. 9.	329. 12.	368. 17.	400. 23.	427. 22.
N=	6	6	6	6	6
	276. 12.	331. 26.	369. 35.	403. 45.	425. 51.
N=	6	6	6	6	6
	278. 7.	319. 17.	355. 27.	385. 35.	408. 41.
N=	6	6	6	6	6
	279. 9.	307. 22.	331. 45.	365. 36.	382. 33.
N=	6	6	6	6	6
=====					

- \* INDICATES SIGNIFICANT DIFFERENCE FROM CONTROL BY DUNNETT'S TEST,  
ALPHA=.05, TWO SIDED.
- † INDICATES SIGNIFICANT DIFFERENCE FROM CONTROL BY MILCOXON'S TEST,  
ALPHA=.05, TWO SIDED.

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TABLE II

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
GROUP MEAN BODY WEIGHT DATA.  
MALE RATS.

TABLE OF MEANS, STANDARD DEVIATIONS, AND SAMPLE SIZES.

DOSE	DAY1	DAY8	DAY15	DAY22	DAY28
1500M G/KG					
=====					
CONTROL	282.	330.	365.	405.	429.
	9.	19.	27.	31.	29.
N=	6	6	6	6	6
D3	279.	314.	341.	368.	389.*
	7.	22.	29.	31.	32.
N=	6	6	6	6	6
=====					

- \* INDICATES SIGNIFICANT DIFFERENCE FROM CONTROL BY DUNNETT'S TEST,  
ALPHA=.05, TWO SIDED.
- 6 INDICATES SIGNIFICANT DIFFERENCE FROM CONTROL BY WILCOXON'S TEST,  
ALPHA=.05, TWO SIDED.

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TABLE III

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
GROUP MEAN BODY WEIGHT DATA.  
FEMALE RATS.

TABLE OF MEANS, STANDARD DEVIATIONS, AND SAMPLE SIZES.

DOSE	DAY1	DAY8	DAY15	DAY22	DAY28
1500M G/KG					
=====					
CONTROL	229. 8. N= 6	241. 6. 6	254. 6. 6	263. 9. 6	269. 11. 6
MM	225. 12. N= 6	233. 14. 6	238. 19. 6	245. 20. 6	252. 20. 5
	223. 9. N= 6	238. 11. 6	244. 12. 6	253. 12. 6	260. 18. 6
	228. 8. N= 6	237. 16. 6	246. 21. 6	252. 21. 6	258. 20. 6
	228. 10. N= 6	234. 9. 6	238. 12. 6	246. 16. 6	253. 14. 6
	229. 9. N= 6	233. 15. 6	243. 26. 6	253. 28. 6	257. 30. 6
	233. 14. N= 6	249. 18. 6	252. 29. 6	269. 22. 6	272. 22. 6
	229. 10. N= 6	237. 16. 6	253. 19. 6	260. 24. 6	266. 20. 6
	227. 9. N= 6	234. 16. 5	240. 19. 5	246. 20. 5	255. 22. 5
=====					

\* INDICATES SIGNIFICANT DIFFERENCE FROM CONTROL BY DUNNETT'S TEST,  
ALPHA=.05, TWO SIDED.  
‡ INDICATES SIGNIFICANT DIFFERENCE FROM CONTROL BY MILCOXON'S TEST,  
ALPHA=.05, TWO SIDED.

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TABLE IV

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
GROUP MEAN BODY WEIGHT DATA.  
FEMALE RATS.

TABLE OF MEANS, STANDARD DEVIATIONS, AND SAMPLE SIZES.

DOSE	DAY1	DAY8	DAY15	DAY22	DAY28
1500 MG/K					
=====					
CONTROL	226. 12. N= 6	237. 19. 6	242. 16. 6	245. 22. 6	255. 18. 6
D3	226. 8. N= 6	235. 18. 6	242. 15. 6	248. 19. 6	247. 23. 6
=====					

- \* INDICATES SIGNIFICANT DIFFERENCE FROM CONTROL BY DUNNETT'S TEST,  
ALPHA=.05, TWO SIDED.
- ‡ INDICATES SIGNIFICANT DIFFERENCE FROM CONTROL BY MILCOXON'S TEST,  
ALPHA=.05, TWO SIDED.

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TABLE V

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
 WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
 GROUP MEAN FOOD CONSUMPTION DATA: DAILY BASIS.  
 MALE RATS.

TABLE OF MEANS, STANDARD DEVIATIONS, AND SAMPLE SIZES.

DOSE            DAYS1-7   DS8-15   DS16-22   DS23-28  
 1500M  
 G/KG

```

=====
CONTROL      30.8      31.3      31.9*      32.3
             4.8      4.2      4.8      5.5
             N=    6      6      6      6
             *
             30.8      31.7      32.3      32.5
             1.6      2.1      2.6      2.4
             N=    6      6      6      6
             *
             31.4      32.1      33.4      31.3
             2.7      3.6      3.0      6.1
             N=    6      6      6      6
             *
             30.1      31.8      32.4      34.3
             3.8      4.7      4.5      3.5
             N=    6      6      6      6
             *
             31.2      31.5      33.4      33.4
             3.6      4.6      3.4      3.6
             N=    6      5      5      5
             *
             31.0      31.7      32.0      33.8
             1.5      2.0      2.4      2.5
             N=    6      6      6      6
             *
             31.4      32.5      33.6      33.4
             4.5      4.8      4.4      5.9
             N=    6      6      6      6
             *
             30.3      30.1      31.3      32.5
             1.8      2.5      3.4      3.9
             N=    6      5      6      6
             *
             26.5      26.8      28.1      28.3
             2.3      5.6      2.3      2.1
             N=    6      6      6      6
=====
  
```

\* INDICATES SIGNIFICANT DIFFERENCE FROM CONTROL BY DUNNETT'S TEST,  
 ALPHA=.05, TWO SIDED.  
 † INDICATES SIGNIFICANT DIFFERENCE FROM CONTROL BY MILCOXON'S TEST,  
 ALPHA=.05, TWO SIDED.

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TABLE VI

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
GROUP MEAN FOOD CONSUMPTION DATA: DAILY BASIS.  
MALE RATS.

TABLE OF MEANS, STANDARD DEVIATIONS, AND SAMPLE SIZES.

DOSE            DAYS1-7   DS8-15   DS16-22   DS23-28  
1500M  
G/KG

=====

CONTROL	31.6	31.0	32.3	32.0
	3.8	4.6	3.7	2.8
N=	6	6	6	6
D3	26.7*	25.7*	26.1*	26.3*
	3.4	3.5	3.0	2.4
N=	6	6	6	6

=====

- \* INDICATES SIGNIFICANT DIFFERENCE FROM CONTROL BY DUNNETT'S TEST,  
ALPHA=.05, TWO SIDED.
- 6 INDICATES SIGNIFICANT DIFFERENCE FROM CONTROL BY WILCOXON'S TEST,  
ALPHA=.05, TWO SIDED.

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TABLE VII

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
 WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
 GROUP MEAN RAT FOOD CONSUMPTION DATA: DAILY BASIS.  
 FEMALE RATS.

TABLE OF MEANS, STANDARD DEVIATIONS, AND SAMPLE SIZES.

DOSE            DAYS1-7   DS8-15   DS16-22   DS23-28  
 1500M  
 G/KG

```
=====
```

DOSE	DAYS1-7	DS8-15	DS16-22	DS23-28
CONTROL	20.9	22.8	22.8	22.4
	0.6	1.2	1.3	1.7
N=	6	6	6	6
PM	19.4	20.4	20.3	20.8
	1.5	2.1	2.5	3.1
N=	6	6	6	5
	20.4	22.2	22.1	21.6
	2.2	2.4	2.2	2.2
N=	6	6	6	6
	19.9	22.3	22.0	21.7
	2.4	2.5	2.4	2.5
N=	6	6	6	6
	20.4	21.6	22.1	21.5
	0.5	2.6	1.3	1.9
N=	6	6	6	6
	19.6	21.4	22.0	22.3
	3.4	3.6	3.1	4.0
N=	6	6	6	6
	21.7	23.2	24.3	24.1
	1.7	3.5	1.7	2.7
N=	6	6	6	6
	20.5	23.4	22.4	22.7
	2.3	2.9	3.0	2.0
N=	6	6	6	6
	18.2*	21.7	21.6	23.3
	1.2	2.3	1.9	2.3
N=	5	5	5	5

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=====
```

\* INDICATES SIGNIFICANT DIFFERENCE FROM CONTROL BY DUNNETT'S TEST,  
 ALPHA=.05, TWO SIDED.  
 † INDICATES SIGNIFICANT DIFFERENCE FROM CONTROL BY MILCOXON'S TEST,  
 ALPHA=.05, TWO SIDED.

TABLE VIII

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
GROUP MEAN FOOD CONSUMPTION DATA: DAILY BASIS.  
FEMALE RATS.

TABLE OF MEANS, STANDARD DEVIATIONS, AND SAMPLE SIZES.

DOSE	DAYS1-7	DS8-15	DS16-22	DS23-28
1500M				
G/KG				
=====				
CONTROL	21.2	22.5	22.0	21.7
	2.8	2.3	3.0	1.9
N=	6	6	6	6
D3	17.4	20.6	19.5	19.1
	3.3	1.9	1.8	2.4
N=	6	6	6	6
=====				

- \* INDICATES SIGNIFICANT DIFFERENCE FROM CONTROL BY DUNNETT'S TEST,  
ALPHA=.05, TWO SIDED.
- ‡ INDICATES SIGNIFICANT DIFFERENCE FROM CONTROL BY WILCOXON'S TEST,  
ALPHA=.05, TWO SIDED.

TABLE IX

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
GROUP MEAN ABSOLUTE AND RELATIVE ORGAN WEIGHT DATA.  
MALE RATS.

TABLE OF MEANS, STANDARD DEVIATIONS, AND SAMPLE SIZES.

DOSE	BODY	BRAIN		HEART		LIVER		SPLEEN		TESTES		KIDNEYS	
1500M	WEIGHT												
G/KG	(GRAMS)	(GRAMS)	(G/100)										
CONTROL	387.8	1.96	0.51	1.35	0.35	11.6	3.0	0.722	0.187	3.18	0.82	3.10	0.80
	39.3	0.16	0.03	0.22	0.05	1.7	0.2	0.108	0.027	0.30	0.06	0.44	0.06
	N= 6	6	6	6	6	6	6	6	6	6	6	6	6
MM	388.8	2.01	0.52	1.32	0.34	14.3	3.7	0.775	0.199	3.52	0.91	3.49	0.95*
	23.8	0.05	0.04	0.10	0.01	2.0	0.3	0.097	0.017	0.20	0.06	0.31	0.08
	N= 6	6	6	6	6	6	6	6	6	6	6	6	6
	388.1	2.03	0.53	1.31	0.34	12.2	3.1	0.700	0.183	3.57	0.92	3.50	0.91*
	39.3	0.12	0.05	0.10	0.03	1.8	0.2	0.066	0.032	0.28	0.07	0.31	0.06
	N= 6	6	6	6	6	6	6	6	6	6	6	6	6
	396.2	2.01	0.51	1.30	0.33	12.7	3.2	0.804	0.204	3.26	0.83	3.33	0.84
	39.3	0.12	0.05	0.11	0.02	1.7	0.2	0.093	0.020	0.34	0.11	0.31	0.04
	N= 6	6	6	6	6	6	6	6	6	6	6	6	6
	375.9	1.98	0.53	1.41	0.38	11.5	3.1	0.705	0.187	3.34	0.89	3.27	0.87
	29.1	0.07	0.03	0.17	0.05	1.2	0.3	0.131	0.029	0.20	0.08	0.34	0.06
	N= 5	5	5	5	5	5	5	5	5	5	5	5	5
	390.6	2.03	0.52	1.33	0.34	12.8	3.3	0.865	0.222	3.35	0.86	3.50	0.90
	16.9	0.08	0.03	0.06	0.02	0.9	0.1	0.159	0.043	0.29	0.08	0.22	0.06
	N= 6	6	6	6	6	6	6	6	6	6	6	6	6
	389.3	1.99	0.52	1.35	0.35	13.8	3.6	0.693	0.179	3.62	0.92	3.32	0.85
	42.3	0.07	0.04	0.22	0.04	2.4	0.9	0.110	0.026	0.55	0.04	0.40	0.06
	N= 6	6	6	6	6	6	6	6	6	6	6	6	6
	372.6	2.04	0.55	1.29	0.35	12.7	3.4	0.631	0.169	3.29	0.88	3.35	0.90
	37.0	0.09	0.05	0.09	0.03	3.8	0.8	0.122	0.025	0.39	0.06	0.49	0.07
	N= 6	6	6	6	6	6	6	6	6	6	6	6	6
	342.0	1.93	0.57	1.10*	0.32	16.1*	4.7‡	0.615	0.179	2.68	0.79	3.19	0.93*
	29.9	0.08	0.04	0.11	0.03	2.0	0.3	0.112	0.021	0.12	0.06	0.49	0.07
	N= 6	6	6	6	6	6	6	6	6	6	6	6	6

\* INDICATES SIGNIFICANT DIFFERENCE FROM CONTROL BY DUNNETT'S TEST,  
ALPHA=.05, TWO SIDED.  
‡ INDICATES SIGNIFICANT DIFFERENCE FROM CONTROL BY MILCOXON'S TEST,  
ALPHA=.05, TWO SIDED.

TABLE X

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
GROUP MEAN ABSOLUTE AND RELATIVE ORGAN WEIGHT DATA.  
MALE RATS.

TABLE OF MEANS, STANDARD DEVIATIONS, AND SAMPLE SIZES.

DOSE 1500M G/KG	BODY WEIGHT (GRAMS)	BRAIN WEIGHT (GRAMS) (G/100)	HEART WEIGHT (GRAMS) (G/100)	LIVER WEIGHT (GRAMS) (G/100)	SPLEEN WEIGHT (GRAMS) (G/100)	TESTES WEIGHT (GRAMS) (G/100)	KIDNEYS WEIGHT (GRAMS) (G/100)						
CONTROL	373.6	1.99	0.54	1.34	0.36	12.8	3.4	0.709	0.190	3.25	0.87	3.27	0.88
	33.0	0.11	0.05	0.09	0.04	2.8	0.7	0.093	0.020	0.26	0.08	0.30	0.12
	N= 6	6	6	6	6	6	6	6	6	6	6	6	6
D3	352.0	1.96	0.56	1.27	0.36	16.8*	4.8*	0.634	0.181	3.26	0.93	3.43	0.97
	30.3	0.14	0.04	0.20	0.06	2.1	0.3	0.046	0.015	0.45	0.13	0.47	0.05
	N= 6	6	6	6	6	6	6	6	6	6	6	6	6

\* INDICATES SIGNIFICANT DIFFERENCE FROM CONTROL BY DUNNETT'S TEST,  
ALPHA=.05, TWO SIDED.

‡ INDICATES SIGNIFICANT DIFFERENCE FROM CONTROL BY WILCOXON'S TEST,  
ALPHA=.05, TWO SIDED.

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TABLE XI

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
GROUP MEAN ABSOLUTE AND RELATIVE ORGAN WEIGHT DATA.  
FEMALE RATS.

TABLE OF MEANS, STANDARD DEVIATIONS, AND SAMPLE SIZES.

DOSE 1500M G/KG	BODY WEIGHT		BRAIN WEIGHT		HEART WEIGHT		LIVER WEIGHT		SPLEEN WEIGHT		OVARIES WEIGHT		KIDNEYS WEIGHT	
	(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)
CONTROL	244.6	1.75	0.71	0.93	0.38	7.64	3.13	0.538	0.220	0.094	0.039	1.83	0.75	
	9.0	0.09	0.03	0.06	0.03	0.93	0.48	0.057	0.020	0.014	0.006	0.10	0.04	
	N= 6	6	6	6	6	6	6	6	6	6	6	6	6	
MM	228.7	1.74	0.76	0.85	0.37	7.12	3.11	0.455	0.200	0.093	0.040	1.80	0.78	
	17.1	0.17	0.10	0.11	0.02	0.62	0.08	0.014	0.016	0.011	0.003	0.22	0.06	
	N= 5	5	5	5	5	5	5	5	5	5	5	5	5	
	236.6	1.80	0.76	0.84	0.36	7.56	3.20	0.468	0.198	0.090	0.038	1.78	0.75	
	13.9	0.08	0.02	0.04	0.02	0.39	0.15	0.044	0.021	0.012	0.005	0.11	0.06	
	N= 6	6	6	6	6	6	6	6	6	6	6	6	6	
	235.6	1.84	0.79	0.87	0.37	7.37	3.13	0.562	0.238	0.093	0.039	1.88	0.80	
	17.8	0.04	0.05	0.05	0.02	0.61	0.08	0.085	0.022	0.018	0.008	0.16	0.03	
	N= 6	6	6	6	6	6	6	6	6	6	6	6	6	
	230.3	1.79	0.78	0.85	0.37	7.48	3.24	0.548	0.237	0.100	0.043	1.83	0.79	
	14.9	0.05	0.05	0.04	0.02	0.89	0.19	0.094	0.033	0.028	0.010	0.19	0.04	
	N= 6	6	6	6	6	6	6	6	6	6	6	6	6	
	234.2	1.88	0.81	0.86	0.37	6.64	2.82	0.624	0.265	0.083	0.036	1.79	0.76	
	26.4	0.05	0.09	0.13	0.03	1.13	0.18	0.367	0.148	0.007	0.003	0.17	0.03	
	N= 6	6	6	6	6	6	6	6	6	6	6	6	6	
	243.0	1.84	0.76	0.91	0.38	9.37*	3.86	0.462	0.191	0.094	0.038	1.94	0.80	
	19.3	0.10	0.05	0.09	0.03	1.15	0.46	0.061	0.030	0.018	0.005	0.21	0.05	
	N= 6	6	6	6	6	6	6	6	6	6	6	6	6	
	244.6	1.80	0.74	0.87	0.36	7.81	3.19	0.533	0.219	0.095	0.039	1.93	0.79	
	21.5	0.11	0.09	0.10	0.02	1.06	0.23	0.090	0.037	0.017	0.006	0.19	0.02	
	N= 6	6	6	6	6	6	6	6	6	6	6	6	6	
	226.0	1.79	0.80	0.87	0.39	11.68*	5.19†	0.468	0.206	0.097	0.043	1.86	0.83	
	17.2	0.06	0.07	0.06	0.02	1.31	0.73	0.056	0.024	0.016	0.008	0.15	0.10	
	N= 5	5	5	5	5	5	5	4	4	5	5	5	5	

\* INDICATES SIGNIFICANT DIFFERENCE FROM CONTROL BY DUNNETT'S TEST,  
ALPHA=.05, TWO SIDED.

† INDICATES SIGNIFICANT DIFFERENCE FROM CONTROL BY MILCOXON'S TEST,  
ALPHA=.05, TWO SIDED.

TABLE XII

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
GROUP MEAN ABSOLUTE AND RELATIVE ORGAN WEIGHT DATA.  
FEMALE RATS.

TABLE OF MEANS, STANDARD DEVIATIONS, AND SAMPLE SIZES.

DOSE 1500M G/KG	BODY	BRAIN		HEART		LIVER		SPLEEN		OVARIES		KIDNEYS	
	WEIGHT (GRAMS)	WEIGHT (GRAMS)	(G/100)										
CONTROL	230.5	1.76	0.76	0.79	0.34	6.70	2.90	0.507	0.219	0.087	0.037	1.77	0.77
	14.7	0.12	0.06	0.20	0.08	0.82	0.21	0.112	0.040	0.021	0.007	0.13	0.04
	N= 6	6	6	6	6	6	6	6	6	5	5	6	6
D3	223.4	1.75	0.79	0.91	0.41	9.63*	4.31*	0.448	0.199	0.079	0.036	1.88	0.84
	19.9	0.06	0.07	0.05	0.04	0.95	0.15	0.089	0.024	0.015	0.008	0.20	0.09
	N= 6	6	6	6	6	6	6	6	6	6	6	6	6

\* INDICATES SIGNIFICANT DIFFERENCE FROM CONTROL BY DUNNETT'S TEST,  
ALPHA=.05, TWO SIDED.

‡ INDICATES SIGNIFICANT DIFFERENCE FROM CONTROL BY WILCOXON'S TEST,  
ALPHA=.05, TWO SIDED.

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TABLE XIII - 26

Incidence of Necropsy Findings for All Study Animals  
Dow Corning Corporation

A 28-Day Oral Gavage Study of Low Molecular Weight Silicone Oligomers In Rats

Project Number: 1010-13 Species: Rat  
This report was printed on 07-13-1989.

Issue/ Diagnosis/ Modifier	Group 1		Group 2		Group 3		Group 4	
	M	F	M	F	M	F	M	F
<u>All Issues</u>	( 5)	( 4)	( 5)	( 4)	( 4)	( 5)	( 3)	( 4)
Within normal limits	5	4	5	4	4	5	3	4
<u>Kidneys</u>	( 1)	( 0)	( 1)	( 1)	( 2)	( 0)	( 3)	( 0)
Dilated	1	0	1	1	2	0	3	0
pelvis, unilateral	1	0	1	1	2	0	3	0
<u>Lungs</u>	( 0)	( 0)	( 0)	( 1)	( 0)	( 0)	( 0)	( 0)
Congestion	0	0	0	1	0	0	0	0
Fibrin	0	0	0	1	0	0	0	0
pleura	0	0	0	1	0	0	0	0
<u>Skin/Subcutis</u>	( 0)	( 1)	( 0)	( 0)	( 0)	( 1)	( 0)	( 0)
Alopecia	0	1	0	0	0	1	0	0
focal	0	1	0	0	0	1	0	0
<u>Thoracic Cavity</u>	( 0)	( 0)	( 0)	( 1)	( 0)	( 0)	( 0)	( 0)
Hydrothorax- serosanguineous	0	0	0	1	0	0	0	0
<u>Uterus</u>	( 0)	( 1)	( 0)	( 0)	( 0)	( 0)	( 0)	( 2)
Dist with fluid-normal cyclic change	0	1	0	0	0	0	0	2
<u>Remaining Issues</u>	( 1)	( 2)	( 1)	( 2)	( 2)	( 1)	( 3)	( 2)
Within normal limits	1	2	1	2	2	1	3	2

Titles:

Group 1 Control(Water)

Group 2 M

Group

Group

All modifiers are printed.

( ) = Total Findings

TABLE XIII (Cont'd) . 26'

Incidence of Necropsy Findings for All Study Animals (continued)

Dow Corning Corporation

A 28-Day Oral Gavage Study of Low Molecular Weight Silicone Oligomers In Rats

Project Number: 1010-13 Species: Rat

This report was printed on 07-13-1989.

Tissue/ Diagnosis/ Modifier	Group 5		Group 6		Group 7		Group 8	
	M	F	M	F	M	F	M	F
<u>All Tissues</u>	( 6)	( 3)	( 4)	( 4)	( 5)	( 4)	( 4)	( 4)
Within normal limits	6	3	4	4	5	4	4	4
<u>Kidneys</u>	( 0)	( 0)	( 1)	( 0)	( 0)	( 0)	( 2)	( 1)
Congestion	0	0	0	0	0	0	1	0
Dilated	0	0	1	0	0	0	1	1
pelvis, unilateral	0	0	1	0	0	0	1	1
<u>Liver</u>	( 0)	( 0)	( 0)	( 0)	( 1)	( 0)	( 1)	( 0)
Congestion	0	0	0	0	1	0	1	0
<u>Lungs</u>	( 0)	( 1)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
Consolidation	0	1	0	0	0	0	0	0
multifocal	0	1	0	0	0	0	0	0
<u>Skin/Subcutis</u>	( 0)	( 1)	( 0)	( 1)	( 0)	( 0)	( 0)	( 0)
Abscess(es)	0	0	0	1	0	0	0	0
single	0	0	0	1	0	0	0	0
Alopecia	0	1	0	0	0	0	0	0
focal	0	1	0	0	0	0	0	0
<u>Spleen</u>	( 0)	( 0)	( 1)	( 1)	( 0)	( 0)	( 1)	( 0)
Congestion	0	0	0	0	0	0	1	0
Increased size	0	0	0	1	0	0	0	0
Mass/nodule	0	0	1	0	0	0	0	0
<u>Thyroid</u>	( 0)	( 0)	( 0)	( 1)	( 0)	( 1)	( 0)	( 0)
Abscess(es)	0	0	0	0	0	1	0	0
single	0	0	0	0	0	1	0	0
Cyst(s)	0	0	0	1	0	0	0	0
single	0	0	0	1	0	0	0	0
<u>Uterus</u>	( 0)	( 1)	( 0)	( 1)	( 0)	( 1)	( 0)	( 1)
Dist with fluid-normal cyclic change	0	1	0	1	0	1	0	1
<u>Remaining Tissues</u>	( 0)	( 3)	( 2)	( 2)	( 1)	( 2)	( 2)	( 2)
Within normal limits	0	3	2	2	1	2	2	2

Titles:

Group 5

Group 6

Group 7

Group 8

All modifiers are printed.

( ) = Total findings

TABLE XIII (Cont'd) - 27

Incidence of Necropsy Findings for All Study Animals  
Dow Corning Corporation

A 28-Day Oral Gavage Study of Low Molecular Weight Silicone Oligomers In Rats

Project Number: 1010-13 Species: Rat  
This report was printed on 07-13-1989.

Issue/ Diagnosis/ Modifier	Group 9		Group 10		Group 11	
	M	F	M	F	M	F
<u>All Issues</u>	( 5)	( 3)	( 6)	( 6)	( 5)	( 3)
Within normal limits	5	3	6	6	5	3
<u>Kidneys</u>	( 1)	( 0)	( 0)	( 0)	( 0)	( 2)
Dilated	1	0	0	0	0	1
pelvis, unilateral	1	0	0	0	0	1
Focus(i)- pale	0	0	0	0	0	1
single, unilateral	0	0	0	0	0	1
<u>Liver</u>	( 0)	( 2)	( 0)	( 0)	( 1)	( 0)
Congestion	0	2	0	0	1	0
<u>Skin/Subcutis</u>	( 0)	( 1)	( 0)	( 0)	( 0)	( 0)
Alopecia	0	1	0	0	0	0
multifocal	0	1	0	0	0	0
<u>Uterus</u>	( 0)	( 1)	( 0)	( 0)	( 0)	( 2)
Dist with fluid-normal cyclic change	0	1	0	0	0	2
<u>Remaining Issues</u>	( 1)	( 3)	( 0)	( 0)	( 1)	( 3)
Within normal limits	1	3	0	0	1	3

Notes:

Group 9

Group 10 Control(Sesame)

Group 11 D3

( ) = Total Findings

All modifiers are printed.

APPENDIX I

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL BODY WEIGHT DATA.  
MALE RATS.

DOSE 1500M G/KG	ANIMAL NUMBER	DAY1	DAY8	DAY15	DAY22	DAY28
=====						
CONTROL	4201	262.	295.	321.	350.	368.
	4202	269.	327.	371.	411.	434.
	4203	270.	311.	335.	360.	375.
	4204	284.	346.	377.	423.	457.
	4205	289.	355.	406.	446.	468.
	4206	287.	345.	385.	428.	453.
	MEAN	277.	330.	366.	403.	426.
	ST. DEV.	11.	23.	32.	39.	44.
	N=	6	6	6	6	6
=====						
MM	4213	268.	321.	361.	395.	413.
	4214	270.	334.	379.	419.	447.
	4215	277.	318.	349.	377.	393.
	4216	277.	330.	376.	415.	435.
	4217	287.	341.	393.	440.	466.
	4218	292.	343.	379.	405.	426.
	MEAN	279.	331.	373.	409.	430.
	ST. DEV.	9.	10.	15.	22.	26.
	N=	6	6	6	6	6
=====						

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APPENDIX I (CONT.)

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL BODY WEIGHT DATA.  
MALE RATS.

DOSE 1500M G/KG	ANIMAL NUMBER	DAY1	DAY8	DAY15	DAY22	DAY28
=====						
	4225	269.	292.	320.	348.	372.
	4226	267.	306.	330.	360.	380.
	4227	278.	340.	389.	433.	456.
	4228	276.	341.	386.	427.	431.
	4229	286.	352.	406.	465.	489.
	4230	289.	359.	392.	435.	419.
	MEAN	278.	332.	371.	410.	425.
	ST.DEV.	9.	27.	36.	44.	45.
	N=	6	6	6	6	6
=====						
	4237	264.	330.	370.	407.	435.
	4238	273.	321.	350.	386.	411.
	4239	277.	330.	372.	411.	441.
	4240	281.	340.	392.	440.	465.
	4241	283.	319.	344.	358.	380.
	4242	291.	367.	417.	456.	486.
	MEAN	278.	335.	374.	410.	436.
	ST.DEV.	9.	18.	27.	36.	38.
	N=	6	6	6	6	6
=====						

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APPENDIX I (CONT.)

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL BODY WEIGHT DATA.  
MALE RATS.

DOSE 1500M G/KG	ANIMAL NUMBER	DAY1	DAY8	DAY15	DAY22	DAY28
=====						
	4249	272.	308. *****	*****	*****	*****
	4333	266.	308.	322.	355.	378.
	4251	278.	308.	357.	402.	428.
	4252	282.	326.	366.	412.	434.
	4253	288.	333.	371.	388.	402.
	4254	284.	350.	381.	426.	446.
	MEAN	278.	322.	359.	397.	418.
	ST.DEV.	8.	17.	23.	27.	27.
	N=	6	6	5	5	5
=====						
	4261	265.	312.	353.	385.	407.
	4262	271.	318.	346.	385.	408.
	4263	273.	338.	383.	426.	457.
	4264	284.	344.	389.	425.	442.
	4265	287.	334.	370.	407.	440.
	4266	282.	330.	365.	372.	407.
	MEAN	277.	329.	368.	400.	427.
	ST.DEV.	9.	12.	17.	23.	22.
	N=	6	6	6	6	6
=====						

\*\*\*\*\* INDICATES DEAD ANIMALS OR MISSING VALUES

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APPENDIX I (CONT. )

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL BODY WEIGHT DATA.  
MALE RATS.

DOSE 1500M G/KG	ANIMAL NUMBER	DAY1	DAY8	DAY15	DAY22	DAY28
=====						
	4273	257.	296.	329.	356.	366.
	4274	269.	306.	326.	343.	364.
	4275	273.	329.	371.	406.	426.
	4276	283.	347.	399.	435.	452.
	4277	286.	364.	410.	458.	488.
	4278	290.	342.	380.	421.	456.
	MEAN	276.	331.	369.	403.	425.
	ST.DEV.	12.	26.	35.	45.	51.
	N=	6	6	6	6	6
=====						
	4285	269.	308.	334.	360.	373.
	4286	271.	307.	338.	364.	389.
	4287	277.	326.	369.	410.	437.
	4288	283.	332.	375.	396.	422.
	4289	287.	340.	392.	435.	467.
	4290	281.	298.	323.	344.	359.
	MEAN	278.	319.	355.	385.	408.
	ST.DEV.	7.	17.	27.	35.	41.
	N=	6	6	6	6	6
=====						

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APPENDIX I (CONT. )

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL BODY WEIGHT DATA.  
MALE RATS.

DOSE 1500M G/KG	ANIMAL NUMBER	DAY1	DAY8	DAY15	DAY22	DAY28
=====						
	4297	265.	302.	343.	377.	390.
	4298	278.	272.	245.*	306.	333.
	4299	273.	298.	329.	348.	368.
	4300	283.	315.	346.	372.	384.
	4301	288.	337.	378.	413.	433.
	4302	289.	316.	347.	373.	386.
	MEAN	279.	307.	331.	365.	382.
	ST.DEV.	9.	22.	45.	36.	33.
	N=	6	6	6	6	6
=====						

\* INDICATES STATISTICAL OUTLIERS WHICH ARE NOT EXCLUDED FROM CALCULATIONS

APPENDIX II

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL BODY WEIGHT DATA.  
MALE RATS.

DOSE	ANIMAL	DAY1	DAY8	DAY15	DAY22	DAY28
1500M	NUMBER					
G/KG						
=====						
CONTROL	4309	270.	304.	328.	367.	398.
	4310	278.	341.	373.	424.	451.
	4311	279.	319.	352.	393.	419.
	4312	281.	319.	351.	379.	398.
	4313	283.	340.	382.	417.	438.
	4314	298.	356.	403.	450.	471.
	MEAN	282.	330.	365.	405.	429.
	ST.DEV.	9.	19.	27.	31.	29.
	N=	6	6	6	6	6
=====						
D3	4321	272.	300.	318.	342.	364.
	4322	272.	303.	331.	359.	371.
	4323	273.	282.	299.	325.	347.
	4324	282.	330.	365.	397.	422.
	4325	285.	329.	358.	386.	402.
	4326	287.	339.	372.	398.	425.
	MEAN	279.	314.	341.	368.	389.
	ST.DEV.	7.	22.	29.	31.	32.
	N=	6	6	6	6	6
=====						

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APPENDIX III

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL BODY WEIGHT DATA.  
FEMALE RATS.

DOSE	ANIMAL	DAY1	DAY8	DAY15	DAY22	DAY28
1500M	NUMBER					
G/KG						
=====						
CONTROL	4207	219.	232.	242.	250.	254.
	4208	226.	235.	256.	265.	271.
	4209	223.	241.	254.	262.	262.
	4210	234.	245.	257.	263.	279.
	4211	238.	246.	260.	277.	283.
	4212	235.	244.	252.	263.	266.
	MEAN	229.	241.	254.	263.	269.
	ST.DEV.	8.	6.	6.	9.	11.
	N=	6	6	6	6	6
=====						
MM	4219	213.	216.	221.	228.	228.
	4220	214.	222.	224.	222.	*****
	4221	218.	232.	229.	245.	243.
	4222	232.	233.	240.	251.	258.
	4223	234.	234.	239.	243.	247.
	4224	240.	258.	273.	279.	282.
	MEAN	225.	233.	238.	245.	252.
	ST.DEV.	12.	14.	19.	20.	20.
	N=	6	6	6	6	5
=====						
***** INDICATES DEAD ANIMALS OR MISSING VALUES						

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APPENDIX III (CONT.)

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL BODY WEIGHT DATA.  
FEMALE RATS.

DOSE 1500M G/KG	ANIMAL NUMBER	DAY1	DAY8	DAY15	DAY22	DAY28
-----------------------	------------------	------	------	-------	-------	-------

=====

4231	210.	230.	244.	251.	255.
4232	217.	231.	234.	244.	252.
4233	226.	235.	239.	250.	262.
4234	220.	230.	232.	242.	235.
4235	232.	242.	247.	255.	263.
4236	235.	257.	266.	275.	291.

MEAN	223.	238.	244.	253.	260.
ST.DEV.	9.	11.	12.	12.	18.

N=	6	6	6	6	6
----	---	---	---	---	---

=====

4243	222.	227.	230.	241.	245.
4244	224.	223.	229.	230.	235.
4245	219.	224.	225.	229.	242.
4246	230.	236.	257.	264.	265.
4247	235.	247.	258.	269.	275.
4248	240.	263.	276.	278.	286.

MEAN	228.	237.	246.	252.	258.
ST.DEV.	8.	16.	21.	21.	20.

N=	6	6	6	6	6
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=====

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APPENDIX III (CONT.)

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
 WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
 INDIVIDUAL BODY WEIGHT DATA.  
 FEMALE RATS.

DOSE 1500M G/KG	ANIMAL NUMBER	DAY1	DAY8	DAY15	DAY22	DAY28
=====						
	4255	215.	222.	230.	228.	244.
	4256	218.	226.	227.	230.	236.
	4257	228.	237.	248.	262.	270.
	4258	230.	236.	230.	238.	245.
	4259	239.	240.	234.	253.	256.
	4260	240.	245.	257.	266.	267.
	MEAN	228.	234.	238.	246.	253.
	ST.DEV.	10.	9.	12.	16.	14.
	N=	6	6	6	6	6
=====						
	4267	215.	217.	214.	224.	227.
	4268	222.	218.	221.	230.	227.
	4269	235.	237.	263.	271.	278.
	4270	231.	235.	236.	249.	254.
	4271	230.	233.	238.	247.	251.
	4272	239.	259.	283.	299.	303.
	MEAN	229.	233.	243.	253.	257.
	ST.DEV.	9.	15.	26.	28.	30.
	N=	6	6	6	6	6
=====						

APPENDIX III (CONT.)

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL BODY WEIGHT DATA.  
FEMALE RATS.

DOSE 1500M G/KG	ANIMAL NUMBER	DAY1	DAY8	DAY15	DAY22	DAY28
=====						
	4279	214.	227.	215.	262.	251.
	4280	217.	231.	224.	237.	240.
	4335	249.	270.	286.	295.	292.
	4282	236.	243.	246.	251.	270.
	4283	238.	258.	270.	283.	284.
	4338	241.	264.	274.	285.	292.
	MEAN	233.	249.	252.	269.	272.
	ST.DEV.	14.	18.	29.	22.	22.
	N=	6	6	6	6	6
=====						
	4291	215.	220.	222.	223.	230.
	4292	218.	230.	242.	249.	263.
	4293	236.	218.	250.	253.	261.
	4294	228.	250.	265.	273.	277.
	4295	238.	253.	272.	291.	289.
	4296	237.	251.	267.	273.	277.
	MEAN	229.	237.	253.	260.	266.
	ST.DEV.	10.	16.	19.	24.	20.
	N=	6	6	6	6	6
=====						

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APPENDIX III (CONT.)

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
 WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
 INDIVIDUAL BODY WEIGHT DATA.  
 FEMALE RATS.

DOSE 1500M G/KG	ANIMAL NUMBER	DAY1	DAY8	DAY15	DAY22	DAY28
	4303	215.	224.	220.	228.	233.
	4304	226.	235.	238.	252.	254.
	4334	221.	224.	233.	241.	250.
	4306	231.	227.	238.	231.	247.
	4307	229.	*****	*****	*****	*****
	4308	242.	261.	272.	278.	292.
	MEAN	227.	234.	240.	246.	255.
	ST.DEV.	9.	16.	19.	20.	22.
	N=	6	5	5	5	5

\*\*\*\*\* INDICATES DEAD ANIMALS OR MISSING VALUES

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APPENDIX IV

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL BODY WEIGHT DATA.  
FEMALE RATS.

DOSE 1500 MG/K	ANIMAL NUMBER	DAY1	DAY8	DAY15	DAY22	DAY28
=====						
CONTROL	4315	221.	226.	230.	238.	254.
	4316	223.	232.	243.	238.	253.
	4336	209.	215.	226.	212.	228.
	4318	226.	239.	246.	257.	260.
	4319	232.	242.	237.	248.	250.
	4337	245.	270.	272.	279.	285.
	MEAN	226.	237.	242.	245.	255.
	ST. DEV.	12.	19.	16.	22.	18.
	N=	6	6	6	6	6
=====						
D3	4327	212.	211.	226.	221.	216.
	4328	222.	223.	233.	241.	238.
	4329	226.	234.	235.	246.	247.
	4330	230.	236.	245.	246.	241.
	4331	237.	262.	269.	279.	287.
	4332	229.	246.	246.	252.	250.
	MEAN	226.	235.	242.	248.	247.
	ST. DEV.	8.	18.	15.	19.	23.
	N=	6	6	6	6	6
=====						

APPENDIX V

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL MEAN FOOD CONSUMPTION DATA: DAILY BASIS.  
MALE RATS.

DOSE ANIMAL DAYS1-7 DS8-15 DS16-22 DS23-28  
1500M NUMBER  
G/KG

=====

CONTROL	4201	24.3	26.0	25.7	24.5
	4202	31.0	32.0	33.7	32.3
	4203	25.6	26.6	26.6	26.7
	4204	35.3	32.9	31.9	37.0
	4205	35.0	36.4	36.3	36.3
	4206	33.6	34.1	36.9	36.7
	MEAN	30.8	31.3	31.9	32.3
	ST.DEV.	4.8	4.2	4.8	5.5
	N=	6	6	6	6

=====

MM	4213	28.3	29.4	29.6	29.5
	4214	32.9	32.4	32.7	34.3
	4215	31.0	31.3	30.6	30.0
	4216	30.6	33.3	34.7	33.7
	4217	31.9	34.4	36.0	35.3
	4218	30.1	29.3	30.1	32.3
	MEAN	30.8	31.7	32.3	32.5
	ST.DEV.	1.6	2.1	2.6	2.4
	N=	6	6	6	6

=====

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APPENDIX V (CONT.)

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL MEAN FOOD CONSUMPTION DATA: DAILY BASIS.  
MALE RATS.

DOSE 1500M G/KG	ANIMAL NUMBER	DAYS1-7	DS8-15	DS16-22	DS23-28
-----------------------	------------------	---------	--------	---------	---------

=====					
4225		27.4	26.7	28.9	30.5
4226		28.9	28.6	30.4	30.7
4227		31.4	33.3	34.7	35.3
4228		33.6	35.3	35.7	34.2
4229		33.4	35.4	36.4	36.8
4230		33.9	33.4	34.4	20.0
MEAN		31.4	32.1	33.4	31.3
ST.DEV.		2.7	3.6	3.0	6.1
N=		6	6	6	6
=====					

4237		29.1	29.7	29.1	29.7
4238		27.1	26.6	28.4	39.3
4239		29.3	29.9	31.9	34.7
4240		29.1	36.9	39.1	36.5
4241		28.3	29.0	29.3	31.0
4242		37.7*	38.4	36.7	34.5
MEAN		30.1	31.8	32.4	34.3
ST.DEV.		3.8	4.7	4.5	3.5
N=		6	6	6	6
=====					

\* INDICATES STATISTICAL OUTLIERS WHICH ARE NOT EXCLUDED FROM CALCULATIONS

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APPENDIX V (CONT.)

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL MEAN FOOD CONSUMPTION DATA: DAILY BASIS.  
MALE RATS.

DOSE ANIMAL DAYS1-7 DS8-15 DS16-22 DS23-28  
1500M NUMBER  
G/KG

=====

4249	25.9	*****	*****	*****
4333	35.3	24.0	30.0	29.7
4251	29.4	31.3	33.1	35.0
4252	33.1	33.6	35.0	35.0
4253	29.4	32.1	30.6	29.7
4254	34.1	36.3	38.3	37.8
MEAN	31.2	31.5	33.4	33.4
ST.DEV.	3.6	4.6	3.4	3.6
N=	6	5	5	5

=====

4261	29.4	31.3	30.3	30.7
4262	30.0	28.9	29.7	32.8
4263	31.0	32.6	34.6	36.0
4264	32.7	34.7	34.0	35.7
4265	33.0	32.1	33.9	36.0
4266	29.9	30.6	29.3	31.3
MEAN	31.0	31.7	32.0	33.8
ST.DEV.	1.5	2.0	2.4	2.5
N=	6	6	6	6

=====

\*\*\*\*\* INDICATES DEAD ANIMALS OR MISSING VALUES

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APPENDIX V (CONT.)

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL MEAN FOOD CONSUMPTION DATA: DAILY BASIS.  
MALE RATS.

DOSE 1500M G/KG	ANIMAL NUMBER	DAYS1-7	DS8-15	DS16-22	DS23-28
-----------------------	------------------	---------	--------	---------	---------

```
=====
```

4273	26.0	27.4	28.9	26.3
4274	26.7	25.6	27.6	26.5
4275	31.1	35.1	36.3	35.7
4276	34.0	36.0	34.4	33.0
4277	37.9	37.3	39.0	39.8
4278	32.4	33.6	35.4	38.8
MEAN	31.4	32.5	33.6	33.4
ST.DEV.	4.5	4.8	4.4	5.9
N=	6	6	6	6

```
=====
```

4285	29.1	29.6	28.7	28.7
4286	29.1	28.1	28.6	30.8
4287	30.3	31.4	31.7	32.7
4288	32.9	33.7	32.6	33.0
4289	31.9	*****	37.3	39.8
4290	28.3	27.7	29.1	30.2
MEAN	30.3	30.1	31.3	32.5
ST.DEV.	1.8	2.5	3.4	3.9
N=	6	5	6	6

```
=====
```

\*\*\*\*\* INDICATES DEAD ANIMALS OR MISSING VALUES

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APPENDIX V (CONT.)

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL MEAN FOOD CONSUMPTION DATA: DAILY BASIS.  
MALE RATS.

DOSE ANIMAL DAYS1-7 DS8-15 DS16-22 DS23-28  
1500M NUMBER  
G/KG

=====

4297	26.0	30.7	30.9	31.7
4298	25.3	16.0*	26.3	27.5
4299	23.4	27.3	25.7	27.0
4300	28.6	30.0	30.0	29.3
4301	29.6	30.3	29.3	28.2
4302	26.1	26.6	26.1	25.8
MEAN	26.5	26.8	28.1	28.3
ST.DEV.	2.3	5.6	2.3	2.1
N=	6	6	6	6

=====

\* INDICATES STATISTICAL OUTLIERS WHICH ARE NOT EXCLUDED FROM CALCULATIONS

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APPENDIX VI

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL FOOD CONSUMPTION DATA: DAILY BASIS.  
MALE RATS.

DOSE ANIMAL DAYS1-7 DS8-15 DS16-22 DS23-28  
1500M NUMBER  
G/KG

=====  
CONTROL 4309 28.0 26.0 30.3 30.8  
4310 34.4 33.0 34.1 33.8  
4311 29.3 27.3 29.4 30.7  
4312 27.4 28.1 28.3 28.0  
4313 35.0 34.4 33.3 32.2  
4314 35.7 37.4 38.3 36.2  
  
MEAN 31.6 31.0 32.3 32.0  
ST.DEV. 3.8 4.6 3.7 2.8  
  
N= 6 6 6 6  
=====

D3 4321 23.0 22.9 26.4 25.0  
4322 25.0 25.3 24.9 23.7  
4323 22.9 20.4 20.7 23.8  
4324 30.4 29.4 29.4 28.7  
4325 29.3 27.0 27.3 27.8  
4326 29.3 29.0 27.6 29.0  
  
MEAN 26.7 25.7 26.1 26.3  
ST.DEV. 3.4 3.5 3.0 2.4  
  
N= 6 6 6 6  
=====

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APPENDIX VII

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL FOOD CONSUMPTION DATA: DAILY BASIS.  
FEMALE RATS.

DOSE 1500M G/KG	ANIMAL NUMBER	DAYS1-7	DS8-15	DS16-22	DS23-28
=====					
CONTROL	4207	20.1	21.9	21.4	19.7
	4208	21.4	24.9	24.3	23.8
	4209	20.7	22.6	21.6	21.2
	4210	21.3	22.0	23.7	24.3
	4211	21.3	23.5	24.0	22.3
	4212	20.3	22.0	22.0	23.2
	MEAN	20.9	22.8	22.8	22.4
ST.DEV.	0.6	1.2	1.3	1.7	
N=	6	6	6	6	
=====					
MM	4219	17.9	19.3	19.3	19.8
	4220	19.4	18.4	17.3	*****
	4221	18.9	19.3	20.6	18.0
	4222	19.0	21.4	21.6	22.0
	4223	19.0	19.9	18.7	18.5
	4224	22.4*	24.1	24.3	25.7
	MEAN	19.4	20.4	20.3	20.8
ST.DEV.	1.5	2.1	2.5	3.1	
N=	6	6	6	5	
=====					

\* INDICATES STATISTICAL OUTLIERS WHICH ARE NOT EXCLUDED FROM CALCULATIONS  
\*\*\*\*\* INDICATES DEAD ANIMALS OR MISSING VALUES

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APPENDIX VII (CONT.)

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL FOOD CONSUMPTION DATA: DAILY BASIS.  
FEMALE RATS.

DOSE ANIMAL DAYS1-7 DS8-15 DS16-22 DS23-28  
1500M NUMBER  
G/KG

=====

4231	19.9	21.9	21.6	21.2
4232	21.1	23.0	22.6	21.8
4233	16.9	18.4	20.0	19.5
4234	19.6	20.6	19.3	18.8
4235	21.3	23.9	24.1	24.3
4236	23.6	25.1	25.0	23.8
MEAN	20.4	22.2	22.1	21.6
ST.DEV.	2.2	2.4	2.2	2.2
N=	6	6	6	6

=====

4243	19.1	21.6	21.3	20.5
4244	17.7	19.1	19.7	19.2
4245	17.9	20.3	19.1	19.8
4246	19.6	23.6	23.0	22.7
4247	20.7	23.3	23.6	21.8
4248	24.3	25.9	25.4	26.0
MEAN	19.9	22.3	22.0	21.7
ST.DEV.	2.4	2.5	2.4	2.5
N=	6	6	6	6

=====

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APPENDIX VII (CONT. )

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL FOOD CONSUMPTION DATA: DAILY BASIS.  
FEMALE RATS.

DOSE ANIMAL DAYS1-7 DS8-15 DS16-22 DS23-28  
1500M NUMBER  
G/KG

```
=====
```

4255	20.1	22.1	21.7	24.0
4256	20.6	20.3	20.4	20.8
4257	19.6	23.1	22.7	23.2
4258	20.4	22.3	20.9	20.3
4259	20.4	17.3	23.7	19.0
4260	21.0	24.7	22.9	21.5
MEAN	20.4	21.6	22.1	21.5
ST.DEV.	0.5	2.6	1.3	1.9
N=	6	6	6	6

```
=====
```

4267	16.4	17.6	18.6	17.7
4268	18.7	17.6	18.9	19.2
4269	15.9	22.7	22.3	22.3
4270	20.1	20.6	22.4	21.2
4271	21.4	22.6	23.0	24.2
4272	25.0	27.0	27.0	29.0
MEAN	19.6	21.4	22.0	22.3
ST.DEV.	3.4	3.6	3.1	4.0
N=	6	6	6	6

```
=====
```

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APPENDIX VII (CONT.)

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL FOOD CONSUMPTION DATA: DAILY BASIS.  
FEMALE RATS.

DOSE ANIMAL DAYS1-7 DS8-15 DS16-22 DS23-28  
1500M NUMBER  
G/KG

=====  
4279 19.9 18.9 24.6 22.3  
4280 19.6 19.3 21.1 19.7  
4335 22.5 26.1 24.6 24.5  
4282 21.6 22.7 24.1 25.5  
4283 23.0 25.4 25.6 27.3  
4338 23.8 27.0 25.9 25.3  
  
MEAN 21.7 23.2 24.3 24.1  
ST.DEV. 1.7 3.5 1.7 2.7  
  
N= 6 6 6 6  
=====

4291 19.0 18.3 17.7 19.3  
4292 19.9 23.1 20.9 23.3  
4293 17.6 24.1 22.4 22.5  
4294 20.7 24.0 24.3 23.8  
4295 24.4 27.4 26.6 25.3  
4296 21.4 23.3 22.7 21.8  
  
MEAN 20.5 23.4 22.4 22.7  
ST.DEV. 2.3 2.9 3.0 2.0  
  
N= 6 6 6 6  
=====

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APPENDIX VII (CONT.)

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL FOOD CONSUMPTION DATA: DAILY BASIS.  
FEMALE RATS.

DOSE 1500M G/KG	ANIMAL NUMBER	DAYS1-7	DS8-15	DS16-22	DS23-28
=====					
	4303	17.4	18.1	18.9	20.2
	4304	17.7	21.4	22.1	21.7
	4334	17.2	21.3	23.0	23.8
	4306	18.4	23.4	20.3	25.7
	4308	20.1	24.1	23.6	25.0
	MEAN	18.2	21.7	21.6	23.3
	ST.DEV.	1.2	2.3	1.9	2.3
	N=	5	5	5	5
=====					

APPENDIX VIII

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL FOOD CONSUMPTION DATA: DAILY BASIS.  
FEMALE RATS.

DOSE 1500M G/KG	ANIMAL NUMBER	DAYS1-7	DS8-15	DS16-22	DS23-28
=====					
CONTROL	4315	20.3	23.0	22.6	23.3
	4316	20.9	24.4	23.4	23.0
	4336	18.3	18.7	16.3	18.8
	4318	20.0	21.4	21.4	20.3
	4319	21.3	22.0	23.3	21.3
	4338	26.5	25.3	25.0	23.7
	MEAN	21.2	22.5	22.0	21.7
ST.DEV.	2.8	2.3	3.0	1.9	
N=	6	6	6	6	
=====					
D3	4327	13.3	19.4	17.9	19.8
	4328	16.6	20.4	17.9	16.5
	4329	17.6	19.1	19.9	17.5
	4330	14.9	19.9	19.6	18.5
	4331	22.1	24.4*	22.7	23.5
	4332	20.1	20.6	18.9	18.8
	MEAN	17.4	20.6	19.5	19.1
ST.DEV.	3.3	1.9	1.8	2.4	
N=	6	6	6	6	
=====					

\* INDICATES STATISTICAL OUTLIERS WHICH ARE NOT EXCLUDED FROM CALCULATIONS

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APPENDIX IX

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL ABSOLUTE AND RELATIVE ORGAN WEIGHT DATA.  
MALE RATS.

DOSE	ANIMAL	BODY	BRAIN		HEART		LIVER		SPLEEN		TESTES		KIDNEYS	
1500M	NUMBER	HEIGHT	WEIGHT	(G/100)	(GRAMS)	(G/100)								
G/KG		(GRAMS)	(GRAMS)	(G/100)										
CONTROL	4201	333.3	1.72	0.52	1.04	0.31	9.8	2.9	0.572	0.172	2.77	0.83	2.41	0.72
	4202	391.5	1.85	0.47	1.71	0.44	13.3	3.4	0.903	0.231	3.39	0.87	3.31	0.85
	4203	347.3	1.90	0.55	1.32	0.38	9.1	2.6	0.721	0.208	2.99	0.86	2.79	0.80
	4204	411.9	2.15	0.52	1.42	0.34	12.3	3.0	0.691	0.168	3.30	0.80	3.67	0.89
	4205	432.9	2.07	0.48	1.28	0.30	12.7	2.9	0.692	0.160	3.04	0.70	3.26	0.75
	4206	410.0	2.08	0.51	1.35	0.33	12.5	3.0	0.752	0.183	3.58	0.87	3.18	0.78
	MEAN		387.8	1.96	0.51	1.35	0.35	11.6	3.0	0.722	0.187	3.18	0.82	3.10
ST. DEV.		39.3	0.16	0.03	0.22	0.05	1.7	0.2	0.108	0.027	0.30	0.06	0.44	0.06
N=		6	6	6	6	6	6	6	6	6	6	6	6	6
MM	4213	377.8	1.93	0.51	1.25	0.33	13.8	3.7	0.736	0.195	3.32	0.88	3.10	0.82
	4214	399.8	2.04	0.51	1.34	0.34	15.8	4.0	0.844	0.211	3.83	0.96	3.86	0.97
	4215	349.9	2.05	0.59	1.21	0.35	11.6	3.3	0.705	0.201	3.37	0.96	3.74	1.07
	4216	397.6	1.95	0.49	1.39	0.35	14.3	3.6	0.765	0.192	3.69	0.93	3.80	0.96
	4217	420.3	2.02	0.48	1.48	0.35	17.3	4.1	0.931	0.222	3.44	0.82	4.00	0.95
	4218	387.4	2.05	0.53	1.26	0.33	13.0	3.4	0.667	0.172	3.44	0.89	3.63	0.94
	MEAN		388.8	2.01	0.52	1.32	0.34	14.3	3.7	0.775	0.199	3.52	0.91	3.69
ST. DEV.		23.8	0.05	0.04	0.10	0.01	2.0	0.3	0.097	0.017	0.20	0.06	0.31	0.08
N=		6	6	6	6	6	6	6	6	6	6	6	6	6

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APPENDIX IX (CONT.)

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL ABSOLUTE AND RELATIVE ORGAN WEIGHT DATA.  
MALE RATS.

DOSE 1500M G/KG	ANIMAL NUMBER	BODY HEIGHT (GRAMS)	BRAIN WEIGHT		HEART WEIGHT		LIVER WEIGHT		SPLEEN WEIGHT		TESTES WEIGHT		KIDNEYS WEIGHT	
			(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)
	4225	343.1	1.84	0.54	1.26	0.37	11.4	3.3	0.750	0.219	3.47	1.01	3.34	0.97
	4226	345.5	2.08	0.60	1.19	0.34	10.5	3.0	0.789	0.228	3.45	1.00	3.22	0.93
	4227	420.6	2.14	0.51	1.39	0.33	13.4	3.2	0.671	0.160	3.86	0.92	3.87	0.92
	4228	405.2	2.16	0.53	1.47	0.36	12.0	3.0	0.648	0.160	3.39	0.84	3.79	0.94
	4229	437.3	1.98	0.45	1.30	0.30	15.1	3.5	0.725	0.166	3.97	0.91	3.66	0.84
	4230	376.6	2.00	0.53	1.26	0.33	10.8	2.9	0.617	0.164	3.27	0.87	3.14	0.83
	MEAN	388.1	2.03	0.53	1.31	0.34	12.2	3.1	0.700	0.183	3.57	0.92	3.50	0.91
	ST. DEV.	39.3	0.12	0.05	0.10	0.03	1.8	0.2	0.066	0.032	0.28	0.07	0.31	0.06
	N=	6	6	6	6	6	6	6	6	6	6	6	6	6
	4237	395.5	2.21	0.56	1.21	0.31	13.3	3.4	0.951	0.240	3.82	0.97	3.62	0.92
	4238	371.5	2.00	0.54	1.27	0.34	12.4	3.3	0.744	0.200	2.80	0.75	3.01	0.81
	4239	398.8	2.03	0.51	1.28	0.32	11.2	2.8	0.819	0.205	3.42	0.86	3.30	0.83
	4240	427.8	1.99	0.47	1.44	0.34	14.6	3.4	0.838	0.196	3.22	0.75	3.55	0.83
	4241	336.8	1.86	0.55	1.17	0.35	10.4	3.1	0.676	0.201	3.19	0.95	2.90	0.86
	4242	446.9	1.95	0.44	1.43	0.32	14.5	3.2	0.798	0.179	3.09	0.69	3.60	0.81
	MEAN	396.2	2.01	0.51	1.30	0.33	12.7	3.2	0.804	0.204	3.26	0.83	3.33	0.84
	ST. DEV.	39.3	0.12	0.05	0.11	0.02	1.7	0.2	0.093	0.020	0.34	0.11	0.31	0.04
	N=	6	6	6	6	6	6	6	6	6	6	6	6	6

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APPENDIX IX (CONT.)

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL ABSOLUTE AND RELATIVE ORGAN WEIGHT DATA.  
MALE RATS.

DOSE 1500M G/KG	ANIMAL NUMBER	BODY WEIGHT (GRAMS)	BRAIN WEIGHT		HEART WEIGHT		LIVER WEIGHT		SPLEEN WEIGHT		TESTES WEIGHT		KIDNEYS WEIGHT	
			(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)
	4333	356.5	1.97	0.55	1.32	0.37	10.7	3.0	0.764	0.214	3.43	0.96	2.92	0.82
	4251	342.6	1.91	0.56	1.30	0.38	11.8	3.4	0.627	0.183	3.42	1.00	3.21	0.94
	4252	399.1	1.93	0.48	1.42	0.36	13.0	3.3	0.805	0.202	3.18	0.80	3.74	0.94
	4253	369.1	1.98	0.54	1.70	0.46	9.9	2.7	0.513	0.139	3.09	0.84	3.02	0.82
	4254	412.2	2.10	0.51	1.29	0.31	12.3	3.0	0.814	0.197	3.59	0.87	3.47	0.84
	MEAN	375.9	1.98	0.53	1.41	0.38	11.5	3.1	0.705	0.187	3.34	0.89	3.27	0.87
	ST.DEV.	29.1	0.07	0.03	0.17	0.05	1.2	0.3	0.131	0.029	0.20	0.08	0.34	0.06
	N=	5	5	5	5	5	5	5	5	5	5	5	5	5
	4261	372.8	2.14	0.57	1.28	0.34	11.5	3.1	0.760	0.204	3.35	0.90	3.42	0.92
	4262	379.8	2.06	0.54	1.38	0.36	13.3	3.5	0.780	0.205	2.89	0.76	3.22	0.85
	4263	408.5	2.06	0.50	1.25	0.31	13.8	3.4	0.660	0.162	3.21	0.79	3.40	0.83
	4264	409.2	2.02	0.49	1.38	0.34	13.2	3.2	0.900	0.220	3.36	0.82	3.46	0.85
	4265	399.0	1.99	0.50	1.30	0.33	13.2	3.3	1.017	0.255	3.74	0.94	3.86	0.97
	4266	374.4	1.90	0.51	1.39	0.37	11.9	3.2	1.071	0.286	3.55	0.95	3.64	0.97
	MEAN	390.6	2.03	0.52	1.33	0.34	12.8	3.3	0.865	0.222	3.35	0.86	3.50	0.90
	ST.DEV.	16.9	0.08	0.03	0.06	0.02	0.9	0.1	0.159	0.043	0.29	0.08	0.22	0.06
	N=	6	6	6	6	6	6	6	6	6	6	6	6	6

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APPENDIX IX (CONT.)

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL ABSOLUTE AND RELATIVE ORGAN WEIGHT DATA.  
MALE RATS.

DOSE 1500M G/KG	ANIMAL NUMBER	BODY		BRAIN		HEART		LIVER		SPLEEN		TESTES		KIDNEYS	
		WEIGHT (GRAMS)	WEIGHT (G/100)												
	4273	335.7	1.91	0.57	1.25	0.37	18.2	5.4*	0.703	0.209	2.95	0.88	3.09	0.92	
	4274	341.0	1.91	0.56	1.17	0.34	10.9	3.2	0.522	0.153	2.95	0.87	2.65	0.78	
	4275	391.2	2.01	0.51	1.25	0.32	12.7	3.2	0.692	0.177	3.66	0.94	3.66	0.94	
	4276	415.7	2.03	0.49	1.40	0.34	13.2	3.2	0.766	0.184	3.92	0.94	3.52	0.85	
	4277	439.4	2.03	0.46	1.78*	0.41	14.4	3.3	0.633	0.144	4.23	0.96	3.67	0.84	
	4278	412.6	2.07	0.50	1.27	0.31	13.5	3.3	0.843	0.204	3.98	0.96	3.34	0.81	
	MEAN	389.3	1.99	0.52	1.35	0.35	13.8	3.6	0.693	0.179	3.62	0.92	3.32	0.85	
	ST. DEV.	42.3	0.07	0.04	0.22	0.04	2.4	0.9	0.110	0.026	0.55	0.04	0.40	0.06	
	N=	6	6	6	6	6	6	6	6	6	6	6	6	6	
	4285	343.6	1.93	0.56	1.35	0.39	10.7	3.1	0.638	0.186	2.69	0.78	3.05	0.89	
	4286	360.9	1.96	0.54	1.19	0.33	10.6	2.9	0.489	0.135	3.17	0.88	2.87	0.80	
	4287	394.7	2.13	0.54	1.35	0.34	19.9*	5.0*	0.812	0.206	3.37	0.85	3.89	0.99	
	4288	377.8	1.99	0.53	1.30	0.34	12.6	3.3	0.644	0.170	3.59	0.95	3.69	0.98	
	4289	430.5	2.14	0.50	1.38	0.32	12.9	3.0	0.700	0.163	3.81	0.89	3.78	0.88	
	4290	328.0	2.07	0.63	1.18	0.36	9.5	2.9	0.504	0.154	3.12	0.95	2.83	0.86	
	MEAN	372.6	2.04	0.55	1.29	0.35	12.7	3.4	0.631	0.169	3.29	0.88	3.35	0.90	
	ST. DEV.	37.0	0.09	0.05	0.09	0.03	3.8	0.8	0.122	0.025	0.39	0.06	0.49	0.07	
	N=	6	6	6	6	6	6	6	6	6	6	6	6	6	

\* INDICATES STATISTICAL OUTLIERS WHICH ARE NOT EXCLUDED FROM CALCULATIONS

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APPENDIX IX (CONT.)

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL ABSOLUTE AND RELATIVE ORGAN WEIGHT DATA.  
MALE RATS.

DOSE 1500M G/KG	ANIMAL NUMBER	BODY WEIGHT	BRAIN WEIGHT		HEART WEIGHT		LIVER WEIGHT		SPLEEN WEIGHT		TESTES WEIGHT		KIDNEYS WEIGHT	
		(GRAMS)	(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)
	4297	356.7	1.94	0.54	1.08	0.30	18.0	5.0	0.666	0.187	2.68	0.75	3.44	0.96
	4298	294.0	1.84	0.63	0.93	0.32	13.5	4.6	0.438	0.149	2.54	0.86	2.52	0.86
	4299	331.0	1.95	0.59	1.25	0.38	15.2	4.6	0.596	0.180	2.56	0.77	3.12	0.94
	4300	342.6	1.90	0.55	1.14	0.33	14.4	4.2	0.692	0.202	2.86	0.83	3.18	0.93
	4301	304.8	2.06	0.54	1.18	0.31	17.8	4.6	0.748	0.194	2.66	0.69	3.97	1.03
	4302	343.0	1.86	0.54	1.03	0.30	17.7	5.2	0.547	0.159	2.75	0.80	2.92	0.85
	MEAN	342.0	1.93	0.57	1.10	0.32	16.1	4.7	0.615	0.179	2.68	0.79	3.19	0.93
	ST. DEV.	29.9	0.08	0.04	0.11	0.03	2.0	0.3	0.112	0.021	0.12	0.06	0.49	0.07
	N=	6	6	6	6	6	6	6	6	6	6	6	6	6

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APPENDIX X

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL ABSOLUTE AND RELATIVE ORGAN WEIGHT DATA.  
MALE RATS.

DOSE 1500M G/KG	ANIMAL NUMBER	BODY WEIGHT (GRAMS)	BRAIN WEIGHT		HEART WEIGHT		LIVER WEIGHT		SPLEEN WEIGHT		TESTES WEIGHT		KIDNEYS WEIGHT	
			(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)
CONTROL	4309	353.5	1.97	0.56	1.34	0.38	10.8	3.1	0.630	0.178	3.29	0.93	3.02	0.85
	4310	403.6	2.01	0.50	1.39	0.34	13.6	3.4	0.717	0.178	3.60	0.89	3.70	0.92
	4311	385.6	2.08	0.54	1.31	0.34	10.6	2.7	0.681	0.177	3.35	0.87	2.96	0.77
	4312	363.0	1.77*	0.49	1.17	0.32	10.0	2.8	0.639	0.176	2.81	0.77	3.11	0.86
	4313	411.7	2.06	0.50	1.42	0.34	17.1	4.2	0.885	0.215	3.24	0.79	3.27	0.79
	4314	324.3	2.05	0.63	1.41	0.43	14.7	4.5	0.702	0.216	3.23	1.00	3.54	1.09
	MEAN		373.6	1.99	0.54	1.34	0.36	12.8	3.4	0.709	0.190	3.25	0.87	3.27
ST.DEV.		33.0	0.11	0.05	0.09	0.04	2.8	0.7	0.093	0.020	0.26	0.08	0.30	0.12
N=		6	6	6	6	6	6	6	6	6	6	6	6	6
D3	4321	323.0	1.97	0.61	1.48	0.46	16.4	5.1	0.606	0.188	3.70	1.15	3.07	0.95
	4322	342.4	1.83	0.53	1.05	0.31	17.0	5.0	0.567	0.166	2.78	0.81	3.26	0.95
	4323	314.1	1.84	0.59	1.01	0.32	13.3	4.2	0.636	0.202	2.64	0.84	2.78	0.89
	4324	386.9	2.13	0.55	1.28	0.33	18.8	4.9	0.690	0.178	3.31	0.86	3.90	1.01
	4325	364.2	2.13	0.58	1.32	0.36	16.1	4.4	0.680	0.187	3.66	1.00	3.71	1.02
	4326	381.3	1.88	0.49	1.48	0.39	18.9	5.0	0.624	0.164	3.44	0.91	3.88	1.02
	MEAN		352.0	1.96	0.56	1.27	0.36	16.8	4.8	0.634	0.181	3.26	0.93	3.43
ST.DEV.		30.3	0.14	0.04	0.20	0.06	2.1	0.3	0.046	0.015	0.45	0.13	0.47	0.05
N=		6	6	6	6	6	6	6	6	6	6	6	6	6

\* INDICATES STATISTICAL OUTLIERS WHICH ARE NOT EXCLUDED FROM CALCULATIONS

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APPENDIX XI

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL ABSOLUTE AND RELATIVE ORGAN WEIGHT DATA.  
FEMALE RATS.

DOSE	ANIMAL	BODY	BRAIN		HEART		LIVER		SPLEEN		OVARIES		KIDNEYS		
1500M	NUMBER	WEIGHT													
G/KG		(GRAMS)	(GRAMS)	(G/100)											
CONTROL	4207	232.0	1.71	0.74	1.03	0.44	9.39	4.05*	0.470	0.203	0.101	0.044	1.78	0.77	
	4208	247.4	1.90	0.77	0.95	0.38	7.50	3.03	0.638	0.258*	0.116	0.047	1.98	0.80	
	4209	240.3	1.63	0.68	0.94	0.39	7.31	3.04	0.526	0.219	0.097	0.040	1.72	0.72	
	4210	254.2	1.77	0.70	0.88	0.35	6.68	2.63*	0.558	0.220	0.090	0.035	1.89	0.74	
	4211	254.6	1.78	0.70	0.92	0.36	7.71	3.03	0.529	0.208	0.076	0.030	1.76	0.69	
	4212	239.1	1.70	0.71	0.88	0.37	7.23	3.02	0.507	0.212	0.085	0.036	1.83	0.77	
	MEAN		244.6	1.75	0.71	0.93	0.38	7.64	3.13	0.538	0.220	0.094	0.039	1.83	0.75
ST.DEV.		9.0	0.09	0.03	0.06	0.03	0.93	0.48	0.057	0.020	0.014	0.006	0.10	0.04	
N=		6	6	6	6	6	6	6	6	6	6	6	6	6	
MM	4219	209.3	1.90	0.91	0.75	0.36	6.64	3.17	0.439	0.210	0.076	0.036	1.44	0.69	
	4221	217.4	1.51	0.69	0.82	0.38	6.54	3.01	0.474	0.218	0.092	0.042	1.74	0.80	
	4222	235.8	1.61	0.68	0.82	0.35	7.47	3.17	0.454	0.193	0.092	0.039	1.87	0.79	
	4223	227.5	1.86	0.82	0.81	0.36	6.91	3.04	0.463	0.204	0.096	0.042	1.97	0.87	
	4224	253.5	1.80	0.71	1.04	0.41	8.03	3.17	0.446	0.174	0.107	0.042	1.97	0.78	
	MEAN		228.7	1.74	0.76	0.85	0.37	7.12	3.11	0.455	0.200	0.093	0.040	1.80	0.78
	ST.DEV.		17.1	0.17	0.10	0.11	0.02	0.62	0.08	0.014	0.016	0.011	0.003	0.22	0.06
N=		5	5	5	5	5	5	5	5	5	5	5	5	5	

\* INDICATES STATISTICAL OUTLIERS WHICH ARE NOT EXCLUDED FROM CALCULATIONS

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APPENDIX XI (CONT.)

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL ABSOLUTE AND RELATIVE ORGAN WEIGHT DATA.  
FEMALE RATS.

DOSE 1500M G/KG	ANIMAL NUMBER	BODY WEIGHT (GRAMS)	BRAIN WEIGHT (GRAMS) (G/100)	HEART WEIGHT (GRAMS) (G/100)	LIVER WEIGHT (GRAMS) (G/100)	SPLEEN WEIGHT (GRAMS) (G/100)	OVARIES WEIGHT (GRAMS) (G/100)	KIDNEYS WEIGHT (GRAMS) (G/100)						
	4231	230.5	1.69	0.73	0.87	0.38	7.64	3.31	0.428	0.186	0.073	0.032	1.60	0.69
	4232	232.1	1.81	0.78	0.89	0.38	7.62	3.28	0.517	0.223	0.093	0.040	1.73	0.75
	4233	237.3	1.80	0.76	0.84	0.35	8.01	3.38	0.405	0.171	0.077	0.032	1.75	0.74
	4234	223.2	1.74	0.78	0.78	0.35	7.03	3.15	0.493	0.221	0.095	0.043	1.92	0.86
	4235	233.1	1.79	0.77	0.81	0.35	7.17	3.08	0.464	0.199	0.099	0.042	1.82	0.78
	4236	263.3*	1.94	0.74	0.87	0.33	7.89	3.00	0.498	0.189	0.103	0.039	1.87	0.71
	MEAN	236.6	1.80	0.76	0.84	0.36	7.56	3.20	0.468	0.198	0.090	0.038	1.78	0.75
	ST.DEV.	13.9	0.08	0.02	0.04	0.02	0.39	0.15	0.044	0.021	0.012	0.005	0.11	0.06
	N=	6	6	6	6	6	6	6	6	6	6	6	6	6
	4243	225.9	1.87	0.83	0.84	0.37	6.74	2.98	0.568	0.251	0.117	0.052	1.89	0.84
	4244	211.9	1.79	0.84	0.83	0.39	6.68	3.15	0.474	0.224	0.086	0.041	1.61	0.76
	4245	224.2	1.83	0.82	0.83	0.37	7.10	3.17	0.476	0.212	0.072	0.032	1.85	0.83
	4246	241.3	1.84	0.76	0.94	0.39	7.74	3.21	0.560	0.228	0.081	0.034	1.85	0.77
	4247	253.8	1.90	0.75	0.84	0.33	8.03	3.16	0.600	0.236	0.087	0.034	1.97	0.78
	4248	256.5	1.83	0.71	0.91	0.35	7.93	3.09	0.702	0.274	0.112	0.044	2.09	0.81
	MEAN	235.6	1.84	0.79	0.87	0.37	7.37	3.13	0.562	0.238	0.093	0.039	1.88	0.80
	ST.DEV.	17.8	0.04	0.05	0.05	0.02	0.61	0.08	0.085	0.022	0.018	0.008	0.16	0.03
	N=	6	6	6	6	6	6	6	6	6	6	6	6	6

\* INDICATES STATISTICAL OUTLIERS WHICH ARE NOT EXCLUDED FROM CALCULATIONS

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APPENDIX XI (CONT.)

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL ABSOLUTE AND RELATIVE ORGAN WEIGHT DATA.  
FEMALE RATS.

DOSE 1500M G/KG	ANIMAL NUMBER	BODY WEIGHT (GRAMS)	BRAIN WEIGHT (GRAMS)	BRAIN WEIGHT (G/100)	HEART WEIGHT (GRAMS)	HEART WEIGHT (G/100)	LIVER WEIGHT (GRAMS)	LIVER WEIGHT (G/100)	SPLEEN WEIGHT (GRAMS)	SPLEEN WEIGHT (G/100)	OVARIES WEIGHT (GRAMS)	OVARIES WEIGHT (G/100)	KIDNEYS WEIGHT (GRAMS)	KIDNEYS WEIGHT (G/100)
	4255	216.7	1.71	0.79	0.80	0.37	6.83	3.15	0.478	0.221	0.060	0.028	1.66	0.77
	4256	213.4	1.78	0.83	0.85	0.40	6.36	2.98	0.390	0.183	0.079	0.037	1.56	0.73
	4257	247.6	1.75	0.71	0.82	0.33	8.13	3.28	0.614	0.248	0.140	0.057	2.01	0.81
	4258	224.0	1.84	0.82	0.85	0.38	7.13	3.18	0.600	0.268	0.107	0.048	1.86	0.83
	4259	232.4	1.83	0.79	0.88	0.38	7.64	3.29	0.629	0.271	0.101	0.043	1.85	0.80
	4260	247.6	1.81	0.73	0.91	0.37	8.79	3.55	0.576	0.233	0.110	0.044	2.02	0.82
	MEAN	230.3	1.79	0.78	0.85	0.37	7.48	3.24	0.548	0.237	0.100	0.043	1.83	0.79
	ST.DEV.	14.9	0.05	0.05	0.04	0.02	0.89	0.19	0.094	0.033	0.028	0.010	0.19	0.04
	N=	6	6	6	6	6	6	6	6	6	6	6	6	6
	4267	209.2	1.85	0.88	0.67	0.32	5.38	2.57	0.415	0.198	0.077	0.037	1.63	0.78
	4268	210.1	1.87	0.89	0.77	0.37	5.87	2.79	0.501	0.238	0.084	0.040	1.67	0.79
	4269	241.7	1.97	0.82	0.87	0.36	7.21	2.98	1.365*	0.565*	0.089	0.037	1.74	0.72
	4270	230.8	1.85	0.80	0.97	0.42	6.58	2.85	0.428	0.185	0.074	0.032	1.83	0.79
	4271	232.3	1.89	0.81	0.84	0.36	6.24	2.69	0.474	0.204	0.084	0.036	1.74	0.75
	4272	281.1	1.84	0.65	1.03	0.37	8.57	3.05	0.561	0.200	0.092	0.033	2.10	0.75
	MEAN	234.2	1.88	0.81	0.86	0.37	6.64	2.82	0.624	0.265	0.083	0.036	1.79	0.76
	ST.DEV.	26.4	0.05	0.09	0.13	0.03	1.13	0.18	0.367	0.148	0.007	0.003	0.17	0.03
	N=	6	6	6	6	6	6	6	6	6	6	6	6	6

\* INDICATES STATISTICAL OUTLIERS WHICH ARE NOT EXCLUDED FROM CALCULATIONS

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APPENDIX XI (CONT.)

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL ABSOLUTE AND RELATIVE ORGAN WEIGHT DATA.  
FEMALE RATS.

DOSE	ANIMAL	BODY	BRAIN	HEART	LIVER	SPLEEN	OVARIES	KIDNEYS						
1500M	NUMBER	WEIGHT												
G/KG		(GRAMS)												
	4279	228.0	1.87	0.82	0.84	0.37	10.54	4.62	0.571	0.250*	0.089	0.039	1.74	0.76
	4280	219.1	1.77	0.81	0.77	0.35	7.28	3.32	0.407	0.186	0.069	0.031	1.66	0.76
	4335	268.3	1.89	0.70	0.94	0.35	10.15	3.78	0.462	0.172	0.111	0.041	2.25	0.84
	4282	237.2	1.71	0.72	0.98	0.41	9.38	3.95	0.401	0.169	0.077	0.032	2.03	0.86
	4283	242.9	1.82	0.75	0.97	0.40	9.76	4.02	0.464	0.191	0.111	0.046	2.01	0.83
	4338	262.6	1.99	0.76	0.97	0.37	9.12	3.47	0.464	0.177	0.105	0.040	1.93	0.73
	MEAN	243.0	1.84	0.76	0.91	0.38	9.37	3.86	0.462	0.191	0.094	0.038	1.94	0.80
	ST.DEV.	19.3	0.10	0.05	0.09	0.03	1.15	0.46	0.061	0.030	0.018	0.005	0.21	0.05
	N=	6	6	6	6	6	6	6	6	6	6	6	6	6
	4291	211.1	1.79	0.85	0.75	0.36	6.61	3.13	0.487	0.231	0.072	0.034	1.66	0.79
	4292	239.2	2.01	0.84	0.78	0.33	6.64	2.78	0.376	0.157	0.087	0.036	1.82	0.76
	4293	233.7	1.82	0.78	0.89	0.38	7.70	3.29	0.624	0.267	0.093	0.040	1.85	0.79
	4294	257.8	1.67	0.65	0.87	0.34	8.90	3.45	0.588	0.228	0.117	0.045	2.14	0.83
	4295	272.7	1.76	0.65	1.02	0.37	9.07	3.33	0.538	0.197	0.086	0.032	2.11	0.77
	4296	253.3	1.75	0.69	0.91	0.36	7.95	3.14	0.585	0.231	0.112	0.044	2.02	0.80
	MEAN	244.6	1.80	0.74	0.87	0.36	7.81	3.19	0.533	0.219	0.095	0.039	1.93	0.79
	ST.DEV.	21.5	0.11	0.09	0.10	0.02	1.06	0.23	0.090	0.037	0.017	0.006	0.19	0.02
	N=	6	6	6	6	6	6	6	6	6	6	6	6	6

\* INDICATES STATISTICAL OUTLIERS WHICH ARE NOT EXCLUDED FROM CALCULATIONS

APPENDIX XI (CONT.)

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL ABSOLUTE AND RELATIVE ORGAN WEIGHT DATA.  
FEMALE RATS.

DOSE 1500M G/KG	ANIMAL NUMBER	BODY WEIGHT (GRAMS)	BRAIN WEIGHT (GRAMS) (G/100)	HEART WEIGHT (GRAMS) (G/100)	LIVER WEIGHT (GRAMS) (G/100)	SPLEEN WEIGHT (GRAMS) (G/100)	OVARIES WEIGHT (GRAMS) (G/100)	KIDNEYS WEIGHT (GRAMS) (G/100)						
	4303	211.6	1.76	0.83	0.85	0.40	10.01	4.73	0.452	0.214	0.084	0.040	1.76	0.83
	4304	228.5	1.84	0.81	0.91	0.40	11.40	4.99	0.397	0.174	0.093	0.041	1.80	0.79
	4334	215.6	1.84	0.85	0.78	0.36	13.64	6.33	0.500	0.232	0.122	0.057*	2.12	0.98
	4306	219.8	1.80	0.82	0.89	0.40	12.00	5.46	*****	*****	0.085	0.039	1.76	0.80
	4308	254.7	1.70	0.67	0.93	0.37	11.37	4.46	0.524	0.206	0.103	0.040	1.84	0.72
	MEAN	226.0	1.79	0.80	0.87	0.39	11.68	5.19	0.468	0.206	0.097	0.043	1.86	0.83
	ST.DEV.	17.2	0.06	0.07	0.06	0.02	1.31	0.73	0.056	0.024	0.016	0.008	0.15	0.10
	N=	5	5	5	5	5	5	5	4	4	5	5	5	5

\* INDICATES STATISTICAL OUTLIERS WHICH ARE NOT EXCLUDED FROM CALCULATIONS  
\*\*\*\*\* INDICATES DEAD ANIMALS OR MISSING VALUES

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APPENDIX XII

28-DAY SUBCHRONIC ORAL GAVAGE FEASIBILITY STUDY  
WITH VARIOUS LOW MOLECULAR WEIGHT SILICONE OLIGOMERS.  
INDIVIDUAL ABSOLUTE AND RELATIVE ORGAN WEIGHT DATA.  
FEMALE RATS.

DOSE 1500M G/KG	ANIMAL NUMBER	BODY WEIGHT (GRAMS)	BRAIN WEIGHT		HEART WEIGHT		LIVER WEIGHT		SPLEEN WEIGHT		OVARIES WEIGHT		KIDNEYS WEIGHT	
			(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)	(GRAMS)	(G/100)
CONTROL	4315	225.7	1.81	0.80	0.78	0.35	6.37	2.82	0.386	0.171	0.070	0.031	1.70	0.75
	4316	233.1	1.75	0.75	0.93	0.40	7.49	3.21	0.646	0.277	0.088	0.038	1.95	0.84*
	4336	207.6	1.76	0.85	0.39*	0.19*	5.36	2.58	0.304	0.185	0.064	0.031	1.58	0.76
	4318	242.0	1.75	0.72	0.90	0.37	6.86	2.83	0.610	0.252	0.114	0.047	1.78	0.74
	4319	225.0	1.56	0.69	0.87	0.39	6.56	2.92	0.467	0.208	*****	*****	1.73	0.77
	4337	249.7	1.92	0.77	0.89	0.36	7.58	3.04	0.550	0.220	0.099	0.040	1.86	0.74
	MEAN	230.5	1.76	0.76	0.79	0.34	6.70	2.90	0.507	0.219	0.087	0.037	1.77	0.77
ST.DEV.	14.7	0.12	0.06	0.20	0.08	0.82	0.21	0.112	0.040	0.021	0.007	0.13	0.04	
N=	6	6	6	6	6	6	6	6	6	5	5	6	6	
D3	4327	197.1	1.77	0.90	0.94	0.48	8.33	4.23	0.371	0.188	0.065	0.033	1.99	1.01
	4328	213.6	1.76	0.82	0.82	0.38	9.48	4.44	0.447	0.209	0.096	0.045	1.73	0.81
	4329	221.7	1.72	0.78	0.93	0.42	9.23	4.16	0.416	0.188	0.071	0.032	1.63	0.74
	4330	223.0	1.64	0.74	0.91	0.41	9.36	4.20	0.378	0.170	0.088	0.039	1.81	0.81
	4331	257.7	1.79	0.69	0.97	0.38	11.10	4.31	0.614	0.238	0.061	0.024	2.20	0.85
	4332	227.2	1.80	0.79	0.88	0.39	10.29	4.53	0.463	0.204	0.094	0.041	1.91	0.84
	MEAN	223.4	1.75	0.79	0.91	0.41	9.63	4.31	0.448	0.199	0.079	0.036	1.88	0.84
ST.DEV.	19.9	0.06	0.07	0.05	0.04	0.95	0.15	0.089	0.024	0.015	0.008	0.20	0.09	
N=	6	6	6	6	6	6	6	6	6	6	6	6	6	

\* INDICATES STATISTICAL OUTLIERS WHICH ARE NOT EXCLUDED FROM CALCULATIONS  
\*\*\*\*\* INDICATES DEAD ANIMALS OR MISSING VALUES

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STUDY TITLE: A 28-Day Subchronic Oral Gavage Feasibility Study of various Low Molecular Weight Oligomers in Rats.

HISTOPATHOLOGY ADDENDUM:

Histopathologic examination was performed on the limited tissues collected at gross necropsy.

Lung and pleural inflammatory changes consistent with dosing errors due to aspiration and/or traumatic instillation of foreign material into the thorax were present in 10/66 males and 20/66 females. Those changes were present in animals from all groups and constitute a confounding factor in understanding the peroral toxic effects attributable to the articles under investigation.

Liver changes were recorded at low frequency in all groups, but many affected animals also had confounding dosing error-related lung changes. Group #6 females, group #2 (MM) males, group #9 males, and group #11 (D3) males each had increased frequency of liver changes in the absence of confounding lung changes. No definitive histopathological correlates to increased liver weight were detectable.

Kidney changes consisting of increased hyaline or eosinophilic droplets in the proximal tubule epithelial cells (Hyaline Droplet Nephropathy (HDN)) were noted in every male in groups #2 (MM), #9 and #11 (D3). That change is apparently unique to male rats and is due to alteration in the urinary excretion of alpha-2-microglobulin. The condition has been related to exposure to a variety of volatile hydrocarbons in which the parent compound or metabolite complexes with alpha-2-microglobulin and is deposited in secondary lysosomes. A recent paper (1) by Lehman-McKeeman, et al, reviews the literature on hyaline droplet nephropathy in rats, its relationship to renal carcinogenesis in chronic studies, and its apparent lack of correlates in other species. The relationship between increased mean kidney weight and HDN in this study is not clear, as group #11 (D3) males did not have statistically significant increase in mean kidney weight in the presence of HDN, but group #3 males had significantly increased mean kidney weight without notable increase in hyaline droplets. Very mild renal proximal tubular epithelial cell degeneration/regeneration in 5/6 group #3 females suggests test article-related increased cell turnover.

All other histopathologic findings were considered to be within the normal range of variation for animals of this strain and age, euthanatized in this manner, or were attributable to intercurrent disease or processing artifact.

In summary, definite test article-related changes were present in livers and kidneys of male rats administered MM, , or D3. Female rats administered had subtle kidney changes that were probably test article-related. Females administered MM or had liver changes that were considered related to gavage treatment but not necessarily to the test article. These results are drawn from a limited screening study with few exposed animals and incomplete tissues. This report should not be construed as an adequate oral toxicology assessment of any of the materials.

(1) Lehman-McKeeman L.D., Rodriguez, P.A., Caudill, D., Fey, M.L., Eddy, C.L., Asquith, T.N. Hyaline Droplet Nephropathy Resulting From Exposure to 3,5,5-Trimethylhexanoyloxybenzene Sulfonate. Toxicology and Applied Pharmacology 107, 429-438 (1991).

GROUP #2 HEXAMETHYLDISILOXANE (MM)

Four of five MM-treated males free of confounding lung changes had evidence of intracanalicular and/or intracellular bile stasis, with granulomatous cholangitis in one. Six of six MM-treated males had markedly increased incidence of hyaline droplets in proximal tubule epithelium of the kidneys.

Two of five surviving MM-treated females had increased hepatocyte nuclear pleomorphism, suggesting increased cell turnover in the liver. Renal tubular mineralization was evident in 2/5 females.

GROUP #3

No test article-related histopathologic changes were evident in -treated males. Very mild renal proximal tubular degeneration/regeneration in 5/6 females suggests test article-related increased cell turnover.

GROUP #4

No test article-related histopathologic changes were evident in -treated males or females.

GROUP #5

No test article-related histopathologic changes were evident in -treated males or females.

GROUP #6

No test article-related histopathologic changes were evident in treated males. Focal hepatic necrosis with local inflammation was present in 3/5 females without evidence of confounding dosing errors. This change is more consistent with bacterial embolization than toxic hepatic injury, and so is considered to be treatment-related but not necessarily test article-related.

GROUP #7

No test article-related histopathologic changes were evident in -treated males or females.

GROUP #8

No test article-related histopathologic changes were evident in -treated males or females.

GROUP #9

Six of six -treated males had markedly increased incidence of hyaline droplets in proximal tubule epithelium of the kidneys. Liver changes consisting of centrilobular hepatocyte swelling and decreased cytoplasmic granularity were recognized in most males. No -related histopathologic changes were noted in females.

GROUP #11 HEXAMETHYLCYCLOTRISILOXANE (D3)

Six of six D3-treated males had markedly increased incidence of hyaline droplets in proximal tubule epithelium of the kidneys. Three of six males administered only the sesame oil vehicle also had HDN, but those inclusions were morphologically distinct from those in the D3-treated males. Three of five D3-treated males free of confounding lung changes had evidence of intracanalicular and/or intracellular bile stasis, with granulomatous cholangitis in one and multifocal hepatocellular necrosis in another. No D3-related histopathologic changes were noted in females.

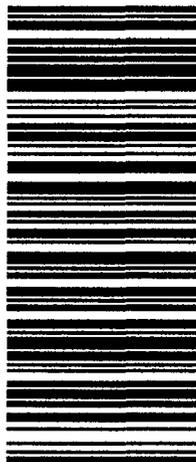
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