

**TSCA NON-CONFIDENTIAL BUSINESS INFORMATION**

**DOCUMENT DESCRIPTION**

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CONTROL Nº**

**DATE**

**8EHQ-09-17683**

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**10/14/09**

**COMMENTS:**

**ORIGINAL**

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October 05, 2009

TSCA Document Control Center (7407)  
Office of Pollution Prevention and Toxics  
US Environmental Protection Agency  
Attn: TSCA Section 8(e) Coordinator  
Ariel Rios Building  
1200 Pennsylvania Avenue, NW  
Washington, DC 20004



Re: TSCA Section 8(e) Notification of Substantial Risk  
Dodecamethylpentasiloxane  
CAS No.: 141-63-09

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, Dow Corning is submitting information from an 28-day oral toxicity (gavage) study conducted with dodecamethylpentasiloxane (CAS No. 141-63-09) in Sprague-Dawley Rats. 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 Substance**

Dodecamethylpentasiloxane  
CAS No.: 141-63-09

**Finalized Study**

28-Day Oral (Gavage) Toxicity Study in the Sprague-Dawley Rat with Dodecamethylpentasiloxane

**Summary**

This study was conducted in accordance with OECD 407 test guideline. Groups were comprised of five animals per sex and were sacrificed after 28 days of repeated dose treatment. Daily dose levels were 0, 25, 250, and 1000 mg/kg in corn oil vehicle. An additional five rats/sex/group were included in the 0 and 1000 mg/kg dose groups as satellite recovery groups. These animals were treated for 28 days and then allowed a 14-day treatment-free recovery period after which they were sacrificed. The notable findings of significance for this study included bile duct proliferation in males at 1000 mg/kg and in females at 250 and 1000 mg/kg dose groups. There was also presence of periportal hepatocellular

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vacuolation in males at 250 and 1000 mg/kg dose groups and in females at all dose levels (25, 250 and 1000 mg/kg/day).

After 14-day recovery period, no findings were diagnosed that distinguished treated rats from the control rats.

## Details

### **Study Design**

In this subacute toxicity study, dodecamethylpentasiloxane was administered daily by oral gavage to Sprague-Dawley rats of both sexes at dose levels of 25, 250 and 1000 mg/kg/day for 28 consecutive days. A control group was treated similarly with the vehicle, dried and deacidified corn oil.

The groups, comprised of five animals per sex, were sacrificed the day after the last dose. An additional five rats/sex /group were dosed at the 0 and 1000 mg/kg dose levels. These animals were treated for 28 days and then allowed a 14-day treatment-free recovery period after which they were sacrificed.

Clinical signs, outside cage observation, food consumption and body weights were recorded periodically during the treatment and recovery periods. Functional observational battery, locomotor activity and grip strength were performed during week 4.

At the end of the dosing and the treatment-free recovery period, blood samples were withdrawn for hematology and clinical chemistry analysis. Urine samples were collected for urinalyses. All animals were killed, necropsied and examined post mortem. Histological examinations were performed on organs and tissues from all control and high dose animals, and on liver from all animals.

### **Results**

Mean absolute and relative liver weights were elevated in males treated with 250 and 1000 mg/kg. Relative liver weight was increased 19% ( $p<0.01$ ) and 16% ( $p<0.01$ ) for the 250 and 1000 mg/kg dose groups, respectively. Increase in absolute liver weight reached statistical significance only in 250 mg/kg dose group (20%,  $p<0.05$ ). In females, both mean absolute and relative liver weights were elevated at all dose levels. Absolute liver weight was increased 20% ( $p<0.05$ ), 26% ( $p<0.01$ ) and 33% ( $p<0.01$ ), and relative liver weight was increased 16% ( $p<0.01$ ), 25% ( $p<0.01$ ) and 28% ( $p<0.01$ ) for the 25, 250 and 1000 mg/kg dose groups, respectively. The increase in liver weights was reversible after 14-day recovery period. Macroscopically, accentuated lobular pattern was only noted on the liver of the males treated with 1000 mg/kg.

Microscopic evaluation of tissues collected from the main study animals revealed the following test article related effects (presented as incidence, mean severity grade): Bile duct proliferation was noted in males at 1000 mg/kg (4/5, 1.0) compared to the controls (2/5, 1.0), and in females at 250 (4/5, 1.0) and 1000 mg/kg (4/5, 1.0) compared to the controls (1/5, 1.0). Periportal hepatocellular vacuolation was only present in males at 250 mg/kg (2/5, 1.0) and 1000 mg/kg (3/5, 1.0). In females, periportal hepatocellular vacuolation was seen at all dose levels with increased severity (5/5, 1.4, 5/5, 2.0 and 4/5, 2.0 at 25, 250 and 1000 mg/kg, respectively) compared to the controls (2/5, 1.0). After 14-day recovery period, no findings were diagnosed that distinguished treated rats from the controls.

**Actions**

Dow Corning Corporation will notify EPA of any further relevant information that may be developed concerning this material. The final report for the subject study is attached. 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

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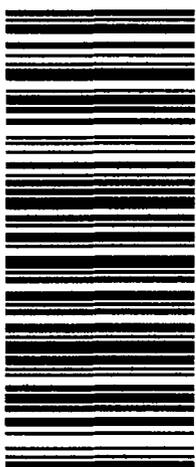
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<p>CONNIE LAFRAMBOISE 989-496-5393 DOW CORNING 2200 WEST SALZBURG AUBURN MI 48611</p> <p style="text-align: right;"><b>LTR</b></p> <p style="text-align: right;"><b>1 OF 1</b></p> <p><b>SHIP TO:</b> CBIC - DOCUMENT CONTROL OFFICE (202) 564-8999 EPA - OPPT DOCUMENT CONTROL OFFICER EPA EAST, MAIL: (7407), ROOM: 6248 1201 CONSTITUTION AVENUE, NW <b>WASHINGTON DC 20460-0006</b></p>	<p><b>MD 201 9-80</b></p> 	<p><b>UPS NEXT DAY AIR</b></p> <p><b>1</b></p> <p>TRACKING #: 1Z 464 696 25 9107 6451</p> 	<p><b>BILLING: P/P</b></p> <p>Reference# 1: TSCA 8(e) 100909</p> <p style="font-size: small;">UPS 11.7.03. WXP0E60 93.0A 07/2009</p>  <p style="text-align: right; font-size: x-small;">TM</p>
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