ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

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COMMENTS:

DOES NOT CONTAIN CBI

328374

Shin-Etsu

Via Courier

July 12, 2010

8EHQ-0710-18033A
DCN: 88100000358

TSCA Confidential Business Information Center (7407M)
EPA East – Room 6428
Attn: Section 8(e)
U.S. Environmental Protection Agency
Ariel Rios Building
1201 Constitution Avenue, NW
Washington, DC 20004-3302

Re: TSCA Section 8(e) Notification of Substantial Risk: R-BAC Catalyst inhibitor

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, Shin-Etsu Silicones of America Inc. (Shin-Etsu) submits information concerning a study with R-BAC catalyst inhibitor (R-BAC). Shin-Etsu 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

R-BAC catalyst inhibitor (R-BAC)

Name: 4,7,10,15-Tetraoxa-14-silaecos-19-yn-18-ol,14,14-dibutyl-1,1,1,2,2,3,3,5,6,6,8-undecafluoro-18-methyl-5,8-bis(trifluoromethyl)-

CAS RN 717825-76-8

Studies

Repeated Dose 28-Day Oral Toxicity Study in Rat

Summary

B.N.

CONTAINS NO CBI

In a repeated-dose oral toxicity study with R-BAC in Wistar rats there were various changes in hematology and blood chemistry parameters in the mid and high dose groups (males and females); organ to body weight increases of liver (high dose only), kidney and testes in high and mid-dose male rats, and organ to body weight increases of liver (high dose only), and decreases of brain and adrenal gland weights in mid and high dose female rats. Histopathological changes in the liver and epididymis were reported for high dose male rats. The No-Observed-Adverse-Effect-Level (NOAEL) of R-BAC is 5 mg/kg bw.

Details

Study Design

In a 28-day repeated dose toxicity test following The Guidelines for the Testing of Chemicals (State Environmental Protection Administration of China 2004.5) and The Guidelines for the Hazard Evaluation of New Chemical Substances (State Environmental Protection Administration of China 2004.4), Wistar rats (10/sex/group) were exposed by oral gavage to R-BAC in edible oil at dose levels of 5, 50 and 1000 mg/kg bw. Control animals were administered edible oil. Rats were observed daily throughout the study and body weights were recorded. At the end of the 28 day exposure period, samples were collected for hematology, blood chemistry, and urinalysis; gross necropsies were performed and histopathology conducted for selected tissues. Organ weights were recorded for selected organs.

Results

There were no clinical signs or adverse changes in body weights.

In the middle and high dose groups of male rats there was a significant increase in hematological and blood chemistry parameters reported as compared to control animals (total erythrocyte count, hemoglobin concentration, hematocrit, platelets, lymphocytes, alanine aminotransferase, aspartate aminotransferase, alkaline phosphate, blood urea nitrogen, sodium and potassium). Granular cell count was decreased compared to controls in the middle and high dose group males. In the high dose group males, cholesterol was increased and creatinine was decreased compared to controls. In the middle and high dose groups of female rats there was a significant decrease in hematological parameters (hemoglobin concentration and hematocrit) and a significant increase in blood chemistry parameters(alanine aminotransferase, total protein, creatinine, glucose and albumin) compared to control animals.

In the middle and high dose groups of male rats there was a significant increase in liver weight relative to body weight. In high dose group males there was a significant increase in kidney and testicle weight relative to body weight. In the middle and high dose groups of female rats there was a significant increase in liver weight relative to body weight and a significant decrease in brain and adrenal gland weight relative to body weight. There were no effects on urinalysis parameters. Histopathological examination showed changes in the liver and epididymis of high dose group male rats. There were no histopathological findings in female animals.

Based on findings in male and female rats at 50 and 1000 mg/kg bw, the NOAEL of R-BAC is 5 mg/kg bw.

Action

If you have any questions concerning this submission, please contact me at (330) 630-9860, hamuro@shinetsua.com , or at the address provided below.

Sincerely,

Jun Hamuro
President
Shin- Etsu Silicones of America, Inc.
1150 Damar Drive
Akron, OH 44305

3283774

R-BAC L-05-0016

28 day study

From: Origin ID: CAKA (330) 630-9860
Carmen Brown
SHIN-ETSU SILICONES
1150 DAMAR DR

AKRON, OH 44305

J102010805258225

Ship Date: 12JUL10
ActWgt: 1.0 LB
CAD: 1505183/INET3060

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