

ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ-12-18871	8813000029	11/6/12

COMMENTS:

DOES NOT CONTAIN CBI



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October 31, 2012
TSCA Confidential Business Information Center (7407M)
EPA East - Room 6428 Attn: Section 8(e)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001



Ref: Test Item: Phenol, 4,4'-(1-methylethylidene)bis[2,6-dibromo-, polymer with 2-chloromethyl)oxirane (CASRN: 40039-93-8)
Test: OPPTS 870.3050 Repeated Dose 28-Day Oral Toxicity Study in Rodents

To Whom It May Concern,

ICL-IP America Inc. has recently conducted EPA OPPTS 870.3050 Repeated Dose 28-Day Oral Toxicity Study in Rodents (OECD Guidelines for the Testing of Chemicals No. 407) on its product Phenol, 4,4'-(1-methylethylidene)bis[2,6-dibromo-, polymer with 2-chloromethyl)oxirane (CASRN: 40039-93-8). Below is the test summary:

Methods. The test item was administered by gavage to three groups, each of five male and five female Wistar Han™:RccHan™:WIST strain rats, for twenty-eight consecutive days, at dose levels of 30, 300 and 1000 mg/kg bw/day. A control group of five males and five females was dosed with vehicle alone (Arachis oil BP). Two recovery groups, each of five males and five females, were treated with the high dose (1000 mg/kg bw/day) or the vehicle alone for twenty-eight consecutive days and then maintained without treatment for a further fourteen days.

Clinical signs, body weight change and food and water consumption were monitored during the study. Haematology, blood chemistry and urinalysis were evaluated for all non-recovery group animals at the end of the treatment period and for all recovery group animals at the end of the treatment-free period.

Results.

Mortality. There were no unscheduled deaths during the study.

Clinical Observations. There were no toxicologically significant clinical signs detected in treated animals.

Behavioural Assessment. There were no toxicologically significant changes in the behavioural parameters measured.

Functional Performance Tests. There were no toxicologically significant changes in functional performance.

Sensory Reactivity Assessments. There were no treatment-related changes in sensory reactivity.

Body Weight. A reduction in body weight gains was evident for males treated with 1000 mg/kg bw/day when compared to controls, during the treatment period. No such effects were detected in females treated with 1000 mg/kg bw/day or animals of either sex treated with 300 or 30 mg/kg bw/day.

Food Consumption. No adverse effect on food consumption was detected. Food efficiency was however reduced for males treated with 1000 mg/kg bw/day.

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Water Consumption. There were no toxicologically significant effects on water consumption.

Haematology. There were no toxicologically significant effects detected in the haematological parameters examined.

Blood Chemistry. Animals of either sex treated with 1000 and 300 mg/kg bw/day showed an increase in alanine aminotransferase levels. Bile acids were also higher for animals of either sex treated with 1000 mg/kg bw/day with the effect extending into the 300 mg/kg bw/day female dose group. Females treated with 1000 and 300 mg/kg bw/day showed an increase in aspartate aminotransferase. Recovery 1000 mg/kg bw/day males continued to show an increase in alanine aminotransferase and recovery 1000 mg/kg bw/day females continued to show an increase in bile acid. No such effects were detected in animals of either sex treated with 30 mg/kg bw/day.

Urinalysis: There were no toxicologically significant effects detected in the urinalytical parameters measured.

Necropsy. There were no toxicologically significant macroscopic abnormalities detected.

Organ Weights. Males treated with 1000 and 300 mg/kg bw/day showed a reduction in absolute liver weight. Relative liver weights for these animals were however increased. No such effects were detected for females treated with 1000 or 300 mg/kg bw/day or in animals of either sex treated with 30 mg/kg bw/day.

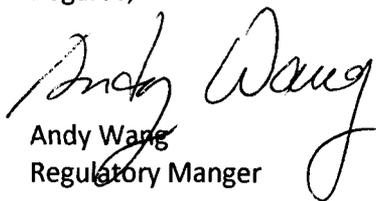
Histopathology. The following treatment-related microscopic findings were detected:

Liver: Minimal centrilobular hypertrophy was evident in all males treated with 1000 and 300 mg/kg bw/day and in three females each treated with 1000 and 300 mg/kg bw/day. At 1000 mg/kg bw/day, associated minimal increased glycogen deposits was also evident in either sex.

Conclusion. The oral administration of Brominated Epoxy having Epoxy Equivalent of 400gr/eq to rats by gavage, at dose levels of 30, 300 and 1000 mg/kg bw/day, resulted in treatment-related effects in animals of either sex treated with 1000 and 300 mg/kg bw/day. The effect on body weight gain detected in 1000 mg/kg bw/day males was considered to represent an adverse effect of treatment. The microscopic liver changes (identified as centrilobular hypertrophy) and metabolic blood chemical changes (identified as increases in alanine aminotransferase, aspartate aminotransferase or bile acids) at 1000 and 300 mg/kg bw/day were a consequence of treatment, however are considered not to represent an adverse health effect. As such the No Observed Adverse Effect Level (NOAEL) was considered to be 1000 mg/kg bw/day for females and 300 mg/kg bw/day for males.

Please feel free to contact me at (914) 269-5928 if you have any questions.

Regards,


Andy Wang
Regulatory Manger

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From: (914) 269-5924
Kim Johnson
ICL-IP America
Ardsley Park

Origin ID: CTXA



J12201209200325

Ardsley, NY 10502

Ship Date: 05NOV12
ActWgt: 1.0 LB
CAD: 9626040/NET3300

Delivery Address Bar Code



SHIP TO: (914) 269-5928

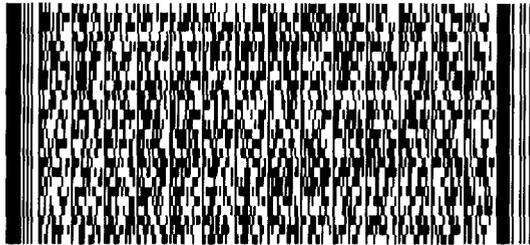
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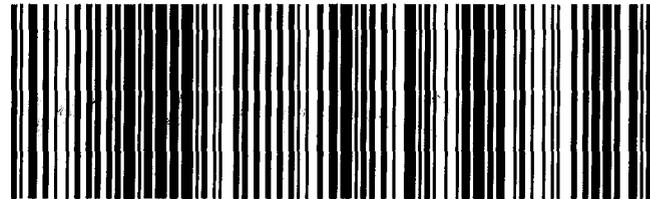
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PRIORITY OVERNIGHT

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