

ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

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8EHQ-10-18168	8811000052	11/5/10

COMMENTS:

DOES NOT CONTAIN CBI



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November 4, 2010

Office of Pollution Prevention and Toxics
U.S. EPA
Attn: Section 8(e)
1201 Constitution Avenue, NW
Washington, DC 20004

8EHQ-1110-18168A
DCN:88110000052

Subject: TSCA 8(e) Notice



11/10/10 11:10

Dear U.S. EPA:

On behalf of Akzo Nobel Surface Chemistry LLC, we are submitting results from an oral (gavage) fourteen day range-finding study in rats, with an initial assessment of the maximum tolerated dose, on bis (2-hydroxyethyl) coco alkylamine, CAS# 61791-31-9. The study was sponsored by Akzo Nobel Surface Chemistry AB acting as the lead company for the European APAG Primary Fatty Amine Consortium.

This fourteen day range-finding study was performed to identify appropriate dose levels for an OECD 422 Reproduction/Developmental Toxicity Screening Test.

[NOTE: Based on the results of a separate dermal irritation study in rabbits, this substance is considered corrosive to skin, and this should be kept in mind when evaluating the results from the fourteen day range-finding study.]

In order to determine the maximum tolerated dose, groups of three female rats were dosed via oral gavage at levels of 50 -500 mg/kg/day for up to five days. Significant toxicity was observed in the 500 and 350 mg/kg/day groups. The maximum tolerated dose was estimated to be in the range of 200 – 300 mg/kg/day.

For the fourteen day range-finding groups of six rats (3M/3F) were dosed via oral gavage at levels of 75, 150, or 250 mg/kg/day. One control group was dosed with the vehicle only (Arachis oil BP).

Animals in the 250 mg/kg/day group showed significant toxicity with respect to clinical signs, weight loss, and necropsy findings that included sloughing and thickening of the non-glandular region of the stomach. As a result, all animals in this group were sacrificed on day 10 of the study. The 150 mg/kg/day group showed slight body weight loss, increased absolute liver weights and a thickened non-glandular region of the stomach. The 75 mg/kg/day group

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showed a lower degree of toxicity that included increased absolute liver weights (males only) and one animal with a thickened non-glandular region of the stomach.

Conclusions

A NOEL (No-Observed-Effect Level) was not established due to increased absolute liver weights and macroscopic changes in the stomach in both the low (75 mg/kg/day) and mid dose (150 mg/kg/day) groups. The high dose group (250 mg/kg/day) showed significant toxicity as previously described.

Please contact me if you have any questions at 312-544-7191.

Sincerely,

Edwin C. Bisinger Jr., PhD, DABT
Director
Regulatory & Applied Life Sciences
Akzo Nobel Services Inc.
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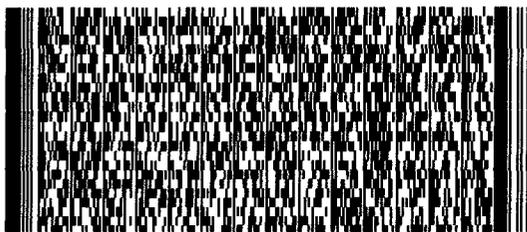
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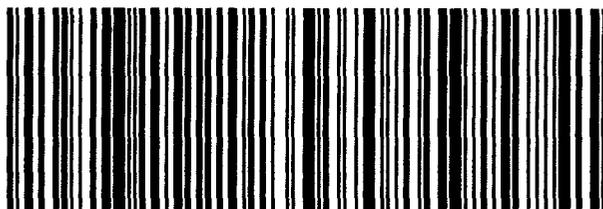


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