

ORIGINAL

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8EHQ-10-18167	<b>8811000051</b>	11   5   10

COMMENTS:

**DOES NOT CONTAIN CBI**

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**AkzoNobel**

Tomorrow's Answers Today

November 4, 2010

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

8EHQ-1110-18167A  
DCN:88110000051

**Subject: TSCA 8(e) Notice**



Dear U.S. EPA:

On behalf of Akzo Nobel Surface Chemistry LLC, we are submitting results from an OECD 422 Reproduction/Developmental Toxicity Screening Test 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.

[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 OECD 422 study.]

In the OECD 422 study, groups of 10 male and 10 female rats were treated by gavage once daily for up to 45 consecutive days (including a two week maturation phase, pairing, gestation and early lactation for females). A Control Group was dosed with the vehicle only (Arachis oil BP). Control and High Dose Recovery Groups (males only) were also included. The following dose levels were used:

Control Group:	0 mg/kg body weight/day
Low Dose Group:	10 mg/kg body weight/day
Mid Dose Group:	30 mg/kg body weight/day
High Dose Group:	125 mg/kg body weight/day

Recovery Control Group:	0 mg/kg body weight/day (males only)
Recovery High Dose Group:	125 mg/kg body weight/day (males only)

#### Adverse effects in Parental Animals

A higher incidence of increased salivation was observed following dosing in the Mid and High Dose Groups and in males in the Low Dose Group when compared to the Control Group. Lower body weights and reduced water consumption were noted in females in the High Dose Group during the lactation phase when compared to the control Group.

**CONTAINS NO CBI**

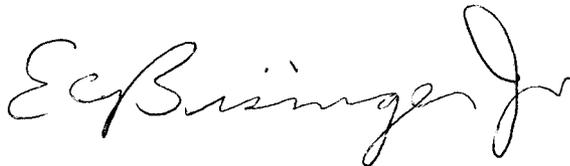
Histopathology findings included acanthosis (thickening) with hyperkeratosis in the forestomach of the High dose Group and in males of the Mid dose Group. This effect regressed in the High Dose Recovery Group. [NOTE: From a human hazard standpoint, the fore stomach is not present in humans.]

Adverse effects in reproductive parameters

Lower litter sizes due to lower numbers of corpora lutea and implantation sites, and higher post implantation losses were observed in the High Dose Group. Four interim offspring deaths were observed in the High and Mid Dose Groups compared to zero deaths in the Low Dose and Control Groups.

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.  
525 W. Van Buren St.  
Chicago, IL 60607-3835

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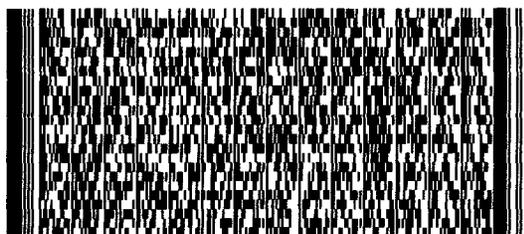
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**U.S. EPA ( Attn: Section 8 e)**  
**Office of Pollution Prevention & Tox**  
**1201 CONSTITUTION AVE NW**

**WASHINGTON, DC 20460**

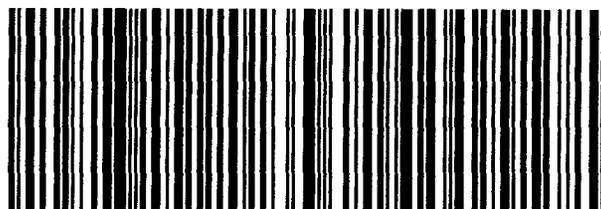


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