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October 10, 2012

US EPA Office of Pollution Prevention and Toxics  
EPA East Building Room 6428  
Attn: Section 8(e)  
1201 Constitution Avenue, NW  
Washington, DC 20004

Cc: Polymer Chemicals bv  
Arkema France  
Pergan GmbH  
United Initiators GmbH & Co. KG



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

**Re: OECD 407 28-day study with Bis(2,4-dichlorobenzoyl) peroxide (CAS# 133-14-2), paste, 50% in silicone oil**

Dear TSCA Section 8(e) Coordinator:

On behalf of Akzo Nobel Polymer Chemicals LLC we are submitting preliminary results from an OECD 407 (28-day) study on Bis(2,4-dichlorobenzoyl) peroxide CAS 133-14-2, paste, 50% in silicone oil (CAS 62129-63-9; polydimethylsiloxanes 49-51% as the solubilizer). The study was sponsored by Akzo Nobel Polymer Chemicals bv.

Male and female (5/sex/group) Wistar Han™:RccHan™:WIST strain rats were dosed by oral gavage at 0, 100, 300 and 1000 mg test item/kg/day in Arachis oil BP (vehicle).

No unscheduled death occurred. Clinical signs observed on the study were restricted to post-dosing salivation for three males receiving 1000 mg/kg/day on one or two occasions towards the end of the treatment period all animals. Functional observations did not reveal any obvious effects of treatment with meaningful dose relationship.

Lower mean body weight gain and food consumption were seen in females (week 1). Lower mean body weight gain in males (week 4) had little impact on overall body weight gain. At 1000 mg/kg bw/day, water consumption was higher than control throughout most of the study.

**Hematology:** Although for males at all dosages, mean cell hemoglobin concentration was lower than control, there was neither a dosage relationship nor were other statistically significant differences for other erythrocyte parameters. For females at all dosages, prothrombin times were longer than control but there was no consistent dosage relationship. For males at 1000 mg/kg bw/day higher mean platelet count was statistically significant compared to control.

**Clinical chemistry:** At 1000 mg/kg bw/day, higher alanine aminotransferase and alkaline phosphatase levels for both sexes attained statistical significance when compared with control. Higher albumin/globulin ratio (and chloride levels) were significantly higher than control at 1000 (both sexes) and 300 (males) mg/kg bw/day, but the higher ratios were unaccompanied by significant differences from control for total protein or albumin levels. At all dosage, levels of total bilirubin, blood urea (but no dosage relationship) and total cholesterol (not at 100 mg/kg bw/day) were lower than control in males.

**Necropsy:** No macroscopic abnormalities were apparent at terminal necropsy. At 1000 mg/kg bw/day, increased absolute and body weight relative liver weights for both sexes attained statistical significance compared with control. For males at 1000 mg/kg bw/day,

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higher absolute and body weight relative kidney weights and lower spleen and prostate/seminal vesicle weights attained statistical significance compared with control. For females at 300 mg/kg bw/day and both sexes at 1000 mg/kg bw/day, higher absolute and body weight relative spleen weights attained statistical significance compared with control. For females at 300 and 1000 mg/kg bw/day, lower absolute and body weight relative uterus weights attained statistical significance compared with control; there was no dosage relationship apparent for body weight adjusted values.

**Histology:** In the initial examination (control and 1000 mg/kg bw/day), the treatment-related histomorphologic changes were observed in liver and thyroid glands of both sexes and testes & epididymides of males. Findings in the 1000 mg/kg bw/day group are summarised below;

**Liver:** Cytoplasmic eosinophilic change (increased eosinophilic stainability) of hepatocytes, located mainly in centrilobular region, was observed in both sexes. The degree of the enlargement of hepatocytes was not so prominent. Similar findings (i.e. cytoplasmic change with or without unequivocal enlargement) are sometimes observed in the liver of rats treated with the lower dose of the drug-metabolizing enzyme inducers.

**Thyroid glands:** Hypertrophy of follicular cells was recorded in both sexes. A possible relationship between the enhanced metabolic activity in the liver was considered.

**Testes:** Increased Sertoli-cell vacuolation was recorded.

**Epididymides:** Interstitial edema with mixed inflammatory cell infiltration as well as decreased intraductal sperm & increased intraductal cell debris.

**In summary,** only minimal effects of marginal toxicological significance were noted in one or two clinical, hematologic and chemistry parameters mostly at 1000 mg/kg/day. Histologic changes in liver, thyroid, testes and epididymides were also noted at the high dose, 1000 mg/kg/day.

Please contact me at (312) 544-7062 if you have any questions regarding this letter.

Sincerely,

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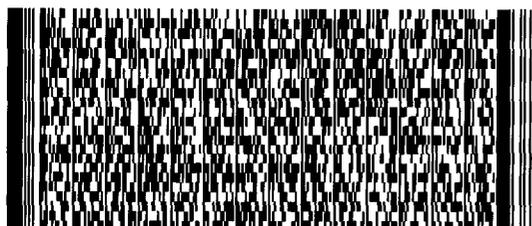
**Section 8(e)**  
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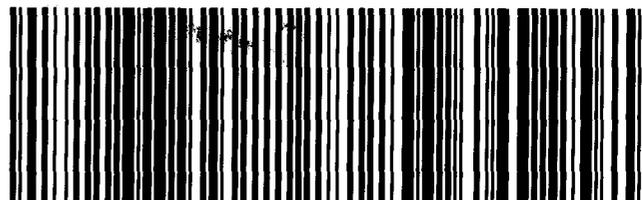
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