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Tomorrow's Answers Today

September 10, 2010

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

8EHQ-0910-18100A



Subject: TSCA 8(e) Notice

On behalf of Akzo Nobel Polymer Chemicals LLC, we are submitting results from a draft OECD 421 Reproduction/Developmental Toxicity Screening Test on tert-butyl perbenzoate CAS# 614-45-9. The study was sponsored by Akzo Nobel Polymer Chemicals bv, Arkema France, Pergan GmbH and United Initiators GmbH & Co. KG.

Four groups of 10 males and 10 females were treated by gavage once daily. Males were treated over a 14-day pre-pairing period and during the pairing period up to one day before necropsy. Females were treated throughout the prepairing, pairing, gestation and lactation period up to day 4 post partum. The following dose levels were used:

- Group 1: 0 mg/kg body weight/day (control group)
- Group 2: 100 mg/kg body weight/day
- Group 3: 300 mg/kg body weight/day
- Group 4: 750 mg/kg body weight/day (males only)
1000 mg/kg body weight/day (females only)

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Parent Animals

At 1000 mg/kg, one female was found dead on day 6 of the pre-pairing period. Slight reduction of body weight was observed on the day before death. At necropsy, thymus was discolored dark red, lungs were incompletely collapsed and discolored reddish and with greenish foci on the left lobe. However, the cause of death could not be established by the organs and tissue examined.

Males in the 300 and 750 mg/kg dose groups exhibited signs of discomfort such as bedding material in the mouth and salivation before and after administration were noted.

Females in the 1000 mg/kg dose group exhibited ruffled fur and soft feces were observed occasionally in few animals. Signs of discomfort such as salivation before or after administration and bedding material in mouth were observed from the second week of the pre-pairing onwards.

Food Consumption

In males at 750 mg/kg, mean food consumption was statistically significantly lower during the first week of the pre-pairing period. In females, mean food consumption was not affected by the treatment with the test item at any dose level.

Body Weights

In males at 750 mg/kg, mean body weight gain was statistically significantly lower starting on day 6 of the pre-pairing period. No statistically significant changes were noted in mean body weight. In females, mean body weights and mean body weight gain were not affected by the treatment with the test item at any dose level.

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Reproductive Data

There was no effect on reproductive parameters

Organ Weights

Organ weights were not affected.

Macroscopical Findings and Histopathological Examinations

There were no macroscopic or histopathological findings attributed to the test article.

Litter Data - F1 Pups

At 1000 mg/kg, mean pup weight was statistically significantly lower on day 4 post partum and this was considered to be due to the treatment of the dams with the test item.

Conclusion

Based on the clinical signs observed in females at 1000 mg/kg, on lower food consumption and body weight gain in males at 750 mg/kg, the general NOAEL (No-Observed-Adverse-Effect Level) was considered to be 300 mg/kg.

For reproduction toxicity, the NOEL (No Observed Effect Level) was at 1000 mg/kg/day for females and at 750 mg/kg for males.

Based on the lower mean pup weight at 1000 mg/kg, the NOEL for developmental toxicity was considered to be 300 mg/kg bw/day.

Please contact me if you have any questions at 312-544-7061

Sincerely,

Louette J. Rausch, M.S.
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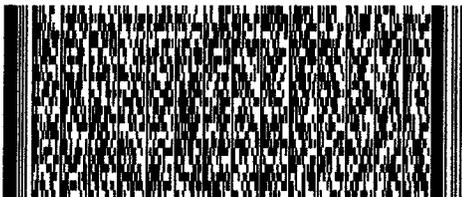
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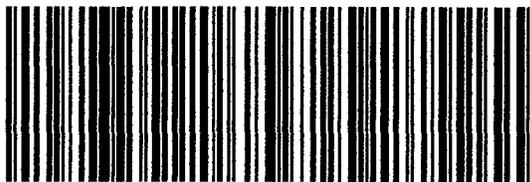


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