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COMMENTS:

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Tomorrow's Answers Today



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2012 AUG -8 AM 10:35

August 7, 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



SUBJECT: TSCA 8(e) Notice

Re: 28-day repeat dose oral gavage study (OECD 407) on O-(2-ethylhexyl) O,O-tert-pentyl peroxy carbonate (CAS 70833-40-8)

Dear TSCA Section 8(e) Coordinator:

On behalf of Akzo Nobel Polymer Chemicals LLC we are submitting preliminary results on an OECD 407 study, "O-(2-ethylhexyl) O,O-tert-pentyl peroxy carbonate (CAS #70833-40-8): 28-Day Oral Toxicity (Gavage) Study in the Wistar Rat". The study was sponsored by Akzo Nobel Polymer Chemicals bv.

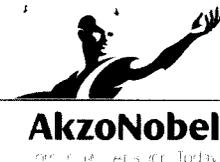
Wistar rats (5 males and 5 females per group) were orally administered with 100, 300 and 1000 mg/kg/day of O-(2-ethylhexyl) O,O-tert-pentyl peroxy carbonate daily for 28 days. A control group received the vehicle, PEG 300, only. Administration of the test item did not result in death or effects on clinical signs, the functional observational battery, body weights, the hematology and clinical biochemistry parameters, or macroscopic appearance.

Test item-related microscopic changes were noted. Forestomach mucosal necrosis was recorded in males treated with 100 mg/kg/day and both sexes treated with 300 mg/kg/day and 1000 mg/kg/day. This was considered to be local injury caused by a repeatedly gavaged irritative/corrosive substance. It was considered that there was no biological sex difference on producing the gastric lesions. In the forestomach of the affected rats, hyperkeratosis/parakeratosis, reactive squamous hypertrophy/hyperplasia, dyskeratosis and/or mucosal/submucosal edema and inflammatory cell infiltration were observed as well. These were considered to be a local injury and represented subsequent adverse reactions caused by a repeatedly gavaged irritative/corrosive substance.

Slightly elevated liver weights noted in the females treated with 300 or 1000 mg/kg/day were considered to be adaptive changes of metabolic origin. In the liver, centrilobular hepatocellular hypertrophy was recorded at a minimal severity in one male and one female treated with 1000 mg/kg/day. There were no further indicators of liver injury, hence, this lesion was considered to be one of metabolic adaptation (as would enzyme induction), and was deemed to be not adverse.

Increased severity of hyaline droplets in the renal proximal tubules was recorded in male animals treated with 1000 mg/kg/day. This was considered to be induced by metabolic

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overload of protein specific to male rats and similar to alpha-2 microglobulin, derived from hyperfunction of the liver. Increased incidence and severity of renal tubular basophilia were considered to be a secondary tubular injury caused by the enhanced hyaline droplet deposition.

Based on the results of this study, the no-observed-effect-level (NOEL) and the no-observed-adverse-effect-level (NOAEL) for O-(2-ethylhexyl) O,O-tert-pentyl peroxy carbonate was considered to be below 100 mg/kg/day, the lowest dose tested in this study.

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

Sincerely,

R. Krishnaraj 8/7/2012

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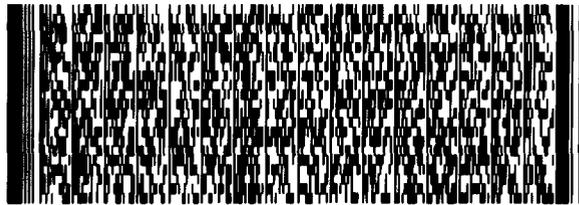
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AKZO NOBEL INC.
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CHICAGO, IL 60607
UNITED STATES US

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US EPA OFFICE OF POLLUTION
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