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DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ- 07- 16973	89130000188	12/21/12

COMMENTS: 8EFU

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AkzoNobel

Tomorrow's Answers Today

December 17, 2012

U.S. Environmental Protection Agency
EPA East - Room 6428 Attn: Section 8(e)
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Washington, DC 20004-3302
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Subject: TSCA 8(e) Notice

Supplemental information to 8EHQ-07-16973

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On behalf of Akzo Nobel Polymer Chemicals LLC, we are submitting results from a dose range-finding study on Peroxide, 1,1'-bis(1,1-dimethylethyl), CAS# 110-05-4.

This study is the dose range-finding phase of a 90-day inhalation study being conducted under REACH. In this study, di-tert-butyl peroxide was administered daily by nose-only inhalation to SPF-bred Wistar outbred rats of both sexes at dose levels of 100, 1,000 or 10,000 mg/m³ six hours per day for fourteen days. The control group was exposed to air. Each dose group and the control group contained five animals per sex. Clinical signs, food consumption and body weights were recorded periodically during the acclimatization and treatment periods. At the end of the dosing period, all animals were sacrificed and subjected to necropsy and *post mortem* examination.

Test item-related increases in mean relative organ weights were noted in the liver, kidney and adrenal glands. At 10,000 mg/m³, the mean relative liver, kidney and adrenal weights (organ weight / body weight) were significantly increased in males. In females, only relative liver weight was significantly increased at 10,000 mg/m³. At 1,000 mg/m³, the only statistically significant effect was increased relative adrenal gland weight in males. Since this was only a dose range-finding study, histopathologic examination of these organs was not performed. The laboratory also reported that the animals' tails were stiff and had quick and short-lasting movements.



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Page two of two

These results generally corroborate those in the 8(e) submission referenced above in which the results of an OECD 422 subchronic toxicity and reproductive/developmental toxicity screening study were reported. In that study, the predominant effects reported were increased relative liver and kidney weight.

It is unlikely that this chemical poses a widespread risk to human health or the environment. Di-tert-butyl peroxide is an organic peroxide; it is used as a free-radical polymerization initiator, so it decomposes in use. It is also used in applications regulated by the Food and Drug Administration; for examples, see 21 CFR 177.2600.

We will provide additional information as it becomes available. If you have any questions, please contact me at 908.707.3756.

Sincerely,



David B. Bower, Ph.D.
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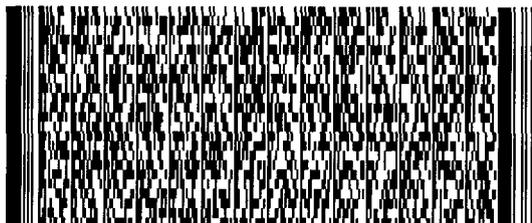
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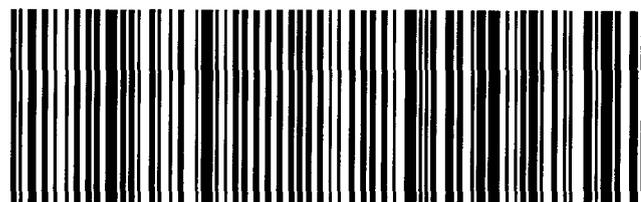
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