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Richard Denison
<rdenison@environmentaldefense.org>

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To NCIC OPPT@EPA, ChemRTK HPV@EPA, Rtk Chem@EPA, NCIC HPV@EPA, Karen Boswell/DC/USEPA/US@EPA, richard.balcomb@cibasc.com
cc lucierg@msn.com, Karen Florini <KFlorini@environmentaldefense.org>, Richard Denison <RDenison@environmentaldefense.org>

bcc

Subject Environmental Defense comments on Irganox 1330/Ethanox 330 (CAS# 1709-70-2)

(Submitted via Internet 1/7/05 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and richard.balcomb@cibasc.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for **Irganox 1330/Ethanox 330 (CAS# 1709-70-2)**.

The test plan and robust summaries for Irganox 1330/ Ethanox 330 were submitted by Ciba Specialty Chemicals. The chemical name for this substance is 1,3,5-trimethyl-2,4,6-tris (3,5-di-t-butyl-4-hydroxybenzyl) benzene. According to the test plan, Irganox 1330 is used to protect organic substrates against thermo-oxidative degradation. It is used in polyethylene and polypropylene products for the stabilization of pipes, molded articles, wires, cables and dielectric films, and in other polymers and copolymers.

The sponsor asserts that existing data are adequate for all of the SIDS endpoints required under the HPV program. The sponsor further asserts that Irganox 1330 appears to possess a low order of mammalian and ecological toxicity. While overall we agree with these assertions based on careful review of the robust summaries, we do have several questions regarding the test plan and robust summaries, specifically the need for clarifications and additional information to address environmental and health concerns. These concerns and questions are itemized as follows:

1. The sponsor states in the test plan that Irganox is immobilized in the polymer matrix and hence that environmental releases and human exposures are considered minimal. However, no data demonstrating the extent of immobilization and no monitoring data are provided to substantiate this claim. If such data are available, they should be provided in a revised test plan.
2. Irganox 1330 is not readily biodegradable and fugacity modeling indicates that it should preferentially partition into the sediment, as it is not water-soluble. Since these properties indicate potential for environmental accumulation, have sediments in the proximity of industrial facilities manufacturing or using Irganox 1330 been monitored for contamination?
3. The biodegradation studies indicate that about 10% of Irganox 1330 is biodegraded after 28 days. What are the biodegradation products, are they water-soluble and are they toxic to fish, aquatic invertebrates and/or algae?

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4. The mammalian toxicity studies have not shown any adverse health effects following chronic exposures as high as 10,000 ppm Irganox 1330 in the diet. The robust summaries do not convert this dietary exposure to mg/kg/day, which is the customary expression of LOAELs or NOAELs. This conversion should be made in a revised test plan.
5. Although chronic studies have not demonstrated any adverse health effects, toxicokinetic information would be helpful regarding clearance times and the potential for accumulation in mammalian systems.
6. The sponsor states that in vitro data coupled with repeat dose, cancer studies and reproductive studies are adequate to conclude that Irganox 1330 is not genotoxic. We agree with this line of reasoning.

Thank you for this opportunity to comment.

George Lucier, Ph.D.
Consulting Toxicologist, Environmental Defense

Richard Denison, Ph.D.
Senior Scientist, Environmental Defense