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rdenison@environmentaldefense.org

06/05/2004 12:51 PM

To: NCIC OPPT@EPA, ChemRTK HPV@EPA, Rtk Chem@EPA, Karen Boswell/DC/USEPA/US@EPA, kdntsich@dow.com, NCIC HPV@EPA
cc: luciery@msn.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org
Subject: Environmental Defense comments on Cycloaliphatic Epoxy Resin ERL-4221 (CAS# 2386-87-0)

(Submitted via Internet 6/5/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, luciery@msn.com and kdntsich@dow.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Cycloaliphatic Epoxy Resin ERL-4221 (CAS# 2386-87-0).

The test plan and robust summaries for cycloaliphatic epoxy resin was submitted by Dow Chemical Company. This substance is prepared by reacting peracetic acid with the diolefin precursor in a closed system. The resulting product, ERL-4221, is comprised of a mixture of the diepoxy (82-89%), higher molecular weight soluble oligomers (8-13%) and the monoepoxy derivative (0-5%). ERL-4221, according to the test plan, is used to produce coatings and inks for packaging and it is also used to formulate encapsulants for various electrical applications. It is used in other applications as a reactive acid scavenger to stabilize sensitive organic systems.

The test plan includes a section on protective measures for preventing or limiting worker exposures, but no information is provided on the potential for environmental contamination or for consumer exposure. If such information is available, we recommend that it be included in the test plan.

The test plan and robust summaries are complete and contain sufficient detail on the studies used to fulfill HPV requirements. The sponsor concludes that no additional studies are needed. We agree with this conclusion, with one possible exception concerning the adequacy of data for the reproductive toxicity endpoint. The sponsor contends that the repeat dose toxicity studies have included histological analyses of male and female reproductive tracts and that the results were negative. However, in the 90-day study, a yellow material was noted in the urogenital area of females after doses of 750 mg/kg/day. This finding was apparently not further evaluated, although it was not reported in a later 28-day study that dosed animals up to 500 mg/kg/day. What is the significance of the yellow material and does it only occur at higher doses for longer exposure periods? If the sponsor provides an explanation for the finding that indicates that it does not constitute a reproductive effect, then we agree that no further studies are needed. If this explanation is inadequate, then we recommend that the sponsor conduct a reproductive toxicity study.

Other points are as follows:

1. Most of the existing studies reported in the test plan and robust summaries use the commercial mixture ERL-4221 as the test substance, rather than the pure cycloaliphatic epoxy resin. We agree with the use of the

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mixture, as it better represents real-life exposures.

2. Ecotoxicity studies are sufficient to conclude that ERL-4221 possesses low to moderate acute toxicity to aquatic species.

3. ERL-4221 is mutagenic in some in vitro, but not in vivo, systems. These studies meet the HPV requirements for genetic toxicity tests.

4. The repeat dose and developmental toxicity studies are well-described and they appear to be well-conducted.

Thank you for this opportunity to comment.

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

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