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Anh Nguyen
06/01/2004 02:40 PM

To: NCIC HPV@EPA
cc:
Subject: Fw: Environmental Defense comments on Neodecanoic Acid, 1,2-epoxypropyl Ester (Glydexx N10) (CAS# 26761-45-5)

----- Forwarded by Anh Nguyen/DC/USEPA/US on 06/01/2004 02:39 PM -----



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To: NCIC OPPT@EPA, ChemRTK HPV@EPA, Rtk Chem@EPA, Karen Boswell/DC/USEPA/US@EPA, Nigel.j.sarginson@exxonmobil.com
cc: MTC@mchsi.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org
Subject: Environmental Defense comments on Neodecanoic Acid, 1,2-epoxypropyl Ester (Glydexx N10) (CAS# 26761-45-5)

(Submitted via Internet 6/1/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and Nigel.j.sarginson@exxonmobil.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Neodecanoic Acid, 1,2-epoxypropyl Ester (Glydexx N10) (CAS# 26761-45-5).

ExxonMobil, in response to EPA's High Production Volume (HPV) Chemical Challenge, has submitted robust summaries and a test plan describing available data for neodecanoic acid, 1,2-epoxypropyl ester, known commercially as Glydexx N10.

Our review of this submission indicates it is somewhat cursory and provides minimal background information and data to address the SIDS elements required under EPA's HPV Challenge. Unfortunately, no background information is provided to describe the transport and uses of this chemical and no mention is made of the potential for human and environmental exposure. Information on possible release into the environment would seem important in light of the fact that this chemical has appreciable toxicity to all three aquatic species tested.

Most of the SIDS elements required under the HPV Challenge are addressed, but the results of those studies are only briefly described in the test plan. Questions raised by our review of the test plan are the following:

1. Degree of biodegradation; it is not clear whether Glydexx N10 degraded 11.8% in 28 days, or if that was the amount left after 28 days.
2. We would question the suitability of an examination of the reproductive organs in a 5-week repeated dose study to address the SIDS element for reproductive toxicity. Five weeks does not seem long enough.
3. On page 5 it is stated that due to its low vapor pressure, inhalation exposure is expected to pose negligible hazard. This statement seems inconsistent with the data presented in Table 3 that indicate that >99% of the parent compound would be distributed into the air.
4. It appears that as a result of some "loss of data" or a disagreement with a second manufacturer of Glydexx N10 (see letter of submission), the SIDS elements for reproductive/developmental toxicity are not addressed. Further, it appears that these studies will not be done until ExxonMobil reaches agreement with the second manufacturer or they otherwise "find" the data. We do not think this submission should be considered complete and acceptable until and unless these studies are done and reported or at least

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proposed to be done.

We note the following oversights or inconsistencies in the robust summaries:

1. The purity of the test substance was not given in any toxicity study.
2. Several studies of biodegradation seem to have produced a wide range of results. Most studies indicate minimal degradation. This range of results should be presented more clearly in the test plan.
3. In a study of toxicity to fish, 100% mortality was observed at 5.5 mg/l in 24 hours. This is inconsistent with the EC50 of 9.61 mg/l in 96 hours reported in the test plan.
4. In most of the toxicity studies with mammals, the test substance is usually given as "other TS". It is not clear exactly what substance "other TS" actually refers to. Further review of these studies implies that Glydext N10 was administered as neat chemical; however, that is not confirmed and it appears possible that it was administered as a solution of unstated concentration. The form of the chemical actually used needs to be clearly stated.
5. A minor point: in the subchronic study with rats, the 5,000 mg/kg dose was omitted from the list of doses administered.

In summary, we do not consider this submission acceptable to meet the requirement of the HPV Challenge Program.

Thank you for this opportunity to comment.

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