201-16838

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

HEADQUARTERS
501 FRONT STREET
NORFOLK, VA 23510
TEL 757-622-PETA
FAX 757-622-0457

June 23, 2010

Lisa P. Jackson, Administrator
U.S. Environmental Protection Agency
Ariel Rios Building, 1101 -A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Subject: Public Comments on the HPV Challenge Program Test Plan for 2-(2-aminoethoxy) ethanol (AEE; CAS No. 929-06-6) by the AEE Consortium (BASF and Huntsman Corporations).

The following comments on the HPV Challenge Program test plan for AEE by the AEE Consortium are submitted on behalf of People for the Ethical Treatment of Animals and the Physicians Committee for Responsible Medicine.

We are very concerned that a proposed OECD Test Guideline No. 422, Combined Repeated Dose Toxicity Study with Reproduction/Developmental Toxicity Screening Test, is already underway for AEE. Preliminary results from the dose-finding portion of this test are summarized in the test plan. In its October 1999 letter to manufacturers/importers, EPA specifically stated that "[c]ompanies shall allow 120 days between the posting of test plans and the implementation of any testing plans." The sponsor notes that AEE has been pre-registered under REACH and that "the testing proposal also supports data gathering requirements in association with REACH." If this test is in fact being conducted under REACH with the results to be used to support HPV program requirements, the sponsor should make this clear.

In addition, the weight of existing evidence strongly suggests that AEE is unlikely to be a developmental toxicant. Data exist for acute, repeated dose, and genetic toxicity. Oral and dermal LD_{50} values are reported to be 1260 mg/kg bw – 5660 mg/kg bw. In a 90-day OECD Test Guideline No. 411 repeated dose toxicity study, no systemic toxicity was observed at the highest dose tested, 175 mg/kg/day. Further, no effects were observed on male and female reproductive organs evaluated in this study. Similarly, all genetic toxicity tests produced negative results. While developmental toxicity data have not been found for AEE, its low systemic toxicity, the absence of reproductive organ effects in a 90-day OECD guideline study and negative results in genetic toxicity tests indicate a low potential for developmental toxicity.

EPA guidance states that HPV program "[p]articipants may conclude that there is sufficient data, given the totality of what is known about a chemical… that certain endpoints need not be tested." There are sufficient data for AEE that developmental toxicity need not be tested. Further, the proposed OECD Test Guideline No. 422 study is already underway in violation of EPA guidance requiring 120 days between the posting of test plans and the implementation of testing.

Thank you for your attention to these comments. I can be reached at (757) 622-7382, ext. 8001, or via e-mail at josephm@peta.org.

Sincerely,

Joseph Manuppello
Research Associate
Research & Investigations