

201-16828

January 4, 2010

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

RECEIVED
10 JAN -5 11 8:04



PETA

PEOPLE FOR THE ETHICAL
TREATMENT OF ANIMALS

Subject: Public Comments on the HPV Challenge Program Test Plan for Oxirane, reaction products with ammonia, distillation residue (CAS No. 68953-70-8) by Huntsman Petrochemical Corporation and INEOS Oxide, a division of INEOS Americas LLC.

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

The following comments on the HPV Challenge Program test plan for CAS No. 68953-70-8 by Huntsman Petrochemical Corporation and INEOS Oxide are submitted on behalf of People for the Ethical Treatment of Animals and the Physicians Committee for Responsible Medicine.

We commend the sponsors for their thoughtful use of existing data on triethanolamine (TEA), a substance with an extensive IUCLID dossier, to fill fish acute, repeat dose and reproduction and developmental toxicity endpoints. As stated in the test plan, CAS No. 68953-70-8 is the distillation residue from alkanolamines production typically contains at least 80% triethanolamine (TEA). Because of this relatively high percentage of TEA, the toxicity of CAS No. 68953-70-8 would be expected to be very similar to that of commercial TEA. In addition, both chemicals give comparable results in acute and genetic toxicity tests and are practically nontoxic. The resulting reduction in proposed testing saves animals' lives and is consistent with the HPV Challenge Program's goal of obtaining screening level hazard information.

While no reproduction studies were found for either CAS No. 68953-70-8 or TEA, no toxicity to reproductive organs was reported in any of the repeated-dose toxicity studies on TEA. Therefore, reproduction toxicity is unlikely for CAS No. 68953-70-8. Developmental toxicity studies for TEA summarized in the test plan and the IUCLID dossier show no change in maternal mortality, number of viable litters, litter size, percent survival of pups, or birth weight or weight gain of pups when mice were dosed with TEA by gavage and no increase in malformations when hair dyes containing TEA were applied to the skin of rats. In addition, the TEA dossier includes a study in chick embryos that reported no significant increase in the incidence of malformations. In its Guidance for Meeting the SIDS Requirements, EPA states that when a 90-day repeated dose study is available and is sufficiently documented with respect to studying effects on the reproductive organs and a developmental study is available, the requirements for the reproduction toxicity endpoint are satisfied.

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

Sincerely,

Joseph Manuppello
Research Associate
Research & Investigations