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201-15240

04 MAY -6 PM12:14

Anh Nguyen

05/05/04 09:13 AM

To: NCIC HPV@EPA

cc:

Subject: Fw: Environmental Defense comments on  
N-Ethyl-N-(3-methylphenyl)-1,2-ethanediamine (CAS# 19248-13-6)

----- Forwarded by Anh Nguyen/DC/USEPA/US on 05/05/2004 09:12 AM -----



**rdenison@environmentald  
efense.org**

05/05/2004 08:51 AM

To: NCIC OPPT@EPA, ChemRTK HPV@EPA, Rtk Chem@EPA, Karen  
Boswell/DC/USEPA/US@EPA, Deyo@eastman.com

cc: luciery@msn.com, kflorini@environmentaldefense.org,  
rdenison@environmentaldefense.org

Subject: Environmental Defense comments on N-Ethyl-N-(3-methylphenyl)-1,2-ethanediamine  
(CAS# 19248-13-6)

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

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for N-Ethyl-N-(3-methylphenyl)-1,2-ethanediamine (CAS# 19248-13-6).

The test plan and robust summaries for N-ethyl-N-(3-methylphenyl)-1,2-ethanediamine (EMPE) were submitted by Eastman Chemical Company. The sponsor states that EMPE is used as a closed-system intermediate in the process of synthesizing color developer.

The test plan and robust summaries were informative and well-written and we appreciate the detailed presentation of the industrial processes using EMPE. The justification for considering EMPE as a closed-system intermediate was convincing; indeed, it could serve as a model for proposed closed-system intermediates submitted by other companies.

EMPE is synthesized from its precursor EMAA. EMPE is reacted to form CD-3 sulfonamide, which in turn is an intermediate in the process used to make color developer CD-3. The sponsor indicates that regular testing of the color developer has never detected any residual EMPE. EMPE manufactured by the sponsor is made and entirely consumed at a single site in Tennessee, and is not transported off site. The sponsor states that, to its knowledge, it is the sole manufacturer of EMPE. Unreacted EMPE, according to the sponsor, is sent to an on-site wastewater treatment facility or an on-site hazardous waste incinerator.

The sponsor proposes to conduct a combined reproductive/developmental toxicity study on EMPE. We agree with this proposal given that no studies are currently available on these endpoints. The sponsor points out that reproductive toxicity studies are not required for closed-system intermediates, but the proposed combined developmental/reproductive toxicity study will address reproductive toxicity concerns associated with potential exposure of workers. For the same reason, the sponsor may wish to add a repeat dose toxicity component to the combined reproductive/developmental toxicity study.

Other comments are as follows:

1. Available studies indicate that EMPE is toxic to fish, aquatic invertebrates and algae, with LC50s and EC50s in the range of 1-7 mg/L. No data are available on water stability and the sponsor proposes to address this knowledge gap with a technical discussion. We believe that the sponsor should conduct a water stability study on EMPE because of its known toxicity to aquatic species.

2. Aqueous wastes containing EMPE are sent to an on-site wastewater treatment facility. However, no information was provided on the

concentration of EMPE in the wastewater streams entering the wastewater facility or the concentrations remaining in streams after wastewater treatment. Likewise, no information was provided on concentrations of EMPE potentially released from reaction vessels although modeling data are apparently available. Monitoring and modeling data in air and water are needed to definitively conclude that EMPE is totally contained and consumed on site.

3. The sponsor states that prudent worker safety practices are in place. It would be more informative if a brief summary of those practices along with data on workplace levels of EPME could be provided.

Thank you for this opportunity to comment.

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

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