

**ETHYLENEAMINES PRODUCT STEWARDSHIP DISCUSSION GROUP
AEEA TESTING CONSORTIUM**

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TSCA Section 8(e) Coordinator
Document Control Officer (MC-7407)
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460-0001

Re: Toxic Substances Control Act -- Section 8(e)



Dear TSCA Section 8(e) Coordinator:

The Ethyleneamines Product Stewardship Discussion Group (EPSDG) Aminoethylethanolamine (AEEA) Testing Consortium, c/o Mr. Timothy J. Cawley, c/o Bergeson & Campbell, P.C., 1203 Nineteenth Street, N.W., Suite 300, Washington, D.C. 20036-2401, submits to the U.S. Environmental Protection Agency (EPA), pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA), interim results of an enhanced Organization for Economic Cooperation and Development (OECD) 421 Reproduction/Developmental Toxicity Screening Test with AEEA (CAS No. 111-41-1).¹ The EPSDG AEEA Testing Consortium is comprised of the following companies: Akzo Nobel Functional Chemicals, LLC, BASF Corporation, The Dow Chemical Company, and Huntsman Corporation. The study was performed by BASF Aktiengesellschaft, Ludwigshafen, Germany.

This information is being submitted, as required under TSCA Section 8(e), within 30 calendar days after the date this information was obtained. A summary describing the nature of the adverse effects being reported is provided below.

¹ This letter is a follow-up to our previous submissions on July 3, 2002 (regarding an OECD 421 Reproduction/Developmental Toxicity Screening Test in Wistar rats (strain CrIGlxBrlHan:WI) with AEEA); October 28, 2003 (regarding a histopathology study that was a follow-up study to the OECD 421 study); and April 20, 2004/May 26, 2005 (regarding a probe study that was a follow-up study to the OECD 421 study). The enhanced OECD 421 study that is the subject of this notice is another follow-up study to the original OECD 421 study.

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- **Methods:** The aim of this study was to define a no observed adverse effect level (NOAEL) for the developmental toxic effects of AEEA on the great pericardial blood vessels of Wistar rats as observed in an earlier conducted OECD 421 study. The study exceeded OECD 421 Guideline requirements and EPA's Health Effects Test Guidelines (OPPTS 870.3550). The test substance was administered as an aqueous solution by oral gavage to 25 male and female rats per group at doses of 0, 0.2, 1, 5, and 50 mg/kg-bw. The males were treated for approximately 5 weeks; 2 weeks pre-mating, 2 weeks mating, and 1 week post-mating. In females, the treatment lasted from 2 weeks pre-mating, 2 weeks mating, and gestation through day 4 post-delivery. Developmental toxicity was assessed through an examination of day 4 pups. All offspring were preserved for histopathologic processing and examination.

- **Results:** No clinical observations and no effects on fertility and reproduction were noted in the parental animals. At necropsy, 60/270 offspring exposed to 50 mg/kg-bw showed alterations of the major pericardial blood vessels, such as aneurysm and/or dilation of aortic arch, ductus arteriosus, pulmonary trunk, innominate artery, and descending aorta. 1/290 offspring exposed to 5 mg/kg-bw and 1/322 offspring exposed to 1 mg/kg-bw had an aneurysm of ductus arteriosus.

Any subsequent information regarding the developmental toxicity of this chemical from this study that is considered to present a substantial risk to human health or the environment under TSCA Section 8(e) will be submitted to EPA.

If you have any questions, please contact Lynn L. Bergeson at (202) 557-3801 or lbergeson@lawbc.com.

Sincerely,

Timothy J. Cawley

Timothy J. Cawley, Chair
EPSDG AEEA Testing Consortium

cc: EPSDG AEEA Testing Consortium (via e-mail)