

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

(Faint stamp: Receipt No. 0001)

April 6, 2009

Via Certified MailReturn Receipt Number 7008 1300 0001 4454 9514

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, DC 20460-0001



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EPA

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 a preliminary experiment to explore the p.o. (gavage) administration of AEEA (CAS No. 111-41-1) to pregnant female rats of various strains and in separate laboratories. 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.

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 discussed below.

- **Methods:** The intent of this experiment was to assess the *in vivo* occurrence of dissecting aortic aneurysms (DAA) in newborn rat pups born to dams given AEEA p.o. (by gavage) administration. In these pilot experiments, graded doses of AEEA were administered daily p.o. to Sprague-Dawley rat dams weighing 145-160 g on gestational days (GD) 14-21 (previous studies utilized the Wistar strain of rat). Pups were killed on day 1 of life, generally from 6-12 hours after birth. At autopsy, vessels were examined under a dissecting microscope, and multiple histologic sections examined microscopically.

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Huntsman Corporation • Eric D. Ewen • 10003 Woodloch Forest Drive • The Woodlands, Texas 77380
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ETHYLENEAMINES PRODUCT STEWARDSHIP DISCUSSION GROUP AEEA TESTING CONSORTIUM

TSCA Section 8(e) Coordinator
April 6, 2009
Page 2

- **Results:** No overt signs of toxicity were noted in treated dams or newborn pups at one day of age. No apparent difference in litter size, mean fetal weight, or numbers of stillborn pups was evident between experimental and control groups. Gross observation confirmed by histopathologic, microscopic study of thoracic and abdominal vessels showed an incidence of DAA which was 100% at the higher doses (*see* Table 1). Dissection involved contiguous vessels and mediastinal interstitial spaces to a lesser extent.
- **Assessment:** DAA in pups following AEEA administration to Wistar rat dams, as previously reported to EPA in prior TSCA Section 8(e) submissions by the Consortium, occurs in the Sprague-Dawley strain of laboratory rat. Similar dosing procedure and protocol give similar pathologic results, although only a small number of animals were tested and additional research will be required to establish a more robust dose-response relationship.

Table 1
Dissecting Aortic Aneurysm (DAA) in Newborn Rats from Pregnant Mother Rats (Dams) Treated with AEEA by Gavage (Gestational Days 14-20) Confirmed by Histologic Examination

Dose (mg/kg) (n = Pups/Dams)	DAA in Pups (%)	Mediastinal Hemorrhage (%)	Dissection in Pulmonary Artery (%)	Dissection in Carotid Artery (%)
Control (7/1)	0	0	0	0
10 (27/2)	30	4	0	0
50 (24/2)	88	80	4	38
100 (26/2)	100	100	39	39
150 (38/4)	100	100	79	79

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.

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TSCA Section 8(e) Coordinator
April 6, 2009
Page 3

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
Ethyleneamines Product Stewardship
Discussion Group AEEA Testing Consortium

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