

ETHYLENEAMINES PRODUCT STEWARDSHIP DISCUSSION GROUP
AEEA TESTING CONSORTIUM

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August 7, 2009

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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, DC 20460-0001

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



DCN:89090000355

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), additional 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. Experimental procedures were previously described in a letter submitted to EPA under TSCA Section 8(e) on April 6, 2009. At necropsy, vessels were examined under a dissecting microscope, and 5-6 cross sections of thoracic organs examined in histologic sections stained with H & E by standard light microscopy. The results described here represent further analysis of the microscopic sections. Specifically, the gross observations previously reported were confirmed by histopathologic, microscopic study of thoracic and abdominal vessels, which showed an incidence of dissecting aortic aneurysm (DAA) that was 100% at the higher doses (*see* Table 1). A grading system was devised to determine a dose-response relationship with grades from I to IV (*see* Table 2). Lesion grade was found to be directly dependent on dose. Furthermore, dissection of the pulmonary artery and/or carotid artery was found to be dependent on dose and, therefore, on lesion grade (Table 3). These data are also shown in graphic form as Figure 1. These data also indicate that

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severe lesions seen at higher doses are associated with more extensive vascular dissection as well as hemorrhage outside the vascular system, specifically into mediastinum.

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
Ethyleneamines Product Stewardship
Discussion Group AEEA Testing Consortium

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

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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

Table 2: Lesion Grade of Dissecting Aortic Aneurysm (DAA) in Newborn Rats from Pregnant Mother Rats (Dams) Treated with AEEA by Gavage (Gestational Days 14-20)

AEEA Dose (mg/kg)(n = Pups/Dams)	Grade I *	Grade II *	Grade III *	Grade IV *
Control (7/1)	0	0	0	0
10 (27/2)	62.5	25	12.5	0
50 (24/2)	14.3	47.6	33.3	4.8
100 (26/2)	15.4	53.8	23.1	7.7
150 (38/4)	5.3	31.6	44.7	26.3

- * Grade I: one section with DAA out of all sections from neck to diaphragm
- * Grade II: two sections with DAA out of all sections from neck to diaphragm
- * Grade III: three sections with DAA out of all sections from neck to diaphragm
- * Grade IV: four sections with DAA out of all sections from neck to diaphragm
(all groups have 5-6 thoracic sections/newborn rat pup)

Table 3: Dissection in Pulmonary Artery and/or Carotid Artery by DAA Lesion Grade (%)

AEEA Dose (mg/kg)(n = Pups/Dams)	Grade I	Grade II	Grade III	Grade IV
Control (7/1)	0	0	0	0
10 (27/2)	0	0	0	0
50 (24/2)	0	50	71.4	100
100 (26/2)	25	57.1	100	100
150 (38/4)	50	75	94.1	100

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FIGURE 1:
Dissecting Aortic Aneurysm (DAA) Grade in Newborn Rats
from Dams Treated with AEEA by Gavage (%)

