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Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue NW
Washington, DC 20460



Attention: TSCA 8(e) Coordinator

RE: Information Acquired for Methylaminoethanol (CAS# 109-83-1) Developmental Toxicity Range-finding Study in Rats

Dear TSCA 8(e) Coordinator:

The American Chemistry Council's (ACC) Amines Panel¹ is submitting on behalf of its members the results of a pre-postnatal toxicity range-finding study with Methylaminoethanol (CAS# 109-83-1) in Wistar rats. The purpose of this study was to determine an appropriate range of dose levels for a definitive Reproductive Developmental Toxicity Screening Test. The study was conducted in accordance with OECD 421 guidelines. The data provided herein are being submitted in accordance with the U.S. Environmental Protection Agency's interpretation of Section 8(e) of the Toxic Substances Control Act (TSCA).

The test substance was administered via gavage to groups of 3 pregnant young rats from gestation day 6 to postnatal day 3. The dose levels were 0, 50, 160 and 450 mg/kg body weight/day. The dams were allowed to litter and rear their pups until postnatal day 4 at which time all pups were sacrificed and examined grossly.

The following is a summary of the most relevant results from Dose Groups 1, 2, and 3.

Dose Group 1 (50 mg/kg body weight/day):

- No test substance-related findings in dams and pups

Contains No CB!

CONTAINS NO CB!

¹ Panel members are Air Products, Arkema, BASF, Celanese, Dow, DuPont, Ertisa, Mitsubishi Gas Chemical, Mitsubishi Rayon, Taminco.

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ACC Amines Panel
Methylaminoethanol OECD 421 Rangefinding Study
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Dose Group 2 (150 mg/kg body weight/day):

Dams:

- Urine discoloured (3 out of 3 animals)
- Salivation after treatment (3 out of 3 animals)

Pups:

- No test substance-related findings

Dose Group 3 (450 mg/kg body weight/day):

Dams:

- Urine discoloured (3 out of 3 animals)
- Salivation after treatment (3 out of 3 animals)
- Insufficient nursery/maternal care (1 out of 3 animals)

Pups:

- Six out of 32 pups died ahead of schedule
- Eleven out of 32 pups were cannibalized
- Viability index: 43% (100% in the control group)
- Reduced mean pup body weight on PND 4 (control was set to 100%), i.e. 81% (male and female) and 79% (male only)
- Reduced mean pup body weight change between PND 1-4 (control was set to 100%), i.e. 49% (male and female) and 44% (male only)

While being submitted in accordance with relevant TSCA 8(e) guidance, the Panel has made no determination as to whether a substantial risk of injury to health or the environment is actually presented by these findings.

If you have any questions, please contact me, the Amines Panel Manager at 703-741-5605 or nancy_sandrof@americanchemistry.com.

Sincerely,



Nancy Sandrof
Manager, Amines Panel
American Chemistry Council