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The Dow Chemical Company  
Midland, Michigan 48674  
USA

1803 BUILDING  
June 10, 2009

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Office of Pollution Prevention and Toxics  
Environmental Protection Agency  
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Washington, DC 20460-0001



8EHQ-0609-17334B

RE: 8EHQ-08-17334  
3-AMINO-4-OCTANOL  
CASRN 1001354-72-8



DCN: 89090000298

Dear Sir/Madam:

On December 2, 2008, The Dow Chemical Company (Dow) submitted findings related to the subject chemical (ref.: 8EHQ-08-17334) that described a very slight degeneration of the testis germinal epithelium in 5 of 12 animals. See attached letter.

Based on follow-up studies that are described below, Dow now concludes that this finding was unrelated to treatment with the subject chemical.

As described in the original letter, there was a very slight degeneration of the testis germinal epithelium in 5 of 12 animals (3 unilateral; 2 bilateral) in the 150 mg/kg/day dose group, compared to an incidence of 2, 3, and 1 of 12 animals (all unilateral) in the 0, 15, and 60 mg/kg/day dose groups. This degeneration was characterized by loss and disruption of the germinal epithelial cells, and vacuolation of germinal and Sertoli cells. The incidence of this observation in the 150 mg/kg/day dose group was above concurrent and historical controls (Text Table 2), although it was noted that in a previous 28-day study in a different strain of rat, that administered a slightly higher dose of 3-amino-4-octanol by the same route of administration, similar effects on the testis were not observed.

The histological observations in the testes reported in the previous submission (ref.: 8EHQ-08-17334) are now deemed unrelated to the treatment with 3-amino-4-octanol due to the fact that a follow-up 90-day study administering by gavage a dose of 150 mg/kg/day 3-amino-4-octanol to both strains of rats used previously did not reproduce the histopathologic findings despite the extended duration of treatment, which allowed for completion of a full spermatogenic cycle. Based on these data, the histopathologic observations were interpreted to be spontaneous or spurious alterations, unassociated with exposure to 3-amino-4-octanol.

In addition, gavage administration of 3-amino-4-octanol at dose levels up to, and including, 150 mg/kg/day produced no indication of reproductive toxicity at any dose level. There were no effects on prenatal/early neonatal growth and survival of the offspring.

**Contains No CBI**

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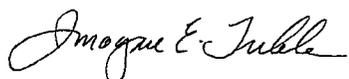
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EPA, TSCA Section 8(e) Coordinator  
June 10, 2009  
Page 2

Based on these results, the no-observed-effect level (NOEL) for systemic and reproductive toxicity was 150 mg/kg/day, the highest dose level tested.

Questions may be directed to the undersigned.

Sincerely,

A handwritten signature in cursive script that reads "Imogene E. Treble".

Imogene E. Treble  
PH: 732-563-5706  
FAX: 732-563-6074  
E-MAIL: [trebleie@dow.com](mailto:trebleie@dow.com)

jt

Attachment

1803 BUILDING  
December 2, 2008

The Dow Chemical Company  
Midland, Michigan 48674  
USA

[CONTAINS NO CONFIDENTIAL BUSINESS INFORMATION]

VIA CERTIFIED MAIL RETURN RECEIPT REQUESTED 7004 2890 0001 1272 3525

Document Processing Center (7407M)  
(Attn: TSCA Section 8(e) Coordinator)  
Office of Pollution Prevention and Toxics  
Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460-0001

RE: 3-AMINO-4-OCTANOL  
CASRN 1001354-72-8

Dear Sir/Madam:

The following information is being submitted by The Dow Chemical Company (Dow) pursuant to current guidance issued by EPA indicating EPA's interpretation of Section 8(e) of the Toxic Substances Control Act. Dow has made no determination as to whether a significant risk of injury to health or the environment is actually presented by the findings.

The test substance was administered by gavage at 0, 15, 60 or 150 mg/kg/day to groups of male and female Crl:CD(SD)rats for two weeks pre-breeding, through gestation, and up to lactation day 4(females) or 32 (males).

Treatment-related findings were limited to very slight degeneration of the testis germinal epithelium in 5 of 12 animals (3 unilateral; 2 bilateral) in the 150 mg/kg/day dose group, compared to background incidence of 2, 3, and 1 of 12 animals (all unilateral) in the 0, 15, and 60 mg/kg/day dose groups. The finding was deemed treatment-related in the 150 mg/kg/day dose groups due to a combination of the increased incidence (unilateral+bilateral) above concurrent and historical controls, and the bilateral observation in only the high-dose group. This degeneration was characterized by loss and disruption of the germinal epithelial cells, and vacuolation of germinal and Sertoli cells. The toxicological significance of this finding is questionable in light of the fact that a previous study of similar duration and slightly higher dose, in a different strain of rat, did not show these effects.

There were no treatment-related effects on mating, conception, fertility, post-implantation loss, litter size, pup weight or survival, or organ weights.

Questions may be directed to the undersigned.

Sincerely,



Linda C. Burgert  
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FAX: 989-638-9933  
E-MAIL: [lburgert@dow.com](mailto:lburgert@dow.com)

jt