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Office of Toxic Substances  
U.S. Environmental Protection Agency  
401 M Street, SW  
Washington, D.C. 20460  
Attn: 8(e) Coordinator

**COMPANY SANITIZED**

Re: bis(hydrogenated tallowalkyl) methylamine  
CAS Number 061788-63-4

Dear 8(e) Coordinator:

hereby submits the following information under Section 8(e) of the Toxic Substance Control Act. While the submitter does not necessarily believe the information indicates a significant risk of injury to health or the environment, EPA guidance seems to indicate that these effects in laboratory animals should be reported to the Agency.

Ten male and ten female Fischer 344 rats per group were given test diets formulated to supply 0, 1, 5, 25 or 250 mg of the test material/kilogram body weight/day (mg/kg/day) for 13 weeks. Standard toxicologic parameters were evaluated. Actual dosages received were as follows: males - 0, 1.1, 5.3, 28.8 or 261.9 mg/kg/day and females - 0, 1.1, 5.4, 27.1 or 264.0 mg/kg/day.

Organ weight effects were observed at the high dose level of 250 mg/kg/day wherein lower terminal body weights were accompanied by a corresponding secondary increase in the relative organ/body weight ratio for adrenal, kidney, liver and testes.

Gross necropsy and histopathologic examination of both sexes ingesting the test material for 13 weeks indicated treatment-related effects within the jejunum of the small intestine, mesenteric lymph node, spleen, mediastinal lymph node, interstitium of the ovary and possibly the liver. The principal response was an infiltrate of macrophage type cells accompanied by other inflammatory cells within these tissues. All of the above listed target tissues were affected by treatment with the high dose level of 250

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mg/kg/day. At the next lower dose level of 25 mg/kg/day, target tissues were limited to the jejunum of the small intestine and the mesenteric lymph node.

Based on the multiple parameters evaluated in this study, the no-observed-effect-level (NOEL) for the test material was the targeted concentration of 1 mg/kg/day which corresponds to an actual dietary intake of 1.1 mg/kg/day for males and female Fischer 344 rats.

Questions concerning these findings may be directed to the undersigned.

Sincerely,

**Best Available Copy**