

ETHYL CORPORATION
Health and Environment Department

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ETHYL CORPORATION - RETURN RECEIPT REQUESTED
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MAY - 8 AM 8:00

Attention: Section 8(a) Coordinator

Dear Sir:

RE: BEHQ 1286-0648

This is a follow-up to an 8(a) submission (BEHQ 1286-0648) Ethyl Corporation made in December 1986. Pursuant to the Agency's letter dated January 16, 1987, Ethyl Corporation is submitting additional preliminary results of a two-year bioassay on diethyltoluene diamine in Sprague Dawley rats.

The in-life phase of a two year oncogenicity study has been completed. Dose levels were 0, 10, 35 or 70 ppm in the diet. Each dose group was composed of 50 male and 50 female rats. Histopathological analysis of tissues is completed and draft pathology results are summarized as follows:

A significant increase in neoplastic (hepatocellular carcinoma) and proliferative lesions in liver (eosinophilic and basophilic foci) and thyroids (follicular cell hypertrophy) of high dose male rats and in the liver (hepatocellular adenoma) of the high dose female rats was found. A significant increase in fibroadenoma of the mammary gland was present in the mid and high dose females. This finding is complicated by the high incidence of mammary gland adenocarcinomas in the control females.

All three dose groups of treated males had an increased incidence and severity of degenerative changes in the liver (focal and multifocal cystic degeneration and multifocal necrosis). An increased incidence of basophilic foci was found in high dose females. Pancreatic acinar cell atrophy was found in the high dose male rats. Follicular cell hyperplasia/follicular cysts were increased in the thyroids of the mid and high dose males. Renal cysts and tubular hyperplasia, which may have been an exacerbation of chronic nephropathy, and cataracts (6) were present in high dose male rats. The relevance of treatment to the renal and ocular changes is equivocal.

2

No treatment-related neoplastic or non-neoplastic changes were noted in any of the other tissues examined. A variety of spontaneous neoplasms and incidental lesions were present in both the control and treated rats.

Compilation of the in-life data is underway and the final report is being written. We will keep you informed of the results of the study.

If you have any questions, please call me at (504) 388-7608.

Sincerely,
ETHYL CORPORATION

R. L. Smith

R. L. Smith, PhD
Director
Toxicology and Regulatory Affairs