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DuPont Haskell Laboratory
for Toxicology and Industrial Medicine
Elkton Road, P.O. Box 50
Newark, DE 19714-0050



DuPont Haskell Laboratory

8EHQ - 0898 - 14130

August 7, 1998

Via Federal Express

Document Processing Center (7407)
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street SW
Washington, D.C. 20460-0001

PDC# 8898000099

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Dear 8(e) Coordinator:

8EHQ-98-14130
1,1,3,3-Tetramethylurea
CAS # 632-22-4

This letter is to inform you of the preliminary results of a recently conducted rat inhalation developmental toxicity study with the above referenced test material.

Groups of 25 assumed pregnant rats were exposed by inhalation (6 hours/day) to the test material over days 6-20 of gestation (days 6-20G) to targeted exposure concentrations of 0, 2, 20, or 100 ppm. On day 21 of gestation, the rats were euthanized and examined grossly. The uterine contents were examined and the fetuses were weighed, sexed and examined externally, viscerally, and skeletally.

Clear evidence of maternal and developmental toxicity was seen at 100 ppm. There was a significant, compound-related reduction in mean maternal weight change evident over days 6-8, 8-10, 10-12, 12-14, 16-18, and 18-20G. The overall weight change (days 6-21G) was significantly reduced and was 70/52% (using the absolute final weight/final weight adjusted for the products of conception) of control. There were significant, compound-related reductions (87-91% of control) in mean maternal body weight starting on day 8G and persisting until the end of the study. Mean maternal food consumption was significantly reduced at this level throughout the study; overall food consumption (days 6-21G) was 80% of control. There was no other evidence of maternal toxicity at this level. Regarding developmental toxicity, mean fetal weight was significantly reduced (83% of control). There was no other evidence of developmental toxicity at this level.

At 20 ppm, there was evidence of maternal toxicity. Mean maternal weight change was significantly reduced over days 6-8 and 6-21G (only when using the final weight adjusted for the products of conception); overall weight gain was 83% of control. There was a slight, but significant reduction in mean food consumption over days 6-8G; overall food consumption (days 6-21G) was no affected. There was no other evidence of maternal toxicity at this level. There was no evidence of developmental toxicity at this level.



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At 2 ppm, there was no evidence of maternal or developmental toxicity.

The findings described above appear to be reportable, based upon EPA guidance regarding the reportability of such data under TSCA Section 8(e) criteria.

Sincerely,

A handwritten signature in black ink that reads "A. Michael Kaplan". The signature is written in a cursive style with a long horizontal line extending to the right.

A. Michael Kaplan, Ph.D.
Manager-Regulatory Affairs

AMK/SMM:jat
(302)366-5260