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Document Title	SUPPORT: LETTER FROM DUPONT HASKELL LAB TO USEPA INFORMING OF ADDITNL RESLTS OF ATOX INHALATION & RAT BONE MARROW MICRONUCLEUS ASSAY W/1,1,3,3,3-PENTAFLUOROPROPENE, DATED 02/21/00		
Chemical Category	1-PROPENE, 1,1,3,3,3-PENTAFLUORO-		

SUPPORT

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8EHQ-0200-14638

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

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DuPont Haskell Laboratory

February 21, 2000

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

MR# 32623



8EHQ-00-14638

Dear 8(e) Coordinator:

1-Propene, 1,1,3,3,3-pentafluoro-
CAS# 690-27-7

This letter is to inform you of additional results from an acute inhalation toxicity study conducted in rats and previously reported to you in our letter of January 21, 2000 and the results of a rat bone marrow micronucleus assay by inhalation.

Acute Inhalation Toxicity Study

Four groups of 5 male and 5 female 8-week old CrI:CD[®](SD)IGS BR rats were exposed nose-only to gas atmospheres of the test material for a single, 4-hour period. Concentrations tested included 500, 2000, 3300, and 4500 ppm. Rats underwent a 14-day recovery period following exposure. The lung, liver, and kidneys from rats in the 500 and 2000 ppm groups were examined microscopically. An unexposed control group of rats was not used for comparative purposes.

Compound-related microscopic findings were present in the kidneys of male and female rats exposed to 500 or 2000 ppm of the test compound. In all 2000 ppm rats found dead within 5 days following the exposure, kidney lesions were characterized by severe acute necrosis of renal tubules. Kidney changes in all 500 and 2000 ppm rats that survived the 14-day observation period primarily consisted of regeneration of renal tubules. The extent of tubular regeneration was dose related and tended to be more prominent in male rats compared to females.

Other microscopic findings that may be related to compound exposure include the following:

- Acute necrosis and inflammation in the lungs of 1 female rat exposed to 2000 ppm
- Pulmonary hemorrhage in 2 males exposed to 2000 ppm and 1 female exposed to 500 ppm
- Inflammation and transitional cell hyperplasia of the renal pelvis in 1 female exposed to 2000 ppm
- Periportal fatty change in the liver of 1 male and 1 female exposed to 2000 ppm

In addition to these findings, microscopic changes suggestive of hypertrophy were present in the livers of 500 ppm male rats. However, comparison with a study control group would be necessary to definitively diagnose this change.



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Rat Bone Marrow Micronucleus Assay by Inhalation

Two groups (low and intermediate concentrations) of 5 male 8-week old CrI:CD[®](SD)IGS BR rats and 1 group (high concentration) of 16 male 8-week old CrI:CD[®](SD)IGS BR rats were exposed nose-only to gas atmospheres of the test material for a single, 6-hour period. Concentrations were targeted at 300, 600, and 1200 ppm. A concurrent control group of 10 male rats of the same age was exposed nose-only to air only.

Groups of 5 rats at the 0, 300, and 600 ppm concentrations were sacrificed 24 hours post exposure and evaluated for micronucleated polychromatic erythrocytes (MNPCEs). The first 10 of 16 animals from the 1200 ppm group were also sampled 24 hours (5 rats) and 48 hours (5 rats) after treatment and evaluated for micronuclei. The remaining 6 rats from this group were sacrificed without evaluation. In addition, a group of 5 vehicle control rats was sacrificed 48 hours post exposure and evaluated for MNPCEs.

A statistically significant increase in the frequency of MNPCEs was observed in rats exposed to 1200 ppm and sampled 24 hours after treatment. Rats at the highest concentration that were sampled 48 hours post exposure did not show a statistically significant elevation in MNPCE scores; however, 2 out of 5 rats did respond comparably to positive control rats.

The MNPCE counts for the 2 lower concentrations were not significantly elevated over the vehicle controls; however 2 out of 5 animals in each group did respond comparably to positive control rats. In addition, the Jonckheere test for trends from the 0 to the 1200 ppm groups was statistically significant at a level of $\alpha = 0.05$.

Under these experimental conditions, 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. Michael Kaplan, Ph.D.
Director - Regulatory Affairs

AMK/JRB:clp
(302)366-5260

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