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

PDCN: 88980000162
PDCN 88980000163

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Dear 8(e) Coordinator:

8EHQ-98-14195
8EHQ-98-14196
1,1-Difluoro-1,2,2-trichloroethane (HCFC-122)
CAS# 354-21-2

This letter is to inform you of the preliminary results of the interim 90-day sacrifice for a 6-month inhalation study in rats with the above referenced test material.

Four groups of male and female Crl:CD® (SD)BR rats were exposed (whole body) by inhalation, to vapor atmospheres of the test material at concentrations of 0, 25, 250, or 750 ppm, six hours/day, five days/week, for a total of 65 exposures. Rats were monitored throughout the study for clinical signs of toxicity, food consumption, and body weight changes. Blood and urine samples were collected for clinical pathology evaluations and rats were examined for gross and microscopic pathological changes.

Female rats exposed to 750 ppm consistently had statistically significant decreased mean body weights.

Compound-related increases in liver weights were present in the 250 and 750 ppm groups. Microscopically, these liver weight changes were associated with generally minimal hepatocellular hypertrophy, centrilobular apoptosis, and increased pigment. Hypertrophy was typically characterized by minimal increases in cytoplasmic area and loss or decrease in the normal basophilic stippling of hepatocytes. In males, centrilobular hepatocytes often had clear granular swelling and, in some animals, variably-sized, clear vacuoles. Similar cytoplasmic granularity has been noted in association with peroxisome proliferation. The presence of apoptosis in the affected groups may represent a controlled mechanism to eliminate excess cells, rather than a manifestation of toxic injury to hepatocytes. Hepatic beta-oxidation rates were increased in all dose groups, with 219%, 375%, and 334% of control values at 25, 250 and 750 ppm, respectively.

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Lung weights were increased in 750 ppm male rats relative to controls, but these increases were not associated with a definitive microscopic correlate. Microscopically, an increased incidence of minimal, focal alveolar histiocytosis was present in 250 and 750 ppm male rats. This is a common spontaneous lesion in rats and the severity and distribution of the lesion in the affected rats were not consistent with a compound-related effect (i.e. lesions were focal and without a discernible distribution pattern, such as an acinar pattern). Therefore, the alveolar histiocytosis in 250 and 750 ppm male rats is considered unlikely to be compound-related, pending results of the final sacrifice.

No compound-related adverse effects were noted in the clinical chemistry, food consumption, or clinical signs of toxicity.

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. Conclusions as to the significance of these findings awaits the results of the 6-month sacrifice.

Sincerely,

A. Michael Kaplan

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

AMK/AJO:jmg
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