

PROGRAM FOR ALTERNATE FLUOROCARBON TOXICITY TESTING

June 20, 1991

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

U.S. Environmental Protection Agency
Office of Toxic Substances
TSCA 8(e) Coordinator
401 M Street, SW
Washington, DC 20460

RE: Toxic Substances Control Act - Section 8(e)
Substantial Risk Reporting

Dear Sir:

In January 1988, the Program for Alternate Fluorocarbon Toxicity Testing (PAFT) was created to conduct comprehensive toxicological evaluations of substitutes under development as alternatives to the CFCs. The current PAFT members include Allied-Signal, AKZO, Asahi Glass, ATOCHEM, Central Glass, Daikin, Du Pont, Hoechst, ICI, ISC (Rhone Poulenc), Solvay & Cie, Montefluos, Showa-Denko, and Ulsan Chemical, many of whom conduct business in the United States. Throughout this program, PAFT has voluntarily worked with EPA to discuss these programs, expanding them to focus on Agency concerns and sharing the results with EPA as soon as they become available. PAFT expects to continue to work closely with the Agency as the program evolves.

One of the first compounds to be evaluated under the PAFT program was HCFC-123, 1,1-dichloro-2,2,2-trifluoroethane (CAS #306-83-2)*. While substantial testing has been completed on this material, PAFT is currently evaluating the data from a two-year rat inhalation toxicity/carcinogenicity study. This study is being conducted for PAFT at Du Pont's Haskell Laboratory for Toxicology and Industrial Medicine. Although all of the animals have not yet been evaluated, histopathological examination of tissues from male rats on the study has indicated an exposure-related increase in benign testicular and benign pancreatic tumors. The letter and table summarizing these preliminary findings is attached. It is our judgment that these findings meet EPA's criteria for submission under TSCA Section 8(e). This submission is being made on behalf of all member companies of PAFT.

*This material had a minimum organic purity of 99.8% by weight with a maximum of 7.5% HCFC-123a (1,2-dichloro-1,1,2-trifluoroethane, CAS #354-23-4) allowed.

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In considering the significance of these findings, several factors should be taken into account: 1) The findings themselves are preliminary, no tissues have been evaluated from female rats and several males in the low- and mid-level groups still remain to be evaluated. 2) The tumors themselves are benign, appeared late in the study, and did not cause death. In fact, no histological lesions of any consequence were seen in 10 rats/sex/exposure level sacrificed at one year. Furthermore, survival at two years increased with increasing exposure concentration. (Please see attached Table.) 3) PAFT is still conducting extensive toxicology research on HCFC-123, including a two-generation reproduction study and a series of metabolism studies. The above findings will be included in the PAFT evaluation of the carcinogenic potential of HCFC-123.

The current exposure level recommended by many of our companies is 100 ppm as an 8-hour time weighted average. Based on the current findings, companies are reviewing their recommendations on exposure levels.

PAFT will continue to keep the Agency and the world community apprised of progress and findings in the PAFT programs.

Sincerely,

Charles F. Reinhardt
Charles F. Reinhardt, M.D.
Director
Haskell Laboratory for
Toxicology and Industrial
Medicine
E.I. du Pont de Nemours &
Company

George M. Rusch
George M. Rusch, Ph.D., D.A.B.T.
Director of Toxicology
Allied-Signal Inc.
Chairman
PAFT Toxicology Committee

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Encs.