
40 CFR Part 799**[OPTS-42044A; FRL-3462-5]****Hexafluoropropylene Oxide;
Termination of Rulemaking****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule; termination.

SUMMARY: EPA is terminating rulemaking under the Toxic Substances Control Act (TSCA) for mutagenicity, oncogenicity, and reproductive effects testing of hexafluoropropylene oxide (HFPO; CAS No. 428-59-1). EPA's decision is based on the analysis of manufacturing and processing information submitted by the sole manufacturer (and processor) of HFPO which demonstrated that exposure to HFPO in the workplace is being controlled to levels which are not expected to present an unreasonable risk of health effects.**FOR FURTHER INFORMATION CONTACT:** Michael M. Stahl, Acting Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. EB-44, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

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SUPPLEMENTARY INFORMATION: EPA is terminating rulemaking under section 4(a) of TSCA for health effects testing of HFPO.

I. Background

The Interagency Testing Committee (ITC) designated the category of halogenated alkyl epoxides for priority testing consideration in its Second Report, published in the *Federal Register* of April 19, 1978 (43 FR 16684). HFPO was one of seven chemical substances (chemicals) in the category of halogenated alkyl epoxides. The ITC recommended that halogenated alkyl epoxides be considered for testing for oncogenicity, mutagenicity, teratogenicity, and other chronic effects. The ITC also recommended that epidemiology studies be considered. The other six chemicals in this category were: Epichlorohydrin (ECH), 1,1,1-trichloro-2,3-epoxy-propane (TCPO), 1,4-dichloro-2,3-epoxybutane (DCBO), tetrafluoroethylene oxide (TFEO), 1,1,1-trichloro-3,4-epoxybutane (TCBO), and 1-bromo-2,3-epoxybutane (EBH). The ITC's recommendations were based on high production levels for one member of this category (500 million pounds per year for ECH), a National Institute for Occupational Safety and Health (NIOSH) estimate of 50,000 to 140,000 workers exposed to ECH each year, an expected increase in the use of other halogenated alkyl epoxides, and limited studies on the oncogenic, mutagenic, teratogenic, and other chronic effects of members of this category of substances.

After considering all the available information on the category of halogenated alkyl epoxides, EPA responded to ITC's recommendation by issuing a proposed rule, published in the *Federal Register* of December 30, 1983 (48 FR 57686), which would require oncogenicity, mutagenicity, and reproductive effects testing for HFPO under the authority of section 4(a)(1)(A) of TSCA. EPA took this action because chemicals that are structurally similar to HFPO (i.e., ECH) have demonstrated oncogenic, mutagenic, and reproductive activity in animals and EPA believed there was the potential for HFPO to elicit similar effects, and because monitoring data indicated there was workplace exposure to HFPO (Ref. 1). In addition, reduced spermatogenesis was observed in a subchronic study on HFPO, suggesting that HFPO may produce reproductive effects (Ref. 2).

In the *Federal Register* of December 30, 1983 (48 FR 57695), EPA also published a "decision not to test" the other six chemicals in the category of halogenated alkyl epoxides. EPA

decided that testing of ECH was not necessary because there are already sufficient data available on this chemical. EPA decided that the testing of TCPO, DCBO, and TFEO was not appropriate because none of these three chemicals are listed on the TSCA inventory and thus are subject to review under TSCA section 5(a) before they are manufactured for uses under TSCA jurisdiction. In the case of TCBO and EBH, EPA found that TCBO is not being manufactured, imported, or processed and EBH is being produced in quantities of 25 pounds or less solely for research and development.

The proposed rule contained a chemical profile of HFPO. Specific data on the quantity of HFPO produced annually and the number of workers employed during its production and processing were claimed to be confidential business information (CBI). EPA found the annual production of HFPO to be relatively low and the number of workers employed to be relatively few.

During the comment period following the publication of the HFPO proposed rule, EPA received manufacturing and processing design, industrial hygiene, and engineering-control information from E.I. Du Pont De Nemours & Company (Du Pont), the sole manufacturer and processor of HFPO in the United States (Ref. 3). Du Pont summarized its HFPO operation as follows: The entire HFPO manufacturing process is carried out in a totally closed and automated system; all process vents are scrubbed with caustic before being discharged to the atmosphere; before any piping breaks are made, process materials are evacuated through a caustic scrubber; protective equipment (acid suit with air supplied helmet) is required when making all piping breaks (e.g., sampling); the presence of HFPO in the exhaust air is monitored using a Miran IR Analyzer; and all HFPO produced is used in the production of fluorinated substances and is not present in free form after processing.

Based on analysis of the information submitted by Du Pont, EPA believes that exposure to HFPO in the workplace is being controlled to levels which are not expected to present an unreasonable risk of adverse health effects even if the adverse effects for which it is suspected based on analogy to ECH are verified. The monitoring data from HFPO manufacturing and processing sites showed that concentrations of HFPO in the workplace are generally below 0.1 parts per million (ppm), which was the limit of detection, and in no case above 2 ppm.

Furthermore, EPA has also issued a combined TSCA significant new use rule (SNUR) under section 5(a)(2) and section 8(a) reporting rule for HFPO published in the *Federal Register* of October 27, 1987 (52 FR 41296). The SNUR for HFPO will ensure that EPA is notified if HFPO is manufactured, imported, or processed for any use other than as an intermediate in the manufacture of fluorinated substances in an enclosed process. Because the SNUR will not provide notification of future manufacturing, importing, and processing activities associated with HFPO's current use, EPA has required reporting under section 8(a) if HFPO activities not covered by the SNUR are initiated.

These rules will allow EPA to track the use of HFPO and to investigate the health and environmental impacts of such activities.

EPA is issuing this notice to terminate the proposed test rule for HFPO because: EPA believes that Du Pont is presently controlling the exposure to HFPO in the workplace to levels which are not expected to present an unreasonable risk of health effects; and EPA has issued the combined SNUR/section 8(a) rule for HFPO to be used as a mechanism to monitor any increases in exposures to HFPO in the future. EPA may reconsider the need for testing of HFPO at that time.

II. Rulemaking Record

A section 4 record, containing the basic information considered by EPA in developing its decision on HFPO, is available for Public inspection in the TSCA Public Docket Office, NE-G004, 401 M St., SW., Washington, DC from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays (docket number OPTS-42044A). CBI, while part of the rulemaking record is not available for public review.

The rulemaking record includes the following information:

A. Supporting Documentation

- (1) The *Federal Register* notice containing the ITC designation of halogenated alkyl epoxides to the Priority List (43 FR 16684; April 19, 1978).
- (2) The *Federal Register* notice containing EPA's proposed test rule on HFPO (48 FR 57686; December 30, 1983).
- (3) The *Federal Register* notice containing final significant new use and section 8(a) rules for HFPO (52 FR 41296; October 27, 1987).
- (4) Communications consisting of letters, contact reports of telephone conversations, and meeting summaries.

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B. References

(1) US Environmental Protection Agency. Assessment of Testing Needs: Hexafluoropropylene Oxide Support Document, Washington, DC, Office of Toxic Substances (1983).

(2) E.I. Du Pont De Nemours & Company. 90-Day exposure study with hexafluoropropylene oxide (February 28, 1988).

(3) E.I. Du Pont De Nemours & Company. Comments on EPA's Proposed Test Rule for hexafluoropropylene oxide submitted to Public Information Office, USEPA (March 28, 1984).

Therefore, 40 CFR 799.2150 *Hexafluoropropylene oxide*, proposed in the Federal Register of December 30, 1983 (48 FR 57686), is hereby terminated.

List of Subjects in 40 CFR Part 799

Testing, Environmental protection,
Hazardous substances, Chemicals,
Recording and reporting requirements.

Dated: October 4, 1988.

Victor J. Kimm,

*Acting Assistant Administrator for Pesticides
and Toxic Substances.*

[FR Doc. 88-23731 Filed 10-13-88; 8:45 am]

BILLING CODE 6560-60-01

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