

6. Other competency standards.

Treatment would be made once in any area, and the application period would be from December 1983 through April 30, 1984. To prevent unreasonable hazard to the environment, the Applicant proposes to apply baits inside main runways of active Apodontia burrows in piles at least 12 inches from any surface opening and to avoid burrows in or near the edges of streams.

This notice does not constitute a decision by EPA on the application itself. The chemical 3,4,5-trimethoxybenzoyl methyl reserpate is an unregistered pesticide and therefore, the Agency has decided that public notice and opportunity for public comment pursuant to 40 CFR 166.10 is called for as a part of the informal adjudication for specific exemptions. Accordingly, interested persons may submit written views on this subject to the Program Management and Support Division at the address above. The comments must be received on or before January 19, 1984, and should bear the identifying notation OPP-180635. All written comment filed pursuant to this notice will be available for public inspection in Rm. 236, Crystal Mall No. 2, at the address given above, from 8:00 a.m. to 4 p.m., Monday through Friday, except legal holidays.

The Agency, accordingly, will review and consider all comments received during the comment period in determining whether to issue the emergency exemption requested by Oregon.

Dated: December 18, 1983.

James M. Conlon,
Acting Director, Office of Pesticide Programs.
[FR Doc. 84-3 Filed 1-3-84; 8:45 am]
BILLING CODE 6560-50-M

[PF-358; PH-FRL 2439-5]

Certain Companies; Pesticide and Feed Additive Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received pesticide and feed additive petitions relating to the establishment of tolerances for residues of certain pesticide chemicals in or on certain commodities.

ADDRESS: By mail, submit written comments to:

Program Management and Support Division (TS-757C), Attn: Product Manager (PM) 17, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.

In person, deliver comments to: Rm. 236, CM #2, Environmental Protection Agency, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Written comments must be identified by the document control number [PF-358]. All written comments filed in response to this notice will be available for public inspection in the Program Management and Support Division office at the address above from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Timothy A. Gardner, PM-17, CM #2, Rm. 207, (703-557-2690).

SUPPLEMENTARY INFORMATION: EPA gives notice that the Agency has received the following pesticide and feed additive petitions relating to the establishment of certain pesticide chemicals in or on certain commodities in accordance with the Federal Food, Drug, and Cosmetic Act. The analytical method for determining residues, where required, is given in each petition.

Initial Filings

1. PP 4F2985. ICI Americas, Inc., Agricultural Chemicals Division, Concord Pike and New Murphy Road, Wilmington, DE 19897. Proposes amending 40 CFR 180.378 by establishing tolerances for the combined residues of the insecticide permethrin [(3-phenoxyphenyl) methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate] and its metabolites in or on the commodity tomatoes at 2.0 parts per million (ppm). The proposed analytical method for determining residues is gas chromatography.

2. PP 4F2995. ICI Americas, Inc. Proposes amending 40 CFR 180.378 by establishing tolerances for the combined residues of the insecticide permethrin or on the commodity pistachios at 0.1 ppm. The proposed analytical method for determining residues is gas chromatography.

3. PP 4F2981. FMC Corp., Agricultural Chemical Group, 2000 Market St., Philadelphia, PA 19103. Proposes amending 40 CFR 180.378 by establishing tolerances for the combined residues of the insecticide permethrin in or on the commodity sunflowers at 0.05 ppm. The proposed analytical method for determining residues is gas chromatography.

4. PP 4F3003. Shell Oil Co., Suite 200, 1025 Connecticut Ave., NW, Washington, D.C. 20036. Proposes amending 40 CFR 180.379 by establishing tolerances for residues of the insecticide cyano-(3-phenoxyphenyl) methyl-4-chloro-alpha-(1-methylethyl)

benzeneac... in or on the commodity... as follows:

Commodities	Parts per million (ppm)
Alfalfa	10.0
Alfalfa	25.0
Eggs	0.2
Fat of cattle, goats, hogs, horses, and sheep	2.0
Meat of cattle, goats, hogs, horses, and sheep	0.5
Sheep	0.5
Pork fat	9.0
Poultry fat	0.15
Poultry meat byproducts	0.15
Poultry meat	0.03
Sorghum grain	8.0
Sorghum fodder and forage	15.0

The proposed analytical method for determining residues is gas chromatography.

5. FAP 4H5419. Shell Oil Co. Proposes amending 21 CFR Part 561 by establishing a regulation permitting residues of the above insecticide (PP 4F3003) in or on the commodity sorghum milled products at 15.0 ppm.

6. PP 4F2994. Shell Oil Co. Proposes amending 40 CFR 180.379 by establishing tolerances for residues of the above insecticide (PP 4F3003) in or on the commodity English walnuts at 0.2 ppm. The proposed analytical method for determining residues is gas chromatography.

7. PP 4F3004. Shell Oil Co. Proposes amending 40 CFR 180.379 by establishing tolerances for residues of the above insecticide (PP 4F3003) in or on the commodities grass hay and grass (pasture and rangeland) at 15.0 ppm.

8. PP 4F3002. SDS Biotech Corp., 7528 Auburn Rd., P.O. Box 348, Plainesville, OH 44077. Proposes amending 40 CFR 180.379 by establishing tolerances for residues of the above insecticide (PP 4F3003) in or on the commodities poultry eggs at 0.03 ppm; poultry fat, meat and meat byproducts at 0.2 ppm. The proposed analytical method for determining residues is gas chromatography.

(Sec. 408(d)(2) 68 Stat. 512 (21 U.S.C. 346a(d)(2); 409(b)(5), 72 Stat. 1786 (21 U.S.C. 346))

Dated: December 20, 1983.

Douglas D. Camp,
Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 84-2 Filed 1-3-84; 8:45 am]
BILLING CODE 6560-50-M

[OPTS-42049; OTS-FRL 2501-7]

1,2-Butylene Oxide; Response to the Interagency Testing Committee

AGENCY: Environmental Protection Agency (EPA).

Phil

ACTION: Notice.

SUMMARY: The First Report of the Interagency Testing Committee (ITC) designated the category of alkyl epoxides for consideration by EPA for health and environmental effects testing. This notice provides EPA's response to the ITC's recommendations with respect to 1,2-butylene oxide, one member of the alkyl epoxides category. Other category members are being addressed in separate Federal Register notices.

The available data and the testing in progress on 1,2-butylene oxide appear to address adequately the ITC's concerns that this chemical's potential for carcinogenicity, teratogenicity, and other chronic effects be evaluated. In the case of reproductive and neurotoxic effects, EPA believes that testing being performed for these effects on propylene oxide can also serve as the basis for any needed regulation and control of 1,2-butylene oxide exposure for these two effects. A decision for additional mutagenicity testing on 1,2-butylene oxide will be postponed until the results of a number of mutagenicity tests on 1,2-butylene oxide and ethylene oxide are analyzed by the Agency. EPA is not pursuing the ITC's recommendation for an epidemiological study because a toxicological endpoint has not been sufficiently well characterized to warrant an epidemiological study at this time.

EPA has sufficient data to reasonably predict the environmental fate of 1,2-butylene oxide. Consequently, EPA is not initiating rulemaking under section 4(a) of the Toxic Substances Control Act (TSCA) to require health or environmental fate testing of 1,2-butylene oxide at this time.

DATE: Submit written comments on or before February 21, 1984.

ADDRESS: Submit written comments in triplicate identified by the document control number (OPTS-42049) to:

TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-108, 401 M St. SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Jack P. McCarthy, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St. SW., Washington, D.C. 20460. Toll free: (800-424-9085). In Washington, D.C.: (554-1404). Outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Background

Section 4(a) of the Toxic Substances Control Act (TSCA) (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) authorizes EPA to promulgate regulations requiring testing of chemical substances and mixtures to develop data relevant to determining the risks that such chemicals may present to health and the environment.

Section 4(e) of TSCA established an Interagency Testing Committee (ITC) to recommend to EPA a list of chemicals to be considered for the promulgation of testing rules under section 4(a) of TSCA. The ITC placed the alkyl epoxides category on its priority testing list in October 1977. The ITC recommended testing the alkyl epoxides for carcinogenicity, mutagenicity, teratogenicity, other chronic effects, and environmental effects. The ITC recommended that the chronic effects testing consider organ effects and behavioral changes and that the environmental testing focus on the fate of epoxides in the environment. Epidemiological studies were also recommended for two or three of the highest exposure compounds if suitable cohorts could be identified.

The alkyl epoxides category, as defined by the ITC, includes all noncyclic aliphatic hydrocarbons with one or more epoxide functional groups. This notice addresses a single member of this category, 1,2-butylene oxide. Other members of the category will be addressed in other Federal Register notices.

A. Production and Uses

1. Production. Dow Chemical Company is the only U.S. producer of 1,2-butylene oxide (Ref. 1). This production occurs at the Midland, Michigan, plant using the chlorohydrin process. 1,2-Butylene oxide produced by this process is at least 98 percent pure (Ref. 2).

In 1977, 1,2-butylene oxide production in the U.S. was approximately 5.7 million pounds or about 0.1 percent of the total alkyl epoxides produced (Ref. 3). Total demand for 1,2-butylene oxide was estimated at eight million pounds in 1978 (Ref. 4). The same source projected demand to increase moderately to about ten million pounds in 1983 and eleven million pounds in 1985 (Ref. 4). According to Dow (Ref. 5), 1,2-butylene oxide is produced in the U.S. in quantities of less than 10 million pounds per year, and about a half million pounds is imported into the U.S. annually. However, according to BOC-Imports (Ref. 6), imports of 1,2-butylene oxide totalled 2.5 million pounds in 1981.

2. Uses. According to Dow, the primary use of 1,2-butylene oxide is as a stabilizer in chlorinated hydrocarbon solvents. About 75 percent of 1,2-butylene oxide is used for this purpose and constitutes 0.1 to 0.7 weight percent of the solvent formulation. About 20 percent is used as a chemical intermediate and about 5 percent is exported (Refs. 3 and 5).

B. Human Exposure

1. Occupational exposure. The National Occupational Hazard Survey estimated 43,705 people were exposed to 1,2-butylene oxide (Ref. 7). Estimates on human exposure to 1,2-butylene oxide provided by Dow (Ref. 5) are shown in this table.

TABLE—DOW'S ESTIMATES ON HUMAN EXPOSURE TO 1,2-BUTYLENE OXIDE

Activity	Number of persons exposed
Manufacturing	<100
Processing	<500
Distribution	<100
Use and disposal	<50,000

The large number of persons exposed during the use of 1,2-butylene oxide reflects its major use as a solvent stabilizer. Dow has conducted industrial hygiene surveys to determine occupational exposure to 1,2-butylene oxide. A review of Dow surveys for the past 10 years shows the exposure levels in the air to 1,2-butylene oxide (Ref. 5) from its use as a stabilizer for the following solvents: trichloroethylene—1,2-butylene oxide exposure <0.5 parts per million (ppm); 1,1,1-trichloroethane—1,2-butylene oxide exposure <0.5 ppm; and dichloromethane—1,2-butylene oxide exposure <1 ppm.

In the absence of an Occupational Safety and Health Administration (OSHA) standard or an American Conference of Governmental Industrial Hygienists threshold limit value (ACGIH TLV), Dow has set a 40 ppm 8-hour time-weighted-average (TWA) limit for exposure in its manufacturing and processing facilities.

2. Consumer exposure. Chlorinated solvents such as 1,1,1-trichloroethane are available to consumers and may contain 1,2-butylene oxide as a stabilizer. Therefore, consumers may be exposed to low levels of 1,2-butylene oxide when they use these solvents.

II. Analysis of the ITC's Concerns

EPA's response to the specific ITC recommendations is set forth below.

A. Carcinogenicity

The National Toxicology Program (NTP) is sponsoring an inhalation bioassay with 1,2-butylene oxide with B6C3F1 mice and Fisher 344 rats. Exposure levels are 0, 200, and 400 ppm in the rats and 0, 50, and 100 ppm in the mice. The exposure phase began in November 1981, and is to run to November 1983. The data from this study should be sufficient to reasonably determine the carcinogenic effects of 1,2-butylene oxide.

B. Mutagenicity

1,2-Butylene oxide gave positive results in gene mutation assays in *Salmonella* (Refs. 8 through 11), in *N. crassa* (Ref. 12), in mouse lymphoma cells (Ref. 8), and in feeding studies in *Drosophila* in the sex-linked recessive lethal test (Ref. 8). A negative result was observed in *Drosophila* in the sex-linked recessive lethal test via inhalation (Ref. 13).

A positive result in a feeding study in *Drosophila* in the reciprocal translocation test, a test to detect chromosomal aberrations, has been reported (Ref. 8). Negative results have also been reported by McGregor (Ref. 3) in the following tests to detect chromosomal aberrations and primary DNA damage: (1) Dominant lethal in male rats; (2) sperm abnormality test in male mice; (3) cytogenetic test in male and female rat bone marrow cells; and (4) unscheduled DNA synthesis assay in human diploid fibroblasts.

For a number of reasons, EPA is not proposing additional mutagenicity testing on 1,2-butylene oxide at this time. First, EPA believes that a further evaluation needs to be made of the apparently conflicting results from the two sex-linked recessive lethal tests in *Drosophila* on 1,2-butylene oxide. A feeding study was positive (Ref. 8), while an inhalation study was negative (Ref. 13). Secondly, a number of mutagenicity tests are in progress on ethylene oxide, which is the alkyl epoxide having two fewer carbon atoms than 1,2-butylene oxide. On the basis of structure activity relationship considerations between 1,2-butylene oxide and ethylene oxide, and the fact that ethylene oxide consistently has shown greater activity in mutagenesis assays, and has tested positive in more mutagenesis assays than 1,2-butylene oxide, EPA believes that results of the ongoing mutagenicity testing on ethylene oxide along with available data on 1,2-butylene oxide will provide a balance as to what, if any, further mutagenicity testing on 1,2-butylene oxide may be appropriate. Inhalation

mutagenicity testing in progress on ethylene oxide includes: (1) Mouse specific locus test; (2) biochemical specific locus test in mice; (3) heritable translocation test in mice; (4) sperm alkylation in mice; and (5) sperm alkylation in *Drosophila*.

After the data from the ongoing ethylene oxide mutagenicity testing and existing 1,2-butylene oxide mutagenicity data, including that from the two sex-linked recessive lethal tests in *Drosophila*, are analyzed by the Agency, the Agency will consider: (1) Whether a mouse specific locus test or other additional mutagenicity testing on 1,2-butylene oxide is necessary or (2) whether ethylene oxide and/or propylene oxide mutagenicity data will provide a sufficient basis for mutagenicity risk assessment for 1,2-butylene oxide without further testing of 1,2-butylene oxide for this effect. In making its analysis, EPA will take into account available data on other effects that may provide sufficient basis for regulation. The Agency is interested in public comment on the various aspects of assessing mutagenicity testing needs for 1,2-butylene oxide.

C. Teratogenicity

A teratogenicity study on 1,2-butylene oxide in rats and in rabbits via inhalation at concentrations of 250 ppm and 1,000 ppm has been reported by Sikov *et al.* (Ref. 14). Wistar rats were exposed for 7 hours per day, 5 days per week 3 weeks. They were then mated and exposed daily through the 19th day of gestation (dg 19). New Zealand white rabbits were artificially inseminated and exposed for 7 hours daily through dg 24. The rats were killed at dg 21 and the rabbits at dg 30. Pregnant animals were examined for toxic changes including altered tissue weights and histopathologic effects. Litters were evaluated using several measures of embryotoxicity and live fetuses were examined for external, visceral, and skeletal malformations. No significant effects were observed in the rats exposed to either 250 ppm or 1,000 ppm 1,2-butylene oxide. Maternal toxicity, developmental toxicity and embryotoxicity were observed in the rabbit at 1,000 ppm. Specific effects observed were: (1) Maternal mortality; (2) fetuses markedly smaller than controls; (3) decrease in number of live fetuses per litter; and (4) increased frequency of resorptions. At 250 ppm significantly elevated mortality in the dams was observed. No other significant effects were observed at 250 ppm in the rabbit.

The data from this study are sufficient to reasonably determine the teratogenic effects of 1,2-butylene oxide.

D. Other Chronic Effects

As a matter of general policy under section 4 of TSCA, EPA generally accepts data from well-conducted oncogenicity studies as being sufficient to assess the chronic toxicity of a chemical. EPA has concluded that adequate data will be available from the various subchronic studies (Refs. 15 through 17) that have been conducted and the ongoing oncogenicity study to reasonably determine or predict the other chronic effects of 1,2-butylene oxide with the exception of reproductive and neurotoxic effects.

E. Reproductive Effects

Both male and female reproductive organs were examined microscopically from mice and rats exposed to sublethal concentrations of 1,2-butylene oxide in a 9-day subchronic study (Ref. 16) and a 90-day subchronic study with exposures of up to 600 ppm 1,2-butylene oxide (Ref. 16), without any detectable treatment-related effects indicative of impaired reproductive function. EPA is not aware of any reproductive effects studies on 1,2-butylene oxide.

EPA concludes that it does not have sufficient data to reasonably predict or determine the reproductive effects of 1,2-butylene oxide. However, EPA is not proposing further reproductive effects testing of 1,2-butylene oxide at this time. EPA proposed to Dow that the results of the industry-sponsored propylene oxide 2-generation reproduction study (OFTS-42028A, appearing elsewhere in this issue of the Federal Register, discusses EPA's conclusions with respect to testing needs for propylene oxide) serve as the basis for any needed regulation and control of 1,2-butylene oxide exposure for reproductive effects. Factors relating to this proposal were that (a) Dow is the only domestic producer of 1,2-butylene oxide, (b) almost all exposures to 1,2-butylene oxide are low-level exposures resulting from its use as a stabilizer in chlorinated hydrocarbon solvents, and (c) testing to date, including that for mutagenicity and teratogenicity, has shown 1,2-butylene oxide to have a lower order of toxicity than propylene oxide. EPA believes that controlling 1,2-butylene oxide exposure on the basis of propylene oxide reproductive effects data will provide at least as much protection as basing control of 1,2-butylene oxide on a 1,2-butylene oxide reproductive effects study. Dow has agreed to EPA's proposal. If propylene oxide shows

adverse reproductive effects. Dow will enter into discussions with the Agency, which will determine what actions are required to reduce occupational exposure to 1,2-butylene oxide as a result of its manufacture, distribution in commerce, processing, use, and disposal. Such actions would continue in effect until Dow came forward with new data showing that such actions are unnecessary for 1,2-butylene oxide (Ref. 18). Because of this agreement between Dow and EPA, EPA is not proposing reproductive effects testing of 1,2-butylene oxide at this time.

F. Neurotoxicity

Miller *et al.* (Ref. 18) have conducted 9-day and 90-day subchronic studies on 1,2-butylene oxide in mice and rats. A number of neuropathological examinations were conducted. In addition to the histopathology of nervous tissue, all animals were observed daily for appearance and change in demeanor. In the 9-day study, all mice exposed to 1,600 ppm 1,2-butylene oxide died. The only lesions observed in the nervous system in either study were non-specific degeneration and inflammation of the olfactory epithelium, even at sublethal concentrations. These studies are weak negatives because no systematic functional tests were performed, no data were reported, and pathological methods were not described. This neurotoxicity assessment can best be regarded as demonstrating that no profound (rather than no) effects occurred owing to exposure to 1,2-butylene oxide. EPA concludes that it does not have sufficient data to reasonably predict or determine the neurotoxicity of 1,2-butylene oxide.

However, EPA is not proposing further neurotoxicity testing of 1,2-butylene oxide at this time. EPA proposed to Dow that the results of the industry-sponsored propylene oxide neurotoxicity testing (OPTS 42028A, appearing elsewhere in this issue of the Federal Register, discusses EPA's conclusions with respect to testing needs for propylene oxide) serve as the basis for regulation and control of 1,2-butylene oxide exposure for neurotoxicity. Factors relating to this proposal were that (a) Dow is the only domestic producer of 1,2-butylene oxide, (b) almost all exposures to butylene oxide are low level exposures resulting from its use as a stabilizer in chlorinated hydrocarbon solvents, and (c) testing to date, including that for mutagenicity, carcinogenicity, and neurotoxicity, has shown 1,2-butylene oxide to have a lower order of toxicity than propylene oxide. EPA believes that controlling 1,2-

butylene oxide exposure on the basis of propylene oxide neurotoxicity data will provide at least as much protection as basing control of 1,2-butylene oxide exposure on a 1,2-butylene oxide neurotoxicity study. Dow has agreed to EPA's proposal. If propylene oxide shows adverse neurotoxic effects, Dow will enter into discussions with the agency, which will determine what actions are required to reduce occupational exposure to 1,2-butylene oxide during its manufacture, distribution in commerce, processing, use, and disposal. Such actions would continue in effect until Dow came forward with new data showing that such actions are unnecessary for 1,2-butylene oxide (Ref. 18). Because of this agreement between Dow and EPA, EPA is not proposing neurotoxicity testing of 1,2-butylene oxide at this time.

G. Epidemiology

The Agency has concluded that a toxicological endpoint has not been sufficiently well characterized for 1,2-butylene oxide to warrant requiring an epidemiological study at this time.

H. Environmental Fate: Sufficiency of Data

The ITC expressed concern for the reaction products of alkyl epoxides in the environment. Therefore, the ITC recommended that the fate of alkyl epoxides in the environment should be determined through testing. EPA has concluded that there are sufficient data to reasonably predict the environmental fate, including the characterization of degradation products, of the 1,2-butylene oxide that might be released during manufacturing, distribution in commerce, processing, use, and disposal and that there is no need for EPA to require testing to further characterize the fate of such releases.

On the basis of the atmospheric emission factor of 0.000802 for propylene oxide as a result of the chlorohydrin process (Ref. 19), EPA estimates the amount of 1,2-butylene oxide lost to the atmosphere during production to be 8,000 lbs. annually. On the basis of structure-activity relationship considerations between propylene oxide and 1,2-butylene oxide, EPA predicts that 1,2-butylene oxide will undergo atmospheric hydrolysis and oxidation via hydroxyl-free radicals with rates similar to those of propylene oxide. The estimated half-life for atmospheric oxidation via hydroxyl-free radicals for propylene oxide is 6.1 days (Ref. 20). On the basis of structure-activity relationship considerations between propylene oxide and 1,2-butylene oxide, one would predict that the atmospheric

reaction mechanisms and degradation products for 1,2-butylene oxide closely parallel those for propylene oxide. (OPTS 42028A, appearing elsewhere in this issue of the Federal Register, discusses EPA's conclusions with respect to testing needs for propylene oxide.)

There are no published data on the release of 1,2-butylene oxide into bodies of water or any monitoring data of 1,2-butylene oxide concentrations in water. However, on the basis of structure-activity relationship considerations among 1,2-butylene oxide, propylene oxide, and ethylene oxide, EPA estimates the hydrolysis half-life of 1,2-butylene oxide to be similar to those for ethylene oxide and propylene oxide. The hydrolysis half-lives of ethylene oxide and propylene oxide at pH 7 are approximately 14 days (Ref. 21) and 12 days (Ref. 22), respectively. Hydrolysis of butylene oxide would produce butylene glycol. In salt water, butylene chlorohydrin would also be produced. A BOD₅ for 1,2-butylene oxide of 6 percent has been measured (Ref. 23).

On the basis of the environmental release, biodegradation, and environmental fate information on 1,2-butylene oxide or its homologs discussed above, EPA concludes that sufficient data exist to reasonably predict the environmental fate, including the characterization of degradation products, of the 1,2-butylene oxide that might be released during the manufacture, distribution in commerce, processing, use and disposal of 1,2-butylene oxide and that there is no need for EPA to require testing to further characterize that fate of such releases.

I. Other Testing

Although it was not recommended by the ITC, EPA recognized that a data gap existed for dermal sensitization testing of 1,2-butylene oxide. Dow Chemical Company is conducting this test voluntarily. The study began in October 1983 and the final report is due in January 1984.

III. Decision Not To Require Testing

The EPA has decided not to initiate rulemaking at this time under section 4(a) of TSCA to require further health and environmental fate testing of 1,2-butylene oxide. This decision is based on a review of the available data and ongoing testing for this chemical and on agreements reached between EPA and Dow Chemical Company, the sole U.S. manufacturer of 1,2-butylene oxide, that exposure to the chemical will be restricted based on testing of propylene oxide to be performed. The most recent

information available to EPA indicates that available data are sufficient to reasonably predict or determine the mutagenicity and environmental fate of 1,2-butylene oxide.

Data from ongoing testing should be sufficient to reasonably predict the carcinogenicity of 1,2-butylene oxide. A decision for additional mutagenicity testing on 1,2-butylene oxide will be postponed until the result of a number of mutagenicity tests on 1,2-butylene oxide and ethylene oxide are analyzed by the Agency. Reproductive and neurotoxic effects testing are not being proposed because Dow has accepted EPA's proposal that propylene oxide testing will serve as the basis for any needed regulation and control of 1,2-butylene oxide exposure for these two effects. EPA is not proposing an epidemiological study for 1,2-butylene oxide because a toxicological endpoint has not been sufficiently well characterized to warrant an epidemiological study at this time. Therefore, EPA is not proposing a test rule for 1,2-butylene oxide at this time. Should new information reveal a need for additional testing, the Agency reserves the right to promulgate a test rule.

IV. Issues

1. EPA is not proposing reproductive neurotoxic effects testing of 1,2-butylene oxide because Dow has accepted EPA's proposal that propylene oxide testing will serve as the basis for regulating and control of 1,2-butylene oxide exposure for these effects. The agency invites comments on this approach.

2. For a number of reasons, EPA is not proposing additional mutagenicity testing on 1,2-butylene oxide at this time. First, EPA believes that a further evaluation needs to be made of the apparently conflicting results from the two sex-linked recessive lethal tests in *Drosophila* on 1,2-butylene oxide. A feeding study was positive (Ref. 8), while an inhalation study was negative (Ref. 13). Secondly, a number of mutagenicity tests are in progress on ethylene oxide, which is the alkyl epoxide having two fewer carbon atoms than 1,2-butylene oxide. On the basis of structure-activity relationship considerations between 1,2-butylene oxide and ethylene oxide, and the fact that ethylene oxide consistently has shown greater activity in mutagenesis assays and has tested positive in more mutagenesis assays than 1,2-butylene oxide, EPA believes that results of the ongoing mutagenicity testing on 1,2-butylene oxide, along with available data on 1,2-butylene oxide, will provide guidance as to what, if any, further

mutagenicity testing on 1,2-butylene oxide may be appropriate. Inhalation mutagenicity testing in progress on ethylene oxide includes: (1) Mouse specific locus test; (2) biochemical specific locus test in mice; (3) heritable translocation test in mice; (4) sperm alkylation in mice; and (5) sperm alkylation in *Drosophila*.

After the data from the ongoing ethylene oxide mutagenicity testing and existing 1,2-butylene oxide mutagenicity data, including the results from the two sex-linked recessive lethal tests in *Drosophila*, are analyzed by the Agency, the Agency will consider: (1) Whether a mouse specific locus test or other additional mutagenicity testing on propylene oxide is necessary, or (2) whether ethylene oxide and/or propylene oxide mutagenicity data will provide a sufficient basis for mutagenicity risk assessment for 1,2-butylene oxide without further testing of 1,2-butylene oxide for this effect. In making its analysis, EPA will take into account available data on other effects that may provide sufficient basis for regulation. The Agency is interested in public comment on the various aspects of assessing mutagenicity testing needs for 1,2-butylene oxide.

V. References

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- (17) NTP. 1981. Prechronic test phase review of 1,2-epoxybutane. Submitted to NTP by Battelle Pacific Northwest Laboratories, Richland, Washington 99352.
- (18) Dow Chemical Co. 1983 (May 24). Midland, Michigan. Letter to Steve Newburg-Rinn, Assessment Division, Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, DC 20460.
- (19) SAI. 1981. Human exposure to atmospheric concentrations of selected chemicals. Prepared by Science Applications, Inc. (SAI) for the Office of Air Quality Planning and Standards, Office of Air, Noise, and Radiation, U.S. Environmental Protection Agency, Washington, DC 20460.
- (20) Cupitt LT. 1980. Fate of toxic and hazardous materials in the air environment (project summary). Environmental Sciences Research Laboratory, Research Triangle Park, NC 27711. EPA-600/53-80-084.
- (21) Bronsted NJ, Kilpatrick M. 1929. Kinetic studies on ethylene oxide. J Am Chem Soc 50:428-461.
- (22) Koskikallio J, Whalley E. 1959. Effects of pressure on the spontaneous and the base-catalyzed hydrolysis of epoxides. Can J Chem 37:783-787.
- (23) Union Carbide Co. 1978. TSCA sec. 8(d) submission 8DHQ-1078-03305. Supplementary test results on butylene oxide, ethylene oxide, and propylene oxide. Washington, DC: Office of Toxic Substances, U.S. Environmental Protection Agency.

VI. Public Record

EPA has established a public record for this testing decision, docket number OPTS-42049. This record includes:

- (1) Federal Register notice designating the alkyl epoxides category to the priority list.
- (2) Letters.
- (3) Contact reports of telephone conversations and meeting summaries.
- (4) Published and unpublished data.

This record, containing the basic information considered by the Agency in developing the decision, is available for inspection in the Office of Pesticide and Toxic Substances (OPTS), reading room from 8:00 a.m. to 4:00 p.m. Monday through Friday, except legal holidays, in Rm. E-107, 401 M St. SW., Washington, D.C. 20460. The Agency will supplement the record periodically with additional relevant information received.

(Sec. 4, 90 Stat. 2003; (15 U.S.C. 2601)

Dated: December 23, 1983.

Alvin L. Alm,

Acting Administrator.

[FR Doc. 84-73 Filed 1-3-84; 8:45 am]

BILLING CODE 6560-50-M

[OPP-62005; FRL 2501-8]

Griffin Technical Chlorothalonil; Intent To Hold a Hearing To Determine Whether To Cancel Registration

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Intent to Hold a Hearing.

SUMMARY: The Administrator intends to hold a hearing under section 6(b)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA) (7 U.S.C. 136d(b)(2)) to determine whether a registration for technical chlorothalonil held by the Griffin Corporation and bearing pesticide registration number 1218-268 (Griffin Technical Chlorothalonil) should be cancelled.

DATE: Notices indicating an intention to participate in this hearing must be filed by February 3, 1984. (See Unit III of this Notice for a discussion of the contents of a Notice of Intent to Participate.)

ADDRESS: Notices of Intent to Participate must be submitted to: Ms. Bessie Hammel, Hearing Clerk (A-110), U.S. Environmental Protection Agency, Room 3708A, Waterside Mall, 401 M Street, SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: William L. Jordan, Office of General Counsel (LE-132P), Room 513, West Tower, 401 M Street, SW., Washington, DC 20460, Telephone: (202) 382-7505.

SUPPLEMENTARY INFORMATION: The Diamond Shamrock Corporation (Diamond Shamrock) in submittals dated June 28, 1983, and July 21, 1983, has petitioned the Environmental Protection Agency to cancel the registration for technical chlorothalonil (Griffin Technical Chlorothalonil, Reg. No. 1218-268) issued to the Griffin Corporation (Griffin) on January 10, 1983. Griffin's registration authorizes the sale and distribution of the product for use in the formulation of end use products. In July of 1983, Diamond Shamrock assigned all its rights and interests relating to its registration of chlorothalonil and its related data to SDS Biotech Corporation, a joint venture between Diamond Shamrock and Showatenko KK, a Japanese corporation. Throughout this notice, references to Diamond Shamrock are intended to include SDS Biotech Corporation where appropriate.

I. Background

By letter dated June 19, 1979, Diamond Shamrock and EPA entered into an agreement which provided that EPA would not take any registration action for a pesticide containing chlorothalonil as an active ingredient without providing 30 days prior notice in writing to Diamond Shamrock advising as to the nature of the proposed registration action. The Griffin registration in question was issued without the provision of formal written notice of the proposed registration action by EPA to Diamond Shamrock under the terms of the agreement.

In its July 21, 1983, submittal to EPA, Diamond Shamrock states that the Administrator has the authority to cancel the Griffin Technical Chlorothalonil registration under FIFRA section 6(b). Section 6(b) states in pertinent part:

... If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted, does not comply with the provisions of this Act * * * the Administrator may issue a notice of his intent either

- (1) To cancel its registration * * * or
- (2) To hold a hearing to determine whether or not its registration should be cancelled * * *

Diamond Shamrock alleges that Griffin was required to submit with its application "a citation to data. . . that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions. . . ." FIFRA sec. 3(c)(1)(D). Diamond Shamrock further alleges that Griffin did not comply with this requirement because the Diamond

Shamrock data which Griffin cited in order to fulfill the data requirements for registration were not available for EPA to consider in support of Griffin's registration until EPA had complied with the terms of the agreement between Diamond Shamrock and EPA regarding later written notice. Specifically, Diamond Shamrock provided the following analysis of its position:

The very purpose of the EPA-Diamond agreement was to prevent reliance on Diamond's data by follow-on applicants (or the Administrator) until Diamond had an opportunity to seek judicial relief blocking such reliance. In effect, the agreement expressly barred EPA from "considering" the Diamond data, in the sense of issuing a registration based on that data, until Diamond had been given thirty days notice and opportunity to obtain judicial relief in the event EPA refused to deny the follow-on registration. Therefore, the data cited by Griffin was not data which Griffin could properly cite under Section 3(c)(1)(D) or which EPA could properly "consider" under Section 3(c)(5)(B) without prior notice to Diamond. The data was simply not available from a legal standpoint at least until after that notice had occurred. Under Section 6 EPA must, in Diamond's view, cancel Griffin's registration in order to effectuate its agreement with Diamond and restore Diamond's rights.

On the other hand, Griffin claims that it obtained its registration for Griffin Technical Chlorothalonil in complete compliance with the statutory requirements. It argues further that EPA's authority to cancel registrations is limited to very specific grounds and that the claim being made by Diamond Shamrock does not constitute a basis for cancelling the registration of a pesticide product.

It thus appears that there is a dispute as to whether the material required to be submitted by Griffin complied with the provisions of FIFRA. Therefore, it is appropriate to hold a hearing to determine whether the registration should be cancelled. See Fifteen Registrations Held by Velsicol Corp.; Intent to Hold Hearing, 44 FR 21706 (March 30, 1979).

II. Statement of Issues

EPA's Rules of Practice, 40 CFR Part 164, govern the initiation and conduct of formal adjudicatory hearings under FIFRA. Section 164.20 provides that a proceeding shall be commenced whenever "the Administrator decides to call a hearing to determine whether or not the registration of a pesticide should be cancelled * * *." The Administrator is filing with the Hearing Clerk a copy of this Notice and a statement of issues for the hearing. In addition, the