40 CFR Part 799

[OPTS-42028B; FRL-2931-2]

Propylene Oxide; Testing Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule promulgated under section 4(a) of the Toxic Substances Control Act (TSCA) requires manufacturers and processors of propylene oxide (CAS No. 75-56-9) to test this chemical for developmental toxicity. Test standards and reporting deadlines are being proposed elsewhere in this issue of the **Federal Register.**

DATES: In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern ["daylight" or "standard" as appropriate] time on December 11, 1985. This rule shall become effective on January 10, 1986.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Room E-543, 401 M Street SW., Washington, DC 20460. Toll Free: (800-424-9065). In Washington, DC: (554-1404). Outside the USA: (Operator 202-554-1404).

SUPPLEMENTARY INFORMATION: In the Federal Register of January 4, 1984 (49 FR 430), EPA issued a proposed rule under section 4(a) of TSCA to require testing of propylene oxide for teratogenic effects. The Agency is now promulgating a final rule requiring testing of propylene oxide for teratogenic effects or, more appropriately, developmental toxicity.

I. Introduction

This notice is part of the overall implementation of section 4 of the Toxic Substances Control Act (TSCA, Pub. L. 94-469, 90 Stat. 2003 *et seq.*, 15 U.S.C. 2601 *et seq.*), which contains authority for EPA to require development of data relevant to assessing the risks to health and the environment posed by exposure to particular chemical substances or mixtures.

Under section 4(a)(1) of TSCA, EPA must require testing of a chemical substance to develop health or environmental data if the Administrator finds that:

(A) (i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment.

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or

(B) (i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

For a more complete understanding of the statutory section 4 findings, the reader is directed to the Agency's first proposed testing rule package (chloromethane and chlorinated benzenes, published in the **Federal Register** of July 18, 1980; 45 FR 48510) and to the second package (dichloromethane, nitrobenzene, and 1,1,1-trichloroethane, published in the **Federal Register** of June 5, 1981; 46 FR 30300) for in-depth discussions of the general issues applicable to this action.

II. Background

A. Profile

Propylene oxide (CAS No. 75-56-9) is a volatile colorless liquid that has an ether-like odor and is extremely flammable. It has a boiling point of 34.23 °C (Ref. 1) and a density of 0.859 gram per milliliter (g/ml) at 0 °C (Ref. 1). Its solubility in water is 405,000 parts per million (ppm) at 20 °C (Ref. 1).

In 1980, domestic production of propylene oxide totaled 1.77 billion pounds. Propylene oxide is produced by two firms, Dow and ARCO Chemical Companies, at four sites in the United States. Dow uses the chlorohydrin process at its propylene oxide plants; ARCO uses the peroxidation process. Each process accounts for about 50 percent of total U.S. capacity. Propylene oxide's major use is as a chemical intermediate. It is also used as a stabilizer in dichloromethane. In 1977, there were 32 processors of proplyene oxide (Ref. 2). Estimates indicate that in excess of 40,000 people may be exposed to propylene oxide during its manufacturing, processing, and use (Ref. 2). For a more detailed discussion of the production, uses, and exposure of propylene oxide, see the propylene oxide support document (Ref. 2), which is part of this rulemaking record, and which is available from the TSCA Assistance Office.

B. ITC Recommendations

In the First Report of the Interagency Testing Committee (ITC), published in the **Federal Register** of October 12, 1977 (42 FR 55026), the ITC designated the category of alkyl epoxides for priority consideration for epidemiological studies and testing for carcinogenicity, mutagenicity, teratogenicity, other chronic effects, and environmental fate. Propylene oxide is one member of the alkyl expoxides category.

C. Proposed Rule

EPA issued a proposed rule published in the Federal Register on January 4, 1984 (49 FR 430), requiring that testing of propylene oxide be performed for teratogenicity. In the proposal, the EPA based its testing requirements on the authority of section 4(a)(1)(A) and (B) of TSCA.

EPA's testing decision on propylene oxide as discussed in that proposed rule (Ref. 3) and the propylene oxide support document (Ref. 2) are outlined below.

An inhalation teratology study, sponsored by the National Institute for Occupational Safety and Health (NIOSH), conducted at a single concentration of 500 ppm in rats and rabbits was reported to produce no effects in rabbits but some maternal and developmental toxicity in rats (Ref. 4). EPA concluded in the proposed rule that because a no-effect level had not been determined for developmental toxicity in the rat and it could not determine whether the developmental toxicity observed was a result of the maternal toxicity, additional teratogenicity testing in the rat was warranted. These data, together with known substantial worker exposure and substantial production, formed the basis for EPA's proposed test rule under TSCA sections 4(a)(1) (A) and (B) (Ref. 3).

EPA's rationale, as discussed in the proposed rule (Ref. 3) and the propylene oxide support document (Ref. 2), for not proposing other testing for propylene oxide was as follows: The Agency concluded that existing data were sufficient to reasonably predict the environmental fate of propylene oxide and that data from completed and ongoing testing should be sufficient to reasonably determine the reproductive and neurotoxic effects and carcinogenicity of propylene oxide. EPA postponed its decision on additional mutagenicity testing of propylene oxide until the results of a number of mutagencity tests in progress on the closely related chemical, ethylene oxide, were analyzed by the Agency. EPA also postponed proposing an epidemiological study for propylene oxide until after the Agency evaluated the results of three carcinogenicity studies on propylene oxide.

III. Public Comments

The Agency received comments from two sources: A combined industry submission by Dow Chemical Company and ARCO Chemical Company (Ref. 5) and NIOSH (Ref. 6). The comments addressed teratogenicity and mutagenicity testing of propylene oxide. EPA, in the propoosed rule (Ref. 3), also had asked for comments on whether the control of propylene oxide for its established oncogenicity would be sufficient to provide adequate protection against other health effects of concern. However, comments were not received on this issue. No comments were received on EPA's exposure assessment of propylene oxide (Ref. 2) of EPA's economic impact analysis of the NPRM for propylene oxide (Ref. 7)

Comments on teratogenicity testing were made by Dow, ARCO, and NIOSH. Dow and ARCO commented that some significance had been assigned by EPA reviewers to the ratio of resorptions to implantation sites in the NIOSH teratology study (Ref. 3). The two companies stated that a careful examination of these percentages and the standard deviation (controls—5.96±6.27, Group 2—7.88±8.54) make it apparent that there is a very large variation around the mean for both the control and the exposed group (the deviations being larger than the means). Dow and ARCO concluded that such a large variation in response among both control and treated animals does not allow the conclusion that there is any biological or statistical difference between the two groups. The Agency in reviewing the study noted this observation, but found these results to be statistically significant. In addition, other adverse developmental effects were observed.

Dow and ARCO commented that in the NIOSH teratology study (Ref. 4) "there is ample evidence of maternal toxicity with only minor musculoskeletal and sternebral anomalies evident in fetuses." EPA does not consider significant increases in rib dysmorphology, reduction in skeletal ossification, or decreases in fetal body weight and crown-rump length "minor" if observed in the absence of maternal toxicity. EPA does not believe that the present study allows an evaluation of whether such effects occur in the absence of maternal toxicity. Dow and ARCO also commented that all of these effects have been related to maternal toxicity caused by various chemicals. While this is true, they may also be elicited in the absence of maternal toxicity (Ref. 8). In addition, maternal toxicity does not always lead to developmental toxicity as evidenced by the fact that there are numerous compounds that elicit the former but not the latter (Refs. 9 through 12).

The Dow and ARCO comments identified three published reports (Refs. 13 through 15) in which delayed skeletal ossification and dysmorphic ribs are described as changes often occurring with maternal toxicity, and not indicative of significant development toxicity when observed at maternally toxic doses. EPA does not disagree with this interpretation; however, what the comments failed to report is that the study by Murray *et al.* (Ref. 13) based its conclusion on actual data from a three-dose level teratology study. For that compund, development toxicity was only observed in the presence of maternal toxicity. At exposure levels which caused little or no maternal toxicity, there were no effects on embryonal or fetal development. For propylene oxide, EPA does not have the advantage of a study in which maternally toxic and nontoxic doses were tested; therefore, EPA cannot come to the same conclusion as reached in the Murray *et al.* (Ref. 13) study. The Murray *et al.* study (Ref. 13) is also a good example of how maternal toxicity does not always occur concurrently with the same syndrome of adverse developmental effects. That is, while effects of skeletal alteration were observed, there was no effect on fetal body weight or crown-rump length.

Dow and ARCO commented that results of the two-generation reproduction study sponsored by Dow and ARCO (Ref. 16) will provide sufficient information to adequately assess the developmental toxicity potential of propylene oxide. EPA does not agree for several reasons: (1) The endpoints examined in a reproduction study are different from those in a developmental toxicity study; (2) the highest exposure level in the ongoing reproduction study (300 ppm) is 200 ppm below that used in the NIOSH teratology study (Ref. 4) and may be too low for the purposes of a developmental toxicity study, that is, in a developmental toxicity study, exposure occurs at a significant level over a limited period of gestation (10 days) in order to maximize detection of any potential effect, whereas in a reproduction study, animals are exposed for a much longer period, prior to, during, and after mating, at a lower level of exposure; and (3) results of the NIOSH teratology study (Ref. 4) suggest that prolonged exposure resulted in some degree of acclimation in the rats because the fetuses exhibiting the greatest degree of adverse effects were those in which exposure began on day 7 as opposed to those which began on day 1 and those whose mothers began treatment 3 weeks prior to mating.

NIOSH commented that, although it is not clear whether the rib dysmorphology and reduced skeletal ossification observed in the NIOSH study (Ref. 4) were due to maternal toxicity or were manifestations of developmental effects,

they concluded the rib defects to be "suggestive of embryotoxic response under maternally toxic conditions of the exposure." EPA is not convinced of this conclusion since there are no data showing that propylene oxide does not cause developmental effects in the absence of maternal toxicity. Only further testing would resolve this issue.

NIOSH commented that if EPA, after considering the results of the NIOSH teratology study (Ref. 4) and other factors relating to propylene oxide, concludes that additional teratogenicity studies are needed, NIOSH would suggest species other than the rat or rabbit. NIOSH commented that if additional teratogenicity studies were done in the rat, a rat strain other than Sprague-Dawley should be used since this species and strain was only marginally sensitive under maternally toxic conditions of exposure. EPA believes that this recommendation of selecting another strain appears appropriate. However, it is not possible to identify a "more sensitive" strain before conducting a study. Although EPA may not be able to identify a more sensitive strain at the present time, a well-conducted study using at least three exposure levels, the highest of which should produce maternal toxicity, should answer the concern as to whether or not developmental toxicity is elicited only at maternally toxic levels. If the alternate strain fails to elicity any developmental toxicity even at maternally toxic levels, this still would provide the answer to the concern as to whether the embryo/fetus is more vulnerable toxic effects than the adult. A search of the Environmental Teratogen Information Center data base which contains over 33,000 files indicated that the most commonly used strains of rats to assess teratogenicity or developmental toxicity include Sprague-Dawley, Wistar, Long-Evans, Charles River CD, and Fisher 344. Selection of one of these strains, other than Sprague-Dawley, to test propylene oxide would be appropriate. The structurally related compounds, ethylene oxide and butylene oxide, have been tested in the Fisher 344 and Wistar strains, respectively.

Comments on mutagenicity testing were made by Dow and ARCO. The producers stated their belief that there are ample mutagenicity data on propylene oxide. Dow and ARCO also stated that there are a number of unresolved scientific issues on the interpretation, extrapolation, and application of mutagenicity data to assess human risk. Since these issues were being addressed separately by EPA, Dow and ARCO believed that any further extensive mutagenicity testing of propylene oxide should await the resolution of these basic scientific issues. The Agency has recently published its position on these mutagenicity issues in its final test rule for the C9 aromatic hydrocarbons (50 FR 20662; May 17, 1985). However, EPA has decided not to propose additional mutagenicity testing of propylene oxide for the reasons outlined in Unit IV.C below.

IV. Testing Decisions

EPA has decided to promulgate a final rule for developmental toxicity testing of propylene oxide (see Unit V below). However, the Agency has decided not to propose carcinogenicity or mutagenicity testing or epidemiological studies on propylene oxide under section 4(a) of TSCA at this time. EPA's rationale for these decisions is discussed below.

A. Developmental Toxicity

The results of a teratogenicity study sponsored by NIOSH have been reported (Ref. 4). Maternal toxicity, reproductive performance, and developmental toxicology were evaluated in Sprague-Dawley rats and New Zealand rabbits following 7 hr/day inhalation exposures to 500 ppm propylene oxide. Rabbits were artificially inseminated and placed on one of the following exposure regimens: (1) Filtered air (control); (2) chemical exposure from days 7 through 10 of gestation (dg); or (3) chemical exposure from 1 through 19 dg. Rat-exposure regimens were as follows: (1) Filtered air (control); (2) chemical exposure from 7 through 16 dg; (3) chemical exposure from 1 through 16 dg; or (4) chemical exposure for 5 days/week for 3 weeks prior to mating and daily from 1 through 16 dg. Unexposed male rats and unexposed male rabbits were used in mating and artificial insemination procedures, respectively. Necropsies were performed on rats at 21 dg and on rabbits at 30 dg. Pregnant animals were examined for toxic changes, including histopathology. Reproductive measures included the determination of number of corpora lutea, implantation sites, resorptions, dead fetuses, and live fetuses. Live fetuses were weighed, measured, and subjected to external visceral and skeletal examination to detect morphologic anomalies.

No evidence of maternal toxicity, embryotoxicity, or teratogenicity was detected in rabbits exposed to 500 ppm of propylene oxide. However, maternal and developmental toxicity were seen in the Sprague-Dawley rat. In all groups of rats exposed to 500-ppm propylene oxide, food consumption decreased, body weights were lower, and changes in tissue weights were observed. The number of corpora lutea and implantation sites per dam and live fetuses per litter decreased in rats that received propylene oxide prior to mating. The percentage of resorbed implantation sites was highest in rats exposed to propylene oxide from 7 through 16 dg. Fetal size was reduced, and the incidence of rib dysmorphology increased in all propylene-oxide-exposed litters.

In a developmental toxicity study, any observed adverse effects on development are worthy of further consideration. According to Wilson (Refs. 17 and 18), there are four manifestations of developmental toxicity: (1) In utero death; (2) growth retardation; (3) structural malformation; and (4) functional deficits. On the basis of the adverse effects on development observed in the NIOSH teratology study in rats described above, EPA concludes that additional developmental toxicity testing in the rat is necessary because: (1) A no-observed-effect level for developmental toxicity was not determined in the rat, and (2) one cannot determine it the developmental toxicity observed in the rat can be attributed entirely to maternal toxicity.

B. Carcinogenicity

EPA has reviewed the results of three carcinogenicity studies conducted by the European producers of propylene oxide (Ref. 19), the National Toxicology Program (NTP) (Ref. 20) and NIOSH (Ref. 21), and has concluded that the data from these studies are sufficient to reasonably predict or determine the carcinogenicity of propylene oxide. The results of these studies are summarized below.

The European chronic inhalation study (Ref. 19) demonstrated that propylene oxide was oncogenic in the rat as partially manifested by a statistically significant ($p < 0.01$) increase in mammary tumors in female rats at 300 ppm of propylene oxide and a statistically significant increase ($p < 0.005$) in the mean number of mammary fibroadenomas per mammary fibroadenoma-bearing female rat at all dosage levels (30, 100, and 300 ppm propylene oxide).

The results of the NTP 2-year carcinogenesis studies on propylene oxide in rats and mice as reported in the NTP Technical report (Ref. 20) are as follows: Groups of 50 F344/N rats and 50 B6C3F$_1$ mice of each sex were exposed to air containing propylene oxide at concentrations of 0 (chamber control),

200, or 400 ppm for 6 hours per day, 5 days per week, for 103 weeks.

The survival of rats exposed to propylene oxide was comparable with that of the controls; terminal body weights were lower than those of the controls for high dose males (8 percent weight reduction) and high dose females (6 percent weight reduction). Survival of exposed male and female mice decreased relative to that of the controls (male: control, 42/50; low dose, 34/50; high dose, 29/50; female: 38/50; 29/50; 10/50), but the difference was significant only for animals in the high dose groups. High-dose female mice had a mean terminal body weight 10 percent below that of the controls; high dose male mice had a terminal body weight 22 percent below that of the controls.

The respiratory epithelium of the nasal turbinates was one of the primary tissues affected in male and female rats; exposure-related increases occurred in the incidences of suppurative inflammation, epithelial hyperplasia, and squamous metaplasia. Papillary adenomas, involving the respiratory epithelium and underlying submucosal glands of the nasal turbinates, were observed in three female rats and in two male rats exposed to propylene oxide at 400 ppm. The incidence of adenomas in females was significant by the trend tests.

The proportions of high-dose female rats with C-cell adenomas and with C-cell carcinomas of the thyroid gland were increased, but only the combined incidence of these tumors was significant (2/45; 2/35; 7/37). These tumors were not considered to be related to exposure to propylene oxide because there was no other evidence for C-cells being a target tissue and because there was no increase in C-cell hyperplasia.

The combined incidences of female rats with endometrial stromal polyps and endometrial stromal sarcomas of the uterus were significantly increased in the dosed groups (3/49; 12/50; 10/47). However, the occurrence of these lesions in the dosed groups was similar to the average (306/1,502, 20 percent) seen in untreated controls in NTP carcinogenesis studies, and hence this increase was not regarded as being related to exposure to propylene oxide.

The respiratory epithelium of the nasal turbinates was also one of the primary tissues affected in male and female mice; exposure-related increases occurred in the incidences of inflammation, and squamous metaplasia was observed in one low-dose male and two high-dose female mice. One squamous cell carcinoma and one papilloma occurred in the nasal cavity of different high dose male mice, and two high-dose female mice had adenocarcinomas of the nasal cavity. The endothelial cells of the submucosal vascular plexus in the nasal turbinates also appeared to be a major site affected in high dose male mice. There high dose male and three high-dose female mice had a saccular dilation (classified as angiectasis) of submucosal turbinate vessels. Further, hemangiomas were seen in the nasal cavity of 5/50 high-dose male mice and 3/50 high-dose female mice, and hemangio-sarcomas were found in the nasal cavity of 5/50 high-dose male mice and 2/50 high-dose female mice. The increased incidences of hemangiomas in males and females and of hemangiosarcomas in males were statistically significant. Vascular tumors were not present in the nasal turbinates of any low-dose or control mice.

Under the conditions of these studies, NTP concluded that there was "some evidence of carcinogenicity" for F344/N rats, as indicated by increased incidences of papillary adenomas of the nasal turbinates in male and female rats exposed to propylene oxide at 400 ppm. NTP also concluded that for male and female $B6C3F_1$ mice, there was "clear evidence of carcinogenicity", as indicated by increased incidences of hemaniomas or hemangiosarcomas of the nasal turbinates at 400 ppm. In the respiratory epithelium of the nasal turbinates, propylene oxide also caused suppurative inflamation, hyperplasia, and squamous metaplasia in rats and inflammation in mice.

In the NIOSH study (Ref. 21), the chronic inhalation toxicity and carcinogenicity of propylene oxide were evaluated in a 2-year inhalation bioassay. Three groups of male weanling Fischer 344 rats, 80 per group, were exposed at: (1) 0 ppm (control; filtered air); (2) 100-ppm propylene oxide; and (3) 300-ppm propylene oxide (7 hours per day, 5 days per week) for 104 weeks. Body weights from rats exposed to propylene oxide at both exposure concentrations were significantly reduced compared to controls. A statistically significant increase in mortality was observed in all groups of exposed rats compared to controls. Skeletal muscle atrophy in the absence of any sciatic nerve neuropathology was found in rats exposed at 300-ppm propylene oxide. Among rats exposed to propylene oxide there was a dose-dependent increase in the incidence of complex epithelial hyperplasia in the nasal passages, and two adenomas were detected in the nasal passages of rats exposed at 300 ppm propylene oxide. The only compound-related oncogenic effect was a marked increase in the incidence of adrenal pheochromocytomas in treated animals: 25/78 at 100 ppm and 22/80 at 300 ppm vs. 8/78 at 0 ppm propylene oxide (controls). All rat groups were affected by an outbreak of *Mycoplasma pulmonis* infection which occurred about 16 months into the study. According to NIOSH (Ref. 21), this infection alone and in combination with the epoxide exposures affected the survival of rats in this study and influenced the development of the proliferative lesions in the nasal mucosa of the propylene oxide-exposed rats. No treatment-related changes in any clinical chemistry or urinalysis indices were detected.

C. Mutagenicity

The propylene oxide proposed test rule (Ref. 3) stated that EPA's decision concerning the need for additional mutagenicity testing on propylene oxide would be postponed until the results of a number of mutagenicity tests in progress on ethylene oxide, including the mouse specific-locus test, were analyzed by the Agency. Ethylene oxide is a closely related member of the alkyl epoxides category. For a review of the mutagenicity data on propylene oxide, see the propylene oxide support document (Ref. 2). The proposed rule (Ref. 3) also stated that in making its analysis EPA would take into account available data on other effects that may provide sufficient basis for regulations.

EPA has concluded that additional mutagenicity testing of propylene oxide is not necessary because: (1) Ethylene oxide, which is closely related to propylene oxide, was negative in the mouse specific-locus test; and (2) carcinogenicity and mutagenicity are probably mechanistically related for this alkylating agent, and exposure control on the basis of carcinogenicity should provide substantial protection against mutagenic effects.

D. Epidemiology

The propylene oxide proposed test rule states, "When the Agency has evaluated the results of all the oncogenicity studies on propylene oxide, it will determine whether an epidemiological study is necessary" (Ref. 3). EPA has concluded that an epidemiological study is not feasible for propylene oxide at this time (Ref. 22). There are two groups of workers with potential exposure to propylene oxide who may be considered for epidemiological study. One group, approximaely 2,000 workers, is exposed in either the production (2 companies) or processing (32 companies) of propylene oxide (Refs. 23 and 24). In a 1978 submission to EPA, Dow (one of the

producers) stated that it had approximately 100 workers who routinely worked in propylene oxide production areas (Ref. 25). EPA estimates that a similar number of workers are exposed in the other producers' facilities. The second group, approximately 40,000 workers, is occupationally exposed in the urethane foam industry where propylene oxide is used as a stabilizer in dichloromethane (Ref. 23).

For a retrospective epidemiological study to be feasible, several conditions must be met. First, a sufficient number of workers must be exposed. Second, a sufficient level of exposure must exist, and the exposure must be unique, i.e, not accompanied by exposures to other chemicals that could affect outcome. Third, the exposure must have occurred in the past to allow for disease development. Last, records must exist which allow following the prospective study population for a length of time. A prospective epidemiological study requires that the first two conditions be met.

At least two of the above conditions are lacking for propylene oxide-exposed workers. The answer to the first condition is twofold. Although production workers are the preferred group for study since exposure to other confounding chemicals is, usually, less than that for processing workers, not enough workers exist in production of propylene oxide to do an epidemiological study. Therefore, any cohort study of these workers would have insufficient power to detect small increases in cancer outcomes. On the other hand, a cohort study in the urethane foam industry would, most likely, have the necessary power. However, in the urethane foam industry, if any epidemiological study, it would be impossible to separate exposure to propylene oxide from that to dichloromethane and/or other chemicals that are known or suspected carcinogens. Therefore, condition two has not been met; a unique exposure does not occur.

In light of the unsatisfactory answers to conditions one and two, EPA concludes that an epidemiological study is not feasible for propylene oxide.

E. Reproductive Effects

On July 9, 1985, Dow Chemical Company submitted its final report entitled "Propylene Oxide: Two-Generation Reproduction Study in Fischer 344 Rats" under section 8(d) of TSCA (Ref. 26). EPA is evaluating the results. The submitter concluded that inhalation exposure of male and female Fischer 344 rats to 30, 100, or 300 ppm of propylene oxide for two generations did not adversely affect reproduction even at an exposure concentration that caused a significant reduction in body weight in both sexes.

V. Final Test Rule for Propylene Oxide

A. Findings

EPA is basing the final testing requirements for propylene oxide on the authority of section 4(a)(1)(A) and (B) of TSCA.

The 4(a)(1)(A) findings for developmental toxicity are as follows:

EPA finds that the manufacture, processing, and use of propylene oxide may present an unreasonable risk of injury to human health due to developmental toxicity because (1) available animal studies suggest that propylene oxide has a developmental toxicity potential, and (2) in excess of 40,000 individuals are potentially exposed to propylene oxide as a result of its manufacture, processing, and use.

EPA also finds that there are insufficient animal and human data to reasonably determine or predict the developmental toxicity of propylene oxide. The finding of "may present an unreasonable risk" of developmental toxicity is based on a NIOSH inhalation teratology study (Ref. 4). Rats and rabbits were exposed to a single concentration of 500-ppm propylene oxide. Neither developmental toxicity nor maternal toxicity was observed in rabbits exposed to 500-ppm. However, developmental and maternal toxicity were observed among female rats and their pups exposed to 500-ppm propylene oxide. A no-effect level for developmental toxicity in the rat could not be determined, and one cannot determine whether the developmental toxicity observed in the study can be attributed entirely to maternal toxicity.

EPA finds that additional developmental toxicity testing of propylene oxide is necessary to develop additional data to reasonably evaluate the developmental risks posed by exposure to propylene oxide.

The 4(a)(1)(B) findings for developmental toxicity are as follows:

There are substantial amounts of propylene oxide produced in or imported into the United States each year. The annual U.S. production volume of propylene oxide is estimated to be approximately 1.8 billion pounds, with another 90 million pounds imported into the United States each year.

Estimates indicate that over 40,000 people may be exposed to propylene oxide each year via manufacturing, processing, and use activities.

EPA finds that there are insufficient data from the NIOSH teratology study (Ref. 4) from which to reasonably determine or predict the developmental toxicity from exposure to propylene oxide, and that additional testing of propylene oxide for developmental toxicity is necessary to develop such data.

On the basis of these findings, the Agency is requiring for propylene oxide a developmental toxicity test in rats.

B. Required Testing

The Agency believes that developmental toxicity testing should be performed via inhalation in the rat and that some sign of maternal toxicity should be demonstrated at the highest dose.

EPA is requiring that a developmental toxicity study on propylene oxide be conducted by the inhalation route. The agency believes that the TSCA test guideline which appears at 40 CFR 798.4350 (published in the Federal Register of September 27, 1985; 50 FR 39252) is appropriate for determining the developmental hazard of propylene oxide. A copy of this TSCA Guideline is in the public record for this rulemaking, docket number [OPTS–42028B].

EPA intends to propose shortly in a separate Federal Register notice, certain revisions to the health and environmental effects and chemical fate TSCA Test Guidelines to provide more explicit guidance on the necessary minimum elements for each study. In addition, these revisions will avoid repetitive chemical-by-chemical changes to the guidelines in their adoption as test standards for chemical-specific test rules. EPA is proposing that these modifications be adopted in the test standards for propylene oxide.

All data must be developed and reported in accordance with the TSCA Good Laboratory Practice Standards in 40 CFR Part 792.

C. Test Substance

EPA is requiring that propylene oxide of at least 99.0 percent purity be used as the test substance. Such a grade is readily available commercially.

D. Persons Required To Test

Section 4(b)(3)(B) specifies that the activities for which the Agency makes section 4(a) findings (manufacturing, processing, distribution, use and/or disposal) determine who bears the responsibility for testing. Manufacturers are required to test it the findings are based on manufacturing ("manufacture" is defined in section 3(7) of TSCA to include "import"). Processors are

required to test if the findings are based on processing. (Section 3(10) of TSCA, defines "process" as the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce.) Both manufacturers and processors are required to test if the exposures giving rise to the potential risk occur during use, distribution, or disposal. Because EPA has found that the manufacture, processing, and use of the propylene oxide may give rise to substantial exposure and may present an unreasonable risk of injury to health, persons who manufacture or process, or who intend to manufacture or process, propylene oxide at any time from the effective date of this test rule to the end of the reimbursement period are subject to this rule. The end of the reimbursement period will be 5 years after the submission of the final report required under the test rule. As discussed in the Agency's Test Rule Development and Exemption Procedures (40 CFR Part 790), EPA expects that manufacturers will conduct testing and that processors will ordinarily be exempted from testing.

Because TSCA contains provisions to avoid duplicative testing, not every person subject to this rule must individually conduct testing. Section 4(b)(3)(A) of TSCA provides that EPA may permit two or more manufacturers or processors who are subject to the rule to designate one such person or a qualified third person to conduct the tests and submit data on their behalf. Section 4(c) provides that any persons required to test may apply to EPA for an exemption from that requirement. The Agency expects that the current manufacturers of propylene oxide will form the reimbursement pool and sponsor the testing required. Manufacturers and processors who are subject to the testing requirements of this rule must comply with the test rules and exemption procedures in 40 CFR Part 790.

E. Test Rule Development and Exemptions

Elsewhere in this issue of the Federal Register, the Agency is proposing that a TSCA test guideline be utilized as the test standard for the development of data under this rule for propylene oxide. As discussed in that document and in previous documents (50 FR 20652; May 17, 1985), EPA has reviewed the method for the development of test rules and has decided that for most section 4 rulemakings, the Agency will utilize single-phase rulemaking. In light of this decision, EPA has reevaluated the process for developing test standards for section 4 rulemakings initiated under a two-phase process and has determined that for certain of these two-phase rules, TSCA test guidelines are available for promulgation as relevant test standards. EPA has decided that where TSCA or other appropriate test guidelines are available, the Agency, in most cases will propose the relevant guidelines as the test standards for those rules.

EPA believes that, in line with its commitment to expedite the section 4 rulemaking process, it is appropriate to propose the applicable TSCA test guidelines as test standards at the same time as a Phase I final test rule is issued. With regard to the rulemaking for propylene oxide, a TSCA test guideline is available for the testing requirement included in this Phase I final rule. Thus, in the accompanying document, the Agency is proposing this TSCA test guideline as a test standard.

The public, including the manufacturers and processors subject to the Phase I rule, will have an opportunity to comment on the use of the TSCA test guidelines. The Agency will review the submitted comments and will modify the TSCA guidelines, where appropriate, when the test standards are promulgated.

During the development of a test rule under the two-phase process, persons subject to the Phase I final rule are normally required to submit proposed study plans (see 40 CFR 790.30(a)(2); 50 FR 20652, 20658 (May 17, 1985)). However, because EPA is proposing an applicable TSCA test guideline as the test standard for the study required by this Phase I final rule, persons subject to the rule, i.e., manufacturers and processors of propylene oxide, are not required to submit proposed study plans for the required testing. Persons subject to this rule, however, are still required to submit notices of intent to test or exemption applications in accordance with 40 CFR 790.25; 50 FR 20652, 20657 (May 17, 1985). Moreover, once the test standard is promulgated, persons who have notified EPA of their intent to test must submit study plans (which adhere to the promulgated test standards) no later than 30 days before the initiation of each required test. (see 40 CFR 790.39(a)(1); 50 FR 20652, 20658 (May 17, 1985)).

Processors of propylene oxide subject to this rule, unless they are also manufacturers, will not be required to submit letters of intent, exemption applications, or study plans (before testing is initiated) unless manufacturers fail to sponsor the required tests. The basis for this decision is that manufacturers are expected to pass an appropriate portion of the test costs on to processors through the pricing of products containing propylene oxide.

EPA's final regulations for the issuance of exemptions from testing requirements are in 40 CFR Part 790. In accordance with those regulations, any manufacturer or processor subject to this Phase I test rule may submit an application to EPA for an exemption from conducting any or all of the tests required under this rule. If manufacturers perform all the required testing, processors will be granted exemptions automatically without having to file applications.

In the accompanying Federal Register notice, EPA is proposing deadlines for the submission of test data. Such deadlines are required under section 4(b)(1)(C) of TSCA. These proposed data submission deadlines are open for public comment and may be modified, where appropriate, when the final Phase II test rule is promulgated.

The Agency is proposing that the above referenced TSCA Health Effects Test Guideline be considered the test standard for the purposes of the proposed test for propylene oxide. The TSCA guideline for developmental toxicity testing specifies generally accepted minimal conditions for determining developmental toxicity for substances like propylene oxide. The Agency's review of the guidelines, which occurs yearly as described in the Federal Register of September 22, 1982 (47 FR 41857), has found no reason to conclude that this protocol needs to be modified significantly.

F. Reporting Requirements

EPA is requiring that all data developed under this rule be reported in accordance with the EPA Good Laboratory Practice (GLP) standards pursuant to 40 CFR Part 792, published in the Federal Register of November 29, 1983 (48 FR 53922).

EPA is required by TSCA section 4(b)(1)(C) to specify the time period during which persons subject to a test rule must submit test data. The Agency is proposing these deadlines elsewhere in the issue of the Federal Register.

TSCA section 12(b) requires that persons who export or intend to export to a foreign country any substance subject to testing requirements under TSCA section 4 notify EPA of such exportation or intent to export. While the results of required testing may not be available for some time, a notice to the foreign government about the export of such substances subject to test rules serves to alert them to the Agency's concern about the substances. It gives these governments the opportunity to

request such data that the Agency may currently possess plus whatever data may become available as a result of testing activities. Thus, upon the effective date of this rule, persons who export or intend to export propylene oxide must submit notices to the Agency pursuant to TSCA section 12(b)(1) and 40 CFR Part 707. For additional information, see the **Federal Register** of December 16, 1980 (45 FR 82844).

TSCA section 14(b) governs Agency disclosure of all test data submitted pursuant to section 4 of TSCA. Upon receipt of data required by this rule, the Agency will announce the receipt within 15 days in the **Federal Register** as required by section 4(d). Test data received pursuant to this rule will be made available for public inspection by any person except in those cases where the Agency determines that confidential treatment must be accorded pursuant to section 14(b) of TSCA.

G. Enforcement Provisions

The Agency considers failure to comply with any aspect of a section 4 rule to be a violation of section 15 of TSCA. Section 15(1) of TSCA makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to: (1) Establish or maintain records or (2) submit reports, notices, or other records required by the Act or any regulations issued under TSCA.

Additionally, TSCA section 15(4) makes it unlawful for any person to fail or refuse to permit entry or inspection as required by section 11. Section 11 applies to any "establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce . . ." The Agency considers a testing facility to be a place where the chemical is held or stored and, therefore, subject to inspection. Laboratory audits and/or inspections will be conducted periodically in accordance with the procedures outlined in TSCA section 11 by designated representatives of the EPA for the purpose of determining compliance with the final rule for propylene oxide. These inspections may be conducted for purposes which include verification that testing has begun, that schedules are being met, that reports accurately reflect the underlying raw data and interpretations and evaluations thereof, and that the studies are being conducted according to EPA GLP standards and the test standards established in the second phase of this rulemaking.

EPA's authority to inspect a testing facility also derives from section 4(b)(1) of TSCA, which directs EPA to promulgate standards for the development of test data. These standards are defined in section 3(2)(B) of TSCA to include those requirements necessary to assure that data developed under testing rules are reliable and adequate, and such other requirements as are necessary to provide such assurance. The Agency maintains that laboratory inspections are necessary to provide this assurance.

Violators of TSCA are subject to criminal and civil liability. Persons who submit materially misleading or false information in connection with the requirement of any provision of this rule may be subject to penalties calculated as if they had never submitted their data. Under the penalty provisions of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty of up to $25,000 per day for each violation. Intentional violations could lead to the imposition of criminal penalties up to $25,000 for each day of violation and imprisonment for up to 1 year. Other remedies are available to EPA under sections 7 and 17 of TSCA, such as seeking an injunction to restrain violations of TSCA section 4.

Individuals as well as corporations could be subject to enforcement actions. Sections 15 and 16 of TSCA apply to "any person" who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies themselves. In particular, this includes individuals who report false information or who cause it to be reported. In addition, the submission of false, fictitious, or fraudulent statements is a violation under 18 U.S.C. 1001.

VI. Economic Analysis of Final Test Rule

EPA has prepared an economic evaluation that examines the cost of the required testing and the potential economic impacts of those costs on the manufacturers and processors of propylene oxide subject to this rule. The analysis considered four market characteristics of propylene oxide: (1) The price sensitivity of demand for propylene oxide, (2) producer cost characteristics, (3) industry structure, and (4) market expectations. Costs of conducting the health effects test required in this rule are estimated to range from $30,728 to $92,185, with annualized test costs ranging from $7,963 to $23,891. From these test costs and an analysis of the market characteristics of propylene oxide, the economic evaluation indicates that the potential for a significant adverse economic impact is low. Furthermore, the additional product costs imposed by the required tests would be between 0.0004 and 0.0012 cent per pound, or between 0.008 and 0.003 percent of the current price per pound (47.5 cents). This suggests that the economic impact would be minimal.

For a more complete and thorough discussion of the methodology used to conduct the economic analysis of this test rule see *Economic Impact Analysis for Final Test Rule for Propylene Oxide* (Ref. 27). A copy of this document is available in the public record for this rulemaking, docket number [OPTS-42028B].

VII. Availability of Test Facilities and Personnel

Section 4(b)(1) of TSCA requires EPA to consider "the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule." Therefore, EPA conducted a study to assess the availability of tests facilities and personnel to handle the additional demand for testing programs negotiated with industry in place of rulemaking. Copies of the study, "Chemical Testing Industry: Profile of Toxicological Testing," October 1981, can be obtained through the NTIS under publication number PB 82-140773.

On the basis of this study, the Agency believes that there will be available test facilities and personnel to perform the testing required in this test rule.

VIII. Rulemaking Record

EPA has established a public record for this rulemaking (docket number OPTS-42028B). This record includes the basic information the Agency considered in developing this proposal, and appropriate **Federal Register** notices. The Agency will supplement the record with additional information as it is received.

This record includes the following information:

A. Supporting Documentation

(1) **Federal Register** notices pertaining to this action consisting of:

(a) Notice containing the First ITC Report designating alkyl epoxides to the Priority List (42 FR 55026; October 12, 1977) and comments received in response thereto.

(b) Notice of the proposed test rule on propylene oxide and comments received in response (48 FR 430; January 4, 1984).

(c) Notice announcing the final decision to require testing of propylene oxide.

(d) Notice adding propylene oxide to the list of chemicals subject to the preliminary assessment information rule. (47 FR 26992; June 22, 1982).

(e) Notice of final rule on EPA's TSCA Good Laboratory Practice Standards (48 FR 53922).

(f) Notice of final rule on test rule development and exemption procedures (49 FR 39774; October 10, 1984).

(g) Notice of final rule concerning data reimbursement (48 FR 41786).

(h) Notice of interim final rule on test rule development and exemption procedures (50 FR 20652; May 17, 1985).

(2) Support documents consisting of:

(a) Propylene oxide technical support document for proposed rule.

(b) Economic impact analysis of NPRM for propylene oxide.

(c) Economic impact analysis of final test rule for propylene oxide.

(3) Communications consisting of:

(a) Written public and intra-agency or interagency memoranda and comments.

(b) Summaries of telephone conversations.

(c) Summaries of meetings.

(4) Reports—published and unpublished factual materials, including contractors' reports.

B. References

(1) Winholtz, M. editor. *The Merck Index*, 9th Ed. Rathway, NJ. Merck and Co. p. 1017. 1976.

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(3) USEPA. Propylene Oxide: Proposed Test Rule. 48 FR 430; January 4, 1984.

(4) Hackett P.L., M.G. Brown, R.L. Buschbom, M.L. Clark, R.A. Miller, R.L. Musie, *et al.* "Teratogenic Study of Ethylene and Propylene Oxide and N-Butyl Acetate." Prepared for the National Institute for Occupational Safety and Health, Cincinnati, Ohio, under contract 2311104277 (NIOSH Contract No. 210–80–0013). 1982.

(5) Dow Chemical Company, Midland, Michigan and Arco Chemical Company, Newtown Square, Pennsylvania. Comments on Proposed Propylene Oxide Test Rule. Submitted to: Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C. March 2, 1984.

(6) NIOSH. Comments by NIOSH on Proposed Propylene Oxide Test Rule. Submitted to: Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C. March 5, 1984.

(7) USEPA. Economic Impact Analysis of NPRM for Propylene Oxide. No date.

(8) Palmer, A. K. Incidence of sporadic malformations, anomalies, and variations in random bred laboratory animals. In: Methods in prenatal toxicology. Evaluation of embryotoxic effects in experimental animals. Neubert D, Merker H–J, Kwasigroh T.E., eds. Stuttgart: George Thieme Publishers, pp. 52–71. 1977.

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(16) Dow Chemical Co., Midland, Michigan. Letter to Steven Newburg-Rinn, Assessment Division, Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C. 20460. May 24, 1983.

(17) Wilson, J.G. Environment and Birth Defects. New York: Academic Press, pp. 28–30. 1973.

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(19) USEPA. TSCA section 8(e) submission 8EHQ–0683–0439, followup response. Submitted to EPA by Dow Chemical Company. CAS reference number: D–979. Reuzel P. G. and C. F. Kuper, authors. "Chronic (28-month) Inhalation Toxicity/Carcinogenicity Study of Propylene Oxide in Rats." Netherlands Organization for Applied Scientific Research, Division for Nutrition and Food Research TNO, Netherlands. Submitted to: Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C. June 3, 1983.

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(22) USEPA. Memorandum: "Feasibility of an Epidemiologic Study of Propylene Oxide Workers." Prepared by C. Scott. Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C. July 13, 1984.

(23) Dow Chemical Co., Midland, Michigan. Propylene oxide: review of health effects and proposal for voluntary testing. Letter to Steve Newburg-Rinn, Assessment Division, U.S. Environmental Protection Agency, Washington, D.C. June 15, 1982.

(24) SRI International. A study of industrial data on candidate chemicals for testing. Prepared for Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C. EPA Contract No. 68–01–4109 (PB 274–284). 1977.

(25) Dow Chemical Co., Midland, Michigan. Response to the recommended toxicological testing for alkyl epoxides by the Interagency Testing Committee. Submitted to: Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C. March 10, 1978.

(26) Dow Chemical Company, Midland, Michigan. "Propylene Oxide: Two-Generation Reproduction Study in Fischer 344 Rats." TSCA 8(d) submission 878216062. Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C. July 9, 1985.

(27) USEPA. Economic Impact Analysis for Final Test Rule for Propylene Oxide. No date.

Confidential Business Information (CBI), while part of the record, is not available for public review. A public version of the record, from which CBI has been deleted, is available for inspection from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays, in Rm. E–107, 401 M Street SW., Washington, D.C.

IX. Other Regulatory Requirements

A. Classification of Rule

Under Executive Order 12291, EPA must judge whether a regulation is "major" and, therefore, subject to the requirement of a Regulatory Impact Analysis. The regulation for this chemical substance is not major because it does not meet any of the criteria set forth in section 1(b) of the Order. First, the actual annual cost of all the testing proposed for propylene oxide is $7,963–23,891, or less than $92,185 over the testing and reimbursement period. Second, because the cost of the required testing will be distributed over a large production volume, the rule will have only very minor effects on users' prices (less than 0.008 percent) for this chemical, even if all test costs were passed on. Finally, taking into account the nature of the market for this substance, the low level of costs involved, and the expected nature of the mechanisms for sharing the costs of the required testing, EPA concludes that there will be no significant adverse economic effects of any type as a result of this rule.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by

Executive Order 12291. Any comments from OMB to EPA, and any EPA response to those comments, are included in the public record.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (15 U.S.C. 601 *et seq.*, Pub. L. 96–354, September 19, 1980), EPA certifies that this test rule will not have a significant impact on a substantial number of small businesses for the following reasons:

1. There are no small manufacturers of propylene oxide.

2. Small processors are not likely to perform testing themselves, or to participate in the organization of the testing effort.

3. Small processors will experience only minor costs in securing exemption from testing requirements.

4. Small processors are unlikely to be affected by reimbursement requirements.

C. Paperwork Reduction Act

The information collection requirements contained in this rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* and have been assigned OMB control number 2070–0033.

List of Subjects in 40 CFR Part 799

Testing, Environmental Protection Agency, Environmental Protection, Hazardous substances, Chemicals.

Dated: November 21, 1985.

John A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

PART 799—[AMENDED]

Therefore, Part 799 is amended as follows:

1. The authority citation for Part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

2. New § 799.3450 is added to read as follows:

§ 799.3450 Propylene oxide.

(a) *Identification of test substance.* (1) Propylene oxide (CAS No. 75–56–9) shall be tested in accordance with this section.

(2) Propylene oxide of at least 99.0-percent purity shall be used as the test substance in all tests.

(b) *Person required to submit study plans, conduct tests, and submit data.* (1) All persons who manufacture or process propylene oxide, other than as an inpurity, from January 10, 1986, to the end of the reimbursement period shall submit letters of intent to conduct testing or exemption applications, study plans, and shall conduct tests, and submit data as specified in this section, Subpart A of this Part, and Part 790 of this chapter.

(2) Persons subject to this section are not subject to the requirements § 790.30(a) (2), (5), and (6) and (b) and § 790.87(a)(1)(ii) of this chapter.

(3) Persons who notify EPA of their intent to conduct tests in compliance with the requirements of this section must submit plans for those tests no later than 30 days before the initiation of each of those tests.

(4) In addition to the requirements of § 790.87(a) (2) and (3) of this chapter, EPA will conditionally approve exemption applications for this rule if EPA has received a letter of intent to conduct the testing from which exemption is sought and EPA has adopted test standards and schedules in a final Phase II test rule.

(c) *Health effects testing*—(1) Developmental toxicity—(i) *Required testing.* An inhalation developmental toxicity test in the rat shall be conducted with propylene oxide.

(ii) [Reserved].

(Information collection requirements approved by the Office of Management and Budget under control number 2070–0033)

[FR Doc. 85–28300 Filed 11–26–85; 8:45 am]

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