40 CFR Part 799

[OPTS-42043A; FRL-3042-6(a)]

Toxic Substances; 1,2-Dichloropropane; Testing Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The EPA (also Agency) is issuing a final test rule under section 4(a) of the Toxic Substances Control Act (TSCA) that requires manufacturers and processors of 1,2-dichloropropane (DCP; CAS Number 78-87-5) to test this chemical for neurotoxicity, mutagenicity (chromosomal aberrations), reproductive effects, developmental toxicity, acute toxicity to marine and freshwater algae and mysid shrimp, and chronic toxicity to mysid shrimp and *Daphnia magna*. Elsewhere in this issue of the **Federal Register**, the Agency is also proposing test standards and reporting deadlines for these tests.

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 September 23, 1986. This rule shall become effective October 23, 1986.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. NE-G004, 401 M St., SW., Washington, D.C. 20460. Toll free (800-424-9065). In Washington, DC: (554-1404). Outside the USA: (Operator-202-554-1404).

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SUPPLEMENTARY INFORMATION: On January 6, 1984, the EPA proposed, under section 4(a) of TSCA that manufacturers and processors of 1,2-dichloropropane conduct health and environmental effects testing of that chemical (49 FR 899). EPA is now issuing a final rule requiring health and environmental effects testing of 1,2-dichloropropane.

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. 2006 *et seq.*; 15 U.S.C. 2603 *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 to 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 (II) 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 test 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

1,2-Dichloropropane ($C_3H_6Cl_2$; CAS No. 78–87–5) is a highly volatile, colorless, stable liquid with a chloroformlike odor. The uses of 1,2-dichloropropane (DCP) are as a captive intermediate in the production of perchloroethylene; as a solvent in ion exchange resin manufacture, toluene diisocyanate production, photographic film manufacture, paper coating, and petroleum catalyst regeneration; and in a mixture that is marketed as a soil fumigant (pesticide).

The Dow Chemical Company is the only manufacturer of isolated DCP in the United States. The estimated annual isolated production is approximately 75 million pounds for 1982 based on information supplied by the Dow Chemical Company (Refs. 1 and 2). Over 95 percent of this isolated production is used on site by Dow as a captive intermediate in the production of perchloroethylene. Approximately 3 million pounds of DCP is marketed by Dow annually as a specialty solvent for industrial use. An estimated 20 million pounds of DCP is also produced as a byproduct in a mixture marketed as a soil fumigant; the remaining 7 million pounds is incinerated. Small quantities of DCP are also produced inadvertently during the manufacture of several other low molecular weight chlorinated aliphatic compounds. As of 1982, Dow no longer sells DCP for consumer use in paint strippers, paint, varnish, and furniture finish removers (Ref. 1).

B. ITC Recommendations

Section 4(e) of TSCA established an Interagency Testing Committee (ITC) to recommend to EPA a list of chemicals to be considered for testing under section 4(a) of the Act. The ITC designated 1,2-dichloropropane (DCP) for priority consideration in its Third Report published in the **Federal Register** of October 30, 1978 (43 FR 50630). The ITC recommended that 1,2-dichloropropane be tested for the following health effects: carcinogenicity, mutagenicity, teratogenicity, and other toxic effects (with emphasis on reproductive and neurological effects). The ITC also recommended that an epidemiological study be performed. The following environmental effects tests were recommended by the ITC: chronic toxicity to fish and invertebrates, effects on avian and mammalian reproduction and behavior, and effects on soil invertebrates and terrestrial insects.

The ITC's testing recommendations were based on high production volume (estimated at 71 million pounds), widespread use as a solvent, and potential for high environmental and human exposure. The ITC believed insufficient information was available to characterize the carcinogenic, mutagenic, and teratogenic potential of DCP. Reproductive and neurological effects testing was recommended because of a stated structural similarity to 1,2-dibromo-3-chloropropane (DBCP) a known human reproductive toxicant. An epidemiologic study was recommended for 1,2-dichloropropane because of insufficient information about the chemical's human health effects and a potentially large exposure pattern.

The ITC recommended environmental effects tests for 1,2-dichloropropane because of its belief that the chemical's volatility and high specific gravity may result in localized impacts on those environments receiving continuous exposure associated with this chemical's use and disposal. Also, according to the ITC, the potential for DCP to bioaccumulate suggested the need for environmental effects testing to determine the biological significance of exposure.

C. Proposed Rule

EPA issued a proposed rule, published in the **Federal Register** of January 6, 1984 (49 FR 899) which would require health and environmental effects testing for 1,2-dichloropropane.

In evaluating the ITC's testing recommendations for 1,2-dichloropropane (DCP), EPA considered all available relevant information including information presented in the ITC's report recommending testing consideration; production volume, use, exposure, and release information reported by the manufacturer of DCP under TSCA section 8(a) (40 CFR Part 712—Chemical Information Rule, Subpart B—Manufacturers Reporting—Preliminary Assessment Information); unpublished health and safety studies submitted by the manufacturer and processors of DCP under the TSCA section 8(d) Health and Safety Data Reporting Rule (40 CFR Part 716); and other published and unpublished data available to the Agency. On the basis of the evaluation, as described in the proposed rule and its accompanying technical support document (included in the public record for this action), EPA proposed nervous system effects, reproductive effects, teratogenicity (developmental toxicity), and mutagenicity testing requirements, as

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well as acute and chronic toxicity tests for aquatic invertebrates and an aquatic plant test for DCP under section 4(a)(1)(8) of TSCA. By these actions, EPA responded to the ITC's designation of 1,2-dichloropropane.

In basing its proposed DCP health and environmental effects testing on the authority of section 4(a)(1)(B) of TSCA, EPA found that 1,2-dichloropropane is manufactured, processed, and used in substantial quantities, and may result in substantial human exposure. EPA also found that 1,2-dichloropropane enters or may reasonably be anticipated to enter the environment in substantial quantitites. Furthermore, EPA found that there are insufficient data available to reasonably determine or predict the result of this exposure and release in the areas of mutagenic, teratogenic, reproductive, and neurotoxic effects, and acute and chronic toxicity for aquatic invertebrates and aquatic plants. Finally, EPA found that testing is necessary to develop the data needed to evaluate the Potential for DCP's exposure and release to cause these effects. These findings were based on the following information, as reported in the DCP Support Document:

1. Although Dow Chemical Company is the only manufacturer of 1,2-dichloropropane in the United States, the marketing volume (3 million pounds in 1982), the 1,2-dichloropropane production volume (an estimated 41 million pounds in 1981) and the 1,2-dichloropropane production capacity (41–144 million pounds, based on DCP co-product propylene oxide production capacity) were substantial.

2. Information available at that time indicated that a substantial number of consumers were potentially exposed to DCP, since DCP was then a component of 10 products available as paints, varnishes, and furniture finish removers. Also, a large number of workers in various occupations were potentially exposed to 1,2-dichloropropane. According to a 1972–74 National Occupational Hazard Survey, there are over 700,000 workers exposed to 1,2-dichloropropane resulting from its manufacture. This conclusion is based on the National Institute for Occupational Safety and Health's identification of 18 occupations in 17 industries, involving over 9,000 workers using 1,2-dichloropropane in nonagricultural applications. Furthermore, 1,2-dichloropropane had been identified as a contaminant of ground water and drinking water. The Suffolk County Department of Health Services, Long Island, New York, identified 1,2-dichloropropane from non-pesticidal sources in ground water. Also, the Philadelphia Water Department identified 1,2-dichloropropane in finished drinking water (6.1 μg/L). The estimated total annual load of 1,2-dichloropropane to the aquatic environment was approximately 4.9 million pounds. EPA concluded that this exposure pattern constituted "substantial exposure" as that term is used in section 4 of TSCA.

3. There were insufficient data on the teratogenic, reproductive, mutagenic, and neurotoxic effects upon which to reasonably determine or predict the effects of exposure. Health effects testing, therefore, was determined to be necessary to develop these data.

4. Acute, subchronic, and chronic effects tests and an oncogenicity test were not proposed for 1,2-dichloropropane. The Dow Chemical Company has conducted tests to determine the acute and subchronic effects of 1,2-dichloropropane by the inhalation route of exposure in rats, mice, and rabbits. NTP has performed a 90-day subchronic study, as well as a 2-year bioassay to determine the oncogenic potential of 1,2-dichloropropane. An epidemiological study was not proposed because the exposure pattern to 1,2-dichloropropane was so general EPA doubted that an exposed population could be identified that was not exposed to this chemical and other chemicals simultaneously.

5. Substantial quantities of 1,2-dichloropropane were released to the environment. The atmospheric compartment is readily contaminated with 1,2-dichloropropane because 1,2-dichloropropane is very volatile (vapor pressure = 50 mm Hg at 25 °C). Total atmospheric releases of 1,2-dichloropropane were estimated to be approximately 1.4×10^5 pounds per year. Also, quantities of 1,2-dichloropropane released to the aquatic environment were estimated to be 4.9 million pounds annually.

6. There were insufficient data to characterize the effects of 1,2-dichloropropane on aquatic invertebrates and aquatic plants. EPA proposed studies on acute and chronic toxicity to aquatic invertebrates and effects on algae. There were sufficient data to characterize the effects of 1,2-dichloropropane on soil invertebrates, terrestrial insects, and fish.

7. The Agency did not propose an avian reproduction test for 1,2-dichloropropane because then recent unpublished research at an EPA laboratory (ERL-Corvallis) had shown that a chemical as volatile as 1,2-dichloropropane is very unlikely to yield useful results if tested for avian toxicity according to available methodology.

III. Response to Public Comments

The comments received by the Agency in response to the proposed rule for 1,2-dichloropropane were from Dow Chemical Company. The Agency did not receive any comments which, in the Agency's judgment, rebutted the substantial production, human exposure, and environmental release findings for 1,2-dichloropropane. However, new information on the mutagenic effects of DCP has become available since publication of the proposed rule and has led EPA to reconsider its testing requirement for gene mutation. Major issues identified during the comment period are discussed below. All quotations are taken from Dow's written comments (Ref. 2).

A. Production, Release and Exposure

Dow concluded in its comments that there is neither substantial nor significant human exposure to 1,2-dichloropropane and that there is no substantial release to the environment, thus making the proposed testing unnecessary. This conclusion is based on "a comprehensive analysis of new information on the quantity of 1,2-dichloropropane produced, the limited amount released, and more importantly, the low exposure levels anticipated and preliminary results of recent and currently ongoing toxicological studies."

EPA disagrees with this conclusion and is now basing its section 4(a)(1)(b) finding on more recent production and exposure information (see Unit IV.A) contained in an exposure assessment document (Ref. 3) prepared by Versar, Inc. under contract with EPA. The isolated production volume cited by Dow in the comments (approximately 75 million pounds annually) is the same figure used in the Agency's analysis of release and exposure for isolated DCP. The Agency's analysis also examines releases and exposure from inadvertent production of DCP.

In discussing the aquatic release of DCP, Dow cited a figure (10,000 lbs/yr at <1 ppm) only for the release due to the propylene oxide process (DCP is a co-product of propylene oxide production). While acknowledging that "Dow cannot authoritatively comment on the releases from other ion exchange manufacturers," Dow did state that "Dow's ion exchange manufacturing process does not result in any release of 1,2-dichloropropane into the environment." The contention that DCP is released to the aquatic environment only as a result of Dow's on-site

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processing is directly contradicted by the ongoing Philadelphia Geographic Area Multimedia Pollutant Survey conducted by EPA/IEMD (see Unit IV. A). This survey found levels of DCP in the ambient air of the city of Philadelphia, in air at the Northeast Water Pollution Control Plant, which receives the industrial discharge from the Rohm and Haas Company (an industrial user of DCP), and in the intake and treated water of the Baxter Water Treatment Plant, also on the Delaware River. The Agency believes that these monitoring data, along with other available exposure information, support its finding of significant release and exposure.

With regard to occupational exposure, Dow does not believe that there is significant or substantial human occupational exposure to 1,2-dichloropropane because "there are probably less than 500 persons potentially occupationally exposed to 1,2-dichloropropane." The Agency does not agree, because although that figure is probably a good estimate for the number of workers directly exposed via inhalation at DCP production and industrial use facilities, it does not take into account direct inhalation exposure to DCP due to industrial wastewater treatment, public wastewater treatment, and sewer maintenance, or indirect inhalation exposure to DCP by non-production workers employed at DCP production and use facilities (see Unit II.C).

B. Mutagenicity

1. In the proposed test rule for DCP, EPA had proposed requiring a *Drosophila* sex-linked recessive lethal test. Dow Chemical Company in its comments pointed out that the National Toxicology Program (NTP) had evaluated the mutagenic potential of DCP in *Drosophila* after injection and inhalation exposure. The Agency has reviewed the NTP *Drosophila* sex-linked recessive lethal (SLRL) test, which yielded negative results. The Agency finds that the gene mutation data on DCP are adequate to reasonably predict the potential of DCP to cause gene mutation. Therefore, EPA will not require further testing for gene mutation at this time.

2. Dow also commented on the proposed tiered testing scheme for determination of mutagenic effects, stating their belief that "EPA has not articulated which human risks are related to this testing and furthermore has not specified or described the methodology by which the data could be used to assess those risks." Dow also believes "the scheme incorporates a rigid decision tree that precludes any scientific judgement and evaluation to determine whether further testing is necessary." The Agency disagrees with these comments for the following reasons.

As described in detail in the final Phase I test rule for the C_9 aromatic hydrocarbon fraction (50 FR 20662, 20668–71), the Agency believes that there is a consensus in the scientific community on both the need for, and the manner of, identifying mammalian mutagens, and that its proposed scheme for identifying these agents is in keeping with those recommended by experts in the field of mammalian mutagenesis. Further, while EPA recognizes that there is, as yet, no generally accepted single methodology for estimating human risk from mutagenic agents, it is the Agency's view that appropriate methodologies do exist and are usable.

In the case of DCP, only the second tier of mutagenicity testing (dominant lethal assay) is being required at this time, without an automatic trigger to the end point test (heritable translocation assay). This decision is based on available information for a structurally similar chemical, 1,2-dibromo-3-chloropropane (DBCP), indicating that mice are not sensitive to DBCP in the dominant lethal assay (Ref. 5). The rat is therefore the recommended species to use in the dominant lethal assay for DCP, but cannot be recommended for the heritable translocation assay because a successful assay has not been conducted with the rat to date. Results from the dominant lethal assay will be reviewed by the Agency, and a decision made at that time concerning the need for any further chromosomal aberrations testing.

3. Dow Chemical Company believes that "if testing for chromosomal effects is to be done, the micronucleus assay is preferable to the dominant lethal test." In their written comments, Dow compares the two tests noting several "advantages" to the micronucleus assay compared to the dominant lethal test. The Agency does not believe that this substitution is acceptable, because the micronucleus assay in rats would provide information basically the same as that already provided by the NTP assays in both cytogenetic and sister chromatid exchange assays. It would not assess chromosomal effects on germ cell tissues which are measured by the dominant lethal assay.

C. Reproductive/Teratogenic Effects

Dow Chemical Co. cited several studies previously conducted or currently underway in support of their belief that "it is unnecessary to initiate an inhalation reproduction study" pending completion of a Dow subchronic (13-week) study. The other studies cited in the comments are a 10-week inhalation study of reproductive effects on male and female rats of Shell DD, a pesticide mixture, and the NTP carcinogen bioassay in which observations were made for reproductive effects.

The Agency does not agree with this comment for the following reasons. The Dow 13-week subchronic study has not yet been made available to the Agency, and the Agency does not believe a 13-week study can substitute for a two-generation study on reproduction. The comment notes that a testicular weight decrease was noted in rabbits dosed with 1,2-dichloropropane for 2 weeks; this effect had not been observed in the Dow 13-week study. Pending completion of histopathology in this latter study, Dow did not see a reason to undertake a reproduction study. The Agency does not agree because although some chemicals demonstrate testicular histopathology at lower dose levels than fertility effects, other chemicals cause fertility effects at lower dose levels than those doses which cause detectable testicular histopathology.

The test substance (Shell DD) used in the 10-week inhalation study cited by Dow is a mixture containing other compounds that are acutely toxic orally and/or exhibit other toxicological effects that do not allow assessment of DCP by itself.

Since the carcinogen bioassay study is not a two generation study, the Agency believes it cannot substitute for a two-generation reproductive effects study, particularly in the case of DCP, a chemical with substantial release and exposure.

D. Neurotoxicity

For the proposed neurotoxicity testing, Dow commented that the only reported effects in an inhalation assay involved exposures at 1,000 and 1,500 ppm. Dow noted that no effects were seen in a 2-week study or in a NTP 2-year cancer bioassay. Lastly, Dow noted that a 13-week study is forthcoming. For the inhalation assay, the Agency believes that the methods used to assess neurotoxic effects are not sufficiently sensitive to detect possible effects. For the two other studies cited, neither was designed to detect neuropathological changes and thus the Agency believes that they are inappropriate for evaluating the possible effects.

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E. Other Toxic Effects

Shell Oil Company submitted a report titled "Toxicology of five chemicals: The acute oral and percutaneous toxicity, skin and eye irritancy and skin sensitizing potential of DCP (light ends)", however, the data do not address any of the endpoints required in this test rule.

F. Environmental Effects

Dow Chemical Company believes that environmental effects testing is not necessary "because there are sufficient data already available to predict the effects of the current exposures of aquatic species to 1,2-dichloropropane." This conclusion relies on a national mean level for DCP to assert that exposure levels are 11,000 times below the no-observed-effects level (NOEL) and 26,000 times lower than the daphnid static acute LC_{50}, and on an "in general" rule of thumb to assert that algal testing is unnecessary. The Agency disagrees with this comment, however, because the daphnid test was conducted with unmeasured concentrations, thus making the results questionable if not invalid, and a "national mean" is an invalid basis for comparison. Site-specific data are needed for such a comparison, as now are available to the Agency for the Delaware River. Also, a NOEL has not been established for this chemical. The Agency does not believe that extrapolating fish or invertebrate data to estimate possible effects levels in algae is appropriate for this test rule, because although a correlation in toxic response may exist between the two groups of organisms for certain chemicals or categories of chemicals, no evidence is available to support the idea that this relationship holds true for all chemicals. The Agency is concerned in this test rule with the development of data to allow hazard assessment of a specific chemical, DCP, and does not believe data exist to support the extrapolation of fish or invertebrate data for DCP to possible effects level in algae.

IV. Final Test Rule for 1,2-Dichloropropane

A. Findings

EPA is basing its 1,2-dichloropropane health and environmental effect testing requirements on the authority of section 4(a)(1)(B) of TSCA. EPA finds that DCP is produced and released to the environment in substantial quantities, and that the manufacture, processing, use, and disposal may result in substantial human exposure to this chemical. These findings are based on the following information:

1. Although Dow Chemical Company is the only manufacturer of isolated DCP in the United States, the isolated production volume (estimated 74.9 million pounds in 1982), the marketing production volume (estimated at 3 million pounds in 1982), and the inadvertent (not isolated) production volume (estimated at 20 million pounds in 1982) are substantial (Refs. 1, 2 and 3).

2. In order to assess human and environmental exposure to 1,2-dichloropropane, the Agency contracted with Versar, Inc. to develop a comprehensive exposure assessment (Ref. 3). The document examined exposures as a result of TSCA-regulated environmental releases, including monitoring data from the Integrated Environmental Management Project for Philadelphia, Pennsylvania; releases and exposures related to the pesticidal use of DCP were not investigated. The following information is summarized from this document, and indicates the substantial release of and exposure to DCP:

a. The total estimated annual environmental releases from production and industrial use are 772,000 lbs to the air, 198,000 lbs to water, and 176,000 lbs to land disposal sites for a total of 1,146,000 lbs. These releases include process emissions to the air, secondary air emissions resulting from volatilization during wastewater treatment, releases to water in wastewater effluent, air release via incineration, and land disposal of solid waste residues, tars, and ash residues from incineration.

b. Occupational exposure to DCP involves approximately 500 workers exposed to direct inhalation (estimated to range from 31 to 410 g/person/yr) at DCP production and industrial use facilities. An estimated 900 workers may be exposed to direct inhalation (0.020 to 0.27 g/person/yr) as a result of the volatilization of DCP from wastewater during treatment operations. There is also potential for exposure (4.8 to 100 mg/yr) to DCP of non-production workers at DCP production and use facilities.

c. The general populations of five metropolitan areas are exposed to atmospheric concentrations of DCP as a result of airborne releases during production and industrial use of DCP, and volatilization of DCP during wastewater treatment. This atmospheric exposure results in doses estimated at 36 to 240 mg/person/yr. Approximately 880,000 people in the city of Philadelphia, PA are estimated to ingest an average of 0.043 μg/kg/day, or 1.1 mg/yr, and a maximum of 0.43 μg/kg/day, or 11 mg/yr, of DCP as a result of the consumption of drinking water contaminated with DCP from industrial wastewater discharge of the chemical.

d. Monitoring information has also been provided by the ongoing Philadelphia Geographic Area Multimedia Pollutant Survey, conducted by EPA/IEMD (Ref. 3). DCP was measured in Philadelphia at average levels of 0.2 to 3.5 $\mu g./m^3$ in the ambient air of various sectors of the city, and 36.7 to 569.8 $\mu g./m^3$ in air downwind of the Northeast Water Pollution Control Plant (NEWPCP), which receives the industrial discharge from the Rohm and Haas Company.

e. A monitoring study was conducted at the NEWPCP and in the Delaware River. Sampling sites were chosen (1) near the Baxter Drinking Water Plant upstream from the NEWPCP; (2) midway between the NEWPCP and the Baxter plant, to show upstream (tidal) movement of DCP from NEWPCP; and (3) two miles upstream of Baxter.

The data from the three locations indicate that diluted effluent from NEWPCP reaches the Baxter Drinking Water Plant, but that concentrations drop significantly upstream of the tidal excursion. Tidal excursion of the NEWPCP effluent affects the intake water for the Baxter Drinking Water Plant since the water is withdrawn during high tide. Data obtained from the Philadelphia Water Department during the IEMD monitoring study show that the average DCP concentration in the intake water over 1982 through 1983 was 1.6 μg/l, and the average concentration in the treated water was 1.5 μg/l.

3. There are insufficient data on the developmental, reproductive, mutagenic (chromosomal aberrations), and neurotoxic effects upon which to reasonably determine or predict the effects of exposure from the manufacturing, processing, use, and disposal of DCP. Health effects testing, therefore, is necessary to develop these data. As indicated in the proposed test rule (49 FR 399; January 6, 1984), there are sufficient data to characterize the acute, subchronic and chronic effects of DCP, and an NTP 2-year bioassay has been completed and is adequate to determine the oncogenic potential of DCP.

4. There are insufficient data to characterize the effects of DCP on aquatic invertebrates and aquatic plants from its manufacture, processing, and use. EPA is requiring that studies be conducted on acute and chronic toxicity to aquatic invertebrates and acute effects on algae. There are sufficient data to characterize the effects of DCP

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on soil invertebrates, terrestrial insects, and fish.

B. Required Testing

EPA is requiring that 1,2-dichloropropane be tested for developmental, reproductive, mutagenic (chromosomal aberrations), and neurotoxic effects, as well as acute and chronic toxicity to aquatic invertebrates and acute toxicity to algae.

C. Test Substance

EPA is requiring that 1,2-dichloropropane of at least 99 percent purity be used as the test substance. DCP of this purity is available commercially. EPA has specified a relatively pure substance for testing because the Agency is interested in evaluating the effects attributed to DCP itself. This requirement will increase the likelihood that any toxic effects observed are related to DCP and not to any impurities.

D. Persons Required to Test

Section 4(b)(3)(B) of TSCA specifies that the activities for which the Agency makes section 4(a) findings (manufacture, processing, distribution, use and/or disposal) determine who bears the responsibility for testing. Manufacturers are required to test if 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. 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 available data are inadequate to reasonably determine or predict the effects on human health and the environment as a result of the manufacturing, processing, use, and disposal of DCP, EPA is requiring that persons who manufacture or process, or who intend to manufacture or process this chemical, at any time from the effective date of this test rule to the end of the reimbursement period, be subject to the rule. The end of the reimbursement period will be 5 years after the last final report is submitted or an amount of time equal to that which was required to develop data if more than 5 years after the submission of the last final report required under the test rule. As discussed in the Agency's test rule 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 a test 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 person required to test may apply to EPA for an exemption from that requirement. The Agency anticipates that the current manufacturer of DCP will sponsor the required testing. Manufacturers and processors who are subject to the testing requirements of this rule must comply with the test rule and exemption procedures in 40 CFR Part 790. Manufacturers (including importers) subject to this rule are required to submit either a letter of intent to perform testing or an exemption application within 30 days after the effective date of the final test rule. The required procedures for submitting such letters and applications are described in 40 CFR Part 790.

Processors subject to this rule, unless they are also manufacturers, will not be required to submit letters of intent or exemption applications, or to conduct testing unless manufacturers fail to submit notices of intent to test or later fail to sponsor the required tests. The Agency expects that the manufacturers will pass an appropriate portion of the costs of testing on to processors through the pricing of their products or reimbursement mechanisms. If manufacturers perform all the required tests, processors will be granted exemptions automatically. If manufacturers fail to submit notices of intent to test or fail to sponsor all the required tests, the Agency will publish a separate notice in the **Federal Register** to notify processors to respond; this procedure is described in 40 CFR Part 790.

EPA is not requiring the submission of equivalence data as a condition for exemption from the required testing. As noted in Unit IV. C., EPA is interested in evaluating the effects attributable to DCP itself and has specified a relatively pure substance for testing.

E. Test Rule Development and Exemptions

Elsewhere in today's **Federal Register**, the Agency is proposing that certain TSCA test guidelines be utilized as test standards for the development of data under this rule for 1,2-dichloropropane. As discussed in that notice and in previous notices (50 FR 20652), EPA has reviewed the method for 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 DCP, TSCA test guidelines are available for all the testing requirements included in this Phase I final rule. Thus, in the accompanying notice, the Agency is proposing these TSCA test guidelines as test standards.

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 within 90 days after the effective date of the Phase I rulemaking. See 40 CFR 790.50(a)(2). However, because EPA is proposing applicable TSCA test guidelines as the test standards for the studies required by this Phase I final rule, persons subject to the rule, i.e., manufacturers and processors of DCP, are not required to submit proposed study plans for the required testing at this time. Persons subject to this rule, however, are still required to submit notices of intent to test or exemption applications in accordance with 40 CFR 790.45. For the rule, once the test standards are 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 45 days before the initiation of each required test. Processors of DCP 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

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fail to sponsor the required tests (see Unit IV. D).

Because persons subject to this rule for DCP are not required to submit proposed study plans for approval, EPA will grant conditional exemptions under this rule following EPA's receipt of a letter of intent to conduct the required tests, rather than after receipt and approval of a study plan. Notice of EPA's adoption of the proposed test standards and deadlines will be announced in a final Phase II test rule.

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.

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.

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 today's **Federal Register.**

TSCA section 12(b) requires that persons who export or intend to export to a foreign country any 1,2-dichloropropane subject to the testing requirements of this rule 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 that these exported substances are 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 DCP must submit notices to the Agency pursuant to TSCA section 12(b)(1) and 40 CFR Part 707. For additional information, see 49 FR 45581, November 19, 1984—Notification of Chemical Export; Applicability of Final Test Rules.

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, (2) submit reports, notices, or other information, or (3) permit access to or copying of records required by the Act or any regulation 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/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 DCP. 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 the TSCA GLP standards and the test standards proposed rule 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(12)(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 provision 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 with each day of operation in violation constituting a separate violation. This provision would be applicable primarily to manufacturers or processors who fail to submit a letter of intent or an exemption request and who continue manufacturing or processing after the deadlines for such submissions. This provision would also apply to processors that fail to submit a letter of intent or an exemption application and continue processing after the Agency has notified them of their obligation to submit such documents (see 40 CFR 790.48(b)). Intentional violations could lead to the imposition of criminal penalties of up to $25,000 for each day of violation and imprisonment of up to one year. In determining the amount of penalty, EPA will take into account the seriousness of the violation and the degree of culpability of the violator as well as the other factors listed in section 16. 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.

V. Economic Analysis of Rule

To assess the potential economic impact of this rule, EPA has prepared an economic analysis that evaluates the potential for significant economic impacts on the industry as a result of the required testing. The economic analysis estimates the costs of conducting the required testing and evaluates the potential for significant adverse economic impact as a result of these test costs by examining four market characteristics of DCP: (1) Price sensitivity of demand, (2) industry cost characteristics, (3) industry structure, and (4) market expectations.

Total direct testing costs for the final rule for DCP are projected to range from $325,620 to $416,670. Since DCP, as manufactured by the sole manufacturer,

is a byproduct of propylene oxide manufacture, the direct costs of testing have been dispersed over the annual production of propylene oxide. In addition, the costs for teratogenic effects testing for propylene oxide, required in a previous rule (Ref. 4), have been added to the corresponding costs for DCP.

The annualized test costs (using a cost of capital of 25 percent over a period of 15 years) range from $93,914 to $122,296. Based upon Dow Chemical's 1984 estimated production volume of 907 million pounds of propylene oxide, the estimated unit test costs for DCP and propylene oxide range from 0.010 to 0.013 cents per pound. These unit costs are equivalent to 0.02 to 0.03 percent of the current price of propylene oxide.

Based on these costs and the economic characteristics of the DCP industry, the economic analysis indicates that the potential for adverse economic effect due to the estimated test costs is low. This conclusion is based upon the following observations:

1. Propylene oxide, the main product in DCP production, is used mainly as a captive intermediate and has a relatively inelastic demand.

2. The market expectations for propylene oxide and many of its derivatives are favorable.

3. Dow manufactures DCP and propylene oxide at two highly integrated plants where minor cost increases can be dispersed over numerous end products.

4. The estimated total unit test costs (i.e., the test costs for DCP and propylene oxide) are negligible, or less than 0.013 cents per pound or 0.03 percent of propylene oxide price in the upper-bound case.

Refer to the economic analysis for a complete discussion of test cost estimation and the potential for economic impact resulting from these costs.

VI. 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 test facilities and personnel to handle the additional demand for testing services created by section 4 test rules. Copies of the study, "Chemical Testing Industry: Profile of Toxicological Testing," October, 1981, can be obtained through the National Technical Information Service, 5285 Port Royal Road, Springfield, Va. 22161 (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.

VII. Public Record

EPA has established a record for this rulemaking (docket number OPTS-42043). This record includes the basic information the Agency considered in developing this rule, 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 rule consisting of:

(a) Notice of proposed rule on 1,2-dichloropropane (January 6, 1984; 49 FR 899).

(b) Notice containing the ITC designation of 1,2-dichloropropane to the Priority List (October 30, 1978; 43 FR 50630).

(c) Notice of final rule on EPA's TSCA Good Laboratory Practice Standards (November 29, 1983; 48 FR 53922).

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

(e) Interim final rule for test rule development and exemption procedures (May 17, 1985; 50 FR 20652).

(f) Notice of final rule concerning data reimbursement (July 11, 1983; 48 FR 31786).

(g) Notice of final rule on the C_9 aromatic hydrocarbon fraction (May 17, 1985; 50 FR 20662).

(2) Support documents consisting of:

(a) 1,2-Dichloropropane technical support document for proposed test rule.

(b) Economic impact analysis of final test rule for 1,2-dichloropropane.

(3) Communications consisting of:

(a) Written public comments.

(b) Summaries of telephone conversations.

(c) Meeting summaries.

(4) Reports—published and unpublished factual materials.

B. References

(1) Dow. The Dow Chemical Company. Letter to Mr. Steven D. Newburg-Rinn, Chief, Test Rules Development Branch (TS-778), Office of Toxic Substances, USEPA, Washington, DC. (1983)

(2) Dow. The Dow Chemical Company Comments on 1,2-dichloropropane proposed test rule. **Federal Register** 49:899. Submitted to TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, USEPA, Washington, DC. Control Number OPTS-42043 (1984)

(3) Versar, Inc. Exposure Assessment for test rules development for 1,2-dichloropropane. Washington, DC: U.S. Environmental Protection Agency, Office of Toxic Substances. Contract No. 68-02-3968.

(4) EPA. Notice of final rule on propylene oxide testing requirements. **Federal Register** 50:48762. (November 27, 1985).

(5) USEPA. U.S. Environmental Protection Agency. Response to TRDB request on mutagenicity data review of 1,2-dichloropropane. Intra-agency memorandum to Katherine Hart, Existing Chemical Assessment Division, from the Toxic Effects Branch, Health and Environmental Review Division. May 13, 1986.

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. NE-G004, 401 M Street SW., Washington, DC.

VIII. Other Regulatory Requirements

A. Executive Order 12291

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 annual costs of testing are expected to range from $93,914 to $122,296 over the expected market life of 1,2-dichloropropane. 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 the producer's costs or users' prices for this chemical substance. 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 impact 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 written 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 business for the following reasons:

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(1) There are no small manufacturers of 1,2-dichloropropane.

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

(3) Small processors will experience only minor costs if any in securing exemption from testing requirements.

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

EPA concludes that there will be no significant adverse economic impact of any type as a result of this rule.

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, Hazardous substances, Chemicals, Recordkeeping and reporting requirements.

Dated: August 2, 1986.

J.A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

PART 799—[AMENDED]

Therefore, 40 CFR 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. Section 799.1550 is added, to read as follows:

§ 799.1550 1,2-Dichloropropane.

(a) *Identification of test substance.* (1) 1,2-Dichloropropane (CAS No. 78–87–5) shall be tested in accordance with this section.

(2) 1,2-Dichloropropane of at least 99 percent purity shall be used as the test substance.

(b) *Persons required to submit study plans, conduct tests, and submit data.* (1) All persons who manufacture or process 1,2-dichloropropane, from October 23, 1986 to the end of the reimbursement period shall submit letters of intent to test, exemption applications, and shall conduct tests in accordance with Part 792 of this chapter and submit data as specified in paragraphs (a); (b) (1), (2), (3), and (4); (c) (1), (2), (3), and (4); and (d) of this section; Subpart A of this Part; and Parts 790 and 792 of this chapter for two-phase rulemaking.

(2) Persons subject to this section are not subject to the requirements of §§ 790.50(a) (2), (5), (6), and (b) (2) and (4), 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 45 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 rule.

(c) *Health effects testing*—(1) *Neurotoxicity*—(i) *Required testing.* The following neurotoxicity testing shall be conducted for 1,2-dichloropropane:

(A) A neuropathology test.

(B) A motor activity test.

(C) A functional observational battery.

(ii) [Reserved]

(2) *Mutagenic effects*—(i) *Required testing.* A dominant lethal assay shall be conducted with 1,2-dichloropropane.

(ii) [Reserved]

(3) *Developmental toxicity*—(i) *Required testing.* A developmental toxicity test shall be conducted with 1,2-dichloropropane.

(ii) [Reserved]

(4) *Reproductive effects*—(i) *Required testing.* A two-generation reproductive effects study shall be conducted with 1,2-dichloropropane.

(ii) [Reserved]

(d) *Environmental effects testing*—(1) *Mysid acute toxicity*—(i) *Required testing.* A mysid shrimp acute toxicity test shall be conducted with 1,2-dichloropropane.

(ii) [Reserved]

(2) *Algal acute toxicity*—(i) *Required testing.* An algal acute toxicity test shall be conducted with 1,2-dichloropropane.

(ii) [Reserved]

(3) *Daphnid chronic toxicity*—(i) *Required testing.* A daphnid chronic toxicity test shall be conducted with 1,2-dichloropropane.

(ii) [Reserved]

(4) *Mysid shrimp chronic toxicity*—(i) *Required testing.* A mysid shrimp chronic toxicity test shall be conducted with 1,2-dichloropropane.

(ii) [Reserved].

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

[FR Doc. 86–20260 Filed 9–8–86; 8:45 am]

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