

**ENVIRONMENTAL PROTECTION
AGENCY**

40 CFR Part 799

(OPTS-42043B; FRL-3042-6)

**1,2-Dichloropropane: Proposed Test
Rule; Proposed Testing Standards****AGENCY:** Environmental Protection
Agency (EPA).**ACTION:** Proposed rule.

SUMMARY: This document proposes that: (1) Pharmacokinetics (absorption, distribution, metabolism, and excretion) testing be conducted with 1,2-dichloropropane (CAS Number 78-87-5), (2) certain Toxic Substances Control Act (TSCA) test guidelines be utilized as the test standards for required studies for 1,2-dichloropropane, and (3) test data be submitted within specified time frames. Elsewhere in this issue of the Federal Register, EPA is also issuing a final test rule establishing certain testing requirements under section 4(a) of the Toxic Substances Control Act (TSCA) for manufacturers and processors of 1,2-dichloropropane.

DATES: Submit written comments on or before October 24, 1986. If persons request time for oral comment by October 9, 1986, EPA will hold a public meeting on this proposed rule in Washington, DC. For further information on arranging to speak at the meeting, see Unit VI of this preamble.

ADDRESS: Submit written comments, identified by the document control number (OPTS-42043B), in triplicate to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Room NE-C004, 401 M Street SW., Washington, DC 20460.

A public version of the administrative record supporting this action (with any confidential business information deleted) is available for inspection at the above address from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

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 (800-424-8065). In Washington, DC: (554-1404). Outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION: The EPA is proposing that pharmacokinetic testing be conducted with 1,2-dichloropropane (DCP) and is proposing test standards for DCP testing, including time frames for test data submission.

I. Background

Section 4(e) of TSCA (Pub. L. 94-469, 90 Stat. 2003; 15 U.S.C. 2601) 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 on 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. Also, 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.

On January 6, 1984 (49 FR 899), the EPA issued a proposed test rule for DCP under section 4(a)(1)(B) of TSCA. The Agency proposed that manufacturers and processors of DCP conduct the following health and environmental effects tests for the chemical: Neurotoxicity (inhalation); mutagenic effects (chromosomal aberrations and gene mutation); teratogenicity (inhalation); reproductive effects (two-generation via inhalation); mysid shrimp acute toxicity (flow-through conditions); algal toxicity (marine and freshwater); and daphnia (*Daphnia magna*) and mysid chronic toxicity. The proposed test rule for DCP did not include pharmacokinetic testing of DCP.

Since the test rule for DCP was proposed, new information on the type and extent of human exposure has been obtained. Although the inhalation route of exposure is still of concern to the Agency because of occupational and general population exposure, several factors indicate the oral rather than inhalation (as proposed) route of exposure to be more appropriate for conducting the health effects tests: (1) The elimination of consumer exposure because Dow Chemical Co. no longer sells DCP for use in paint strippers, paint, varnish, and furniture finish removers; (2) the exposure of over 800,000 people in the city of Philadelphia, PA to drinking water contaminated with DCP; (3) concerns of the National Toxicology Program over DCP in drinking water; and (4) potential concerns of EPA's Office of Solid Waste and the Office of Emergency and Remedial Response over DCP in ground

water. Therefore, the Agency is proposing at this time that health effects testing be conducted via the oral route of administration, and that an oral-inhalation comparative pharmacokinetic study be performed with DCP. This study will allow the Agency to reasonably predict and compare the distribution and metabolism of DCP in the body as a result of oral or inhalation exposure (See Unit III).

Elsewhere in this issue of the Federal Register, EPA is promulgating a Phase I final rule pursuant to TSCA section 4 that establishes certain testing requirements for manufacturers and processors of 1,2-dichloropropane (DCP). That Phase I rule specifies the following testing requirements for DCP: (1) Nervous system effects testing including a neuropathology test, a motor activity test, and a functional observation battery; (2) mutagenic effects (chromosomal aberrations); (3) developmental toxicity; (4) a 2-generation reproductive effects test; (5) mysid shrimp acute toxicity; (6) algal toxicity; and (7) daphnid and mysid chronic toxicity.

Once the Phase I test rule becomes effective, manufacturers and processors of DCP would normally be required, under the existing two-phase process, to submit proposed study plans and schedules for both the initiation of testing and the submission of study data in accordance with 40 CFR 790.50. EPA would review the submitted study plans and schedules and would thereafter issue them (with any necessary modifications) in a Phase II test rule proposal. That proposal would request comment on the ability of the proposed study plans to ensure that the resulting data would be reliable and adequate. After evaluating and responding to public comment, EPA would adopt, with any necessary modifications, the study plans and reporting schedules, in a Phase II final rule as the required test standards and data submission deadlines in 40 CFR 790.52.

However, in the case of the DCP test rule, which was initiated under the two-phase process, EPA has now decided to propose the relevant TSCA test guidelines in this document as the test standards (see Unit IV) and at the same time issue the DCP final rule. In addition, EPA is proposing that the data from the required studies be submitted within certain time periods. These time periods will serve as the data submission deadlines required by TSCA section 4(b)(1) (see Unit V). The reasons for this change in the test rule process for DCP are discussed below.

II. Change in the Test Rule Development Process

A. Test Standards and Data Submission Deadlines

TSCA section 4(b)(1) specifies that test rules shall include standards for the development of test data ("test standards") and deadlines for submission of test data. Under a two-phase process utilized by EPA since 1982 (March 28, 1982; 47 FR 13012) and formally adopted in the fall of 1984 (October 10, 1984; 49 FR 39774), test standards and data submission deadlines were to be adopted during the second phase of the rulemaking process. Upon issuance of the Phase I final rule, which established the effects and characteristics for which a given chemical substance must be tested, persons subject to the rule would be required by a specified date to submit study plans detailing the methodologies and protocols they intended to use to perform the required tests. Such study plans were to include proposed schedules for the initiation and completion of testing and submission of test data in accordance with 40 CFR 790.50 (a) and (c). The Agency would then publish these study plans and solicit public comment. In the second phase, after consideration of public comment, the Agency would promulgate the Phase II final rule adopting the study plans (with any necessary modifications) as the test standards for the development of test data and deadlines for submission of test data.

In December 1983, the Natural Resources Defense Council (NRDC) and the Industrial Union Department of the American Federation of Labor-Congress of Industrial Organizations (AFL-CIO) filed an action under TSCA section 20 challenging, among other things, the use of the two-phase process. In an August 23, 1984 Opinion and Order, the U.S. District Court for the Southern District of New York found that utilization of the two-phase rulemaking process was permissible. However, the Court also held that the Agency was subject to a standard of promulgating test rules within a reasonable time frame (*NRDC v. EPA*, 595 F Supp. 1255 (S.D.N.Y. 1984)).

Subsequent to the issuance of that Opinion, the Agency decided that in order to expedite the development of section 4 test rules, EPA would utilize a single-phase rulemaking process for most test rules. In the notice announcing this decision, published in the Federal Register of May 17, 1985 (50 FR 20652), EPA stated that the single-phase approach offers a number of advantages.

over the two-phase process. In this single-phase approach, the Agency proposes (in one notice) not only the effects for which testing will be required but also proposes pertinent TSCA or other appropriate guidelines as the test standards and time frames for the submission of test data. After receiving and evaluating public comment on the proposed testing requirements, test guidelines, and data submission deadlines, EPA promulgates a final rule.

This single-phase approach shortens the rulemaking period and expedites the initiation of required testing relative to the two-phase rulemaking process. The single-phase process also eliminates the requirement under the two-phase approach for industry to submit test protocols for approval. Moreover, by allowing commenters to submit alternative testing methodologies during the comment period, the single-phase approach preserves the flexibility of the two-phase process.

These same advantages, i.e., expedited initiation of testing and the elimination of study plan submission requirements for persons subject to a Phase I rule, are factors EPA considered in deciding to modify the rulemaking process for DCP. By proposing both pertinent TSCA test guidelines as the test standards and data submission deadlines at the time of issuance of the Phase I final rule, EPA expects that the Phase II final rule will be issued 6 months sooner than would occur if the usual two-phase process was followed. Thus, required testing will be initiated on an expedited basis. In addition, for each of the required tests for DCP, appropriate TSCA test guidelines are available (Unit III). Thus, EPA believes that there is no need for manufacturers and processors of DCP to develop proposed study plans for EPA and public review during the rulemaking process. The pharmacokinetics test for DCP is being proposed under the single-phase test rule development process.

B. Modifications to Requirements Under a Phase I Final Rule for 1,2-Dichloropropane

As indicated in Unit II.A, persons subject to the DCP Phase I final rule and who have notified EPA of their intent to test would normally be required to submit proposed study plans and proposed data submission deadlines within a specified time of the final rule's effective date in accordance with 40 CFR 790.50(a) and (c). However, because EPA is proposing certain TSCA guidelines as the test standards, and data submission deadlines, persons subject to the Phase I final rule are not required at this time to submit study

plans for the required testing or proposed dates for the initiation and completion of that testing. Manufacturers and processors of DCP are invited to comment on both the proposed test standards and the data submission deadlines. The Agency will consider these comments in issuing the Phase II final rule.

However, persons subject to the Phase I final rule for DCP are still required to submit notices of intent to test or exemption applications in accordance with 40 CFR 790.45. Moreover, once the test standards and reporting deadlines are promulgated in the Phase II final rule, those persons who have notified EPA of their intent to test must submit specific study plans (which adhere to the promulgated test standards) no later than 45 days before the initiation of each required test, 40 CFR 790.50(a)(1).

III. Proposed Test Rule

A. Data Contained in the Final Phase I Test Rule

The final Phase I test rule for 1,2-dichloropropane, appearing elsewhere in this issue of the Federal Register, contains (1) DCP's profile, (2) EPA's previous findings with respect to DCP, (3) a description of the persons who would be required to conduct the proposed health and environmental effects tests, and (4) a description of the test substance to be used for conducting the tests.

Since the proposed test rule for DCP was issued, new information on the production, use, and environmental distribution of DCP has become available. The sources of this information include public comment on the proposed rule, including current production and use information from the only U.S. producer of isolated DCP (Dow Chemical Company), and recent comprehensive monitoring data for the chemical in the vicinity of a major industrial user of DCP in Philadelphia, PA.

Testing of DCP was proposed under TSCA section 4(a)(1)(B). In support of this finding, the Agency contracted with Versar, Inc. to prepare a document assessing human and environmental exposure to DCP (Ref. 1). The document examined exposures as a result of TSCA-regulated environmental releases, including monitoring data from the Integrative Environmental Management Project for Philadelphia, PA; releases and exposures related to the pesticidal use of DCP were not investigated. A summary of this information is found in Unit IV of the final Phase I test rule for DCP.

B. Findings

EPA is basing its proposed oral-inhalation comparative pharmacokinetic testing requirement 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, and use may result in substantial human exposure to this chemical. The detailed basis for this finding is found in Unit IV.A. of the final Phase I test rule for DCP, published elsewhere in this issue of the Federal Register.

The EPA also finds that there are insufficient data to reasonably predict and compare the distribution and metabolism of DCP in the body as a result of oral or inhalation exposure due to DCP's manufacture, processing, and use, and that an oral-inhalation comparative pharmacokinetic study of DCP is necessary to develop such data.

IV. Proposed Test Standards

EPA is proposing at this time that an oral-inhalation comparative pharmacokinetics test (absorption, distribution, metabolism, and excretion) be conducted, according to the pharmacokinetic guideline under 40 CFR 798.7475, published in the Federal Register proposed rule for cumene (50 FR 46104; November 6, 1985), a copy of which is in the docket for DCP, and as modified in § 798.1550(c)(5)(iii)(B). The proposed pharmacokinetic study will allow the Agency to reasonably predict and compare the distribution and metabolism of DCP in the body as a result of oral or inhalation exposure.

In the final Phase I test rule for DCP, the required testing includes neurotoxicity, mutagenic effects (chromosomal aberrations), developmental effects, reproductive effects, mysid shrimp acute toxicity, algal acute toxicity, and daphnid and mysid chronic toxicity.

The required nervous system effects testing falls into three categories. The data from the neuropathology testing will detect and characterize morphologic changes in the nervous system, if and when they occur, and determine a no-effect level for such changes.

Motor activity has been extensively studied in both behavioral pharmacology and behavioral toxicology (Refs. 2 through 5), through the use of rodents. The history of the development of psychoactive drugs indicates that the motor activities of rats and mice are predictive of psychoactive potential in humans (Refs. 4 through 7).

The functional observational battery is a non-invasive procedure designed to detect gross functional deficits in young adult rodents resulting from exposure to chemicals and to better quantify neurotoxic effects detected in other studies. While this battery of tests is not intended to provide a detailed evaluation of neurotoxicity, it is designed to be used in conjunction with neuropathologic evaluation and/or general toxicity testing. EPA is proposing that the neuropathology, motor activity, and functional observational battery testing be conducted according to 40 CFR 798.6400, 798.6200, and 798.6050, respectively.

EPA is proposing that the required dominant lethal assay be conducted for DCP according to 40 CFR 798.5430. Dominant lethal effects cause embryonic or fetal death. Induction of a dominant lethal event after exposure to a chemical substance indicates that the substance has affected germinal tissue of the test species. Dominant lethals are generally accepted to be the result of chromosomal damage (structural and numerical anomalies) but gene mutations and toxic effects cannot be excluded. As discussed in the DCP Phase I final test rule, available information for a structurally similar chemical, 1,2-dibromo-3-chloropropane (DBCP), indicates that mice are not sensitive to DBCP in the dominant lethal assay. The rat is therefore proposed as the test species for this assay.

The required developmental toxicity study is designed to determine the potential of DCP to induce structural and/or other abnormalities in the fetus which may arise from exposure of the mother during pregnancy. These developmental effects include permanent structural or functional abnormalities that occur during the period of embryonic development. EPA is proposing that the developmental toxicity study be conducted according to 40 CFR 798.4900.

The required two-generation reproductive effects testing is designed to provide general information concerning the effects of DCP on gonadal function, conception, parturition, and the growth and development of the offspring. The study may also provide information about effects of DCP on neonatal morbidity, mortality, and preliminary data on teratogenesis. EPA is proposing that the reproductive effects testing be conducted according to 40 CFR 798.4700.

EPA is proposing that the required health effects tests be conducted via the oral route of exposure, because the human exposure pattern described by the new information (see Unit III. B.) has

led EPA to believe that the oral route of administration is now the most appropriate for conducting the required health effects tests.

The algal acute toxicity test is designed to develop data on the phytotoxicity of DCP to freshwater and marine algae. EPA is proposing that testing using systems that control for DCP evaporation be conducted with marine and freshwater algae according to 40 CFR 797.1050.

For the purpose of developing data on the acute toxicity of DCP to aquatic invertebrates, EPA is proposing that testing using flow-through systems and measured concentrations be conducted with mysid shrimp according to 40 CFR 797.1930. To develop data on the chronic toxicity of DCP to aquatic invertebrates, EPA is proposing that testing be conducted with *Daphnia magna* and the mysid shrimp according to 40 CFR 797.1330 and 797.1950, respectively.

V. Reporting Requirements

EPA is proposing that all data developed under this rule be reported in accordance with its final TSCA Good Laboratory Practice (GLP) standards in 40 CFR Part 792.

In accordance with 40 CFR Part 790, test sponsors are required to submit individual study plans at least 45 days prior to the initiation of each study.

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. Specific reporting requirements for each of the proposed test standards follow:

1. The pharmacokinetic, neurotoxicity, dominant lethal assay, and all environmental effects tests shall be completed and the final results submitted to the Agency within 1 year of the effective date of the final Phase II test rule. Progress reports on all studies shall be provided every 6 months.

2. The developmental toxicity tests shall be completed and the final results submitted to the Agency within 18 months of the effective date of the final Phase II test rule. Interim progress reports shall be provided every 6 months.

3. The two-generation reproductive effects toxicity test shall be completed and final results submitted to the Agency within 29 months of the effective date of the final Phase II test rule. Interim progress reports shall be provided every 6 months.

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.

VI. Issues for Comment

EPA invites comment on the following issues:

1. The proposed testing requirement for an oral inhalation comparative pharmacokinetic study with DCP.
2. Requiring the oral, rather than inhalation, route of administration in conducting health effects tests with DCP.
3. The proposed use of the TSCA test guidelines as the test standards for the required testing of 1,2-dichloropropane.
4. The proposed schedule for the required testing.

VII. Economic Analysis of Proposed Rule

To assess the economic impact of this proposed rule, EPA has prepared an economic evaluation (Ref. 8) that examines the cost of the required testing, both for pharmacokinetics testing alone and in conjunction with testing required in the DCP final rule, and analyzes four market characteristics of DCP: (1) Demand sensitivity, (2) cost characteristics, (3) industry structure, and (4) market expectations. The economic evaluation for the DCP proposed test rule, which estimates a testing cost of \$144,610 to \$191,680 for pharmacokinetic testing, and a total testing cost of \$470,230 to \$606,350 for both the tests required in the final rule and the pharmacokinetic testing, indicates that the potential for adverse economic effects due to the estimated cost of testing is low. The annualized total test costs for DCP range from \$121,855 to \$157,648. This conclusion is based on the following observations (Ref. 8):

1. Propylene oxide (PO), the main product in DCP production, is used mainly as a captive intermediate and has a relatively inelastic demand.
2. The market expectations for PO and many of its derivatives are favorable.
3. Dow manufactures DCP and PO 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 PO) are negligible, or less than 0.02 cents per pound or 0.04 percent of PO price in the upperbound case.

Refer to the economic analysis (Ref. 8) for a complete discussion of test cost

estimation and the potential for economic impact resulting from these costs.

VIII. 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 and test 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 82-146773.

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 proposed rule.

IX. Public Meetings

If persons indicate to EPA that they wish to present oral comments on this proposed rule to EPA officials who are directly responsible for developing the rule and supporting analyses, EPA will hold a public meeting subsequent to the close of the public comment period in Washington, DC. Persons who wish to attend or to present comments at the meeting should call the TSCA Assistance Office (TAO): Toll Free: (800-424-8065); in Washington, DC: (554-1404); Outside the U.S.A. (Operator-202-554-1404), by October 9, 1986. A meeting will not be held if members of the public do not indicate that they wish to make oral presentations. While the meeting will be open to the public, active participation will be limited to those persons who arranged to present comments and to designated EPA participants. Attendees should call the TAO before making travel plans to verify whether a meeting will be held.

Should a meeting be held, the Agency would transcribe the meeting and include the written transcript in the public record. Participants are invited, but not required, to submit copies of their statements prior to or on the day of the meeting. All such written materials will become part of EPA's record for this rulemaking.

X. Public Record

EPA has established a record for this rulemaking, [docket number (OPTS-42043)]. This record includes basic information considered by the Agency 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

The supporting documents for this rulemaking consist of the proposed and final Phase I test rules on 1,2-dichloropropane.

B. References

- (1) 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. 68-02-3088.
- (2) Reiter, L.W. "Use of activity measures in behavioral toxicology." *Environmental Health Perspectives* 28:9-20. (1978)
- (3) Reiter, L.W. and MacPhail, R.C. "Motor activity: A survey of methods with potential use in toxicity testing." *Neurobehavioral Toxicology* 1:Suppl. 2, 59-66. (1979)
- (4) Irwin, S. "Comprehensive observational assessment: In A systematic, quantitative procedure for assessing the behavioral and physiologic state of the mouse." *Psychopharmacology*, 12:223-227. (1968)
- (5) Kinnard, E.J. and Wetman, M. "Techniques utilized in the evaluation of psychotropic drugs on animals' activity." *Journal Pharmaceutical Science*, 55:995-1002. (1966)
- (6) Dewa, P.R. "The measurement of the influence of drugs on voluntary activity in mice." *British Journal Pharmacology Chemotherapy*, 8:45-48. (1963)
- (7) Turner, R.A. "Screening Methods in Pharmacology." New York: Academic Press, pp. 24-34. (1965)
- (8) EPA. Economic Impact Analysis of Final and Proposed Test Rule for 1,2-Dichloropropane. U.S. Environmental Protection Agency, Washington, DC (1986)

The record is open 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 20460.

XI. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirements of a Regulatory Impact Analysis. This test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order. The economic analysis of the testing of 1,2-dichloropropane is discussed in the Phase I test rule appearing elsewhere in this issue of the Federal Register and Unit VII of this notice.

B. Regulatory Flexibility Act

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

- (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 efforts.
- (3) Small processors will experience only very minor costs if any in securing exemption from testing requirements.
- (4) Small processors are unlikely to be affected by reimbursement requirements, and any testing costs passed on to small processors through price increases will be small.

C. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this proposed rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq., and has assigned OMB control number 2070-0033. Comments on these requirements should be submitted to the Office of Information and Regulatory Affairs: OMB, 726 Jackson Place NW., Washington, DC 20503, marked "Attention: Desk Officer for EPA". The final rule package will respond to any OMB or public comments on the information collection requirements.

List of Subjects in 40 CFR Part 799

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

Dated: August 27, 1986.

J.A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

PART 799—(AMENDED)

Therefore, it is proposed that 40 CFR Part 799 be amended as follows:

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

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

2. By amending § 799.1550 by adding paragraphs (b)(5), (c)(1) (ii) and (iii), (2) (ii) and (iii), (3) (ii) and (iii), (4) (ii) and (iii) and (5), and (d)(1) (ii) and (iii), (2) (ii) and (iii), (3) (ii) and (iii), and (4) (ii) and (iii), to read as follows:

§ 799.1550 1,2-Dichloropropane.

(b)
 (5) All persons who manufacture or process 1,2-dichloropropane, from the effective date of the final rule for pharmacokinetics testing to the end of the reimbursement period, shall submit letters of intent to test, exemption applications, and shall conduct tests and submit data as specified in paragraphs (a), (b)(5), and (c)(5) of this section, Subpart A of this Part, and Parts 790 and 792 of this chapter for single-phase rulemaking.

(c)
 (1)

(ii) *Test standards.* The neurotoxicity testing of 1,2-dichloropropane, consisting of a neuropathology test, a motor activity test, and a functional observational battery, shall be conducted in accordance with §§ 798.6400, 798.6200, and 798.6050 of this chapter, respectively, using the oral route of exposure. The animals shall be dosed with DCP for a minimum of 5 days per week, over a period of at least 90 days.

(iii) *Reporting requirements.* (A) The neurotoxicity tests shall be completed and the final results submitted to the Agency within 1 year of the effective date of the Phase II final test rule.

(B) Interim progress reports shall be provided at 6 month intervals, beginning 6 months after the effective date of the final Phase II test rule and ending with the submission of the Final Test Report.

(2)

(ii) *Test standards.* The dominant lethal assay shall be conducted with 1,2-dichloropropane using the rat in accordance with § 798.5450 of this chapter.

(iii) *Reporting requirements.* (A) The dominant lethal assay shall be completed and the final results submitted to the Agency within 1 year of the effective date of the final Phase II test rule.

(B) Interim progress reports shall be provided at 6 month intervals, beginning 6 months after the effective date of the Phase II final test rule and ending with the submission of the Final Test Report.

(3)

(ii) *Test standard.* The developmental toxicity testing shall be conducted with 1,2-dichloropropane in accordance with § 798.4900 of this chapter, using the oral route of exposure.

(iii) *Reporting requirements.* (A) The developmental toxicity study shall be completed and the final results submitted to the Agency within 18 months of the effective date of the Phase II final test rule.

(B) Interim progress reports shall be provided at 6 months intervals, beginning 6 months after the effective

date of the Phase II final test rule and ending with the submission of the Final Test Report.

(4)

(ii) *Test standard.* The two-generation reproductive effects testing shall be conducted with 1,2-dichloropropane in accordance with § 798.4700 of this chapter, using the oral route of exposure.

(iii) *Reporting requirements.* (A) The two-generation reproductive effects test shall be completed and the final results submitted to the Agency within 20 months of the effective date of the Phase II final test rule.

(B) Interim progress reports shall be provided at 6 month intervals, beginning 6 months after the effective date of the Phase II final test rule and ending with the submission of the Final Test Report.

(5) *Pharmacokinetic studies—(i) Required testing.* Oral and inhalation pharmacokinetic testing shall be conducted with 1,2-dichloropropane.

(ii) *Test standard.* (A) The oral and inhalation pharmacokinetic testing shall be conducted with 1,2-dichloropropane in accordance with § 798.7475 of this chapter and modifications specified in paragraph (c)(5)(ii)(B) of this section.

(B) *Modifications.*

(2) The requirement under § 798.7475(c)(2)(iii)(C) of this chapter for testing DCP is modified so that collection of excreta (urine, feces, and expired air) occurs at 0, 4, 8, 16, 24, and 48 hours posttreatment, or until 95 percent of the dose has been excreted.

(2) The requirement under § 798.7475(c)(2)(iii)(D) of this chapter for testing DCP is modified so that the concentration of hydrocarbon in inspired and expired air and blood shall be measured at 0, 5, 10, 15, and 30 minutes, and at 1, 2, 4, 8, 16, 24, and 48 hours during and after inhalation exposure.

(3) The requirement under § 798.7475(c)(3)(i)(A) of this chapter for testing DCP is modified so that the levels of total ¹⁴C-label shall be determined in whole blood and blood plasma or blood serum at 0, 4, 8, 16, 24, and 48 hours after dosing rats in groups A-B and F-H.

(4) The requirement under § 798.7475(c)(3)(i)(B) of this chapter for testing DCP is modified so that the quantities of total ¹⁴C-label excreted in expired air, urine, and feces by rat groups A-B and F-H shall be determined at 0, 4, 8, 16, 24, and 48 hours after dosing and if necessary, daily thereafter until at least 90 percent of the dose has been excreted or until 7 days after dosing, whichever occurs first.

(5) The requirement under § 798.7475(d)(3)(vi) of this chapter for

testing DCP is modified to require the reporting of biotransformation pathways and quantities of the test substance and its metabolites in urine, feces, and expired air collected after oral administration (single, low, and high doses) and inhalation exposure (low, intermediate, and high concentrations).

(iii) *Reporting requirements.* (A) The pharmacokinetic test shall be completed and the final results submitted to the Agency within 1 year of the effective date of the Phase II final test rule.

(B) Interim progress reports shall be provided at 6 month intervals, beginning 6 months after the effective date of the Phase II final test rule and ending with the submission of the Final Test Report.

(d)

(1)

(ii) *Test standard.* The mysid shrimp acute toxicity testing of 1,2-dichloropropane shall be conducted as a flow-through test using *Mysidopsis bahia* in accordance with § 797.1930 of this chapter.

(iii) *Reporting requirements.* (A) The mysid acute toxicity test shall be completed and the final report submitted to the Agency within 1 year of the effective date of the Phase II final rule.

(B) Progress reports shall be submitted to the Agency at 6 month intervals, beginning 6 months after the effective date of the Phase II final test rule.

(2)

(ii) *Test standard.* The algal acute toxicity testing of 1,2-dichloropropane shall be conducted with marine and freshwater algae using systems that control for 1,2-dichloropropane evaporation in accordance with § 797.1050 of this chapter.

(iii) *Reporting requirements.* (A) The algal acute toxicity test shall be completed and the final report submitted to the Agency within 1 year of the effective date of the Phase II final test rule.

(B) Progress reports shall be submitted to the Agency at 6 month intervals, beginning 6 months after the effective date of the Phase II final test rule.

(3)

(ii) *Test standard.* The daphnid chronic toxicity testing of 1,2-dichloropropane shall be conducted as a flow-through test using *Daphnia magna* in accordance with § 797.1330 of this chapter.

(iii) *Reporting requirements.* (A) The daphnid chronic toxicity test shall be completed and the final report submitted to the Agency within 1 year of the effective date of the Phase II final test rule.

(B) Progress reports shall be submitted to the Agency at 6 month intervals.

beginning 6 months after the effective date of the Phase II final test rule.

(4)

(ii) *Test standard.* The mysid-shrimp chronic toxicity testing of 1,2-dichloropropane shall be conducted as a flow-through test using *Mysidopsis bahia* in accordance with § 797.1950 of this chapter.

(iii) *Reporting requirements.* (A) The mysid chronic toxicity test shall be completed and the final report submitted to the Agency within 1 year of the effective date of the Phase II final test rule.

(B) Progress reports shall be submitted to the Agency at 6 month intervals, beginning 6 months after the effective date of the Phase II final test rule.

(Information collection requirements have been approved by the Office of Management and Budget under control number 2070-0083)

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