SW., Washington, DC 20460. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 522(a) and 1 CFR part 51. The method is incorporated as it exists on the effective date of this rule and a notice of any change to the method will be published in the FEDERAL REGISTER.

(ii) *Reporting requirements.* (A) The biodegradation test in an aquatic system shall be completed and the final report submitted to EPA within 15 months of the effective date of the final rule.

(B) An interim progress report shall be submitted to EPA 6 months after the effective date of the final rule.

(2) *Volatilization*—(i) *Required testing.* A test for volatilization from aquatic system shall be conducted with cumene in accordance with the method described in an article by Smith et al. entitled "Prediction of the Volatilization Rates of High-Volatility Chemicals from Natural Water Bodies," published in Vol. 14, Number 11, of the American Chemical Society's *Environmental Science & Technology*, 1980, which is incorporated by reference. The method is available for public inspection at the Office of the Federal Register, Rm. 8301, 11th and L St., NW., Washington, DC 20408, and copies may be obtained from the EPA TSCA Public Docket Office (TS–793), Rm. G–004 Northeast Mall, 401 M St., SW., Washington, DC 20460. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 522(a) and 1 CFR part 51. The method is incorported as it exists on the effective date of this rule and a notice of any change to the method will be published in the FEDERAL REGISTER.

(ii) *Reporting requirements.* (A) The volatilization test in an aquatic system shall be completed and the final report submitted to EPA within 12 months of the effective date of the final rule.

(B) An interim progress report shall be submitted to EPA 6 months after the effective date of the final rule.

(f) *References.* For additional background information, the following references should be consulted:

(1) Lamb, J.C. and Chapin, R.E. "Experimental models of male reproductive toxicology," *Endocrine Toxicology.* Eds. J.A. Thomas, K.S. Korach, J.A. McLachlan. New York, NY: Raven Press, pp. 85–115 (1985).

(2) Johnson, L., Petty, C.S., and Neaves, W.B. "A comparative study of daily sperm production and testicular composition in humans and rats," *Biology of Reproduction*, 22:1233–1243. (1980).

(3) Blazak, W.F., Ernest, T.L., and Stewart, B.E. "Potential indicators of reproductive toxicity: Testicular sperm production and epididymal sperm number, transit time and motility in Fischer 344 rats," *Fundamental and Applied Toxicology*, 5:1097–1103 (1985).

(g) *Effective date.* (1) The effective date of this final rule for cumene is September 9, 1988, except for paragraphs (d)(1)(i) and (d)(1)(ii)(A), and (e)(1)(ii)(A) of this section. The effective date for paragraphs (d)(1)(i), (d)(1)(ii)(A), and (e)(1)(ii)(A) of this section is March 1, 1990.

(2) The guidelines and other test methods cited in this rule are referenced as they exist on the effective date of the final rule.

[53 FR 28204, July 27, 1988, as amended at 55 FR 7325, Mar. 1, 1990; 56 FR 23230, May 21, 1990; 58 FR 34205, June 23, 1993]

§ 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, other than as an impurity, from October 23, 1986 to the end of the reimbursement period, shall submit letters of intent to conduct testing or exemption applications, conduct tests, and submit data as specified in paragraphs (c)(1), (c)(2), (c)(3), and (c)(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.

(5) All persons who manufacture or process 1,2-dichloropropane, other than as an impurity, from November 18, 1987 to the end of the reimbursement period, shall submit letters of intent to conduct testing or submit exemption applications, conduct tests, and submit data as specified in paragraph (c)(5) of this section, subpart A of this part, and parts 790 and 792 of this chapter for single-phase rulemaking.

(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) *Test standards.* The neurotoxicity testing with 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 reports submitted to EPA within 1 year of the effective date of the final Phase II rule.

(B) An interim progress report shall be submitted to EPA 6 months after the effective date of the final Phase II rule.

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

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

(iii) *Reporting requirements.* (A) The dominant lethal assay shall be completed and the final report submitted to EPA within 18 months of the effective date of the final Phase II rule.

(B) An interim progress report shall be submitted to EPA 6 months after the effective date of the final Phase II rule.

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

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

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

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

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

(ii) *Test standard.* (A) The 2-generation reproductive effects testing with 1,2-Dichloropropane shall be conducted using the oral route of exposure in accordance with § 798.4700 except for the provisions in paragraphs (c)(7)(i) and (c)(7)(iii) of § 798.4700.

(B) For the purpose of this section, the following provisions also apply:

(*1*) A gross examination shall be made at least once each day. Pertinent behavioral changes, signs of difficult or prolonged parturition, and all signs of toxicity, including mortality, shall be recorded. These observations shall be reported for each individual animal. Food and water consumption for all animals shall be monitored at least weekly except during the mating period.

(*2*) Each litter should be examined as soon as possible after delivery for the number of pups, stillbirths, live births, sex, and the presence of gross anomalies. Live pups should be counted and litters weighed at birth or soon there-

after, and at least weekly after parturition.

(iii) *Reporting requirement.* (A) The two-generation reproductive effects test shall be completed and the final report submitted to EPA within 29 months of the effective date of the final Phase II rule.

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

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

(ii) *Test standard.* (A) The oral and inhalation pharmacokinetic testing with 1,2-dichloropropane shall be conducted in accordance with § 795.230 of this chapter, except for the provisions in paragraphs (c)(2) (i), (ii) (A) and (B), (iii) (C) and (D), and (3)(ii) of § 795.230.

(B) For the purpose of this section, the following provisions also apply:

(*1*) *Test Substance.* The studies require the use of both non-radioactive and ^{14}C-labeled test substance. The non-radioactive test substance shall be at least 99 percent pure, while the radiochemical purity of the ^{14}C-labeled test substance may be slightly less than 99 percent. Both preparations are needed to investigate the provisions of paragraph (a)(2) of this section. The use of ^{14}C-test substance is recommended for the provisions in paragraph (a)(1), (2), and (3) of this section in order to facilitate the work, improve the reliability of quantitative determinations, and increase the probability of observing previously unidentified metabolites.

(*2*) *Oral study.* At least two doses shall be used in the study, a "low" and "high" dose. When administered orally, the "high" doses should induce some overt toxicity such as weight loss. If data from prior repeated dosing studies is utilized to select the "high" dose, overt toxicity need not be elicited in this exposure group. The "low" dose shall not induce observable effects attributable to the test substance. Oral dosing shall be performed by gavage using an appropriate vehicle.

(*3*) *Inhalation study.* Three concentrations shall be used in the study. Upon exposure, two higher concentrations should ideally induce some overt symptoms of toxicity, although the intermediate concentration may be excluded from this condition. If data from prior repeated dosing studies is utilized to select the high dose, overt toxicity need not be elicited in this exposure group. The lowest concentration shall not induce observable effects attributable to the test substance.

(*4*) *Collection of excreta.* After oral administration (Groups A and B) and inhalation exposure (Groups F through H) the rats shall be placed in individual metabolic cages and excreta (urine, feces and expired air) shall be collected from 0 to 24 hours and from 24 to 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*) *Kinetic studies.* Groups C through E should be used to determine the concentration of the test substance in blood at 0, 5, 10, 15, and 30 minutes, and at 1, 2, 4, 8, 16, 24, and 48 hours after initiation of inhalation exposure. If experimentally feasible, blood obtained from the ^{14}C-exposed rats from Groups F through H may be used to determine the test substance concentrations.

(*6*) *Biotransformation after oral and inhalation exposure.* Appropriate qualitative and quantitative methods shall be used to assay urine specimens collected from each rat in Groups A and B and F through H. The radiometric analyses of urine, feces and expired air should be conducted individually for each rat, but samples from each rat per time point may be pooled for analytical determination of parent compound and metabolite identification. Metabolite identification shall be attempted for those routes of excretion which contain greater than 10 percent of the oral dose or, in the inhalation study, greater, than 10 percent of the body burden at the end of exposure.

(iii) *Reporting requirements.* (A) The pharmacokinetic test shall be completed and the final report submitted to EPA within 17 months of the effective date of the final single-phase pharmacokinetics rule.

(B) An interim progress report shall be submitted to EPA 6 months after

e effective date of the final single-
ase rule.
d) *Environmental effects testing*—(1)
sid acute toxicity—(i) *Required testing.*
mysid shrimp acute toxicity test
all be conducted with 1,2-
hloropropane.
ii) *Test standard.* The mysid shrimp
ute toxicity test with 1,2-dichloro-
opane shall be conducted as a flow-
ough test with measured concentra-
ns using *Mysidopsis bahia* in accord-
ce with §797.1930 of this chapter.
iii) *Reporting requirements.* (A) The
sid acute toxicity test shall be com-
ted and the final report submitted
EPA within 1 year of the effective
te of the final Phase II rule.
B) An interim progress report shall
submitted to EPA 6 months after
e effective date of the final Phase II
le.
2) *Algal acute toxicity*—(i) *Required*
ting. An algal acute toxicity test
all be conducted with 1,2-
hloropropane.
ii) *Test standard.* (A) The algal acute
xicity tests with 1, 2-dichloropropane
all be conducted with marine and
eshwater algae using systems that
ntrol for 1,2-dichloropropane evapo-
tion in accordance with §797.1050 of
is chapter, except for the provisions
paragraph (c)(1)(ii), (3)(iii), (4)(iv),
(i)(B), (d)(3)(ii) and (iii), (e)(4) and (5)
§797.1050.
B) For the purpose of this section,
e following provisions shall also
ply to the algal acute toxicity tests:
1) At 48, 72, 96, and 120 hours, enu-
erate the algal cells in all containers
determine the inhibition or stimula-
on of growth in test containers com-
red to controls. Use data to define
e concentration-response curve, and
lculate the EC_{10}, EC_{50}, and EC_{90}
lues.
2) The test is performed once for
ch of the recommended algal species
selected alternates. Test chambers
ould contain equal volumes of test
lution and approximately 1×10^4
lenastrum cells/ml or 7.7×10^4
eletonema cells/ml of test solution.
ie algae should be exposed to each
ncentration of test chemical for up
120 hours. The exposure period may
shortened if data suitable for the
purposes of the range-finding tests can
be obtained in less time.
3) The test begins when algae from 7
to 10-day-old stock cultures are placed
in the test chambers containing test
solutions having the appropriate con-
centrations of the test substance. At
the end of 120 hours, the algal growth
response (number or weight of algal
cells/ml) in all test containers and con-
trols should be determined by an indi-
rect (spectrophotometry, electronic
cell counters, dry weight, etc.) or a di-
rect (actual microscopic cell count)
method. Indirect methods should be
calibrated by a direct microscopic
count. The percentage inhibition of
stimulation of growth for each con-
centration, EC_{10}, EC_{50}, EC_{90}, and the
concentration-response curves are de-
termined from these counts.
4) At the end of the test and after
aliquots have been removed for algal
growth-response determinations, mi-
croscopic examination, mortal stain-
ing, or subculturing, the replicate test
containers for each chemical con-
centration may be pooled into one sam-
ple. An aliquot of the pooled sample
may then be taken and the concentra-
tion of test chemical determined. In
addition, the concentration of test
chemical associated with the algae
alone should be determined. Separate
and concentrate the algal cells from
the test solution by centrifuging or fil-
tering the remaining pooled sample
and measure the test substance con-
centration in the algal-cell con-
centrate. The concentrations associ-
ated with the algae do not have to be
measured if data are provided that
demonstrate that substantive amounts
of the test substance are lost during
transfer of algae to centrifuge tubes or
during centrifugation.
5) Test chambers containing *Selena-*
strum shall be illuminated continuously
and those containing *Skeletonema* shall
be provided a 14-hour light and 10-hour
dark photoperiod under fluorescent
lamps providing 300±25uEin/m^2 sec (ap-
proximately 400 ft-c) measured adja-
cent to the test chambers at the level
of test solution.
6) Stock algal cultures should be
shaken twice daily by hand. Test con-
tainers may be shaken by hand or
placed on a rotary shaking apparatus

and oscillated at approximately 100 cycles/minute for *Selenastrum* and at approximately 60 cycles/minute for *Skeletonema* during the test. The rate of oscillation should be determined at least once daily during testing.

(*7*) The number of algal cells per milliliter in each treatment and control and the method used to derive these values at the beginning, 48, 72, and 96 hours, and end of the test; the percentage of inhibition or stimulation of growth relative to controls; and other adverse effects in the control and in each treatment.

(*8*) The 120-hour EC_{10}, EC_{50}, and EC_{90}, values, and when sufficient data have been generated, the 48, 72, and 96 hour LC_{50}'s and 95 percent confidence limits, the methods used to derive these values, the data used to define the shape of the concentration-response curve and the goodness-of-fit determination.

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

(B) An interim progress report shall be submitted to EPA 6 months after the effective date of the final Phase II rule.

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

(ii) *Test standard.* The daphnid chronic toxicity test with 1,2-dichloropropane shall be conducted as a flowthrough 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 EPA within 1 year of the effective date of the final Phase II rule.

(B) An interim progress report shall be submitted to EPA 6 months after the effective date of the final Phase II rule.

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

(ii) *Test standard.* The mysid shrimp chronic toxicity test with 1,2-dichloropropane shall be conducted as a flowthrough 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 EPA within 15 months of the effective date of the final Phase II rule.

(B) An interim progress report shall be submitted to EPA 6 months after the effective date of the final Phase II rule.

(e) *Effective date.* (1) The effective date of the final Phase II rule and the final single-phase pharmacokinetics rule for 1,2-Dichloropropane is November 18, 1987, except for paragraphs (c)(4)(ii), and (d)(4)(iii)(A) of this section. The effective date for paragraphs (c)(4)(ii), and (d)(4)(iii)(A) of this section is March 1, 1990.

(2) The guidelines and other test methods cited in this rule are referenced as they exist on the effective date of the final rule.

[51 FR 32087, Sept. 9, 1986, as amended at 52 FR 37144, Oct. 5, 1987; 54 FR 27355, June 29, 1989; 55 FR 7325, Mar. 1, 1990; 58 FR 34205, June 23, 1993]

§ 799.1560 Diethylene glycol butyl ether and diethylene glycol butyl ether acetate.

(a) *Identification of test substances.* (1) Diethylene glycol butyl ether (DGBE), CAS Number 112–34–5, and diethylene glycol butyl ether acetate (DGBA), CAS Number 124–17–4, shall be tested in accordance with this section.

(2) DGBE of at least 95 percent purity and DGBA of at least 95 percent purity shall be used as the test substances.

(b) *Persons required to submit study plans, conduct tests, and submit data.* All persons who manufacture (including import) or process or intend to manufacture or process DGBE and/or DGBA, other than as an impurity, after April 11, 1988, to the end of the reimbursement period shall submit letters of intent to conduct testing, submit study plans and conduct tests, and submit data, or submit exemption applications as specified in this section, subpart A of this part, and parts 790 and 792 of this chapter for single-phase rulemaking. Persons who manufacture or process DGBE are subject to the requirements to test DGBE in this section. Only persons who manufacture or