to EPA within 17 months of the effective date of the final Phase II test rule.

(B) Progress reports shall be submitted to the Agency for the morphologic transformation assay at 6-month intervals, the first of which is due within 6 months of the effective date of the final Phase II rule.

(4) *Developmental toxicity*—(i) *Required testing.* A developmental toxicity study shall be conducted individually with *ortho-*, *meta-*, and *para*-cresol.

(ii) *Test standards.* (A) *Developmental toxicity.* This study shall be conducted individually with *ortho-*, *meta-*, and *para*-cresols in accordance with § 798.4900 of this chapter, except for provisions in § 798.4900(e)(5).

(B) For the purposes of this section the following provision also applies: *Administration of test substance.* The test substance shall be administered by oral gavage.

(iii) *Reporting requirements.* (A) The developmental toxicity study shall be completed and final results submitted to the Agency within 12 months of the effective date of the final Phase II test rule.

(B) Progress reports shall be submitted to the Agency for the developmental toxicity study at 6-month intervals, the first of which is due within 6 months of the effective date of the final Phase II rule.

(5) *Reproductive effects—(i) Required testing.* A two-generation reproductive effects study shall be conducted individually with *ortho-*, *meta-*, and *para*-cresol.

(ii) *Test standards.* (A) *Reproduction and fertility effects.* This study shall be conducted individually with *ortho-*, *meta-*, and *para*-cresols in accordance with § 798.4700 of this chapter, except for provisions in § 798.4700(c)(5)(i)(A).

(B) For the purposes of this section the following provision also applies: *Administration of the test substance—Oral studies.* The test substance shall be administered by oral gavage.

(iii) *Reporting requirements.* (A) The reproduction and fertility effects study shall be completed and final results submitted to the Agency within 29 months of the effective date of the final Phase II test rule.

(B) Progress reports shall be submitted to the Agency for the reproduction and fertility effects study at 6-month intervals, the first of which is due within 6 months of the effective date of the final Phase II rule.

(d) *Effective date.* The effective date of the final Phase II rule for cresols is July 6, 1987.

[51 FR 15782, Apr. 28, 1986, as amended at 52 FR 19087, May 20, 1987; 54 FR 27355, June 29, 1989; 58 FR 34205, June 23, 1993]

§ 799.1285 Cumene.

(a) *Identification of test substance.* (1) Cumene (isopropylbenzene, CAS No. 98–82–8) shall be tested in accordance with this section.

(2) Cumene 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.* All persons who manufacture (including import or byproduct manufacture) or process or intend to manufacture or process cumene, other than as an impurity, after September 9, 1988, to the end of the reimbursement period shall submit letters of intent to conduct testing, submit study plans, 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.

(c) *Health effects*—(1) *Oral and inhalation pharmacokinetic test*—(i) *Required testing.* Pharmacokinetic testing using the oral and inhalation routes shall be conducted with cumene in accordance with § 795.230 of this chapter.

(ii) *Reporting requirements.* (A) The pharmacokinetic testing shall be completed and the final report submitted to EPA within 15 months of the effective date of the final rule.

(B) Interim progress reports shall be submitted to EPA at 6-month intervals beginning 6 months after the effective date of the final rule, until the final report is submitted to EPA.

(2) *Subchronic inhalation toxicity*—(i) *Required testing.* (A) A subchronic inhalation toxicity test shall be conducted with cumene in accordance with § 798.2450 of this chapter except for the provisions of paragraphs (d)(1)(iv), (5), (6), (9), (12)(iii), (13)(i), and (e)(3)(iv)(D) of § 798.2450.

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

(*1*) *Animal selection—Numbers.* At least 30 animals (15 males and 15 females) shall be used for each test group.

(*2*) *Exposure conditions.* The animals shall be exposed to the test substance 6 hours per day, 5 days per week for 13 weeks (65 days of exposure).

(*3*) *Observation of animals.* Animals shall be weighed weekly, and their food and water consumption shall also be measured weekly.

(*4*) *Gross pathology.* The following additional organs shall be preserved in a suitable medium for future histopathological examination: The vas deferens, the oviducts, and the vagina.

(*5*) *Histopathology.* The accessory genital organs (epididymis), prostate, seminal vesicles) and the vagina shall be examined histopathologically. In addition, preparations of testicular and associated reproductive organ samples for histology shall follow the recommendations of Lamb and Chapin (1985) under paragraph (f)(1) of this section, or an equivalent procedure, with particular attention directed toward achieving optimal quality in the fixation and embedding, and including an evaluation of the spermatogenic pattern. Spermatid counts shall be performed as described by Johnson et al. (1980) and Blazak et al. (1985) under paragraphs (d) (2) and (3) of this section or an equivalent procedure. Epididymal sperm count and sperm morphology shall also be done.

(*6*) *Test report—Individual animal data.* The specific test report information shall include "Food and water consumption data."

(ii) *Reporting requirements.* (A) The subchronic toxicity test shall be completed and the final report submitted to EPA within 15 months of the effective date of the final rule.

(B) Interim progress reports shall be submitted to EPA at 6-month intervals beginning 6 months after the effective date of the final rule, until the final report is submitted to EPA.

(3) *Inhalation developmental toxicity—*(i) *Required testing.* An inhalation developmental toxicity test shall be conducted with cumene in accordance with § 798.4350 of this chapter.

(ii) *Reporting requirements.* (A) The inhalation developmental toxicity test shall be completed and the final report submitted to EPA within 15 months of the effective date of the final rule.

(B) Interim progress reports shall be submitted to EPA at 6-month intervals beginning 6 months after the effective date of the final rule, until the final report is submitted to EPA.

(4) *Neurotoxicity—*(i) *Required testing.* (A) Neurotoxicity tests shall be conducted with cumene by inhalation in accordance with §§ 798.6050, 798.6200, and 798.6400 of this chapter. Each test shall be performed for a period of 90 days.

(ii) *Reporting requirements.* (A) The neurotoxicity tests shall be completed and the final reports submitted to EPA within 15 months of the effective date of the final rule.

(B) Interim progress reports for each test shall be submitted to EPA at 6-month intervals beginning 6 months after the effective date of the final rule, until the applicable final report is submitted to EPA.

(5) *Two-generation reproductive effects—*(i) *Required testing.* A two-generation reproductive effects test shall be conducted with cumene in accordance with § 798.4700 of this chapter if either the gross or histopathological evaluation of the reproductive tissues in male or female exposed animals from the subchronic exposure test specified in paragraph (c)(2) of this section shows adverse effects or if significant alteration in reproductive organ weights occurs in the subchronic exposure test which can be related to exposure to cumene. EPA will hold a public program review, following submission of the subchronic toxicity test, to decide whether the two-generation reproductive effects test is to be required. If required, the test should be conducted using the oral route of exposure.

(ii) *Reporting requirements.* (A) The two-generation reproductive effects test shall be completed and the final report submitted to EPA within 29 months following EPA's notification to the test sponsor, through certified letter or FEDERAL REGISTER notice, that testing shall be initiated.

(B) Interim progress reports shall be submitted to EPA at 6-month intervals beginning 6 months after the date of EPA's notification to the test sponsor

that testing shall be initiated, until the final report is submitted to EPA.

(d) *Environmental effects*—(1) *Aquatic acute toxicity*—(i) *Required testing.* (A) Saltwater and freshwater invertebrate and vertebrate tests, in a flow-through system, shall be conducted with cumene on the following organisms: *Daphnia magna*, to be conducted in accordance with §797.1300 of this chapter; *Mysidopsis bahia* to be conducted in accordance with §797.1930 of this chapter, and *Salmo gairdneri* and *Cyprinodon variegatus* to be conducted in accordance with §797.1400 of this chapter except for the provisions in paragraph (d)(3)(iii) of §797.1400. The total and dissolved (e.g., filtered) concentrations of the test substance shall be measured in each test chamber and delivery chamber before the test and in each test chamber at 0, 24, and 48 hours (*Daphnia magna*) and 0, 48, and 96 hours (*Mysidopsis bahia*, *Salmo gairdneri*, and *Cyprinodon variegatus*) to ascertain whether it is in solution.

(B)(*1*) For the purpose of this section, the following provisions also apply:

(*2*) *Temperature.* The test temperature shall be 12° C for rainbow trout. Excursions from the test temperature shall be no greater than † 2° C. The temperature shall be measured at least hourly in one test chamber.

(ii) *Reporting requirements.* (A) The acute toxicity tests shall be completed and the final reports submitted to EPA within 18 months of the effective date of the final rule.

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

(2) *Aquatic chronic toxicity*—(i) *Required testing.* Aquatic chronic toxicity tests, in a flow-through system, shall be conducted with cumene on *Daphnia magna*, in accordance with §797.1330 of this chapter, and *Mysidopsis bahia*, in accordance with §797.1950 of this chapter, if the results of the acute toxicity tests conducted for those species under paragraph (d)(1) of this section show EC_{50} or LC_{50} of less than or equal to 1 mg/L. The total and dissolved (e.g., filtered) concentrations of the test substance shall be measured in each test chamber and the delivery chamber before the test and in each test chamber and the delivery chamber at 0, 7, 14, and 21 days to ascertain whether it is in solution.

(ii) *Reporting requirements.* (A) The acute toxicity tests conducted with *Daphnia magna*, *Salmo gairdneri*, and *Cyprinodon variegatus* shall be completed and the final reports submitted to EPA by March 9, 1990. The acute toxicity test conducted with *Mysidopsis bahia* shall be completed and the final report submitted to EPA by May 13, 1990.

(B) An interim progress report for each chronic test shall be submitted to EPA 18 months after the effective date of the final rule.

(3) *Aquatic early life stage toxicity*—(i) *Required testing.* Aquatic early life stage toxicity tests, in a flow-through system, shall be conducted with cumene on *Salmo gairdneri* and *Cyprinodon variegatus*, in accordance with §797.1600 of this chapter, if the results of the acute toxicity tests conducted for those species under paragraph (d)(1) of this section show LC_{50} of less than or equal to 1 mg/L.

(ii) *Reporting requirements.* (A) The early life stage toxicity tests, if required under paragraph (d)(3) of this section, shall be completed and the final reports submitted to EPA within 24 months of the effective date of the final rule.

(B) An interim progress report for each test shall be submitted to EPA 18 months after the effective date of the final rule.

(e) *Chemical fate*—(1) *Biodegradation*—(i) *Required testing.* Biodegradation testing in an aquatic system shall be conducted with cumene in accordance with the method described in an article by Bourquin et al. entitled "An Artificial Microbial Ecosystem for Determining Effects and Fate of Toxicants in a Salt-Marsh Environment," reprinted from Vol. 18 of the Society of Industrial Microbiology's *Developments in Industrial Microbiology*, chapter 11, 1977, 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 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