§ 799.19 Chemical imports and exports.

Persons who export or who intend to export chemical substances or mixtures listed in subpart B, subpart C, or subpart D of this part are subject to the requirements of 40 CFR part 707.

[71 FR 66245, Nov. 14, 2006]

Subpart B—Specific Chemical Test Rules

§ 799.1053 Trichlorobenzenes.

(a) Identification of testing substance.

(1) 1,2,3- and 1,2,4-trichlorobenzenes, CAS Numbers 87–61–6 and 120–82–1 respectively, shall be tested in accordance with this section.

(2) The substances identified in paragraph (a)(1) of this section shall be 99 percent pure and shall be used as the test substances in each of the tests specified.

(3) For health effects testing required under paragraph (e) of this section, the test substance shall not contain more than 0.05 percent benzene and 0.05 percent hexachlorobenzene.

(b) Persons required to submit study plans, conduct tests, and submit data.

(1) All persons who manufacture or process substances identified in paragraph (a)(1) of this section, other than an impurity, from May 21, 1986, to the end of the reimbursement period, shall submit a letter of intent to test or exemption applications and shall conduct tests, in accordance with part 792 of this chapter, and submit data as specified in 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) and § 790.87(a)(1)(ii) of this chapter.

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

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

(5) For health effects testing required under paragraph (e) of this section, all persons who manufacture (import) or process 1,2,4-trichlorobenzene, other than as an impurity, after the effective date of this rule (August 21, 1986) to the end of the reimbursement period shall submit letters of intent to conduct testing or exemption applications, submit study plans, conduct tests, and submit data as specified in this section, subpart A of this part, and parts 790 and 792 of this chapter for single-phase rulemaking.

(c) [Reserved]

(d) Environmental effects testing.

1,2,3- and 1,2,4-trichlorobenzenes shall be tested in accordance with this section.

(i) Marine invertebrate acute toxicity testing—(1) Required testing. Testing using measured concentrations, flow through or static renewal systems, and systems that control for evaporation of the test substance, shall be conducted for 1,2,3- and 1,2,4-trichlorobenzenes. Testing shall be conducted with mysid shrimp (Mysidopsis bahia) to develop data on the acute toxicity of the above chlorobenzene isomers to marine invertebrates.

(ii) Test standards. The marine invertebrate (mysid shrimp, Mysidopsis bahia) acute toxicity testing for 1,2,3- and 1,2,4-trichlorobenzenes shall be conducted in accordance with § 797.1930 of this chapter.

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

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

(ii) Marine fish acute toxicity testing—

(1) Required testing. Testing using measured concentrations, flow through systems, and systems that control for evaporation of the test substance shall be conducted for 1,2,3-trichlorobenzene. Testing shall be conducted with Silversides (Menidia menidia) to develop data on the acute toxicity of 1,2,3-trichlorobenzene to saltwater fish.
(ii) Test standard. The marine fish (silverside minnow, *Menidia menidia*) acute toxicity test shall be conducted for 1,2,3-trichlorobenzene in accordance with §797.1400 of this chapter.

(iii) Reporting requirements. (A) The marine fish (silverside minnow, *Menidia menidia*) acute toxicity test shall be completed and the final results submitted within 1 year of the effective date of the Phase II final test rule.

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

(3) Freshwater fish acute toxicity testing—(i) Required testing. Testing using measured concentrations, flow through systems, and systems that control evaporation of the test substance shall be conducted for 1,2,3-trichlorobenzene. A 96-hour LC50 test shall be conducted with the fathead minnow (*Pimephales promelas*) to develop data on the acute toxicity of 1,2,3-trichlorobenzene to freshwater fish.

(ii) Test standard. The freshwater fish (fathead minnow, *Pimephales promelas*) acute toxicity test shall be conducted for 1,2,3-trichlorobenzene in accordance with §797.1400 of this chapter.

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

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

(4) Freshwater invertebrate acute toxicity testing—(i) Required testing. Testing using measured concentrations, flow through or static renewal systems, and systems that control for evaporation of the test substance shall be conducted for 1,2,3-trichlorobenzene. A 96-hour EC50 shall be conducted for one species of *Gammarus* to develop data on the acute toxicity of 1,2,3-trichlorobenzene to aquatic freshwater invertebrates.

(ii) Test standard. The freshwater invertebrate (Gammarus sp.) acute toxicity test shall be conducted for 1,2,3-trichlorobenzene in accordance with §795.120 of this chapter.

(iii) Reporting requirements. (A) The freshwater invertebrate acute toxicity test shall be completed and the final report submitted to EPA within 411 days 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.

(5) Mysid shrimp chronic toxicity testing—(i) Required testing. Testing using measured concentrations, flow through or static renewal systems, and systems that control for evaporation of the test substance shall be conducted for 1,2,4-trichlorobenzene. Testing shall be conducted with mysid shrimp (*Mysidopsis bahia*) to develop data on the chronic toxicity of 1,2,3-trichlorobenzene, should the acute LC50 of this chemical to mysid shrimp be determined to be less than 1 ppm.

(ii) Test standards. The mysid shrimp (*Mysidopsis bahia*) chronic toxicity test shall be conducted for 1,2,4-trichlorobenzene in accordance with §797.1950 of this chapter. Testing shall also be conducted according to §797.1950 for 1,2,3-trichlorobenzene should the results of testing required by (d)(1)(ii) of this section yield an acute LC50 for this chemical substance of less than 1 ppm.

(iii) Reporting requirements. (A) The mysid shrimp chronic toxicity test for 1,2,4-trichlorobenzene shall be completed and the final report submitted to EPA within 1 year of the effective date of the final Phase II rule. The mysid shrimp chronic toxicity test for 1,2,3-trichlorobenzene, (required if the LC50 is less than 1 ppm), shall be completed and final report submitted to EPA within 15 months of the effective date of the final Phase II rule.

(B) 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 until the final report is submitted to EPA.

(e) Health effects testing—(1) Oncogenicity—(i) Required testing. A test for oncogenic effects shall be conducted with 1,2,4-TCB in accordance with §796.3300 of this chapter.
(B) The route of administration for the oncogenicity testing for 1,2,4-TCB shall be via the animal feed.

(C) Two rodent species shall be used and one shall be the Fischer-344 rat.

(i) Reporting requirements. (A) The oncogenicity test shall be completed and the final results submitted to EPA by June 30, 1994.

(B) Progress reports shall be submitted to the Agency every 6 months after the effective date of the final rule.

(ii) Effective date. (1) The effective date of the final phase II rule is August 14, 1987, except for paragraphs (d)(4)(iii)(A) and (e)(1)(ii)(A) of this section. The effective date for paragraph (d)(4)(iii)(A) of this section is March 1, 1990. The effective date for paragraph (e)(1)(ii)(A) of this section is June 12, 1992.

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

§ 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.

(b) Persons required to submit study plans, conduct tests, and submit data. All persons who manufacture (including import) 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 rule-making. Persons who manufacture or process DGBE are subject to the requirements to test DGBE in this section. Only persons who manufacture or process DGBA are subject to the requirements to test DGBA in this section.

(c) Health effects testing—(1) Subchronic toxicity—(i) Required testing. (A) A 90-day subchronic toxicity test of DGBE shall be conducted in rats by dermal application in accordance with § 798.2250 of this chapter except for the provisions in paragraphs (e)(9)(iv), (10)(i)(A) and (ii)(B), (11) (ii) and (iii), and (12)(i) of § 798.2250.

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

(1) A satellite group to evaluate fertility shall be established. Control males shall be cohabited with control females, and males and females administered the high dose shall be cohabited. Endpoints to be evaluated shall include percent mated; percent pregnant; length of gestation; litter size; viability at birth, on Day 4, and weaning, on Day 21; sex of the offspring; and litter weights at birth and Days 4, 7, 14, and 21. Litters shall be standardized on day 4 in accordance with the reproductive and fertility effects guideline, § 798.4700(c)(6)(iv) of this chapter. Gross examinations shall be made at least once each day and physical or behavioral anomalies in the dam or offspring shall be recorded. At weaning, dams shall be sacrificed and examined for resorption sites indicative of post-implantation loss. An additional 20 males and 40 females will have to be added to the subchronic study of this test. If the animals in the high dose group exhibit marked toxicity (e.g. greater than 20 percent weight loss), then the fertility tests shall be conducted in the next highest dose group.

(2) Cage-side observations shall include, but not be limited to, changes in skin and fur; eyes and mucous membranes; respiratory, circulatory autonomic, and central nervous systems; somatomotor activity; and behavior pattern. In addition a daily examination for hematuria shall be done.

(3) Certain hematological determinations shall be carried out at least three times during the study period.