of TSCA must adhere to the TSCA GLP's. Sponsors must notify the laboratory that the study is being conducted pursuant to TSCA section 4. Sponsors are also responsible for ensuring that laboratories conducting the test abide by the TSCA GLP standards. In accordance with §792.12 of this chapter, a certification concerning adherence to the TSCA GLP's must be submitted to EPA.

§799.11 Availability of test guidelines.

(a) The TSCA and FIFRA guidelines for the various study plans are available from the National Technical Information Service (NTIS). Address and telephone number: National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703–487–4650).

(b) The OECD guidelines for the various study plans are available from the following address: OECD Publication and Information Center, 1750 Pennsylvania Ave., NW., Washington, DC 20006 (202–724–1857).

§799.12 Test results.

Except as set forth in specific chemical test rules in subpart B of this part, a positive or negative test result in any of the tests required under subpart B is defined in the TSCA test guidelines published by NTIS.

§799.17 Effects of non-compliance.

Any person who fails or refuses to comply with any aspect of this part or part 790 is in violation of section 15 of TSCA. EPA will treat violations of Good Laboratory Practice Standards as indicated in §792.17 of this chapter.

§799.19 Chemical imports and exports.

Persons who export or who intend to export substances listed in subpart B or subpart C of this part are subject to the requirements of part 707 of this title.

[51 FR 23718, June 30, 1986]

Subpart B—Specific Chemical Test Rules

§799.500 Anthraquinone.

(a) *Identification of test substance.* (1) 9,10-anthraquinone (CAS No. 84–65–1) (hereinafter "anthraquinone") shall be tested in accordance with this section.

(2) Anthraquinone 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, import or process anthraquinone, other than as an impurity, from July 20, 1987 to the end of the reimbursement period shall submit letters of intent to conduct testing or exemption applications, submit study plans, conduct tests (in accordance with part 792 of this chapter), and submit data as specified in this section, subpart A of this part, and part 790 of this chapter for single-phase rulemaking.

(c) *First tier chemical fate and environmental effects testing*—(1) *Water solubility*—(i) *Required testing.* Water solubility tests shall be conducted with anthraquinone in accordance with the test guideline specified under §796.1860 of this chapter. The tests shall be conducted at 12 °C and 22 °C for use in tests with cold and warm water species.

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

(B) A progress report shall be submitted 6 months after the effective date of the final rule.

(2) *Fish acute toxicity*—(i) *Reqired testing.* (A) Fish acute toxicity tests shall be conducted with Anthraquinone using chinook salmon, *Oncorhynchus tshawytscha*, or coho salmon, *Oncorhynchus kisutch* (cold water species); bluegill, *Lepomis macrochirus* (warm water species); and rainbow trout, *Salmo gairdneri* (cold water species) in accordance with the test guideline specified under §797.1400 of this chapter, except for paragraphs (c)(4)(i) and (6)(iii)(A)(*2*) of §797.1400.

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

(*1*) A minimum of 20 fish each shall be exposed to each of five or more test substance concentrations. The highest concentration shall be less than or equal to the solubility limit of anthraquinone. At least one concentration shall be between 1 part per billion (ppb) and 10 ppb.

(2) 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 to ascertain whether it is in solution.

(3) The test shall be performed under flowthrough conditions.

(4) In each chamber at 4, 7, and 14 days. If no dose-dependent mortality is observed by days 7 and 14, the concentration of dissolved test substance shall be measured in the chambers with the two highest concentrations only.

(ii) *Reporting requirements.* (A) The fish acute toxicity tests for chinook salmon, *Oncorhynchus tshawytscha,* or coho salmon, *Oncorhynchus kisutch,* and rainbow trout, *Salmo gairdneri,* shall be completed and the final results submitted to EPA within 12 months of the effective date of the final rule. The fish acute toxicity test for bluegill, *Lepomis macrochirus,* shall be completed and the final results submitted to EPA within 14 months of the effective date of the final rule.

(B) A progress report shall be submitted 6 months after the effective date of the final rule.

(3) *Aquatic invertebrate acute toxicity—*(i) *Required testing.* (A) Aquatic invertebrate acute toxicity tests shall be conducted with anthraquinone using *Daphnia magna* or *D. pulex* and oyster, *Crassostrea virginica,* using the test guidelines specified under §§ 797.1300 and 797.1800 of this chapter, except for paragraph (c)(4)(ii) of § 797.1300.

(B) For the purpose of this section as it relates to § 797.1300 of this chapter, the following provisions also apply:

(*1*) A minimum of 20 daphnids per concentration shall be exposed to five or more concentrations of the test substance chosen in a geometric series in which the ratio is between 1.5 and 2.0 (e.g., 2, 4, 8, 16, 32, and 64 milligrams per liter (mg/L)). The highest concentration shall be less than or equal to the solubility limit of anthraquinone. At least one concentration shall be between 1 ppb and 10 ppb. An equal number of daphnids shall be placed in two or more replicates. If solvents, solubilizing agents or emulsifiers have to be used, they shall be commonly used carriers and shall not possess a synergistic or antagonistic effect on the toxicity of the test chemical. The concentration of solvent shall not exceed 0.1 milliliter per liter (ml/l).

(*2*) The test shall be performed under flowthrough conditions.

(*3*) 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 to ascertain whether it is in solution.

(*4*) The stability of the stock solution for the duration of the experiment must be analyzed and reported.

(*5*) The pH of the test solution shall be 7.

(C) For the purpose of this section as it relates to § 797.1800 of this chapter the following provisions also apply:

(*1*) The highest test concentration shall be less than or equal to the solubility limit of anthraquinone.

(*2*) At least one test concentration shall be between 1 ppb and 10 ppb.

(*3*) 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 to ascertain whether it is in solution.

(ii) *Reporting requirements.* (A) The invertebrate acute toxicity tests shall be completed and the final results submitted to EPA within 14 months of the effective date of the final rule.

(B) A progress report shall be submitted 6 months after the effective date of the final rule.

(4) *Sediment toxicity to benthic invertebrates—*(i) *Required testing.* A sediment toxicity test shall be conducted using one of the following two methods. (A) *Rhepoxynius* partial life cycle toxicity in sediment: A 10-day toxicity test in a static seawater system shall be conducted with the marine amphipod, *Rhepoxynius abronius,* using clean sediments having low, medium, and high organic carbon content spiked with anthraquinone in the concentration range of 0.01 to 1 part per million (ppm), according to the test guideline specified in the American Society for Testing and Materials Special Technical Testing Publication 854 (ASTM STP 854) entitled, "Phoxocephalid Amphipod Bioassay for Marine Sediment Toxicity," by R.C. Swartz, W.A. DeBen, J.K.P. Jones, J.O. Lamberson,

and F.A. Cole and published in *Aquatic Toxicology and Hazard Assessment: Seventh Symposium,* ASTM STP 854, pp. 284–307, R.D. Caldwell, R. Purdy, and R.C. Bahner, Eds., 1985, which is incorporated by reference. (B) *Chironomus* partial life cycle toxicity in sediment: A 14-day toxicity test in a flowthrough system shall be conducted with the freshwater midge, *Chironomus tentans,* using clean, natural sediments having low, medium, and high organic carbon content spiked with anthraquinone in the concentration range of 0.01 to 1 ppm, according to the test guideline specified in the American Society for Testing and Materials Special Technical Testing Publication 854 (ASTM STP 854) entitled, "Aquatic Safety Assessments of Chemicals Sorbed to Sediments," by W.J. Adams, R.A. Kimerle, and R.G. Mosher and published in *Aquatic Toxicology and Hazard Assessment: Seventh Symposium,* ASTM STP 854, pp. 429–452, R.D. Caldwell, R. Purdy, and R.C. Bakner, Eds., 1985, which is incorporated by reference. The ASTM STP 854 is available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC. This incorporation by reference was approved by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This material is incorporated as it exists on the effective date of this rule, and a notice of any change in this material will be published in the FEDERAL REGISTER. Copies of the incorporated material may be obtained from the TSCA Public Docket Office (TS–793), Rm. NE–G004, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, or from the American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103.

(ii) *Reporting requirements.* (A) The sediment toxicity test shall be completed and the final results submitted to the Agency within 2 years of the effective date of the final rule.

(B) Progress reports shall be submitted at 6-month intervals beginning 6 months after the effective date of the final rule.

(5) *Bioconcentration*—(i) *Required testing.* (A) A bioconcentration test shall be conducted with anthraquinone using oyster, *Crassostrea virginica,* in accordance with the test guideline specified under § 797.1830 of this chapter, except for paragraphs (c)(4) (ii) and (vi)(A) of § 797.1830.

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

(*1*) At least two concentrations shall be tested which are at least a factor of 10 apart to assess the propensity of the substance to bioconcentrate. The concentrations selected should not stress or adversely affect the oysters and should be less than one-tenth the EC50 determined in either the range-finding or 96-hour definitive test under § 797.1800 of this chapter. The test concentrations shall be less than the solubility limit of the test substance in water and shall be close to 1 ppb to 10 ppb. The limiting factor of how low one can test is based on the detection limits of the analytical methods. The concentration of the test substance in the test solution should be at least 10 times greater than the detection limit in water.

(*2*) The test shall not be started until the test substance delivery system has been observed to be functioning properly and the test substance concentrations have equilibrated (i.e, the concentration does not vary more than 20 percent). Analyses of two sets of test solution samples taken prior to test initiation should document this equilibrium. At initiation (time 0), the total and dissolved (e.g, filtered) concentrations of test substance shall be measured in the delivery chamber and each test chamber prior to the addition of oysters to the test chambers to ascertain whether it is in solution.

(ii) *Reporting requirements.* (A) The bioconcentration test shall be completed and the final results submitted to EPA within 21 months of the effective date of the final rule.

(B) Progress reports shall be submitted at 6-month intervals beginning 6 months after the effective date of the final rule.

(d) *Second-tier chemical fate and environmental effects testing.* The following second-tier tests shall be conducted if EPA determines that the total annual volume of anthraquinone manufactured and imported in the United States dur-

; a single calendar year exceeds 3 llion pounds, and the acute toxicity ;ting triggers described in this para- ıph are met. EPA will monitor the)duction and importation volume of thraquinone by the requirement ıer §704.30 of this chapter that man- ıcturers and importers of thraquinone submit section 8(a) re- :ts to the Agency. EPA will publish ;ification in the FEDERAL REGISTER notify the test sponsors by certified ter if the manufacture/importation ume trigger and an acute toxicity gger are met.

1) *Biodegradability in activated sludge tems*—(i) *Required testing.* (A))degradability tests in activated dge systems shall be conducted with thraquinone in accordance with the t method entitled "Inherent degradability: Modified SCAS (semi- ıtinuous activated sludge) test for emical substances that are water in- uble or water insoluble and volatile" specified under §795.45 of this chap- except for paragraphs (b)(2)(i) (E), and (iii)(C) of §795.45, if EPA deter- nes that the production/importation ume of anthraquinone in the United ıtes during a single calendar year eeds 3 million pounds, and any of following conditions is met:

l) The LC50 of the most sensitive ı or the EC50 of the daphnid or oys- , as determined by the acute tox- ty tests conducted in accordance h paragraph (c) (2) or (3) of this sec- n, respectively, is less than 100 ıes the predicted environmental con- ıtration (PEC) in water, i.e., less ın 500 ppb;

2) The LC50 of *Rhepoxynius* or *ronomus*, as determined by the sedi- nt toxicity test conducted in accord- e with paragraph (c)(4) of this sec- n, is less than 100 times the PEC in iment, i.e., less than 10 ppm; or

3) The oyster bioconcentration fac- , as determined by the oyster concentration test conducted in ac- dance with paragraph (c)(5) of this tion, is greater than 3,000.

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

l) A stock solution of C^{14}-labeled thraquinone shall be prepared at a ıcentration of 2 mg/L which gives a t substance concentration of 0.1 mg/L anthraquinone at the start of each aeration cycle if no biodegradation is occurring.

(*2*) If anthraquinone is insoluble in water at 2 mg/L, it may be necessary to use ultrasound dispersion to obtain a uniform stable suspension. Alternatively, C^{14}-labeled anthraquinone may be added directly to the aeration units to give a concentration of 0.1 mg/L anthraquinone at the start of each aeration cycle.

(*3*) One hundred ml of settled sewage are added to the control units, and 95 ml of settled sewage plus 5 ml of the C^{14}-labeled anthraquinone stock solution or suspension (2 mg anthraquinone/l) are added to the test units. If test substance is added directly to aeration units, 100 ml of settled sewage are added, as in the control units.

(ii) *Reporting requirements.* (A) The biodegradability tests in activated sludge systems shall be completed and the final results submitted to the Agency within 1 year of the date of EPA's notification of the test sponsor by certified letter or FEDERAL REGISTER notice announcing that the total annual volume of anthraquinone manufactured and imported in the United States during a single calendar year exceeds 3 million pounds and that one or more of the triggers described in paragraph (d)(1)(i) of this section has been met.

(B) A progress report shall be submitted 6 months after EPA's notification of the test sponsor by certified letter or the publication of the FEDERAL REGISTER notice announcing that testing is necessary.

(2) *Biodegradation rate*—(i) *Required testing.* Biodegradation rate tests shall be conducted with anthraquinone at concentrations at or below the water solubility as determined under the testing specified in paragraph (c)(1)(i) of this section, and close to the predicted environmental concentration in sediment, i.e., 0.1 ppm, in accordance with the test guideline described in the article by A.W. Bourquin et al. entitled "An Artificial Microbial Ecosystem for Determining Effects and Fate of Toxicants in a Salt-Marsh Environment," if EPA determines that the production/importation volume of anthraquinone

in the United States during a single calendar year exceeds 3 million pounds, and any of the following conditions is met:

(A) The LC50 of the most sensitive fish species or the EC50 for the daphnid or oyster, as determined by the acute toxicity tests conducted in accordance with paragraphs (c) (2) and (3) of this section respectively, is less than 100 times the predicted environmental concentration (PEC) in water, i.e., less than 500 ppb;

(B) The LC50 of *Rhepoxynius* or *Chironomus*, as determined by the sediment toxicity test conducted in accordance with paragraph (c)(4) of this section, is less than 100 times the PEC in sediment, i.e., less than 10 ppm; or

(C) The oyster bioconcentration factor, as determined by the oyster bioconcentration test conducted in accordance with paragraph (c)(5) of this section, is greater than 3,000. The A.W. Bourquin et al. article, entitled "An Artificial Microbial Ecosystem for Determining Effects and Fate of Toxicants in a Salt-Marsh Environment" published in *Developments in Industrial Microbiology*, Vol. 18, chapter 11, 1977, is incorporated by reference and is available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC. This incorporation by reference was approved by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This material is incorporated as it exists on the date of approval, and a notice of any change in this material will be published in the FEDERAL REGISTER. Copies of the incorporated material may be obtained from the TSCA Public Docket Office (TS–793), Rm. NE–G004, Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, or from the Society for Industrial Microbiology, P.O.Box 12534, Arlington, VA 22209–8534.

(ii) *Reporting requirements.* (A) Biodegradation rate tests shall be completed and the final results submitted to the Agency within 1 year of the date of EPA's notification of the test sponsor by certified letter or a FEDERAL REGISTER notice announcing that the total annual volume of anthraquinone manufactured and imported in the United States during a single calendar year exceeds 3 million pounds and that one or more of the triggers described in paragraph (d)(2)(i) of this section has been met.

(B) A progress report shall be submitted 6 months after EPA's notification of the test sponsor by certified letter or the publication of the FEDERAL REGISTER notice announcing that testing is necessary.

(3) *Fish chronic toxicity*—(i) *Required testing.* (A) Fish chronic toxicity tests shall be conducted with anthraquinone in accordance with the test guideline specified under §797.1600 of this chapter, except for paragraph (c)(6)(iv) of §797.1600, if EPA determines that the production/importation volume of anthraquinone in the United States during a single calendar year exceeds 3 million pounds, and if the most sensitive fish species (with the lowest median lethal concentration (LC50)) in the acute toxicity tests conducted in accordance with paragraph (c)(2) of this section has an LC50 less than 100 times the predicted environmental concentration (PEC) in water, i.e., less than 500 ppb.

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

(*1*) Prior to the addition of the test substance to the dilution water, it is recommended that the test substance stock solution be analyzed to verify the concentration. After addition of the test substance, the total and dissolved (e.g., filtered) concentrations of the test substance shall be measured at the beginning of the test in each test chamber and delivery chamber to ascertain whether it is in solution. The concentration of test substance shall be measured in one replicate at each test concentration at least once a week thereafter. Replicates should be alternated each week. If a malfunction in the delivery system is discovered, water samples shall be taken immediately from the affected test chambers and analyzed.

(*2*) The highest concentration shall be less than or equal to the solubility limit of anthraquinone.

(*3*) At least one test concentration shall be between 1 ppb and 10 ppb.

(ii) *Reporting requirements.* (A) Fish chronic toxicity tests shall be com-

pleted and the final results submitted to the Agency within 2 years of the date of EPA's notification of the test sponsor by certified letter or a FEDERAL REGISTER notice announcing that the total annual volume of anthraquinone manufactured and imported in the United States during a single calendar year exceeds 3 million pounds and that the trigger described in paragraph (d)(3)(i)(A) of this section has been met.

(B) Progress reports shall be submitted at 6-month intervals beginning 6 months after EPA's notification of the test sponsor by certified letter or the publication of the FEDERAL REGISTER notice announcing that testing is necessary.

(4) *Daphnid chronic toxicity*—(i) *Required testing.* (A) Daphnid chronic toxicity test shall be conducted with anthraquinone using *Daphnia magna* or *D. pulex* in accordance with the test guideline specified under § 797.1330 of this chapter, except for paragraph (c)(4)(ii) of § 797.1330, if EPA determines that the total annual volume of anthraquinone manufactured and imported in the United States during a single calendar year exceeds 3 million pounds, and the median effective concentration (EC50) determined in accordance with paragraph (c)(3) of this section is less than 100 times the PEC in water, i.e., less than 500 ppb.

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

(*1*) A minimum of 20 daphnids per concentration shall be exposed to five or more concentrations of the substance chosen in a geometric series in which the ratio is between 1.5 and 2.0, (e.g., 2, 4, 8, 16, 32, 64 mg/L). An equal number of daphnids shall be placed in two or more replicates. The highest concentration shall be less than or equal to the solubility of anthraquinone. At least one concentration shall be between 1 ppb and 10 ppb. Solutions shall be analyzed for chemical concentration prior to use and at designated times during the test.

(*2*) The pH of the test solution shall be 7.

(*3*) The total and dissolved (e.g., filtered) concentrations of test substance shall be measured in each test chamber and the delivery chamber before the test to ascertain whether it is in solution.

(*4*) The test shall be performed under flowthrough conditions;

(*5*) The stability of the stock solution for the duration of the experiment must be analyzed and reported.

(ii) *Reporting requirements.* (A) The daphnid chronic toxicity test shall be completed and the final results submitted to the Agency within 2 years of the date of EPA's notification of the test sponsor by certified letter or a FEDERAL REGISTER notice announcing that the total annual volume of anthraquinone manufactured and imported in the United States during a single calendar year exceeds 3 million pounds and that the trigger described in paragraph (d)(4)(i) of this section has been met.

(B) Progress reports shall be submitted at 6-month intervals beginning 6 months after EPA's notification of the test sponsor by certified letter or the publication of the FEDERAL REGISTER notice announcing that the testing is necessary.

(e) *Effective date.* (1) The effective date of this final rule is July 20, 1987, except for paragraphs (c)(2)(i)(A), (c)(2)(i)(B)(*4*), (c)(2)(ii)(A), (c)(3)(ii)(A), and (c)(5)(ii)(A) of this secton. The effective date for paragraphs (c)(2)(i)(A), (c)(2)(i)(B)(*4*), (c)(2)(ii)(A), (c)(3)(ii)(A), and (c)(5)(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.

[52 FR 21028, June 4, 1987, as amended at 53 FR 12526, Apr. 15, 1988; 54 FR 27354, June 29, 1989; 55 FR 7324, Mar. 1, 1990; 58 FR 34205, June 23, 1993]

§ 799.925 Biphenyl.

(a) *Identification of test substance.* (1) Biphenyl (CAS No. 92–52–4) shall be tested in accordance with this rule.

(2) Biphenyl 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 or process Biphenyl from the effective date of this rule [October 28, 1985] to the end of the reimbursement period shall submit letters of intent to conduct testing or ex-