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-

emption applications, submit study plans, conduct tests and submit data as specified in this section, subpart A of this part, and part 790—*Test Rule Development and Exemption Procedures* of this chapter.

(c) *Environmental effects testing*—(1) *Fish early life stage toxicity testing*—(i) *Required testing.* Testing using flow-through systems shall be conducted with rainbow trout to develop data on the chronic toxicity of biphenyl to aquatic vertebrates.

(ii) *Test standard.* The test shall be conducted in accordance with the revised EPA-approved modified study plan submitted to EPA by the Biphenyl Work Group: "Embryo-Larval Toxicity Test with Rainbow Trout, *Salmo gairdneri* Richardson." This revised EPA-approved modified study plan, with modifications approved by EPA on August 7, 1987, and October 16, 1987, is available for inspection in EPA's OPPTS Reading Room, Rm. NE G–004, 401 M St. SW., Washington, DC 20460. Copies of this study plan are available to the public in the OPPTS reading room.

(iii) *Reporting requirements.* The embryo-larval toxicity test of biphenyl with rainbow trout shall be completed and a final report submitted to the Agency within 72 weeks of the effective date of the final Phase II rule. However, if this study is performed before the flow-through chronic toxicity test with *Daphnia magna* described in paragraph (c)(2) of this section, then the final report for this rainbow trout early-life-stage shall be completed and a final report submitted to the Agency within 42 weeks from the effective date of the final Phase II rule. Progress reports shall be submitted at 6-month intervals beginning 6 months after the effective date of the final Phase II rule.

(2) *Daphnid chronic toxicity testing*—(i) *Required testing.* Testing using flow-through systems shall be conducted with daphnids to develop data on the chronic toxicity of biphenyl to aquatic invertebrates.

(ii) *Test standard.* The test shall be conducted in accordance with the revised EPA-approved modified study plan submitted to EPA by the Biphenyl Work Group: "Flow-Through Chronic Toxicity Test with *Daphnia magna* Straus." This revised EPA-approved modified study plan, with modifications approved by EPA on August 7, 1987, and October 16, 1987, is available for inspection in EPA's OPPTS Reading Room, Rm. NE G–004, 401 M St. SW., Washington, DC 20460. Copies of this study plan are available to the public in the OPPTS reading room.

(iii) *Reporting requirements.* The flow-through chronic toxicity test of biphenyl with *Daphnia magna* shall be completed and a final report submitted to the Agency within 30 weeks from the effective date of the final Phase II rule. However, if the embryo-larval toxicity test with rainbow trout described in paragraph (c)(1) of this section is performed before this study, then the final report for this chronic *Daphnia magna* study shall be completed and a final report submitted to the Agency within 72 weeks from the effective date of the final Phase II rule. Progress reports shall be submitted at 6-month intervals beginning 6 months after the effective date of the final Phase II rule.

(3) *Oyster acute toxicity testing*—(i) *Required testing.* Testing using systems that control for biphenyl evaporation shall be conducted with oysters to develop data on the acute toxicity of sediment-associated biphenyl to benthic invertebrates.

(ii) *Test standard.* The testing shall be conducted in accordance with the revised EPA-approved modified study plan submitted to EPA by the Biphenyl Work Group: "Oyster Shell Deposition Bioassay and Range-finding Study". This revised EPA-approved modified study plan is available for inspection in EPA's OPPTS Reading Room, Rm. NE–G004, 401 M Street, SW., Washington, DC 20460; copies of this study plan are available for distribution to the public in the OPPTS Reading Room.

(iii) *Reporting requirements.* The oyster shell deposition and range-finding study with biphenyl shall be completed and a final report submitted to EPA within 515 days from the effective date of the final Phase II rule. Progress reports shall be submitted at 6–month intervals beginning 6 months after the effective date of the final Phase II rule.

(4) *Oyster bioconcentration testing*—(i) *Required testing.* Testing using systems that control for biphenyl evaporation

shall be conducted with oysters to develop data on the potential chronic toxicity and bioconcentration of sediment-associated biphenyl to benthic invertebrates.

(ii) *Test standard.* The testing shall be conducted in accordance with the revised EPA-approved modified study plan submitted to EPA by the Biphenyl Work Group: "Flow-Through Oyster Bioconcentration Study". This revised EPA-approved modified study plan is available for inspection in EPA's OPPTS Reading Room, Rm. NE–G004, 401 M Street, SW., Washington, DC 20460; copies of this study plan are available for distribution to the public in the OPPTS Reading Room.

(iii) *Reporting requirements.* The oyster bioconcentration study shall be completed and a final report submitted to the Agency within 87 weeks from the effective date of the final Phase II rule. Progress reports shall be submitted at 6-month intervals beginning 6 months after the effective date of the final Phase II rule.

(d) *Chemical fate testing*—(1) *Aerobic biodegradation*—(i) *Required testing.* Testing using systems that control for and quantify biphenyl evaporation that use a ratio of undisturbed sediment to water of 3:1—2:1 and that provide a mass balance of biphenyl distributed in water and sediment, volatilized or degraded to CO_2 or other products before and after biodegradation shall be conducted to develop data on the persistence of biphenyl in aerobic sediments.

(ii) *Test standard.* The testing shall be conducted in accordance with the revised EPA-approved modified study plan submitted to EPA by the Biphenyl Work Group: "Aerobic Biodegradation Study." This revised EPA-approved modified study plan, with modifications approved by EPA on October 13, 1987, is available for inspection in EPA's OPPTS Reading Room, Rm. NE G–004, 401 M St. SW., Washington, DC 20460. Copies of this study plan are available to the public in the OPPTS reading room.

(iii) *Reporting requirements.* The aerobic biodegradation study with biphenyl shall be completed and a final report submitted to the Agency within 52 weeks of the effective date of the final Phase II rule. Progress reports shall be submitted at 6-month intervals beginning 6 months after the effective date of the final Phase II rule.

(2) *Anaerobic biodegradation*—(i) *Required testing.* Testing using systems that control for and quantify biphenyl evaporation that use a ratio of undisturbed sediment to water of 3:1—2:1 and that provide a mass balance of biphenyl distributed in water and sediment, volatilized or degraded to CO_2 or other products before and after biodegradation shall be conducted with biphenyl to develop data on the persistence of biphenyl in anaerobic sediments.

(ii) *Test standard.* The testing shall be conducted in accordance with the revised EPA-approved modified study plan submitted to EPA by the Biphenyl Work Group: "Anaerobic Biodegradation Study." This revised EPA-approved modified study plan, with modifications approved by EPA on October 13, 1987, is available for inspection in EPA's OPPTS Reading Room, Rm. NE G–004, 401 M St. SW., Washington, DC 20460. Copies of this study plan are available to the public in the OPPTS reading room.

(iii) *Reporting requirements.* The anaerobic biodegradation study with biphenyl shall be completed and a final report submitted to EPA within 64 weeks of the effective date of the final Phase II rule. Progress reports shall be submitted at 6-month intervals beginning 6 months after the effective date of the final Phase II rule.

(3) *Partitioning water/sediment study*—(i) *Required testing.* Testing using systems that control for and quantify biphenyl evaporation that use a ratio of undisturbed sediment to water of 1:3 shall be conducted with biphenyl to develop data on the partitioning of biphenyl to water and sediment.

(ii) *Test standard.* The testing shall be conducted in accordance with the revised EPA-approved modified study plan submitted to EPA by the Biphenyl Work Group: "Partitioning Water/Sediment Study." This revised EPA-approved modified study plan, with modifications approved by EPA on October 13, 1987, is available for inspection in EPA's OPPTS Reading Room, Rm. NE G–004, 401 M St., SW., Washington, DC 20460. Copies of this study plan are

available to the public in the OPPTS reading room.

(iii) *Reporting requirements.* The partitioning water/sediment testing shall be completed and a final report submitted to EPA by June 1, 1988, for the river test, and by July 15, 1988, for the lake test. Progress reports shall be submitted to EPA at 6-month intervals beginning 6 months after the effective date of the final Phase II rule.

(e) *Effective date.* (1) The effective date of this final Phase II rule for biphenyl is July 17, 1987, except for paragraph (c)(3)(iii) of this section. The effective date for paragraph (c)(3)(iii) 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.

[50 FR 37188, Sept. 12, 1985, as amended at 52 FR 20713, June 3, 1987; 54 FR 27354, June 29, 1989; 55 FR 7324, Mar. 1, 1990; 58 FR 34205, June 23, 1993]

§ 799.940 Bisphenol A.

(a) *Identification of test substance.* (1) Bisphenol A (CAS Number 80–05–7) (hereinafter"BPA") shall be tested in accordance with this section.

(2) BPA of at least 99 percent purity shall be used as the test substance.

(3) BPA shall be administered as a dust for inhalation with a target mass median aerodynamic diameter of 0.1 to 5 micrometers.

(b) *Persons required to submit study plans, conduct tests, and submit data.* All persons who manufacture or process BPA, other than as an inpurity, November 3, 1986 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 testing*—(1) *Required inhalation toxicity testing.* Subchronic toxicity and recovery testing including the satellite test group, shall be conducted with BPA in accordance with the TSCA Health Effects Test Guideline for Inhalation Toxicity in §798.2450(a), (b), (c) and (e) of this chapter. The following additional testing requirements apply to bisphenol A:

(i) *Test procedures*—(A) *Animal selection*—(*1*) *Species and strain.* A mammalian species shall be used for testing. A variety of rodent species may be used although the rat is the preferred species. Commonly used laboratory strains shall be employed. If another mammalian species is used, the tester shall provide justification/reasoning for its selection.

(*2*) *Age.* Young adult animals shall be used. At the commencement of the study the weight variation of animals shall not exceed ±20 percent of the mean weight for each sex.

(*3*) *Sex.* (*i*) Equal numbers of animals of each sex shall be used at each dose level.

(*ii*) Females shall be nulliparous and nonpregnant.

(*4*) *Numbers.* (*i*) At least 20 animals (10 females and 10 males) shall be used for each test group.

(*ii*) If interim sacrifices are planned, the number of animals shall be increased by the number of animals scheduled to be sacrificed before the completion of the study.

(B) *Control groups.* A concurrent control group is required. This group shall be an untreated or sham-treated control group. Except for treatment with the test substance, animals in the control group shall be handled in a manner identical to the test group animals. Where a vehicle is used to help generate an appropriate concentration of the substance in the atmosphere, a vehicle control group shall be used. If the toxic properties of the vehicle are not known or cannot be made available, both untreated and vehicle control groups are required.

(C) *Satellite group.* A satellite group of 20 animals (10 animals per sex) shall be treated with the high concentration level for 90 days and observed for reversibility, persistence, or delayed occurrence of toxic effects for a posttreatment period of not less than 28 days.

(D) *Dose levels and dose selection.* (*1*) In subchronic toxicity tests, it is desirable to have a dose-response relationship as well as a no-observed-toxic-effect level. Therefore, at least three dose levels with a control and, where