

40 CFR Parts 704 and 799

[OPTS-42076; TSH-FRL 2906-S]

Anthraquinone; Proposed Reporting and Recordkeeping Requirements and Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing that manufacturers (including importers) and processors of 9,10-anthraquinone (CAS No. 84-65-1), hereinafter "anthraquinone", be required, under section 4 of the Toxic Substances Control Act (TSCA), to perform testing for water solubility, bioconcentration, and acute toxicity to aquatic organisms. The Agency is also proposing, under section 8 of TSCA, that manufacturers and importers of anthraquinone be required to submit an annual report to EPA stating the volume of this substance manufactured or imported during their latest corporate fiscal year. Testing for biodegradation and chronic toxicity of aquatic organisms will be required if the acute toxicity or

bioconcentration test results and the annual production and importation level meet specified criteria. This proposed rule is in response to the Interagency Testing Committee's (ITC's) designation of anthraquinone for priority consideration for chemical fate and environmental effects testing.

DATES: Submit written comments on or before January 6, 1986. If persons request an opportunity to submit oral comment by December 23, 1985, EPA will hold a public meeting on this rule in Washington, D.C. For further information on arranging to speak at the meeting see Unit IX of this preamble.

ADDRESSES: Submit written comments, identified by the document control number (OPTS-42078), in triplicate to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, RM: E-108, 401 M St., SW., Washington, D.C. 20460.

A public version of the administrative record supporting this action (with any confidential business information deleted) is available for inspection at the above address from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. E-543, 401 M St., SW., Washington, D.C. 20460. Toll free: (800-424-9065). In Washington, D.C.: (554-1404); Outside the USA: (Operator -202-554-1404).

SUPPLEMENTARY INFORMATION: EPA is issuing a proposed test rule under section 4(a) of TSCA in response to the ITC's designation of anthraquinone for chemical fate and environmental effects testing consideration and reporting requirements under section 8(a) to require manufacturers and importers to report to EPA the volume of anthraquinone manufactured or imported during their latest corporate fiscal year.

I. Introduction

A. ITC Recommendation

TSCA (Pub. L. 94-469, 90 Stat. 2003 et seq.; 15 U.S.C. 2601 et seq.) established the ITC under section 4(e) to recommend to EPA a list of chemicals to be considered for testing under section 4(a) of the Act.

The ITC designated anthraquinone (CAS No. 84-65-1) for priority consideration in its 15th Report submitted to EPA on November 6, 1984, and published in the Federal Register of November 29, 1984 (49 FR 46931). The ITC recommended that anthraquinone

be considered for chemical fate testing, including water solubility and biodegradation, and ecological effects testing, including acute toxicity to fish, aquatic invertebrates, and algae, and chronic toxicity to aquatic organisms, conditional upon results of acute tests. The bases for these recommendations were as follows: the chemical fate and toxicity tests that were reviewed had been performed at test concentrations that exceeded and reported water solubility level of anthraquinone; the resulting data could not be interpreted reliably or were inadequate to quantify the acute and potential chronic toxicity to aquatic organisms; and the data indicated that anthraquinone may be toxic to aquatic organisms since organisms were killed in the toxicity tests.

B. Test Rule Development Under TSCA

Under Section 4(a) of TSCA, EPA shall by rule require testing of a chemical substance or mixture to develop appropriate test data if the Administrator finds that:

(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment.

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted; and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or

(B) (i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture;

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted; and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

EPA uses a weight-of-evidence approach in making a section 4(a)(1)(A)(i) finding; both exposure and toxicity information are considered in determining whether available data support a finding that the chemical may present an unreasonable risk. For the finding under section 4(a)(1)(B)(i), EPA considers only production, exposure, and release information to determine

whether there is or may be substantial production and significant or substantial human exposure or substantial release to the environment. For the findings under sections 4(a)(1)(A)(ii) and 4(a)(1)(B)(ii), EPA examines toxicity, fate studies to determine whether existing information is adequate to reasonably determine or predict the effects of human exposure to, or environmental release of, the chemical. In making the finding under section 4(a)(1)(A)(iii) or 4(a)(1)(B)(iii) that testing is necessary, EPA considers whether ongoing testing will satisfy the information needs for the chemical and whether testing which the Agency might require would be capable of developing the necessary information.

EPA's process for determining when these findings apply is described in detail in EPA's first and second proposed test rules as published in the Federal Register of July 18, 1980 (45 FR 48524) and June 5, 1981 (46 FR 30300). The section 4(a)(1)(A) findings are discussed at 45 FR 48524 and 46 FR 30300, and the section 4(a)(1)(B) findings are discussed at 46 FR 30300.

In evaluating the ITC's testing recommendations for anthraquinone, EPA considered all available relevant information including the following: information presented in the ITC's report recommending testing consideration; production volume; use, exposure, and release information reported by manufacturers of anthraquinone under the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR Part 712); health and safety studies submitted under the TSCA section 8(d) Health and Safety Data Reporting Rule (40 CFR Part 716) for anthraquinone; and published and unpublished data available to the Agency. Based on its evaluation, as described in this proposed rule, EPA is proposing chemical fate and environmental effects testing requirements for anthraquinone under section 4(a)(1)(B). By these actions, EPA is responding to the ITC's designation of anthraquinone for priority testing consideration.

C. TSCA Section 8(a) Recordkeeping And Reporting

Section 8(a) of TSCA (15 U.S.C. 2607(a)) authorizes EPA to require persons (other than small manufacturers, importers, and processors as defined in § 704.3) who manufacture, import or process a chemical substance, to submit such reports as the Administrator may reasonably require. In order to monitor production and importation volume of

anthraquinone. EPA is proposing in this same Federal Register document as the section 4 testing requirements that manufacturers and importers be required to submit an annual report to EPA stating the volume of this substance manufactured or imported during their latest corporate fiscal year.

II. Review of Available Data

A. Profile

Anthraquinone is a pale yellow crystalline solid. Its melting point is 286 °C, and its boiling point is 377 °C (Ref. 1). Anthraquinone has a low calculated vapor pressure of 6.7×10^{-6} mm Hg at ambient temperatures (Ref. 2). Anthraquinone is soluble in organic solvents, and the log octanol/water partition coefficient has been reported to be 3.39 (Ref. 1). Various values have been reported for its solubility in water: 0.05 mg/l (Ref. 3) and 0.5 mg/l (Ref. 4), but these values are not supported by data. From the experimentally determined log K_{ow} of 3.39, EPA has estimated anthraquinone's water solubility to be 0.29 mg/l (Ref. 2).

B. Production

There is currently no manufacture of anthraquinone in the United States. The Toms River Chemical Corp., a subsidiary of Ciba-Geigy Corp., in Toms River, NJ, produced anthraquinone in the United States until about 5 years ago (Ref. 5).

EPA has identified three importers of anthraquinone with total estimated annual imports of about 700,000 lb. based on 1983 and 1984 reports. The U.S. International Trade Commission reported total imports of 813,322 lb. for 1983 (Ref. 24).

Anthraquinone has been found in the combustion products of fossil fuels; Robertson et al. found anthraquinone in the exhaust of a turbine aircraft engine at levels of up to 58.49 ng/m³ (Ref. 9). In 1982, Ehrhardt et al. suggested that anthraquinone may be formed in the atmosphere by photooxidation of anthracene (Ref. 10). Another inadvertent source of production was reported by Oyler et al., who found that anthracene under conditions simulating a water chlorination treatment process gave a 61 to 78 percent conversion to anthraquinone (Ref. 11).

C. Use

There are two major industrial uses of anthraquinone in the United States. The principal use is in the production of anthraquinone dyes, so named because of the presence of an anthraquinone nucleus (usually extensively substituted) in the molecular structure. Although

some anthraquinone dyes employ anthraquinone as a starting material, there are many others in which anthraquinone is only formed as a nonisolated intermediate (Ref. 1). The primary use of anthraquinone as a starting material in dyestuff manufacture is in the production of sulfonic acid derivatives of anthraquinone. This reaction is achieved by treating anthraquinone with fuming sulfuric acid in the presence of a mercury catalyst (Ref. 1). The chemical principles that underlie the production of dyestuffs from anthraquinone via sulfonic acid derivatives (Ref. 12) imply that several major dye products may be produced from anthraquinone starting material; but the proprietary nature of dyestuff industry practices makes it difficult to identify specific dye products (Ref. 1).

The second major industrial use of anthraquinone that appears to be growing in importance is its catalytic use in the paper-pulping industry. Anthraquinone catalyzes the removal of lignin from wood, thereby increasing pulp yield and quality. This use has application to both the soda and Kraft chemical pulping processes at typical levels of 0.025 to 0.1 percent of the bone-dry wood weight. The use of anthraquinone is also reported to reduce reaction (delignification) time and the need for sodium sulfite in paper pulping, resulting in savings in energy and raw materials and in reducing undesirable sulfur byproducts (Ref. 13). The use of anthraquinone has been approved by the Food and Drug Administration at levels up to 0.1 percent in paper products contacting food products (Ref. 14).

Because of the apparent economic benefits of using anthraquinone in the pulping industry, it is expected that anthraquinone's use will increase (Ref. 15). EPA estimates that the future market for anthraquinone in pulping could possibly exceed 7 million pounds per year (Ref. 16).

In Europe, anthraquinone receives wide usage as a bird repellent in protecting planted seeds (Ref. 17). At present, anthraquinone is not registered for use as a bird repellent in the United States (Ref. 18).

D. Exposure and Release

Anthraquinone has been reported to be present in the waste effluents of dye-manufacturing and paper-pulping plants (Refs. 25 and 26). Games and Hites (Ref. 25) investigated the effluent discharges of South Carolina dye-manufacturing plant in July 1976 using sensitive high-resolution gas chromatography/mass spectrometry (GC/MS) techniques. The

plant utilized 3 million gallons of noncontaminated water daily in its processes, which were discharged along with organic materials into the plant waste treatment system. A total of 600 tons of organic materials were discharged annually for treatment. The waste treatment plant used neutralization, aerobic, and settling processes with a total residence time of 19 days. The treated waste was discharged directly into a tidal river, which resulted in an approximate 1,000-fold dilution of the treated waste. The investigators sampled both the untreated and treated waste effluent, as well as the water and bottom sediments of the waste-receiving river. Because the plant manufactured a variety of dyes on a batch basis, a total of 9 weekly composite samples of wastewater were collected over a 2.5-month period. Anthraquinone was detected in 6 of the composite samples at levels of 49 to 110 ppb. Anthraquinone was not detected in the treated effluent or in the water or sediment of the waste-receiving river (Ref. 25). However, a more typical residence time in the waste treatment facility for the industry is 6 days and not 19 days as in this study (Ref. 25); and this difference in residence time may have caused the reported absence of anthraquinone in the treated wastewater.

In a laboratory simulation, Zanello et al. determined the concentration of anthraquinone in the waste effluents from Kraft pulping using 0.1 percent anthraquinone and also determined the concentration in the treated effluent after it was subjected to the waste treatment conditions typical of those used in full-scale plants (Ref. 26). The waste effluent from pulping was prepared by mixing 5.0 liters of black (digesting) liquor, 7.0 liters of chlorine-stage effluent, and 4.0 liters of caustic-extraction-stage effluent and diluting to 75 liters with tap water. The concentration of anthraquinone in this simulated waste effluent was 2.7 ppm. The simulated final (treated) mill effluents were produced by treating the simulated waste effluents in complete-mix activated sludge units. The units were fed at a rate which produced a hydraulic detention time of 8 hours. The mean cell residence time of 7.3 days was controlled by daily removal of sludge from the unit. The concentration of anthraquinone in the treated effluent was found to be 2.2 ppm. The simulated waste treatment process typical of the pulping industry had reduced the concentration of anthraquinone from 2.7 ppm to 2.2 ppm (a 19-percent reduction

The Agency received effluent monitoring data and treatability data from one paper pulping plant which was submitted under section 8(a) of TSCA. These data indicated that anthraquinone is present in effluents released to receiving streams in the upper ppb to lower ppm range. Specific levels were claimed as Confidential Business Information. Using these data and assuming a stream low flow rate that corresponds to the median for U.S. pulp and paper mills, EPA estimates that the receiving stream would have an anthraquinone concentration in water of 5 ppb. Because the time required for the build-up of anthraquinone in sediment is much longer, a median receiving stream with a mean flow rate was assumed and EPA's estimate of the concentration in the sediment is 0.1 ppm (Ref. 27).

Urban air samples collected in St. Louis, Missouri, have been found to contain a number of polycyclic quinones derived from polynuclear aromatic hydrocarbons, including 9,10-anthraquinone at unquantified levels (Ref. 20). Pankow et al. (Ref. 21) examined rainfall for content of trace organic compounds and reported that the average content of anthraquinone in rainfall from four storms in the spring of 1982 in a rural area 12 miles west of Portland, Oregon, was 6 ng/1. Rainfall collected in the Fall of 1982 from five storms over the city of Portland contained an average of 48 ng/1 anthraquinone. The author suggested that the source of the anthraquinone was either primary combustion processes or subsequent oxidation of polycyclic aromatic hydrocarbons (PAH) in the atmosphere. Stahl et al. (Ref. 22) subjected a pile of Texas lignite coal to an artificial rainfall and found that the rainwater acquired a concentration of 0.7 ug/1 anthraquinone after leaching through the coal pile.

Finished drinking water samples from 12 municipalities in the Great Lakes region were found to contain anthraquinone in concentrations ranging from 0 to 72 ng/1, with the average of 24 readings being 9.9 ng/1 (Ref. 23).

In summary, the available monitoring data suggest that the occurrence of anthraquinone in the environment due to inadvertent production is widespread, but generally at very low concentrations. Most environmental populations will be exposed to these low background levels of anthraquinone with the only significant exposures above background expected to occur from point source industrial discharges. The two major uses of anthraquinone, in dye manufacture and paper pulping, are anticipated to release anthraquinone in

treated waste water to receiving streams. EPA expects that steady-state environmental concentrations of anthraquinone will be established by continuous effluent discharges. According to chemical fate predictions, anthraquinone released to water will remain in water, with some adsorption to bottom sediment. Under these conditions, the principal exposed environmental populations would include bottom-dwelling (benthic) fishes and invertebrates and organisms living in the water column. Chronic exposure situations in water column organisms may be created if anthraquinone is continuously discharged and/or persists in bottom sediments which serve as a reservoir for replacing anthraquinone dissipated in the water column by transport and various degradative mechanisms.

E. Chemical Fate

Although anthraquinone can be present in the air and drinking water at very low levels due to inadvertent production, the most significant release of anthraquinone to the environment is in treated industrial waste water. Its low vapor pressure (6.7×10^{-16} mm Hg, Ref. 2), moderate octanol/water partition coefficient ($\log K_{ow} = 3.39$, Ref. 1), a log soil adsorption coefficient ($\log K_{oc}$) of 3.18, and low Henry's Law constant (2.29×10^{-11} atm-m³ per mole, Ref. 1) indicate that anthraquinone should remain in water because of a negligible potential to volatilize from water and a limited tendency to adsorb to sediment. EPA estimates that 100 percent of anthraquinone released to water will remain in water and 50 percent will persist for more than 8 to 10 months (Ref. 2).

In studies conducted by C-I-L, Inc. and Mobay Chemical Corp., anthraquinone was found to have a half-life in an activated sludge biodegradation system of 5 to greater than 20 days (Refs. 4 and 28). C-I-L investigated the biodegradation of anthraquinone by determining the biochemical oxygen demand (BOD) over a 27-day period using an anthraquinone concentration of 500 mg/1 in the test solutions. One series of solutions was inoculated with a microbial culture acclimated to anthraquinone; the other was inoculated with a culture not acclimated to anthraquinone. The results indicated that the anthraquinone had completely degraded after 18 days in the acclimated culture and after 24 days in the nonacclimated culture. In addition, 61 and 45 percent of the anthraquinone had degraded in 5 days in the acclimated and nonacclimated cultures, respectively (Ref. 4). Mobay

determined the BOD in 20 days in acclimated and unacclimated cultures containing 2.4 ppm anthraquinone. The BOD₂₀ in the acclimated culture was 313 mg oxygen per gram of anthraquinone which corresponded to 40 percent biodegradation. The BOD₂₀ in the unacclimated culture was 313 mg oxygen per gram of anthraquinone or 15 percent biodegradation (Ref. 28).

C-I-L also submitted a study showing that anthraquinone at concentrations greater than 10 ppm has a negative impact on the anaerobic digestion process. This study found that anthraquinone decreased methane production and increased volatile acid production during the anaerobic digestion of household waste as it would occur in cesspools or septic tanks. The anaerobic digestion systems contained a mixture of primary solids, digested sludge, tissue paper, and varying concentrations of anthraquinone (0.01, 0.05, 0.5, 1.0, 10, and 50 ppm). Three concentrations of anthraquinone (1.0, 10, and 50 ppm) exceeded the reported water solubility. The mixtures and appropriate controls were incubated in laboratory digesters at 38° C for 60 days. Cumulative gas production (primarily CO₂ and methane) in all anthraquinone-spiked test units was greater than that produced in the controls by day 60. Production of gases in units with anthraquinone concentrations from 0.01 to 1.0 ppm progressed at a relatively rapid rate throughout the test period while units with 10 and 50 ppm exhibited slower initial rates of production, which was found to be due to an inhibition of methane production during the first 14 days of incubation. A similar trend was observed in the destruction of volatile acids. Controls and anthraquinone concentrations from 0.01 to 1.0 ppm experienced radical reduction in concentration of volatile acids (1,253 to 820 ppm) after 7 days of digestion with no indication of lag time, whereas units with 10 and 50 ppm anthraquinone showed a significant increase in volatile acid production (1,100 to 3,197 ppm) over the same time period. This indicates that anthraquinone at concentrations above 10 ppm may have a significant negative impact on anaerobic digestion. However, the volatile acid levels and methane levels in all units approximate that of the controls after day 31 and day 39, respectively. In addition, lag times of 3 and 6 days in reaching pH 7 were observed in units with anthraquinone concentrations of 10 and 50 ppm, respectively (Ref. 4).

In summary, the broad range of reported biodegradation half-lives and

the indication of adverse effects on anaerobic digestion raise concern over the persistence and degradability of anthraquinone. Also, the lack of biodegradation data under environmentally relevant conditions, i.e., at potential environmental concentrations and in natural waters with their unique physical, chemical and microbial characteristics, make the available data inadequate to evaluate the chemical fate of anthraquinone.

F. Environmental Effects

The acute toxicity of anthraquinone to fathead minnows was determined using a 96-hour static bioassay. Test conditions included a temperature of 20 to 20.5 °C, pH of 7.3 to 7.6, dissolved oxygen of 8.7 to 8.1 mg/l, and fish loading of 0.34 g fish/l. Nominal test concentrations of 1.8 to 7.5 g/l were greatly in excess of the reported solubility limit of 0.5 mg/l. Under these conditions, a 96-hour median lethal concentration (LC₅₀) of 2.65 g/l was determined (average of duplicate measurements) with 95-percent confidence limits of 2.27 to 3.09 g/l. The 24- and 48-hour LC₅₀ values were reported to be 3.35 g/l and 3.0 g/l, respectively. The authors reported that the fish gills were coated with undissolved anthraquinone and speculated that resultant suffocation produced the observed mortality. At the lowest nominal concentration tested (1.8 g/l), 7 percent mortality was obtained at 96 hours (compared to 0 percent in controls). Therefore, the test conditions chosen failed to demonstrate a level at which no acute effects were observed at 96 hours (Ref. 4). Chillingworth reported no effects to fathead minnows exposed to 180 ppm anthraquinone (Ref. 29). Applegate et al. exposed pairs of rainbow trout, bluegill sunfish, and larval sea lampreys to 5 ppm of anthraquinone at 55 °F for 24 hours and observed no mortalities (Ref. 30). C-I-L, Inc., reported that exposure of fathead minnows to 0.4 ppm anthraquinone produced virtually no lethality over 28 days (Ref. 4). Using different species, MacPhee and Ruelle obtained complete mortality in 13 hours or less in single specimens of chinook salmon, coho salmon, and northern squawfish exposed to 10 ppm anthraquinone at 52 °F (Ref. 31).

Anthraquinone does not bioconcentrate significantly. The measured bioconcentration factor is 24 in fathead minnow (Ref. 4), 56 in bluegill (Refs. 3 and 28), and 127 in *Daphnia pulex* (Refs. 3 and 28). The calculated bioconcentration factor is 222 based on the measured log K_{ow} of 3.39 (Ref. 32).

The acute toxicity of anthraquinone to the aquatic invertebrate, *Daphnia pulex*, was investigated by C-I-L, Inc. With nominal concentrations ranging from 1 ppm to 314 ppm and triplicate determinations, the 48-hour median effective concentration (EC₅₀, endpoint was immobilization) of anthraquinone was determined to be 110 ppm, with 95 percent confidence limits of 70 to 170 ppm. EC₅₀ values for 24 and 96 hours were reported as 178 ppm and 46.3 ppm, respectively (Ref. 4).

Chillingworth reported no effects in the algae *Selenastrum capricornutum* exposed to 1 and 10 ppm anthraquinone (Ref. 29).

When radish seeds, *Raphanus* sp., were soaked with anthraquinone solutions ranging from 100 to 500 parts per thousand (ppt), the median effective dose (ED₅₀) inhibiting germination was 455 ppt with growth and production of the hypocotyl and radicle diminished at 400 and 500 ppt (Ref. 4). The growth and development of wheat and soybean seedlings were not affected by exposure to 500 ppm anthraquinone, using criteria of shoot height and biomass, root biomass, and pathology (Ref. 4). Metcalf noted minimal fungicidal activity of anthraquinone when compared to a variety of quinones active against *A Alternaria solani* (Ref. 33).

Schafer et al. screened a number of chemicals for acute toxicity and repellence in avian species. Oral LC₅₀ values of 100 ppm and 300 ppm were reported for anthraquinone in the red-winged blackbird (*Agelaius phoeniceus*) and the house sparrow (*Passer domesticus*). A 46.1-ppm feed concentration repelled 50 percent of an exposed red-winged blackbird population (Ref. 6).

The available aquatic toxicity data are not adequate to evaluate the effects of anthraquinone on fish and aquatic invertebrates.

III. Findings

EPA is basing its proposed testing of anthraquinone on the authority of section 4(a)(1)(B) of TSCA. Existing data indicate that anthraquinone may be imported in substantial quantities and that substantial environmental release may be reasonably anticipated to occur. Annual imports of anthraquinone are 813,000 lb. and could possibly exceed 7 million pounds per year. Discharge data from one wood pulping plant using anthraquinone as a catalyst show that the plant is currently releasing effluents with anthraquinone concentrations in upper ppb to lower ppm range. There are approximately 100 pulping plants in the U.S. that could potentially use anthraquinone in their processing (Ref.

34). If this use of anthraquinone increases, such releases could become widespread. For these reasons, annual reporting under § 8(a) is necessary to allow EPA to monitor increases in the production and importation of anthraquinone.

EPA also finds that the data now available are insufficient to reasonably determine or predict the chemical fate and environmental effects of releases from the use and processing of anthraquinone.

There is no measured value for anthraquinone's solubility in water, and the reported values of 0.05 mg/l (Ref. 3) and 0.5 mg/l (Ref. 4) are not supported by data. A third value for water solubility is EPA's estimate of 0.3 mg/l (Ref. 2).

The Agency finds that the biodegradation studies submitted by C-I-L, Inc. (Ref. 4) and Mobay Chemical Corp. (Ref. 28) were conducted at concentrations exceeding the water solubility of anthraquinone and presented a half-life range (5 to greater than 20 days in activated sludge) too broad to reasonably predict anthraquinone's persistence in the environment. This broad range is particularly unsatisfactory since the typical waste treatment residence times for the dye and pulp industries are 6 and 8 days, respectively (Refs. 25 and 26). The Agency also finds that the submitted studies are not necessarily relevant to assessing biodegradation by microbial populations in natural waters, which possess a different array of microbial communities, and physical and chemical characteristics compared to waste-treatment systems.

Considering release and chemical fate information presented in Units II.D and E above, EPA expects that potential exposure to anthraquinone will be greatest for fish, aquatic invertebrates, and benthic organisms. EPA finds that there are no toxicity or bioconcentration data on benthic organisms and no chronic effects data on fish and aquatic invertebrates.

After reviewing and evaluating the existing acute toxicity data for aquatic organisms experimentally exposed to anthraquinone, EPA has determined that sufficient data exist for fathead minnow, but additional data are necessary to determine whether salmonids are substantially more sensitive as suggested by the MacPhee and Ruelle study (Ref. 31). EPA also finds that additional acute toxicity studies of fish and aquatic invertebrates are necessary since the existing studies were done at concentrations exceeding the water solubility of anthraquinone.

EPA finds that sufficient data are available from the study done by Chillingworth (Ref. 29) to reasonably predict anthraquinone's toxicity to algae.

Finally, EPA finds that testing is necessary to develop the chemical fate and environmental effects data described above.

IV. Proposed Rule

A. Proposed Testing and Test Standards

The Agency is proposing that chemical fate and environmental effects testing be conducted on anthraquinone in accordance with specific test guidelines set forth in Title 40 of the Code of Federal Regulations as enumerated below. Test methods under new Parts 796, 797, and 798 were published in the Federal Register of September 27, 1985 (50 FR 39252).

In view of the prospect for a growing market for anthraquinone due to use in pulping and the projected economic impact of the full set of aquatic tests EPA believes would be necessary to adequately assess the environmental risks of anthraquinone, the Agency is proposing that testing be conducted in two tiers. By tiering testing, EPA expects to obtain limited data now from the first tier to better assess the potential for expanded releases of anthraquinone to pose significant risks. Should the use of anthraquinone as a pulping catalyst expand substantially, the second tier of testing will provide the more complete data needed to evaluate the possible risks associated with substantially larger aquatic releases of the chemical.

EPA is proposing that the first tier testing of anthraquinone be conducted now to determine (1) the water solubility to properly design the subsequent proposed tests, using the TSCA guideline entitled "Water Solubility, Generator Column Method" as specified in § 796.1860; (2) the acute toxicity to chinook salmon, *Oncorhynchus tshawytscha*, or coho salmon, *Oncorhynchus kisutch*; bluegill, *Lepomis macrochirus*; and rainbow trout, *Salmo gairdneri*, using the TSCA guideline entitled "Fish acute toxicity test" as specified in § 797.1400 and as modified in § 799.500(c)(2)(i)(B); (3) the acute toxicity to the invertebrates *Daphnia magna* or *D. pulex*, and oyster, *Crassostrea virginica*, using the TSCA guidelines entitled "Daphnid acute toxicity test" as specified in § 797.1300 and as modified in § 799.500(c)(3)(i)(B) and "Oyster acute toxicity test" as specified in § 797.1800 and as modified in § 799.500(c)(3)(i)(C); (4) the marine sediment toxicity to the amphipod, *Rhepoxynius abronius*, according to the

method of R.C. Swartz, et al., "Phoxocephalid Amphipod Bioassay for Marine Sediment Toxicity", published in the American Society for Testing and Materials Special Technical Publication 854 (ASTM STP 854), R.D. Caldwell et al. (eds.) (Ref. 7); and (5) bioconcentration in oyster, *Crassostrea virginica*, using the TSCA guideline entitled "Oyster bioconcentration test" as specified in § 797.1830 and as modified in § 799.500(c)(5)(i)(B). EPA would prefer to require bioconcentration testing in a freshwater benthic invertebrate but the Agency is unaware of a test guideline which has been sufficiently tested to insure the reliability of results. If such a test guideline is found EPA will consider substituting it for the bioconcentration test in oyster.

In order to evaluate the potential hazard of the median lethal concentrations (LC₅₀'s) generated by the Tier II tests, EPA is proposing that the LC₅₀'s be compared to the predicted environmental concentrations (PEC's) for anthraquinone in water and sediment, i.e., 5 ppb and 0.1 ppm respectively, which have been determined from reported discharge levels (see Unit I.D above) (Ref. 27).

EPA is also proposing that a second tier of tests shall be conducted if two triggers are met—a hazard trigger and a production/import level trigger. The hazard trigger will be met if the median lethal concentrations (LC₅₀'s) generated by the Tier I tests are less than 100 times the predicted environmental concentrations. The production/import level trigger will be met when annual production/import levels reach 3 million lb. EPA will use the section 8(a) reporting to monitor the production/import levels.

If both triggers are met, EPA is proposing that the Tier II tests be required based on the results of the Tier I tests as follows. If the most sensitive fish, i.e., the fish with the lowest LC₅₀ as determined by the above-proposed acute toxicity tests, has an LC₅₀ less than 100 times the predicted environmental concentration (PEC) for water, i.e., less than 500 ppb, testing of anthraquinone shall be conducted to determine the chronic toxicity to the most sensitive fish, using the TSCA guideline entitled "Fish early life stage toxicity test" as specified in § 797.1600 and as modified in § 799.500(d)(3)(i)(B). If the daphnid has an EC₅₀ as determined by the above-proposed acute toxicity test which is less than 100 times the PEC for water, i.e., less than 500 ppb, testing of anthraquinone shall be conducted to determine the chronic toxicity to daphnid, using the TSCA guideline entitled "Daphnid chronic

toxicity test" as specified in § 797.1330 and as modified in § 799.500(d)(4)(i)(B).

Testing of anthraquinone to determine the chronic toxicity to *Rhepoxynius* or oyster or some other marine or freshwater benthic invertebrate is proposed, as there is no known acceptable guideline that can serve as a test standard. However, the combined test results from the oyster acute toxicity test and the oyster bioconcentration test will provide an indication of potential toxicity of anthraquinone to filter feeding organisms.

If the LC₅₀ for fish, daphnid, or oyster is less than 100 times the PEC in water, i.e., less than 500 ppb, or if the LC₅₀ for *Rhepoxynius* in the marine sediment toxicity test is less than 100 times the PEC in sediment, i.e., less than 10 ppm, or if the oyster bioconcentration factor is greater than 3,000, then EPA is proposing that testing of anthraquinone shall be conducted to determine (1) the biodegradability in sludge systems, using the test method entitled "Inherent Biodegradability: modified SCAS (Semicontinuous activated sludge) Test for chemical substances that are water insoluble or water insoluble and volatile" as specified in § 796.3341 and (2) biodegradation rate using the protocol described in a study by Bourquin et al. (Ref. 8).

EPA chose to trigger second tier testing with an increase in production/import level for two reasons. First, the use of anthraquinone increases Agency's concerns for environmental release and the potential for unreasonable risk to the environment increase. Under such conditions, the need for further testing to fully characterize the hazard potential and chemical fate of anthraquinone becomes essential. If the data developed in the first tier of testing don't meet at least one of the hazard triggers described above, there would be no potential to trigger further testing and thus no need for continued section 8(a) reporting; EPA then would remove the section 8(a) reporting requirement and publish a notice of such action in the Federal Register.

However, if these data suggest concern and if use continues to increase to 3 million lb per year, the second tier of testing is considered essential. EPA also chose a production/import level of 3 million lb. per year because it represents substantial market growth of the chemical over current levels and a level at which EPA's analysis indicates the second-tier tests will not cause an adverse economic impact. The section 8(a) reports will be the means to

determine when the 3-million-lb-trigger is met.

The Agency is proposing that the above-referenced TSCA Chemical Fate and Environmental Effects Test Guidelines and other cited methods be considered the test standards for the purposes of the proposed tests for anthraquinone. The TSCA guidelines for chemical fate and aquatic toxicity testing specify generally accepted minimal conditions for determining chemical fate and aquatic animal toxicities for substances like anthraquinone to which aquatic life is expected to be exposed. The Agency's review of the guidelines, which occurs on a yearly basis as described in the Federal Register September 22, 1982 (47 FR 41657), has found no reason to conclude that these protocols need to be modified significantly. However, several chemical specific modifications were deemed necessary to ensure that the test concentrations adequately define the dose-response curve and are adequately maintained throughout the duration of the test. These modifications are listed in § 799.500 of this rule.

EPA intends to propose shortly in a separate Federal Register notice certain revisions to these TSCA Test Guidelines to provide more explicit guidance on the necessary minimum elements for each study. In addition, these revisions will avoid repetitive chemical-by-chemical changes to the guidelines in their adoption as test standards for chemical-specific test rules. EPA is proposing that these modifications be adopted in the test standards for anthraquinone. Additionally, the ASTM guideline (Ref. 7) and the test procedures employed by Bourquin et al. (Ref. 8) specify, in EPA's judgment, minimal test conditions and practices for acceptable investigations of anthraquinone's toxicity in sediment to marine amphipods and rate of biodegradation. Although the Agency has not issued TSCA testing guidelines for benthic invertebrates or biodegradation rate, the testing procedures found in these references reflect the current state-of-the-art for such testing and are being proposed as acceptable methods for testing anthraquinone toxicity to benthic invertebrates and biodegradation rate.

B. Test Substance

EPA is proposing that 9.10- anthraquinone of at least 99-percent purity be used as the test substance. Anthraquinone of this purity is commercially available at nominal cost (Ref. 19). EPA has specified a highly pure substance for testing because the Agency is interested in evaluating the

effects attributable to anthraquinone itself.

C. Persons Subject to the Rule

1. *Persons Required to Test.* Section 4(b)(3)(B) of TSCA specifies that the activities for which the Agency makes section 4(a) findings (manufacture, processing, distribution, use and/or disposal) determine who bears the responsibility for testing. Manufacturers are required to test if the findings are based on manufacturing ("manufacture" is defined in section 3(7) of TSCA to include "import"). Processors are required to test if the findings are based on processing. Both manufacturers and processors are required to test if the exposures giving rise to the potential risk occur during use, distribution, or disposal.

Because EPA has found that the release from the processing and use of anthraquinone may reasonably be anticipated to give rise to substantial environmental release, EPA is proposing that persons who manufacture and/or process, or who intend to manufacture and/or process, anthraquinone at any time from the effective date of the final test rule to the end of the reimbursement period be subject to the testing requirements contained in this proposed rule. The end of the reimbursement period will be 5 years after the last final report is submitted.

Because TSCA contains provisions to avoid duplicative testing, not every person subject to this rule must individually conduct testing. Section 4(b)(3)(A) of TSCA provides that EPA may permit two or more manufacturers or processors who are subject to the rule to designate one such person or a qualified third person to conduct the tests and submit data on their behalf. Section 4(c) provides that any person required to test may apply to EPA for an exemption from the requirement. EPA promulgated procedures for applying for TSCA section 4(c) exemptions in 40 CFR Part 790.

When both manufacturers and processors are subject to a test rule, EPA expects that manufacturers will conduct the testing and that processors will ordinarily be exempted from testing. As described in 40 CFR Part 790, processors will be granted an exemption automatically without filing applications if manufacturers perform all of the required testing. Manufacturers are required to submit either a letter of intent to perform testing or an exemption application within 30 days after the effective date of the test rule.

EPA is not proposing to require the submission of equivalence data as a condition for exemption from the

proposed testing for anthraquinone. As noted in Unit IV.B above, EPA is interested in evaluating the effects attributable to anthraquinone itself and has specified a highly pure substance for testing.

Manufacturers and processors who are subject to this test rule must comply with the test rule development and exemption procedures in 40 CFR Part 790 for single-phase rulemaking.

EPA is exempting from these testing requirements those manufacturers and processors that produce and process anthraquinone only as an impurity. Persons who manufacture or process anthraquinone as a byproduct or as a nonisolated intermediate are subject to the testing requirements set forth in this rule. The total anthraquinone imports and domestic production, including that produced as a byproduct or a nonisolated intermediate, will be used in determining reimbursement shares under the Data Reimbursement Final Rule (46 FR 41786; September 19, 1983). The Agency's rationale for these decisions follows.

EPA is exempting those manufacturers and processors that produce anthraquinone only as an impurity because the EPA findings under section 4(a) are based on exposures to anthraquinone that are a result of intentional manufacture, processing, and distribution of anthraquinone. In addition, it would be difficult for both EPA and manufacturers and processors to identify with complete assurance all chemical substances which contain anthraquinone solely as an impurity. Further, the Agency would find it difficult to apply both the exemption and reimbursement processes to those who manufacture and/or process anthraquinone solely as an impurity. The Agency's reimbursement regulations issued pursuant to section 4(c) state that those who manufacture or process chemical substances as impurities will not be subject to test requirements unless the rule specifically states otherwise (40 CFR 791.46(b)). EPA finds no basis to impose such a requirement in this rule. EPA is including persons who manufacture or process anthraquinone as a byproduct or nonisolated intermediate because these activities constitute intentional manufacture and processing of anthraquinone.

2. *Persons Required To Submit Production and Import Information.* Persons (other than small manufacturer and importers) who manufacture or import anthraquinone as of the effective date of the final rule, plus persons (other than small manufacturers and

importers) who manufacture or import the substance after that date, would be required to submit section 8(a) data under this rule. Although TSCA section 8(a)(3)(A)(ii) would allow EPA to require reporting by small manufacturers and small importers of anthraquinone (because anthraquinone is concurrently being made subject to a section 4 rule), EPA has determined that such reporting is not necessary to achieve the purposes of this rule.

D. Reporting Requirements.

1. *Under Section 4.*—EPA is proposing that all data developed under this rule be reported in accordance with its TSCA Good Laboratory Practice (GLP) standards, which appear in 40 CFR Part 792.

In accordance with 40 CFR Part 790 under single-phase rulemaking procedures, test sponsors are required to submit individual study plans at least 30 days prior to the initiation of each study.

EPA is required by TSCA section 4(b)(1)(C) to specify the time period during which persons subject to a test rule must submit test data. The Agency is proposing specific reporting requirements for each of the proposed test standards as follows:

1. The water solubility, acute toxicity, sediment toxicity and bioconcentration tests shall be completed and the final results submitted to EPA within 1 year of the effective date of the final test rule. Quarterly progress reports shall be required.

2. The fish and daphnid chronic toxicity tests shall be completed and the final results submitted to the Agency within 1 year of the date that EPA published a Federal Register notice reporting that production/imports have reached 3 million lb. per year if those criteria necessary to trigger chronic aquatic toxicity testing are met. If this testing is triggered, quarterly progress reports shall be required.

3. The biodegradability in sludge and biodegradation rate tests shall be completed and the final results submitted to EPA within 1 year of the date that EPA publishes a Federal Register notice reporting that production/imports have reached 3 million lb. per year if those criteria necessary to trigger biodegradation testing are met. If this testing is triggered, quarterly progress reports shall be required.

TSCA section 14(b) governs Agency disclosure of all test data submitted pursuant to section 4 of TSCA. Upon receipt of data required by this rule, the Agency will publish a notice of receipt in the Federal Register as required by section 4(d).

Persons who export a chemical substance or mixture that is subject to a section 4 test rule are subject to the export reporting requirements of section 12(b) of TSCA. Final regulations interpreting the requirements of section 12(b) are in 40 CFR Part 707 (45 FR 82844; December 16, 1980). In brief, as of the effective date of the final test rule, an exporter of anthraquinone must report to EPA the first annual export or intended export of anthraquinone to any one country. EPA will notify the foreign country concerning the test rule for the chemical.

2. *Under Section 8.*—Any person who manufactured or imported anthraquinone during the person's latest complete corporate fiscal year prior to the effective date of the final rule must submit an initial report to EPA 60 days after the effective date of the final rule. Any person who manufactures or imports anthraquinone after the effective date of the final rule must submit a report 60 days after the conclusion of their corporate fiscal year in which they initially manufactured or imported anthraquinone.

Any person who manufactures or imports anthraquinone following the year for which an initial report was submitted, must submit a subsequent report for each year in which he/she manufactured or imported the named substance 60 days after the conclusion of their corporate fiscal year in which they manufactured or imported anthraquinone.

The report must contain the following information:

- (1) Company name and address.
- (2) Name, address, and telephone number of the principal technical contact.
- (3) The quantity (by weight) of anthraquinone manufactured or imported during the latest corporate fiscal year.

E. Enforcement Provisions

The Agency considers failure to comply with any aspect of a section 4 rule or a section 8 rule to be a violation of section 15 of TSCA. Section 15(1) of TSCA makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to: (1) Establish or maintain records, (2) submit reports, notices, or other information, or (3) permit access to or copying of records required by the Act or any regulation or rule issued under TSCA.

Additionally, TSCA section 15(4) makes it unlawful for any person to fail or refuse to permit entry or inspection as required by section 11. Section 11

applies to any "establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce . . .". The Agency considers a testing facility to be a place where chemical is held or stored and, therefore, subject to inspection. Laboratory inspections and data audits will be conducted periodically in accordance with the authority and procedures outlined in TSCA section 11 by duly designated representatives of the EPA for the purpose of determining compliance with any final rule for anthraquinone. These inspections may be conducted for purposes which include verification that testing has begun, that schedules are being met, and that reports accurately reflect the underlying raw data and interpretations and evaluations to determine compliance with TSCA GLP standards and the test standards established in the rule.

EPA's authority to inspect a testing facility also derives from section 4(b)(1) of the TSCA, which directs EPA to promulgate standards for the development of test data. These standards are defined in section 3(12)(B) of TSCA to include those requirements necessary to assure that data developed under testing rules are reliable and adequate, and to include such other requirements as are necessary to provide such assurance. The Agency maintains that laboratory inspections are necessary to provide this assurance.

Violators of TSCA are subject to criminal and civil liability. Persons who submit materially misleading or false information in connection with the requirement of any provision of this rule may be subject to penalties which may be calculated as if they never submitted their data. Under the penalty provision of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty of up to \$25,000 for each violation with each day of operation in violation constituting a separate violation. This provision would be applicable primarily to manufacturers or processors that fail to submit a letter of intent or an exemption request and then continue manufacturing or processing after the deadlines for such submission. Knowing or willful violations could lead to the imposition of criminal penalties up to \$25,000 for each day of violation and imprisonment for up to 1 year. In determining the amount of penalty, EPA will take into account the seriousness of the violation and the degree of culpability of the violator as well as all the other factors listed in section 16.

Other remedies are available to EPA under section 17 of TSCA, such as seeking an injunction to restrain violations of TSCA section 4.

Individuals as well as corporations could be subject to enforcement actions. Sections 15 and 16 of TSCA apply to "any person" who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies themselves. In particular, this includes individuals who report false information or who cause it to be reported. In addition, the submission of false, fictitious, or fraudulent statements is a violation under 18 U.S.C. 1001.

V. Issues for Comment

Through all aspects of this proposed rule are open to comment, EPA is soliciting comment particularly on the following issues:

(1) EPA is not aware of standard methods with which industry has adequate experience to test for bioconcentration and chronic toxicity in benthic invertebrates when the test substance is added to sediment. The Agency would welcome information concerning the availability of such methods.

(2) EPA would welcome comments on its two-tiered approach to testing, the hazard-based and production/import-based triggers, and the mechanism for determining whether the production/import trigger is met.

VI. Economic Analysis of Proposed Rule

To evaluate the potential economic impact of test rules, EPA has adopted a two-stage approach. All candidates for test rules go through a Level I analysis. This consists of evaluating each chemical or chemical group on four principal market characteristics: (1) Demand sensitivity, (2) cost characteristics, (3) industry structure, and (4) market expectations. The results of the Level I analysis, along with the consideration of the costs of the required tests, indicate whether the possibility of a significant adverse economic impact exists. Where the indication is negative, no further economic analysis is done for the chemical substance or group. However, for those chemical substances or groups where the Level I analysis indicates a potential for significant economic impact, a more comprehensive and detailed analysis is conducted. This Level II analysis attempts to predict more precisely the magnitude of the expected impact.

Total testing costs for the proposed rule for anthraquinone are estimated to range from \$32,380 to \$100,200. This

estimate includes the costs for both the required minimum series of tests as well as the conditional ones. The total cost of Tier I tests is estimated to range from \$13,650 to \$43,900. The annualized cost of the mandatory minimum (Tier I) tests (using a cost of capital 25 percent over a period of 15 years) range from \$3,540 to \$11,380. Based on the 1983 importation level of 813,000 pounds, the unit test costs range from 0.4 to 1.4 cents per pound. In relation to the current list price of \$2.25 per pound (Ret. 19) for anthraquinone, these costs are equivalent to 0.17 to 0.62 percent of price.

The total cost of the conditional (Tier II) tests is estimated to range from \$18,730 to \$56,300 with the annualized cost (using a cost of capital of 25 percent over a period of 15 years) ranging from \$6,047 to \$18,225. When production/imports reach 3 million pounds per year, the unit test costs of the Tier II test independent of the Tier I tests range from 0.16 to 0.48 cents per pound. In relation to the current list price of \$2.25 per pound for anthraquinone, the combined Tier I and Tier II unit costs (0.6 to 1.9 cents per pound) are equivalent to 0.25 to 0.86 percent of price.

EPA estimates that the cost of preparing and submitting the section 8(a) report would be minimal. Shall manufacturers and importers are exempt from reporting and there is no official form to be completed. A company may submit the information in whatever manner it finds appropriate. A company's cost of reporting under the rule will be a function of the cost of labor for those doing the reporting and the number of hours it takes for them to comply. We estimate that the direct filing cost for the section 8(a) report ranges from \$150 to \$500.

The Level I economic analysis indicates that the potential for adverse economic effects due to the estimated test cost is low. This conclusion is based on the following observations: (1) The market expectations for anthraquinone are optimistic; (2) the estimated unit test costs are low; and (3) Tier II tests are dependent on market growth to 3 million pounds per year. A Level II analysis is not necessary.

VII. Availability of Test Facilities and Personnel

Section 4(b)(1) of TSCA requires EPA to consider "the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule." Therefore, EPA conducted a study to assess the availability of test facilities and personnel to handle the additional

demand for testing services created by section 4 test rules. Copies of the study, Chemical Testing Industry: Profile of Toxicological Testing, can be obtained through the NTIS (PB 82-140773). On the basis of this study, the Agency believes that there will be available test facilities and personnel to perform the testing in this proposed rule.

VIII. Availability of Test Guidelines

The following guidelines, study plans, and other relevant sources of information cited in this rulemaking are available from the following source:

American Society for Testing and Materials (ASTM), 1916 Race St., Philadelphia, PA 19103. (215-229-5585).

IX. Public Meetings

If persons indicate to EPA that they wish to present oral comments on this proposed rule to EPA officials who are directly responsible for developing the rule and supporting analyses, EPA will hold a public meeting subsequent to the close of the public comment period in Washington, D.C. Persons who wish to attend or to present comments at the meeting should call the TSCA Assistance Office (TAO): Toll Free: (800-424-9085); Washington, D.C.: (554-1404); outside the U.S.A. (Operator—202-554-1404) by December 23, 1985. A meeting will not be held if members of the public do not indicate that they wish to make oral presentations. While the meeting will be open to the public, active participation will be limited to those persons who arranged to present comments and to designated EPA participants. Attendees should call the TAO before making travel plans to verify whether a meeting will be held.

Should a meeting be held, the Agency will transcribe the meeting and include the written transcript in the public record. Participants are invited, but not required, to submit copies of their statements prior to or on the day of the meeting. All such written materials will become part of EPA's record for this rulemaking.

X. Public Record

EPA has established a record for this rulemaking. (docket number OPTS-42076). This record contains the basic information considered by the Agency in developing this proposal and appropriate Federal Register notices.

This record includes the following information:

A. Supporting Documentation

(1) Federal Register notices pertaining to this rule consisting of:

(a) Notice containing the ITC designation of anthraquinone to the Priority List (49 FR 46931; November 29, 1984).

(b) Rules requiring TSCA section 8(a) and (d) reporting on anthraquinone (49 FR 46739, 49 FR 46741; November 28, 1984).

(c) Notice containing TSCA test guidelines cited as test standards for this rule.

(d) Notice of final rulemaking on data reimbursement (48 FR 31786; July 11, 1983).

(e) Notice of final rule on single-phase test rule development and exemption procedures (50 FR 20652; May 17, 1985).

(f) TSCA GLP Standards (48 FR 53922; Nov. 29, 1983).

(2) Anthraquinone economic analysis.

(3) Communications before proposal consisting of:

(a) Written public comments and letters.

(b) Contact reports of telephone conversations.

(c) Meeting summaries.

(4) Reports—published and unpublished factual materials.

B. References

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- (2) USEPA. U.S. Environmental Protection Agency. "Chemical property and environmental behavior estimates for chemicals on the 15th ITC priority list." Intra-agency memo from Pat Harrigan, EED, to Jeff Davidson, TRDB, November 29, 1984.
- (3) ICI Americas, Inc. Indirect Food Additive Petition for the use of 9, 10-anthraquinone as a pulping processing aid. Volume 1, Section H. Submitted to Food and Drug Administration, August 9, 1978.
- (4) C-I-L, Inc. Unpublished study: Environmental Testing Programs for Anthraquinone. W.O. No. 1274-05-01. Prepared by Roy F. Weston, Inc., West Chester, PA, April 1980.
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EPA will supplement this record with relevant information as received. Confidential Business Information (CBI) while part of the record, is not available for public review. A public version of the record, from which CBI has been deleted, is available for inspection in the OPTS Reading Rm. E-107, 401 M St., SW., Washington, D.C., from 8 a.m. to

p.m. Monday through Friday, except legal holidays.

XI. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and therefore subject to the requirement of a Regulatory Impact Analysis. EPA has determined that this test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order, i.e., it will not have an annual effect on the economy of at least \$100 million, will not cause a major increase in prices, and will not have a significant adverse effect on competition or the ability of U.S. enterprises to compete with foreign enterprises.

This proposed regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any comments from OMB to EPA, and any EPA response to those comments, are included in the rulemaking record.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (15 U.S.C. 601 *et seq.*, Pub. L. 96-354, September 19, 1980), EPA is certifying that this rule if promulgated, will not have a significant impact on a substantial number of small businesses because: (1) they are not expected to perform testing themselves, or to participate in the organization of the testing effort; (2) they will experience only very minor costs in securing exemption from testing requirements; and (3) they are unlikely to be affected by reimbursement requirements and (4) small manufacturers and importers would be exempt from the reporting provisions of the rule.

C. Paperwork Reduction Act

The information collection requirements contained in this rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and have been assigned OMB control numbers 2070-0033 and 2070-0067. Comments on these requirements should be submitted to the Office of Information and Regulatory Affairs of OMB marked "Attention: Desk Officer for EPA." The final rule package will respond to any OMB or public comments on the information collection requirements.

List of Subjects in 40 CFR Parts 704 and 799

Testing, Environmental Protection, Hazardous Substances, Recordkeeping and Reporting Requirements, Chemicals.

Dated: October 31, 1985.

John A. Moore,
Assistant Administrator for Pesticides and Toxic Substances.

Therefore, it is proposed that 40 CFR Chapter I be amended as follows:

PART 704—[AMENDED]

1. Part 704 is amended as follows:

a. The authority citation for Part 704 continues to read as follows:

Authority: 15 U.S.C. 2607

b. By adding § 704.69 to read as follows:

§ 704.69. Anthraquinone.

(a) *Substance for which reporting is required.* The chemical substance for which reporting is required under this rule is 9, 10-Anthraquinone (Chemical Abstract Service Registry Number 84-85-1).

(b) *Persons who must report.* The following persons unless exempt as provided in § 704.5 of this chapter are subject to the reporting requirements of this rule: a person may be required to report more than once in response to this rule.

(1) *Initial reporting.* Persons who manufactured or imported 9,10-Anthraquinone for commercial purposes during the person's latest complete corporate fiscal year prior to (the effective date of the final rule).

(2) *Subsequent reporting.* Persons who manufacture or import 9,10-Anthraquinone for commercial purposes after (the effective date of the final rule). The persons described in this paragraph (b)(2) include persons who reported initially in response to paragraph (b)(1) of this section and persons who commence the manufacture or importation of 9,10-Anthraquinone after (the effective date of the final rule).

(c) *When to report*—(1) *Initial reporting.* Persons described in paragraph (b)(1) of this section must submit an initial report within 60 days of (the effective date of the final rule).

(2) *Subsequent reporting.* Persons described in paragraph (b)(2) of this section must submit a report within 60 days of the completion of any corporate fiscal year during when they manufactured or imported 9,10-Anthraquinone. This requirement shall be applicable to persons who reported initially for the rule and persons who commence the manufacture or importation of 9,10-Anthraquinone after

(the effective date of the final rule). Persons shall submit a separate report for each corporate fiscal year in which they are subject to the rule.

(d) *What information to report.* All persons subject to this rule shall report the following information to EPAS.

(1) Company name and headquarter address.

(2) Name, address, and telephone number (including area code) of the company's principal technical contact

(3) The quantity (in pounds) of 9,10-Anthraquinone manufactured or imported during the person's latest complete corporate fiscal year.

(e) *Where to send reports.* Reports must be submitted by certified mail to the United States Environmental Protection Agency, Document Processing Center, P.O. Box 2070, Rockville, MD 30852. Attn: Anthraquinone.

PART 799—[AMENDED]

a. The authority citation for Part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

b. By adding § 799.500, and the OMB control number to read as follows:

§ 799.500 Anthraquinone.

(a) *Identification of test substance.* (1) 9,10-Anthraquinone (CAS No. 84-85-1) (hereinafter "anthraquinone") shall 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, process anthraquinone, other than as impurity, from the effective date of the final rule (44 days after date of publication of the final rule in the Federal Register) 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 § 796.1960 of this chapter.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency least 30 days prior to initiating testing.

(B) The water solubility test shall be completed and the final results

submitted to the Agency within 1 year of the effective date of the final rule.

(C) Quarterly progress reports shall be submitted.

(2) *Fish acute toxicity*—(i) *Required testing.* (A) Fish acute toxicity tests shall be conducted with anthraquinone using chinook salmon, *Oncorhynchus tshawytscha*, or coho salmon, *Oncorhynchus kisutch*; bluegill, *Lepomis macrochirus*; and rainbow trout, *Salmo gairdneri* in accordance with the test guideline specified under § 797.1400 of this chapter and using modifications of the fish acute toxicity test for anthraquinone specified in paragraph (c)(2)(i)(B) of this section.

(B) Modifications. The following modifications for testing anthraquinone are required.

(1) At least five test concentrations shall be used. The highest concentration shall be less than or equal to the solubility limit of anthraquinone as determined under the testing specified in paragraph (c)(1)(i) of this section.

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

(3) *Concentration of dissolved test chemical.* The requirement under § 797.1400 of this chapter is modified to require that the concentration of test substance shall be measured in each test chamber and the delivery chamber before the test to ascertain whether it is in solution. The total and dissolved (e.g., filtered) concentrations shall be determined.

(4) The test shall be performed under flow-through conditions; the minimum volume of the test solution delivered to each test aquarium in 24 hours shall be 5 times the aquarium volume.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 30 days prior to initiating testing.

(B) The fish acute toxicity tests shall be completed and the final results submitted to the Agency within 1 year of the effective date of the final rule.

(C) Quarterly progress reports shall be submitted.

(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, respectively, and using modifications of the daphnid and oyster acute toxicity tests for anthraquinone specified in paragraph (c)(3)(i)(B) and (C) of this section.

(B) Modifications of the daphnid acute toxicity test. The following modifications for testing anthraquinone are required.

(1) At least five test concentrations shall be used. The highest concentration shall be less than or equal to the solubility limit of anthraquinone as determined under the testing specified in paragraph (c)(1)(i) of this section.

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

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

(4) Concentration of dissolved test chemical. The requirement under § 797.1300 of this chapter is modified to require that the concentration of test substance shall be measured in each test chamber and the delivery chamber before the test to ascertain whether it is in solution. The total and dissolved (e.g., filtered) concentrations shall be determined.

(5) The delivery and test chambers shall be covered.

(6) The test shall be performed under flow-through conditions; the minimum volume of the test solution delivered to each test aquarium in 24 hours shall be 5 times the aquarium volume.

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

(C) Modifications of the oyster acute toxicity test. The following modifications for testing anthraquinone are required.

(1) At least five test concentrations shall be used. The highest concentration shall be less than or equal to the solubility limit of anthraquinone as determined under the testing specified in paragraph (c)(1)(i) of this section.

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

(3) *Concentration of dissolved test chemical.* The requirement under § 797.1800 of this chapter is modified to require that the concentration of test substance shall be measured in each test chamber and the deliver chamber before the test to ascertain whether it is in solution. The total and dissolved (e.g., filtered) concentrations shall be determined.

(4) The test shall be performed under flow-through conditions; the minimum volume of the test solution delivered to each test aquarium in 24 hours shall be 5 times the aquarium volume.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 30 days prior to initiating testing.

(B) The invertebrate acute toxicity tests shall be completed and the final results submitted to the Agency within 1 year of the effective date of the final rule.

(C) Quarterly progress reports shall be submitted.

(4) *Sediment toxicity*—(i) *Required testing.* A sediment toxicity test shall be

conducted using clean sediments having low, medium, and high clay content spiked with anthraquinone in the concentration range of 0.01 to 1 ppr using the marine amphipod, *Rhepoxynius abronius*, according to test guideline specified in the American Society for Testing and Materials Special Technical 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. The ASTM STP 854 is available for inspection at the Office of the Federal Register, Rm. 8401, 1100 L St., NW., Washington, DC. This incorporation by reference was approved by the Director of the Office of the Federal Register. 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 Document Control Officer (TS-793), Office of Toxic Substances, EPA, Rm. 107, 401 M St., SW., Washington, DC 20460, and from the American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 30 days prior to initiating testing.

(B) The sediment toxicity test shall be completed and the final results submitted to the Agency within 1 year of the effective date of the final rule.

(C) Quarterly progress reports shall be submitted.

(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 and using modifications of the oyster bioconcentration test for anthraquinone specified in paragraph (c)(5)(i)(B) of this section.

(B) Modifications. The following modifications for testing anthraquinone are required.

(1) The test concentration shall be less than the solubility limit of anthraquinone as determined under the testing specified in paragraph (c)(1)(i) of this section, and should be close to 1 ppb to 10 ppb.

(2) At least two concentrations shall be tested which are at least a factor of 10 apart.

(3) Concentration of dissolved test chemical. The requirement under § 797.1830 of this chapter is modified to require that the concentration of test substance shall be measured in each test chamber and the delivery chamber before the test to ascertain whether it is in solution. The total and dissolved (e.g., filtered) concentrations shall be determined.

(4) The test shall be performed under flow-through conditions; the minimum volume of the test solution delivered to each test aquarium in 24 hours shall be 5 times the aquarium volume.

(i) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 30 days prior to initiating testing.

(B) The bioconcentration test shall be completed and the final results submitted to the Agency within 1 year of the effective date of the final rule.

(C) Quarterly progress reports shall be submitted.

(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 during a single calendar year exceeds 3 million pounds, and the acute toxicity testing triggers described in this paragraph are met. EPA will monitor the production and importation volume of anthraquinone by requiring at 40 CFR 704.89 that manufacturers and importers of anthraquinone submit section 8(a) reports to the Agency. EPA will publish notification in the Federal Register if the manufacture/importation volume trigger and an acute toxicity trigger are met. If an acute toxicity trigger is not met and EPA determines that neither second-tier testing nor further section 8(a) reporting is necessary, EPA will publish notification of this determination in the Federal Register and will terminate the section 8(a) reporting requirements for anthraquinone.

(1) *Biodegradability in sludge systems—(i) Required testing.*

Biodegradability tests in sludge systems 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 method entitled "Inherent Biodegradability: Modified SCAS (semicontinuous activated sludge) Test for Chemical Substances that are Water Insoluble or Water Insoluble and

Volatile" as specified under § 796.3341 of this chapter, 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 any of the following conditions is met: (A) the LC₅₀ of a fish or daphnid or oyster, as determined by the acute toxicity tests conducted in accordance with paragraph (c)(2) or (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*, 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.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 30 days prior to initiating testing.

(B) The biodegradability tests in sludge systems shall be completed and the final results submitted to the Agency within 1 year of the date of 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.

(C) Quarterly progress reports shall be submitted.

(2) *Biodegradation rate—(i) Required testing.* (A) 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 a study 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 total annual volume of anthraquinone manufactured and imported in the United States during a single calendar year exceeds 3 million pounds, and any of the following conditions is met: (1) the LC₅₀ of a fish or 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; (2) the LC₅₀ of *Rhepoxynius*, 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 (3) 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 Bourquin et al. article, published in *Developments in Industrial Microbiology*, vol. 18, chapter 11, 1977, is available for inspection at the Office of the Federal Register, Rm. 6401, 1100 L St., NW., Washington, DC. This incorporation by reference was approved by the Director of the Office of the Federal Register. 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 Document Control Officer (TS-793), Office of Toxic Substances, EPA, Rm. 107, 401 M St., SW., Washington, DC 20460, and from the Society for Industrial Microbiology, P.O.B. 12534, Arlington, VA 22209-8534.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 30 days prior to initiating testing.

(B) Biodegradation rate tests shall be completed and the final results submitted to the Agency within 1 year of the date of 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.

(C) Quarterly progress reports shall be submitted.

(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 § 797.1800 of this chapter and using modifications of the fish chronic toxicity test for anthraquinone specified in paragraph (d)(3)(i)(B) of this section, 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 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) Modifications. The following modifications for testing anthraquinone are required.

(1) At least five test concentrations shall be used. The highest concentration

shall be less than or equal to the solubility limit of anthraquinone as determined under the testing specified in paragraph (c)(1)(i) of this section.

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

(3) Concentrations of dissolved test chemical. The requirement under § 797.1600 of this section is modified to require that the concentration of test substance shall be measured in each test chamber and the delivery chamber before the test to ascertain whether it is in solution. The total and dissolved (e.g., filtered) concentrations shall be determined.

(4) The test shall be performed under flow-through conditions: the minimum volume of the test solution delivered to each test aquarium in 24 hours shall be 5 times the aquarium volume.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 30 days prior to initiating testing.

(B) Fish chronic toxicity tests shall be completed and the final results submitted to the Agency within 1 year of the date of 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.

(C) Quarterly progress reports shall be submitted.

(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 and using modifications of the daphnid chronic toxicity test for anthraquinone specified in paragraph (d)(4)(i)(B) of this section. 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) Modifications. The following modifications for testing anthraquinone are required.

(1) At least five test concentrations shall be used. The highest concentration shall be less than or equal to the solubility limit of anthraquinone as determined under the testing specified in paragraph (c)(1)(i) of this section.

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

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

(4) Concentration of dissolved test chemical. The requirement under

§ 797.1330 of this chapter is modified to require that the concentration of test substance shall be measured in each test chamber and the delivery chamber before the test to ascertain whether it is in solution. The total and dissolved (e.g., filtered) concentration shall be determined.

(5) The delivery and test chambers shall be covered.

(6) The test shall be performed under flow-through conditions: the minimum volume of the test solution delivered to each test aquarium in 24 hours is 5 times the aquarium volume.

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

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 30 days prior to initiating testing.

(B) The Daphnid chronic toxicity test shall be completed and the final results submitted to the Agency within 1 year of the date of 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.

(C) Quarterly progress reports shall be submitted.

(Information collection requirements have been approved by the Office of Management and Budget under control numbers 2070-0033 and 2070-0067.)

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