

**ENVIRONMENTAL PROTECTION
AGENCY****40 CFR Part 790**

(OPTS-42096; FRL-3223-4)

**2, 6-Di-Tert-Butylphenol; Proposed
Test Rule****AGENCY:** Environmental Protection
Agency (EPA).**ACTION:** Proposed rules.

SUMMARY: EPA is proposing that manufacturers and processors of 2,6-di-tert-butylphenol (DTBP, CAS No. 128-39-2) be required, under section 4 of the Toxic Substances Control Act (TSCA), to perform testing for chemical fate and environmental effects. This rule is proposed in response to the Interagency Testing Committee's (ITC's) designation of DTBP for priority consideration for chemical fate, health effects, and ecological effects testing.

DATES: Submit written comments on or before August 24, 1987. If persons request an opportunity to submit oral comment by August 10, 1987, EPA will hold a public meeting on this rule in Washington, DC. For further information on arranging to speak at the meeting see Unit VII of this preamble.

ADDRESS: Submit written comments, identified by the document control number (OPTS-42096), in triplicate to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. NE-C004, 401 M St., SW., Washington, DC 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, DC 20460, (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 DTBP for health effects, chemical fate and ecological effects testing consideration. The Agency is proposing testing for DTBP under section 4(a)(1)(A) of TSCA because of the potential for release of DTBP into ambient waters and because of DTBP's estimated acute toxicity to aquatic and benthic organisms. EPA has concluded that existing data are inadequate to assess the risks to the

environment posed by exposure to DTBP and that testing of DTBP is necessary to develop such data.

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 recommended DTBP (CAS No. 128-39-2) with intent to designate for health effects, ecological effects and chemical fate testing in its 17th Report, published in the *Federal Register* of November 19, 1986 (50 FR 47603). The ITC designated DTBP for priority consideration in its 18th Report, published in the *Federal Register* of May 19, 1986 (51 FR 18366). The ITC recommended that DTBP be considered for health effects testing, including toxicokinetics and chronic toxicity; chemical fate testing, including persistence in aerobic and anaerobic sediments; and ecological effects testing, including acute toxicity and bioconcentration in benthic organisms.

The ITC's rationale for health effects testing was based on concern for the potential for human exposure, pronounced effects on the prothrombin index, and DTBP's irritant action.

The ITC's rationale for chemical fate testing was based on: (1) DTBP's identification in surface waters, wastewater, and sediments; (2) DTBP's high aquatic release potential; and (3) DTBP's potential to partition to and persist in sediments.

The ITC's rationale for ecological effects testing was based on: (1) DTBP's estimated acute toxicity to fish at low concentrations (< mg/L); (2) the lack of acute and chronic toxicity data for aquatic and benthic species; and (3) the potential to bioconcentrate based on the estimated log K_{ow} value of 5.4.

**B. Opportunity for Negotiating a
Consent Order**

EPA has issued an Interim Final Rule that amends EPA's procedural regulations in 40 CFR Part 790 for the development and implementation of testing requirements under section 4 of TSCA. The amendments established procedures for using enforceable consent agreements to require testing under section 4 of the Act. EPA intends to use such consent agreements where a consensus exists among the Agency, affected manufacturers and/or processors, and interested members of the public about the need for and scope

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of testing requirements. The consent agreement provides an option to the test rule development process, facilitating the rapid development of test data without the necessity of EPA using the lengthy rulemaking process.

Where EPA concludes that the Agency and the affected firms and interested parties cannot reach a consensus on the testing requirements or other provisions to be included in the consent agreement, the Agency will proceed with rulemaking under section 4(a) of TSCA. A description of the procedures governing consent agreements and test rules appears in detail in the Federal Register of June 30, 1986 (51 FR 23706).

The first step in determining the feasibility of developing a consent agreement for a specific chemical is the identification of interested parties who may wish to participate in negotiations with EPA. In the Federal Register of July 2, 1986 (51 FR 24222), EPA announced the decision that the Agency was considering developing a testing consent agreement for DTBP. This notice requested interested parties to identify themselves. Ethyl Corporation and Schenectady Chemicals, Inc. requested participation in negotiating a consent order; however, a final agreement was not obtained. Consequently, the Agency is proceeding with rulemaking under section 4(a) of TSCA.

C. 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 Agency 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 section 4(a)(1)(A)(ii) and (B)(ii), EPA examines toxicity and 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 (B)(iii) that testing is necessary, EPA considers whether ongoing testing will satisfy the informational 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, 1986 (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 DTBP, EPA considered all available relevant information including the following: Information presented in the ITC's report recommending testing consideration and any public comments on the ITC's recommendations; production volume, use, exposure, and release information reported by manufacturers of DTBP 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) concerning DTBP; and published and unpublished data available to the Agency. From its evaluation, as described in this proposed rule, EPA is proposing chemical fate and environmental effects testing requirements for DTBP under section 4(a)(1)(A). By this section, EPA is responding to the ITC's designation of DTBP for priority testing consideration.

II. Review of Available Data

A. Profile

DTBP is a crystalline solid that is soluble in many organic solvents; estimates of its solubility in water range from 0.4 to 2.5 mg/L. (Refs. 1, 2). DTBP has an estimated vapor pressure of <0.01 mm Hg at 20 °C, a melting point of 39 °C (Refs. 3, 4, 5), and an estimated log K_{ow} value of 5.43 (Ref. 6).

B. Production

DTBP is produced domestically by three corporations: Ethyl Corporation, Schenectady Chemicals, Inc., and PMC Specialties Group. The combined production capacity of DTBP is estimated to be 24 to 34 million pounds per year (Refs. 7, 8). Aceto Corporation is an importer of DTBP. The actual production and import volumes for 1986 have been submitted as confidential business information (CBI).

DTBP is manufactured by a batch or continuous alkylation process. In the reaction sequence, DTBP is manufactured by reacting either phenol or p-cresol with isobutene gas and a catalyst in a closed reactor at temperatures ranging from 105 to 115 °C. The raw product is purified by washing, filtration to remove the catalyst, and distillation. The product is shipped in 55-gallon drum containers or trailers. At all three production sites in the U.S. the material is packaged in the molten state (Ref. 9).

C. Uses

Specific information on DTBP use was voluntarily supplied by the manufacturers as CBI (Ref. 10, CBI). According to the ITC and other non-CBI sources approximately 75 to 95 percent of DTBP is used as a synthetic intermediate for the production of higher molecular weight phenolic antioxidants (Refs. 3, 9). These higher molecular weight antioxidants are mixed into synthetic polymers and plastics such as polypropylene to prevent oxidative degradation during processing and use of the plastic. DTBP is also incorporated into fuels, oils, plastics, rubber, and other products as an oxidation inhibitor and stabilizer (Ref. 3).

D. Environmental Release

DTBP is expected to enter the environment mainly as a result of wastewater releases from sites where DTBP is made and used.

Releases to water due to the manufacture of DTBP are possible during the water washing and neutralization step, cleaning of the equipment, and the washing of the

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containers such as drums and tank trailers. Releases to land occur due to disposal of filter solids and the heavy ends from the distillation column.

At the Schenectady production site, releases to water may be minimal. The equipment used for manufacture is dedicated for production of alkylated phenol; therefore, cleaning is rarely done. The tank trucks are handled by a common carrier, and cleaning of the tank trucks is not done on the Schenectady site. The residue is landfilled (Ref. 9).

At the Ethyl manufacturing site in Orangeburg, South Carolina, releases to water are due to the phase separation of the reaction product. The equipment used to manufacture DTBP is also used to manufacture alkylated phenol; therefore, equipment washing is seldom done. Some material is either landfilled or incinerated.

At the PMC manufacturing site in Santa Fe Springs, California, releases to water occur during washing of the equipment and shipping containers. The submitter did not estimate the amount of material released to land but it is likely that some of the material is released via disposal of spent filters and distillation bottoms (Ref. 9).

Processors may release DTBP to water in the production of higher molecular weight antioxidants; however, release to water is not expected in other applications such as formulating additives for fuels or lubricants (Ref. 9).

The ITC cited studies by Jungclaus et al. (Ref. 11) and Lopez-Avila et al. (Ref. 12) that reported DTBP levels in sediments, receiving waters and effluents from a specialty chemical plant in Rhode Island. The manufacturers of DTBP provided release data under section 8(a) of TSCA (submitted as CBI). Predicted environmental concentrations (PECs) for these plant sites are confidential; however, given DTBP's predicted acute toxicity to environmental organisms (Unit II.H.1), the Agency concluded that these levels (Ref. 13, CBI) are sufficient to support a "may present an unreasonable risk" finding under TSCA section 4(a)(1)(A).

E. Chemical Fate

Because of its high $\log K_{ow}$, DTBP is expected to partition readily to sediments; its reactivity and persistence in this medium are not well characterized. Volatilization of DTBP should be slow because of the low estimated vapor pressure. Some volatilization from water to air has been reported (Ref. 14) but no half-life was calculated. DTBP is expected to be rapidly oxidized in air (Ref. 15). The very few experimental data are

insufficient to characterize the chemical fate of DTBP.

F. Human Exposure

1. *Occupational.* The National Occupational Hazard Survey conducted by the National Institute for Occupational Safety and Health during 1972-1974 estimated that 2,192 people in six industries were exposed to DTBP in the workplace in 1970 (Ref. 16). However, EPA estimates that the number of potentially exposed workers is now much lower and that 12 to 45 workers are involved in the manufacture of DTBP (Ref. 9). In addition to section 8(a) submissions, the manufacturers have provided further exposure information claimed as CBI. The Agency estimates that 38 to 60 workers are potentially exposed to DTBP a few days a year in the manufacture of high molecular weight antioxidants (Ref. 9). The number of workers exposed to DTBP as a fuel or lubricant additive is not known; however, exposures are expected to be low because of the low concentrations of DTBP in formulated products (actual concentrations are CBI) (Ref. 9).

In the manufacture of DTBP there is a potential for inhalation and dermal exposure. At all three manufacturing sites, the worker activities include sampling/analysis, changing of the filters, product loading into drums or trailers, and possible cleaning of the equipment. The highest exposures could occur during the sampling (during production process) and loading operations. For the processing of DTBP into high molecular weight antioxidants exposures may occur during the connection and disconnection of transfer lines and the sampling of shipping containers. Protective clothing (e.g. gloves, goggles, respirators) is reported to be typically used (Ref. 9). EPA concludes that occupational exposures to DTBP are low and intermittent and that fewer than 100 workers are probably involved.

2. *Consumer and general population.* Some DTBP is used at low levels in gasoline, fuel oils, and such products as plastics and rubber. The low volatility of DTBP, the nature of the products in which it is used and the low concentrations of DTBP employed indicate a low potential for significant or substantial human exposure from these sources. EPA estimated the consumer exposure to DTBP in gasoline if gasoline were spilled on the skin every time the consumer used a self-service pump. If the frequency of use is once every 5 days, the estimated exposure is 13.6 ug/kg/yr (Refs. 17, 18).

DTBP will adsorb strongly to soil particles and partition to the sediment, and thus it is not expected to persist in water sufficiently to exceed low steady-state levels in discharge areas. Using data submitted as CBI, EPA has estimated possible levels of DTBP in drinking water near Ethyl's Orangeburg, SC site, as well as levels which could occur in fish due to bioconcentration. These estimates are considered CBI. The amounts of DTBP that could be consumed from drinking water, if concentrations of 0.001 to 0.006 mg/L were present as reported by Jungclaus (Ref. 11), would be 0.01 to 0.06 mg/kg/yr (Ref. 17). No other sources of exposure for the general population were identified.

G. Health Effects

1. *Pharmacokinetics.* Only limited data are available on the absorption, distribution and excretion of DTBP. Freitag et al. (Ref. 14) reported on a survey of a large number of diverse compounds for biologic fate following oral administration to male Wistar rats. The DTBP used in this study was 98 percent pure and uniformly radiolabeled with ^{14}C in the ring. The animals in groups of three were administered the compound by gavage at a level of 25 ug/rat (147 ug/kg body weight) daily for the first 3 days of the study. Feces and urine were collected during the 7 days of the study, and at termination on the 8th day, selected tissue samples were taken for analysis of radioactivity distribution and retention.

During the course of the study, 72.4 percent of the label was excreted in the feces, while 10.8 percent was eliminated in the urine. Although elimination of radioactivity in the urine was indicative of absorption, the study design did not permit determination of the extent of absorption or whether the eliminated material was parent compound or metabolite. Tissue analysis on the 8th day indicated that a total of 2.9 percent of the radiolabel was retained by the entire carcass. The amount of material retained by the liver and lungs was 0.10 and <0.01 percent (the detection limit) of the administered dose, respectively, while the adipose tissue retained 0.03 percent of the administered dose/g of tissue. Approximately 15 percent of the administered radioactivity was not accounted for.

2. *Acute, subchronic and chronic toxicity.* Studies assessing the acute effects of DTBP in a variety of species using different routes of exposure have been submitted under section 8(d) and have been summarized (Ref. 19).

Only the study by Ethyl Corporation (Refs. 20, 21) used sufficiently high doses to allow calculation of an oral LD50. Their LD50 value of 5.26 g/kg is consistent with the studies by Ciba-Geigy (Ref. 22) and Shell Oil Co. (1986) where only sporadic deaths occurred at doses up to 5 g/kg. Most of these reports provided no description of the signs of toxicity with the exception of the study by Ciba-Geigy (Ref. 23) where dyspnea, exophthalmos, tremors, ruffled fur and altered body posture were reported. Some of these signs were observed at each dose level, with the severity and length of time to recovery increasing in a dose-related manner. At the highest dose, 5 g/kg, there were no residual signs of toxicity by day 9.

Studies using other routes of administration (inhalation and dermal) (Refs. 20, 21, 23) failed to define a lethal dose. In the inhalation study, the exposure was too low for this purpose. Dermal LD50 values for rats were reported to be greater than 1 g/kg and greater than 32 g/kg. These studies as well as other acute data submitted indicate that DTBP is not highly toxic after acute exposure by either the oral or dermal routes.

DTBP has also been tested for its potential to cause skin and eye irritation. In experiments where pure DTBP was applied directly to intact and abraded skin, slight erythema and edema were observed for intact skin, with more pronounced effects for abraded skin (Refs. 23, 24). However, marked irritation was caused by a DTBP-containing material identified as TK 12 891. In this study, 0.5g of TK 12 891 as a 50 percent solution in polyethylene glycol 400:adins (70:30) was applied to the intact and abraded skin of rabbits. A high degree of irritation was reported with the occurrence of ischemic areas, erythema, and in one animal loss of the stratum corneum (Ref. 25).

TK 13 126, which contains 30 percent of DTBP, was tested by Ciba-Geigy (Ref. 26) for the potential to cause depigmentation of the skin in black guinea pigs. Groups of five male and five female guinea pigs received daily application (except weekends) of 0.1 mL of a 1, 3 or 10 percent solution of TK 13 126 over a period of 8 weeks. Under these test conditions, no effect on pigmentation was observed. In eye irritation tests by Ethyl Corp. (Ref. 27) and Shell Oil Co. (Ref. 23) DTBP was shown to be nonirritating. Ciba-Geigy (Ref. 28) reported that TK 12 891 was a minimal eye irritant.

DTBP failed to induce delayed contact hypersensitivity in guinea pigs (Ref. 29).

From these data DTBP appears to be a mild to moderate irritant. Certain formulations containing DTBP, or particular application methods, may cause a higher degree of irritation.

Several survey studies of alkylphenols have been conducted. DTBP was studied as well as other phenolic antioxidants, such as BHT, a commonly used food additive and analog for DTBP. In one study DTBP and other structurally related antioxidants were examined for their potential to induce pulmonary edema in male ddY mice (Ref. 30). A group of four animals received a single intraperitoneal injection of DTBP at 2.27 mmol/kg (466 mg/kg) and were assessed 4 days later for body weight, wet lung weight and dry lung weight changes. This treatment resulted in no DTBP-induced changes, although an 11.5 percent decrease in body weight and 103 and 50 percent increases in wet and dry lung weight were observed for the analog BHT at the same molar dose. The two other alkylphenols tested, 2-tert-butyl-4-methyl- and 2-tert-butyl-4,6-dimethylphenol, which both have a 4-methyl group, also produced lung edema, whereas DTBP and other alkylphenols lacking the 4-methyl group were inactive when tested.

In a short-term feeding study conducted by Takahashi and Hiraga (Ref. 31), groups of 5 to 10 male Sprague-Dawley rats were fed diets containing phenolic antioxidants or potential metabolites for 3 weeks. DTBP was included in the diet at a level of 5.44 mmol/100 g, which resulted in a daily consumption of 4.55 mmol/kg (937 mg/kg). On day 19, two of the 10 animals exposed to DTBP died. These animals, along with four that were killed at the end of the study, had extensive hemorrhaging. The tissues involved included epididymis, muscle, thymus, pleural cavity, cranial cavity and submaxillary lymph nodes, along with intragastric pools of blood. The prothrombin index was decreased to 19 percent of control. Five groups of 10 rats each were also fed for 3 weeks with the analog BHT at doses ranging from 2.62 to 4.48 mmol/kg/day. These levels produced the same toxic effect of decreased prothrombin index and deaths due to hemorrhage. The prothrombin index was decreased to 11 to 12 percent of the control value. The dose used for DTBP was equal on a molar basis to the BHT LD50 resulting from hemorrhage. Other compounds which caused hemorrhaging were 2,5-di-tert-butylhydroquinone and 2,4,5-tributylphenol. Butylated hydroxyanisole and the aldehyde,

alcohol and acid derivatives of BHT were inactive.

Effects of DTBP on hepatic drug-metabolizing enzymes have been studied in rats and mice by Gilbert et al. (Refs. 32, 33) and in mice and *in vitro* systems by Rahimtula et al. (Ref. 34). Effects on enzyme systems were reported; however, this may not be an indication of potential hazard. Phenolic antioxidants typically induce enzymes, including detoxification enzymes, which may play a prominent role in the protective effects attributed to them such as anticarcinogenic and antimutagenic activity (Ref. 35).

3. *Teratogenicity and reproductive effects.* No data were found on the teratogenicity or reproductive system toxicity of DTBP.

The ITC cited a study performed by Telford et al. (Ref. 36) on the effects of DTBP on fetal reabsorption in rats. On review of this study, it was apparent that the data extracted were for 2,2-methylenebis(4-ethyl-6-tert-butylphenol) and not DTBP. DTBP was not one of the compounds tested.

4. *Mutagenicity.* Dean et al. (Ref. 37) reported on the genotoxicity testing of 41 industrial chemicals performed by Shell Toxicology Laboratories between the years 1975 and 1981. DTBP was tested in 1976 for reverse mutation in *Salmonella typhimurium* strains TA1535, TA1537, TS1536, TA98 and TA100; and in *Escherichia coli* strains WP2 and WP2 UVRA, for mitotic gene conversion in *Saccharomyces cerevisiae* JDI, and for the ability to cause chromosomal damage in cultured rat liver cells. The microbial assays were performed both in the presence and absence of an exogenous metabolic activation system prepared from Aroclor 1254 pretreated rats. The DTBP tested which was >98 percent pure, was negative in all test systems.

5. *Carcinogenicity.* No data were available on the carcinogenic potential of DTBP.

H. Environmental Effects

1. *Acute toxicity.* No data were found for DTBP. On the basis of published data on related compounds (Ref. 38) an LC50 to fish of 0.28 mg/L is estimated.

2. *Chronic toxicity.* No information was found on the chronic toxicity of DTBP to environmental organisms.

3. *Bioconcentration.* A bioconcentration factor (BCF) of 800 after 1 day was measured in an alga (*Chlorella*) (Ref. 2). The measured BCF in a fish (golden orfe), was 660 after 3 days (Ref. 14). The estimated BCF of DTBP in fish, based on a log P of 5.43 and using the method of Veith et al. (Ref.

39) is 8,200; the actual BCF may be lower if DTBP is metabolized, as suggested by the study in the golden orfe.

III. Findings

EPA is basing its proposed chemical fate and environmental effects testing for DTBP on the authority of section 4(a)(1)(A) of TSCA.

EPA finds that the release of DTBP from its manufacture and processing may present an unreasonable risk to the environment. The estimated log K_{ow} of 5.4 and the estimated LC50 of 0.28 mg/L for fish suggest that DTBP may be very toxic to aquatic and benthic organisms, particularly under chronic exposure conditions, at concentrations which may approach PECs. No environmental effects testing data on DTBP have been identified in the literature or made available to the Agency. Available data are insufficient to reasonably determine or predict the environmental effects and chemical fate of DTBP in sediments and water. The Agency has determined that testing is necessary to develop environmental effects and chemical fate data. EPA believes that the data resulting from these test requirements will be relevant to a determination that the manufacturing or processing of DTBP does or does not present an unreasonable risk of injury to the environment.

EPA is not proposing testing for health effects at this time. The ITC recommended toxicokinetics and chronic testing for DTBP, citing the main health concerns as DTBP's ability to cause hemorrhaging and skin irritation. Takahashi and Hirage reported that DTBP, as well as other phenolic antioxidants such as the food additive BHT, caused hemorrhaging when fed to rats at high levels for 3 weeks.

EPA has reviewed available data on health effects and potential human exposure. The few specific health effects identified in the literature occur only at relatively high exposure levels in animals. EPA's review of potential human exposure (see Unit II.F) to DTBP

leads the Agency to conclude that the amounts released to the environment as a result of activities involving DTBP, and the amounts to which workers may be exposed during manufacturing and processing and to which other people may be exposed by contact with products containing DTBP, are extremely low, well below the animal exposure levels. From the available information, taken as a whole, EPA does not find at this time that DTBP may present an unreasonable risk of human health effects.

EPA is not proposing at this time the bioconcentration testing recommended by the ITC. Although DTBP may bioconcentrate in aquatic organisms if it is not metabolized readily, EPA has considered the potential for consumption of DTBP from this source, using in part CBI release data, and concluded that such consumption is not likely to be substantial or significant. In addition, DTBP's relatively low mammalian toxicity indicates that consumption of DTBP-contaminated organisms by fish-eating animals (including man) is not likely to result in any secondary toxicity to the consuming organisms. Therefore, EPA does not find that bioconcentration testing is necessary for DTBP.

IV. Proposed Rule

A. Proposed Testing and Test Standards

On the basis of the information presented in Unit II and the findings set forth in Unit III, EPA is proposing chemical fate and environmental effects testing for DTBP. The tests are to be conducted in accordance with EPA's TSCA Good Laboratory Practice standards in 40 CFR Part 792 and specific TSCA test guidelines as enumerated in 40 CFR Parts 796 and 797, or other published test methods as specified in this test rule for DTBP. Final revisions to the TSCA test guidelines were published in the Federal Register of May 20, 1987 (52 FR 19056); the Agency is proposing that these revisions

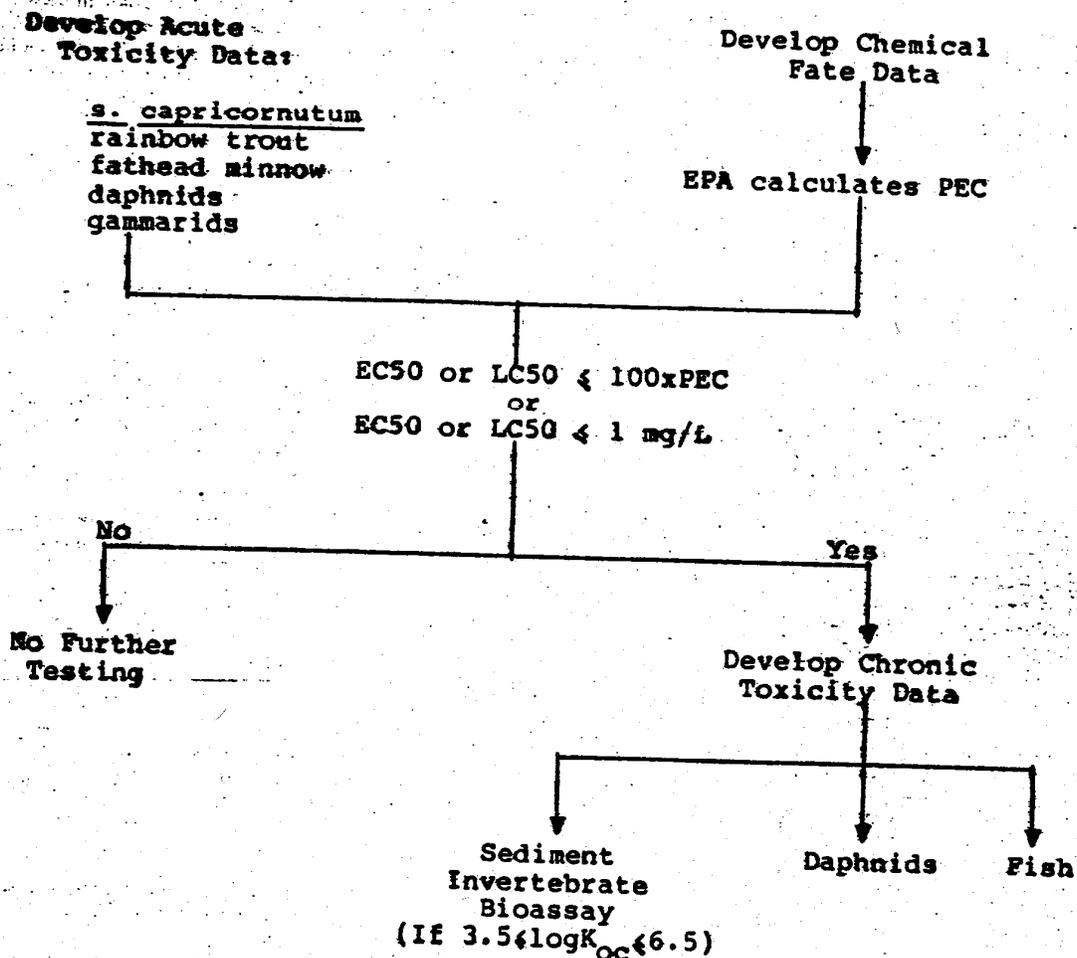
be adopted in the test standards for DTBP.

The chemical fate tests to be conducted for DTBP are: (1) Water solubility, using the guideline at 40 CFR 796.1860; (2) aerobic aquatic biodegradability using the guideline at 40 CFR 796.3100; (3) anaerobic biodegradability using the guideline at 40 CFR 796.3140; (4) photolysis, using the guideline at 40 CFR 796.3765; and (5) sediment adsorption isotherm, using the guideline at 40 CFR 796.2750. The sediment-water partition coefficient K determined in the latter test shall be used to calculate K_{oc} values using the equation $K_{oc} = K/(\text{percent of organic carbon in each test sediment})$.

Aquatic toxicity tests to be conducted using measured concentrations of DTBP include: (1) Acute toxicity to freshwater alga, *Selenastrum capricornutum*, using the test guideline at 40 CFR 797.1050, and as modified under 799.1605 (d)(1)(i)(B); (2) acute toxicity to rainbow trout and fathead minnows in a flow-through system, using the guideline at 40 CFR 797.1400 as modified under 799.1605(d)(2)(i)(B); (3) acute toxicity to daphnids using the guideline at 40 CFR 797.1300; and (4) acute toxicity to gammarids, using the guideline at 40 CFR 797.1310. Using previously published equations (50 FR 39348; September 27, 1985) the Agency estimates that the time for DTBP to reach steady state concentrations in fish will be greater than the four days used for most fish acute toxicity tests. Therefore, the fish acute toxicity test must be extended to 14 days to allow for sufficient uptake of DTBP to produce any acute effects. All the acute toxicity data from these tests will be used to help determine whether chronic testing is necessary.

EPA is also proposing that a daphnid life-cycle test be conducted using measured concentrations of DTBP in a flow-through system, using the guideline at 40 CFR 797.1330, if either of the decision criteria in the following Fig. 1 is satisfied.

Fig. 1--PROPOSED DECISION LOGIC FOR DEVELOPING CHEMICAL FATE AND ENVIRONMENTAL EFFECTS DATA FOR DTBP



Testing for early-life stage toxicity to fish shall also be conducted using measured concentrations of DTBP in a flow-through system using the guideline at 40 CFR 797.1000, if either of the decision criteria in Fig. 1 is satisfied. The test species shall be the fish with the lower LC50 value.

A benthic sediment invertebrate bioassay shall be conducted using the method of Adams et al. (Ref. 40), if chronic fish and aquatic invertebrate testing must be performed (see Fig. 1) and if the value of log K_{oc} as determined in the sediment adsorption isotherm test lies in the range 3.5-6.5.

This 14-day toxicity test shall be conducted with the midge (*Chironomus tentans*) in a flow-through system using three different DTBP-spiked clean, freshwater sediments having low, medium, and high organic carbon content.

The data from any required chronic effects testing will assist EPA in conducting quantitative risk assessments for DTBP, and thus will be of critical importance in determining whether DTBP presents an unreasonable risk of environmental effects.

EPA will use the data from the required chemical fate tests, together

with CBI release data for DTBP, to calculate a new PEC value for DTBP. If further testing is not otherwise triggered, the Agency will notify the test sponsor if the next set of tests must be performed because the PEC-based criterion has been met.

The water solubility test should be completed before any other tests are initiated, in order that the solubility information can be used in designing the remaining tests.

The Agency is proposing that the above referenced chemical fate and environmental effects test guidelines and modifications and other cited

methods be considered the test standards for the purposes of the testing proposed above for DTBP. The TSCA test guidelines for chemical fate and aquatic toxicity testing specify generally accepted minimal conditions for determining chemical fate and aquatic toxicities for substances such as DTBP to which aquatic life is expected to be exposed. Conducting the required studies in accordance with these TSCA guidelines will ensure that the test results are reliable and adequate.

B. Test Substance

EPA is proposing that DTBP of at least 98 percent purity be used as the test substance; DTBP of this purity is commercially available. EPA has specified a relatively pure substance for testing because the Agency is interested in evaluating the effects attributable to DTBP itself.

C. Persons Required To Test

Section 4(b)(3)(B) specifies that the activities for which the EPA 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 findings are based on distribution, use, or disposal.

Because EPA has found that there are insufficient data and experience to reasonably determine or predict the effects of the manufacture and processing of DTBP on the environment, EPA is proposing that persons who manufacture and/or process, or who intend to manufacture and/or process, DTBP other than as an impurity 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 or an amount of time after the submission of the last final report required under the test rule equal to that which was required to develop data, if more than 5 years.

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.

Manufacturers (including importers) subject to this rule 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 final test rule. The required procedures for submitting such letters and applications are described in 40 CFR Part 790.

Processors subject to this rule, unless they are also manufacturers, will not be required to submit letters of intent or exemption applications, or to conduct testing unless manufacturers fail to submit notices of intent to test or later fail to sponsor the required tests. The Agency expects that the manufacturers will pass an appropriate portion of the costs of testing on to processors through the pricing of their products or reimbursement mechanisms. If manufacturers perform all the required tests, processors will be granted exemptions automatically. If manufacturers fail to submit notices of intent to test or fail to sponsor all the required tests, the Agency will publish a separate notice in the Federal Register to notify processors to respond; this procedure is described in 40 CFR Part 790.

EPA is not proposing to require the submission of equivalence data as a condition for exemption from the proposed testing for DTBP. As noted in Unit IV.B, EPA is interested in evaluating the effects attributable to DTBP itself and has specified a relatively pure substance for testing.

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

D. Reporting Requirements

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 45 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 chemical fate tests and acute toxicity tests in fresh water algae, fish, and aquatic invertebrates shall be completed and the final reports submitted to EPA within 12 months of the effective date of the final test rule. Semi-annual progress reports to EPA are required 6 months from the effective date of the rule.

2. The early life-stage toxicity test in fish, the life-cycle test in aquatic invertebrates, and the sediment invertebrate bioassay, if required, shall be completed and the final reports submitted to EPA within 12 months of the date of notification by EPA that these tests are required. Semiannual progress reports to EPA are 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 the final 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 which 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. In brief, as of the effective date of the final test rule, an exporter of DTBP must report to EPA the first annual export or intended export of DTBP to any one country. EPA will notify the foreign country concerning the test rule for the chemical.

EPA is continuing to review issues relating to the application of section 12(b) requirements to exporters of section 4 chemicals and may propose to revise 40 CFR Part 707 in a separate rulemaking.

E. Enforcement Provisions

The Agency considers failure to comply with any aspect of a section 4 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 TSCA 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 the 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 purpose of determining compliance with any final rule for DTBP. 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, and 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 the final rule may be subject to penalties which may be calculated as if they never submitted their data. Under the penalty provisions 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 that fail to submit a letter of intent or an exemption request and that continue manufacturing after the deadlines for such submissions. This provision would also apply to processors that fail to submit a letter of intent or an exemption application and continue processing after the Agency has notified them of their obligation to submit such documents (see 40 CFR 790.28(b)). Intentional violations could lead to the imposition of criminal penalties of 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

This proposed rule specifies TSCA test guidelines and an independent, published test method as the test standards for chemical fate and environmental effects. The Agency is soliciting comments as to whether the chemical fate and environmental effects test guidelines (and the independent method) are appropriate and applicable for the testing of DTBP. Also regarding the testing of DTBP, the Agency requests comments on:

1. The adequacy of the proposed testing to characterize the chemical fate and ecological effects of DTBP.
2. The reporting times for the identified chemical fate and ecological effects tests.
3. Whether there are any other testing approaches that should be considered.
4. EPA's proposed approach to developing chronic toxicity data. The Agency believes that for chemicals where there are not substantial differences between EC50 or LC50 values for algae, fish and aquatic invertebrates and where these EC50 or LC50 values are less than or equal to either 1 mg/L or 100 X PEC, then an aquatic invertebrate life cycle test and a fish early-life cycle test should be conducted. The Agency believes this is a cost-effective approach to obtaining Maximum Acceptable Toxic Concentration (MATC) data on sensitive life stages of aquatic invertebrates and fish and believes these are minimal data necessary to assess the environmental risk of TSCA-regulatable chemicals. The Agency solicits comments on this approach. Specifically, the Agency requests submission of data that would help define when differences between EC50 or LC50s of algae, fish and invertebrates are so large that chronic effects concern can be narrowed to only one class of organisms, i.e., eliminating

the need to conduct chronic tests of fish or aquatic invertebrates if acute toxicity ratios exceed a specific value.

5. EPA's proposed approach to acute aquatic toxicity testing using a cluster of organisms. For TSCA chemicals released to fresh water the Agency believes that acute aquatic toxicity may be adequately characterized by testing in five organisms representing three phyla. The Agency believes that reliable acute toxicity data developed for the five organisms listed in Fig. 1 can provide an estimate of general species sensitivity because of the spectrum of biochemical, physiological and structural features displayed by these organisms. The Agency believes it is more cost effective to develop acute aquatic toxicity data on this cluster of species and to use these data as a surrogate for the range of sensitivity for most freshwater organisms than to test dozens of organisms; this cluster species concept has been described by Dr. Donald Mount of EPA's Environmental Research Laboratory, Duluth MN (Ref. 41). Reliable acute toxicity data are data developed by accepted methods that include measuring test substance concentrations before, during and after testing and using static-renewal or flow-through test systems (for fish and aquatic invertebrates) for chemicals that may volatilize, hydrolyze, photolyze, or biodegrade. If reliable data are available on other freshwater fish, these data may be substituted for data on fathead minnows. If reliable data are available on other freshwater invertebrates, these data may be substituted for data on gammarids.

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

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more precisely the magnitude of the expected impact.

Total testing costs for the proposed rule for DTBP are estimated to range from \$60,000 to \$107,000. This estimate includes the costs for the required minimum series of tests as well as any conditional ones. The annualized test costs (using a cost of capital of 7 percent over a period of 15 years) range from \$7,200 to \$11,800. Based on an estimated production volume of 34 million pounds a year, the unit test cost is approximately 0.03 cents per pound. In relation to the current price of approximately \$1.00 per pound (98 percent purity) of DTBP, these costs are equivalent to 0.03 percent of price.

Based on these costs and market characteristics of DTBP, the economic analysis indicates that the potential for significant adverse economic impact as a result of this test rule is low. This conclusion is based on the following observations: (1) The annualized unit cost of the testing required in this rule is very low; (2) there is a low likelihood of substitution of alternative products owing to test costs; and (3) the market expectations for DTBP are optimistic.

Refer to the economic analysis which is contained in the public record for this rulemaking for a complete discussion of test cost estimation and potential for economic impact resulting from these costs.

VII. 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, DC. Persons who wish to attend or to present comments at the meeting should call the TSCA Assistance Office (TAO): (202) 554-1404, by August 10, 1987. A meeting will not be held if members of the public do not indicate that they wish to make oral presentation. 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.

VIII. 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.

IX. Rulemaking Record

EPA has established a record for this rulemaking (docket number OPTS-42096). 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) Notices containing the ITC's intent to designate DTBP to the Priority List (50 FR 47603; Nov. 19, 1985), and designation (51 FR 18369, May 19, 1986).

(b) Rules requiring TSCA section 8(a) and 8(d) reporting on DTBP (50 FR 47538; Nov. 19, 1985).

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

(d) Notice containing revision of TSCA test guidelines cited as test standards for this rule.

(2) Support document consisting of economic impact evaluation for DTBP.

(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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(10) Industry submission. DTBP manufacturers response to EPA's Focus Meeting questions. The following documents are CBI: DCN 408600006; 408600007; 4086800011; 4086800013. (1986).

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(17) EPA. Information package for Division Directors meeting for DTBP: Memorandum dated (June 17, 1986).

(18) EPA. Test Rules Exposure and Environmental Fate Analysis, Alkylated Phenol Antioxidants. Thomas, M. Exposure Assessment Branch. (1985).

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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. G-004, NE Mall, 401 M St. SW., Washington, DC, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays. The Agency will supplement this record periodically with additional relevant information received.

X. 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 any 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. enterprise 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 written 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 test rule, if promulgated, will not have a significant impact on a substantial number of small businesses because: (1) They are not likely to perform testing themselves or to participate in the organization of the testing effort, (2) they will experience only very minor cost in securing exemption from testing requirements, and (3) they are unlikely to be affected by reimbursement requirements.

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 number 2070-0033. Comments on these requirements should be submitted to the Office of Information and Regulatory Affairs; OMB; 726 Jackson Place, NW, Washington, DC 20503 marked "Attention: Desk Officer for EPA." The final rule will respond to any OMB or public comments on the information collection requirements.

List of Subjects in 40 CFR Part 799

Testing, Environmental protection, Hazardous substances, Chemicals, Environmental effects, Recordkeeping and reporting requirements.

Dated: June 17, 1987.

J.A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

PART 799—[AMENDED]

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

1. In Part 799:

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

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

b. By adding § 799.1605 to read as follows:

§ 799.1605 2,6-Di-tert-butylphenol.

(a) *Identification of test substance.* (1) 2,6-Di-tert-butylphenol (DTBP, CAS No. 128-39-2) shall be tested in accordance with this section.

(2) DTBP of at least 98 percent purity shall be used as the test substance.

(b) ~~Persons required to submit study plans, conduct tests, and submit data.~~ All persons who manufacture (import) or process DTBP, other than as an impurity, after the effective date of the final rule to the end of the reimbursement period shall submit exemption applications, submit study plans, conduct tests, and submit data as specified in this section, Subpart A of this Part, and Parts 790 and 792 of this chapter for single-phase rulemaking.

(c) ~~Chemical fate—(1) Water solubility (Generator Column Method)—~~

(i) ~~Required testing.~~ Water solubility testing shall be conducted with DTBP in accordance with § 796.1860 of this chapter.

(ii) ~~Reporting requirements.~~ (A) The water solubility test shall be completed and the final report submitted to EPA within 12 months of the effective date of the final rule.

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

(2) ~~Aerobic aquatic biodegradability—(1) Required testing.~~ Aerobic aquatic biodegradation testing shall be conducted with DTBP in accordance with § 796.3100 of this chapter.

(ii) ~~Reporting requirements.~~ (A) The aerobic aquatic biodegradation test shall be completed and the final report submitted to EPA within 12 months of the effective date of the final rule.

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

(3) ~~Anaerobic biodegradability—(1) Required testing.~~ An anaerobic biodegradability test shall be conducted with DTBP in accordance with § 796.3140 of this chapter.

(ii) ~~Reporting requirements.~~ (A) The anaerobic biodegradability test shall be completed and the final report submitted to EPA within 12 months of the effective date of the final rule.

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

(4) ~~Photolysis—(1) Required testing.~~ A photolysis test shall be conducted with DTBP in accordance with § 796.3765 of this chapter.

(ii) ~~Reporting requirements.~~ (A) The photolysis test shall be completed and the final report submitted to EPA within 12 months of the effective date of the final rule.

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

(5) ~~Sediment adsorption isotherm—~~

(i)(A) ~~Required testing.~~ A sediment

adsorption isotherm test shall be conducted with DTBP in accordance with the guideline specified in § 796.2750 of this chapter and the modification specified in paragraph (e)(4)(i)(B) of this section.

(B) ~~Modification.~~ The requirements under § 796.2750(c) of this chapter are modified to require calculation of a K_{oc} value for each test sediment using the equation $K_{oc} = K/(\text{percent of organic carbon in test sediment})$.

(ii) ~~Reporting requirements.~~ (A) The sediment adsorption isotherm test shall be completed and the final report submitted to EPA within 12 months of the effective date of the final rule.

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

(d) ~~Ecological effects—(1) Algal acute toxicity—(i) Required testing.~~ (A) Algal acute toxicity testing shall be conducted with DTBP using *Selenastrum capricornutum* in accordance with § 797.1050 of this chapter and the modification specified in paragraph (d)(1)(i)(B) of this section.

(B) ~~Modification.~~ The requirements under § 797.1050 (c)(1)(ii) and (c)(6)(i)(B) of this chapter are modified to require that the algal cells at the end of 24, 48, and 72 hours also be enumerated and that the final separation of the algal cells from the test solution be done using an ultrafiltration (e.g. 0.45 micrometer pore size) technique.

(ii) ~~Reporting requirements.~~ (A) The algal acute toxicity test shall be completed and the final report submitted to EPA within 12 months of the effective date of the final rule.

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

(2) ~~Fish acute toxicity—(1) Required testing.~~ (A) Fish acute toxicity testing shall be conducted with DTBP using *Salmo gairdneri* (rainbow trout) and *Pimephales promelas* (fathead minnow) in accordance with § 797.1400 of this chapter and the modification specified in paragraph (d)(2)(i)(B) of this section.

(B) ~~Modification.~~ The requirements under § 797.1400 (c)(4)(iv) and (c)(6)(iii)(A) of this chapter are modified to require that the test continue for 14 days and that mortality and concentrations of DTBP be measured at the end of 0, 4, 8, 12 and 14 days.

(ii) ~~Reporting requirements.~~ (A) The fish acute toxicity tests shall be completed and the final report submitted to EPA within 12 months of the effective date of the final rule.

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

(3) ~~Daphnid acute toxicity—(1) Required testing.~~ Daphnid acute toxicity testing shall be conducted with DTBP using *Daphnia magna* or *D. pulex* in accordance with § 797.1300 of this chapter.

(ii) (A) The daphnid acute toxicity test shall be completed and the final report submitted to EPA within 12 months of the effective date of the final rule.

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

(4) ~~Gammarus acute toxicity—(1) Required testing.~~ *Gammarus* acute toxicity testing shall be conducted with DTBP using *G. lacustris*, *G. fasciatus*, or *G. pseudolimnaeus* in accordance with § 797.1310 of this chapter.

(ii) ~~Reporting requirements.~~ (A) The *Gammarus* acute toxicity test shall be completed and the final report submitted to EPA within 12 months of the effective date of the final rule.

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

(5) ~~Daphnid chronic toxicity—(1) Required testing.~~ Daphnid chronic toxicity testing shall be conducted with DTBP using *Daphnia magna* or *D. pulex* in accordance with § 797.1330 of this chapter, if the algal EC50, the 14-day LC50 for either fish species, or the gammarid or daphnid 48-hour LC50 determined in accordance with paragraph (d) (1), (2), (3), and (4) of this section is equal to or less than 1 mg/l, or if the algal EC50 value or one or more of the fish or aquatic invertebrate LC50 values determined in accordance with paragraph (d) (1), (2), (3), and (4) of this section is less than or equal to 100 times the predicted environmental concentration (PEC). EPA will calculate the PEC from data submitted to EPA pursuant to paragraph (c) of this section and will notify the test sponsor if the PEC criterion is met.

(ii) ~~Reporting requirements.~~ (A) The daphnid chronic toxicity test, if required shall be completed and the final report submitted to EPA within 12 months of the date of notification by EPA that the test is required.

(B) A progress report shall be submitted to EPA 6 months after the date of notification by EPA that the test is required.

(6) ~~Fish early-life stage toxicity—(1) Required testing.~~ A fish early-life stage toxicity test shall be conducted with DTBP in accordance with § 797.1600 of this chapter, using the fish with the lower LC50 value [either the rainbow trout (*Salmo gairdneri*) or the fathead minnow (*Pimephales promelas*)], if the algal EC50, the 14-day LC50 for either

fish species, or the gononid or diploid LC50 determined in accordance with paragraph (d) (1), (2), (3), and (4) of this section is equal to or less than 1 mg/L or the algal EC50 value or one or more of the fish or aquatic invertebrate LC50 values determined in accordance with paragraph (d) (1), (2), (3), and (4) of this section is less than or equal to 100×PEC. EPA will calculate the PEC from data submitted to the Agency pursuant to paragraph (c) of this section, and will notify the test sponsor if the PEC criterion is met.

(ii) *Reporting requirements.* (A) The fish early life stage toxicity test, if required, shall be completed and the final report submitted to EPA within 12 months of the date of notification by EPA that the test is required.

(B) A progress report shall be submitted to EPA 6 months after the date of notification by EPA that the test is required.

(7) *Benthic sediment invertebrate bioassay.* (i) *Required testing.* A benthic sediment invertebrate bioassay shall be conducted with the midge (*Chironomus tentans*) if chronic toxicity testing is required pursuant to paragraph (d)(5) of this section and if the log of the K_{ow} determined under paragraph (c)(5) of this section is greater than or equal to 3.5 and less than or equal to 6.5. DTBP-spiked clean freshwater sediments containing low, medium and high organic carbon content shall be used according to the test guideline specified in the American Society for Testing and Materials Special Technical Publication 854 (ASTM STP 854) entitled, "Aquatic Safety Assessment of Chemicals Sorbed to Sediments," by W.J. Adams, R.A. Kimerle, and R.G. Masher and published in *Aquatic Toxicology and Hazard Assessment: Seventh Symposium*, ASTM STP 854, pp. 429-453. 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, Room 8401, 1100 L St., NW., Washington, DC. This incorporation by reference was approved by the Director 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, NE-G004, 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) The benthic sediment invertebrate bioassay,

if required, shall be completed and the final report submitted to EPA within 12 months of the date of notification by EPA that the test is required.

(B) A progress report shall be submitted to EPA 6 months after the date of notification by EPA that the test is required.

(e) *Effective date.* (44 days after publication of the final rule in the Federal Register).

[Information collection requirements have been approved by the Office of Management and Budget under Control Number 2070-0033.]

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