[OPTS-41021; FRL-3017-2]

Eighteenth Report of the Interagency Testing Committee to the Administrator; Receipt of Report and Request for Comments Regarding Priority List of Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Interagency Testing Committee (ITC), established under section 4(e) of the Toxic Substances Control Act (TSCA), transmitted its Eighteenth Report to the Administrator of EPA on May 1, 1986. This report, which revises and updates the Committee's priority list of chemicals, adds one chemical to the list for priority consideration by EPA in the promulgation of test rules under section 4(a) of the Act. The new chemical is tributyl phosphate. This chemical is not designated for response within 12 months. Two substances previously recommended with intent to designate, cyclohexane and 2,6-di-tert-butylphenol (50 FR 47603), are now designated for response within 12 months. The Eighteenth Report is included in this notice. The Agency invites interested persons to submit written comments on the Report, and to attend a Focus Meeting to help narrow and focus the issues raised by the ITC's recommendations. Members of the public are also invited to inform EPA if they wish to be notified of subsequent public meetings on these chemicals. ITC also notes the removal of 6 chemicals from the priority list because EPA has responded to the ITC's previous recommendations for testing of the chemicals.

DATES: Written comments should be submitted by June 18, 1986. A Focus Meeting will be held on June 17, 1986.

ADDRESSES: Send written submissions to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-108, 401 M St., SW., Washington, DC 20460.

Submissions should bear the document control number (OPTS-41021).

The public record supporting this action, including comments, is available for public inspection in Rm. E-107 at the address noted above from 8 a.m. to 4 p.m. Monday through Friday, except legal holidays. The Focus Meeting will be held at EPA Headquarters, Rm. 103 NE Mall, 401 M St., SW., Washington, DC. Persons planning to attend the Focus Meeting and/or seeking to be informed of subsequent public meetings on this chemical, should notify the TSCA Assistance Office at the address listed below. To insure seating accommodations at the Focus Meeting, persons interested in attending are asked to notify EPA at least one week ahead of the scheduled date.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Toll Free: (800-424-9065). In Washington, DC: (554-1404). Outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION: EPA has received the Report of the TSCA Interagency Testing Committee to the Administrator.

I. Background

TSCA (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) authorizes the Administrator of EPA to promulgate regulations under section 4(a) requiring testing of chemical substances and mixtures in order to develop data relevant to determining the risks that such chemical substances and mixtures may present to health and the environment.

Section 4(e) of TSCA established and Interagency Testing Committee to make recommendations to the Administrator of EPA of chemical substances and mixtures to be given priority consideration in proposing test rules under section 4(a). Section 4(e) directs the Committee to revise its list of recommendations at least every 6 months as necessary. The ITC may "designate" up to 50 substances and mixtures at any one time for priority consideration by the Agency. For such designations, the Agency must within 12 months either initiate rulemaking or issue in the **Federal Register** its reasons for not doing so. The ITC's Eighteenth Report was received by the Administrator on May 1, 1986, and follows this Notice. The Report adds one substance to the TSCA section 4(e) priority list.

II. Written and Oral Comments and Public Meetings

EPA invites interested persons to submit detailed comments on the ITC's new recommendations. The Agency is interested in receiving information concerning additional or ongoing health and safety studies on the subject chemicals as well as information relating to the human and environmental exposure to these chemicals. A notice is published elsewhere in today's **Federal Register** adding the substance recommended in the ITC's Eighteenth Report to the TSCA section 8(d) Health and Safety Data Reporting Rule (40 CFR Part 716). The section 8(d) rule requires the reporting of unpublished health and safety studies on the listed chemicals. This chemical will also be added to the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR Part 712) published elsewhere in this issue. The section 8(a) rule requires the reporting of production volume, use, exposure, and release information on the listed chemicals.

A Focus Meeting will be held to discuss relevant issues pertaining to this chemical and to narrow the range of issues/effects which will be the focus of the Agency's subsequent activities in responding to the ITC recommendations. The Focus Meeting will be held on June 17, 1986 at EPA Headquarters, Rm. 103 NE Mall, 401 M St., SW., Washington, DC. This meeting is intended to supplement and expand upon written comments submitted in response to this notice. The meeting will be held at 10 a.m.

Persons wishing to attend this meeting or subsequent meetings on this chemical should call the TSCA Assistance Office at the toll free number listed above at least one week in advance.

All written submissions should bear the identifying docket number (OPTS-41021).

III. Status of List

In addition to adding the one recommendation to the priority list, the ITC's Eighteenth Report notes the removal of six chemicals from the list since the last ITC report because EPA has responded to the Committee's prior recommendations for testing of the chemicals. Subsequent to the ITC's preparation of its Seventeenth Report, EPA responded to the ITC's recommendations for six additional chemicals. The six chemicals removed and the dates of publication in the **Federal Register** of EPA's responses to the ITC for these chemicals are: anthraquinone, November 6, 1985 (50 FR 46090); cumene, November 6, 1985 (50 FR 46104); mercaptobenzothiazole, November 6, 1985 (50 FR 46121); octamethylcyclotetrasiloxane, October 30, 1985 (50 FR 45123); pentabromoethylbenzene, November 13, 1985 (50 FR 46785); sodium N-methyl-N-oleoyltaurine, November 6, 1985 (50 FR 46178). The report also notes that cyclohexane and 2,6-di-tert-butylphenol, which were originally recommended with intent to designate (50 FR 47603, November 19, 1985), have now been designated for response within 12 months by the ITC.

The current list contains seven designated substances, one chemical recommended with intent-to-designate, and two recommended substances.

Authority: 15 U.S.C. 2603.

Dated: May 6, 1986.

J. Merenda,

Director, Existing Chemical Assessment Division.

Eighteenth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency

Summary

Section 4 of the Toxic Substances Control Act of 1976 (TSCA, Pub. L. 94–469) provides for the testing of chemicals in commerce that may present an unreasonable risk of injury to health or the environment. It also provides for the establishment of a Committee (ITC), composed of representatives from eight designated Federal agencies, to recommend chemical substances and mixtures (chemicals) to which the Administrator of the U.S. Environmental Protection Agency (EPA) should give priority consideration for the promulgation of testing rules.

Section 4(e)(1)(A) of TSCA directs the Committee to recommend to the EPA Administrator chemicals to which the Administrator should give priority consideration for the promulgation of testing rules pursuant to section 4(a). The Committee is required to designate those chemicals, from among its recommendations, to which the Administrator should respond within 12 months by either initiating a rulemaking proceeding under section 4(a) or publishing the Administrator's reason for not initiating such a proceeding. At least 6 months, the Committee makes those revisions in the TSCA section 4(e) Priority List that it determines to be necessary and transmits them to the EPA Administrator.

As a result of its deliberations, the Committee is revising the TSCA section 4(e) Priority List by the addition of one chemical, and is noting the removal of six as a result of responses by EPA. The Committee also is designating two chemicals that have been recommended with intent-to-designate in the seventeenth report.

The Priority List is divided into three parts. Part A contains those recommended chemicals and groups designated for priority consideration and response by the EPA Administrator within 12 months. Part B contains those chemicals and groups recommended with intent-to-designate. This category was established by the Committee in its seventeenth report (50 FR 47603; November 19, 1985) to take advantage of rules promulgating automatic reporting requirements for non-designated ITC recommendations under the section 8(a) Preliminary Assessment rule and the TSCA section 8(d) Health and Safety Data Reporting rule. Information received following recommendation with intent-to-designate may influence the Committee to either designate or not designate the chemical or group of chemicals in a subsequent report to the Administrator. Part C contains chemicals and groups of chemicals that have been recommended for priority consideration by EPA without being designated for response within 12 months.

The changes to the Priority List are presented, together with the types of testing recommended, in the following Table 1:

TABLE 1.—ADDITIONS TO THE SECTION 4(E) PRIORITY LIST—MAY 1986

Chemical/group	Recommended studies
A. Designated for response within 12 months:	
Cyclohexane [1] (CAS No. 110–82–7).	Health Effects: Chronic toxicity including oncogenicity and neurotoxicity; teratogenicity; reproductive toxicity.
2,6-Di-*tert*-butylphenol [2] (CAS No. 128–39–2).	Health Effects: Toxicokinetics; chronic toxicity.
	Chemical Fate: Persistence in aerobic and anaerobic sediments.
	Ecological Effects: Acute toxicity to benthic organisms; bioconcentration in benthic organisms.
NOTE: Cyclohexane and 2,6-Di-*tert*-butylphenol were recommended with intent-to-designate by the Committee in the seventeenth report (50 FR 47603).	
B. Recommended with intent-to-designate:	
Tributyl phosphate [3] (CAS No. 126–73–8).	Health Effects: Chronic toxicity including oncogenic, neurotoxic, renal, reproductive and developmental effects.
	Chemical Fate: Persistence in anaerobic soils and sediments.
	Ecological Effects: Chronic effects on aquatic and terrestrial plants; chronic effects on daphnids and/or other aquatic invertebrates; acute and chronic effects on benthic organisms and soil invertebrates, if found persisent under anaerobic conditions.
C. Recommended without being designated for response within 12 months: None.	
CA Index Names (9 CI):	
1. Cyclohexane	
2. Phenol, 2,6,-bis(1,1-dimethyl ethyl)-	
3. Phosphoric, acid, tributyl ester.	

TSCA Interagency Testing Committee

Statutory Member Agencies and Their Representatives

Council on Evironmental Quality
Harvey Doerksen, Member
Department of Commerce
Patrick D. Cosslett, Member(*1*)
Environmental Protection Agency
John D. Walker, Member and Vice Chairperson
Laurence S. Rosenstein, Alternate
National Cancer Institute
Richard Adamson, Member(*2*)
Elizabeth K. Weisburger, Alternate(*3*)
National Institute of Environmental Health Sciences
James K. Selkirk, Member(*4*)
National Institute For Occupational Safety and Health
Rodger L. Tatken, Member and Chairperson
National Science Foundation
Rodger W. Baier, Member
Jarvis L. Moyers, Alternate
Occupational Safety and Health Administration
Stephen Mallinger, Alternate

Liaison Agencies and Their Representatives

Consumer Product Safety Commission
Lakshmi C. Mishra (*5*)
Department of Agriculture
Richard M. Parry, Jr.
Elise A. B. Brown(*6*)
Department of Defense
Edmund Cummings
Food and Drug Administration
Arnold Borsetti
National Library of Medicine
Vera Hudson
National Toxicology Program
Dorothy Canter

Committee Staff

Robert H. Brink, Executive Secretary
Norma Williams, ITC Coordinator

Support Staff

Alan Carpien—Office of the General Counsel, EPA

Notes

(*1*) Appointed on December 2, 1985.
(*2*) Appointed on October 28, 1985.
(*3*) Appointed on October 28, 1985.
(*4*) Appointed on February 21, 1986.
(*5*) Appointed on December 13, 1985.
(*6*) Appointed on January 6, 1986.

The Committee acknowledges and is grateful for the assistance and support given the ITC by staff of Dynamac Corporation (technical support contractor) and personnel of the EPA Office of Toxic Substances.

Chapter 1—Introduction

1.1 *Background.* The TSCA Interagency Testing Committee (Committee) was established under section 4(e) of the Toxic Substances Control Act of 1976 (TSCA, Pub. L. 94–469). The specific mandate of the Committee is to recommend to the

Administrator of the U.S. Environmental Protection Agency (EPA) chemical substances and mixtures in commerce that should be given priority consideration for the promulgation of testing rules to determine their potential hazard to human health and/or the environment. TSCA specifies that the Committee's recommendations shall be in the form of a Priority List, which is to be published in the **Federal Register**. The Committee is directed by section 4(e)(1)(A) of TSCA the designate those chemicals on the Priority List to which the EPA Administrator should respond within 12 months by either initiating a rulemaking proceeding under section 4(a) or publishing the Administrator's reason for not initiating such a proceeding. There is no statutory time limit for EPA response regarding chemicals that ITC has recommended but not designated for response within 12 months.

At least every 6 months, the Committee makes those revisions in the section 4(e) Priority List that it determines to be necessary and transmits them to the EPA Administrator.

The Committee is comprised of representatives from eight statutory member agencies and six liaison agencies. The specific representatives and their affiliations are named in the front of this report. The Committee's chemical review procedures and priority recommendations are described in previous reports (Ref. 1 and 2).

1.2 *Committee's previous reports.* Seventeen previous reports to the EPA Administrator have been issued by the Committee and published in the **Federal Register** (Ref. 1 and 2). Ninety-one entries (chemicals and groups of chemicals) were recommended for priority consideration by the EPA Administrator and designated for response within 12 months. In addition, four chemicals and one group of chemicals were recommended without being so designated.

1.3 *Committee's activities during this reporting period.* Between October 1, 1985, and March 31, 1986, the Committee continued to review chemicals fromits fourth and fifth scoring exercises, and from nominations by Member Agencies, Liaison Agencies and State Agencies.

The Committee contacted chemical manufacturers and trade associations to request information that would be of value in its deliberations. Most of those contacted provided unpublished information on current production, exposure, uses, and effects of chemicals under study by the Committee.

During this reporting period, the Committee reviewed available information on 32 chemicals and 3 large classes of chemicals. One chemical was selected for addition to the section 4(e) Priority List, and 12 were deferred indefinitely. The remaining chemicals are still under study.

On February 12, 1986, the ITC published an Intent-to-Designate notice (51 FR 5250) that listed isopropanol and described additional information needed by the ITC to reach a more informed decision on whether or not to designate isopropanol in a subsequent report to the EPA Administrator. A deadline of March 31, 1986 was provided for receipt of relevant information.

The Committee requested information on genotoxicity, carcinogenicity, and reproductive and developmental effects on isopropanol per se, uncontaminated with isopropyl sulfate. Information has been received indicating that some of the requested information is being developed in ongoing studies. The Committee is awaiting details on these studies and expects to make a decision on isopropanol prior to the next report to the EPA Administrator.

In its seventeenth report to the Administrator of EPA (Ref. 2), the ITC announced the establishment of a "recommended with intent-to-designate" category, to take advantage of recent rules promulgating automatic reporting requirements for non-designated ITC recommendations under the section 8(a) Preliminary Assessment rule (50 FR 34805) and the TSCA section 8(d) Health and Safety Data Reporting rule (50 FR 34809). The 8(a) and 8(d) rules require the submission to EPA of information on production, use, exposure and unpublished health and safety studies that may not be publicly available. The ITC noted that information received following "recommendation with intent-to-designate" of a chemical or group of chemicals may influence the Committee to either designate or not designate that chemical or group of chemicals in a subsequent report to the Administrator.

When a chemical or group of chemicals is placed in the "recommended with intent-to-designate" category in a report to the Administrator, the ITC will review information submitted to the EPA and to the ITC following recommendation and will then take one of the following actions:

(a) Designate the chemical or group in the next ITC report, or

(b) Recommend the chemical or group without designation, in the next ITC report, providing a rationale for not designating the chemical or group, or

(c) Remove the chemical or group from the Priority List, in the next ITC report, providing a rationale for that removal, or

(d) Defer a decision, stating the reasons for the deferral and noting that a decision will be announced on or before a given date.

It is anticipated that deferral of a decision will occur infrequently. On occasion, however, the volume and/or complexity of information received may make it necessary to delay a decision. Whenever the deferral option is required, it is anticipated that a final decision (Designation, Recommendation or Removal) will be announced within 6 to 9 months following the report in which the chemical or group of chemicals was placed in the "recommended with intent-to-designate" category.

1.4 *The TSCA section 4(e) Priority List.* Section 4(e)(1)(B) of TSCA directs the Committee to: ". . . make such revisions in the [priority] list as it determines to be necessary and . . . transmit them to the Administrator together with the Committee's reasons for the revisions." Under this authority, the Committee is revising the Priority List by adding one chemical: tributyl phosphate. Tributyl phosphate is being recommended with intent-to-designate in this report. In addition, the Committee is designating for response within 12 months two chemicals that were recommended with intent-to-designate in the seventeenth report. The designated chemicals are cyclohexane and 2,6-di-*tert*butylphenol. The testing recommended for these chemicals and the rationales for the recommendations are presented in Chapter 2 of this report.

Six chemicals are being removed from the Priority List because the EPA Administrator has responded to the Committee's prior recommendations for testing them. They are listed in the following Table 2 with citations to EPA responses:

TABLE 2.—REMOVALS FROM THE TSCA SECTION 4(E) PRIORITY LIST OCTOBER 1, 1985 THROUGH MARCH 31, 1986

Chemical/group	EPA responses	
	FEDERAL REGISTER citation	Publication date
Anthraquinone	50 FR 46090	Nov. 6, 1985.
Cumene	50 FR 46104	Nov. 6, 1985.
Mercaptobenzothiazole.	50 FR 46121	Nov. 6, 1985.
Octamethylcyclotetrasiloxane.	50 FR 46123	Oct. 30, 1985.
Pentabromoethylbenzene.	50 FR 46785	Nov. 13, 1985.
Sodium N-methyl-N-oleoyltaurine.	50 FR 46178	Nov. 6, 1985.

Removal of 81 entries was noted in previous reports (Ref. 1 and 2). To date, 87 chemicals and groups of chemicals have been removed from the Priority List.

With the one recommendation and six removals noted in this report, 10 entries now appear on the section 4(e) Priority List. The Priority List is divided in the following Table 3 into three parts; namely, A, Chemicals and Groups of Chemicals Designated for Response Within 12 Months, B, Chemicals and Groups of Chemicals Recommended with Intent-to-Designate, and C, Chemicals and Groups of Chemicals Recommended Without Being Designated for Response Within 12 Months. Table 3 follows:

TABLE 3.—THE TSCA SECTION 4(e) PRIORITY LIST—MAY 1986

Entry	Date of designation
A Chemical and groups of chemicals recommended as designated for response within 12 months:	
1. Cyclohexane	May 1986.
2. 2,6-Di-*tert*-butylphenol	May 1986.
3. Methyl cyclopentane	May 1985.
4. Tetrabromobisphenol A	may 1985.
5. Triethylene glycol monomethyl ether	May 1985.
6. Triethylene glycol monoethyl ether	May 1985.
7. Triethylene glycol monobutyl ether	May 1985.

B. Chemicals and groups of chemicals recommended with intent-to-designate:

Entry	Date of recommendation
1. Tributyl phosphate	May 1986
C. Chemicals and groups of chemicals recommended without being designated for response within 12 months:	
1. 3,4-Dichlorobenzotrifluoride	May 1985.
2. Diisodecyl phenyl phosphite	November 1985.

References

(1) Sixteenth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, May 21, 1985, 50 FR 20930-20939. Includes references to Reports 1 through 15 and an annotative list of removals.

(2) Seventeenth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, November 19, 1985, 50 FR 47603-47612.

Chapter 2—Recommendations of the Committee

2.1 *Chemicals recommended for priority consideration by the EPA Administrator.* As provided by section 4(e)(1)(B) of TSCA, the Committee is adding the following chemical substance to the section 4(e) Priority List: Tributyl phosphate. The recommendation of tributyl phosphate is being made after considering the factors identified in section 4(e)(1)(A) and other relevant information, as well as the professional judgment of Committee members. In addition, the Committee is designating for response within 12 months two chemical substances that were recommended with intent-to-designate in the seventeenth report. The designated chemicals are cyclohexane and 2,6-di-*tert*-butylphenol.

2.2 *Chemicals designated for response within 12 months.*

2.2.a Cyclohexane.

In the seventeenth report to the Administrator of EPA (50 FR 47603), cyclohexane was recommended with intent-to-designate. The rationale for that recommendation appears in the seventeenth report. Information reviewed by the Committee in response to the seventeenth report included any public comments on the Committee's recommendations; production volume, use, exposure, and release information reported by manufacturers of cyclohexane under the TSCA section 8(a) Preliminary Assessment rule; health and safety studies submitted under the TSCA section 8(d) Health and Safety Data Reporting rule; and any unpublished and published data available to the Committee. The information included acute toxicity studies, skin and eye irritation studies and additional genotoxicity studies (Phillips Petroleum Co., 1986). Summary data from acute toxicity, skin irritation and repeated dose (six months) studies were also received from other submitters (Eastman Kodak Co., 1986; Dow Chemical Co., 1986). Although ecological effects testing was not recommended for cyclohexane, information dealing with environmental persistence also was received (Shell Oil Co., 1986).

After reviewing the information, the Committee concluded that data are still lacking on chronic (two-year) effects, especially oncogenicity and neurotoxicity. Teratogenic and reproductive effects studies also are absent. For these reasons and for the reasons previously presented (50 FR 47603) the Committee is now designating cyclohexane for response within twelve months and recommending that it be tested for the following:

Health Effects:

Chronic effects including oncogenicity and neurotoxicity (with special emphasis on neuropathology).

Teratogenicity and reproductive toxicity.

References

(1) Dow Chemical Co., Midland, MI. Letter from L. Hampton to Document Control Officer, U.S. EPA. January 31, 1986.

(2) Eastman Kodak Co., Rochester, N.Y. Letter from R. L. Raleigh to U.S. EPA. January 15, 1986.

(3) Phillips Petroleum Co., Bartlesville, OK. Letter from J.R. Rust to Document Control Officer/OPTS, U.S. EPA. January 15, 1986.

(4) Shell Oil Co., Washington, DC. Letter from E.L. Hobson to U.S. EPA. February 5, 1986.

2.2.b 2,6-Di-*tert*-butylphenol.

In the seventeenth report to the Administrator of EPA (50 FR 47603), 2,6-di-*tert*-butylphenol was recommended with intent-to-designate. The rationale for that recommendation appears in the seventeenth report. Information reviewed by the Committee in response to the seventeenth report included any public comments on the Committee's recommendations; production volume, use, exposure and release information reported by manufacturers of 2,6-di-*tert*-butylphenol under the TSCA section 8(a) Preliminary Assessment rule; health and safety studies submitted under the TSCA section 8(d) Health and Safety Data Reporting rule; and any unpublished and published data available to the Committee. The information included data on acute oral and percutaneous LD50 studies with rats; skin and eye irritation with rabbits; skin depigmentation, skin sensitization and delayed contact hypersensitivity with guinea pigs; rat hepatocyte primary culture and DNA repair tests; an Ames *Salmonella* microsomal assay; intravenous toxicity to mice and a report on the physiological response of experimental animals to the absorption of alkylated phenols and anilines (Ciba-Geigy, 1986; DuPont, 1986; Ethyl, 1986; Shell, 1986). Also included was a summary on ecological effects (Dow, 1986).

After reviewing the information, the Committee concluded that data are still lacking on toxicokinetics, chronic toxicity, persistence in sediments, acute

toxicity to benthic organisms and bioconcentration in benthic organisms. For these reasons and for the reasons previously presented (50 FR 47603) the Committee is now designating 2,6-di-*tert*-butylphenol for response within twelve months and recommending that it be tested for the following:

Chemical Fate:
Persistence in aerobic and anaerobic sediments
Health Effects:
Toxicokinetics and chronic toxicity
Ecological Effects:
Acute Toxicity to benthic organisms
Bioconcentration in benthic organisms

References

(1) Ciba-Geigy. Ciba-Geigy Corp., Ardsley, N.Y. Letter from A. DiBattista to U.S. EPA. February 12, 1986.

(2) Dow. Dow Chemical Co., Midland, MI. Letter from L. Hampton to U.S. EPA. January 31, 1986.

(3) DuPont. E.I. DuPont de Nemours and Co., Wilmington, DE. Letter from K.D. Dastur to U.S. EPA. January 14, 1986.

(4) Ethyl. Ethyl Corporation, Baton Rouge, LA. Letter from L. L. Weir to Document Control Officer, Office of Pesticides and Toxic Substances, U.S. EPA. February 4, 1986.

(5) Shell. Shell Oil Co., Washington, DC. Letter from E. L. Hobson to U.S. EPA. February 5, 1986.

2.3. *Chemicals recommended with intent-to-designate but not designated for response within 12 months.*

2.3.a Tributyl Phosphate.

Summary of recommended studies. It is recommended that tributyl phosphate (TBP) be tested for the following:

A. Chemical Fate: Persistence in anaerobic soils and sediments.

B. Health Effects: Chronic toxicity including oncogenic, neurotoxic, renal, reproductive and developmental effects.

C. Ecological Effects: Chronic effects on aquatic and terrestrial plants; Chronic effects on daphnids and/or other aquatic invertebrates.

Acute and chronic effects on benthic organisms and soil invertebrates, depending on the results from persistence studies—

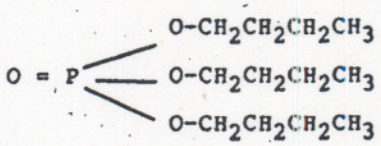
Physical and Chemical Information

CAS Number: 126-73-8.

Synonyms: Phosphoric acid, tributyl ester (9CI); Tributoxyphosphine oxide; Tri-*n*-butyl phosphate.

Acronym: TBP.

Structure:



Empirical Formula: $C_{12}H_{27}O_4P$.

Molecular Weight: 266.32.

Melting Point: $< -80°C$ (Ref. 47, TDB, 1986).

Boiling Point: 289°C at 760 mmHg (Ref. 11, CRC, 1983).

Vapor Pressure: 7.3 mmHg at 150°C (Ref. 23, Laham et al., 1984); 0.07 mmHg at 25°C (estimated; Ref. 48, U.S. EPA, 1985).

Air Vapor Density: 9.2 (Ref. 28, Monsanto, 1985).

Solubility in Water: 420 mg/L at 25°C (Ref. 17, General Electric, 1983); 280 mg/L (Ref. 39, Saeger et al., 1979).

Solubility in Organic Solvents: Soluble in ether, benzene carbon disulfide, ethanol, mineral oil, and gasoline (Ref. 11, CRC, 1983).

Specific Gravity: 0.977-0.978 at 20/20°C (Ref. 28, Monsanto, 1985).

Log Octanol/Water Partition Coefficient (log P): 4.0 (Ref. 39, Saeger et al., 1979); 2.36 (Ref. 20, Hansch and Leo, 1979).

Description of Chemical (ambient conditions): Clear, colorless, odorless liquid (Ref. 47, TDB, 1986).

Rationale for Recommendations

I. Exposure information—A. *Production/use.* There are at least three, and maybe as many as five, manufacturers of TBP in the United States. CEH (1981, Ref. 8) reported that at least 5 million pounds of the compound were produced in 1979. Annual production since then has been reported at 3 million pounds for 1982 and estimated at 3 million pounds for 1983 (Ref. 9, CEH, 1983). Current annual production has been estimated at 3 to 5 million pounds (Ref. 48, U.S. EPA, 1985.)

A major use of TBP is as a nonflammable component of hydraulic fluids in the control systems of commercial aircraft. Industrial fluids and lubricants account for another large share. Liquid phosphate esters are the basestocks for fire-resistant oils used in die-casting, air compressors, gas turbines, and many other applications. TBP may also be used as a solvent/plasticizer for certain polymers, an industrial solvent, an antifoam agent, and a pigment grinding assistant. It has been estimated (Ref. 28, Monsanto, 1985) that about 24 percent goes into hydraulic fluids, 50 percent into uses as a plasticizer, and 26 percent for miscellaneous uses.

B. *Occupational exposure.* The National Occupational Hazard Survey, conducted in 1972, estimated that 323,477 workers were potentially exposed to TBP in the workplace (Ref. 31, NIOSH, 1976). Preliminary data from the National Occupational Exposure Survey indicate that, in 1980, 12,111 workers (including 427 women) were potentially exposed to the compound in the workplace (Ref. 32, NIOSH, 1984).

The following limits have been established for workplace airborne concentrations of TBP:

8-hour TWA-PEL 5 mg/m³ (Ref. 34, OSHA, 1985).

8-hour TLV-TWA 2.5mg/m³ (0.2 ppm) (Ref. 2, ACGIH, 1985).

C. *Environmental release.* It is likely that most TBP is released to surface waters from industrial effluents and from the release of hydraulic fluids to storm drains and drainage ditches and to land and water via landfill disposal of oil wastes and plastics.

There is considerable evidence for widespread, low-level environmental exposures to TBP. It has been detected in fish and human lipid tissues, in municipal and industrial effluents, river water, estuarine water, ground water, drinking water, snow, and sediments. LeBel and Williams (1983, Ref. 25) analyzed 16 human adipose tissue samples from cadavers and found TBP at 9.0 ng/g, on an extracted fat basis, in the tissue from one cadaver. Dunlap et al. (1979, Ref. 14) found TBP at 1.7 ug/L in ground water below a landfill. Grob and Grob (1974, Ref. 18) measured TBP in water at or near Zurich, Switzerland, and found concentrations of 10 to 82 ng/L. Zoeteman et al. (1981, Ref. 51) measured TBP in ground waters in the Netherlands at 0.01 to 0.1 ug/L. Meijers and van der Leer (1976, Ref. 26) found TBP at up to 10 ug/L in the Waal River in the Netherlands. Sheldon and Hites (1978, Ref. 42) reported finding TBP in Delaware River water at 60 to 2,000 ng/L. Shackelford et al. (cited in U.S. EPA, 1985, Ref. 48) reported finding TBP in plant effluents form a variety of industries. Mean concentrations were from 15 ug/L to 1,880 ug/L. Williams and LeBel (1981, Ref. 50) examined drinking water form 29 municipalities across Canada and found measurable TBP in samples from each location, as well as in water form the Atlantic and Pacific Oceans, the Great Lakes, Lake Winnipeg, the St. Lawrence River, and the Columbia River. Concentrations ranged from 0.2 to 62 ng/L. Piet et al. (1981, Ref. 36) identified TBP at 100 ng/L in drinking water processed from surface water using sand filtration. The unfiltered water had no detectable TBP. TBP appears to be found nearly everywhere in the environment at low concentrations. No information was found on the natural occurrence of TBP.

II. Chemical fate information—A. *Transport.* TBP has moderate solubility in water and moderate vapor pressure at ambient temperatures. It also has a

moderate log P value (4.0, measured). The physical and chemical characteristics of TBP indicate that it wil partition throughout the environment and appear almost everywhere, including biolipids.

B. *Persistence.* A study of the primary biodegradation of TBP by a river water die-away method (Ref. 39, Saeger et al., 1979) found 50 percent loss of the parent compound in about 3.5 days and complete loss in 7 days. These same investigators, using a carbon dioxide evolution method, also reported CO_2 evolution at 30 percent of theory in 7 days and 81 percent of theory in 28 days. Initial concentrations of TBP in the test units were 1 and 20 mg/L, respectively. These results indicate relatively rapid and complete biodegradation of TBP is aerated surface waters. There was no evidence of nonbiological degradation of TBP in sterile controls. Francis et al. (1980, Ref. 15) observed no anaerobic biodegradation of TBP incubated for 30 days at 28°C with anaerobic bacteria isolated from a waste disposal site. No other information on anaerobic biodegradation was found, and the potential for anaerobic biodegradation must be considered unknown.

Hydrolysis is very slow at most environmental pH's (Ref. 48, U.S. EPA, 1985). Atmospheric oxidation is not expected to be significant.

C. *Rationale for chemical fate recommendations.* Because of its moderate water solubility, log P, and vapor pressure, TBP should partition to natural waters, soils and sediments, biota, and air. TBP appears to be biodegraded rapidly and completely in aerobic surface waters. Its fate in soils and sediments is not clear. It is likely to persist in the atmosphere until returned to earth by virtue of its high vapor density or in precipitation. TBP that partitions to biota may become a part of the food chain. The ubiquitous environmental appearance of TBP at low concentrations may mean that it is not effectively degraded below some threshold concentration or that the continuous release of TBP into the environment leads to some low-level equilibrium concentration reflecting both input and removal processes. The monitoring evidence, showing widespread low concentrations of TBP, justifies the consideration of potential environmental effects resulting from continuous, low-level exposures. Tests should be conducted to evaluate the persistence of TBP in anaerobic sediments and soils.

III. Biological effects of concern to human health—A. *Metabolism and toxicokinetics.* Suzuki et al. (1984, Ref. 46) studied the excretion and biotransformation of TBP in rats. In animals dosed with [^{14}C]-TBP, 66 percent of an oral dose and 81 percent of an intraperitoneal dose were excreted in 24 hours. The two major metabolities present in urine were the hydrolysis products dibutyl and monobutyl phosphates. Other metabolites present were the result of oxidation of the butyl chain.

The effect of TBP on enzyme activity in rats has been studied by Oishi et al. (1980, Ref. 33). In animals fed a diet containing 0.5 or 1 percent TBP for 10 weeks, serum transaminase and alkaline phosphatase activities were significantly decreased. There was no difference in cholinesterase activity in serum, whereas brain cholinesterase activity was significantly increased. Blood coagulation time was significantly prolonged.

B. *Acute and subchronic (short-term) effects.* The acute effects of TBP have been studied by Smyth Carpenter (1944, Ref. 43), Chambers and Casida (1967, Ref. 10), Vanedkar (1957, Ref. 49), Suzuki et al. (1977, Ref. 45), Sabine and Hayes (1952, Ref. 38), Johannsen et al. (1977, Ref. 21), and Mitomo et al. (1980, Ref. 27). Sites and biological effects of acute testing were paralysis due to weak cholinesterase inhibition, anesthetic effect, skin and mucous membrane irritation, lung edema, and degeneration of kidney tubules.

Laham et al. (1983, Ref. 22) studied the effect of TBP in rats fed 0.28 and 0.42 mL/kg TBP by gavage for 14 days. In the high-dose group, a significant ($p<0.05$) reduction of caudal nerve conduction velocity accompanied by morphological changes in the sciatic nerve were observed in males. In both sexes of the high dose groups, electron microscopy showed a retraction of Schwann cell processes of the surrounding sciatic unmyelinated fibers, indicating an early response to a chemical insult.

In another study, Laham et al. (1984, Ref. 23) administered TBP by gavage to rates at concentrations of 0.14 and 0.42 mL/kg for 14 consective days. In the high dose group, a significant decrease in hemoglobin in females, a low incidence of degenerative changes in the testes in males, significant changes in amylase and triglyceride activity in females and an increased amylase activity in males were observed. In addition, a significant increase in potassium levels was observed in females both low- and high-dose groups.

Mitomo et al. 1(1980, Ref. 27) studied the effects of TBP on rats and mice that were fed TBP daily in their diets at concentrations of 0, 0.05, 0.2, and 1.0 percent for 3 months. Results of the studies showed a dose-dependent derpression in body weight gain; an increase in liver, kidney, and testes weights; a decrease in uterus weight; and an increase in blood urea nitrogen values in both mice and rats at high-dose levels. Diarrhea was also observed. Similar effects were seen in 9- and 10-week studies when TBP was fed to rats (Ref. 33, Oishi et al., 1980).

Cascieri et al. (1985, Ref. 7) fed rats diets containing TBP at levels of 0, 8, 40, 200, 1,000 or 5,000 ppm for 90 days. Significant changes were seen in blood parameters and liver weight at the highest dose. Urinary bladder cell hyperplasia was observed in both sexes at the highest dose. At 1,000 ppm it was only noted in the males.

In a recent study, TBP was administered by gavage over an 18-week period to rats. Low-dose animals received 0.20 g/kg/day throughout the experiment and the high dose animals received 0.30 g/kg/day for the first six weeks. For the remaining twelve weeks, the high-dose level was increased to 0.35 g/kg/day. All test rats examined developed diffuse epithelial hyperplasia of the urinary bladder (Ref. 24, Laham et al., 1985).

C. *Genotoxicity.* Hanna and Dyer (1975, Ref. 19) tested tributyl phosphate in *S. typhimurium, E. coli* and *Drosophila.* No mutagenic effects were observed.

D. *Oncogenicity.* No information was found. Trimethyl phosphate, a structural analog, was tested for carcinogenicity in rats and mice (Ref. 30, NCI, 1978). It induced adenocarcinomas of the endometrium in female mice and benign fibromas of the subcutaneous tissue in male rats.

E. *Reproductive and developmental effects.* When tested in chicken eggs, TBP was found to be weakly teratogenic (Ref. 37, Roger et al., 1969). No mammalian reproductive and developmental effects information was found in the literature searched.

F. *Chronic (long-term) effects.* No information was found.

G. *Observations in humans.* Workers exposed to 15 mg/m^3 of TBP complained of nausea and headache (Ref. 1, ACGIH, 1980). The principal routes of exposure are skin contact and inhalation. Signs of exposure include nausea, headache, irritation of the eyes and dermatitis (Ref. 44, Stauffer, 1984).

H. *Rationale for health effects recommendations.* Thousands of workers and consumers are potentially exposed to TBP. There is a potential for human exposure to low levels of TBP due to its uses as a flame retardant in aircract hydraulic fluid, for uranium extraction, as an industrial solvent, and

as a plasticizer. TBP has been detected at low levels in municipal and industrial effluents, sediments, and in river, estuarine, ground, and drinking waters. It has also been detected in human and fish lipid tissues.

Available information on health effects are limited to acute and subchronic effects. In view of the lack of information on the chronic health effects of TBP, the induction of urinary bladder hyperplasia and the carcinogenic effect of trimethyl phosphate, studies on chronic toxicity, including oncogenic, neurotoxic, renal, and reproductive and developmental effects, are recommended.

IV. Ecological effects of concern.—A. *Acute and subchronic (short-term) effects.* TBP produces acute toxicity with a variety of aquatic organisms, at low mg/L concentrations, as shown in Table 4. TBP inhibits the growth of some algae at concentrations of 3 to 10 mg/L (Ref. 48, U.S. EPA, 1985). Bringmann and Kuhn (Refs. 4 and 5, 1978, 1980) found that TBP inhibited the growth of an *Entosiphon* protozoa sp. at 14 mg/L, a *Scenedesmus* algal sp. at 3.2 mg/L, and a *Microcystis* bacteria sp. at 4.1 mg/L.

Gast and Early (1956, Ref. 16) investigated the phytotoxicity of several solvents by dipping plant foliage quickly into solutions of the solvents and observing the effects. Of 86 solvents investigated, TBP was the most toxic. Exposure to a 0.5 percent solution of TBP killed all of the six species tested, including bean, corn, cotton, cucumber, tobacco, and tomato.

TBP applied to vegetation reduced the growth of the roots of rice, radish, and soybean plants at concentrations of 10 to 100 ug/g of soil (Ref. 29, Muir, 1984).

A single-dose oral LD_{50} for the white leghorn adult hen was reported as 1.8 g/kg (Ref. 21, Johannsen et al., 1977).

TABLE 4.—ACUTE TOXICITY TESTS WITH A VARIETY OF AQUATIC ORGANISMS

Organism	24-hr LC_{50} (mg/L)	48-hr LC_{50} (mg/L)	72-hr LC_{50} (mg/L)	96-hr LC_{50} (mg/L)	Reference
Rainbow trout				5 to 9	Dave and Lidman (1978, Ref. 12).
Rainbow trout				11.0	Monsanto (1985, Ref. 28).
Zebrafish	11.4	11.4		11.4	Dave et al. (1981, Ref. 13).
Goldfish				8.8	Sasaki et al. (1981), Ref. 40).
Killfish				9.6	Sasaki et al. (1981), Ref. 40).
Fathead minno				6.4	Monsanto (1985, Ref. 28).
Chlorella		5 to 10			AQUIRE (1986, Ref. 3).
Daphnia	12.8	3.7	2.1		Dave et al. (1981, Ref. 13).

B. *Chronic (long-term) effects.* Penman and Osborne (1976, Ref. 35) reported that TBP, at doses of 0.1 to 0.2 percent, had no reproductive effects on the two-spotted spider mite. A related compound, trimethyl phosphate, produced reproductive effects on guppies, toads, quail, and mites, all at relatively high doses (Ref. 48, U.S. EPA, 1985).

C. *Other ecological effects (biological, behavioral, or ecosystem processes).* Bringmann and Kuhn (1982, Ref. 6) determined effects concentration (EC) values for immobilization of *Daphnia magna.* The EC_0, EC_{50}, and EC_{100} were 5, 30 and 41 mg/L, respectively.

D. *Bioconcentration and food-chain transport.* Given its octanol/water partition coefficient, TBP is likely to partition into lipids of biota. Saeger et al. (1979, Ref. 39) calculated a bioconcentration factor of 190. Sasaki et al. (1981, Ref. 40) studied the absorption and elimination of phosphoric acid esters by killifish and goldfish. They found that the amount of TBP in the fish varied with the species and that bioconcentration in the killifish was about three times greater than in goldfish, using a static water system.

In a followup study, using continuous-flow systems Sasaki et al. (Ref. 41, 1982) found TBP taken up rapidly by killifish and reaching a steady-state concentration within 1 day. It remained at that concentration during 38 days of exposure. The bioconcentration ratio during this time was almost constant, varying from 21 to 35. When exposure to TBP was stopped, elimination was very rapid, with half gone within 1.25 hours and no detectable TBP after 24 hours.

E. *Rationale for ecological effects recommendations.* The available information shows that TBP has acute effects on a variety of aquatic organisms at moderately low concentrations (low parts per million). TBP also has been found acutely toxic to terrestrial plants at 5,000 ppm. Nevertheless, there is low concern for the acute effects of TBP since it does not appear that TBP will persist in aerobic environments at concentrations likely to cause acute effects to biota. However, it does appear that nearly all biota are continuously exposed to low concentrations of TBP and the long-term effects of that exposure are largely unknown. The acute toxicity data with terrestrial plants and algae and the growth inhibition observed with rice, radish, and soybeans lead to the conclusion that long-term studies need to be conducted with both aquatic and terrestrial plants exposed to TBP at low concentrations. The data from the acute daphnid tests by Dave et al. (1981, Ref. 13) showed a high ratio between the 24- and 48-hour LC_{50}'s (12.8/3.6=3.5), suggesting potential chronic effects. Long-term studies, using low TBP concentrations, should be conducted with daphnids and/or other aquatic invertebrates. If anaerobic persistence studies indicate long half-lives for TBP in soils and sediments, bioassays should be conducted with representative benthic organisms and soil invertebrates.

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2.4 *Chemicals and groups of chemicals recommended without being designated for response within 12 months. None.*

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[OPTS–51621; FRL–3012–5]

Certain Chemicals Premanufacture Notices

Correction

In FR Doc. 86–10015, beginning on page 16587, in the issue of Monday, May 5, 1986, make the following corrections:

1. On page 16588, first column, under "P86–931", fifth line, "1,1000–2,000" should read "1,000–2,000".

2. On page 16589, first column, under "P86–946", sixth line, "5/kg" should read "5 g/kg".

3. On the same page, second column, under "P86–948", sixth line, "g/kg" should read "5 g/kg".

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