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Part III

Environmental Protection Agency

Twenty-fifth Report of the Interagency Committee to the Administrator; Receipt of Report and Request for Comments Regarding Priority List of Chemicals; Notice

40 CFR Parts 712 and 716

Preliminary Assessment Information and Health and Safety; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

[OPTS-41032; FRL 3665-4]

Twenty-fifth 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 Twenty-Fifth Report to the Administrator of EPA on November 1, 1989. This report, which revises and updates the Committee's priority list of chemicals, adds 13 chemicals to the list for priority consideration by EPA in promulgation of test rules under section 4(a) of the Act. This list contains five designated chemicals, one intent-to-designate chemical, and seven recommended without designation chemicals. The Twenty-Fifth Report is included with this notice. The designated chemicals are: pentabromodiphenyl ether (CAS No. 32534-81-9), octabromodiphenyl ether (CAS No. 32536-52-0), decabromodiphenyl ether (CAS No. 1163-19-5), hexabromocyclododecane (CAS No. 3194-55-6), and 1,2-bis(2,4,6-tribromophenoxy)ethane (CAS No. 37853-59-1). These chemicals are designated for response within 12 months. Therefore, in response to ITC's designation, EPA will either initiate rulemaking under section 4(a) of TSCA, or publish a **Federal Register** notice explaining the reasons for not initiating such rulemaking within 12 months.

The chemical 4-Vinylcyclohexene (CAS No. 100-40-3), is recommended with intent-to-designate.

The chemicals recommended without intent-to-designate are: 2,4,6-tribromophenol (CAS No. 118-79-6), tetrabromophthalic anhydride (CAS No. 632-79-1), dibromoneopentyl glycol (CAS No. 3296-90-0), Ethylene Bis-(tetrabromophthalimide) (CAS No. 32588-76-4), ethylene bis(5,6-dibromonorbornane-2,3-dicarboximide) (CAS No. 41291-34-3), tribrominated polystyrene (CAS No. 57137-10-7), and ethylene bis(pentabromophenoxide) (CAS No. 61262-53-1).

The ITC has removed one chemical, 1,6-hexamethylene diisocyanate (CAS No. 822-06-0), from the priority list because the EPA published a Notice of Proposed Rulemaking on May 17, 1989 (54 FR 21240).

EPA invites interested persons to submit written comments on the report, and to attend Focus Meetings to help narrow and focus issues raised by the ITC's recommendations. Additionally, EPA is soliciting interest in public participation in the consent agreement process for 4-vinylcyclohexene.

DATES: Written comments should be submitted by January 12, 1990. Written notice interest in being designated an "interested party" to the development of a consent agreement for 4-vinylcyclohexene should be submitted by January 12, 1990. The procedures for negotiations are described in 40 CFR 790.22. All written submissions should bear the identifying docket number (OPTS 41032; FRL 3665-4).

A Focus Meeting will be held on December 13, 1989.

ADDRESS: Send written submissions to: TSCA Public Docket Office (TS-793), Office of Toxic Substances, Environmental Protection Agency, Rm. NE G-004, 401 M St., SW., Washington, DC 20460.

Submissions should bear the document control number (OPTS-41032; FRL 3665-4).

The public record supporting this action, including comments, is available for public inspection in Rm. NE G-004 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 these chemicals, should notify the Environmental Assistance Division at the address listed below. To ensure seating accommodations at the Focus Meetings, persons interested in attending are asked to notify EPA at least one week ahead of the scheduled date.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Rm. E-543B, Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: EPA has received the TSCA Interagency Testing Committee's Report 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 an Interagency Testing Committee to make recommendations to the Administrator of EPA on chemical substances and mixtures to be given priority consideration in proposing test rules under section 4(a). Section 4 (e) directs the ITC 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. The ITC's Twenty-Fifth Report was received by the administrator on November 1, 1989, and follows this Notice. The Report

adds 13 substances 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 substances recommended in the ITC's Twenty-Fifth Report to the TSCA section 8(d) Health and Safety Data Reporting Rule (40 CFR part 716), which requires the reporting of unpublished health and safety studies on the listed chemicals. These chemicals also will 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.

Focus Meetings will be held to discuss relevant issues pertaining to these chemicals 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. EPA is not planning to hold a separate Focus Meeting on the recommended chemicals because the issues raised on the designated flame retardants should be applicable to the non-designated flame retardants.

The Focus Meetings will be held on December 13, 1989, as follows:

10:00 a.m.

Pentabromodiphenyl ether, octabromodiphenyl ether, decabromodiphenyl ether, tribromophenoxy ethane, hexabromocyclododecane.

1:00 p.m.

vinylcycylohexene.

They will be held at EPA Headquarters, Rm. 103 NE Mall, 401 M St., SW., Washington, DC. These meetings are intended to supplement and expand upon written comments submitted in response to this notice.

Persons wishing to attend these meetings, or subsequent meetings on these chemicals, should call Michael Stahl, Environmental Assistance Division, at the telephone number listed above at least 1 week in advance.

This notice also serves to invite persons interested in participating in or monitoring negotiations for a consent agreement for 4-vinylcyclohexene to notify EPA no later than [insert date 30 days after date of publication in the Federal Register]. The Procedures for negotiations are described in 40 CFR 790.22. All Written submissions should bear the identifying docket number (OPTS-41032; FRL 3665-4).

III. Status of List

In addition to adding the 13 recommendations to the priority list, the ITC's Twenty-Fifth Report notes the removal of one chemical, 1,6-hexamethylene diisocyanate, from the list. The current list contains 6 designated substances, 6 chemicals recommended with intent-to-designate, and 20 recommended without designation substances.

Authority: 15 U.S.C. 2603.

Dated: December 1, 1989.

Charles M. Auer,

Acting Director, Existing Chemical Assessment Division.

Twenty-fifth 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 commerce that may present an unreasonable risk of injury to health and 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 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, 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 every 6 months, the Committee makes those revisions 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 one group of chemicals.

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 chemicals and groups of chemicals 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 chemicals or groups 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 NOVEMBER 1989

Chemical/Group	Recommended studies
A. Designated for response within 12 months:	
Brominated flame retardants:	
Brominated diphenyl ethers	
Pentabromodiphenyl ether [1] CAS No. 32534-81-9	Chemical Fate: Water solubility; octanol/water partition coefficient; vapor pressure; sediment and soil adsorption; photolysis; aerobic and anaerobic biodegradation. Health Effects: Pharmaco Kinetics; metabolism; neurotoxicity; reproductive and developmental toxicity; chronic toxicity and oncogenicity testing. Ecological Effects: Acute Toxicity to algae; chronic toxicity to fish and aquatic invertebrates and toxicity to benthic organisms.
Octabromodiphenyl ether [2] CAS No. 32536-52-0	Chemical Fate: Water solubility; octanol/water partition coefficient; vapor pressure; sediment and soil adsorption; photolysis; anaerobic biodegradation rate. Aerobic biodegradation if pentabromodiphenyl ether aerobically biodegrades. Health Effects: Pharmacokinetics; metabolism; neurotoxicity; reproductive toxicity; chronic toxicity and oncogenicity testing. Ecological Effects: Acute toxicity to algae; acute chronic toxicity to fish, and aquatic invertebrates and toxicity to benthic organisms only if penta bromodiphenyl ether causes adverse ecological effects.
Decabromodiphenyl ether [3] CAS No. 1163-19-5	Chemical Fate: Water solubility; octanol/water partition coefficient; vapor pressure; sediment and soil adsorption; photolysis; anaerobic biodegradation. Aerobic biodegradation if pentabromodiphenyl ether aerobically biodegrades. Health Effects: Reproductive toxicity. Ecological Effects: Acute and chronic toxicity to fish and aquatic invertebrates and toxicity to benthic organisms only if pentabromodiphenyl ether causes adverse ecological effects.
1,2-Bis(2,4,6-tribromophenoxy)-ethane [4] CAS No. 37853-59-1	Chemical Fate: Vapor pressure; sediment and soil adsorption; photolysis; aerobic and anaerobic biodegradation. Health Effects: Chronic toxicity with emphasis on hepatotoxicity, neurotoxicity and reproductive effects. Ecological Effects: Acute toxicity to algae, fish and aquatic invertebrates; chronic toxicity to fish and aquatic invertebrates and toxicity to benthic organisms based on results of its acute toxicity testing.
Hexabromocyclododecane [5] CAS No. 3194-55-6	Chemical Fate: Vapor pressure; sediment and soil adsorption; anaerobic biodegradation.

TABLE 1—ADDITIONS TO THE SECTION 4(e) PRIORITY LIST NOVEMBER 1989—Continued

Chemical/Group	Recommended studies
	Health Effects: Pharmacokinetics; metabolism, subchronic toxicity. Ecological Effects: Acute toxicity to fish and aquatic invertebrates; chronic toxicity to fish and aquatic invertebrates and toxicity to benthic organisms based on results of its acute toxicity testing.
B. Recommended with Intent-to-Designate: 4-Vinylcyclohexene [6] CAS No. 100-40-3	Chemical Fate: Aqueous volatilization rate. Health Effects: Pharmacokinetics and oncogenicity by inhalation route of exposure. Ecological Effects: None.
C Recommended Without Being Designated for Response Within 12 Months: Brominated flame retardants:	
2,4,6-Tribromophenol [7] CAS No. 118-79-6	Chemical Fate: Chemical properties and persistence. Health Effects: Chronic toxicity, except for dibromoneopentyl glycol. Ecological Effects: Chronic toxicity.
Tetrabromophthalic anhydride [8] CAS No. 632-79-1	Chemical Fate: Chemical properties and persistence. Health Effects: Chronic toxicity, except for dibromoneopentyl glycol. Ecological Effects: Chronic toxicity.
Dibromoneopentyl glycol [9] CAS No. 3296-90-0	Chemical Fate: Chemical properties and persistence. Health Effects: Chronic toxicity, except for dibromoneopentyl glycol. Ecological Effects: Chronic toxicity.
Ethylene bis-(tetrabromophthalimide) [10] CAS No. 32588-76-4	Chemical Fate: Chemical properties and persistence. Health Effects: Chronic toxicity, except for dibromoneopentyl glycol. Ecological Effects: Chronic toxicity.
Ethylene bis(5,6-dibromonorbornane-2,3-dicarboximide) [11] CAS No. 41291-34-3.	Chemical Fate: Chemical properties and persistence. Health Effects: Chronic toxicity, except for dibromoneopentyl glycol. Ecological Effects: Chronic toxicity.
Tribrominated polystyrene [12] CAS No. 57137-10-7	Chemical Fate: Chemical properties and persistence. Health Effects: Chronic toxicity, except for dibromoneopentyl glycol. Ecological Effects: Chronic toxicity.
Ethylene bis(pentabromo phenoxide) [13] CAS No. 61262-53-1	Chemical Fate: Chemical properties and persistence.
Health Effects: Chronic toxicity, except for dibromoneopentyl glycol.. Ecological Effects Chronic toxicity.	

Notes: CA Index Names (9CI)
[1] Benzene, 1,1'-oxybis-, pentabromo deriv.
[2] Benzene, 1,1'-oxybis-, octabromo deriv.
[3] Benzene, 1,1'-oxybis[2,3,4,5,6]-pentabromo-
[4] Benzene,1,1'-(1,2-ethanediylbis(oxy)bis)2,4,6-tribromo
[5] Cyclododecane, 1,2,5,6,9,10-hexabromo-
[6] Cyclohexene, 4-ethenyl-
[7] Phenol, 2,4,6-Tribromo-
[8] 1,3-Isobenzofurandione, 4,5,6,7-tetrabromo-
[9] 1,3-Propanediol, 2,2-bis(bromomethyl)-
[10] 1H-Isoindole-1,3(2H)-dione, 2,2'-(1,2-ethanediyl)bis[4,5,6,7-tetrabromo-
[11] 4,7-Methano-1H-isoindole-1,3(2H)-dione, 2,2'-(1,2-ethanediyl)bis[5,6-dibromohexahydro-
[12] Benzene, ethenyl-, tribromo deriv., homopolymer
[13] Benzene, 1,1'-[1,2-ethanediylbis(oxy)]bis[2,3,4,5,6-pentabromo-(1,2-bis (pentabromophenoxy)ethane

TSCA Interagency Testing Committee
Statutory Member Agencies and Their Representatives

Council on Environmental Quality
  John C. Jens, Member
Department of Commerce
  Raimundo Prat, Alternate
Environmental Protection Agency
  Letitia Tahan, Member (see Note 1)
  Vincent Nabholtz, Alternate
National Cancer Institute
  Richard Adamson, Member
  Thomas P. Cameron, Alternate
National Institute of Environmental Health Sciences
  James K. Selkirk, Member and Chairperson
National Institute for Occupational Safety and Health
  Rodger L. Tatken, Alternate
National Science Foundation
  Carter Kimsey, Member (see Note 2)
  Jarvis L. Moyers, Alternate
Occupational Safety and Health Administration
  Loretta Schuman, Member and Vice Chairperson (see Note 3)
  Stephen Mallinger, Alternate

Liaison Agencies and Their Representatives

Agency for Toxic Substances and Disease Registry
  Deborah Barsotti
Consumer Product Safety Commission
  Lakshmi C. Mishra
Department of Agriculture
  Richard M. Parry, Jr.
  Elise A.B. Brown
Department of Defense
  Harry Salem
  Melvin E. Anderson
Department of the Interior
  Clifford P. Rice (see Note 4)
  Barnett A. Rattner
Food and Drug Administration
  Arnold Borsetti
National Library of Medicine
  Vera Hudson
National Toxicology Program
  Dorothy Canter
Committee Staff
  Robert H. Brink, Executive Secretary (see Note 5)
  Norma Williams, ITC Program Specialist
Support Staff
  Alan Carpien—Office of the General Counsel, EPA

Notes:

(1) Appointed on August 17, 1989.
(2) Appointed on September 14, 1989.
(3) Appointed on September 14, 1989.
(4) Appointed on October 2, 1989.
(5) Robert Brink died on July 31, 1989. He served 4 years distinguished and faithful service as the ITC Executive Secretary. The Committee deeply regrets his passing. His dedication and outstanding contributions to the goals of the Committee will long be remembered.

The Committee acknowledges and is grateful for the assistance and support given the ITC by the staff of Syracuse Research Corp. (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 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 to 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 composed of representatives from eight statutory member agencies and eight 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 (Refs. 1 through 8).

1.2 *Committee's previous reports.* Twenty-four previous reports to the EPA Administrator have been issued by the Committee and published in the **Federal Register** (Refs. 1 through 9). Seventy-seven chemicals and 20 groups of chemicals were recommended for priority consideration by the EPA Administrator and designated for response within 12 months. In addition, 12 chemicals and five groups of chemicals were recommended without being designated. Overall, in the 24 reports to the EPA Administrator, the Committee has recommended testing for 89 chemicals and 25 groups of chemicals. A complete list of recommended chemicals may be obtained by contacting: Dr. John D. Walker, ITC Acting Executive Secretary, U.S. Environmental Protection Agency (TS-792), 401 M St. SW., Washington, DC 20460, (202) 382-3820.

1.3 *Committee's activities during this reporting period.* Between April 21, 1989 and October 26, 1989, the Committee reviewed chemicals from nominations by Member Agencies, Liaison Agencies and State Agencies and from its sixth scoring exercise.

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 also reviewed available information on 173 chemicals and three groups of over 175 chemicals. One chemical and one group of chemicals were selected for addition to the section 4(e) Priority List; four chemicals were deferred indefinitely. For one group of chemicals the Committee is requesting that EPA propose TSCA section 8(a) and 8(d) rules. The remaining chemicals are still under study.

During this reporting period, the Committee reviewed several for Your Information (FBI), 8(d) and 8(e) documents that are stored on microfiche in the TSCA Public Docket Office, Office of Toxic Substances, Environmental Protection Agency, Room G-004, NE Mall, 401 M St. SW., Washington, DC 20460. These documents are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161 (1-800-336-4700), and from Chemical Information Systems, Inc., 7215 York Road, Baltimore, Maryland 21212 (1-800-CIS-USER). The Committee referenced several of these documents in Chapter 2 of this report and readers are referred to the above address to obtain further information. Beginning with this report, interested parties can also obtain, from the above address, copies of references and information reviews supporting recommendations of chemicals in this report.

The Committee examined testing information on several brominated flame retardants (BFRs) because of concerns related to potential long-term health and ecological effects. Most of the testing was conducted using technical-grade, commercially-available products. The Committee previously designated the following BFRS in the following numbered reports: #2, 1,2-epoxy-3-bromopropane (CAS No. 3132-64-7); #4, 2,4,6-tribromoaniline (CAS No. 147-82-0); #14, 1,2-dibromo-4-(1,2-dibromomethyl) cyclohexane (CAS No. 3322-93-8); #15, pentabromoethylbenzene (CAS No. 85-22-3); and #16, tetrabromobisphenol A (CAS No. 79-94-7). Subsequently, the EPA published **Federal Register** notices in response to these designations.

A few of the BFRs examined by the Committee were listed in the June 22, 1982, Preliminary Assessment Information TSCA section 8(a) final rule (PAIR) which required submission of data quantities of chemicals manufactured, amounts directed to certain classes and uses and the potential exposures and environmental releases associated with the manufacturers' own and immediate customers' processing of the chemicals (47 FR 26992).

A number of the BFRs examined by the Committee were listed in the June 5, 1987, halogenated dibenzo-p-dioxins (HDDs) and dibenzofurans (HDFs) final rule (52 FR 21412). This rule required analytical testing of certain chemicals for HDD/HDF contamination, submission of existing data on contamination of these chemicals with HDDs/HDFs, submission of health and safety studies on HDDs/HDFs and submission of worker allegations of significant adverse reactions to HDDs/HDFs under TSCA sections 4 and 8.

In a February 24, 1988, **Federal Register** notice (53 FR 5466), the Committee requested information on several BFRs.

The Committee is continuing to review information on the chloroalkyl phosphates, recommended with intent-to-designate in the 23rd Report (53 FR 46262), and has not reached a conclusion whether or not to designate one or more of those chemicals.

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 Committees revising the List by adding one chemical, 4-vinylcyclohexene (CAS No. 100-40-3) and one group of chemicals, brominated flame retardants (BFRs). The BFRs include a subgroup of brominated diphenyl ethers [pentabromodiphenyl ether (CAS No. 32534-81-9), octabromodiphenyl ether (CAS No. 32536-52-0), and decabromodiphenyl ether (CAS No. 1163-19-5)], and several other BFRs, including 1,2-bis(2,4,6-tribromophenoxy) ethane (CAS No. 37853-59-1), hexabromocyclododecane (CAS No. 3194-55-6), 2,4,6-tribromophenol (CAS No. 118-79-6), tetrabromophthalic anhydride (CAS No. 632-79-1), dibromoneopentyl glycol (CAS No. 3296-90-0), ethylene bis(tetrabromophthalimide) (CAS No. 32588-76-4), ethylene bis(5,6-dibromonorbornane-2,3-dicarboximide) (CAS No. 41291-34-3), tribrominated polystyrene (CAS No. 57137-10-7), and ethylene bis(pentabromo phenoxide)

(CAS No. 61262–53–1). 1,6-Hexamethylene diisocyanate (CAS No. 822–06–0) was removed from the Priority List because the EPA published a Notice of Proposed Rulemaking on May 17, 1989 (54 FR 21240).

The Priority List is divided in the following Table 2 into three parts; namely, A. Chemicals and Groups of Chemicals Designated for Response Within 12 Months, B. Chemicals and Groups Chemicals Recommended with Intent-to-Designate, and C. Chemicals and Groups of Chemicals Recommended Without Being Designated for Response Within 12 Months. Table 2 follows:

TABLE 2—THE TSCA SECTION 4(e) PRIORITY LIST NOVEMBER 1989

Entry	Date of designation
A. Chemicals and groups of chemicals recommended and designated for response within 12 months:	
Crotonaldehyde	November 1988
Brominated flame retardants	
Brominated diphenyl ethers	
Pentabromodiphenyl ether	November 1989
Octabromodiphenyl ether	November 1989
Decabromodiphenyl ether	November 1989
1,2-Bis(2,4,6-tribromophenoxy)ethane	November 1989
Hexabromocyclododecane	November 1989
B. Chemicals and groups of chemicals recommended with intent-to-designate:	
Chloroalkyl phosphates	
Tris(2-chloroethyl)phosphate	November 1988
Tris(2-chloro-1-propyl)phosphate	November 1988
Tris(1-chloro-2-propyl)phosphate	November 1988
Tris(1,3-dichloro-2-propyl)phosphate	November 1988
Tetrakis(2-chloroethyl)ethylene diphosphate	November 1988
4-Vinylcyclohexene	November 1989
C. Chemicals and groups of chemicals recommended without being designated for response within 12 months:	
C.I. Disperse blue 79	November 1986
N-[5-[bis[2-(acetyloxy)ethyl]amino] -2-[(2-bromo-4,6-dinitrophenyl)azo]- 4-methoxy phenyl]-acetamide	May 1987
N-[5-[bis[2-(acetyloxy)ethyl]amino] -2-[2-chloro-4,6-dinitrophenyl)azo]- 4-methoxy phenyl]-acetamide	May 1987
N-[5-[bis[2-(acetyloxy)ethyl]amino] -2-[(2-chloro-4,6-dinitrophenyl)azo]- 4-ethoxy phenyl]-acetamide	May 1987
Imidazolium quaternary ammonium compounds:	
4,5-dihydro-1-methyl-2-nortallow alkyl-1-(2-tallow amidoethyl), Me sulfates	May 1988
Ethoxylated quaternary ammonium compounds:	
Ethanaminium, 2-amino- N-(2-aminoethyl) -N-(2-hydroxyethyl)-N-methyl-, N,N-ditallow acyl derivs., Me sulfates (salts)	May 1988
Poly(oxy-1,2-ethanediyl),α-[2-[bis(2-aminoethyl)-methylammonio]-ethyl]-ω-hydroxy-, N,N'-dicoco acyl derivs., Me sulfates (salts)	May 1988
Poly(oxy-1,2-ethanediyl),α-[2-[bis(2-aminoethyl)-methylammonio]-ethyl]-ω-hydroxy-, N,N'-bis (hydrogenated tallow acyl) derivs., Me sulfates (salts).	May 1988
Poly(oxy-1,2-ethanediyl),α-[2-[bis(2-aminoethyl)-methylammonio-ethyl]-ω-hydroxy-, N,N'-ditallow acyl derivs., Me sulfates (salts)	May 1988
Poly[oxy(methyl-1,2-ethanediyl)],α-[2-[bis(2-aminoethyl)-methylammonio]-methylethyl] -ω-hydroxy-, N,N'-,ditallow acyl derivs., Me sulfates (salts).	May 1988
Poly(oxy-1,2-ethanediyl),α-[3-[bis(2-aminoethyl)-methylammonio]-2-hydroxypropyl]-ω-hydroxy-, N-coco acyl derivs., Me sulfates (salts)	May 1988
Poly(oxy-1,2-ethanediyl),α-[2-[bis(2-aminoethyl)-methylammonio]-ethyl]-ω-hydroxy-, N,N'-di-C14-18 acyl derivs., Me sulfates, salts)	May 1988
Butyraldehyde	November 1988
2,4,6-Tribromophenol	November 1989
Tetrabromophthalic anhydride	November 1989
Dibromoneopentyl glycol	November 1989
Ethylene bis(tetrabromophthalimide)	November 1989
Ethylene bis(5,6-dibromonorbornane-2,3-dicarboximide)	November 1989
Tribrominated polystyrene	November 1989
Ethylene bis(pentabromo phenoxide)	November 1989

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 annotated 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 47603–7612.

(3) Eighteenth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, May 19, 1986, 51 FR 18368–18375.

(4) Nineteenth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, November 14, 1986, 51 FR 41417–41432.

(5) Twentieth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, May 20, 1987, 52 FR 19020–19026.

(6) Twenty-first Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, November 20, 1987, 52 FR 44830–44837.

(7) Twenty-second Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, May 20, 1988, 53 FR 18196–18210.

(8) Twenty-third Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, November 16, 1988, 53 FR 46262–46278.

(9) Twenty-fourth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, July 27, 1989, 54 FR 31248–31249.

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 to the section 4(e) Priority List one chemical substance, 4-vinylcyclohexene (VCH) (CAS No. 100–40–3), and one group of chemical substances, the brominated flame retardants (BFRs). The BFRs consist of a subgroup of brominated diphenylethers

(BDPEs) [pentabromodiphenyl ether (PBDPE) (CAS No. 32534-81-9), octabromodiphenyl ether (OBDPE) (CAS No. 32536-52-0), and decabromodiphenyl ether (DBDPE) (CAS No. 1163-19-5)] and several other BFRs, including 1,2-bis(2,4,6-tribromophenoxy) ethane (BTBPE) (CAS No. 37853-59-1), hexabromocyclododecane (HBCD) (CAS No. 3194-55-6), 2,4,6-tribromophenol (TBrP) (CAS No. 118-79-6), 3,4,5-6-tetrabromophthalic anhydride (TBPA) (CAS No. 632-79-1), dibromoneopentyl glycol (DBNG) (CAS No. 3296-90-0), ethylene bis(tetrabromophthalimide) (EBTBPA) (CAS No. 32588-76-4), ethylene bis(5,6-dibromonorbornane 2,3-dicarboximide) (EBDNDC) (CAS No. 41291-34-3), tribrominated polystyrene (TBPS) (CAS No. 57137-10-7) and ethylene bis(pentabromophenoxide) (EBPBP) (CAS No. 61262-53-1). The recommendation of these chemicals is made after considering the factors identified in section 4(e)(1)(A) and other relevant information, such as the chemical testing information deficiencies of Member Agencies.

2.2 *Chemicals designated for response within 12 months*—2.2.a *Brominated flame retardants.* Five BFRs that are produced in substantial quantities and that have been detected in the environment or have potential to cause adverse effects were designated for testing.

2.2.a *Brominated diphenylethers—Summary of recommended studies.* The chemical fate and environmental effects testing recommendations are summarized in the following table 3:

TABLE 3—CHEMICAL FATE AND ENVIRONMENTAL EFFECTS TESTING RECOMMENDED (R), TRIGGERED IF PBDPE IS BIODEGRADED (B), TRIGGERED IF PBDPE IS TOXIC (T) OR NOT RECOMMENDED (N) FOR BDPEs

Test	PBDPE	OBDPE	DBDPE
Chemical Fate:			
Water solubility.	R	R	R
Log octanol/water partition coefficient (log P).	R	R	
Vapor pressure.	R	R	R
Sediment and soil adsorption.	R	R	R
Photolysis	R	R	R
Aerobic biodegradation.	R	B	B
Anaerobic biodegradation.	R	R	R
Environmental Effects:			
Algal bioassay.	R	T	N
Fish acute	R	T	T
Aquatic invertebrate acute.	R	T	T
Fish chronic	R	T	T
Aquatic invertebrate chronic.	R	T	T
Benthic organism toxicity.	R	T	T

The health effects testing recommendations for the BDPEs are listed below.

1. *Pentabromodiphenyl ether.* Pharmacokinetics and metabolism, neurotoxicity, chronic toxicity, reproductive and developmental toxicity and oncogenicity.

2. *Octabromodiphenyl ether.* Pharmacokinetics and metabolism, neurotoxicity, chronic toxicity, reproductive toxicity and oncogenicity.

3. *Decabromodiphenyl ether.* Reproductive toxicity. The physical-chemical properties of the BDPE isomeric mixtures recommended for testing are listed in the following Table 4.

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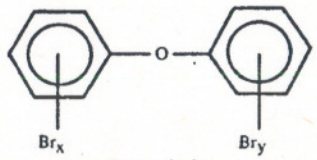
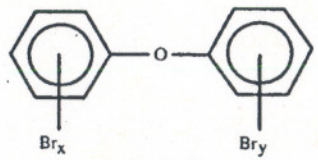
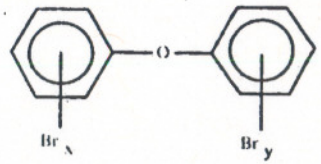
Table 4. Physical-chemical properties of BDPEs recommended for priority testing consideration

Chemical	Pentabromodiphenyl ether	Octabromodiphenyl ether	Decabromodiphenyl ether
CAS No.	32534-81-9	32536-52-0	1163-19-5
Acronym	PBDPE	OBDPE	DBDPE
Synonyms and Trade Names	Pentabromodiphenyl oxide Pentabromophenoxybenzene	Phenyl ether, Octabromo deriv. (8CI) Octabromodiphenyl oxide	Ether, bis (pentabromophenyl) (8CI) Decabromobiphenyl ether Decabromobiphenyl oxide Decabromophenyl ether
Structure	 x + y = 4 - 6	 x + y = 6 - 9	 x + y = 9 - 10
Molecular Weight	564.72	801.42	959.22
Melting Point (C)	202 (E)[a/]	200-250 (E)	295-310
Solubility in water (mg/L at 20 C)	9×10^{-7} (E)	0.02-0.03[b/]	0.02-0.03[b/]
Log Octanol/Water Partition	7.8 (E)	5.5[b/]	5.24[b/]

[a/] Estimated (E)
[b/] Norris (1974)

BILLING CODE 6560-50-C

Rationales for Recommendations

I. Exposure Information

A. *Production/use/disposal/exposure.* The BDPEs are all produced in substantial volumes; actual production volumes are confidential business information (CBI). Environmental release and occupational exposure to BDPEs may be anticipated from manufacturing, processing or use in activities associated with filtration, drying, drumming, bagging, compounding or from phase separation or cleaning residues from drums.

PBDPE is recommended for use in acrylonitrile-butadiene-styrene (ABS) resins, flexible polyurethane foams, polyvinyl chloride wired cable insulation, phenolic thermosets and hot-melt adhesives (Ref. 3, Ethyl, 1988). It may also be used as a flame retardant for epoxides, laminates and coatings, and has special application in the preparation of flame retardant wood treatments. When blended with a variety of chlorinated solvents or triethyl phosphate it may be used for dimensional lumber, shakes and shingles (Ref. 6, Great Lakes, 1982).

OBDPE is recommended as a flame retardant for ABS resins nylon, etc. (Ref. 3, Ethyl, 1988 and Ref. 6, Great Lakes, 1982).

DBDPE is a heat-stable additive flame retardant recommended for use in high-impact polystyrene, thermoset and thermoplasticpolyesters, non-drip polypropylene, cross-linked polyethylene and elastomers (Ref. 3, Ethyl, 1988). It is suggested for use in wire and electrical cable insulation of all types. It is also recommended as a flame retardant for epoxy phenolic, polybutyleneterephthalate, and nylon resins (Ref. 6, Great Lakes, 1982).

B. *Evidence for exposure—Environmental exposure.* PBDPE was detected in fish in Sweden (Ref. 1, Anderson and Blomkvist, 1981), and in mussels and river sediment from Japan (Ref. 17, Watanabe, *et al.*, 1986, 1987). It was also detected (as a component of Bromkal 70-5) in marine mammals and birds from Sweden (Ref. 8, Jansson *et al.*, 1987) and in air, soil and sediments near two U.S. production facilities (Ref. 2, DeCarlo, 1979; Ref. 18, Zweidinger *et al.*, 1979). The U.S. EPA Environmental Research Laboratory in Duluth, MN, measured PBDPE in dead Atlantic Bottle Nose dolphins from the U.S. east coast (Ref. 14, USEPA 1989).

DBDPE was detected in air, particulates, soil and sediments in the vicinity of U.S. production facilities (Ref. 2, DeCarlo,1979; Ref. 18, Zweidinger *et al.*, 1979). It was also detected in shell fish and sediments in Japan (Ref. 17, Watnabe, 1987).

DBDPE was one of more than 300 chemicals and chemical categories on an initial list of toxic chemicals (the Toxics Release Inventory) established under section 313 of the Emergency Planning And Community Right-to-Know Act (Pub. L. 99–499, "EPCRA"). Section 313 of EPCRA requires certain facilities that manufacture, process, or otherwise use toxic chemicals to report annually their environmental releases of such chemicals. For DBDPE, 47 exposure and release data forms (Form Rs) were submitted under section 313 of EPCRA during the 1987 reporting year. The reported releases included over 155,000 pounds a year to air (over 120,000 pounds a year from one domestic production facility), over 20,000 pounds a year of water releases and over 16,000 pounds a year of land releases. Since DBDPE is the most highly brominated of the BDPEs, it is anticipated that OBDPE and PBDPE, which should be more volatile and more water soluble, will be released in at least the same percentage of the production volume as DBDPE. The DBDPE release figures only include releases from producers and formulators, not releases from use and disposal of BDPEs.

II. Chemical Fate Information

A. *Transport.* The estimated water solubility and octanol/water partition coefficients (K_{ow}) for PBDPE and the measured water solubility and K_{ow} values for OBDPE and DBDPE relisted in Table 4. Vapor pressures of BDPEs are estimated to below at ambient temperature, i.e., $<10^{-6}$ mm Hg. Based on these estimates and data, BDPEs are likely to partition to sediments and biota.

B. *Persistence.* DBDPE was susceptible to aqueous photolysis, but no rate was reported (Ref. 11, Norris, *et al.*, 1974).

C. *Rationale for chemical fate recommendations.* The Committee recommends testing to obtain measured water solubility and K_{ow} values for PBDPE because there were no data. Water solubility andK_{ow} testing for OBDPE and DBDPE (Table 3) are also recommended because the shake-flask methods used to provide available data may not be appropriate for hydrophobic compounds. The Committee recommends vapor pressure testing for the BDPEs, because there were no data (Table 3). The Committee also recommends sediment and soil adsorption isotherm testing of all BDPEs because there were no data and there is a need to estimate sediment partitioning and soil mobility. The Committee recommends direct and indirect aqueous photolysis because there were no data on photolysis rates and products (Table 3). Rates of aerobic biodegradation may be inversely proportional to the number of bromines on a BDPE. The Committee recommends aerobic biodegradation testing of PBDPE because there were no data and triggering aerobic biodegradation testing of the higher brominated homologs (OBDPE and DBDPE), if PBDPE is biodegraded. The Committee recommends anaerobic biodegradation testing of all BDPEs because there were no data and these chemicals should be susceptible to reductive debromination. Chemical fate testing is recommended because BDPEs have been detected in the environment and there are insufficient data to reasonably determine or predict their environmental persistence.

III. Health Effects Information

A. *Metabolism and pharmacokinetics.* No information was found for OBDPE, or PBDPE.

Decabromodiphenyl ether. In a disposition study using male rats exposed to diets containing 250–50,000 ppm of DBDPE for 9 to 11 days, the feces contained 82- to 100 percent of the ^{14}C-radiolabel (administered on the last day), while the urine contained :0.012 percent (Rex. 13, NTP, 1986). Most of the radio label in the feces was unmetabolized compound, although three unidentified metabolites were detected. All major tissues except the brain contained small but measurable levels of radioactivity. In a single-dose (gavage) disposition study using rats, all tissue samples contained radio label on day 1 following administration, while only the adrenal glands and spleen contained radio label on day 16 (Ref. 11, Norris *et al.*, 1974, 1975). As with the repeated-exposure study, most of the radioactivity (90- >99 percent) was excreted in the feces.

B. *Acute and subchronic (short-term) effects.*

Pentabromodiphenyl ether. The oral LD_{50} values in male and female rats were 7400 and 5800 mg/kg, respectively, with deaths occurring between the second and seventh day post treatment (Ref. 7, Great Lakes Chemical Corp., 1988). Effects included tremors of the forelimb, reduced activity immediately after treatment (4000 mg/kg and above), hepatotoxicity and gastric lesions (all doses). The hepatotoxic effects observed at the lowest dose (2400 mg/kg) persisted for up to 44 days post treatment. In a second acute oral toxicity study, 4 out of 5 rats died when treated by gavage with 5000 mg per kg.

In an inhalation study there were no deaths in male and female rats exposed for 1 hour to PBDPE at concentrations up to 200 mg/L. The only effects were changes in motor activity and irritation observed during the exposure. In a dermal study, PBDPE applied to the abraded skin of rabbits for 24 hours at dose levels up to 2000 mg/kg produced no compound-related systemic toxic effects.

In 28-day studies, male and female rats given diets containing 100, or 1000 ppm of PBDPE showed no gross effects of treatment (Ref. 7, Great Lakes Chemical Corp., 1988). There was an increase in relative and absolute liver weight in males and females in the high-dose group and in females of the low-dose group. Enlargement of the centrilobular and midzonal liver parenchymal cells was reported in the high-dose group, and thyroid hyperplasia was observed in "several" rats at both dose levels. Except for increased bromine levels in the thyroid and liver, no gross or microscopic effects were observed in male and female rats maintained for 30 days on diets which provided PBDPE at doses between 0.01 and 1.0 mg/kg per day. Bromine levels were generally in the normal range following a 6-week recovery period.

In a 90-day study, when rats were given a diet providing doses of PBDPE of 0, 2, or 100 mg/kg/day, absolute and relative liver weight increased in the mid- and high-dose groups and the amount of porphyrins in the liver and urine increased in the high-dose group (Ref. 7, Great Lakes Chemical Corp., 1988). Compound-related microscopic changes characterized as hepatocytomegaly and thyroid hyperplasia were observed in all dose groups. Liver effects were not reversible during the 24-week recovery period; thyroid effects were reversible.

Octabromodiphenyl ether. In acute toxicity studies none of the rats died during the 14-day observation period after a single oral administration of OBDPE at doses between 50 and 5000 mg/kg, or after a 1-hour inhalation exposure at a level of 2 mg/L (Ref. 7, Great Lakes Chemical Corp. 1988). Similarly, none of the rabbits died during the 14-day observation period following a 24-hour dermal application of OBDPE (200 or 2000 mg/kg) to intact or abraded skin. OBDPE was nonirritating to the skin or eyes of rabbits.

Male and female rats given diets containing 100 or 1000 ppm of OBDPE for 28 days showed no gross effects of treatment (Ref. 7, Great Lakes Chemical Corp., 1988). There was a statistically significant increase in relative liver weights in both sexes at both dose levels. Enlargement of the centrilobular and midzonal liver parenchymal cells was reported in both dose groups, and slight to moderate thyroid hyperplasia was observed in rats of the high-dose group. Similar effects on the liver were observed in male and female rats administered diets containing 100, 1000, or 10,000 ppm of OBDPE for 13 weeks. At the two higher levels the effects persisted in a group observed for an additional 6 months post exposure period. Other compound-related effects included kidney and thyroid lesions in the high-dose group; hyperplastic nodules were considered possible compound-related effects in the liver of one mid-dose and two high-dose rats.

In an inhalation study, groups of male and female rats (25/sex) were exposed to 1.2, 12, 120, or 1200 mg/m^3 OBDPE for 8 hours per day for 14 days (Ref. 7, Great Lakes Chemical Corp.1988). Respiratory rate increased during exposure, but returned to normal by the beginning of the next exposure session. Focal or multifocal to diffuse, cytoplasmic enlargements of the hepatocytes as well as focal hepatocellular necrosis and acidophilic degeneration were also observed. These effects were observed in the mid- and high-dose groups; in all dose groups there was correlation between exposure level and the bromine content of the lungs, liver and fat tissues.

Decabromodiphenyl ether. The acute toxicity of DBDPE was low with all rats surviving following single oral doses up to 5000 mg per kg (Ref. 6, Great Lakes, 1982). Following inhalation exposure to DBDPE at 2 or 48.2 mg/L for 1 hour, rats suffered respiratory difficulty and irritation, but were normal by day 13 (Ref. 6, Great Lakes, 1982).

DBDPE fed to male rats at dietary levels of 0.01, 0.1 or 1.0 percent for 30 days resulted in: liver enlargement at the 0.1 and 1.0 percent levels; liver (cytoplasmic enlargement and vacuolation) and kidney (hyaline degenerative cytoplasmic changes) lesions at the 1.0 percent dietary level; and thyroid hyperplasia at the two highest doses (Ref. 12, Norris, 1975). In a 14-day study, no clinical signs or gross pathology were observed in rats or mice maintained on diets containing DBDPE at levels up to 100,000 ppm, while no gross or microscopic pathology were observed in rats and mice maintained for 13 weeks on diets containing DBDPE at levels up to 50,000 ppm (Ref. 13, NTP, 1986).

C. *Genotoxicity.* PBDPE was negative in the Ames/ *Salmonella* test when tested up to the limits of toxicity both with and without metabolic activation (Ref. 7, Great Lakes Chemical Corp., 1988).

OBDPE was negative in the Ames/ *Salmonella* and the *Saccharomyces* assays when tested to the limits of toxicity both with and without metabolic activation. (Ref. 7, Great Lakes Chemical Corp., 1988). Similarly, OBDPE did not increase sister chromatid exchanges in Chinese hamster ovary cells, or the rate of unscheduled DNA synthesis in WI-38 human fibroblast cells, when these tests were conducted in the presence or absence of a metabolic activation system (Ref. 7, Great Lakes Chemical Corp., 1988).

DBDPE was not mutagenic in the Ames/*Salmonella* and the mouse lymphoma L5178Y/TK$^{+/-}$ assay with and without metabolic activation (Ref. 13, NTP, 1986). DBDPE did not cause sister chromatid exchanges or chromosomal aberrations in Chinese hamster ovary cells *in vitro* (Ref. 13, NAP, 1986) or in bone marrow cells following *in viva* administration (30-100 mg/kg/per day for 90 days prior to mating and through lactation) to male and female rats or their offspring (Rex. 12, Norris et al., 1975).

D. *Oncogenicity.* No information was found on PBDPE or OBDPE.

DBDPE has been tested in male and female rats and mice at dose levels of 25,000 and 50,000 ppm. There was some evidence of carcinogenicity in rats, equivocal evidence in male mice and none in female mice (Rex. 13, NAP, 1986). No neoplastic effects were observed in male and female rats given diets which provided doses of DBDPE of 0.01, 0.1, or 1.0 mg/kg/day for 2 years (Ref. 9, Kociba et al., 1975).

E. *Reproductive and developmental effects.* No information was found on PBDPE.

To study developmental effects, OBDPE was administered by gavage to groups of 10 rats at doses of 2.5, 10, 15, 25, or 50 mg/kg on days 6 through 15 of gestation (Ref. 7, Great Lakes Chemical Corp., 1988). Reduced ossification was observed in the fetuses of the high-dose group and was considered to be related to maternal toxicity. There was also a decrease in mean fetal weight and an increase in post-implantation losses in the high-dose group. Increased serum bromide levels were reported in the 25 and 50 mg/kg groups.

DBDPE did not induce developmental toxic effects in offspring of rats administered DBDPE at doses of 10, 100, or 1000 mg/kg/day on days 6 through 15 of gestation (Ref. 11, Norris et al., 1974; Ref. 12, Norris et al., 1975). There was an

increase in subcutaneous edema and delayed ossification in the fetuses of the high-dose group. In a single-generation reproductive toxicity study using doses of 3, 30, or 100 mg/kg for 90 days prior to mating and through lactation, no treatment-related effects of DBDPE to the offspring rats were reported (Ref. 12, 1975, Norris et al.)

F. *Chronic (long-term) effects.* No information was found on PBDPE or OBDPE.

Lesions of the liver, stomach and spleen were observed in a 103–week feeding study in rats and mice administered diets containing 25,000 or 50,000 ppm of DBDPE (Ref. 13, NTP, 1986). These effects were predominately in the high-dose group. After 2 years of feeding DBDPE to rats at 0.01, 0.1 or 1 percent in the diet, no significant long-term effects were noted (Ref. 9, Kociba et al., 1975).

G. *Observations in humans.* No information was found.

H. *Rationale for health effects recommendations.* The Committee recommends pharmacokinetics, neurotoxicity, reproductive and developmental toxicity, chronic toxicity and oncogenicity testing for PBDPE. The Committee also recommends pharmacokinetics, neurotoxicity, reproductive toxicity, chronic toxicity and oncogenicity testing for OBDPE. These health-effects tests are recommended for PBDPE and OBDPE because there were no data and because acute and subchronic studies indicate not only that effects may be only slowly reversible but that the compounds may accumulate with extended exposure. The Committee recommends reproductive toxicity testing for DBDPE because the available data were developed using a single-generation study in which the effects of DBDPE on male rats were not reported and the high dose was too low to produce toxic effects. Health effects testing is recommended because DBDPEs have been detected in the environment and there are insufficient data to reasonably determine or predict their health effects.

IV. Ecological Effects Information

A. *Acute and subchronic (short-term) effects.* DBDPE EC_{50} values for marine and freshwater algae were >1 mg/L, but concentrations tested were 100 times water solubility levels and exposures were too short (3 days) to permit uptake (Ref. 16, Walsh et al., 1987).

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

C. *Other ecological effects (biological, behavioral, or ecosystem process).* No information was found.

D. *Bioconcentration and food-chain transport.* PBDPE bioconcentration data submitted under TSCA section 8(d) (EPA document #86-890000045) indicated that after 8 weeks of exposing carp to 105 and 9.7 ug/L PBDPE, the maximum bioconcentration factors (BCF) were 5,380 and 11,700 respectively. For OBDPE, bioconcentration data submitted under the same 8(d) document, using the same test organism and method suggested BCFs of :3.8 for any OBDPE concentration. These data suggest that there may have been less membrane permeation and lower uptake by carp for OBDPE than for PBDPE.

E. *Rationale for ecological effects testing recommendation.* The Committee recommends that an algal bioassay, an aquatic invertebrate acute toxicity test and an extended (14–day) fish acute toxicity test be conducted for PBDPE, because there were no data. The Committee recognizes that membrane permeation may be difficult for large chemicals and is requesting molecular cross-sectional area data for PBDPE, OBDPE and DBDPE. The Committee recommends triggering (T) short-term tests for OBDPE and DBDPE if PBDPE is toxic (Table 3). The Committee recommends that aquatic invertebrate and fish chronic toxicity tests as well as a benthic organism toxicity test be conducted for PBDPE (because there were no data) and that testing of OBDPE and DBDPE be triggered if PBDPE is toxic (Table 3). Based on PBDPE and OBDPE bioconcentration data the Committee is not recommending bioconcentration testing for DBDPE. Ecological effects testing is recommended because BDPEs have been detected in the environment and there are insufficient data to reasonably determine or predict their ecological effects.

2.2.a.2 *1,2-Bis(2,4,6-tribromophenoxy) ethane—Summary of recommended studies.* It is recommended that BTBPE be tested for the following:

1. *Chemical fate.* Vapor pressure; sediment and soil adsorption; photolysis; aerobic and anaerobic biodegradation.

2. *Health effects.* Chronic toxicity with emphasis on hepatotoxicity, neurotoxicity and reproductive effects.

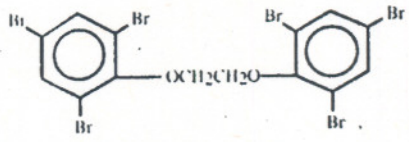
3. *Ecological effects.* Acute toxicity to algae, fish and aquatic invertebrates; chronic toxicity to fish and aquatic invertebrates and toxicity to benthic organisms based on results of its acute toxicity testing.

PHYSICAL AND CHEMICAL INFORMATION

CAS No.: 37853–59–1

Acronym	BTBPE
Synonyms and Trade Names.	Benzene,1,1'-(1,2-ethanediylbis-(oxy)bis)2,4,6 tribromo (9Cl)Bis-1,2-(2,4,6-tribromophenoxy)-ethane1,1'-(1,2-Ethanediylbis(oxy)bis-(2,4,6-tribromobenzene) Fire Master 680 Great Lakes FF680

Structural Formula:



Empirical Formula	$C_{14}H_8Br_6O_2$
Molecular Weight	687.66
Melting Point (°C)	223-225
Solubility in water (mg/L at 20°C).	0.2 (Ref. 4, Great Lakes (1981a)
Log Octanol/Water Partition Coefficient (log P).	3.14 (Ref. 4, Great Lakes (1981a)

I. Exposure Information

A. *Production/use/disposal/exposure.* BTBPE is produced insubstantial volumes; actual production volumes are CBI. BTBPE is used as a flame retardant in ABS polymers and in applications where thermal stability at high processing temperatures is important (Rex. 4, Great Lakes, 1981a). Environmental release may be anticipated from cleaning residues in drums and subsequent release to waste treatment facilities.

B. *Evidence for exposure—Environmental exposure.* BTBPE was detected in air and soil near two U.S. production facilities (Ref. 2, DeCarlo, 1979).

II. Chemical Fate Information

A. *Transport.* Water solubility and Kow data suggest that BTBPE may migrate through soil and desorb from sediment.

B. *Persistence.* BTBPE applied to silica gel and irradiated with UV light was degraded (Ref. 4, Great Lakes, 1981a). Shake-flask biodegradation studies of BTBPE suggested slow degradation, but test concentrations exceeded BTBPE water solubility and recoveries of ^{14}C-BTBPE were <2 percent (Ref. 4, Great Lakes, 1981a).

C. *Rationale for chemical fate recommendations.* The Committee

recommends sediment and soil adsorption isotherm testing and vapor pressure testing at ambient temperature, because there were no data. The Committee recommends direct and indirect photolysis testing because there were no data on photolysis and rates products. The Committee recommends that BTBPE water solubility and vapor pressure data be carefully examined and that an aerobic biodegradation test be designed to adequately measure BTBPE's biodegradation rate. The Committee also recommends anaerobic biodegradation testing because there were no data and because BTBPE should be susceptible to reductive debromination. Chemical fate testing is recommended because BTBPE has been detected in the environment and there are insufficient data to reasonably determine or predict its environmental persistence.

III. Health Effects Information

A. *Metabolism and pharmacokinetics.* Within 4 days of administering radioactive BTBPE to rats, 80 percent and 5 percent of the radioactivity was recovered in the feces and the urine, respectively, indicating likely poor absorption from the gut (Ref. 7, Great Lakes Chemical Corp., 1988).

B. *Acute and Subchronic (Short-Term) Effects.* The acute toxicity of BTBPE was studied by Great Lakes Chemical Corp., (Ref.7, 1988). The oral LD_{50} of BTBPE in male rats, and male and female dogs is >10 g/kg. BTBPE is non-irritating for both abraded and non-abraded skin in rabbits. Acute inhalation, 36.68 mg/L per 4 hours, caused no treatment-related pathology as observed on necropsy at 24 hours post exposure.

Subacute and subchronic toxicity studies also have been reported by Great Lakes Chemical Corp. (Ref. 7, 1988). No compound-related pathology was reported in a 14–day study at the highest concentration tested (10 percent in the diet). Male weaning rats given diets containing 100, or 1000 ppm of BTBPE for 28 days showed no compound-related pathology 6, 12, or 18 days after cessation of treatment. In a 90–day study, albino rats given a diet containing 10 percent BTBPE showed liver changes in most of the animals. The lesions consisted of focal or multifocal enlargement of the hepatocytes located within the centrilobular to midzonal regions of the affected liver lobules. The liver lesion incidence was higher in males than in females. No treatment-related changes were reported in the animals fed diets containing 0.1, or 1.0 percent BTBPE in this study, or in the animals exposed via inhalation to 20 mg BTBPE/L, 4 hours per day, 5 days per week for 21 days in another study.

C. *Genotoxicity.* Negative results were reported in the Ames/*Salmonella* test with or without metabolic activation (Ref. 7, Great Lakes Chemical Corp., 1988).

D. *Oncogenicity.* No information was found.

E. *Reproductive and Developmental Effects.* BTBPE was negative in a teratology study in rats. The doses ranged from 30 mg/kg to 10,000 mg/kg (Ref. 7, Great Lakes Chemical Corp., 1988).

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

G. *Observations in humans.* No information was found.

H. *Rationale for health effects recommendations.* The Committee recommends chronic toxicity studies with emphasis on hepatotoxicity, neurotoxicity and reproductive effects because there were no data. Health effects testing is recommended because BTBPE has been detected in the environment and there are insufficient data to reasonably determine or predict its health effects.

IV. Ecological Effects Information

A. *Acute and subchronic (short-term) effects.* BTBPE LC_{50} values for bluegill, rainbow trout and killifish were 1531, 1410 and 230 mg/L, respectively (Ref. 4, Great Lakes, 1981a).

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

C. *Other ecological effects (biological, behavioral, or ecosystem process).* No information was found.

D. *Bioconcentration and food-chain transport.* BTBPE bioconcentration data submitted under TSCA section 8(d) (document #86–890000045) indicated that after 8 weeks of exposing carp to 0.27 and 0.026 mg/L BTBPE; the maximum BCFs were 27 and 43, respectively.

E. *Rationale for ecological effects testing recommendation.* The Committee recommends algal and aquatic invertebrate acute toxicity testing because there were no data and fish acute toxicity testing because available LC_{50} values are >1000 times higher than BTBPE's water solubility. The Committee recommends that BTBPE chronic toxicity testing and benthic organism toxicity testing be triggered (T) based on results of its acute toxicity testing. Bioconcentration testing is not recommended because available BCFs are similar to a predicted BCF of 13 (based on a log K_{ow} of 3.14). Ecological effects testing is recommended because BTBPE has been detected in the environment and there are insufficient data to reasonably determine or predict its ecological effects.

2.2.a.3 *Hexabromocyclododecane—Summary of recommended studies.* It is recommended that HBCD be tested for the following:

1. *Chemical fate.* Vapor pressure; sediment and soil adsorption; anaerobic biodegradation.

2. *Health effects.* Pharmacokinetics; metabolism; subchronic toxicity.

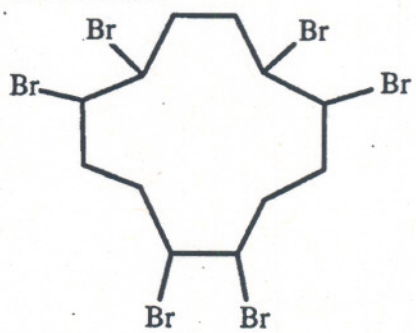
3. *Ecological effects.* Acute toxicity to fish and aquatic invertebrates; chronic toxicity to fish and aquatic invertebrates and toxicity to benthic organism based on results of its acute toxicity testing.

PHYSICAL AND CHEMICAL INFORMATION

CAS No.: 3194–55–60

Acronym	HBCD
Synonyms and Trade Names.	Cyclododecane, 1,2,5,6,9,10-hexabromo-(8CI, 9CI) CD-75P Saytex HBCD

Structural Formula:



Empirical Formula	$C_{12}H_{18}Br_6$
Molecular Weight	641.70
Melting Point (°C)	185-195
Solubility in Water (mg/L).	0.008 (Ref. 5, Great Lakes, 1981b)
Log Octanol/Water Partition Coefficient (log P).	5.81 (Ref. 5, Great Lakes, 1981b)

I. Exposure Information

Production/use/disposal/exposure. HBCD is produced in substantial volumes; actual production volumes are CBI. It is used as a flame retardant in textile coatings, adhesives, latex binders, unsaturated polyesters, expanded polystyrene foams, and other styrene resins (Ref. 5, Great Lakes, 1981b). It is also used as a flame retardant in polyvinyl chloride wire, cable, polystyrene, and polypropylene (Ref. 3, Ethyl, 1988). Environmental release and occupational exposure data are scarce but some releases and exposures may occur based on processing or use.

II. Chemical Fate Information

A. *Transport.* Water solubility and K_{ow} data suggest that HBCD may partition to sediments and biota.

B. *Persistence.* An HBCD aerobic biodegradation study suggested that HBCD was susceptible to degradation (Ref. 5, Great Lakes, 1981b).

C. *Rationale for chemical fate recommendations.* The Committee recommends sediment and soil adsorption, vapor pressure, and direct and indirect aqueous photolysis testing because there were no data. The Committee recommends anaerobic biodegradation testing because there were no data and because HBCD should be susceptible to reductive debromination. Chemical fate testing is recommended because there is potential for environmental release of HBCD from use and processing and there are insufficient data to reasonably determine or predict environmental persistence.

III. Health Effects Information

A. *Metabolism and pharmacokinetics.* No information was found.

B. *Acute and subchronic (short-term) effects.* The acute toxicity of HBCD when administered to rats by inhalation or oral route was low (Ref. 3, Ethyl Corp., 1988; Ref. 5, Great Lakes, 1981b). When applied to rabbit eyes, HBCD was a mild irritant (Ref. 3, Ethyl Corp., 1988, Ref. 5, Great Lakes, 1981b). HBCD was minimally irritating to rabbit skin (Ref. 5, Great Lakes, 1981b). No subchronic toxicity studies were found in the literature.

C. *Genotoxicity.* HBCD was not mutagenic in the Ames/*Salmonella* assay with and without metabolic activation (Ref. 5, Great Lakes, 1981b).

D. *Oncogenicity.* No information was found.

E. *Reproductive and developmental effects.* No information on reproductive effects was found. HBCD did not induce developmental toxic effects in offspring of rats fed diets containing HBCD at levels of 0.01, 0.1, or 1 percent during days 0 to 20 of gestation (Ref. 10, Murai et al., 1985).

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

G. *Observations in humans.* No information was found.

H. *Rationale for health effects recommendations.* The Committee recommends pharmacokinetics, metabolism and subchronic toxicity studies because there were no data. Health effects testing is recommended because there is a potential for exposure to HBCD from use and processing and there are insufficient data to reasonably determine or predict its health effects.

IV. Ecological Effects Information

A. *Acute and subchronic (short-term) effects.* HBCD algal EC_{50} values ranged from 0.01–0.14 mg/L (Ref. 16, Walsh et al., 1987). These data indicate that HBCD is highly toxic to algae, even though these EC_{50} values exceeded HBCD's water solubility.

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

C. *Other ecological effects (biological, behavioral, or ecosystem process).* No information was found.

D. *Bioconcentration and food-chain transport.* Veith, et al., Ref. 15, 1979, estimated HBCD's BCF would be 18,100.

E. *Rationale for ecological effects testing recommendation.* Based on the algal toxicity data the Committee recommends acute aquatic invertebrate and extended acute fish toxicity testing for HBCD. The Committee recommends that HBCD chronic toxicity testing and benthic organism toxicity testing be triggered based on results of its acute toxicity testing. Ecological effects testing is recommended because HBCD is highly toxic to algae and there are insufficient data to reasonably determine or predict its ecological effects.

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2.3 *Chemicals recommended with intent-to-designate* 2.3.a *4-Vinylcyclohexene—Summary of recommended studies.* It is recommended that 4-vinylcyclohexene (VCH) be tested for the following:

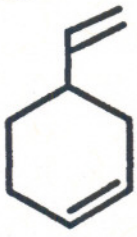
1. *Chemical Fate.* Aqueous volatilization rate.

2. *Health Effects.* Pharmacokinetics and oncogenicity by inhalation route of exposure.

3. *Ecological Effects.* None.

PHYSICAL AND CHEMICAL INFORMATION

CAS Number: 100-40-3

Synonyms:	Cyclohexene, 4-ethenyl- (9 CI) Cyclohexene, 4-vinyl- (8CI) Butadiene dimer 4-Ethenyl-1-cyclohexene 1,2,3,4 tetrahydrostyrene 1-vinyl-3-cyclohexene 1-vinylcyclohex-3-ene 1-vinylcyclohexene-3 4-vinyl-1-cyclohexene 4-vinylcyclohexene-1
Acronym:	VCH
Structural Formula:	
Empirical Formula:	C_8H_{12}
Molecular Weight:	108.2
Physical State at 25 °C:	Liquid (Ref. 21, Sax and Lewis, 1987)
Description of Chemical:	Colorless liquid (Ref. 21, Sax and Lewis, 1987)
Melting Point:	-108.9 °C (Ref. 21, Sax and Lewis, 1987)
Boiling Point:	128 °C (Ref. 21, Sax and Lewis, 1987)
Vapor Pressure:	25.8 mmHg @ 38 °C (Ref. 20, Sandmeyer, 1981) 10.2 mmHg @ 25 °C (Estimated; CHEMBASE)
Specific Gravity:	0.8303 @ 20/4oC (Ref. 21, Sax and Lewis, 1987)
Log Octanol/Water Partition Coefficient:	3.38 (Ref. 10, ISHOW, 1988) 3.316 (estimated; CLOGP3)
Water Solubility at 20 °C:	50 ppm (Ref. 25, USEPA, 1985)
Log K_{oc}:	2.70 (calculated; Ref. 12, Lyman, 1982)
Henry's Constant:	0.218 atm m3/mole (estimated from structure; Ref. 7, Hine and Mookerjee, 1975) 0.0285 atm m3/mole (estimated from water solubility and vapor pressure)

Rationale for Recommendations

I. Exposure Information

A. *Production/use/disposal/exposure/release.* VCH is produced in substantial volumes; actual production volumes are CBI.

VCH is used as an intermediate in the manufacture of 4-vinylcyclohexene mono- and diepoxides, which are used to make epoxy resins, polyesters, coatings, and plastics. VCH also is used in the manufacture of flame retardants, insecticides, plasticizers, and antioxidants (Refs. 8 and 9, IARC, 1976, 1986). Additionally, VCH may have the following uses: as a general chemical intermediate and in the manufacture of flame retardants, flavors and fragrances, and copolymers (Ref. 3, Chemcyclopedia, 1989). VCH may be inadvertently produced by the spontaneous dimerization of butadiene as well as during the manufacture of polymers made from butadiene (e.g., styrene-butadiene rubbers (SBR) and latexes, acrylonitrile-butadiene-styrene (ABS) polymers, and polybutadienes) (Ref. 9, IARC, 1986). The Committee has reviewed the CBI production and exposure information for VCH that was submitted in response to the March 31, 1988 Preliminary Assessment Information Rule (53 FR 10387).

B. *Evidence for exposure—Human Exposure.* Inhalation is the most probable route of worker exposure due to the high vapor pressure of VCH. At locations where VCH is drummed, the air levels typically may be 11 ppm (Ref. 13, Matthiessen, 1986). Dermal exposures may be as high as 4,000 mg/day if protective clothing is not worn (Ref. 28, USEPA, 1985). About 20–25 percent of the chemical produced is isolated, stored in tanks and used at the site of manufacture (Ref. 26, USEPA, 1985).

The air levels of VCH in three manufacturing plants in Italy were: 30–210 $\mu g/m^3$ in a shoe factory (highest levels in the vulcanization area), up to 3 $\mu g/^3$ in a tire retreading factory (highest levels in the extrusion areas), and up to 10 $\mu g/^3$ in an electrical cable insulation plant (Ref. 4, Cocheo, et al., 1983). All three plants used a styrene-butadiene copolymer as the starting material, although natural rubber and cis-polybutadiene polymers also may have emitted some VCH during processing. VCH concentrations of 240–430 $\mu g/^3$ were reported in a room where tires were cured (Ref. 19, Rappaport and Fraser, 1977). The probable source was a cis-polybutadiene elastomer. VCH was found in measurable quantities in the air of two SBR processing plants in Cincinnati, OH (Ref. 15, NIOSH, 1983).

No information was available on consumer exposure to VCH; however, VCH was found at concentrations ranging from 14–210 ppm in ABS plastics used in products such as ladles and food trays. No migration of VCH from these plastics into food simulants (including water, 4 percent acetic acid, 20 percent ethanol) was observed, while some migration into *n*-heptane (a fat simulant) was reported (Ref. 25, Tan and Okada, 1981). The Food and Drug Administration (FDA) refers to VCH as an unregulated additive; a search of FDA information did not reveal any toxicity information that the Committee had not previously retrieved from other sources.

Environmental exposure. In a comprehensive survey sponsored by the Effluent Guidelines Division of the U.S. EPA, VCH was detected at waste water facilities of the following categories (occurrence frequency; median, and maximum concentration in $\mu g/L$): organics and plastics (2; 227, 446.7), rubber processing (6; 78.8, 681.7), publicly owned treatment works (7; 4.9, 8.5).

II. Chemical Fate Information

A. *Transport.* No data were found. The estimated Henry's Law constant suggest that VCH will volatilize from water.

B. *Persistence.* No data were found. In the atmosphere, VCH is likely to react with photochemically-produced hydroxyl radicals and ozone. The estimated half-lives were 4 hr and 1.3 hr, respectively, assuming a hydroxyl radical concentration of 5×10^{-5} per cm^3 and an ozone concentration of 7×10^{11} molecules/cm^3 (Ref. 1, Atkinson, 1987).

C. *Rationale for chemical fate recommendations.* The Committee recommends aqueous volatilization rate testing, because there were no data. Chemical fate testing is recommended because VCH has been detected in the environment and there are insufficient data to reasonably determine or predict its environmental persistence.

III. Health Effects Information

A. *Metabolism and pharmacokinetics.* Metabolism of VCH studied *in vitro* indicated that it was oxidized at either of its two double bonds to produce the corresponding diol compounds via intermediate epoxides (Ref. 6, Gervasi et al., 1981; Ref. 29, Watabe et al., 1981).

Under NTP sponsorship, VCH has been tested for chemical disposition in rats (Ref. 22, Sipes et al., 1989).

No inhalation pharmacokinetics data were found.

B. *Acute and subchronic effects.* Acute effects have been reported by Striegel and Carpenter (Ref. 24, 1961), Bykov (Ref. 2,1968) and Smyth et al. (Ref. 23, 1969). Prechronic (14-day) and subchronic (13-week) studies on VCH were conducted in rats and mice by NTP (Ref. 5, Collins and Manus, 1987). In the 14-day study, NTP reported that:

*** all the mice that received 2,500 or 5,000 mg/kg and 3/5 males that received 1,250 mg/kg 4-vinylcyclohexene died before the end of the studies. Tremors and inactivity were observed in the animals that died. Both vehicle control groups and all dosed groups, except the 300 mg/kg group of females, lost weight (4.0 percent-11.5 percent) during the studies. No compound-related gross changes were noted at necropsy. Histologic examination was limited to the stomach, as it was previously identified as the target organ; no microscopic lesions were detected in this organ.

In the 13-week study, NTP reported that:

*** 9 of 10 male and 5/10 female mice that received 1,200 mg/kg and 2/10 female mice that received 300 mg/kg 4-vinylcyclohexene died before the end of the studies. All other deaths and one of the deaths in the female 1,200 mg/ kg group were considered to be due to gavage error based on tissue injury in the trachea and/or suppurative inflammation in the mediastinum. The sole surviving male receiving 1,200 mg/kg weighed 8 percent less than the vehicle controls, and females receiving 600 mg/kg weighed 5 percent less than the vehicle controls. The final body weights of the other dosed groups were not markedly different from those of the vehicle controls.

Mild, acute inflammation of the stomach was seen in the 1,200 mg/kg groups in three males that died before the end of the study and in one female that lived to the end of the study. In addition, histologic reexamination of the ovaries of the high dose female mice revealed that in all 10 animals, whether they died before or at the end of the study, there was a reduction in the number of primary follicles and mature graafian follicles (the ovaries of female mice receiving lower doses were not similarly examined). No other compound-related clinical signs or histopathologic effects were observed in mice that died or were killed (moribund) during the studies or in mice killed at the end of the studies.

Administration of VCH by inhalation (1 g/m³ for 6 hours/day, over a period of 4 months), inhibited body weight increase and caused leucocytosis, leucopenia and impairment of hemodynamics in rats and mice (Ref. 2, Bykov, 1968).

C. *Genotoxicity.* VCH was non-mutagenic in *Salmonella typhimurium* strains TA98, TA100, TA1535, and TA1537 with or without metabolic activation (Ref. 30, Zeiger et al., 1987). VCH gave a negative response in the cytogenetic (chromosomal aberration/sister chromatid exchange) assays and a positive response in the mouse lymphoma assay (Ref. 17, NTP, 1988).

D. *Oncogenicity.* NTP studied the carcinogenic effect of VCH in rats and mice and found clear evidence of carcinogenicity in female mice, based on a significant increase in the incidence of uncommon ovarian neoplasms. The results were inconclusive in male mice and both sexes of rats because of extensive early mortality (Ref. 17, NTP, 1986). Van Duuren et al. (Ref. 27, 1963) observed carcinogenic effects of VCH in a skin painting study in mice using a commercial grade sample of VCH that was purified by removal of auto-oxidation products with ferrous sulfate, followed by distillation in a nitrogen atmosphere. The carcinogenic effect of VCH in a repeat study could not be confirmed (Ref. 27, Van Duuren, 1965).

E. *Reproductive and developmental effects.* As mentioned in the subchronic section above, VCH caused reduction in the number of primary follicles and mature graafian follicles in the ovary. VCH has been selected for a continuous breeding study by the NTP (Ref. 17, NTP, 1989).

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

G. *Observations in humans.* Workers exposed to VCH (unspecified levels) at a manufacturing site reportedly suffered from keratitis, rhinitis, headache, hypotonia, leucopenia, neutrophilia, lymphocytosis, and unspecified impairment of carbohydrate metabolism (Ref. 2, Bykov, 1968).

A clinical and immunological evaluation was conducted for 31 workers who complained of eye, chest, skin, or nose/throat symptoms at a chemical plant (Ref. 18, Patterson et al., 1988). The presence of symptoms correlated with the degree of exposure to VCH, but the presence or absence of antibodies did not correlate with the presence or absence of the symptoms.

H. *Rationale for health effects recommendation.* The Committee recommends inhalation pharmacokinetic and oncogenicity testing because inhalation is likely to be the major route of human exposure. Health effects testing is recommended because VCH has been detected in the environment and there are insufficient data to reasonably determine or predict its health effects.

IV. Ecological Effects Information

A. *Acute and subchronic (short-term) effects.* VCH's 48-hour EC_{50} for *Daphnia magna* was greater than 100 mg/L (EPA document #FYI-OTS-0785-0397). This EC_{50} was based on a nominal VCH concentration. The 48-hour VCH concentration (and the 48-hour EC_{50} value) is likely to be substantially less than 100 mg/L, because of VCH's propensity to volatilize.

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

C. *Other ecological effects (biological, behavioral, or ecosystem process).* When sewage microorganisms were incubated in the presence of VCH for 16 hours at 23°C, an EC_{50} >200 mg/L was estimated based on turbidity (FYI-OTS-0785-0397). VCH had an LC_{50} of 34.4×10^{-3} M (about 37 mg/L) to the bean plant, *Phaseolus multiflorus* (Ref. 11, Ivens, 1952).

D. *Bioconcentration and food-chain transport.* Based on an estimated log K_{ow} of 3.3, an estimated BCF would be about 260.

E. *Rationale for ecological effects testing recommendation.* Based on results of the disposition study of VCH in mice, the Committee is concerned that fish (if exposed to VCH) might also metabolize VCH to the diepoxide and subsequently develop cancer. The Committee recognizes that while there are no readily-available test guidelines to conduct pharmacokinetic fish studies, that the EPA's Duluth, MN Environmental Research Laboratory has an excellent pharmacokinetics research program. The Committee is not recommending ecological effects testing at this time, but does recommend that if volatilization rate and readily-available monitoring data substantiate the presence of VCH in surface waters, that some fish pharmacokinetic testing be considered.

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2.4 *Chemicals recommended without being designated for response within 12 months*—2.4.a *Brominated flame retardants* (BFRs continued)—*Summary of recommended studies.* Seven BFRs that are produced in substantial quantities, but for which there are few exposure, persistence and effects data, are recommended for testing. With the exceptions noted below, it is recommended that 2,4,6-tribromophenol (TBrP) (CAS No. 118–79–6), 3,4,5,6-tetrabromophthalic anhydride(TBPA) (CAS No. 632–79–1), dibromoneopentyl glycol (DBNG) (CAS No. 3296–90–0), ethylene bis(tetrabromophthalimide) (EBTBPA) (CAS No. 32588–76–4), ethylene bis(5,6-dibromonorbornane 2,3-dicarboximide)(EDBNDC) (CAS No. 41291–34–3), tribrominated polystyrene (TBPS) (CAS No. 57137–10–7) and ethylene bis(pentabromophenoxide) (EBPBP) (CAS No. 61262–53–1) be tested for:

1. *Chemical fate.* Chemical properties and persistence data.

2. *Health effects.* Chronic toxicity.

3. *Ecological effects.* Chronic toxicity.

At this time, based on available TSCA 8(d) submissions, the Committee is not recommending water solubility testing for TBrP and TBPA and octanol-water partition coefficient testing for TBrP, TBPA and DBNG (TSCA 8(d) documents #86–870001215, 870002279, 878216116, 878216117). At this time, the Committee is also not recommending chronic toxicity studies for DBNG, because NTP is conducting carcinogenesis studies.

Physical and Chemical Information

Except for information on water solubility (mg/L) of TBrP (969), TBPA (241) and DBNG (21000) at 25 °C and octanol-water partition coefficients of TBrP (2,198), TBPA (96) and DBNG (12.8), the Committee has no information on physical and chemical properties of the other BFRs at ambient temperatures.

Rationale for Recommendation

I. Exposure Information

A. *Production/use/disposal/exposure/release.* The seven BFRs listed above are all produced in substantial volumes; actual production volumes are CBI.

Three of the BFRs (TBrP, TBPA and DBNG) are reactive flame retardants. In principle, reactive flame retardants should combine with the basic polymer or become part of the basic polymer (as in flame resistant copolymers). However, polymerization processes and other chemical reactions are often not complete and residues of fire-resistant monomers or reactive flame retardants may be entrained in the polymer. Since reactive flame retardants are designed to be retained in the polymer by chemical bonds rather than slow diffusion and slow vaporization, the unreacted residues may be rather mobile. While the Committee is concerned about potential exposures to unreacted residues, it does recognize that there are data for DBNG that suggest that after 2 days of aqueous extraction, a roofing/siding panel resin

released only 0.003 percent of DBNG (#86–870001215). The remaining four BFRs are used to impart flame retardant qualities to polymers, i.e., they are additive flame retardants. The Committee is concerned about potential exposures during manufacturing, processing, use or disposal.

B. *Evidence for exposure—Human exposure.* For TBPA and EBTBPA, the EPA received a FYI submission regarding complaints from employees concerning respiratory problems possibly related to processing (FYI–OTS–0787–0559).

Environmental exposure. TBrP has been detected in the environment. However, the Committee is uncertain of the source of TBrP that is environmentally detected, e.g., from chlorinating waste water, release from polymers, etc.

II. Chemical Fate Information

Few data were found, except those discussed above and the data that suggest DBNG is chemically not microbiologically degraded (#86–870001215). The Committee recommends testing to generate chemical properties and persistence data at ambient temperatures, because there were no data. Chemical fate testing is recommended for the seven BFRs because there is potential for environmental release from manufacturing, processing, use or disposal and there are insufficient data to reasonably determine or predict environmental persistence.

III. Health Effects Information

A number of short-term health effects tests have been conducted for TBrP and DBNG. The NTP is conducting a carcinogenesis study of DBNG (Ref. 1, NTP, 1989); long-term toxicity tests are recommended for the remaining six BFRs, because there were no data. Health effects testing is recommended for six BFRs because there is potential for exposure during manufacturing, processing, use or disposal and because there are insufficient data to reasonably determine or predict health effects.

IV. Ecological Effects Information

Minimal information was available. A TSCA 8(d) submission suggested a DBNG LC_{50} of 97 mg/L for fathead minnows (#86–870002279). Indexing information for another TSCA 8(d) submission indicated that it contained acute toxicity data for a mixture containing TBrP. Closer inspection of this submission revealed that these data were developed using a mother liquor containing only 2 percent tribromophenol (#88–7800184). Long-term ecological effects testing is recommended because there were no data. Ecological effects testing is recommended for the seven BFRs because there is potential for environmental release from manufacturing, processing, use or disposal and there are insufficient data to reasonably determine or predict ecological effects.

Reference

NTP. National Toxicology Program. "NTP CHEMTRACK. [data base]." Research Triangle Park, NC: National Toxicology Program/National Institute of Environmental Health Sciences. U.S. Department of Health and Human Services. Results report as of 10–30–89 (1989).

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