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Part VI

Environmental Protection Agency

Thirtieth Report of the Interagency Testing Committee to the Administrator; Notice

ENVIRONMENTAL PROTECTION AGENCY

[OPPTS-41037; FRL-4071-4]

Thirtieth Report of the Interagency Testing Committee to the Administrator, Receipt of Report and Request for Comments Regarding Priority Testing 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 30th Report to the Administrator of EPA on May 29, 1992. As noted in this Report, which is included with this notice, the Committee revised the Priority Testing List by adding one chemical group, the siloxanes, and four chloroalkyl phosphates: 1,2-ethanediyl tetrakis(2-chloro-1-methylethylene) phosphate (TCIEP); 2,2-bis(chloromethyl)-1,3-propanediyl tetrakis(2-chloroethyl) phosphate (TCEBP); oxydi-2,1-ethanediyl tetrakis(2-chloroethyl) phosphate (TCEDP); and 2-chloro-1-methylethyl bis(2-chloropropyl) phosphate (DCPCEP). These chemicals are recommended. There are no designated or recommended with intent-to-designate chemicals.

The ITC removed two chemicals from the Priority Testing List in the 30th Report as a result of EPA actions. Sodium cyanide and acrylic acid, designated in the 27th ITC Report, were removed because EPA issued a consent order for sodium cyanide on December 17, 1991 (56 FR 65442), and for Acrylic acid on March 4, 1992 (57 FR 7656).

EPA invites interested persons to submit written comments on the Report.

DATES: Written comments should be submitted by August 10, 1992.

ADDRESSES: Send four copies of written submissions to: TSCA Public Docket Office (TS-793), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. NE G004, 401 M St., SW., Washington, DC 20460. Submissions should bear the document control number (OPPTS-41037; FRL-4071-4). The public record supporting this action, including comments, is available for public inspection in Rm. NE G004 at the address noted above from 8 a.m. to noon and 1 p.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (TS-799), Office of Pollution Prevention and Toxics, 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 30th 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 chemicals and chemical groups in order to develop data relevant to determining the risks that such chemicals and chemical groups may present to health or the environment. Section 4(e) of TSCA established the Interagency Testing Committee to recommend chemicals and chemical groups to the Administrator of EPA for priority testing consideration. Section 4(e) directs the ITC to revise the TSCA section 4(e) Priority Testing List at least every 6 months. The ITC's most recent revisions to this List are included in the Committee's 30th Report. The Report was received by the Administrator on May 29, 1992, and is included in this Notice. The Report adds one chemical group and 4 chloroalkyl phosphates to the TSCA section 4(e) Priority Testing List.

II. Written and Oral Comments

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 will be published at a later date in the **Federal Register** adding the substances recommended in the ITC's 30th 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. That notice will also add the chemicals to the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR part 712). The section 8(a) rule requires the reporting of production volume, exposure, and release information on the listed chemicals.

III. Status of List

The ITC's 30th Report notes the addition of one chemical group and 4 chloroalkyl phosphates to the Priority Testing List, and the removal of sodium cyanide and acrylic acid from the List. The current Priority Testing List contains 24 chemicals and 23 chemical groups, 11 of these chemicals are designated.

Authority: 15 U.S.C. 2603.

Dated: June 30, 1992.

Charles M. Auer,

Director, Existing Chemical Assessment Division, Office of Pollution Prevention and Toxics.

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

Summary

The U.S. Congress created the Interagency Testing Committee (ITC) under Section 4(e) of the Toxic Substances Control Act (TSCA) to recommend chemicals and chemical groups to the Administrator of the U.S. Environmental Protection Agency (EPA) for testing under Section 4(a) of TSCA and to facilitate coordination of chemical testing sponsored or required by U.S. Government organizations represented on the Committee. Congress directed the Committee to: (1) organize their recommendations as the Priority Testing List, (2) revise the Priority Testing List at least every 6 months and (3) transmit these revisions to the EPA Administrator for publication in the **Federal Register**. During this reporting period (11/28/91 to 5/27/92), the Committee revised the TSCA section 4(e) Priority Testing List by adding two chemical groups and removing two chemicals.

Recent questions related to the safety of siloxanes for a number of medical uses, including breast implants, prompted the Food and Drug Administration (FDA) to request that the Committee review the health effects of siloxanes. The Committee added a group of 56 siloxanes to the Priority Testing List and recommended them for autoimmune effects, cancer, reproductive effects and developmental toxicity testing and for epidemiological studies.

The Committee also added a group of four chloroalkyl phosphates to the Priority Testing List and recommended them for screening tests, because there are few publicly-available data and because these chemicals are structurally similar to five chloroalkyl phosphates that were recommended in the Committee's 23rd Report.

The Committee removed sodium cyanide and acrylic acid from the Priority Testing List because EPA implemented the Committee's testing recommendations.

The Committee reviewed 350 studies on the 5 chloroalkyl phosphates recommended in the Committee's 23rd Report and deferred them to provide an opportunity for manufacturers to submit exposure data and to discuss voluntary testing.

During this reporting period, a few Committee members participated in EPA's, National Cancer Institute (NCI's) and National Toxicology Program (NTP's) chemical selection meetings, met with the Synthetic Organic Chemical Manufacturers Association and the Chemical Manufacturers Association to discuss completed, ongoing and planned testing of chemical groups and attended the March 18, 1992 U.S. House of Representatives and March 25, 1992 U.S. Senate hearings on TSCA reauthorization. The Committee's Executive Director coordinated testing with the National Toxicology Program, coordinated responses to the Agency for Toxic Substances and Disease Registry's (ATSDR) request for comments on Priority Data Needs and presented an invited paper to the American Society for Testing and Materials on the role of the Committee's testing recommendations in facilitating test method development.

Also during this reporting period, the Committee initiated efforts to develop a Priority Testing Candidate List of chemicals and chemical groups under consideration, conducted a partial review of glycol ethers' reproductive effects data, and formed two subcommittees to review non-public data on ethoxylated and imidazolium quaternary ammonium compounds and to review chemicals nominated by the Occupational Safety and Health Administration (OSHA).

Additions to the Priority Testing List

Additions to the Priority Testing List are presented, together with the types of testing recommended, in Table 1.

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

Group	CAS No.	Chemical	Action	Date	Recommended Tests
Siloxanes			Recommended	5/92	Physical and chemical properties: None, at this time.
					Chemical fate: None, at this time.
					Health effects: Autoimmune effects, reproductive effects, developmental toxicity, cancer and epidemiology studies
					Ecological effects: None, at this time.
Chloroalkyl Phosphates			Recommended	5/92	Physical and chemical properties: melting point, octanol-water partition coefficient, vapor pressure and water solubility.
					Chemical fate: Aerobic biodegradation and hydrolysis rate screening.
					Health effects: Acute toxicity screening.
					Ecological effects: Algal toxicity, fish, aquatic and benthic invertebrate acute toxicity screening.

TSCA Interagency Testing Committee

Statutory member Agencies and Their Representatives

Council on Environmental Quality
Charles Herrick, member (see Note 1)

Department of Commerce
Willie E. May, member
Edward White, alternate (see Note 2)

Environmental Protection Agency
James B. Willis, member
John S. Leizke, alternate

National Cancer Institute
Thomas P. Cameron, member
Richard Adamson, alternate

National Institute for Environmental Health Sciences
Errol Zeiger, member
James K. Selkirk, alternate

National Institute for Occupational Safety and Health
Robert W. Mason, member
Henryka Nagy, alternate (see Note 3)

National Science Foundation
Carter Kimsey, member and Chairperson
Jarvis L. Moyers, alternate

Occupational Safety and Health Administration
Christine Whittaker, member and vice chairperson
Surender Ahir, alternate

Liaison Agencies and Their Representatives

Agency for Toxic Substances and Disease Registry
Sharunda Buchanan, member

Consumer Product Safety Commission
Val Schaeffer, member (see Note 5)
Lakshmi C. Mishra

Department of Agriculture
Donald Derr, member
Ralph T. Ross, alternate (see Note 6)

Department of Defense
Randall S. Wentsel, member

Department of the Interior
Clifford P. Rice, member
Barnett A. Rattner, alternate

Department of Transportation
George Cushmac, member
James O'Steen, alternate

Food and Drug Administration
Edwin J. Mathews, member (see Note 7)
Raju Kammula, alternate

National Library of Medicine
Vera Hudson, member

National Toxicology Program
Victor A. Fung, member (see Note 8)

U.S. International Trade Commission
James Raftery, member
Edward Matusik, alternate

Committee Staff

John D. Walker, Ph.D., Executive Director
Norma S.L. Williams, Executive Assistant

Support Staff

Mary Ellen Levine, Office of the General Counsel, EPA (see Note 9)

Notes:
1. Appointed on February 4, 1992.
2. Appointed on February 6, 1992.
3. Appointed on November 15, 1991.
4. Appointed on November 22, 1991.
5. Appointed on April 2, 1992.
6. Appointed on December 19, 1991.
7. Appointed on December 26, 1991.
8. Appointed member on March 20, 1992.
9. Appointed on January 7, 1992.

The Committee acknowledges the assistance and support given by the staff of Syracuse Research Corp. (technical support contractor) and

personnel of the EPA Office of Pollution Prevention and Toxics.

Chapter 1—Introduction

1.1 *Background.* Background on the TSCA Interagency Testing Committee (ITC) was provided most recently in chapter 1.1 of the 29th Report that was submitted to the EPA Administrator on November 27, 1991 (56 FR 67424, December 30, 1991).

1.2 *Committee's previous reports.* Twenty-nine previous Reports to the EPA Administrator have been issued by the Committee and published in the **Federal Register**. In these 29 Reports, the Committee recommended testing for 124 chemicals and 39 chemical groups. Chemical groups were defined most recently in chapter 1.2 of the 29th Report.

1.3 *Committee's activities during this reporting period.* The Committee's activities during this reporting period (November 28, 1991 to May 27, 1992) are described below.

1.3.a *Chemical and chemical group selections.* During this reporting period, the Committee initiated efforts to develop a Priority Testing Candidate List of chemicals and chemical groups under consideration, reviewed data on siloxanes and chloroalkyl phosphates, conducted a partial review of glycol ethers' reproductive effects data, and formed two subcommittees to review non-public data on ethoxylated and imidazolium quaternary ammonium compounds and to review chemicals nominated by the Occupational Safety and Health Administration.

Siloxanes and chloroalkyl phosphates are recommended, not designated, because the Committee wants to review the TSCA section 8(a) and 8(d) information and any use exposure and release information as well as any physical chemical property information that is voluntarily submitted, before deciding whether to designate or withdraw these chemicals for testing. These recommendations are consistent with the Committee's practice of distinguishing between data needs and data gaps and recommending testing for chemicals with data needs and of comprehensively evaluating chemicals and chemical groups as discussed in Chapter 1.3.a of the ITC's 27th and 29th Reports.

Some chemical groups on the Priority Testing Candidates List that the Committee will be considering in the future were listed in Chapter 1.3.b of the 29th Report.

1.3.b *Comprehensive information processing.* The Committee's approach to comprehensive information processing is described in Chapter 1.3.b of the 29th Report.

1.3.c *Information dissemination.* To promote public understanding of the Committee's functions, some of the activities that occurred during this reporting period are briefly described below.

Some Committee Members and staff attended recent hearings on TSCA reauthorization. On March 18, 1992 hearings were held before the House of Representatives Subcommittee on Environment, Energy and Natural Resources, chaired by Congressman Mike Synar (D-OK). On March 25, 1992 hearings were held before the Senate Environment and Public Works Subcommittee, chaired by Senator Harry Reid (D-NV). EPA discussed its revitalized chemical testing program.

At the invitation of the Chemical Manufacturers Association, the Committee's Chairperson and Executive Director met with the chloroalkyl phosphate manufacturers on April 1, 1992 to discuss completed, ongoing and planned testing and the status of the ITC's review of chloroalkyl phosphates. The manufacturers were asked to supply samples of chloroalkyl phosphates for EPA sponsored fish neurotoxicity tests. They were encouraged to provide information on the uses of chloroalkyl phosphates, the levels of chloroalkyl phosphates that might result from processing and use and information that might explain the low (parts per billion) environmental concentrations of chloroalkyl phosphates. This exposure information is needed to provide some perspective for the chloroalkyl phosphate toxicity data. Additional meetings with the chloroalkyl phosphate manufacturers are planned.

At the invitation of the American Society for Testing and Materials (ASTM), the ITC's Executive Director presented a paper at ASTM's Second Symposium on Environmental Toxicology and Risk Assessment. The Symposium was convened on April 26–29, 1992 in conjunction with ASTM's semi-annual meeting to develop and revise ASTM methods for chemical fate and ecological effects testing. The Executive Director discussed ITC's role in facilitating development of chemical fate and ecological effects test methods.

1.3.d *Information coordination.* Congress directed the Committee to facilitate coordination of chemical testing sponsored or required by U.S. Government organizations represented on the Committee. This directive promotes conservation of U.S. government chemical testing resources by eliminating unnecessary and duplicative testing.

At the request of the National Toxicology Program (NTP), TSCA Section 8(d) reports on health effects of bis-(4-chlorophenyl) sulfone (CAS No. 80–07–9) were provided to facilitate NTP's evaluation of this chemical. The TSCA Section 8(d) reports were submitted to the EPA as a result of the Committee's recommendation for physical and chemical property testing of sulfones in their 27th Report. After the 27th Report was published, the NTP's Executive Committee deferred testing bis-(4-chlorophenyl) sulfone for subchronic and mutagenic effects until the TSCA Section 8 information could be reviewed. NTP is currently reviewing this TSCA Section 8 information.

At the request of the Agency for Toxic Substances and Disease Registry (ATSDR), comments were provided on ATSDR's Priority Data Needs for a number of the 38 hazardous substances (41 CAS numbered chemicals) that were published in the October 17, 1991 **Federal Register** (56 FR 52178). The EPA and NTP provided comments during development of the Priority Data Needs. The ITC's comments are included in ATSDR's Docket number 42. These comments are summarized below. The National Cancer Institute described completed and ongoing studies on arsenic, cadmium, chromium, nickel and polychlorinated biphenyls. The Department of Interior described ongoing wildlife studies on cyanide, polychlorinated biphenyls and selenium. The ITC staff determined that the Committee had considered about 75% of ATSDR's 275 hazardous substances, had recommended about 70 of them for testing, had taken action on 33 of the 38 hazardous substances for which ATSDR determined Priority Data Needs, and had designated 3 of the 38 substances for testing. For the 33 substances on which the ITC had taken action, there may be existing studies that could satisfy ATSDR's Priority Data Needs. For the 3 ITC designated substances, 33 studies were identified that may satisfy ATSDR's Priority Data Needs and 3 studies were identified that may provide useful information related to ATSDR's Priority Data Needs.

In an effort to avoid duplication of effort, ATSDR is considering the Committee's comments and will formally respond to them along with other comments received on the 38 substances. The studies received by ATSDR from the Committee will be screened and reviewed before the Priority Data Needs are finalized.

1.3.e *Referrals.* During this reporting period, the Committee did not refer any

chemicals to member agencies or other organizations for testing consideration.

1.3.f *Deferrals.* During this reporting period, the Committee deferred the five chloroalkyl phosphates recommended in the 23rd Report because of an interest on the part of industry to voluntarily take action on these chemicals. The Chemical Manufacturers Association (CMA) and several chloroalkyl phosphate producers have approached the ITC and EPA to discuss voluntary testing for certain of the chloroalkyl phosphates. It is the interest of the ITC and ITC member agencies to ensure that the hazard of these chemicals is well characterized; additionally, the Committee believes that exposures to these chemicals should be better characterized. The Committee encourages CMA and the chloroalkyl phosphates' producers to offer a formal proposal to EPA, which may result in a testing consent order or other binding agreement through a public process, to develop hazard and exposure data. The Committee also believes that, considering the potential cancer risk of these chemicals, voluntary exposure controls on the part of industry may be appropriate. The Committee is deferring these five chloroalkyl phosphates pending the results of future discussions with industry.

1.3.g *Removals.* Two chemicals designated in the Committee's 27th Report were removed from the Priority Testing List, because EPA implemented the Committee's testing recommendations. On December 17, 1991 and March 4, 1992, EPA published Consent Orders for sodium cyanide (56 FR 65442) and acrylic acid (57 FR 7656), respectively. The most recent table of removals from the Priority Testing List was published in the Committee's 29th Report. As a result of the removals made during this reporting period, 100 chemicals and 18 chemical groups have been removed from the ITC's Priority Testing List.

1.4 *The TSCA section 4(e) Priority Testing List.* Under Section 4(e)(1)(B) of TSCA, Congress directed the Committee to revise the Priority Testing List at least every 6 months and transmit the revised List to the EPA Administrator. Under this authority, the Committee is revising the Priority Testing List by recommending two chemical groups (Table 1).

The Priority Testing List includes 24 chemicals and 23 chemical groups that have been recommended or designated for testing (Table 2). Individual chemicals in Priority Testing List chemical groups are listed in Table 1 of the 24th Report and in the paragraphs following Table 1 of the 26th, 27th, 28th and 29th Reports. For this 30th Report, the individual chemicals in Priority Testing List chemical groups are listed in tables that are included in chapters 2.4.a and 2.4.b. Lists of individual chemicals are provided to minimize any ambiguities associated with TSCA Section 8(a) and 8(d) reporting requirements.

Combining the 100 chemicals and 18 chemical groups that have been removed from the ITC's Priority Testing List with the 24 chemicals and 23 chemical groups currently on the Priority Testing List, reveals that the Committee has recommended or designated 124 chemicals and 41 chemical groups for testing since their first meeting in February 1977.

TABLE 2.—THE TSCA SECTION 4(E) PRIORITY TESTING LIST

Report	Date	Chemical/Group	Action
22	May 1988	Ethoxylated quaternary ammonium compounds	Recommended
22	May 1988	Imidazolium quaternary ammonium compounds	Recommended
23	November 1988	Tetrakis(2-chloroethyl)ethylene diphosphate	Recommended with intent-to-designate
23	November 1988	Tris(1,3-dichloro-2-propyl) phosphate	Recommended with intent-to-designate
23	November 1988	Tris(1-chloro-2-propyl) phosphate	Recommended with intent-to-designate
23	November 1988	Tris(2-chloro-1-propyl) phosphate	Recommended with intent-to-designate
23	November 1988	Tris(2-chloroethyl)-phosphate	Recommended with intent-to-designate
23	November 1988	Butyraldehyde	Recommended
23	November 1988	Brominated flame retardants	Recommended
26	May 1990	Isocyanates	Recommended with intent-to-designate
26	May 1990	Brominated flame retardants	Recommended
26	May 1990	Alkyl phosphates	Recommended
27	November 1990	Acetophenone	Designated
27	November 1990	Phenol	Designated
27	November 1990	*N,N*-Dimethylaniline	Designated
27	November 1990	Ethylacetate	Designated
27	November 1990	2,6-Dimethylphenol	Designated
27	November 1990	Aldehydes	Recommended with intent-to-designate
27	November 1990	2,4-Dinitrophenol	Recommended
27	November 1990	3,4-Dimethylphenol	Recommended
27	November 1990	*N*-phenyl-1-naphthylamine	Recommended
27	November 1990	Sulfones	Recommended
27	November 1990	Substantially produced chemicals in need of subchronic tests.	Recommended
28	May 1991	Acetone	Designated
28	May 1991	*n*-Butanol	Designated
28	May 1991	Isobutanol	Designated
28	May 1991	Di-(2-ethylhexyl)adipate	Designated
28	May 1991	Dimethyl terephthalate	Designated
28	May 1991	Thiophenol	Designated
28	May 1991	*m*-Dinitrobenzene	Recommended
28	May 1991	Allyl alcohol	Recommended
28	May 1991	2,4-Dichlorophenol	Recommended
28	May 1991	Alkynes	Recommended
28	May 1991	Nitroalcohols	Recommended
28	May 1991	Phosphoniums	Recommended
28	May 1991	Hydrazines	Recommended
28	May 1991	Oxiranes	Recommended
28	May 1991	Alkoxysilanes	Recommended
28	May 1991	Aldehyde hydrates	Recommended

TABLE 2.—THE TSCA SECTION 4(E) PRIORITY TESTING LIST—Continued

Report	Date	Chemical/Group	Action
28	May 1991	Propylene glycol ethers and esters	Recommended
28	May 1991	Methyl ethylene glycol ethers	Recommended
28	May 1991	Isothiocyanates	Recommended
28	May 1991	Cyanoacrylates	Recommended
29	November 1991	White phosphorus	Recommended
29	November 1991	Alkyl-, bromo-, chloro-, hydroxymethyl diaryl ethers	Recommended
30	May 1992	Siloxanes	Recommended
30	May 1992	Chloroalkyl phosphates	Recommended

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 Testing List two chemical groups (see Table 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 data needs of Member Agencies.

2.2 *Designated chemicals.* None.

2.3 *Recommended with intent-to-designate chemicals.* None.

2.4 *Recommended chemicals*—2.4.a Siloxanes.

I. Rationale for Recommendation

Recent questions related to the safety of siloxanes for a number of medical uses, including breast implants, prompted the Food and Drug Administration (FDA) to request that the Committee review the health effects of siloxanes. The Committee added a group of 56 siloxanes to the Priority Testing List (Table 3). The Committee recommended siloxanes for testing because of FDA's request, because production volumes are substantial, because of uncertainties related to human exposure, and because of the paucity of publicly-available health effects data for these substances. By recommending these chemicals, the Committee is providing manufacturers, processors, and distributors the opportunity to submit data under TSCA Section 8 and to voluntarily submit physical and chemical property data and use exposure information.

TABLE 3.—RECOMMENDED SILOXANES

CAS No.	Chemical Name
107-46-0	Hexamethyldisiloxane
107-50-6	Tetradecamethylcycloheptasiloxane
107-51-7	Octamethyltrisiloxane
107-52-8	Tetradecamethylhexasiloxane
107-53-9	Tetracosamethylundecasiloxane
141-62-8	Decamethyltetrasiloxane
141-63-9	Dodecamethylpentasiloxane
540-97-6	Dodecamethylcyclohexasiloxane
541-01-5	Hexadecamethylheptasiloxane
541-02-6	Decamethylcyclopentasiloxane
541-05-9	Hexamethylcyclotrisiloxane
546-56-5	Octaphenylcyclotetrasiloxane
556-67-2	Octamethylcyclotetrasiloxane
556-68-3	Hexadecamethylcyclooctasiloxane
556-69-4	Octadecamethyloctasiloxane
556-70-7	Docosamethyldecasiloxane
556-71-8	Octadecamethylcyclononasiloxane
999-97-3	Hexamethyldisilazane
2370-88-9	Tetramethylcyclotetrasiloxane
2374-14-3	Trifluoropropylmethylcyclotrisiloxane
2471-08-1	Hexacosamethyldodecasiloxane
2471-09-2	Octacosamethyltridecasiloxane
2471-10-5	Triacontamethyltetradecasiloxane
2471-11-6	Dotriacontmethylpentadecasiloxane
2554-06-5	Methylvinylcyclosiloxane
2627-95-4	Tetramethyldivinyldisiloxane
2652-13-3	Eicosamethylnonasiloxane
7013-67-8	Non-end blocked siloxanes
9004-73-3	Methylpolysiloxane
9006-65-9	Dimethicone
9016-00-6	Polydimethylsiloxane
18766-38-6	Docosamethylcycloundecasiloxane
18772-36-6	Eicosamethylcyclodecasiloxane
18844-04-7	Hexatriacontamethylheptadecasiloxane
18919-94-3	Tetracosamethylcyclododecasiloxane
23523-12-8	Hexatriacontamethylcyclooctadecasiloxane
23523-14-0	Triacontamethylcyclopentadecasiloxane
23732-94-7	Hexacosamethylcyclotridecasiloxane
36938-50-8	Tetratriacontamethylhexadecasiloxane
36938-52-0	Octatriacontamethyloctadecasiloxane
63148-62-9	Dimethyl silicones and siloxane
67762-90-7	Dimethyl silicones and siloxanes, reaction products with silica
67762-94-1	Dimethylmethylvinylsiloxane

TABLE 3.—RECOMMENDED SILOXANES—Continued

CAS No.	Chemical Name
68037-59-2	Dimethylhydropolysiloxane
68037-74-1	Dimethylpolysiloxanes
68083-14-7	Dimethyldiphenylsiloxane
69430-24-6	Cyclopolydimethylsiloxane
NA[1]	Tetracontamethylnonadecasiloxane
NA[1]	Octacosamethylcyclotetradecasiloxane
NA[1]	Dotetracontamethyleicosasiloxane
NA[1]	Tetracontamethylcycloeicosasiloxane
NA[1]	Octatriacontamethylcyclononadecasiloxane
NA[1]	Tetratriacontamethylcycloheptadecasiloxane
NA[1]	Dotriacontamethylcyclohexadecasiloxane
NA[1]	Polymethyloctadecylsiloxane
NA[1]	Dimethylmethyltrifluoropropylsiloxane

[1] NA = not assigned.

II. Summary of Recommended Tests

Siloxanes are recommended for autoimmune effects, cancer, reproductive effects and developmental toxicity testing and for epidemiological studies (Table 1).

III. Supporting Information

A. *Background.* On November 6, 1984, the Committee designated octamethylcyclotetrasiloxane (OMCTS) for chemical fate and ecological effects testing in the Committee's 15th report (49 FR 46931, November 29, 1984). On May 31, 1991, at the request of EPA, the Committee recommended alkoxysiloxanes for ecological effects testing in the Committee's 28th report (56 FR 41212, August 19, 1991). While health effects testing was not recommended previously, recent questions related to the safety of siloxanes for a number of medical uses, including breast implants, prompted FDA to request that the Committee review the health effects of siloxanes. The Committee is also concerned with widespread human exposure and environmental release of siloxanes. Most of the recommended chemicals were chemicals identified by FDA. At the request of FDA, a few structurally related methyl siloxanes were identified using the Committee's substructure-based chemical selection expert system (SuCSES). SuCSES was also used to identify structural homologs for other siloxanes identified by FDA, but FDA and the Committee did not request that they be recommended for testing at this time.

B. *Physical and chemical properties.* The Committee found limited information on measured physical and chemical properties for the siloxanes listed in Table 3: 29 log octanol/water partition coefficients (generated using High Pressure Liquid Chromatography), 1 measured log octanol/water partition coefficient, 15 melting points, 16 boiling points, 1 water solubility, 13 vapor pressures, and 1 Henry's Law constant (Refs. 19, 27, 31, 43, and 61).

C. *Exposure information—production/use/disposal/exposure/release.* The siloxanes in Table 3 are commercially available or have been identified in various medical uses.

Siloxanes have numerous medical, industrial, consumer, and military uses. They are used in the drug and pharmaceutical, construction, textile, transportation, electrical, electronic, paper and processing industries, tire, plastic, and rubber foundries, in chemical, petroleum, and gas processing as well as in medical devices, cosmetics and toiletries, food and related products, coatings, paint additives, inks, rubber and plastics, polishes, fibers, threads, and household, automotive, and institutional products (Refs. 29, 30, and 66). Siloxanes also are used in plastic and rubber lubricants, damping fluids, heat transfer fluids, oil defoamers, antifoams, viscous fluid drive clutches, speed control devices, liquid springs, dash pots, timing devices, thread and fiber lubricants, and textile softeners (Refs. 29 and 30). They are processed to meet electrical specifications for use in capacitors, pulse transformers, specialty transformers, air-borne and landbased radar equipment, and television circuit components (Refs. 29 and 30). Siloxanes are used in food applications; for example, dimethyl antifoaming agent in juices and beer (Ref. 38). Dimethylpolysiloxanes are useful as a low temperature damping medium, heat transfer medium, dielectric coolant, and a base fluid for low temperature silicone fluids (Refs. 29 and 30). Octamethylcyclotetrasiloxane is in several silicone fluids, which are used in a variety of applications including antiperspirants, facial make-up, hair sprays and skin care products, fermentation processes, instant coffee production, food washing solutions, diet soft drinks, paper coatings and sizing, waste yeast tanks, adhesives, textile sizes, vacuum distillations, deasphalting, brine units, boiler treatments, detergent manufacture, effluent treatments, industrial cleaning solutions, waste water treatment facilities, surfactants, and in window cleaners and panel polishes (Refs. 56 and 66). In 1982, octamethylcyclotetrasiloxane, decamethylcyclopentasiloxane, and dodecamethylcyclohexasiloxane were being evaluated for use in a variety of consumer and industrial products, including household and car care products, specialty wax preparations, other chemical specialty formulations, and coatings (Refs. 66). Decamethylcyclopentasiloxane is used in cosmetics and toiletries, as a vehicle and end blocking agent in antiperspirants and in aerosol products containing insoluble powders (Refs. 29 and 66). Hexamethyldisiloxane is used in cosmetic and personal care product formulations, in the production of octamethylcyclotetrasiloxane, as an adhesion promotor-priming agent for photolithography applications, and as an end blocking agent in the production of fluorosilicone oils (Refs. 7, 31, and 40).

Human exposure—medical. Exposure to siloxanes may occur because of uses as medical fluids, resins, gels and elastomers. Fluid siloxanes are used as lubricants in disposable syringes. Resins, gels and elastomers are used as implants for the augmentation and reconstruction of soft tissues such as breast and testicular tissues. Siloxanes are also used to fabricate tubal occlusion devices for female sterilization, encasement of pacemakers and electrical leads, heart valves, arteriovenus shunts, catheters, urethral stents, penile prothesis, prosthetic finger joints, artifical tendons, and intraocular lenses as well as to construct elastomers that are used as implanted drug delivery systems.

Occupational. The National Occupational Exposure Survey (NOES) conducted during 1981–1983 by NIOSH reported that 14,234 workers were potentially exposed to hexamethyldisiloxane, 367,371 workers were potentially exposed to dimethyl silicones and siloxanes, 935 workers were potentially exposed to octamethylcyclotetrasiloxane, 4,386 workers were potentially exposed to dimethyldiphenylsiloxane, and 6,903 workers were potentially exposed to reaction products of dimethyl silicones and siloxanes with silica (Refs. 50).

Monitoring. Atomic absorption analyses of organic extracts identified dimethylpolysiloxanes in various fruit juices (orange, apple, pineapple, apricot, tomato, lemon, grapefruit, mango, and apricot juice) (Ref. 38). Dimethylpolysiloxanes were quantitatively detected in 51 of 98 samples above the detection limit of 0.2 ppm; 14 of the 51 samples were above 10 ppm and 1 sample had a dimethylpolysiloxanes content of 152 ppm.

Dodecamethylcyclohexasiloxane was identified in drinking water concentrates from New Orleans, LA and Seattle, WA and decamethylcyclopentasiloxane was identified in drinking water concentrates from New Orleans, LA and Cincinnati, OH (Ref. 44).

Based on a method where airborne particles are collected on Teflon filters, extracted with an organic solvent, and then analyzed by pyrolysis gas chromatography/mass spectrometry (GC/MS), polydimethylsiloxanes were frequently detected in indoor airborne particles, especially in office buildings where many silicone-containing products were present, such as electrical contact cleaners, photocopiers, and electronic equipment (Ref. 76). Decamethylcyclopentasiloxane was measured in 29 air samples (0.3–12.4 $\mu g/m^3$) from office buildings located in 7 cities, dodecamethylcyclohexasiloxane was measured in 5 air samples (0.4–16.5 $\mu g/m^3$) from office buildings located in 2 cities, hexadecamethylcyclooctasiloxane was measured in 1 air sample (38 $\mu g/m^3$) from office buildings located in 8 cities, octamethylcyclotetrasiloxane was measured in 11 air samples (0.4–37 $\mu g/m^3$) from office buildings located in 4 cities, hexamethylcyclotrisiloxane was measured in 3 air samples from one office building, and tetradecamethylcycloheptasiloxane was measured in 3 air samples (7.4–10.8 $\mu g/m^3$) from one office building (Ref. 74). Octamethylcyclotetrasiloxane has also been detected in 2 of 5 indoor air samples collected in Northern Italy, 1983–84, at concentrations of 10 $\mu g/m^3$ and 13 $\mu g/m^3$ (Ref. 9). Emissions of hexamethylcyclotrisiloxane and octamethylcyclotetrasiloxane to indoor air have been detected from new carpets (Refs. 35 and 54).

In a study designed to monitor personal exposure to volatile organic compounds, hexamethylcyclotrisiloxane and octamethylcyclotetrasiloxane were detected in air, breath, and tap water samples (Ref. 75). The national survey of human adipose tissue conducted in 1982 analyzed 46 composite samples and found decamethylcyclopentasiloxane in 28 samples and octamethylcyclotetrasiloxane in 21 samples (Ref. 53).

Environmental exposure. Based on a method where airborne particles are collected on Teflon filters, extracted with solvent, and then analyzed by pyrolysis/GC/MS, polydimethylsiloxanes have been frequently detected in outdoor airborne particles. Polydimethylsiloxane concentrations were approximately 1 ng/m^3 in outdoor airborne particles at telephone office sites in Wichita, KS, Lubbock, TX, and Neenah, WI and 2 ng/m^3 in Newark, NJ. (Ref. 76). Decamethylcyclopentasiloxane has been detected at concentrations ranging from 0.21 to 0.9 $\mu g/m^3$ in 3 outdoor air samples, octamethylcyclotetrasiloxane has been detected at concentrations ranging from 6.6 to 22.6 $\mu g/m^3$ in 3 outdoor air samples taken from outside an office building in Newark, NJ, and hexamethylcyclotrisiloxane has been detected at concentrations ranging from 0.9 to 149 $\mu g/m^3$ in 139 outdoor air samples from 8 locations (Ref. 74).

Hexamethylcyclotrisiloxane was detected in 4 of 6 water samples collected from Lake Pontchartrain, LA, in 1980; concentrations ranged from 0.02 to 0.3 $\mu g/L$, and octamethylcyclotetrasiloxane was detected in 1 of 3 samples at 0.03 $\mu g/L$ (Ref. 48). Octamethylcyclotetrasiloxane and dodecamethylpentasiloxane were found in the influent to a sewage treatment facility in Singapore, while only octamethylcyclotetrasiloxane was found in the post-aerated wastewater and sludge (Ref. 42). Octamethylcyclotetrasiloxane and hexamethylcyclotrisiloxane have been detected as volatile emissions from refuse landfills (Ref. 41).

D. *Chemical fate information.* The Committee is not recommending chemical fate testing at this time because it wants to review data developed under TSCA Section 4 for octamethylcyclotetrasiloxane and any chemical fate data that may be submitted under TSCA Section 8(d).

E. *Health effects information.* Health effects data were located for 9 of the 52 recommended siloxanes: hexamethyldisiloxane, octamethyltrisiloxane, dodecamethylpentasiloxane, decamethylcyclopentasiloxane, hexamethylcyclotrisiloxane, octamethylcyclo tetrasiloxane, trifluoropropylmethylcyclotrisiloxane, dimethicone, and polydimethylsiloxane.

Human studies. Available data suggest that polydimethylsiloxane and octamethylcyclotetrasiloxane are not absorbed through intact human skin (Refs. 10, 23, and 34), and that polydimethylsiloxane was not absorbed by the gastrointestinal tract (Refs. 1, 4, and 62).

There have been human case reports of adverse effects from release of polydimethylsiloxane fluid into body tissues. These effects include granuloma formation, ulcer development and acute and latent pneumonitis illness (Refs. 5, 6, 47, and 55). In some cases, adverse effects did not develop for years. The granulomas appeared to be similar to typical foreign-body reaction masses (Refs. 64, 65, and 77), and cases have been reported where these granulomas developed at sites distant from the site of injection of the liquid silicone fluid (Ref. 25). Case reports have also suggested that silicone from breast implants and other prosthetic devices can produce symptoms of autoimmune disease (Refs. 3, 26, 59, and 73). These symptoms are diverse and are similar to scleroderma, systemic lupus erythematosus, and systemic rheumatic disease, and have been described in the literature as human adjuvant disease (Ref. 59). An epidemiologic study of workers exposed to silicones for at least 5 years and followed for 19 years reported a higher than expected incidence of cancers of the skin, large intestine and lung, but a decrease in mortality due to cancers of all types (Ref. 28).

Laboratory studies. Available data suggest that hexamethyldisiloxane and octamethylcyclotetrasiloxane are not absorbed through animal skin (Refs. 10, 15, and 16). Oral administration of octamethylcyclotetrasiloxane to monkeys and rats resulted in gastrointestinal absorption (Refs. 20 and 21). When injected, polydimethylsiloxane distributes throughout the body, but this process is slow if the injection is to an area not accessible to phagocytizing cells (Ref. 33).

Acute animal toxicity tests have been conducted for octamethylcyclotetrasiloxane, hexamethyldisiloxane, dodecamethylpentasiloxane, and four polymeric methyl siloxanes. The oral LD_{50} for these compounds ranged from 40 g/kg to >60 g/kg (Refs. 11, 12, 15, 46, 57, 58, 63, 67, 68, 69, 71, and 72). The dermal LD_{50} was >16 mL/kg and 4.6 g/kg for hexamethyldisiloxane and octamethylcyclotetrasiloxane, respectively (Refs. 63, 67, 68, 69, and 71). Following inhalation exposure to near saturated atmospheres, death occurred in 1–15 minutes (≈4,000 ppm) and 8 hours (≈1,300 ppm), for hexamethyldisiloxane and octamethylcyclotetrasiloxane, respectively (Refs. 57, 63, 69, and 71). For hexamethyldisiloxane and polydimethylsiloxane, only irritation at the injection site was observed following subcutaneous administration (Refs. 8 and 57). No effects were observed following intraperitoneal injection of 10 mL/kg of dodecamethylpentasiloxane or polydimethylsiloxane, but some deaths occurred at > 0.3 mL/kg of hexamethyldisiloxane (Refs. 32 and 57). All of these compounds either produced no irritation or slight irritation to the skin and eyes (Refs. 57, 63, 67, 15, 17, and 18).

Repeat exposure studies in rats and rabbits of hexamethyldisiloxane produced no effects following dermal (20 exposures, dose not reported) or inhalation (20 exposures to 4,400 ppm) exposure. Dermal exposure for 21 days to 40 mg/kg/day of trifluoropropylmethylcyclotrisiloxane produced no effects, but similar exposure to 200 mg/kg/day reduced weight gain, food consumption, serum alkaline phosphatase activity and increased activity of serum enzymes; 5/12 animals died from exposure to 400 mg/kg/day (Refs. 11, 12, 13, 14, 60, 67, 68, 69, and 70). Polydimethylsiloxane produced no effects following oraladministration (20 gavage doses of 20.0 g/kg) (Ref. 57). Octamethylcyclotetrasiloxane reduced body weight and increased liver weight following both oral (2 g/kg/day by gavage for 28 days) and inhalation (700 ppm for 6 hours/day for 90 days) exposures (Refs. 22 and 24). In a chronic study of polydimethylsiloxane in mice, increased mortality was observed in females but not in males exposed for 76 weeks to dietary doses of 1,250 mg/kg/day, while subcutaneous implant of polydimethylsiloxane for 2 years resulted in mesenchymal tumors, some of which were malignant (Refs. 8 and 45).

In a developmental toxicity study, an increase in postimplantation loss was observed in rats following subcutaneous administration of 200 mg/kg of polydimethylsiloxane on gestation days 6–16, but this effect was not observed in a second trial (Refs. 2 and 39). Additionally, no soft tissue or skeletal malformations were observed following oral (1,000 mg/kg/day, gestation days 6–15) or dermal (200 mg/kg, gestation days 6–15) administration to rats, or subcutaneous administration to rabbits (1,000 mg/kg, gestation days 6–18) (Ref. 39).

Gene mutation assays in bacteria and mitotic recombination tests in yeasts were negative for decamethylcyclopentasiloxane, hexamethylcyclotrisiloxane, octamethylcyclotetrasiloxane, hexamethyldisiloxane and octamethyltrisiloxane. A weakly positive result was reported for octamethyltrisiloxane in the mouse lymphoma L5178Y forward mutation assay; negative results were reported for the other siloxanes, both with and without S9 activation (Refs. 36 and 49).

Sister chromatid exchange assays in mouse lymphoma cells were negative for decamethylcyclopentasiloxane, hexamethylcyclotrisiloxane, octamethylcyclotetrasiloxane, and hexamethyldisiloxane. Chromosomal aberration assays in mouse lymphoma cells yielded negative results in the presence and absence of S9 activation for decamethylcyclopentasiloxane, but mixed positive results were reported for others, as follows: hexamethylcyclotrisiloxane and octamethylcyclotetrasiloxane-positive with S9, negative without S9; and hexamethyldisiloxane-negative with S9, positive without S9 (Ref. 36).

In *in vivo* tests, hexamethylcyclotrisiloxane and hexamethyldisiloxane produced no evidence of chromosomal aberrations in the rat bone marrow cytotogenicity assay (Ref. 36). Polydimethylsiloxane fluid did not produce evidence of chromosomal effects in the mouse dominant lethal assay (Ref. 39).

Dermal sensitization was not observed in mice following a challenge with polydimethylsiloxane (Ref. 51). Preliminary findings with subcutaneously-placed, siloxane-containing implants indicated a dose-related decrease in activity of natural killer cells after 180 days; a time course study is currently underway (Ref. 52).

F. *Ecological effects information.* The Committee is not recommending ecological effects testing at this time because it wants to review data developed under TSCA Section 4 for octamethylcyclotetrasiloxane and any ecological effects data that may be submitted under TSCA Section 8(d).

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2.4.b. *Chloroalkyl phosphates.*

I. Rationale for Recommendation

Four chloroalkyl phosphates are recommended for physical and chemical property, chemical fate, health effects and ecological effects screening tests (Table 4). The Committee recommends testing these four chloroalkyl phosphates because they are structurally similar to the five chloroalkyl phosphates recommended in the 23rd Report (53 FR 46262, November 16, 1988) and because there are insufficient data to reasonably determine or predict physical and chemical properties, persistence and health or ecolgical effects.

TABLE 4.—RECOMMENDED CHLOROALKYL PHOSPHATES

CAS No.	Chemical Name	Acronym
34621–99–3	1,2-Ethanediyl tetrakis(2-chloro-1-methylethylene) phosphate	TCIEP
38051–10–4	2,2-Bis(chloromethyl)-1,3-propanediyl tetrakis(2- chloroethyl) phosphate	TCEBP
53461–82–8	Oxydi-2,1-ethanediyl tetrakis(2-chloroethyl) phosphate	TCEDP
76649–15–5	2-Chloro-1-methylethyl bis(2-chloropropyl) phosphate	DCPCEP

II. Summary of Recommended Tests

Four chloroalkyl phosphates (TCIEP, TCEBP, TCEDP and DCPCEP) are recommended for determination of melting point, water solubility, octanol-water partition coefficient, and vapor pressure data, hydrolysis and aerobic biodegradation rate. Also recommended are screening tests to develop acute health effects data (except for TCIEP) and fish, algae and aquatic and benthic invertebrates acute toxicity data (fish and aquatic invertebrate acute toxicity data are available for TCIEP).

III. Supporting Information

A. *Background.* In 1986, two chloroalkyl phosphates, tris(2-chloroethyl) phosphate (TCEP) and tetrakis(2-chloroethyl) ethylenediphosphate (TCEEP) were identified for priority testing consideration during the Committee's Sixth Scoring Exercise (52 FR 10409, April 1, 1987). On May 12, 1988, the Committee decided to expand this group to include other commercially-available chloroalkyl phosphates: tris(2-chloro-1-propyl) phosphate (TCPP), tris(2-chloroisopropyl) phosphate (TCIP), and tris(1,3-dichloroisopropyl) phosphate (TDCP). In its 23rd Report (53 FR 46262, November 16, 1988), the Committee recommended testing for TCEP, TCPP, TCIP, TDCP and TCEEP.

The Committee's computerized substructure-based chemical selection expert system (SuCSES) was developed in 1986 (Ref. 10). In 1988, some components of SuCSES had not been integrated into the system and did not permit the Committee to identify all commercially-available chloroalkyl phosphates. In 1992, with these integrated components, SuCSES was used to identify four additional chloroalkyl phosphates: TCIEP, TCEBP, TCEDP and DCPCEP.

B. *Physical and chemical properties.* No information was found on physical and chemical properties measured at ambient temperature.

C. *Exposure/information—production/use/disposal/exposure/release.* The chloroalkyl phosphates listed in Table 4 are commercially available and may be produced in substantial quantities. Actual production volumes are confidential business information. Chloroalkyl

phosphates are used as flame retardants in flexible and rigid polyurethane foams. These chloroalkyl phosphate-treated foams are used in furniture and bedding that are sold for household, business, and transportation uses.

There are no publicly-available exposure estimates, OSHA occupational exposure standards, publicly-available effluent monitoring data and Toxics Release Inventory data. Uncertainties related to exposure and release of chloroalkyl phosphates may be clarified after the Committee's review of the data obtained under TSCA Section 8(a) and 8(d) along with any other information submitted as a result of the generic request for voluntary use, exposure, release, and physical and chemical property data made in Chapter 1 of the 28th report (56 FR 41212, August 19, 1991).

D. *Chemical fate information.* No chemical fate information was found.

E. *Health effects information.* Except for data described below for TCIEP and TCEBP, no health effects information was found.

Five acute toxicity studies on TCIEP were reviewed. The oral LD50 for male rats was 1.58 g/kg (Ref. 3). No rabbits died when 2 g/kg TCIEP was applied to abraded and non-abraded skin for 24 hours (Ref. 4). Inhalation of 200 mg/liter for 1-hour resulted in death of 3 of 10 rats (Ref. 5). TCIEP was not a skin irritant; however, when 0.1 ml was instilled into the conjunctiva of rabbits eyes, it was irritating (Refs. 6 and 7). In comparison to the studies reviewed on the five chloroalkyl phosphates recommended in the ITC's 23rd Report: by the oral route, TCIEP was less toxic than TCIP and TDCP, and about the same as TCEP and TCEEP; by the inhalation route, TCIEP was more toxic than TCEP, TCPP, TCIP, and TCEEP.

In a 90-day rat dermal toxicity study, TCIEP increased liver weight at 500 mg/kg/day and hypertrophy of the liver and thyroid at 2500 mg/kg/day (Ref. 8). In a pilot developmental toxicity test, 800 mg/kg/day TCEBP increased postimplantation loss at maternally toxic doses (Ref. 9). In comparison to the TSCA 8(d) developmental toxicity studies on chloroalkyl phosphates recommended in the ITC's 23rd Report, TCEBP was less toxic than TCEP, TDCP or TCEEP.

The Committee is aware that Ames, micronucleus, skin sensitization and 90-day developmental toxicity tests were completed for TCIEP and has requested copies of these test reports from the test sponsor.

F. *Ecological effects information.* Except for TCIEP data, no ecological effects information was found.

For TCIEP, the 2-day LC50 for daphnids ranged from 4.1–5.3 mg/L and the 4-day LC_{50} for fathead minnows ranged from 3.0–3.3 mg/L (Refs. 1 and 2). In comparison to the studies reviewed on the chloroalkyl phosphates recommended in the ITC's 23rd Report, LC_{50} values for TCIEP were close to the fish LC50 of TDCP (1.4 mg/L), but less than the fish LC_{50} of TCPP (51 mg/L) or the fish LC_{50} of TCEP (250 mg/L).

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