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Part VII

Environmental Protection Agency

Thirty-First Report of the TSCA
Interagency Testing Committee to the
Administrator; Receipt of Report, Request
for Comments, Opportunity to Initiate
Negotiations for TSCA Section 4 Testing
Consent Agreements; Notice

**ENVIRONMENTAL PROTECTION
AGENCY**

[OPPTS-41038; FRL-4583-4]

**Thirty-First Report of the TSCA
Interagency Testing Committee to the
Administrator; Receipt of Report,
Request for Comments, Opportunity to
Initiate Negotiations for TSCA Section
4 Testing Consent Agreements**
AGENCY: Environmental Protection
Agency (EPA).

ACTION: Notice.

SUMMARY: The TSCA Interagency Testing Committee (ITC), established under section 4(e) of the Toxic Substances Control Act (TSCA), transmitted its Thirty-First Report to the Administrator of EPA on January 28, 1993. This report is included with this notice. As noted in this Report, the ITC revised the *Priority Testing List* by adding one group of 24 chemicals to the list for priority consideration by the EPA Administrator for promulgation of test rules under section 4(a) of the Act. These chemicals are designated for response within 12 months. Therefore, in response to the ITC's designation, EPA will either initiate rulemaking under section 4(a) of TSCA, enter into a testing consent agreement, or publish a *Federal Register* notice explaining the reasons for not initiating such rulemaking within 12 months. The ITC is also revising the recommendations for two chemical groups that were recommended in the ITC's Twenty-Eighth Report. The propylene glycol ethers and esters group is revised by the addition of 2 chemicals and the removal of 29. The methyl ethylene glycol ethers and esters group is modified by the removal of eight chemicals. The ITC's reasons for revising these chemical groups are stated in the Thirty-First Report. There are no recommended with intent-to-designate chemicals or chemical groups in the Thirty-First Report. EPA invites interested persons to submit written comments on the Report.

In addition, EPA is soliciting interested parties for participation in or monitoring of a consent agreement process for the chemicals that were designated for dermal absorption testing. EPA is also inviting manufacturers and/or processors of chemical substances who wish to participate in testing negotiations for the chemicals designated for dermal absorption testing to develop and submit testing consent agreement proposals to EPA.

DATES: Written comments on the Thirty-First ITC Report must be received by

June 4, 1993. Written testing proposals must be received by July 6, 1993. Written notice of interest in being designated an "interested party" to the development or monitoring of a consent agreement for the chemicals designated for dermal absorption testing must be received by July 6, 1993. Those submitting written testing proposals will be considered "interested parties" and do not have to submit separate written notice. EPA will contact all "interested parties" and advise them of meeting dates.

ADDRESSES: Send six copies of written submissions to: TSCA Docket Receipts (TS-790), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. ET G-102, 401 M St., SW., Washington, DC 20460. Submissions should bear the document control number (OPPTS-41038; FRL-4583-4). The public record supporting this action, including comments, is available for public inspection in Rm. ET G-102 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 Street, SW., Rm. E-543B, Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: **Electronic Availability:** This document, along with a complete list of Chemical Abstract Service numbers, and chemical names of chemicals and chemicals in groups on the TSCA section 4(e) *Priority Testing List*, is available as an electronic file on *The Federal Bulletin Board* at 9 a.m. on the date of publication in the *Federal Register*. By modem dial 202-512-1387 or call 202-512-1530 for disks or paper copies. This file is also available in Postscript, Wordperfect and ASCII. The list of chemical abstract Service numbers, and chemical names of chemicals and chemicals in groups on the TSCA section 4(e) *Priority Testing List*, is available in Wordperfect and ASCII.

I. Background

TSCA (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 ("chemicals") in order to develop data relevant to determining whether such chemicals may present unreasonable risks to health or the environment. Section 4(e) of TSCA established the Interagency Testing Committee (ITC) 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 most recent revisions to this List are included in the ITC's Thirty-First Report. The Report was received by the Administrator on January 28, 1993, and is included with this notice. The Report adds 1 group of 24 chemicals to the TSCA section 4(e) *Priority Testing List* and revises the recommendations for 2 chemical groups that were recommended in the ITC's Twenty-Eighth Report.

**II. Written and Oral Comments on
Recommendations**

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 Thirty-First 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, use, exposure, and release information on the listed chemicals.

III. Status of List

The ITC's Thirty-First Report notes the addition of one chemical group to the *Priority Testing List* and the revision of the recommendations for two chemical groups in the Twenty-Eighth Report. The current TSCA section 4(e) *Priority Testing List* contains 24 chemicals and 24 chemical groups; 1 chemical group and 11 chemicals are designated for priority testing consideration.

IV. Testing Consent Agreements

1. Solicitation of Interested Parties. EPA's procedures for requiring the testing of chemical substances under section 4 of TSCA at 40 CFR 790.22, includes the adoption of enforceable consent agreements and the promulgation of test rules. EPA has on numerous occasions been approached by chemical companies interested in negotiating consent agreements for

testing ITC chemicals or chemical groups. As a result of these requests, EPA is now inviting persons interested in participating in or monitoring negotiations on the chemicals designated in the Thirty-First ITC Report to notify EPA in writing. Those who respond to this solicitation by the deadline established in this notice will have the status of "interested parties" and will be afforded opportunities to participate in the negotiation process. These "interested parties" will not incur any obligations by being designated "interested parties."

2. *Solicitation of testing proposals for consent agreement negotiations.* EPA is also now soliciting testing proposals for a consent agreement to perform dermal absorption testing on the 24 chemical substances designated in the Thirty-First Report. Following publication of this notice, manufacturers and/or processors have 60 days to develop and submit testing proposals for any of the chemical substances designated in the Thirty-First Report that they wish EPA to consider as candidates for consent agreement negotiations.

Federal scientists from a number of the ITC's statutory and liaison organizations including the Consumer Product Safety Commission, Environmental Protection Agency, Food and Drug Administration, National Institute for Occupational Safety and Health, and Occupational Safety and Health Administration, have developed a proposed federally-harmonized test protocol that will provide data needed by several U. S. Government Organizations represented on the ITC. This proposed protocol is entitled "Protocol for *in vitro* Percutaneous Absorption Studies" and is available to the public through the TSCA Docket Receipts and the Environmental Assistance Division listed above. This

document should be reviewed before submitting any testing proposals in response to this notice.

For additional technical information on this testing protocol contact Dr. John D. Walker, Executive Director, TSCA Interagency Testing Committee, (202) 260-1820.

All testing proposals submitted should describe the testing to be performed and explain any deviations from the federally harmonized test protocol that are necessary to assure the development of reliable percutaneous absorption data.

EPA will review the submissions and select the most promising submissions as candidates for negotiation. Submissions that fully address the ITC's concerns will have a higher chance of success than those that do not fully address all data needs.

3. *Negotiation of testing program and development of a testing consent agreement.* EPA will follow the negotiation procedures under 40 CFR 790.22, and to the extent feasible, the timetable outlined in 40 CFR part 790, Appendix A to subpart B.

In the case of the 24 substances designated for priority testing consideration in the Thirty-First ITC Report, EPA believes that obtaining testing through the development of consent agreements would be most feasible if interested manufacturers organized a testing consortium. Because of the straightforward and relatively inexpensive nature of the recommended tests for each of the substances (i.e., dermal absorption tests), and the costs to EPA and industry that would be incurred should many consent agreements be pursued, EPA believes that negotiating with an organized group of manufacturers may be the most efficient means to obtain the needed testing.

For additional information about process or negotiations contact Frank Kover, Chief, Chemical Testing and Information Branch, (202) 260-8130.

Authority: 15 U.S.C. 2603.

Dated: April 23, 1993.

Charles M. Auer,
Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Thirty-First Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency

Summary. The Interagency Testing Committee (ITC) was created under Section 4(e) of the Toxic Substances Control Act (TSCA) as an independent advisory committee to the Administrator of the U.S. Environmental Protection Agency (EPA) on setting priorities for the testing of chemicals. The Committee maintains the TSCA section 4(e) *Priority Testing List* and transmits revisions of the List as a Report to the EPA Administrator at least every 6 months for action and publication in the *Federal Register*. This Report presents the ITC's revisions to the *Priority Testing List* resulting from its deliberations during the reporting period May through November 1992.

This revision designates a group of 24 chemicals of regulatory interest to the Occupational Safety and Health Administration (OSHA) for dermal absorption testing. Also, two groups of chemicals previously recommended are revised. The propylene glycol ethers and esters group is revised by adding 2 chemicals and removing 29. The methyl ethylene glycol ethers and esters group is modified by removing eight chemicals.

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

Group	Action	Date	Concern
OSHA Chemicals with no dermal absorption data (listed in Table 2)	Designated	1/93	Dermal absorption testing
Propylene glycol ethers and esters (revised)	Recommended	1/93	Information solicited
Methyl ethylene glycol ethers and esters (revised)	Recommended	1/93	Information solicited

Chapter 1—Introduction

1.1 *Background.* Since its creation in 1976 under Section 4(e) of the Toxic Substances Control Act (Public Law 94-469, 90 Stat. 2003 et seq., 15 U.S.C. 2601 et seq.), the TSCA Interagency Testing Committee (ITC) has sent 30 semi-annual Reports to the Administrator of the U.S. Environmental Protection

Agency (EPA) to advise on setting priorities for the testing of chemicals. These Reports have been published in the *Federal Register* and are also available from the Committee. In this, its Thirty-First Report, the Committee revises its *Priority Testing List* with the addition of one group and the revision of two groups already on the List. A

short version of the *Priority Testing List* appears at the end of this Report. The complete *Priority Testing List* with all individual chemicals in each group is available upon request from the Committee (address and phone number given below) or, electronically available on *The Federal Bulletin Board* (see preamble for the phone number).

The Committee meets monthly and produces its Reports with the help of staff and technical contract support provided by EPA. Committee membership and support personnel are listed at the end of this Report.

Upon receipt of the ITC's Reports, the EPA's Office of Pollution Prevention and Toxics issues information gathering rules under Sections 8(a) and 8(d) of TSCA. These rules require that manufacturers and producers submit (1) production and exposure data and (2) health and safety studies, respectively, within 2 months of the rule's effective date. These submissions are indexed and stored in data bases by EPA and are then available for review by the ITC and others.

1.2 ITC's activities during this reporting period. For the period May 28, 1992 to November 5, 1992, the ITC had six meetings. Chemical groups previously recommended after nomination by the National Institute of Occupational Safety and Health (NIOSH) were reviewed. The individual chemicals comprising these groups are here modified. The ITC also accepted the request of the Occupational Safety and Health Administration (OSHA) to determine testing needs for industrial chemicals which may cause harm to exposed workers by absorption through the skin.

1.3 Revision of Previously Recommended Groups. In the ITC's Twenty-Eighth Report, groups of propylene glycol ethers and esters and methyl ethylene glycol ethers and esters were added to the TSCA section 4(e) *Priority Testing List* for reproductive effects and developmental toxicity testing based on concerns raised by NIOSH (56 FR 41212, August 19, 1991). NIOSH is concerned with glycol ethers and their esters that are metabolized in humans to known reproductive toxicants. The original groups of glycol ethers and esters were selected from industrial chemicals to which workers are exposed, and the groups were expanded by adding structurally similar compounds through a substructure search of the ITC's Substructure-based Computerized Chemical Selection Expert System (SuCCSES).

During this reporting period, NIOSH commented that not all of these chemicals are of concern because of their possible metabolism to reproductive toxicants. The ITC reconsidered the individual members of the groups. Upon review of available metabolism data and consideration of possible structure/activity relationships, the ITC decided to remove some chemicals from both groups. A chemical was removed if: (1) it is expected to be

metabolized to tricarboxylic acid cycle intermediates and therefore of lower concern; (2) it is not expected to be metabolized to reproductive toxicants; (3) there are fewer than 1,000 workers exposed, according to the National Occupational Exposure Survey; or (4) other human exposure (mostly through consumer uses) is not considered likely. The Consumer Product Safety Commission (CPSC) expressed an interest in retaining some of the propylene and methyl ethylene glycol ethers and esters on the *Priority Testing List* and adding two chemicals in order to obtain information submitted under TSCA Sections 8(a) and 8(d). The ITC has a concern that some of these chemicals are likely to be used in consumer products as replacements for ethylene glycol ethers and has no metabolism data available. As a result, the ITC retains some members of both groups on the *List* and adds two chemicals.

Chapter 2—Actions taken by the ITC in this Report

2.1 Designated chemicals. OSHA-nominated chemicals for which no dermal toxicity data are available.

I. Rationale for the Designation

OSHA has established Permissible Exposure Limits (PELs) to protect workers from industrial chemicals. In general, PELs are based on inhalation of airborne dusts and vapors. In those cases where skin absorption could be harmful, the chemicals with PELs are assigned "skin designations." OSHA requested that the ITC help identify chemicals which lack sufficient data for OSHA to determine the need for skin designations and to use their authority to recommend chemicals for priority testing consideration by EPA to obtain these data. To assign a skin designation, OSHA requires acute dermal studies and sufficient dermal absorption data to determine the total exposure of workers. The ITC identified 24 chemicals for which no dermal toxicity or absorption data could be located and which are potentially testable under TSCA. These chemicals are listed in the following Table 2:

TABLE 2.—OSHA CHEMICALS DESIGNATED FOR DERMAL ABSORPTION TESTING

CAS No.	Chemical Name
60-29-7	Ethyl ether
75-85-0	<i>tert</i> -Butyl alcohol
76-22-2	Camphor
78-92-2	<i>sec</i> -Butyl alcohol

TABLE 2.—OSHA CHEMICALS DESIGNATED FOR DERMAL ABSORPTION TESTING—Continued

CAS No.	Chemical Name
78-20-9	Methyl acetate
97-77-8	Dsulfiram
100-25-4	<i>p</i> -Dinitrobenzene
105-46-4	<i>sec</i> -Butyl acetate
106-42-3	<i>p</i> -Xylene
107-31-3	Methyl formate
107-66-4	Dibutyl phosphate
108-03-2	1-Nitropropane
108-87-2	Methylcyclohexane
109-66-0	Pentane
110-83-8	Cyclohexane
111-84-2	Nonane
123-92-2	Isoamyl acetate
142-82-5	<i>n</i> -Heptane
287-92-3	Cyclopentane
532-27-4	<i>a</i> -Chloroacetophenone
540-88-5	<i>tert</i> -Butyl acetate
628-63-7	<i>n</i> -Amyl acetate
7631-90-5	Sodium bisulfite
7681-67-4	Sodium metabisulfite

II. Recommended Tests

The group of chemicals listed in Table 2 above are designated for dermal absorption testing.

III. Supporting Information

In its January 19, 1989 Air Contaminants Rule (54 FR 2332), OSHA stated that:

The purpose of having the skin designation is to prevent the same toxic effects that the chemical causes through inhalation. The inhalation limit is based on keeping exposure below the limit which will create a significant risk of material impairment of health. If skin absorption is possible, an employee might be below the inhalation limit; however, the additional body burden through skin absorption may create the material impairment which the limit attempts to reduce.

In September 1991, OSHA presented a list of 658 chemical substances and mixtures (its Z-1-A Table in 54 FR 2332-2983) to the ITC to assess the availability of dermal absorption data and the need for testing that could be recommended under TSCA. The ITC reviewed the list and determined that 145 polymers, pesticides, complex mixtures, and chlorofluorocarbons (CFCs) are not suitable candidates for consideration because they are not suitable for testing, they are regulated under other Federal authorities, or they are not regulable under TSCA. The

remaining chemicals were divided into two groups based on production volume: greater or less than 1 million pounds, based on the 1989 production figures from the EPA Inventory. Chemicals that are vapors at ambient temperature, are highly reactive, have

low toxicity, are members of chemical groups, or have dermal LD50 values reported in the Registry of Toxic Effects of Chemical Substances were identified in each of the production groups and are deferred for future ITC review. A group of 16 high and 8 low production

chemicals were identified as having no dermal toxicity data and are here designated for dermal absorption testing. The following Figure 1 diagrams the selection process.

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