

ENVIRONMENTAL PROTECTION AGENCY

[OPPTS-41045; FRL-5379-2]

Thirty-Eighth Report of the TSCA Interagency Testing Committee to the Administrator Receipt of Report, Request for Comments, Solicitation of Use and Exposure Data

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-Eighth Report to the Administrator of the EPA on May 31, 1996. In its Thirty-Eighth Report, which is included with this notice, the ITC revises the *Priority Testing List* by adding a group of 18 nonylphenol ethoxylates to the *List* for consideration by the EPA Administrator for promulgation of test rules under section 4(a) of the Act. The ITC also removes two previously recommended High Production Volume Chemicals (HPVC), two previously designated Oxygenated Fuel Additives and previously recommended white phosphorus. The ITC's reasons for removing these chemicals from the *List* are described in the Thirty-Eighth Report. There are no designated or recommended with intent-to-designate chemicals or chemical groups in the Thirty-Eighth Report. EPA invites interested persons to submit written comments on the Report.

DATES: Written comments on the Thirty-Eighth ITC Report should be submitted by August 29, 1996.

ADDRESSES: Comments on the Thirty-Eighth Report should be submitted to both the ITC and the TSCA Public Docket. Send one copy of written submissions to: John D. Walker, ITC Executive Director, U.S. EPA (7401), 401 M St., SW., Washington, DC 20460. Send six copies of written submissions to: TSCA Public Docket Office (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. B-607 NEM, 401 M St., SW., Washington, DC 20460.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: ncic@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All

comments and data in electronic form must be identified by the docket number OPPTS-41045. No "Confidential Business Information" (CBI) should be submitted through e-mail. Electronic comments on the Thirty-Eighth Report may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit III of this document.

The public record supporting this action, including comments, is available for public inspection in Rm. B-607 NEM at the address noted above from 12:00 noon to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT:

Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M Street, SW., Rm. ET-543B, Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551, e-mail: TSCA-Hotline@epamail.epa.gov.
SUPPLEMENTARY INFORMATION: EPA has received the TSCA Interagency Testing Committee's Thirty-Eighth 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 the 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 (ITC) to recommend chemicals and chemical groups to the Administrator of the 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-Eighth Report. The Report was received by the Administrator on May 31, 1996, and is included in this Notice. The Report recommends a group of 18 nonylphenol ethoxylates to the list and removes white phosphorus, 2 High Production Volume Chemicals (HPVC) and 2 Oxygenated Fuel Additives from the list.

II. Status of List

The current TSCA section 4(e) *Priority Testing List* contains 2 chemicals and 10 chemical groups; of these 2 chemicals and 3 chemical groups were designated for testing.

A notice will be published at a later date in the Federal Register adding

certain of the substances recommended in the ITC's Thirty-Eighth 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 certain of 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. Electronic and Oral Comments

The EPA invites interested persons to submit detailed comments on the ITC's Report.

A record has been established for this notice under docket number [OPPTS-41045] (including comments and data submitted electronically as described below). A public version of this record, including printed paper versions of electronic comments, which does not contain any information claimed as CBI, is available for inspection from 12 noon to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in the TSCA Non-confidential Information Center, Rm. NE-B607, 401 M St., SW., Washington, DC, 20460. Electronic comments can be sent directly to the ITC at walker.john@epamail.epa.gov and to the EPA at: ncic@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for the Thirty-Eighth report, as well as the public version as described above, will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the EPA address in "ADDRESSES" at the beginning of this document.

Authority: 15 U.S.C. 2603.

Dated: July 18, 1996.

Charles M. Auer,

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

Thirty-Eighth Report of the Interagency Testing Committee to the Administrator
Summary

This is the 38th Report of the TSCA Interagency Testing Committee (ITC) to the Administrator of the U.S.

Environmental Protection Agency (EPA). In this Report, the ITC is revising its TSCA section 4(e) *Priority Testing List* by recommending 18 nonylphenol ethoxylates and removing white

phosphorus, 2 High Production Volume Chemicals (diethylene glycol monoethyl ether acetate and diethylene glycol dimethyl ether), and 2 Oxygenated Fuel Additives (ethyl tert-butyl ether and

tert-amyl methyl ether). Comments on this Report should be submitted both to the ITC and the TSCA Public Docket. The revised TSCA section 4(e) *Priority Testing List* follows as Table 1.

TABLE 1.—THE TSCA SECTION 4(e) *Priority Testing List* (May 1996)

Report	Date	Chemical/Group	Action
26	May 1990	10 Isocyanates	Recommended with intent-to-designate
27	November 1990	62 Aldehydes	Recommended with intent-to-designate
28	May 1991	Acetone	Designated
28	May 1991	Thiophenol	Designated
29	November 1991	10 Alkyl-, bromo-, chloro-, hydroxymethyl diaryl ethers	Recommended
30	May 1992	13 Siloxanes	Recommended
31	January 1993	24 Chemicals with no dermal toxicity data	Designated
32	May 1993	32 Chemicals with insufficient dermal absorption data	Designated
35	November 1994	24 Chemicals with insufficient dermal absorption data	Designated
36	May 1995	10 High Production Volume Chemicals	Recommended
37	November 1995	28 Alkylphenols and Ethoxylates	Recommended
38	May 1996	18 Nonylphenol Ethoxylates	Recommended

I. Background

The TSCA Interagency Testing Committee (ITC) was established by section 4(e) of the Toxic Substances Control Act (TSCA) "to make recommendations to the Administrator respecting the chemical substances and mixtures to which the Administrator should give priority consideration for the promulgation of a rule for testing under section 4(a).... At least every 6 months..., the Committee shall make such revisions in the List as it determines to be necessary and to transmit them to the Administrator together with the Committee's reasons for the revisions" (Pub. L. 94-469, 90 Stat. 2003 et seq., 15 U.S.C. 2601 et seq.). Since its creation in 1976, the ITC has submitted 37 semi-annual Reports to the EPA Administrator transmitting the *Priority Testing List* and its

revisions. These Reports have been published in the Federal Register and are also available from the ITC. The ITC meets monthly and produces its revisions of the List with the help of staff and technical contract support provided by EPA. ITC members and support personnel are listed at the end of this Report.

Following receipt of the ITC's Report and the addition of chemicals to the *Priority Testing List*, EPA's Office of Pollution Prevention and Toxics adds new chemicals from the List to TSCA section 8(a) and 8(d) rules that require manufacturers and importers of these chemicals to submit TSCA section 8(a) production and exposure data and manufacturers, importers and processors of the listed chemicals to submit TSCA section 8(d) health and safety studies within 60 days of the rule's effective date. The submissions

are indexed and maintained by EPA. The ITC reviews the TSCA section 8(a) and 8(d) information and other available data on chemicals and chemical groups (e.g., TSCA section 8(e) "substantial risk" studies, "For Your Information" (FYI) submissions to EPA, and published papers) to determine if revisions to the List are necessary. Revisions can include changing a general recommendation to a specific designation for testing action by the EPA Administrator within 12 months, modifying the recommended testing, or removing the chemical or chemical group from the List.

II. Revisions to the TSCA Section 4(e) *Priority Testing List*

Revisions to the TSCA section 4(e) *Priority Testing List* are summarized in Table 2.

TABLE 2.—REVISIONS TO THE TSCA SECTION 4(E) *Priority Testing List*

CAS No.	Chemical Name	Action	Date
.....	Nonylphenol ethoxylates (NPEs)	Recommended	5/96
07311-27-5	Ethanol, 2-[2-[2-(p-nonylphenoxy) ethoxy]ethoxy]ethoxy]-		
09016-45-9	Nonylphenol polyethylene glycol ether		
20636-48-0a			
26027-38-3a			
26064-02-8a			
27177-01-1a			
37205-87-1a			
20427-84-3	Ethanol, 2-[2-(p-nonylphenoxy)ethoxy]-		
26027-38-3	p-Nonylphenol polyethylene glycol ether		
27986-36-3a			
37205-87-1a			
98113-10-1a			
26571-11-9	Nonylphenol octa(oxyethylene)ethanol		
27176-93-8	Nonylphenoxydiglycol		
27177-05-5	Nonylphenol hepta(oxyethylene)ethanol		
27177-08-8	Nonylphenol nona(oxyethylene)ethanol		
27986-36-3	Nonylphenoxy ethanol		
37205-87-1	Poly(oxy-1,2-ethanediyl),alpha-(isononylphenyl)-omega-hydroxy		
51938-25-1	Poly(oxy-1,2-ethanediyl),alpha-(2-nonylphenyl)-omega-hydroxy		

TABLE 2.—REVISIONS TO THE TSCA SECTION 4(E) *Priority Testing List*—Continued

CAS No.	Chemical Name	Action	Date
65455-72-3	Decaethylene glycol, isononylphenyl ether		
68412-54-4	Nonylphenoxypropoxyethanol		
152143-22-1 ^a			
127087-87-0	Nonylphenol polyethylene glycol ether		
NA ^b	Nonoxynol-2		
NA	Nonoxynol-3		
NA	Nonoxynol-7		
NA	alpha-(p-Nonylphenol)-omega-hydroxypoly(oxyethylene)		
7723-14-0	White phosphorus	Remove previously designated chemical	5/96
12185-10-3 ^a			
.....	High Production Volume Chemicals	Remove previously recommended chemicals	5/96
111-96-6	Diethylene glycol dimethyl ether		
112-15-2	Diethylene glycol monoethyl ether acetate		
.....	Oxygenated Fuel Additives	Remove previously recommended chemicals	5/96
637-92-3	Ethyl tert-butyl ether		
994-05-8	Tert-amyl methyl ether		

^a Alternate CAS number.

^b Not Assigned

III. Rationale for the revisions

A. ITC's Activities During this Reporting Period

Alkylphenols and ethoxylates, isocyanates and siloxanes. During the six months covered by this Report, the ITC evaluated several chemicals and chemical groups and the ITC's Subcommittees met with two Chemical Manufacturers Association (CMA) Panels and the Silicones Environmental Health and Safety Council (SEHSC). To facilitate communication between U.S. Government organizations needing data on alkylphenols and ethoxylates and the manufacturers, importers, processors, users and distributors of these chemicals, an ITC Subcommittee and the CMA's Alkylphenols and Ethoxylates Panel established the ITC-CMA Alkylphenols and Ethoxylates Dialog Group. To learn more about potential consumer uses of isocyanates, the ITC's Isocyanates Subcommittee met with the CMA's Diisocyanates Panel. To promote cogent discussions of siloxanes health and safety data the ITC's Siloxanes Subcommittee continued to meet with SEHSC.

Diaryl ethers. The ITC is evaluating published and unpublished data for the diaryl ethers recommended in its 29th Report (56 FR 67424, December 30, 1991). The ITC is interested in meeting with manufacturers, importers, processors, and users of these chemicals to discuss use and exposure data and to develop Structure Activity Relationships for predicting potential degradability and safety.

B. Specific Rationales

1. Recommended chemicals— a. Nonylphenol ethoxylates.

Recommendation. Nonylphenol ethoxylates are being added to the *Priority Testing List* to obtain TSCA section 8(a) exposure information and TSCA section 8(d) health and safety studies.

Rationale for recommendation. Nonylphenol ethoxylates are being recommended to meet the data needs of the Department of the Interior, the EPA, and the Food and Drug Administration. Currently, these needs include data on chemical composition of components and impurities, environmental fate of components and impurities and health and ecological effects, toxicokinetics and potential endocrine-modulating effects. The ITC will consider information discussed during meetings of the ITC-CMA Alkylphenols and Ethoxylates Dialog Group and review documents submitted under TSCA section 8 before determining if these chemicals should be removed from the *Priority Testing List* or designated for testing to meet U.S. Government data needs.

Nonylphenol ethoxylates are also being recommended to supplement the list of alkylphenols and ethoxylates that was recommended in the 37th Report (61 FR 4188, February 2, 1996)(FRL-4991-6). The rationale described in the 37th Report for alkylphenols and ethoxylates also applies to the nonylphenol ethoxylates listed in Table 2.

Supporting information—

Nonylphenol ethoxylates. The Substructure-based Computerized Chemical Selection Expert System (SuCCSES) is used to identify chemicals with shared substructures and associated health or ecological effects and similar TSCA production or importation volumes (Ref. 16). SuCCSES was used to identify the alkylphenols and ethoxylates that were added to the *Priority Testing List* in the 37th Report.

After the 37th Report was transmitted to the EPA Administrator, the ITC-CMA Alkylphenols and Ethoxylates Dialog Group developed a strategy to identify important nonylphenol ethoxylates. First, a nonylphenol ethoxylate substructure from SuCCSES and a nonylphenol ethoxylate name fragment was used to search the original TSCA Inventory. Second, the nonylphenol ethoxylates identified by this search were compared to those listed in the Code of Federal Regulations title 21, parts 174-186 (indirect food additives), the Cosmetic Toiletries and Fragrances Association Dictionary, the U.S. Pharmacopoeia/National Formulary and the Food Chemical News Guide. Third, the nonylphenol ethoxylates identified by this comparison were screened against nonylphenol ethoxylates in the OPD Chemical Buyers Directory, McHutcheon's Functional Materials and Chemyclopedia '96. This strategy produced a list of 18 nonylphenol ethoxylates (Table 2). For these 18 nonylphenol ethoxylates there were several Chemical Abstract Service (CAS) numbers including alternate CAS

numbers, and several chemical names including many synonyms (Table 3).

TABLE 3.— CHEMICAL NAMES, SYNONYMS AND ETHOXYLATE UNITS (EO) FOR NONYLPHENOL ETHOXYLATES ADDED TO THE REVISED TSCA SECTION 4(e) *Priority Testing List*

Chemical Names	Synonyms	Average Number of EO Units
Ethanol,2-[2-[2-(<i>p</i> -nonylphenoxy) ethoxy]ethoxy]ethoxy]-	Nonoxynol-4	4
Nonylphenol polyethylene glycol ether	Ethoxylated nonylphenol	> 1
.....	Nonylphenol polyglycol ether	> 1
.....	Nonylphenol polyethylene oxide	> 1
.....	Nonylphenoxypoly(oxyethylene)ethanol	> 1
.....	Poly(oxy-1,2-ethanediyl), alpha-(nonylphenyl)-omega-hydroxy	> 1
.....	Poly(oxyethylene) mono (nonylphenol) ether	> 1
.....	Nonoxynol-5	> 5
.....	Nonoxynol-6	> 6
Ethanol, 2-[2-(<i>p</i> -nonylphenoxy)ethoxy]-		1.5
<i>p</i> -Nonylphenol polyethylene glycol ether	Glycols, polyethylene, mono(<i>p</i> -nonylphenyl) ether	> 1
.....	Alpha-(<i>p</i> -nonylphenyl)-omega-hydroxypoly(oxyethylene)	> 1
.....	Nonoxynol-1	> 1.5
Nonylphenol octa(oxyethylene)ethanol	Nonoxynol-9	9
Nonylphenoxydiglycol	Ethanol, 2-[2-(nonylphenoxy)ethoxy]-	2
Nonylphenol hepta(oxyethylene)ethanol	Nonylphenol octaethoxylate	8
.....	Nonylphenol octaglycol ether	8
.....	Nonoxynol-8	8
Nonylphenol nona(oxyethylene)ethanol	Nonylphenol decaethylene glycol ether	10
Nonylphenoxyethanol	Nonylphenoxyglycol	1-1.5
.....	Ethanol, 2-(nonylphenoxy)-	1-1.5
Poly(oxy-1,2-ethanediyl), alpha-(isononylphenyl)-omega-hydroxy		> 1
Poly(oxy-1,2-ethanediyl), alpha-(2-nonylphenyl)-omega-hydroxy		>1
Decaethylene glycol, isononylphenyl ether		10
Nonylphenoxypolyoxyethanol	Poly(oxy-1,2-ethanediyl), alpha-(nonylphenyl) omega-hydroxy - branched	> 1
Nonylphenol polyethylene glycol ether	Poly(oxy-1,2-ethanediyl), alpha (4-nonylphenyl)-omega-hydroxy - branched	> 1
Nonoxynol-2		2
Nonoxynol-3		3
Nonoxynol-7		7
alpha-(<i>p</i> -Nonylphenol)-omega-hydroxypoly(oxyethylene)		1 to 100

During development of the strategy by the ITC-CMA Alkylphenols and Ethoxylates Dialog Group, issues related to the complex nomenclature and chemical composition of nonylphenol ethoxylates were discussed. During these discussions, it was recognized that for some nonylphenol ethoxylates it is possible to quantify the average number of ethoxylate (EO) units, while for others that are complex mixtures or polymers, it is only possible to state that the average number of EO units is > 1 (Table 3). Obtaining recent production and importation volumes for nonylphenol ethoxylates that are complex mixtures or polymers was a concern for the Dialog Group because these chemicals were exempt from reporting requirements of the EPA's 1986, 1990 and 1994 TSCA section 8(a) Inventory Update Rules (51 FR 21438, June 12, 1986; 55 FR 39586, September 27, 1990; 59 FR 30652, June 14, 1994). However, the Dialog Group recognized that the TSCA section 8(a) Preliminary Assessment Information Rule (PAIR) that EPA automatically promulgates for

any chemicals that the ITC adds to the *Priority Testing List* requires the submission of recent production and importation volume data for all chemicals on the *List*, including complex mixtures or polymers. The ITC will review the PAIR data for all alkylphenols and ethoxylates that are on the *List* and use these data as well as use and exposure data and other information provided to the ITC-CMA Alkylphenols and Ethoxylates Dialog Group to determine which alkylphenols and ethoxylates should be removed from the *List* and which should be considered for designation.

Existing U.S. Government data needs. The ITC identified the same data needs for nonylphenol ethoxylates that were identified for alkylphenols and alkylphenol ethoxylates in its 37th Report. These data needs are summarized above in the rationale for recommendation.

Completed activities of the ITC-CMA Alkylphenols and Ethoxylates Dialog Group. The Dialog Group discussed the history of the ITC's recommendation,

nomenclature issues, chemical composition data, uses of alkylphenols and ethoxylates, ongoing testing and (as discussed above) strategies for identifying nonylphenol ethoxylates. The Dialog Group discussed the TSCA Test Submissions (TSCATS) compatible database that the SEHSC-ITC-EPA workgroup developed for silicone chemicals. The Dialog Group committed to develop a database for alkylphenols and ethoxylates that would include elements that were compatible with TSCATS, the Confidential Business Information Tracking System (CBITS) and the TSCA submissions electronic cover sheet and abstract form.

2. Removal of Chemicals from the Priority Testing List— a. White Phosphorus. Based on concerns of the Department of Interior (DOI), white phosphorus was recommended for chemical fate and ecological effects testing in the ITC's 29th Report (56 FR 67424, December 30, 1991). These concerns included the paucity of data on the persistence of white phosphorus in wetland sediments, the adverse

effects of white phosphorus to birds and wildlife that feed on sediments contaminated with white phosphorus, and the potential for food chain effects including possible elimination of endangered species that may feed on carcasses of birds and wildlife that die from white phosphorus poisoning. In response to the ITC's recommendations, the EPA added white phosphorus (CAS number 7723-14-0) to TSCA section 8(a) and 8(d) rules (58 FR 13556, March 12, 1993). This CAS number also applies to yellow, red and black phosphorus. After these rules were published, the ITC asked EPA to add a second, less commonly used CAS number (12185-10-3) for white phosphorus to TSCA section 8 rules to assure retrieval of unpublished TSCA section 8 data that were indexed on that CAS number. The EPA added this CAS number to TSCA section 8 rules that were published on December 27, 1993 (58 FR 68311). The ITC reviewed published data and data submitted in response to these rules. These data demonstrated the persistence of white phosphorus in sediments, but did not provide any new information to alleviate the DOI's concerns for the ecological effects of white phosphorus. As a result, the ITC designated white phosphorus for ecological effects testing in its 34th Report (59 FR 35720, July 13, 1994).

The ITC did not receive any comments on the EPA's Toxic Release Inventory (TRI) data for white phosphorus that were referenced in its 29th Report. In this Report, the ITC referenced the 1988 and 1989 TRI which reported that over 3,000,000 pounds of white phosphorus were released to the environment. Prior to publishing its 34th Report, the ITC considered whether data from the 1991 and 1992 TRI (which reported that about 300,000 pounds of white phosphorus were released to the environment) would be sufficient environmental release to justify a designation under TSCA section 4(e)(1)(A)(ii). Under this section of TSCA, the ITC must consider "the quantities in which the substance or mixture enters or will enter the environment" before designating any chemical to the EPA Administrator for priority testing consideration. The ITC determined that these releases were sufficient and referenced the 1991 and 1992 TRI in its 34th Report when it designated white phosphorus. After the 34th Report was published, the EPA received a letter from the CMA which identified serious errors in white phosphorus environmental release data reported by industry under the

requirements of the TRI (Ref. 5). According to the CMA, the 1993 TRI releases of white phosphorus should have been about 27,000 pounds, not 318,000 pounds (Ref. 5). According to the 1994 TRI (which includes releases from Federal facilities) about 50,000 pounds of white phosphorus were released to the environment (Ref. 15).

After reviewing the 1995 CMA letter and the 1994 TRI data, EPA requested that the ITC withdraw its designation of white phosphorus because "errors made by industry in TRI reporting have resulted in a serious misconception about the actual environmental releases of white phosphorus and 1994 TRI data indicate that environmental releases of white phosphorus are almost an order of magnitude less than that upon which the ITC based its decision to designate this chemical for testing under section 4 of TSCA" (Ref. 8). In this request EPA also committed "to explore alternative ways to have the needed testing conducted" (Ref. 8).

After reviewing the 1994 TRI data, letters from the CMA and the EPA, and considering EPA's commitment to explore alternative testing mechanisms, the ITC is withdrawing its designation and removing white phosphorus from the *Priority Testing List*.

b. Oxygenated Fuel Additives. The ITC designated the oxygenated fuel additive, methyl tert-butyl ether (MTBE) (CAS number 1634-04-4) for health effects testing in its 20th Report because of concerns for widespread human exposure to low level fugitive emissions of MTBE at gasoline pumps and the need for chronic health effects data (52 FR 19020; May 20, 1987). In response to the ITC's designation, the EPA and MTBE manufacturers negotiated a TSCA section 4 Enforceable Consent Agreement (ECA) to develop pharmacokinetics, genotoxicity, subchronic toxicity, reproductive effects, developmental toxicity, neurotoxicity, and oncogenicity data (53 FR 10391, March 31, 1988). The ITC removed MTBE from the *Priority Testing List* in its 22nd Report (53 FR 18196, May 20, 1988). EPA and other Federal Agencies continue to assess the risks of human exposure to MTBE.

Subsequent to this designation, the ITC recommended ethyl tert-butyl ether (ETBE) (CAS number 637-92-3) and tert-amyl methyl ether (TAME) (CAS number 994-05-8) for health effects testing to meet the data needs of the U.S. EPA (59 FR 35720, July 13, 1994). Subsequently, EPA promulgated TSCA section 8(a) and 8(d) rules for ETBE and TAME (59 FR 60716, November 28, 1994) and met with ETBE and TAME

manufacturers to discuss testing to meet these data needs.

On September 21, 1994, and March 23, 1995, the EPA received letters from the ARCO Chemical Company announcing their intention to voluntarily conduct health effects tests for ETBE (Refs. 1 and 2). These letters indicate that pharmacokinetics, genotoxicity, subchronic toxicity, and neurotoxicity testing will be conducted first, followed by developmental toxicity and reproductive effects testing. EPA's Office of Pollution Prevention and Toxics (OPPT) added ETBE to its Master Testing List (MTL) as a member of the category of "Oxygenated Fuel Additives" to obtain test data to support ongoing activities in EPA's Office of Air and Radiation (OAR).

On March 21, 1995, OPPT published a TSCA section 4 ECA for TAME (60 FR 14910)(FRL-4935-4). The ECA requires pharmacokinetics, genotoxicity, subchronic toxicity, developmental toxicity, and reproductive toxicity testing. Testing will be conducted by the TAME Producers Group which is comprised of the following companies: Amerada Hess Corporation, Chevron U.S.A. Products Company, Citgo Petroleum, Exxon Company U.S.A., and Texaco Refining and Marketing. In addition, TAME is being considered for inclusion in the Screening Information Data Set (SIDS) program, a voluntary international testing program operated under the auspices of the Organization for Economic Cooperation and Development (OECD). OPPT also added TAME to its MTL as a member of the "Oxygenated Fuel Additives" category to obtain test data to support ongoing OAR activities.

The ITC is removing ETBE and TAME from the *Priority Testing List* at this time because testing programs for both chemicals are likely to meet EPA's data needs. If further testing of ETBE or TAME is needed, the EPA may request that the ITC designate the chemicals for testing. In the future, the EPA may nominate other oxygenated fuel additives to the ITC.

c. High Production Volume Chemicals (HPVCs)/Glycol Ethers. Diethylene glycol monoethyl ether acetate (DGEEA) (CAS number 112-15-2) and diethylene glycol dimethyl ether (DGDME) (CAS number 111-96-6) were members of a group of 35 HPVCs that were recommended for 90-day subchronic toxicity testing in the ITC's 27th Report (56 FR 99534, March 6, 1991). SuCCSES was used to select these HPVCs during the ITC's sixth scoring exercise. These HPVCs had annual production volumes exceeding 1 million pounds, but no 90-day subchronic toxicity data to identify

potential health effects concerns. In its 36th Report (60 FR 42982, August 17, 1995)(FRL-4965-6), the ITC solicited specific use and exposure information on DGEEA, DGDME, and ten other HPVCs to facilitate its ability to decide whether these chemicals should be removed from the *Priority Testing List* or designated for testing.

As noted in the 37th Report (61 FR 4188, February 2, 1996), Eastman Chemical Company and Ferro Corporation responded to that solicitation for DGEEA and DGDME, respectively (Refs. 7 and 9). Both DGEEA and DGDME are used as solvents in various applications. Ferro reported that DGDME is also used in reaction medium for the synthesis of certain chemicals and that the use of DGDME as a solvent in semiconductor cleaning operations has decreased. In their letters, both manufacturers stated that exposures to DGEEA and DGDME are low.

Although 90-day subchronic toxicity studies are not available for DGEEA or DGDME, existing toxicity data on these and related glycol ethers and acetates indicate that such studies are not necessary to further identify potential health effects concerns.

DGEEA is expected to be metabolized to diethylene glycol monoethyl ether (DGEE) (CAS number 111-90-0), based on the metabolism of other glycol ether acetates (Ref. 13). Subchronic toxicity studies in which rats, mice and pigs were fed DGEE for 90 days have been conducted (Ref. 10). There was reduced growth in rats and mice at the highest dose levels (5.0% and 5.4%, respectively). Hemoglobin was reduced and relative kidney weights increased in all 3 species at the highest dose levels. In pigs (the most sensitive species in this study), three deaths due to uremia were recorded within the first 3 weeks of exposure at the highest dose level of 1,500 mg/kg after which the dose was reduced to 1,000 mg/kg. The no-observed effect levels established from these studies were 250 mg/kg/day for rats, 850 to 1,000 mg/kg/day for mice and 167 mg/kg/day for pigs. These DGEE data satisfy the need for subchronic toxicity testing of DGEEA.

DGDME caused dose-dependent testicular toxicity in male rats following short-term (10 to 20 days) exposure by inhalation (Ref. 12) and oral administration (Ref. 4). DGDME also caused developmental toxicity when administered to rabbits (Ref. 14) and pregnant CD-1 mice (Ref. 11). Following administration of doses of DGDME, to the male rat (Ref. 3) and the pregnant CD-1 mouse (Ref. 6) some of the DGDME was metabolized to the well-studied

reproductive toxicant, ethylene glycol monomethyl ether (EGME) (CAS number 109-86-4), and its toxic metabolite, methoxyacetic acid. Since 10- to 20-day repeated dose studies with DGDME have identified potential toxicities of concern, 90-day subchronic toxicity testing for the purposes of general toxicity screening is not warranted.

The ITC is removing DGEEA and DGDME from the *Priority Testing List* because sufficient screening data exist to identify potential subchronic toxicities of concern and no additional U.S. Government data needs were identified at this time.

References

1. ARCO. Letter from Dr. Larry S. Andrews, Manager, Toxicology Regulatory Compliance, ARCO Chemical Company to Mr. Charles M. Auer, Director, Chemical Control Division, OPPT/EPA, Washington, DC (1994).
2. ARCO. Letter from Dr. Larry S. Andrews, Manager, Toxicology Regulatory Compliance, ARCO Chemical Company to Mr. Charles M. Auer, Director, Chemical Control Division, OPPT/EPA, Washington, DC (1995).
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