# ENVIRONMENTAL PROTECTION AGENCY

[OPPTS-41055; FRL-6763-6]

# Forty-Seventh Report of the TSCA Interagency Testing Committee to the Administrator; Receipt of Report and Request for Comments

**AGENCY:** Environmental Protection Agency (EPA). **ACTION:** Notice.

**SUMMARY:** The Toxic Substances Control Act (TSCA) Interagency Testing Committee (ITC) transmitted its 47<sup>th</sup> ITC Report to the Administrator of the EPA on November 30, 2000. In the 47th ITC Report, which is included in this notice, the ITC adds 37 indium chemicals and 4 other chemicals discussed in the 46<sup>th</sup> ITC Report as recommended chemicals to its *Priority Testing List*. The ITC requests TSCA section 8(a) Preliminary Assessment Information Reporting (PAIR) rules for the appropriate CAS numbered chemicals and TSCA section 8(d) Health and Safety Data reporting rules be promulgated by the EPA for these chemicals and the 8 nonylphenol polyethoxylate degradation products placed on the Priority Testing List in the 46<sup>th</sup> ITC Report. The ITC is also placing three chloroalkenes as recommended chemicals on the ITC's Priority Testing List in order to solicit information on use, exposure, ecological effects, environmental fate, and health effects under the ITC's Voluntary Information Submission Policy (VISP). This action is part of the ITC's ongoing efforts to screen chemicals with potential to persist and bioconcentrate.

**DATES:** Comments, identified by docket control number OPPTS-41055, must be received on or before May 3, 2001.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the

**SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPPTS-41055 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: For general information contact: Barbara Cunningham, Acting Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 554–1404; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: John D. Walker, ITC Executive Director (7401), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 260–1825; fax: (202) 260– 7895; e-mail address: walker.johnd@epa.gov.

## SUPPLEMENTARY INFORMATION:

#### **I. General Information**

### A. Does this Action Apply to Me?

This notice is directed to the public in general. It may, however, be of particular interest to you if you manufacture (defined by statute to include import) and/or process TSCAcovered chemicals and you may be identified by the North American Industrial Classification System (NAICS) codes 325 and 32411. Because this notice is directed to the general public and other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be interested in this action. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Additional Information, Including Copies of this Document or Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http:// www.epa.gov/. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "**Federal Register**—Environmental Documents." You can also go directly to the **Federal Register** listings at http:// www.epa.gov/fedrgstr/.

You may also access additional information about the ITC and the TSCA testing program through the web site for the Office of Pollution Prevention and Toxics (OPPT) at http://www.epa.gov/ opptintr/, or go directly to the ITC Home Page at http://www.epa.gov/opptintr/ itc/.

2. *In person*. The Agency has established an official record for this action under docket control number OPPTS–41055. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well

as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the TSCA Nonconfidential Information Center, North East Mall Rm. B-607, Waterside Mall, 401 M St., SW., Washington, DC. The Center is open from noon to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Center is (202) 260–7099.

# C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPPTS-41055 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Document Control Office (7407), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. In person or by courier. Deliver your comments to: OPPT Document Control Office (DCO) in East Tower Rm. G-099, Waterside Mall, 401 M St., SW., Washington, DC. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 260-7093.

3. Electronically. You may submit vour comments electronically by e-mail to: oppt.ncic@epa.gov, or mail your computer disk to the address identified above. Do not submit any information electronically that you consider to be CBI. 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 standard disks in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPPTS-41055. Electronic comments may also be filed online at many Federal Depository Libraries.

# D. How Should I Handle CBI Information That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the technical person listed under FOR FURTHER INFORMATION CONTACT.

*E. What Should I Consider as I Prepare My Comments for EPA?* 

We invite you to provide your views and comments on the 47<sup>th</sup> ITC Report. You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. Provide specific examples to illustrate your concerns.

5. Make sure to submit your comments by the deadline in this notice.

6. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

# **II. Background**

The Toxic Substances Control Act (TSCA) (15 U.S.C. 2601 et seq.) authorizes the Administrator of the EPA to promulgate regulations under TSCA 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 ITC to recommend chemicals and chemical groups to the Administrator of the EPA for priority testing consideration. Section 4(e) of TSCA directs the ITC to revise the TSCA section 4(e) Priority *Testing List* at least every 6 months.

1. *The 47*<sup>th</sup> *ITC Report*. The 47<sup>th</sup> ITC Report was received by the EPA Administrator on November 30, 2000, and is included in this notice. In the 47<sup>th</sup> ITC Report, the ITC:

i. Adds 37 indium chemicals (see Table 2 of the 47<sup>th</sup> ITC Report) and 4

other chemicals discussed in the 46<sup>th</sup> ITC Report as recommended chemicals to its Priority Testing List. The ITC requests TSCA section 8(a) PAIR rules for the appropriate CAS numbered chemicals and TSCA section 8(d) Health and Safety Data reporting rules be promulgated by the EPA for these chemicals and the 8 nonylphenol polyethoxylate degradation products placed on the Priority Testing List in the 46<sup>th</sup> ITC Report. The chemicals, for which needed information was not provided in response to the VISP published in the 46<sup>th</sup> ITC Report, are: Pentachlorothiophenol (CAS No. 133– 49–3, from the class

"polychlorobenzenethiols"); tetrachloropyrocatechol (CAS No. 1198– 55–6, from the class

"polychlorophenols"); *p*-toluidine, 5chloro-.alpha.,.alpha.,.alpha.-trifluoro-2nitro-*N*-phenyl- (CAS No. 1806–24–2, from the class

"chlorotrifluoromethylphenoxy benzenes") benzoic acid, 3-[2-chloro-4-(trifluoromethyl)phenoxy]-2-ethoxy-1methyl-2-oxo- (CAS No. 88185–22–2, from the class

"chlorotrifluoromethylphenoxy benzenes"). In addition, no information was provided on the following eight nonylphenol polyethoxylate degradation products: 4-nonylphenol ethoxylate (CAS No. 104–35–8); 4nonylphenol diethoxylate (CAS No. 20427–84–3); 4-nonylphenoxy acetic acid (CAS No. 3115–49–9); 4nonylphenoxy ethoxy acetic acid (CAS No. 106807–78–7); 4-nonylphenoxy diethoxy acetic acid (CAS No. 108241– 00–5); 4-nonylphenoxy triethoxy acetic acid; 4-nonylphenol triethoxylate; and 4-nonylphenol tetraethoxylate.

ii. Places three chloroalkenes [1,3butadiene, 1,1,2,3,4-pentachloro-4-(1methylethoxy)- (CAS No. 68334–67–8); 3-butenoic acid, 2,2,3,4,4-pentachloro-, butyl ester (CAS No. 75147–20–5); and 2,2,3,4,4-pentachloro-3-butenoic acid (CAS No. 85743–61–9)] as recommended chemicals on the *Priority Testing List* in order to solicit information on use, exposure, ecological effects, environmental fate, and health effects under the ITC's VISP. This action is part of the ITC's ongoing efforts to screen chemicals with potential to persist and bioconcentrate.

2. Status of the Priority Testing List. The current TSCA section 4(e) Priority Testing List as of November 2000 can be found in Table 1 of the  $47^{th}$  ITC Report which is included in this notice.

#### List of Subjects

Environmental protection, Chemicals, Hazardous substances.

Dated: March 23, 2001.

#### Charles M. Auer,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics. Seventh Report of the TSCA Interagency Testing Committee to the Administrator, U.S. Environmental Protection Agency

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#### Summary

This is the 47<sup>th</sup> Report of the Toxic Substances Control Act (TSCA) Interagency Testing Committee (ITC) to the Administrator of the U.S. **Environmental Protection Agency** (EPA). In this Report, the ITC is adding 37 indium chemicals and four other chemicals discussed in the 46th Report which was published in the Federal Register of December 1, 2000 (65 FR 75552) (FRL-6594-7) to its Priority *Testing List* so that TSCA section 8(a) Preliminary Assessment Information Reporting (PAIR) and TSCA section 8(d) Health and Safety Data (HaSD) reporting rules will be promulgated by the EPA. There is reason to believe the indium chemicals have potential to cause cancer in humans. The four chemicals discussed in the 46<sup>th</sup> Report that are being added to the Priority Testing List are, pentachlorothiophenol and tetrachloropyrocatechol (from the class polychlorophenols and polychlorobenzenethiols), and ptoluidine, 5-chloro-.alpha.,.alpha.,.alpha.- trifluoro-2-nitro-N-phenyl and benzoic acid, 3-[2-chloro-4-(trifluoromethyl) phenoxy]-, 2-ethoxy-1-methyl-2-oxo (from the class chlorotrifluoromethylphenoxy benzenes). The four chemicals are being

added to the *Priority Testing List*, because information solicited in the ITC's 46<sup>th</sup> Report under the Voluntary Information Submissions Policy (VISP) was not provided to the ITC. The ITC is also asking EPA to promulgate TSCA section 8(a) PAIR and TSCA section 8(d) HaSD reporting rules for the 8 nonylphenol polyethoxylate degradation products that were added to the *Priority Testing List* in the ITC's 46<sup>th</sup> Report, because information requested for these chemicals was not voluntarily provided to the ITC. The ITC is placing three chloroalkenes on the *Priority Testing List* in order to solicit information on use, exposure, ecological effects, environmental fate, and health effects under VISP. This action is part of the ongoing effort to screen chemicals with potential to persist and bioconcentrate. The revised TSCA section 4(e) *Priority Testing List* follows as Table 1 of this unit.

# TABLE 1.—THE TSCA SECTION 4(E) PRIORITY TESTING LIST (NOVEMBER 2000)

| Report | Date          | Chemical/Group  | Action      |
|--------|---------------|---|-------------|
| 28     | May 1991      | Chemicals with low confidence reference dose (RfD)<br>Acetone<br>Thiophenol               | Designated  |
| 30     | May 1992      | 5 Siloxanes   | Recommended |
| 31     | January 1993  | 13 Chemicals with insufficient dermal absorption rate data                                | Designated  |
| 32     | May 1993      | 16 Chemicals with insufficient dermal absorption rate data                                | Designated  |
| 35     | November 1994 | 4 Chemicals with insufficient dermal absorption rate data                                 | Designated  |
| 37     | November 1995 | 10 Alkylphenols and 2 alkylphenol polyethoxylates   | Recommended |
| 39     | November 1996 | 8 Nonylphenol ethoxylates   | Recommended |
| 41     | November 1997 | 18 Alkylphenols, 5 polyalkylphenols and 6 alkylphenol polyethoxylates.                    | Recommended |
| 42     | May 1998      | 3-Amino-5-mercapto-1,2,4-triazole   | Recommended |
| 42     | May 1998      | Glycoluril  | Recommended |
| 42     | May 1998      | Methylal  | Recommended |
| 42     | May 1998      | Ethyl Silicate  | Recommended |
| 46     | May 2000      | 8 Nonylphenol polyethoxylate degradation products   | Recommended |
| 47     | November 2000 | 37 Indium chemicals   | Recommended |
| 47     | November 2000 | Pentachlorothiophenol   | Recommended |
| 47     | November 2000 | Tetrachloropyrocatechol   | Recommended |
| 47     | November 2000 | <i>p</i> -Toluidine, 5-chloroalpha.,.alpha.,.alphatrifluoro-2-nitro-<br><i>N</i> -phenyl. | Recommended |
| 47     | November 2000 | Benzoic acid, 3-[2-chloro-4-(trifluoromethyl)phenoxy]-, 2-<br>ethoxy-1-methyl-2-oxo.      | Recommended |
| 47     | November 2000 | 3 Chloroalkenes   | Recommended |

# I. Background

The ITC was established by section 4(e) of 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 six months..., the Committee shall make such revisions to the *Priority Testing List* as it determines to be necessary and transmit them to the Administrator together with the Committee's reasons for the revisions" (Public Law 94-469, 90 Stat. 2003 et seq., 15 U.S.C. 2601 et seq.). Since its creation in 1976, the ITC has submitted 46 semi-annual (May and November) Reports to the EPA Administrator transmitting the Priority *Testing List* and its revisions. ITC Reports are available from the ITC's web site (http://www.epa.gov/opptintr/itc) within a few days of submission to the Administrator and from http:// www.epa.gov/fedrgstr after publication in the Federal Register. The ITC meets monthly and produces its revisions to the Priority Testing List with administrative and technical support from the ITC staff, ITC members and

their U.S. Government organizations, and contract support provided by EPA. ITC members and staff are listed at the end of this Report.

# **II. TSCA Section 8 Reporting**

A. TSCA section 8 rules. Following receipt of the ITC's Report (and the revised Priority Testing List) by the EPA Administrator, the EPA's Office of Pollution Prevention and Toxics (OPPT) promulgates TSCA section 8(a) PAIR and TSCA section 8(d) HaSD reporting rules for chemicals added to the *Priority Testing List.* These rules require producers and importers of chemicals recommended by the ITC to submit production and exposure reports under TSCA section 8(a) and producers, importers, and processors of chemicals recommended by the ITC to submit unpublished health and safety studies under TSCA section 8(d). These rules are automatically promulgated by OPPT unless otherwise requested by the ITC.

B. *ITC's use of TSCA section 8 and "other information."* The ITC reviews the TSCA section 8(a) PAIR reports, TSCA section 8(d) HaSD studies and *"other information"* that becomes available *after* the ITC adds chemicals to the *Priority Testing List.* "Other information" includes TSCA section 4(a) and 4(d) studies, TSCA section 8(c) submissions, TSCA section 8(e) "substantial risk" notices, "For Your Information" (FYI) submissions, unpublished data submitted to and from U.S. Government organizations represented on the ITC, published papers, as well as use, exposure, effects, and persistence data that are voluntarily submitted to the ITC by manufacturers, importers, processors, and users of chemicals recommended by the ITC. The ITC reviews this information and determines if data needs should be revised, if chemicals should be removed from the Priority Testing List or if recommendations should be changed to designations.

C. Promoting more efficient use of information submission resources. The Voluntary Information Submissions Innovative Online Network (VISION) is accessible through the world wide web (http://www.epa.gov/opptintr/itc/ vision.htm). VISION includes the VISP and links to the TSCA Electronic HaSD Reporting Form (http://www.epa.gov/ opptintr/.er/hasd.htm). The EPA recently revised section 3.2 of the TSCA Electronic HaSD Reporting Form in response to ITC requests to provide

more details on requested use and exposure information (see 46<sup>th</sup> Report). The VISP provides examples of data needed by ITC member U.S. Government organizations, examples of studies that should not be submitted, the milestones for submitting information, guidelines for using the TSCA Electronic HaSD Reporting Form and instructions for electronically submitting full studies. The TSCA Electronic HaSD Reporting Form can be used to provide electronic information on ITC voluntary submissions, TSCA section 8(d) studies (to meet data needs of the ITC member U.S. Government organizations), FYI submissions, and TSCA section 8(e) studies.

The ITC encourages chemical producers, importers, processors, and users to voluntarily provide electronic information via VISION on chemicals for which the ITC is soliciting voluntary information and to establish a dialogue with the ITC to discuss needed data. To enhance visibility, the ITC will be adding all chemicals to the Priority *Testing List* for which it is voluntarily soliciting information along with a request that EPA not immediately promulgate TSCA section 8(a) PAIR and section 8(d) HaSD reporting rules. If the ITC does not receive voluntary electronic information submissions to meet its data needs according to the procedures in VISP, the ITC may then request that EPA promulgate TSCA section 8(a) PAIR and section 8(d) HaSD reporting rules to determine if there are unpublished data to meet those needs. The ITC strongly encourages those companies that must respond to a TSCA section 8(d) HaSD reporting rule to provide data by using the TSCA Electronic HaSD Reporting Form.

D. Requests related to promulgation of TSCA section 8(a) PAIR and section 8(d) HaSD reporting rules. In this Report, the ITC is asking the EPA to promulgate TSCA section 8(a) PAIR and section 8(d) HaSD reporting rules for 37 indium chemicals; pentachlorothiophenol; tetrachloropyrocatechol; p-toluidine, 5chloro- .alpha.,.alpha.,.alpha.-trifluoro-2-nitro-N-phenyl; benzoic acid, 3-[2chloro-4-(trifluoromethyl)phenoxy]-, 2ethoxy-1-methyl-2-oxo; and 8 nonylphenol polyethoxylate degradation products. Reporting rules are being requested for pentachlorothiophenol; tetrachloropyrocatechol; p-toluidine, 5chloro-.alpha.,.alpha.,.alpha.-trifluoro-2nitro-N-phenyl; benzoic acid, 3-[2chloro-4-(trifluoromethyl)phenoxy]-, 2ethoxy-1-methyl-2-oxo; and the 8 nonylphenol polyethoxylate degradation products because needed information was not provided in

response to the voluntary information solicitations published in the 46<sup>th</sup> Report. At this time, the ITC is requesting that EPA not promulgate TSCA section 8(a) PAIR and section 8(d) HaSD reporting rules for the 3 chloroalkenes (1,3-butadiene, 1,1,2,3,4pentachloro-4-(1-methylethoxy)-; 3butenoic acid, 2,2,3,4,4-pentachloro-; and 3-butenoic acid, 2,2,3,4,4pentachloro-butyl ester) to allow chloroalkenes producers, importers, processors, and users an opportunity to voluntarily provide the requested information.

# III. ITC's Activities During this Reporting Period (May to October 2000): Information Solicitations

In its 46<sup>th</sup> Report, the ITC discussed its strategies to screen chemicals for persistence and bioconcentration potential (http://www.epa.gov/opptintr/ itc). These strategies are referred to as **Degradation Effects Bioconcentration** Information Testing Strategies (DEBITS). DEBITS provides a means to prioritize chemicals based on degradation, ecological, or human health effects and bioconcentration information. During this reporting period, the ITC continued to focus its efforts on structural classes of chemicals from a subset of 42 moderate production volume (MPV) chemicals (production/importation volumes between 100,000 and 1,000,000 pounds) with estimated or measured bioconcentration factors (BCFs) > 250 and about 70 structurally related non-MPV chemicals (also with BCFs > 250). In its 46<sup>th</sup> Report, the ITC solicited information on three such structural classes:

1. Polychlorophenols and polychlorobenzenethiols,

2. Chlorotrifluoromethylphenoxy benzenes, and

3. Perfluorinated chemicals.

During this reporting period, the ITC continued its review of chemicals with potential to persist and bioconcentrate and decided to solicit information on chloroalkenes. The ITC is seeking information on uses, exposures, health effects, and ecological effects from the manufacturers, importers, and processors of chloroalkenes. The ITC is requesting that solicited information be electronically submitted before February 28, 2001, consistent with the 90-day milestone of the VISP (http:// www.epa.gov/opptintr/itc/visp.htm) for submitting data through the TSCA Electronic HaSD Reporting Form. DEBITS will continue to be used to prioritize chemicals with potential to persist and bioconcentrate.

# IV. Revisions to the TSCA Section 4(e) Priority Testing List: Chemicals Added to the Priority Testing List

# A. Indium Chemicals

1. *Recommendation*. Indium chemicals are being added to the *Priority Testing List* to obtain importation, production, use, exposure, and health effects information to meet U.S. Government data needs.

2. Rationales for recommendation. There is clear evidence that indium phosphide causes tumors in rats and mice. As a result, indium phosphide and other indium chemicals are considered to be potentially carcinogenic to humans. Use of indium chemicals in the semiconductor and other industries may be increasing. Existing exposure limits may not be adequate to protect workers exposed to indium phosphide and other indium chemicals from an increased risk of lung cancer.

3. Supporting information. In a 2-year inhalation study there was clear evidence of carcinogenic activity of indium phosphide (Chemical Abstract Service number (CAS No.) 22398–80–7) in male and female F344/N rats and male and female B6C3F1 mice (http:// ntp-server.niehs.nih.gov/htdocs/ Results Status/Resstati/M882472.Html). In this study, the incidence of benign and malignant neoplasms were increased in the lungs of male and female rats and mice at doses of 0.03, 0.1, and 0.3 milligram/meter<sup>3</sup> ( $mg/m^3$ ). There was also an exposure-related increase in the incidence of benign and malignant neoplasms of the liver in male and female mice.

For indium and certain indium chemicals, the National Institute for Occupational Safety and Health's (NIOSH) Recommended Exposure Limit (REL), the American Council of **Government Industrial Hygienists** (ACGIH) threshold limit value (TLV), and the Occupational Safety and Health Administration's (OSHA) Permissible Exposure Limit (PEL) for construction and shipvard industries is  $0.1 \text{ mg/m}^3$ . The current occupational exposure limits may not be adequate to protect workers exposed to indium phosphide and other indium chemicals from increased risk of lung cancer, because benign and malignant neoplasms were increased in the lungs of both sexes of rats and mice at doses lower than the PEL, REL, and TLV. Furthermore, experimental studies in hamsters suggest that indium arsenide may induce effects in the lung comparable to indium phosphide. These studies raise the concern for other indium chemicals and their potential health effects.

The indium chemicals are believed to be increasingly used in the manufacture of semiconductors, injection lasers, solar cells, photodiodes, and lightemitting diodes. Worker exposures may occur during manufacturing and handling of these materials. However, there are no publicly available reports in the literature that assess workplace exposures to indium phosphide or other indium chemicals.

4. *Information needs*. The ITC needs: i. Recent non-CBI estimates of annual production or importation volume data and trends, and use information, including percentages of production or importation that are associated with

different uses; ii. Estimates of the number of humans and concentrations of indium chemicals to which humans may be exposed in each relevant use, manufacturing, or processing scenario; iii. Health effects data including

iii. Health effects data including pharmacokinetics, genotoxicity, subchronic toxicity, reproductive, and developmental toxicity, carcinogenicity and any human data from occupationally exposed workers.

The ITC seeks this information in order to adequately assess the extent and degree of exposure and potential hazard associated with the indium chemicals. Information is requested on the 37 indium-containing chemicals in Table 2 of this unit. Manufacturers, processors, and users of indium chemicals are encouraged to provide importation, production, use, exposure, and health effects information using the TSCA Electronic HaSD Reporting Form (http://www.epa.gov/opptintr/.er/ hasd.htm).

TABLE 2.—INDIUM CHEMICALS BEING ADDED TO THE PRIORITY TESTING LIST

| CAS No.    | Chemical name                |
|------------|------------------------------|
| 923–34–2   | Triethylindium               |
| 1303–11–3  | Indium arsenide              |
| 1312-41-0  | Indium antimonide            |
| 1312–43–2  | Indium (III) oxide           |
| 1312–45–4  | Indium (III) telluride       |
| 4194–69–8  | Indium (III) citrate         |
| 7440–74–6  | Indium                       |
| 7783–52–0  | Indium (III) fluoride        |
| 10025–82–8 | Indium (III) chloride        |
| 12018–95–0 | Copper indium diselenide     |
| 12030–14–7 | Indium (II) sulfide          |
| 12030–24–9 | Indium (III) sulfide         |
| 12056–07–4 | Indium selenide              |
| 12672–70–7 | Indium chloride              |
| 12672–71–8 | Indium (I) oxide             |
| 13464–82–9 | Indium (III) sulfate         |
| 13510–35–5 | Indium (III) iodide          |
| 13770–61–1 | Indium (III) nitrate         |
| 13966–94–4 | Indium (I) iodide            |
| 14166–78–0 | Indium (III) fluoride        |
| 14280–53–6 | Indium (I) bromide           |
| 14405-45-9 | Indium tris(acetylacetonate) |

TABLE 2.—INDIUM CHEMICALS BEING ADDED TO THE PRIORITY TESTING LIST—Continued

| CAS No.    | Chemical name                  |
|------------|--------------------------------|
| 20661–21–6 | Indium (III) hydroxide         |
| 22398-80-7 | Indium (I) phosphide           |
| 25114–58–3 | Indium (III) acetate           |
| 25617–98–5 | Indium nitride                 |
| 50926-11-9 | Indium tin oxide               |
| 55326-87-9 | Indium hydroxide               |
| 71243–84–0 | Indium tin oxide               |
| 13465–09–3 | Indium (III) bromide           |
| 13465–10–6 | Indium (I) chloride            |
| 13709–93–8 | Indium (III) borate            |
| 27765-48-6 | Indium (III) tetrafluoroborate |
| 66027–93–8 | Indium (III) sulfamate         |
| 66027–94–9 | Hydroxybis(trifluoroacetato-   |
|            | ,O)indium                      |
| 67816-06-2 | Indium (III) 2-ethylhexanoate  |
| 68310-35-0 | Indium (III) neodecanoate      |
|            |                                |

# B. Chloroalkenes

1. Recommendation. Three chloroalkenes are being added to the Priority Testing List to obtain information on uses, exposures, environmental releases, pharmacokinetics, subchronic toxicity, mutagenicity, reproductive and developmental effects, carcinogenicity, and ecological effects. At this time, the ITC is requesting that EPA not promulgate TSCA section 8(a) PAIR and section 8(d) HaSD reporting rules for these chemicals in order to allow chloroalkenes producers, importers, processors, and users an opportunity to voluntarily provide the requested information.

2. Rationales for recommendation. Two chloroalkenes are believed to be produced in substantial amounts and are predicted to persist and bioconcentrate in the environment. The third chloroalkene is a likely hydrolysis product of one of the other chloroakenes. All three chemicals present suspicion of toxicity based either on mutagenicity data or shared structural similarities with hexachloro-1,3-butadiene.

3. Supporting information. Chloroalkenes under review include 4 chemicals: Hexachloro-1,3-butadiene (CAS No. 87-68-3); 1,3-butadiene, 1,1,2,3,4-pentachloro-4-(1methylethoxy)- (CAS No. 68334-67-8); 3-butenoic acid, 2,2,3,4,4-pentachlorobutyl ester (CAS No. 75147-20-9); and 2,2,3,4,4-pentachloro-3-butanoic acid (CAS No. 85743-61-9). All except the 2,2,3,4,4-pentachloro-3-butenoic acid meet the DEBITS criteria and have BCFs >250. However, 2,2,3,4,4-pentachloro-3butenoic acid is a hydrolysis product of 3-butenoic acid, 2,2,3,4,4-pentachlorobutyl ester. The ITC is not soliciting information on hexachloro-1,3butadiene because data are being developed under the Organization for Economic Cooperation and Development (OECD) Screening Information Data Set (SIDS) program (http://www.oecd.org//ehs/guide/sd97-1.htm). Hexachloro-1,3-butadiene was included to provide opportunities to develop Structure Activity Relationships (SARs).

1,3-Butadiene, 1,1,2,3,4-pentachloro-4-(1-methylethoxy)- meets the DEBITS criteria of ultimate predicted aerobic biodegradation rate of > 2-3 months and estimated log octanol-water partition coefficient (log P) ranging from 3 to 6. 1,3-Butadiene, 1,1,2,3,4-pentachloro-4-(1-methylethoxy)- is a MPV chemical with a log P of 5.14 and estimated BCF of 509. The only health effects data for 1,3-butadiene, 1,1,2,3,4-pentachloro-4-(1-methylethoxy)- were from acute toxicity tests in rats that estimated the LD<sub>50</sub> to be 1,210 mg/kilogram (kg) body weight (Mallinckrodt, 1978a). No ecological effects data were obtained for this chemical. 1,3-Butadiene, 1,1,2,3,4pentachloro-4-(1-methylethoxy)- is structurally similar to hexachloro-1,3butadiene and, therefore, may share some common metabolic pathways and related toxicities. Hexachloro-1,3butadiene is known to be metabolically converted by glutathione S-transferase to the glutathione conjugate, and then to a cysteine sulfoxide, which is cytotoxic to the kidney proximal tubular cells. This metabolic activation is believed to be responsible for the nephrotoxicity associated with the chemical.

3-Butenoic acid, 2,2,3,4,4pentachloro- butyl ester is another MPV chemical with BCF>250. It has an estimated log P of 4.42, and an estimated BCF of 1797. There are no ecological effects data for 3-butenoic acid, 2,2,3,4,4-pentachloro- butyl ester. Acute toxicity and genotoxicity studies were available for the chemical. The rat oral LD<sub>50</sub> value was 2.09 gram (g)/kg body weight (Mallinckrodt, 1978b). Negative results were obtained in a reverse mutation assay using Salmonella typhimurium (TA-1535, TA-1537, TA-1538, TA-98, and TA-100) and Saccharomyces cerevisiae (D4) with or without metabolic activation (Mallinckrodt, 1984a). There was no significant increase in 6-thioguanine resistant mutation frequency in Chinese hamster ovary cells with or without metabolic activation (Mallinckrodt, 1984c). There was a positive response in an Escherichia coli microsuspension assay for DNA damage and in the frequency of sister chromatid exchange and chromosomal aberrations from Chinese hamster ovary cells (Mallinckrodt, 1984b,d,e).

3-Butenoic acid, 2,2,3,4,4pentachloro-butyl ester is likely hydrolyzed to 2,2,3,4,4-pentachloro-3butenoic acid. The latter chemical has a predicted aerobic biodegradation rate of > 2-3 months, an estimated log P of 3.38, an estimated BCF of 3, but its production volume is less than 10,000 pounds per annum. Like its butyl ester. 2,2,3,4,4-pentachloro-3-butenoic acid has some genotoxic activity. It caused reverse mutation in Salmonella *typhimurium* strain TA100 both with and without metabolic activation (Reichert et al. 1984) and induced both unscheduled DNA synthesis (with and without activation) and morphological transformation in Syrian hamster embryo fibroblasts (Schiffmann et al. 1984). 3-Butenoic acid, 2,2,3,4,4pentachloro-butyl ester presents a suspicion of toxicity based on existing data and its metabolic relationship and structural similarity to 2,2,3,4,4pentachloro-3-butenoic acid.

Information Profiles for 1,3-butadiene, 1,1,2,3,4-pentachloro-4-(1methylethoxy)-, 3-butenoic acid, 2,2,3,4,4-pentachloro-butyl ester and 2,2,3,4,4-pentachloro-3-butenoic acid will be available on the ITC's web site (http://www.epa.gov/opptintr/itc). 4. Information needs. The ITC needs

information on uses, exposures, environmental releases, pharmacokinetics, subchronic toxicity, mutagenicity, reproductive and developmental effects, carcinogenicity, and ecological effects for 1,3-butadiene, 1,1,2,3,4-pentachloro-4-(1methylethoxy)-; 3-butenoic acid, 2,2,3,4,4-pentachloro- and 3-butenoic acid, 2,2,3,4,4-pentachloro-butyl ester. In addition, the ITC needs hydrolysis rate data for 3-butenoic acid, 2,2,3,4,4pentachloro-butyl ester. If the information is not voluntarily submitted in accordance with VISP, the ITC will ask EPA to promulgate TSCA section 8(a) PAIR and section 8(d) HaSD reporting rules in a subsequent Report.

# C. Polychlorophenols and Polychlorobenzenethiols

1. *Recommendation*. Pentachlorothiophenol (CAS No. 133– 49–3) and tetrachloropyrocatechol (CAS No. 1198–55–6) are being added to the *Priority Testing List* so that final TSCA section 8(a) and 8(d) rules will be promulgated by the EPA.

2. *Rationale for recommendation*. Information solicited in the 46<sup>th</sup> Report for pentachlorothiophenol and tetrachloropyrocatechol was not provided to the ITC.

3. Supporting information. Pentachlorothiophenol and tetrachloropyrocatechol meet the

DEBITS criteria for persistence and bioconcentration. Pentachlorothiophenol has an estimated BCF of 7066. Tetrachloropyrocatechol's measured BCF ranges from 316-5011. There are no publicly available ecological effects and limited health effects data for pentachlorothiophenol. Tetrachloropyrocatechol has been shown to be highly toxic to fish but little is known about health effects in mammalian species. Pentachlorothiophenol and tetrachloropyrocatechol are metabolites of pentachlorophenol. Pentachlorothiophenol has also been detected in the urine of human populations exposed to hexachlorobenzene. The carcinogenicity, reproductive effects and developmental toxicities of hexachlorobenzene and pentachlorophenol are well known. The ITC believes that pentachlorothiophenol and tetrachloropyrocatechol present a suspicion of toxicity given the metabolic relationship and structural similarity to hexachlorobenzene and pentachlorophenol. Detailed information supporting the addition of pentachlorothiophenol and tetrachloropyrocatechol to the Priority Testing List was provided in the ITC's 46<sup>th</sup> Report.

4. Information needs. The ITC needs information on uses and data on exposures, environmental releases, pharmacokinetics, subchronic toxicity, reproductive and developmental effects, carcinogenicity, and ecological effects for pentachlorothiophenol and tetrachloropyrocatechol. The ITC also needs mutagenicity data for pentachlorothiophenol. Manufacturers, processors, and users of these chemicals are encouraged to provide importation, production, use, exposure, and health effects information using the TSCA Electronic HaSD Reporting Form (http:/ /www.epa.gov/opptintr/.er/hasd.htm).

# D. Chlorotrifluoromethylphenoxy Benzenes

1. *Recommendation. p*-Toluidine, 5chloro- .alpha.,.alpha.,.alpha.-trifluoro-2-nitro-*N*-phenyl (CAS No. 1806–24–2) and benzoic acid, 3-[2-chloro-4-(trifluoromethyl)phenoxy]-, 2-ethoxy-1methyl-2-oxo (CAS No. 88185–2–2) are being added to the *Priority Testing List* so that final TSCA section 8(a) and 8(d) rules will be promulgated by the EPA.

2. Rationale for recommendation. Information solicited in the 46<sup>th</sup> Report for *p*-toluidine, 5-chloro-.alpha.,.alpha.,.alpha.-trifluoro-2-nitro-*N*-phenyl and benzoic acid, 3-[2-chloro-4-(trifluoromethyl)phenoxy]-, 2-ethoxy1-methyl-2-oxo was not provided to the ITC.

3. Supporting information. Eight chlorotrifluoromethylphenoxy benzenes were listed in the ITC's 46<sup>th</sup> Report. All were estimated to persist and seven had estimated BCFs > 250. Six chlorotrifluoromethylphenoxy benzenes were highly toxic to fish. One member of this class, Lactofen is a well-studied herbicide, considered by the U.S. EPA to be a probable human carcinogen. As a result of the oncogenicity and other adverse health effects associated with Lactofen, there is a heightened concern for potential toxicity of the other chlorotrifluoromethylphenoxy benzenes which have not been extensively investigated. Information was solicited for 4 of 8 chlorotrifluoromethylphenoxy benzenes listed in the ITC's 46<sup>th</sup> Report. Lactofen and three HPV chemicals were not included in the solicitation.

In response to the solicitation, the ITC learned that one of these chemicals, phenol, 5-(2-chloro-4-(trifluoromethyl)phenoxy)-2-nitro- (CAS No. 42874-63-5) is a process intermediate that is not isolated from storage nor packaged for distribution in commerce. Another chlorotrifluoromethylphenoxy benzene for which information was solicited, benzene, 2-chloro-1-(3-methylphenoxy)-4-(trifluoromethyl)- (CAS No. 42874-96-4) was previously added to a TSCA section 8(d) HaSD reporting rule as a result of its addition to the Priority Testing List in the ITC's 29th Report (56 FR 67424, December 30, 1991). Since it is already included in a TSCA section 8(d) HaSD reporting rule (47 FR 38780, October 4, 1982) and the reporting period is 10 years in length, benzene, 2chloro-1-(3- methylphenoxy)-4-(trifluoromethyl)- does not have to be added to the Priority Testing List to facilitate that action. The other two chlorotrifluoromethylphenoxy benzenes, *p*-toluidine, 5-chloro-.alpha.,.alpha.,.alpha.-trifluoro-2-nitro-N-phenyl and benzoic acid, 3-[2-chloro-4-(trifluoromethyl)phenoxy]-, 2-ethoxy-1-methyl-2-oxo are being added to the Priority Testing List, because no information was submitted in response to the 46<sup>th</sup> Report solicitation. Detailed information supporting the addition of p-toluidine, 5-chloro-.alpha.,.alpha.,.alpha.-trifluoro-2-nitro-N-phenyl and benzoic acid, 3-[2-chloro-4-(trifluoromethyl)phenoxy]-, 2-ethoxy-

4-(trifluoromethyl)phenoxy]-, 2-ethoxy-1- methyl-2-oxo to the *Priority Testing List* was provided in the ITC's 46<sup>th</sup> Report.

4. *Information needs*. The ITC needs information on uses, exposures, environmental releases, ecological effects, pharmacokinetics, subchronic toxicity, reproductive and developmental effects, mutagenicity, and carcinogenicity for *p*-toluidine, 5chloro-.alpha.,.alpha.,.alpha.-trifluoro-2nitro-*N*-phenyl and benzoic acid, 3-[2chloro-4-(trifluoromethyl)phenoxy]-, 2ethoxy-1-methyl-2-oxo.

# V. References

1. Mallinckrodt Inc. 1978a. Initial Submission: Acute oral toxicity ( $LD_{50}$ ) test in rats (Final Report) with cover letter dated 02/27/92; 10/13/78; EPA Doc. No. 88–920001282; Microfiche No. OTS0535871.

2. Mallinckrodt Inc. 1978b. Initial Submission: Letter submitting one enclosed acute toxicity series study with cover letter dated 02/27/92. EPA Doc. No. 88–920001280; Microfiche No. OTS0535869.

3. Mallinckrodt Inc. 1984a. Mutagenicity evaluation of M-388-48A in the Ames Salmonella/microsome plate test with cover letter dated 12/28/ 84; 03/01/78; EPA Doc. No. FYI-OTS– 0185–0376; Microfiche No. OTS0000376–0.

4. Mallinckrodt Inc. 1984b. Escherichia coli microsuspension assay for DNA damage with compound M276; 02/23/84; EPA Doc. No. FYI-OTS-0185– 0376; Microfiche No. OTS0000376–0.

5. Mallinckrodt Inc. 1984c. CHO/ HGPRT forward mutation assay M276; 02/23/84; EPA Doc. No. FYI-OTS-0185– 0376; Microfiche No. OTS0000376–0.

6. Mallinckrodt Inc. 1984d. *In vitro* sister chromatid exchange in Chinese hamster ovary cells with M276; 07/13/84; EPA Doc. No. FYI-OTS-0185–0376; Microfiche No. OTS0000376–0.

7. Mallinckrodt Inc. 1984e. *In vitro* chromosomal aberrations in Chinese

hamster ovary cells with M276; 12/19/ 84; EPA Doc. No. FYI-OTS-0185–0376; Microfiche No. OTS0000376–0.

8. Reichert D, Neudecker T, Schèutz S. 1984. Mutagenicity of hexachlorobutadiene, perchlorobutenoic acid and perchlorobutenoic acid chloride. *Mutation Research*. 137:89–94.

9. Schiffmann D, Reichert D, Henschler D. 1984. Induction of morphological transformation and unscheduled DNA synthesis in Syrian hamster embryo fibroblasts by hexachlorobutadiene and its putative metabolite pentachlorobutenoic acid. *Cancer Letters*. 23:297–306.

## VI. TSCA Interagency Testing Committee

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