

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2007-1124; FRL-8347-1]

Sixty-First Report of the TSCA Interagency Testing Committee to the Administrator of the Environmental Protection Agency; 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 61st ITC Report to the Administrator of EPA on December 18, 2007. In the 61st ITC Report, which is included with this notice, the ITC is revising the TSCA section 4(e) *Priority Testing List* by adding 4 cresols and removing 35 High Production Volume (HPV) Challenge Program orphan chemicals. The cresols were added to obtain dermal sensitization data. To obtain dermal sensitization data, including case reports of workers and any *in vivo* animal sensitization test data, the ITC is asking EPA to add the 4 cresols to the TSCA section 8(d) Health and Safety Data Reporting (HaSDR) rule. The 35 HPV Challenge Program orphan chemicals are being removed from the *Priority Testing List* either because: Commitments were made to sponsor these chemicals under the EPA's HPV Challenge Program, the Organization for Economic Cooperation and Development (OECD) HPV Screening Information Data Set (SIDS) Program, and/or the International Council of Chemical Associations (ICCA) HPV Initiative, or because the substances were determined by EPA to be "no longer" HPV chemical substances.

DATES: Comments must be received on or before February 27, 2008.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2007-1124, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA-HQ-OPPT-2007-1124. 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) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2007-1124. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or e-mail. The [regulations.gov](http://www.regulations.gov) website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

Docket: All documents in the docket are listed in the docket index available in [regulations.gov](http://www.regulations.gov). To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the [regulations.gov](http://www.regulations.gov) website to view the docket index or access available documents. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only

available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: TSCA-Hotline@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 TSCA-covered 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 person listed under **FOR FURTHER INFORMATION CONTACT**.

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

1. *Submitting CBI.* Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In

addition to one complete version of the comment that includes 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 docket.

Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

The Toxic Substances Control Act (TSCA) (15 U.S.C. 2601 *et seq.*) authorizes the Administrator of 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 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.

You may access additional information about the ITC at <http://www.epa.gov/opptintr/itc>.

A. The 61st ITC Report

The ITC is revising the TSCA section 4(e) *Priority Testing List* by adding 4 cresols and removing 35 HPV Challenge Program orphan chemicals. The cresols were added to obtain dermal sensitization data. To obtain dermal sensitization data, including case reports of workers and any *in vivo* animal sensitization test data, the ITC is asking EPA to add the 4 cresols to the HaSDR rule. The 35 HPV Challenge Program orphan chemicals are being removed from the *Priority Testing List* either because:

1. Commitments were made to sponsor these chemicals under the EPA's HPV Challenge Program, the OECD HPV SIDS Program, and/or the ICCA HPV Initiative, or

2. Because the substances were determined by EPA to be "no longer" HPV chemical substances.

B. Status of the Priority Testing List

The *Priority Testing List* includes 2 alkylphenols, 4 cresols, 5 tungsten compounds, 12 lead compounds, 16 chemicals with insufficient dermal absorption rate data, and 208 HPV Challenge Program orphan chemicals.

List of Subjects

Environmental protection, Chemicals, Hazardous substances.

Dated: January 18, 2008.

Charles M. Auer,

Director, Office of Pollution Prevention and Toxics.

Sixty-First Report of the TSCA Interagency Testing Committee to the Administrator, U.S. Environmental Protection Agency

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Summary

The ITC is revising the Toxic Substances Control Act (TSCA) section 4(e) *Priority Testing List* by adding 4 cresols and removing 35 High Production Volume (HPV) Challenge Program orphan chemicals. The cresols were added to obtain dermal sensitization data. To obtain dermal sensitization data, including case reports of workers and any *in vivo* animal sensitization test data, the ITC is asking EPA to add the 4 cresols to the TSCA section 8(d) Health and Safety Data Reporting (HaSDR) rule. The 35 HPV Challenge Program orphan chemicals are being removed from the *Priority Testing List* either because:

1. Commitments were made to sponsor these chemicals under the EPA's HPV Challenge Program, the Organization for Economic Cooperation and Development (OECD) HPV Screening Information Data Set (SIDS) Program, and/or the International Council of Chemical Associations (ICCA) HPV Initiative, or

2. Because the substances were determined by EPA to be "no longer" HPV chemical substances.

TABLE 1.—TSCA SECTION 4(E) PRIORITY TESTING LIST (NOVEMBER 2007)

ITC Report	Date	Chemical Name/Group	Action
31	January 1993	2 Chemicals with insufficient dermal absorption rate data	Designated
32	May 1993	10 Chemicals with insufficient dermal absorption rate data	Designated
35	November 1994	4 Chemicals with insufficient dermal absorption rate data	Designated
37	November 1995	Branched 4-nonylphenol (mixed isomers)	Recommended
41	November 1997	Phenol, 4-(1,1,3,3-tetramethylbutyl)-	Recommended

TABLE 1.—TSCA SECTION 4(E) PRIORITY TESTING LIST (NOVEMBER 2007)—Continued

ITC Report	Date	Chemical Name/Group	Action
53	November 2003	5 Tungsten compounds	Recommended
55	December 2004	204 HPV Challenge Program orphan chemicals	Recommended
56	August 2005	4 HPV Challenge Program orphan chemicals	Recommended
60	May 2007	Category of Lead and lead compounds (including 12 examples of substances in the category)	Recommended
61	November 2007	4 Cresols	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 rules 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.*). ITC reports are available from the ITC’s website (<http://www.epa.gov/opptintr/itc>) within a few days of submission to the EPA Administrator and from the EPA’s website (<http://www.epa.gov/fedrgstr>) after publication in the **Federal Register**. The ITC 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 Reporting 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) may add the chemicals from the revised *Priority Testing List* to the TSCA section 8(a) Preliminary Assessment Information Reporting (PAIR) or TSCA section 8(d) HaSDR rules. As provided for in the PAIR rule, whenever EPA announces the receipt of an ITC report, EPA amends, unless otherwise instructed by the ITC, the PAIR rule by

adding the recommended (or designated) chemicals that have been added to the *Priority Testing List* by the ITC. The PAIR rule requires manufacturers (including importers) of chemicals added to the *Priority Testing List* to submit to EPA certain production and exposure information (<http://www.epa.gov/oppt/chemtest/pubs/pairform.pdf>). The HaSDR rule requires certain past, current, and proposed manufacturers, importers, and (if specified by EPA) processors of listed chemicals to submit to EPA copies and lists of unpublished health and safety studies on the listed chemicals that they manufacture, import, or (if specified by EPA) process. As provided for in the HaSDR rule, whenever EPA announces the receipt of an ITC report, EPA amends, unless otherwise instructed by the ITC, the HaSDR rule by adding the recommended (or designated) chemicals that have been added to the *Priority Testing List* by the ITC.

B. ITC’s Use of TSCA Section 8 and Other Information

The ITC’s use of TSCA section 8 and other information is described in the 52nd ITC Report (Ref. 1).

C. New Request to Add Chemicals to the TSCA Section 8(d) HaSDR Rule

The ITC is requesting that EPA add cresols to the HaSDR rule only to obtain dermal sensitization data, including case reports of workers and any *in vivo* animal sensitization test data. The ITC is requesting that EPA not add cresols to the PAIR rule. The cresols are discussed in Unit IV. of this report.

III. ITC’s Activities During this Reporting Period (June to November 2007)

During this reporting period, the ITC discussed cresols.

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

A. Chemicals Added to the Priority Testing List

The ITC is adding the cresols listed in Table 2 of this unit to the *Priority Testing List* to obtain unpublished data on dermal sensitization, including case reports of workers and any *in vivo* animal sensitization test data.

TABLE 2.—CRESOLS BEING ADDED TO THE PRIORITY TESTING LIST

CAS No.	Cresol
95–48–7	Phenol, 2-methyl-
106–44–5	Phenol, 4-methyl-
108–39–4	Phenol, 3-methyl-
1319–77–3	Phenol, methyl-

The ITC is aware of the skin sensitization data for phenol, 4-methyl- (*p*-cresol) available at <http://www.oecd.org/dataoecd/17/29/34357669.pdf>. While these data indicate that phenol, 4-methyl- did not cause skin sensitization, data on a mixture containing 0.6% phenol, 4-methyl- did indicate that the mixture caused skin sensitization (Ref. 2).

B. Chemicals Removed from the Priority Testing List

The ITC is removing the 35 HPV Challenge Program orphan chemicals listed in Table 3 of this unit from the *Priority Testing List*.

TABLE 3.—HPV CHALLENGE PROGRAM ORPHAN CHEMICALS BEING REMOVED FROM THE PRIORITY TESTING LIST

CAS No.	Chemical Name	Reference No.
74–97–5	Methane, bromochloro-	3

TABLE 3.—HPV CHALLENGE PROGRAM ORPHAN CHEMICALS BEING REMOVED FROM THE PRIORITY TESTING LIST—
Continued

CAS No.	Chemical Name	Reference No.
75-46-7	Methane, trifluoro-	3
77-86-1	1,3-Propanediol, 2-amino-2-(hydroxymethyl)-	3
99-51-4	Benzene, 1,2-dimethyl-4-nitro-	3
100-64-1	Cyclohexanone, oxime	3
107-45-9	2-Pentanamine, 2,4,4-trimethyl-	3
150-50-5	Phosphorotrithious acid, tributyl ester	4
579-66-8	Benzenamine, 2,6-diethyl-	3
693-07-2	Ethane, 1-chloro-2-(ethylthio)-	3
1115-20-4	Propanoic acid, 3-hydroxy-2,2-dimethyl-, 3-hydroxy-2,2-dimethylpropyl ester	3
1459-93-4	1,3-Benzenedicarboxylic acid, 1,3-dimethyl ester	3
1558-33-4	Silane, dichloro(chloromethyl)methyl-	3
2611-00-9	3-Cyclohexene-1-carboxylic acid, 3-cyclohexen-1-ylmethyl ester	3
3088-31-1	Ethanol, 2-[2-(dodecyloxy)ethoxy]-, 1-(hydrogen sulfate), sodium salt (1:1)	3
3338-24-7	Phosphorodithioic acid, O,O-diethyl ester, sodium salt (1:1)	4
3710-84-7	Ethanamine, N-ethyl-N-hydroxy-	3
6863-58-7	Butane, 2,2'-oxybis-	3
6865-35-6	Octadecanoic acid, barium salt (2:1)	3
7320-37-8	Oxirane, 2-tetradecyl-	3
14666-94-5	9-Octadecenoic acid (9Z)-, cobalt salt (1:?)	3
20469-71-0	Hydrazinecarbodithioic acid, compd. with hydrazine (1:1)	3
28777-98-2	2,5-Furandione, dihydro-3-(octadecenyl)-	3
32072-96-1	2,5-Furandione, 3-(hexadecenyl)dihydro-	3
33509-43-2	1,2,4-Triazin-5(2H)-one, 4-amino-6-(1,1-dimethylethyl)-3,4-dihydro-3-thioxo-	3
61789-32-0	Fatty acids, coco, 2-sulfoethyl esters, sodium salts	3
65996-80-7	Ammonia liquor (coal)	3
65996-81-8	Fuel gases, coke-oven	3
66071-94-1	Corn, steep liquor	3
68476-80-2	Fats and Glyceridic oils, vegetable, deodorizer distillates	3
68478-20-6	Residues, (petroleum), steam-cracked petroleum distillates cyclopentadiene conc., C4-cyclopentadiene-free	3
68514-41-0	Ketones, C12-branched	3
68603-84-9	Carboxylic acids, C5-9	3
68937-70-2	Carboxylic acids, C6-18 and C8-15-di-	3
68937-72-4	Carboxylic acids, di-, C4-11	3
72162-28-8	2-Propanone, reaction products with phenol	3

Twenty-six of the HPV Challenge Program orphan chemicals are being removed from the *Priority Testing List* because commitments were made to sponsor 22 chemicals in the HPV Challenge Program and 4 chemicals in either the OECD SIDS Program or the ICCA HPV Initiative (Ref. 3). Seven chemicals are being removed from the *Priority Testing List* because EPA no longer considers them to be HPV chemical substances (Ref. 3). Two of the HPV Challenge Program orphan chemicals are being removed from the *Priority Testing List* because they were incorrectly listed as HPV Challenge Program orphan chemicals (Ref. 4). Thirty-four of the HPV Challenge Program orphan chemicals are being removed from the 55th ITC Report (Ref. 5). One HPV Challenge Program orphan chemical, 1,3-propanediol, 2-amino-2-(hydroxymethyl)-, is being removed from the 56th ITC Report (Ref. 6).

V. References

1. ITC. Fifty-Second Report of the ITC. **Federal Register** (68 FR 43607, July 23, 2003) (FRL-7314-4). Available on-line at: <http://www.epa.gov/fedrgstr>.

2. Ciba-Geigy Limited. 1987. Initial submission: Tinuvin P step 1 wet cake: skin sensitization test in guinea pigs (final report) with cover letter dated 07-15-92. Document Control Number 88-920004379.

3. EPA. Withdrawal of Certain Chemicals from Preliminary Assessment Information Reporting and Health and Safety Data Reporting Rules. **Federal Register** (71 FR 57439, September 29, 2006) (FRL-8096-5). Available on-line at: <http://www.epa.gov/fedrgstr>.

4. EPA. Removal of Two Chemical Substances from Preliminary Assessment Information Reporting and

Health and Safety Data Reporting Rules. **Federal Register** (72 FR 21119, April 30, 2007) (FRL-8124-9). Available on-line at: <http://www.epa.gov/fedrgstr>.

5. ITC. Fifty-Fifth Report of the ITC. **Federal Register** (70 FR 7364, February 11, 2005) (FRL-7692-1). Available on-line at: <http://www.epa.gov/fedrgstr>.

6. ITC. Fifty-Sixth Report of the ITC. **Federal Register** (70 FR 61520, October 24, 2005) (FRL-7739-9). Available on-line at: <http://www.epa.gov/fedrgstr>.

VI. The TSCA Interagency Testing Committee

Statutory Organizations and Their Representatives

Council on Environmental Quality
Vacant

Department of Commerce

National Institute of Standards and Technology
Dianne Poster, Member, Chair

National Oceanographic and Atmospheric Administration
Tony Pait, Member

Environmental Protection Agency
John Schaeffer, Member
Gerry Brown, Alternate

National Cancer Institute
Vacant

National Institute of Environmental Health Sciences
Scott Masten, Alternate

National Institute for Occupational Safety and Health
Dennis W. Lynch, Member, Vice Chair
Mark Toraason, Alternate

National Science Foundation
Judy Raper, Member

Marge Cavanaugh, Alternate

Occupational Safety and Health Administration
Maureen Ruskin, Member
Thomas Nerad, Alternate

Liaison Organizations and Their Representatives

Agency for Toxic Substances and Disease Registry
Daphne Moffett, Member
Glenn D. Todd, Alternate

Consumer Product Safety Commission
Jacqueline Ferrante, Member

Department of Agriculture
Clifford P. Rice, Member
Laura L. McConnell, Alternate

Department of Defense
Laurie Roszell, Member

Department of the Interior
Barnett A. Rattner, Member

Food and Drug Administration
Kirk Arvidson, Alternate
Ronald F. Chanderbhan, Alternate

Technical Support Contractor
Syracuse Research Corporation

ITC Staff

John D. Walker, Director
Carol Savage, Administrative Assistant

TSCA Interagency Testing Committee (7401M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; e-mail address: savage.carol@epa.gov; url: <http://www.epa.gov/opptintr/itc>.

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