

ENVIRONMENTAL PROTECTION AGENCY
[EPA-HQ-OPPT-2008-0309; FRL-8363-2]
Sixty-Second 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 sixty-second report to the Administrator of EPA on April 17, 2008. In the 62nd ITC Report, which is included with this notice, the ITC is revising the TSCA section 4(e) *Priority Testing List* by removing four tungsten compounds and four cresols.

DATES: Comments must be received on or before June 11, 2008.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2008-0309, 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-2008-0309. 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-2008-0309. 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 62nd ITC Report

The ITC is revising the TSCA section 4(e) *Priority Testing List* by removing four tungsten compounds and four cresols.

B. Status of the Priority Testing List

The *Priority Testing List* includes 2 alkylphenols, 1 tungsten compound, 12 lead compounds, 16 chemicals with insufficient dermal absorption rate data, and 208 High Production Volume (HPV) Challenge Program orphan chemicals.

List of Subjects

Environmental protection, Chemicals, Hazardous substances.

Dated: May 5, 2008.

Charles M. Auer,

Director, Office of Pollution Prevention and Toxics.

Sixty-Second Report of the TSCA Interagency Testing Committee to the Administrator of the 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 removing four tungsten compounds and four cresols. The TSCA section 4(e) *Priority Testing List* is Table 1 of this unit.

TABLE 1.—TSCA SECTION 4(E) PRIORITY TESTING LIST (MAY 2008)

| 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 |
| 53 | November 2003 | Sodium tungstate (Na ₂ (WO ₄)), dihydrate | Recommended |
| 55 | December 2004 | 204 High Production Volume (HPV) Challenge Program orphan chemicals | Recommended |
| 56 | August 2005 | 4 HPV Challenge Program orphan chemicals | Recommended |
| 60 | May 2007 | 12 Lead and lead compounds | 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

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, 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) Health and Safety Data Reporting (HaSDR) rules. 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>). 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 HaSDR rule requires certain past, current, and proposed manufacturers, 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 (<http://www.epa.gov/opptintr/itc>).

III. ITC's Activities During this Reporting Period (December 2007 to May 2008)

During this reporting period, the ITC discussed tungsten compounds and cresols.

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

A. Tungsten Compounds

Of the 22 tungsten compounds added to the *Priority Testing List* in the 53rd ITC Report (Ref. 1) and the 56th ITC

Report (Ref. 2), 12 were removed in the 58th ITC Report (Ref. 3), and 5 were removed in the 59th ITC Report (Ref. 4). At this time the ITC is removing 4 tungsten compounds from the *Priority Testing List* (see Table 2 of this unit).

TABLE 2.—TUNGSTEN COMPOUNDS BEING REMOVED FROM THE PRIORITY TESTING LIST

| CAS No. | Chemical Name |
|------------|--|
| 1314-35-8 | Tungsten oxide (WO ₃) |
| 7440-33-7 | Tungsten |
| 11120-25-5 | Tungstate (W ₁₂ (OH) ₂ O ₄₀ ¹⁰⁻), ammonium (1:10) |
| 13472-45-2 | Tungstate (WO ₄ ²⁻), sodium (1:2), (T-4)- |

Prior to removing these 4 tungsten compounds, the PAIR reports submitted in response to the December 7, 2004, PAIR rule (Ref. 5) were reviewed. The ITC is removing tungstate (W₁₂(OH)₂O₄₀¹⁰⁻), ammonium (1:10) and tungstate (WO₄²⁻), sodium (1:2), (T-4)- because the data submitted in response to the December 7, 2004 PAIR rule suggested low potential for occupational exposure. The ITC is removing tungsten from the *Priority Testing List* because the toxicological profile for tungsten (<http://www.atsdr.cdc.gov/toxprofiles/tp186.html>) summarizes the health effects information. The ITC is removing tungsten oxide (WO₃), a.k.a. tungsten trioxide because of the voluntary information provided by the International Tungsten Industry Association and their cooperation in a National Toxicology Program/National Institute for Occupational Safety and Health research program to address exposure and toxicity data needs. The ITC is retaining tungstate (WO₄²⁻), disodium, dihydrate, (T-4)-, a.k.a. sodium tungstate (Na₂(WO₄)), dihydrate (CAS No. 10213-10-2), on the *Priority Testing List* because of ongoing discussions with the International Tungsten Industry Association to obtain:

1. Recent non-Confidential Business Information estimates of annual production or importation volume data and trends, and chemical-specific use information, including percentages of production or importation that are associated with different uses.

2. Estimates of the number of exposed humans and concentrations of sodium tungstate, dihydrate to which humans may be exposed in each relevant manufacturing, processing, or other occupational scenario.

3. Case studies from occupationally exposed workers and pharmacokinetics, dermal, inhalation, as well as any oral acute toxicity, subchronic toxicity, chronic toxicity, genotoxicity, carcinogenicity, neurotoxicity, reproductive and developmental toxicity, and epidemiology studies.

B. Cresols

Cresols were added to the *Priority Testing List* in the 61st ITC Report to obtain unpublished data on dermal sensitization (Ref. 6). The four cresols are listed in Table 3 of this unit.

TABLE 3.—CRESOLS BEING REMOVED FROM THE PRIORITY TESTING LIST

| CAS No. | TSCA Inventory Name | Common Name |
|-----------|---------------------|------------------|
| 95-48-7 | Phenol, 2-methyl- | <i>o</i> -Cresol |
| 106-44-5 | Phenol, 4-methyl- | <i>p</i> -Cresol |
| 108-39-4 | Phenol, 3-methyl- | <i>m</i> -Cresol |
| 1319-77-3 | Phenol, methyl- | Mixed Cresols |

In response to the 61st ITC Report, the Cresols Panel of the American Chemistry Council (ACC) submitted a February 27, 2008 letter to EPA's Office of Pollution Prevention and Toxics Document Control Office (Ref. 7). The Cresols Panel also submitted several references which are summarized in this unit. In a 1972 report to the Research Institute for Fragrance Materials, Kligman performed a maximization test on 25 volunteers and determined that *p*-cresol at 4% concentration in petrolatum produced no sensitization reactions (Ref. 8). In a 1980 report to the Research Institute for Fragrance Materials, Kligman performed a maximization test on 25 volunteers and determined that *o*-cresol at 4% concentration in petrolatum produced no sensitization reactions (Ref. 9).

In later reports, Bruze (1986) showed that guinea pigs sensitized with 2-methylolphenol (CAS No. 623-05-2) or 4-methylolphenol (CAS No. 90-01-7) and challenged with *o*-cresol or *p*-cresol following a guinea pig maximization test protocol react positively at re-challenge with both *o*- and *p*-cresol (Ref. 10). Bruze and Zimerson (1997) challenged patients with known contact allergy to phenol-formaldehyde resin and methylol phenol to *o*-cresol and *p*-cresol and found that 4 of 10 patients were sensitive to *o*-cresol, and 1 of 2 patients were sensitive to *p*-cresol (Ref.

11). Bruze and Zimerson (2002) established a dose-response relationship to cresol sensitization (Ref. 12). Seidenari et al. (1991) patch-tested adult patients that were sensitized to textile dyes for reaction to *m*-cresol and found that there were positive effects in 2 of 81 patients tested with 2% *m*-cresol (Ref. 13). These findings were summarized in the 2006 Cosmetic Ingredient Review (Ref. 14). At this time there do not appear to be any dermal sensitization studies with mixed cresols.

After reviewing the studies submitted by the Cresols Panel, it was determined that the information contained in this voluntary submission met the data needs. As a result, the ITC is removing *o*-cresol, *p*-cresol, *m*-cresol and mixed cresols from the *Priority Testing List*.

V. References

1. ITC. Fifty-Third Report of the ITC. **Federal Register** (69 FR 2468, January 15, 2004) (FRL-7335-2). Available on-line at: <http://www.epa.gov/fedrgstr>.
2. 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>.
3. ITC. Fifty-Eighth Report of the ITC. **Federal Register** (71 FR 39188, July 11, 2006) (FRL-8073-7). Available on-line at: <http://www.epa.gov/fedrgstr>.
4. ITC. Fifty-Ninth Report of the ITC. **Federal Register** (72 FR 2756, January 22, 2007) (FRL-8110-2). Available on-line at: <http://www.epa.gov/fedrgstr>.
5. EPA. Preliminary Assessment Information Reporting; Addition of Certain Chemicals. **Federal Register** (69 FR 70552, December 7, 2004) (FRL-7366-8). Available on-line at: <http://www.epa.gov/fedrgstr>.
6. ITC. Sixty-First Report of the ITC. **Federal Register** (73 FR 5080, January 28, 2008) (FRL-8347-1). Available on-line at: <http://www.epa.gov/fedrgstr>.
7. ACC. 2008. February 27, 2008 letter from the Cresols Panel of the American Chemistry Council (ACC) to EPA's Office of Pollution Prevention and Toxics Document Control Office. Docket ID Number: EPA-HQ-OPPT-2007-1124.
8. Kligman, A.M. Report to Research Institute for Fragrance Materials (RIFM). November 22, 1972. As cited in: Opdyke

D.L. J. (1974). *Food Cosmetology Toxicology*. 12: 389 and 390. Fragrance raw materials monographs. *p*-Cresol.

9. Kligman, A.M. Report to Research Institute for Fragrance Materials (RIFM). March 26, 1980.

10. Bruze, M. 1986. Sensitizing capacity of 2-methylol phenol, 4-methylol phenol, and 2,4,6-trimethylol phenol in the guinea pig. *American Journal of Contact Dermatitis*. 14: 32-38.

11. Bruze, M. and Zimerson, E. 1997. Cross-reaction patterns in patients with contact allergy to simple phenols. *American Journal of Contact Dermatitis*. 37: 82-86.

12. Bruze, M. and Zimerson, E. 2002. Contact allergy to *o*-cresol - A sensitizer in phenol-formaldehyde resin. *American Journal of Contact Dermatitis*. 13: 198-200.

13. Seidenari, S. Manzini, B.M., and Danese, P. 1991. Contact sensitization to textile dyes: description of 100 subjects. *American Journal of Contact Dermatitis*. 24: 253-258.

14. Cosmetic Ingredient Review (CIR). 2006. Final report on the safety assessment of sodium *p*-chloro-*m*-cresol, *p*-chloro-*m*-cresol, chlorothymol, mixed cresols, *m*-cresol, *o*-cresol, *p*-cresol, isopropylcresols, thymol, *o*-cymen-5-ol, and carvacrol. *International Journal of Toxicology*. 25 (Supplement 1): 29-127.

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, Chair

National Oceanographic and Atmospheric Administration
Tony Pait, Member

Environmental Protection Agency
John Schaeffer, Member
Gerry Brown, Alternate

National Cancer Institute

Vacant

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Dennis W. Lynch, Vice Chair
Mark Toraason, Alternate

National Science Foundation
Judy Raper, Member
Margaret Cavanaugh, Alternate

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