
**ENVIRONMENTAL PROTECTION
AGENCY****[OPP-2002-0324; FRL-7282-2]****Revised Final Health Effects Test
Guideline; Skin Sensitization; Notice of
Availability****AGENCY:** Environmental Protection
Agency (EPA).**ACTION:** Notice.

SUMMARY: With this notice, EPA is announcing the availability of the revised final test guideline for Series 870-Health Effects Test Guidelines, OPPTS 870.2600 Skin Sensitization. EPA has established a unified library for test guidelines issued by the Office of Prevention, Pesticides and Toxic Substances (OPPTS) for use in testing chemical substances to develop data for submission to EPA under the Toxic Substances Control Act (TSCA), the Federal Food, Drug, and Cosmetic Act (FFDCA), or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These test guidelines represent an Agency effort that began in 1991 to harmonize the test guidelines within OPPTS, as well as to harmonize the OPPTS test guidelines with those of the Organization for Economic Cooperation and Development (OECD). The process for developing and amending these test guidelines includes public participation and the extensive involvement of the scientific community, as warranted, including peer review by the Scientific Advisory Panel (SAP), the Scientific Advisory Board (SAB) and other expert scientific organizations, as well as determination of validation status by the Interagency Coordinating Committee for Validation of Alternative Methods (ICCVAM).

FOR FURTHER INFORMATION CONTACT: *For general information contact:* TSCA information contact: TSCA Hotline at TAIS/7408, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone

number: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

FIFRA information contact:

Communications Services Branch (7506C), Field and External Affairs Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5017; fax number: (703) 305-5558.

For FIFRA technical information contact: Deborah McCall, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7109 e-mail address: mccall.deborah@epa.gov.

For TSCA technical information contact: Ronald Ward, Ph.D., Risk Assessment Division (7403M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8926; e-mail address: ward.ron@epa.gov.

SUPPLEMENTARY INFORMATION:**I. Does this Action Apply to Me?**

This action is directed to the public in general. Although this action may be of particular interest to those persons who are or may be required to conduct testing of chemical substances under TSCA, FFDCA, or FIFRA, the Agency has not attempted to describe all the specific entities that may be affected by 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**.

II. How Can I Get Copies of This Document and Other Related Information?*A. Docket*

EPA has established an official public docket for this action under docket identification (ID) number OPP-2002-0324. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is

open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

B. Electronic Access

You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgrstr/>. You may also obtain copies of test guidelines from the EPA Internet Home Page at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit II.A. Once in the system, select "search," then key in the appropriate docket ID number.

III. What Action is EPA Taking?

EPA is announcing the availability of the revised final test guideline for Series 870-Health Effects Test Guideline, OPPTS 870.2600 Skin Sensitization. In 1996, the SAP reviewed the use of the Local Lymph Node Assay (LLNA) as a screening method in the Agency's harmonized test guideline OPPTS 870.2600 Skin sensitization. The LLNA is a test method for assessing the potential allergic contact dermatitis (skin sensitization) of chemicals and compounds. In January 2001, the assay was found to be scientifically valid by ICCVAM peer review (Ref. 1) as an alternative method, where applicable, to the traditional guinea pig tests (Guinea Pig Maximization Test (GPMT) (Ref. 2) and Buehler tests (Ref. 3)) which are currently accepted by regulatory authorities. This alternative test also provides animal welfare advantages. The Agency has now revised its harmonized test guideline OPPTS 870.2600 Skin Sensitization to incorporate the LLNA for use as an alternative method for assessing skin sensitization under the appropriate circumstances. The availability of the draft revised final test guideline OPPTS 870.2600 was announced in the **Federal Register** on September 12, 2001 (66 FR 47478) (FRL-6801-6). The draft revised guideline was reviewed by EPA's SAP in a public meeting on December 11,

2001, and recommendations of the SAP were incorporated into the revised test protocol. The guideline has been harmonized with OECD test guideline 429 Skin Sensitization: Local Lymph Node Assay which was adopted by OECD on April 24, 2002. It should be recognized that there are certain testing situations that may necessitate the use of traditional guinea pig tests. The LLNA may not be appropriate for all types of test materials, such as certain metallic compounds, high molecular weight proteins, strong dermal irritants and materials that do not sufficiently adhere to the ear for an acceptable period of time during treatment. When using the LLNA, particular care should be taken to ensure that hydrophilic materials are incorporated into a vehicle system that wets the skin and does not immediately run off. Thus, wholly aqueous vehicles or test materials and runny liquids are to be avoided. In all instances, the tester must document that appropriate techniques were used to facilitate adherence to the mouse ear for an adequate exposure duration. It may be possible to use the LLNA to test some of these materials if appropriate techniques are used to facilitate adherence. In situations for test materials where the LLNA is not applicable or may provide unreliable or problematic results, the GPMT tests are recommended. Although the LLNA, GPMT, or Buehler tests are considered to be acceptable tests, it is recognized that other tests may give useful results. If other tests are used, the investigator must provide justification/reasoning for use of other procedures and methods and protocols must be provided. A positive and negative control group must be included in each test.

IV. Are There Any Applicable Voluntary Consensus Standards That EPA Should Consider?

This notice of availability does not involve a proposed regulatory action that would require the Agency to consider voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Section 12(d) of NTTAA directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA requires EPA to provide an explanation to

Congress, through Office of Management and Budget (OMB), when the Agency decides not to use available and applicable voluntary consensus standards when the NTTAA directs the Agency to do so.

V. References

The following references are cited in this document.

- (1) *The Murine Local Lymph Node Assay: A Test Method for Assessing the Allergic Contact Dermatitis Potential of Chemicals/Compounds*. Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), National Institutes of Environmental Health Sciences, NIH Publication No. 99-4494 (1999). (Document available at <http://iccvam.niehs.nih.gov/methods/lnadocs/llnarep.pdf>.)
- (2) Magnusson, B. Identification of contact sensitizers by animal assay. *Contact Dermatology* 6:46 (1980).
- (3) Buehler, L.V. Occ1usive patch method for skin sensitization in guinea pigs: the Buehler method. *Food and Chemical Toxicology* 32:97101 (1994).

List of Subjects

Environmental protection, Chemical testing, Test guideline.

Dated: March 11, 2003.

Susan B. Hazen,

Acting Assistant Administrator for Prevention, Pesticides and Toxic Substances.

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