
ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0325; FRL-7282-3]

Revised Final Health Effects Test Guidelines; Acute Toxicity Testing—Background and Acute Oral Toxicity; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: 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, including peer review by the Scientific Advisory Panel (SAP), the Scientific Advisory Board (SAB) and other expert scientific organizations. Guidelines are also reviewed, when appropriate, by the Interagency Coordinating Committee for Alternative Methods (ICCVAM) for determination of validation status. With this notice, EPA is announcing the availability of the revised final test guidelines for Series 870—Health Effects Test Guidelines, OPPTS 870.1000 Acute Toxicity Testing—Background and OPPTS 870.1100 Acute Oral Toxicity.

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 on OPPTS 870.1100 contact: Elizabeth Margosches, Risk Assessment Division (7403M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-7636; e-mail address: margosches.elizabeth@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-2002-0325. 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/fedrgstr/>. 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 submit or view public comments, 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 Guidelines, OPPTS 870.1100 Acute Oral Toxicity. An improved Up-and-Down Procedure (UDP) protocol for acute oral toxicity testing was developed, by a team of regulatory and industry scientists, that is better able to provide the types of testing data needed for U.S. agencies to make regulatory decisions. The revised protocol includes a primary test, a limit test, and determination of the confidence intervals for the LD50. A software program to assist laboratory users in the conduct of the test was also developed. The revised final test guideline was reviewed by EPA’s SAP in a public meeting on December 12, 2001, which was announced in the **Federal Register** on November 15, 2001 (66 FR 57438) (FRL-6811-1), and recommendations of the SAP were incorporated into the test protocol. The ICCVAM reviewed the protocol at an open meeting on July 25, 2000, and again in a public teleconference meeting held on July 21, 2001, where changes recommended in the earlier meeting were reviewed and accepted. The improved UDP was adopted as test guideline 425 by OECD in December 2001. The UDP in this guideline is of value in reducing the number of animals required to determine the acute oral toxicity of a chemical. In addition to the estimation of LD50 and confidence

intervals, the test allows the observation of signs of toxicity. Moreover, use of OECD guidance for humane endpoints should reduce the overall suffering of animals in this type of test. The Agency strongly recommends the use of the revised UDP to meet the testing requirements for industrial chemicals and registration of pesticides. Acute oral toxicity studies using the UDP which are initiated after December 17, 2002, should be in accordance with the UDP described in this guideline. Two other alternative guidelines are available through OECD (420 Acute Oral Toxicity—Fixed Dose Method and 423 Acute Oral Toxicity—Acute Toxic Class Method). These methods assess lethality within a dose range. The Agency is also making available revised final test guideline OPPTS 870.1000 Acute Toxicity Testing—Background to reflect revision of the OPPTS 870.1100 Acute Oral Toxicity test guideline and acceptability of two other OECD alternative guidelines.

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.

List of Subjects

Environmental protection, Chemical testing, Test guideline.

Dated: December 11, 2002.

Stephen L. Johnson,
*Assistant Administrator for Prevention,
Pesticides and Toxic Substances.*

[FR Doc. 02–31612 Filed 12–12–02; 9:03 am]

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