

evaluate acceptability of oral drinking water exposure in rats for neurotoxicity testing, oral drinking water exposure in rats and mice for developmental toxicity testing, and oral drinking water exposure in rats for reproductive toxicity testing.

3. *EPA Program Review.* The use of PK/MECH data and computational dosimetry modeling to support route-to-route extrapolation is a new approach for EPA's Office of Pollution Prevention and Toxics under the TSCA section 4 chemical testing program. It is essential to the success of the TCE ECA alternative testing program for EPA to ensure that the model and the PK/MECH data used to support the route-to-route extrapolations are of the highest quality. For this reason, a Program Review requirement was incorporated into the TCE ECA.

The purpose of the EPA Program Review of the TCE ECA is to determine: (1) Whether it is feasible and appropriate to apply Tier I Program Review testing data and data from other studies acceptable to EPA to support computational route-to-route extrapolations for endpoints listed in the Tier II testing segment of the ECA; (2) whether the data from the Tier I Program Review testing segment provide a sufficient basis for conducting the endpoint testing and/or the computational route-to-route extrapolations specified in the Tier II testing segment; and (3) the nature and scope of any additional work that may be required before Tier II testing and application of the TCE model for route-to-route extrapolation reporting (e.g., development of additional PK/MECH data, modification to the TCE model).

4. *Tier II testing.* This segment of the TCE ECA alternative testing program consists of endpoint testing by oral exposure for neurotoxicity, developmental toxicity and reproductive toxicity. This segment also includes application of the TCE model for quantitative route-to-route extrapolation reporting (oral to inhalation) for Tier II endpoint testing (neurotoxicity, developmental toxicity, reproductive toxicity) and similar computational extrapolation reporting for certain extant studies for immunotoxicity (Ref. 5) and carcinogenicity (Ref. 6).

### III. Next Steps

#### *A. What is the Status of the Testing Program Developed in the ECA for TCE?*

Tier I HAPs testing for TCE is completed and reports for Tier I Program Review testing have been submitted by the Companies. Receipt of

these submissions was announced in **Federal Register** notices of April 10, 2002 (67 FR 17429) (FRL-6831-5); April 12, 2002 (67 FR 17996) (FRL-6831-4); and August 14, 2002 (67 FR 53001) (FRL-7193-1) and are available in the EPA Docket Center (OPPTS-2002-0056). As described in Unit II.C.3., and stated in Part VI. of the TCE ECA, the next step is for EPA to conduct a Program Review on the data collected from the Tier I Program Review testing segment of the TCE ECA alternative testing program. The outcome from this EPA review will determine whether or not additional PK/MECH data and/or model development are needed before Tier II testing and computational dosimetry model reporting for route-to-route extrapolations of Tier II endpoints can proceed as described in the TCE ECA.

#### *B. Is there an Opportunity for Public Participation in EPA's Program Review?*

This notice of availability and request for comments on the Companies' Tier I Program Review testing reports titled: "Pharmacokinetics of 1,1,2-Trichloroethane in Rats and Mice" and "Physiologically Based Pharmacokinetic Model Development, Simulations, and Sensitivity Analysis for Repeated Exposure to 1,1,2-Trichloroethane" provides an opportunity for public participation in the EPA Program Review of the TCE ECA. A description of EPA's objectives in conducting the Program Review for the TCE ECA alternative testing program is provided in Unit II.C.3.

#### *C. What Happens at the Conclusion of EPA's Program Review?*

A description of the possible outcomes of the EPA Program Review is provided in Part VII. of the TCE ECA document (Ref. 2). Following the EPA Program Review, EPA will place in the official public docket for this action (under docket ID number OPPTS-2002-0056) a copy of each comment received, and a copy of the letter informing the HAP Task Force of the outcome from EPA's Program Review.

### IV. References

The official public docket for this action contains the following information:

1. The HAP Task Force. Letter from Peter E. Voytek to Charles M. Auer with attachment titled: Proposal for Pharmacokinetics Study of 1,1,2-Trichloroethane, November 22, 1996. (Available from docket control number OPPTS-42187B.)
2. U.S. EPA, Enforceable Consent Agreement for 1,1,2-Trichloroethane.

September 30, 1999. (CAS No. 79-00-5) (Available from docket control number OPPTS-42198B.)

3. Mazzulo, M., Colacci, A., Grilli, S., Prodi, G., and Arfellini, G. 1,1,2-Trichloroethane: evidence of genotoxicity from short-term tests. *Japanese Journal of Cancer Research*. 77:532-539. 1986.

4. Doherty, A.T., Ellard, S., Parry, E.M., and Parry, J.M. An investigation into the activation and deactivation of chlorinated hydrocarbons to genotoxins in metabolically competent human cells. *Mutagenesis*. 11(3):247-274. 1996.

5. Sanders, V.M., White, Jr., K.L., Shopp, Jr., G.M., and Musson, A.E. Humoral and cell-mediated immune status of mice exposed to 1,1,2-trichloroethane. *Drug and Chemical Toxicology*. 8(5):357-372. 1985.

6. National Cancer Institute (NCI). Bioassay of 1,1,2-trichloroethane for possible carcinogenicity. Carcinogenesis: Technical Report Series No. 74. U.S. Department of Health, Education and Welfare, Public Health Service, National Institutes of Health. 1978.

### List of Subjects

Environmental protection, Hazardous chemicals.

Dated: October 8, 2002.

**Wardner G. Penberthy,**

*Acting Director, Chemical Control Division,  
Office of Pollution Prevention and Toxics.*

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## ENVIRONMENTAL PROTECTION AGENCY

[OPPT-2002-0064; FRL-7277-8]

### Approval of Modifications to Test Marketing Exemption for a Certain Chemical

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

**ACTION:** Notice.

**SUMMARY:** This notice announces EPA's approval of modifications of the test marketing period for a test marketing exemption (TME) under section 5(h)(1) of the Toxic Substances Control Act (TSCA). EPA designated the original test marketing application as TME-02-0006. The test marketing conditions are described in this notice.

**DATES:** This notice is effective October 7, 2002.

**FOR FURTHER INFORMATION CONTACT:** For general information contact: Barbara Cunningham, Acting Director,

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](mailto:TSCA-Hotline@epa.gov).

*For technical information contact:* Jamesine Rogers, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-3453; e-mail address: [rogers.jamesine@epa.gov](mailto:rogers.jamesine@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

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

This action is directed in particular to the chemical manufacturer and/or importer who submitted the TME to EPA. This action may, however, be of interest to the public in general. Since other entities may also be interested, 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 technical person listed under **FOR FURTHER INFORMATION CONTACT**.

###### B. How Can I Get Copies of This Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPPT-2002-0064. 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 EPA Docket Center, Rm. B102-Reading Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566-1744 and the telephone number for the OPPT Docket, which is located in EPA Docket Center, is (202) 566-0280.

2. *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>. A

frequently updated electronic version of 40 CFR part is available at [http://www.access.gpo.gov/nara/cfr/cfrhtml\\_00/Title\\_40/40cfr\\_00.html](http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr_00.html), a beta site currently under development.

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 I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

##### II. What Action is the Agency Taking?

EPA approves the modifications of the test marketing period, production volume, and number of customers for TME-02-0006. EPA has determined that test marketing of the new chemical substance described in this notice, under the conditions set out in the TME applications and modification requests, and for the modified time periods specified in this notice, will not present any unreasonable risk of injury to health or the environment. Production volume, use, and the number of customers must not exceed specifications in the application. All other conditions and restrictions described in the original notice of approval of test marketing application must be met.

###### TME-02-0006

*Notice of approval of original application:* February 27, 2002, (67 FR 8972) (FRL-6825-2).

*Production volume:* CBI.

*Number of customers:* CBI.

*Modified test marketing period:* 6 months.

*Commencing on:* October 8, 2002.

The Agency reserves the right to rescind approval or modify the conditions and restrictions of an exemption should any new information come to its attention which casts significant doubt on its finding that the test marketing activities will not present any unreasonable risk of injury to health or the environment.

##### III. What is the Agency's Authority for Taking this Action?

Section 5(h)(1) of TSCA authorizes EPA to exempt persons from premanufacture notification (PMN) requirements and permit them to manufacture or import new chemical substances for test marketing purposes if

the Agency finds that the manufacture, processing, distribution in commerce, use, and disposal of the substances for test marketing purposes will not present an unreasonable risk of injury to health or the environment. EPA may impose restrictions on test marketing activities and may modify or revoke a test marketing exemption upon receipt of new information which casts significant doubt on its finding that the test marketing activity will not present an unreasonable risk of injury.

##### List of Subjects

Environmental protection, Test marketing exemptions.

Dated: October 7, 2002.

**Rose A. Allison,**

*Acting Chief, New Chemicals Prenotice Management Branch, Office of Pollution Prevention and Toxics.*

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#### ENVIRONMENTAL PROTECTION AGENCY

[OPPT-2002-0062; FRL-7277-6]

##### Approval of Modifications to Test Marketing Exemption for a Certain Chemical

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

**ACTION:** Notice.

**SUMMARY:** This notice announces EPA's approval of modifications of the test marketing period for a test marketing exemption (TME) under section 5(h)(1) of the Toxic Substances Control Act (TSCA). EPA designated the original test marketing application as TME-02-0004. The test marketing conditions are described in this notice.

**DATES:** This notice is effective October 7, 2002.

**FOR FURTHER INFORMATION CONTACT:** *For general information contact:* Barbara Cunningham, Acting Director, 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](mailto:TSCA-Hotline@epa.gov).

*For technical information contact:* Jamesine Rogers, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-3453; e-mail address: [rogers.jamesine@epa.gov](mailto:rogers.jamesine@epa.gov).