

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 799**

[OPPTS-42203A; FRL-5769-7]

RIN 2070-AC76

**Testing Consent Order and Export Notification Requirements for Diethanolamine****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule.

**SUMMARY:** On June 26, 1996, EPA proposed a test rule under section 4(a) of the Toxic Substances Control Act (TSCA) to require manufacturers and processors of 21 hazardous air pollutants (HAPs) to test these substances for certain health effects. Included as one of these chemical substances was diethanolamine (CAS No. 111-42-2). EPA invited the submission of proposals for enforceable consent agreements (ECAs) for pharmacokinetics testing of the HAPs chemicals and received a proposal for testing diethanolamine from the Chemical Manufacturers Association, Alkanolamines Panel (CMA Alkanolamines Panel). In a previous document EPA solicited interested parties to monitor or participate in negotiations on an ECA for diethanolamine. EPA is proposing that if an ECA is successfully concluded for diethanolamine, then the subsequent publication of the TSCA section 4 testing consent order (Order) in the **Federal Register** would add diethanolamine to the table of testing consent orders for substances and mixtures with Chemical Abstract Service Registry Numbers. As a result of the proposed addition of diethanolamine, all exporters of diethanolamine, including persons who do not sign the ECA, would be subject to export notification requirements under section 12(b) of TSCA.

**DATES:** Written comments on this proposed rule must be received on or before May 29, 1998.

**ADDRESSES:** Each comment must bear the docket control number, OPPTS-42203A. All comments should be sent in triplicate to: OPPT Document Control Officer (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Rm. G-99, East Tower, Washington, DC 20460.

Comments and data may also be submitted electronically to: [oppt.ncic@epamail.epa.gov](mailto:oppt.ncic@epamail.epa.gov), following the instructions under Unit IV. of this

preamble. No Confidential Business Information (CBI) should be submitted through e-mail.

All comments which contain information claimed as CBI must be clearly marked as such. Three sanitized copies of any comments containing information claimed as CBI must also be submitted and will be placed in the public record for this document. Persons submitting information on any portion of which they believe is entitled to treatment as CBI by EPA must assert a business confidentiality claim in accordance with 40 CFR 2.203(b) for each such portion. This claim must be made at the time that the information is submitted to EPA. If a submitter does not assert a confidentiality claim at the time of submission, EPA will make the information available to the public without further notice to the submitter.

**FOR FURTHER INFORMATION CONTACT:** For additional information: Susan B. Hazen, Director, Environmental Assistance Division (7408), Rm. ET-543B, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone: (202) 554-1404, TDD: (202) 554-0551; e-mail address: [TSCA-Hotline@epamail.epa.gov](mailto:TSCA-Hotline@epamail.epa.gov).

For technical information: Richard W. Leukroth, Jr., Project Manager, Chemical Information and Testing Branch (7405), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone: (202) 260-0321; e-mail address: [leukroth.rich@epamail.epa.gov](mailto:leukroth.rich@epamail.epa.gov).

**SUPPLEMENTARY INFORMATION:****I. Electronic Availability**

*Internet:* Electronic copies of this document and various support documents are available from the EPA Home Page at the **Federal Register**—Environmental Documents entry for this document under “Laws and Regulations” (<http://www.epa.gov/fedrgstr/EPA-TOX/1998/>).

**II. Development of Enforceable Consent Agreement for Diethanolamine**

Diethanolamine is one of the chemicals proposed for health effects testing in a proposed HAPs test rule under section 4(a) of TSCA in the **Federal Register** of June 26, 1996 (61 FR 33178) (FRL-4869-1). The proposed HAPs test rule was amended on December 24, 1997 (62 FR 67466) (FRL-5742-2). In the proposed HAPs test rule, EPA invited the submission of proposals for pharmacokinetics (PK) testing for the chemicals included in the proposed HAPs test rule. These proposals could

provide the basis for negotiation of ECAs, which, if successfully concluded, would be incorporated into Orders. The PK studies would be used to conduct route-to-route extrapolation of toxicity data from routes other than inhalation to predict the effects of inhalation exposure, as an alternative to testing proposed under the HAPs test rule. A proposal for PK testing for diethanolamine was submitted by the CMA Alkanolamines Panel to EPA on November 25, 1996. The Agency reviewed this alternative testing proposal and prepared a preliminary technical analysis of the proposal which it sent to the CMA Alkanolamines Panel on November 21, 1997. The CMA Alkanolamines Panel responded on December 31, 1997 that it has a continued interest in pursuing the ECA process for diethanolamine. EPA has decided to proceed with the ECA process for diethanolamine. EPA has published a document soliciting interested parties to monitor or participate in negotiations on an ECA for PK testing of diethanolamine (63 FR 3109, January 21, 1998) (FRL-5766-7). The procedures for ECA negotiations are described at 40 CFR 790.22(b).

If the ECA for diethanolamine is successfully concluded, and an Order is published in the **Federal Register**, testing to develop needed data would be required of those persons that have signed the agreement. Section 12(b) of TSCA provides that if any person exports or intends to export to a foreign country a chemical substance or mixture for which the submission of data is required under section 4 of TSCA, that person shall notify EPA of this export or intent to export. This requirement applies to data obtained from either a test rule or an ECA and Order under the authority of section 4 of TSCA. EPA intends the ECA to include the export notification requirements of section 12(b) of TSCA, codified at 40 CFR part 707, subpart D.

**III. Publication of Testing Consent Order**

EPA is proposing that if an ECA is successfully concluded for diethanolamine, the publication of the Order in the **Federal Register** would add diethanolamine to the table in 40 CFR 799.5000, Testing consent orders for substances and mixtures with Chemical Abstract Service Registry Numbers.

Exporters of chemicals listed at 40 CFR 799.5000 are required under 40 CFR 799.19, Chemical imports and exports, to comply with the export notification requirements of 40 CFR part 707, subpart D. This proposed rule,

when finalized, would amend § 799.5000, and, in accordance with 40 CFR 799.19, all exporters of diethanolamine, including persons who do not sign the ECA, would be subject to export notification requirements under 40 CFR part 707, subpart D.

Under 40 CFR 707.65(a)(2)(ii), a person who exports or intends to export for the first time to a particular foreign country a chemical subject to TSCA section 4 data requirements must submit a one-time notice to EPA identifying the chemical and country of import. A single notice can cover multiple chemicals and multiple countries. If additional importing countries are subsequently added, additional export notices must be submitted to EPA. Other procedures for submitting export notifications to EPA are described in 40 CFR 707.65.

Under 40 CFR 707.67, the contents of the export notification from the exporter or intended exporter to EPA shall include:

1. The name of the chemical (i.e., in this case, diethanolamine).
2. The name and address of the exporter.
3. The country(ies) of import.
4. The date(s) of export or intended export.
5. The section of TSCA under which EPA has taken action (i.e., in this case, section 4 of TSCA).

Following receipt of the section 12(b) notification from the exporter or intended exporter, under 40 CFR 707.70, EPA will provide notice of the export or intended export to the affected foreign government(s).

#### IV. Public Record and Electronic Submissions

The official record for this rulemaking (including comments and data submitted electronically as described below), including the public version, that does not include any information claimed as CBI, has been established for this rulemaking under docket control number OPPTS-42203A. The official record for this document also includes all material and submissions filed under docket control number [OPPTS-42187A; FRL-4869-1], the record for the proposed HAPs test rule, as amended, and all materials and submissions filed under docket control number [OPPTS-42187B; FRL-4869-1], the record for the receipt of alternative testing proposals for developing ECAs for HAPs chemicals. The public version of this record is available for inspection from 12 noon to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in the TSCA Nonconfidential Information

Center, Rm. NE B-607, 401 M St., SW., Washington, DC 20460.

Electronic comments can be sent directly to EPA at: [oppt.ncic@epamail.epa.gov](mailto:oppt.ncic@epamail.epa.gov).

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number, OPPTS-42203A. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

#### V. Regulatory Assessment Requirements

##### A. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, EPA does not believe that the impacts of this proposed rule constitute a significant economic impact on small entities.

Export regulations promulgated pursuant to section 12(b) of TSCA—40 CFR part 707, subpart D—require only a one-time notification to each foreign country of export for each chemical for which data are required under section 4 of TSCA. In an analysis of the economic impacts of the July 27, 1993, amendment to the rules implementing section 12(b) of TSCA (58 FR 40238), EPA estimated that the one-time cost of preparing and submitting the TSCA section 12(b) notification was \$62.60. See U.S. EPA, "Economic Analysis in Support of the Final Rule to Amend Rule Promulgated Under TSCA Section 12(b)," OPPT/ETD/RIB, June 1992, contained in the record for this rulemaking, and referenced in the amended proposed HAPs test rule (62 FR 67466, December 24, 1997). Inflated through the last quarter of 1996 using the Consumer Price Index, the current cost is estimated to be \$69.56. Although data available to EPA regarding export shipments of the HAPs chemicals are limited, a small exporter would have to have annual revenues below \$6,956 per chemical/country combination in order to be impacted at a 1% or greater level. For example, a small exporter filing 3 notifications per year would have to have annual sales revenues below \$20,868 (3 x \$6,956) in order to be classified as impacted at the greater than 1% level. EPA believes that it is reasonable to assume that few, if any, small exporters would file sufficient export notifications to be impacted at or above the 1% level. Based on this, the export notification requirements triggered by the ECA for diethanolamine

would be unlikely to have a significant economic impact on small exporters. Because EPA has concluded that there is no significant impact on small exporters, the Agency does not need to determine the number or size of the entities that would be impacted at a 1% or greater level.

Therefore, the Agency certifies that this proposed rule, if finalized, would not have a significant economic impact on small entities.

##### B. Executive Order 12866; Executive Order 12898; Executive Order 13045

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed rule is not a "significant regulatory action" subject to review by the Office of Management and Budget (OMB). It does not involve special considerations of environmental-justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994), nor raise any issues regarding children's environmental-health risks under Executive Order 13045 (62 FR 1985, April 23, 1997) because the Executive Order does not apply to actions expected to have an economic impact of less than \$100 million.

##### C. Paperwork Reduction Act

An agency may not conduct or sponsor, and a person is not required to respond to, an information collection request unless it displays a currently valid control number assigned by OMB. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9. The information collection requirements related to this action have already been approved by OMB pursuant to the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, under OMB control number 2070-0030 (EPA ICR No. 0795). The public reporting burden for the collection of information is estimated to average 0.55 hour per response.

##### D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104-4, establishes requirements for Federal agencies to assess the effects of certain regulatory actions on State, local, and tribal governments and the private sector, and to seek input from State, local, and tribal governments on certain regulatory actions. EPA has determined that this action does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any 1 year. Therefore, this action is not subject to the requirements of sections 202 and 205 of UMRA. The requirements of sections

203 and 204 of UMRA which relate to regulatory requirements that might significantly or uniquely affect small governments and to regulatory proposals that contain a significant Federal intergovernmental mandate, respectively, also do not apply to this proposed rule because the rule would only affect the private sector, i.e., those companies that test chemicals.

*E. National Technology Transfer and Advancement Act*

This proposed regulatory action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Pub. L. 104-113, section 12(d) (15 U.S.C. 272 note). Section 12(d) 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, business practices, etc.) that are developed or adopted by voluntary consensus standards bodies. The NTTAA requires EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. EPA invites public comment on this conclusion.

**List of Subjects in 40 CFR Part 799**

Environmental protection, Chemicals, Exports, Hazardous substances, Health, Laboratories, Reporting and recordkeeping requirements.

Dated: March 13, 1998.

**Lynn R. Goldman,**

*Assistant Administrator for Prevention, Pesticides and Toxic Substances.*

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

**PART 799—[AMENDED]**

1. The authority citation for part 799 would continue to read as follows:

**Authority:** 15 U.S.C. 2603, 2611, 2625.

2. Section 799.5000 is amended by adding diethanolamine to the table in CAS number order to read as follows:

**§ 799.5000 Testing consent orders for substances and mixtures with Chemical Abstract Service Registry Numbers.**

\* \* \* \* \*

CAS number	Substance or mixture name	Testing	FR publication date
* * * * *			
111-42-2	Diethanolamine .....	Health effects .....	[insert date for final rule.]
* * * * *			

\* \* \* \* \*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 799**

[OPPTS-42202A; FRL-5769-6]

RIN 2070-AC76

**Testing Consent Order and Export Notification Requirements for Ethylene Glycol**

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

**ACTION:** Proposed rule.

**SUMMARY:** On June 26, 1996, EPA proposed a test rule under section 4(a) of the Toxic Substances Control Act (TSCA) to require manufacturers and processors of 21 hazardous air pollutants (HAPs) to test these substances for certain health effects. Included as one of these chemical substances was ethylene glycol (CAS No. 107-21-1). EPA invited the submission of proposals for enforceable consent agreements (ECAs) for pharmacokinetics testing of the HAPs

chemicals and received a proposal for testing ethylene glycol from the Chemical Manufacturers Association, Alkanolamines Panel (CMA Alkanolamines Panel). In a previous document EPA solicited interested parties to monitor or participate in negotiations on an ECA for ethylene glycol. EPA is proposing that if an ECA is successfully concluded for ethylene glycol, then the subsequent publication of the TSCA section 4 testing consent order (Order) in the **Federal Register** would add ethylene glycol to the table of testing consent orders for substances and mixtures with Chemical Abstract Service Registry Numbers. As a result of the proposed addition of ethylene glycol, all exporters of ethylene glycol, including persons who do not sign the ECA, would be subject to export notification requirements under section 12(b) of TSCA.

**DATES:** Written comments on this proposed rule must be received on or before *(May 29, 1998)*.

**ADDRESSES:** Each comment must bear the docket control number, OPPTS-42202A. All comments should be sent in triplicate to: OPPT Document Control Officer (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Rm.

G-99, East Tower, Washington, DC 20460.

Comments and data may also be submitted electronically to: oppt.ncic@epamail.epa.gov. following the instructions under Unit IV. of this preamble. No Confidential Business Information (CBI) should be submitted through e-mail.

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**FOR FURTHER INFORMATION CONTACT:** For additional information: Susan B. Hazen, Director, Environmental Assistance Division (7408), Rm. ET-543B, Office of