

Region VII, 901 N. 5th Street, Kansas City, Kansas 66101.

**SUPPLEMENTARY INFORMATION:** This proposed settlement is intended to resolve the liability of Saveway Petroleum at the Great Lakes Container Corporation Superfund Site in St. Louis, Missouri.

Great Lakes Container Corporation is a former drum reclamation company who operated at the Site from 1976 to 1985. The same business was operated as Northwestern Cooperage from the 1950's to 1976 and then operated as Great Lakes Container Corporation. EPA conducted a time-critical removal completed in 1998 that consisted primarily of soil and drum removal. The EPA incurred costs of approximately \$9,127,244.30. The hazardous substances at this Site consisted primarily of lead and polychlorinated biphenyls. Liability is based on the theory that *de minimis* parties arranged for disposal of hazardous substances at the Site by shipping drums for reclamation coated with paint containing lead. The *de minimis* parties either admitted that they sent drums for reclamation to the Site or EPA had separate evidence to prove that *de minimis* parties sent drums for reclamation to the Site.

This settlement is being offered to Saveway because it is liable for no more than one quarter a percent (.25%) of EPA's past costs at the Site. The majority of *de minimis* parties are each required to pay \$4,839.44 or \$5,133.72 depending on whether the party was required to pay prejudgment interest. Other settlements made for six *de minimis* parties varied from \$3,794.19 to \$22,856.56 because more volume-specific information was available for them allowing EPA to refine the calculation. The amount and toxicity of hazardous substances contributed by Saveway was minimal as compared to other parties' shares of hazardous substances. The EPA determined this amount to be Saveway's fair share of liability based on the amount of hazardous substances generated and disposed of at the Site and the volume of waste contributed. However, because Saveway has demonstrated an inability to pay, it will not be required to pay any of EPA's past costs at the Site. As a result, Saveway has agreed to provide access to EPA and maintain records for five (5) years.

The settlement also includes contribution protection from lawsuits by other potentially responsible parties as provided for under section 122(g)(5) of CERCLA, 42 U.S.C. 9622(g)(5). The *de minimis* settlement provides that EPA

covenants not to sue Saveway for response costs at the Site or for injunctive relief pursuant to sections 106 and 107 of CERCLA and section 7003 of the Resource Conservation and Recovery Act of 1976, as amended (RCRA), 42 U.S.C. 6973. The settlement contains a reopener clause which nullifies the covenant not to sue if any information becomes known to EPA that indicates that Saveway no longer meets the criteria for a *de minimis* settlement set forth in section 122(g)(1)(A) of CERCLA, 42 U.S.C. 9622(g)(1)(A). The United States maintains the ability to bring an action in the event that the financial information provided by Saveway was false. The covenant not to sue does not apply to the following matters:

(a) Claims based on the future arrangement for disposal or treatment of any hazardous substance, pollutant, or contaminant at the Site after the effective date of the *de minimis* settlement;

(b) Criminal liability; or

(c) Liability for damages or injury to, destruction of, or loss of the natural resources and for the costs of any natural resource damage assessments.

The *de minimis* settlement will become effective upon the date which the EPA issues a written notice to Saveway that the statutory public comment period has closed and that comments received, if any, do not require modification, or of EPA withdrawal from the settlement.

Dated: May 22, 2003.

**James B. Gulliford,**

*Regional Administrator, Region VII.*

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**BILLING CODE 6560-50-P**

## ENVIRONMENTAL PROTECTION AGENCY

[OPPT-2003-0010; FRL-7300-6]

### 1,2-Ethylene Dichloride; Final Enforceable Consent Agreement and Testing Consent Order

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

**ACTION:** Notice.

**SUMMARY:** Under section 4 of the Toxic Substances Control Act (TSCA), EPA has issued a testing consent order (Order) that incorporates an enforceable consent agreement (ECA) with the Dow Chemical Company, Vulcan Materials Company, Occidental Chemical Corporation, Oxy Vinyls, LP, Georgia Gulf Corporation, Westlake Chemical Corporation, PPG Industries, Inc., and

Formosa Plastics Corporation, U.S.A. The Companies are members of the Hazardous Air Pollutant (HAP) Task Force, which represents the manufacturers of 1,2-ethylene dichloride (EDC). The Companies have agreed to: Conduct toxicity testing, develop pharmacokinetics and mechanistic test data, and develop a computational dosimetry model for quantitative route-to-route extrapolations of dose-response for EDC for acute, subchronic, developmental, reproductive and neurotoxicity effects that were identified in a proposed test rule for hazardous air pollutants. This notice announces the ECA and Order for EDC and summarizes the terms of the ECA.

**DATES:** The effective date of the ECA and Order is May 13, 2003.

**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.

*For technical information contact:* Richard Leukroth or John Schaeffer, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8157; fax number: (202) 564-4765; e-mail address: ccd.citb@epa.gov.

## SUPPLEMENTARY INFORMATION:

### I. General Information

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

This announcement is directed to the public in general. However, as described in Unit IV., this ECA and Order may affect others in that EPA has initiated rulemaking under TSCA section 12(b) (62 FR 67038, December 23, 1997) (FRL-5762-8). When finalized, that rulemaking will require all persons who export or intend to export EDC to comply with the export notification regulations at 40 CFR part 707, subpart D. Although others may be affected by subsequent actions related to this announcement, this ECA and Order only applies to those Companies that are specifically named in this ECA and Order. 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-2003-0010. 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 the 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/fedrgrstr/>.

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. Background

### A. What is EDC?

EDC is used as a chemical intermediate principally in the production of vinyl chloride, but also vinylidene chloride, 1,1,1-trichloroethane, trichloroethylene, tetrachloroethylene, aziridines, and ethylene diamines. It is also used as a solvent. An estimated 77,111 workers are exposed to EDC (Ref. 1). The Chemical Abstract Service Registry Number (CAS No.) for EDC is 107-06-2.

### B. Why Does EPA Need Health Effects Data on EDC?

EPA proposed health effects testing under TSCA section 4(a) for a number of hazardous air pollutants ("HAPs" or "HAP chemicals"), including EDC (61 FR 33178, June 26, 1996) (FRL-4869-1), as amended at 62 FR 67466, December 24, 1997 (FRL-5742-2) and 63 FR 19694, April 21, 1998 (FRL-5780-6). In the original HAPs proposal, the Agency made preliminary findings for EDC (61 FR 33178, 33190, 33191; and Ref. 1) that:

1. EDC may present an unreasonable risk of injury to health.

2. EDC is or will be produced in substantial quantities, and there is or may be substantial human exposures to the chemical.

3. There are insufficient data to determine or predict the effects of activities on human health involving EDC.

4. Testing is necessary to develop health effects data for EDC.

The HAPs rule, as amended, proposed testing of EDC for acute toxicity, subchronic toxicity, developmental toxicity, reproductive effects toxicity, and neurotoxicity (61 FR 33178, 33198, June 26, 1996; 62 FR 67466, 67483, December 24, 1997).

## III. ECA Development and Conclusion

### A. How is EPA Going to Obtain Health Effects Testing on EDC?

In the proposed HAPs test rule, as amended, EPA invited the submission of proposals regarding the performance of pharmacokinetics studies that would permit extrapolation from oral data to predict risk from inhalation exposure. Such proposals could provide the scientific basis for alternative testing to the testing proposed and form the basis for developing needed HAPs data via ECAs (61 FR 33178, 33189, June 26, 1996; 62 FR 67466, 67474, December 24, 1997). EPA uses ECAs to accomplish testing where a consensus exists among EPA, affected manufacturers and/or processors, and interested members of the public concerning the need for and scope of testing (40 CFR 790.1(c)).

The procedures for ECA development are described at 40 CFR 790.22(b).

In response to EPA's request for proposals for ECAs, the HAP Task Force submitted a proposal for alternative testing that included physiologically-based pharmacokinetics (PBPK) studies and computational modeling to inform route-to-route extrapolations of dose-response for EDC on November 22, 1996 (Ref. 2). EPA responded to this proposal on June 26, 1997 (Ref. 3), indicating that the HAP Task Force alternative

approach offered sufficient merit to proceed with discussions for developing an ECA for EDC. Consequently, EPA issued a document which was published in the **Federal Register** of December 19, 1997 (62 FR 66626) (FRL-5763-1), soliciting interested parties to monitor or participate in these discussions.

EPA held a public meeting to develop an ECA for EDC on January 12, 1998. Representatives of the Companies and other interested parties attended this meeting. The participants reached consensus on the general scope of the testing to be required under the ECA. Following the public meeting, the HAP Task Force submitted (March 19, 1999) a revised proposal for a testing program (Ref. 4). On February 13, 2001, EPA responded to the HAP Task Force with comments on the revised proposal and by initiating a draft ECA for consideration by the HAP Task Force (Ref. 5). A final version of the ECA was later circulated to the HAP Task Force for signature, and returned to EPA for signature. On February 3, 2003, EPA received the ECA signed by the Companies. On May 13, 2003, EPA signed the ECA and accompanying Order (Ref. 6).

### B. What Testing Does the ECA for EDC Require?

The EDC ECA alternative testing program has four segments as follows: Tier I HAPs Testing, Tier I Program Review Testing, EPA Program Review, and Tier II Testing. This is described in Table 1 in this unit and includes the following testing, reporting, and review activities:

1. *Tier I HAPs Testing.* This testing consists of endpoint testing, conducted by inhalation exposure, that EPA deemed necessary to meet certain data needs identified in the proposed HAPs test rule, as amended, and includes acute toxicity with bronchoalveolar lavage (BAL) and histopathology, and acute neurotoxicity testing. These tests will be conducted under a combined protocol as described in Appendix D.1 of the ECA.

2. *Tier I Program Review Testing.* Under this segment of the EDC ECA alternative testing program, the Companies will conduct studies to extend the computational dosimetry model of D'Souza *et al.* (1987; 1988; Refs. 7 and 8) in order to apply the model to the specific health effects endpoints for EDC listed in the ECA, validate the model, and verify the model's ability to perform quantitative route-to-route extrapolations of dose-response. In addition, the Companies will sponsor development of

pharmacokinetics and mechanistic (PK/MECH) data to support the application of the model for the endpoints listed under Tier II of the EDC ECA.

Specifically, the PK/MECH testing will develop data to inform:

i. Oral-to-inhalation extrapolation of subchronic toxicity data reported by Daniel, *et al.* (1994; Ref. 9) relevant to corn oil gavage.

ii. Oral-to-inhalation extrapolation of subchronic neurotoxicity data relevant to drinking water exposure of a study to be conducted under Tier II Testing.

iii. Oral-to-inhalation extrapolation of reproductive effects testing conducted under Tier II Testing and each dosing paradigm of studies reported by Alumot *et al.* (1976; Ref. 10), Rao, *et al.* (1980; Ref. 11) and Lane *et al.* (1982; Ref. 12).

In addition, the Companies will provide model simulations with point and uncertainty estimates of internal dose metrics (parent chemical peak and area under the curve (AUC) concentrations in blood and brain, and 24-hour total glutathione-dependent metabolism) in rats and humans to inform quantitative route-to-route extrapolations of dose-response. These simulations will be used to evaluate the acceptability of: Subchronic neurotoxicity testing of oral exposure via drinking water in rats, extant oral subchronic toxicity data of Daniel *et al.*

(1994; Ref. 9) in rats via corn oil gavage, and reproductive toxicity testing of oral exposure via drinking water in rats.

3. *EPA Program Review.* Model development and data from Tier I Program Review Testing are subject to an EPA Program Review. It is essential to the success of the EDC ECA alternative testing program for EPA to ensure that the model and the PK/MECH data used to support the route-to-route extrapolations of dose-response are of the highest quality. The purpose of the EPA Program Review will be to determine:

i. 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 of dose-response for endpoints listed in the Tier II Testing segment of the ECA.

ii. 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 for the dose-responses specified in the Tier II Testing segment.

iii. The nature and scope of any additional work that may be required before Tier II Testing and application of the EDC model for route-to-route extrapolation of dose-response reporting

(e.g., development of additional PK/MECH data, modification to the EDC model).

4. *Tier II Testing and/or Extrapolation Reporting.* This segment of the EDC ECA alternative testing program consists of endpoint testing by drinking water exposure for subchronic neurotoxicity and reproductive toxicity. The reproductive effects toxicity testing is intended to confirm studies reported by Alumot *et al.* (1976; Ref. 10), Rao *et al.* (1980; Ref. 11), and Lane *et al.* (1982; Ref. 12), and provide data needed on fertility index, gestation index, gross necropsy, organ weight, histopathology, estrous cycle, sperm evaluation, vaginal opening, and preputial separation as described in the ECA.

This segment will also include application of the EDC model for quantitative route-to-route extrapolation reporting (oral to inhalation) for Tier II endpoint testing (subchronic neurotoxicity and reproductive toxicity) and similar computational extrapolation reporting for extant subchronic toxicity reported by Daniel *et al.* (1994; Ref. 9).

Testing conducted under this ECA will allow EPA to characterize certain potential health hazards resulting from inhalation exposure to EDC. The following Table 1 sets forth the required testing, test standard, and reporting requirements under the ECA for EDC.

TABLE 1.—REQUIRED TESTING, TEST STANDARD, AND REPORTING REQUIREMENTS FOR EDC

Testing Segment	Required testing	Test standard	Deadline for final report <sup>1</sup> (Months)
Tier I HAPs Testing.	Acute toxicity, with BAL and histopathology (inhalation).	40 CFR 799.9135 (as annotated in ECA Appendix D.1).	18
	Acute neurotoxicity (inhalation).	40 CFR 799.9620 (as annotated in ECA Appendix D.1).	18
Tier I Program Review Testing.	PK/MECH data to support model validation and verification of oral-to-inhalation extrapolation of dose-response for the following data needs in the F344 rat:	ECA Appendix C (1–4).	21
	a. Subchronic toxicity. b. Subchronic neurotoxicity. c. Reproductive toxicity. PBPK model simulations.	ECA Appendix C (1–5).	21
Tier II Testing and/or Extrapolation Reporting.	Subchronic toxicity route-to-route extrapolation of dose-response (oral Tier II Testing to inhalation) of a study reported by Daniel <i>et al.</i> (1994).	ECA Appendix C.2 and C.6.	36
	Subchronic neurotoxicity (oral).	40 CFR 799.9620 (as annotated in ECA Appendix D.2).	42
	Subchronic neurotoxicity route-to-route extrapolation of dose-response (oral Tier II Testing to inhalation).	ECA Appendix C.3 and C.6.	52
	Reproductive toxicity (oral).	40 CFR 799.9380 (as annotated in ECA Appendix D.3).	42

TABLE 1.—REQUIRED TESTING, TEST STANDARD, AND REPORTING REQUIREMENTS FOR EDC—Continued

Testing Segment	Required testing	Test standard	Deadline for final report <sup>1</sup> (Months)
	Reproductive toxicity route-to-route extrapolation of dose-response (oral data to inhalation, including Tier II Testing and extant studies reported by Alumot <i>et al.</i> (1976), Rao <i>et al.</i> (1980), and Lane <i>et al.</i> (1982)).	ECA Appendix C.4 and C.6.	52

<sup>1</sup> Number of months after the effective date of the Order that incorporates this ECA when the final report is due. In addition, every 6 months from the effective date of the Order until the end of the ECA testing program, interim reports describing the status of all testing to be performed under this ECA must be submitted by the Companies to EPA.

### C. What are the Uses for the Test Data for EDC?

EPA would use the data obtained from testing to implement several provisions of section 112 of the Clean Air Act (CAA), including the determination of residual risk, the estimation of the risks associated with accidental releases of chemicals, and other HAP risk assessments. EPA will also use the data from this ECA to fulfill part of the Tier I Testing portion of the Voluntary Children's Chemical Evaluation Program (VCCEP). (For more information about VCCEP, see: <http://www.epa.gov/chemrtk/vccep/>.) In addition, the data will be used by other Federal agencies (e.g., the Agency for Toxic Substances and Disease Registry (ATSDR), the National Institute for Occupational Safety and Health (NIOSH), the Occupational Safety and Health Administration (OSHA), and the Consumer Product Safety Commission (CPSC)) in assessing chemical risks and in taking appropriate actions within their programs (see the proposed HAPs test rule at 61 FR 33178, 33179, June 26, 1996).

### D. Does the ECA for EDC Meet all the Testing Requirements for EDC that were Contained in the Proposed Test Rule?

In the proposed HAPs test rule, as amended, EPA proposed testing of EDC for acute, subchronic, developmental, and reproductive effects and neurotoxicity by the inhalation route of exposure. The ECA alternative testing program for EDC requires inhalation testing for acute toxicity and acute neurotoxicity, and oral drinking water testing for subchronic neurotoxicity and reproductive effects toxicity. The ECA requires the development of PK/MECH data to support computational PBPK modeling to inform quantitative route-to-route extrapolations of dose-response (oral to inhalation) for the endpoints of subchronic toxicity, subchronic neurotoxicity, and reproductive effects toxicity as described in the ECA.

During discussions to develop this ECA, EPA concluded that the

developmental toxicity studies reported by Rao *et al.* (1980; Ref. 11), in rabbits, and Payan *et al.* (1995; Ref. 13), in rats, adequately fulfill the HAPs rulemaking testing requirement for developmental toxicity testing for EDC and, therefore, the ECA does not require, and the final HAPs test rule will not require this testing. In addition, the ECA does not require, and the final HAPs test rule will not require, macrophage function testing (a component of EPA's acute toxicity test guideline 40 CFR 799.9135) because EPA considers existing data by Sherwood *et al.* (1987; Ref. 14) adequate to fulfill this aspect of the acute testing need. Furthermore, the Tier I HAPs Testing endpoints (acute toxicity and acute neurotoxicity) will not be included in the final HAPs test rule because the route of testing to be conducted under this ECA is identical to that specified in the HAPs rulemaking. Finally, depending on the outcome of EPA's Program Review, the Agency anticipates that the balance of the testing for EDC that was contained in the proposed HAPs test rule, as amended, will also not be included in the final HAPs test rule because the Companies will conduct equivalent testing as Tier II Testing and Extrapolation Reporting under this ECA alternative testing program for EDC. Therefore, EPA anticipates the fulfilling of all of the health effects testing requirements, identified in the HAPs proposed rule, as amended, by implementing the ECA and Order.

The issuance of the ECA and Order constitutes final EPA action for purposes of 5 U.S.C. 704.

### E. What if EPA Should Require Additional Health Effects Testing on EDC?

If EPA decides in the future that it requires additional health effects data on EDC, the Agency will initiate a separate action.

### IV. Other Impacts of the ECA for EDC

The issuance of the ECA and Order under TSCA section 4 subjects the Companies that signed the ECA to

export notification requirements under TSCA section 12(b)(1), as set forth at 40 CFR part 707, subpart D, if they export or intend to export EDC.

In the 12(b) proposal published in the **Federal Register** of December 23, 1997 (62 FR 67038) (FRL-5762-8), EPA proposed to amend 40 CFR 799.5000 by adding EDC to the list of chemicals subject to testing consent orders. The listing of a chemical substance at 40 CFR 799.5000 serves as notification to all persons who export or intend to export the chemical substance that:

1. The chemical substance is the subject of an ECA and Order.
2. EPA's export notification regulations at 40 CFR part 707, subpart D, apply to those exporters who have signed the ECA, as well as those exporters who have not signed the ECA (40 CFR 799.19).

When a final rule based on the proposed rule is published in the **Federal Register**, all persons who export or who intend to export EDC will be subject to export notification requirements.

### V. Paperwork Reduction Act

The ECA and Order announced in this notice do not contain any information collection requirements that require additional approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* The information collection requirements related to test rules and ECAs issued under TSCA section 4 have already been approved by OMB under OMB control number 2070-0033 (EPA ICR No. 1139). The one-time public burden for this collection of information is estimated to be approximately 3,364 hours total (Ref. 15). Under the PRA, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection it includes the time needed to review instructions; complete and review the collection of information; and transmit or otherwise disclose the information. An agency

may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control number for EPA's regulations, after initial display in the final rule, are listed in 40 CFR part 9.

## VI. References

1. U.S. EPA, OPPT. *I. Ethylene Dichloride (107-06-2)*. Pp 24–27 In: "TSCA Section 4 Findings for 21 Hazardous Air Pollutants: A Supporting Document for Proposed Hazardous Air Pollutants (HAPs) Test Rule." (June 25, 1996).

2. The HAP Task Force. Letter from Peter E. Voytek to Charles M. Auer with attachment entitled: "Proposal for Pharmacokinetics Study of Ethylene Dichloride, November 22, 1996." (November 22, 1996).

3. U.S. EPA. Letter from Charles M. Auer to Peter E. Voytek with attachment entitled: "Preliminary EPA Technical Analysis of Proposed Industry Pharmacokinetics (PK) Strategy for Ethylene Dichloride, June, 1997." (June 26, 1997).

4. The HAP Task Force. Letter from Peter E. Voytek to Charles M. Auer, U.S. EPA. (March 19, 1999).

5. U.S. EPA. Letter from Charles M. Auer to Peter E. Voytek, HAP Task Force, Re: ECA Development of Ethylene Dichloride (EDC) (OPPTS 42197C, with attachment: "EDC ECA—DRAFT, dated February, 2001." (February 13, 2001).

6. Final Enforceable Consent Agreement for Ethylene Dichloride and Accompanying Testing Consent Order, signed by EPA on May 13, 2003.

7. D'Souza, R.W., Francis, W.R., Bruce R.D., and Andersen, M.E. *Physiologically based pharmacokinetic model for ethylene dichloride and its application in risk assessment*. Pp 286–301, In: *Pharmacokinetics in Risk Assessment*. National Academy Press. Washington, D.C. (1987).

8. D'Souza, R.W., Francis, W.R., and Andersen, M.E. *Physiological model for tissue glutathione depletion and increased resynthesis after ethylene dichloride exposure*. *Journal of Pharmacology and Experimental Therapeutics* 245(2):563–568. 1988.

9. Daniel, F.B., Robinson, M., Olson, G.R., York, R.G., and Condie, L.W. *Ten and ninety-day toxicity studies of 1,2-dichloroethane in Sprague-Dawley rats*. *Drug and Chemical Toxicology* 17: 463–477. 1994.

10. Alumot, E., Nachtomi, E., Mandel, E., Holstein, P., Bondi, A., and Herzberg, M. *Tolerance and acceptable daily intake of chlorinated fumigants in the*

*rat diet*. *Food, Cosmetics and Toxicology* 14: 105–110. (1976).

11. Rao, K.S., Murray, J.S., Deacon, M.M., John, J.A., Calhoun, L.L., and Young, J.T. *Teratogenicity and reproduction studies in animals inhaling ethylene dichloride*. Banbury Report 5: 149–166. (1980).

12. Lane, R.W., Riddle, B.L., and Borzelleca, J.F. *Effects of 1,2-dichloroethane and 1,1,1-trichloroethane in drinking water on reproduction and development in mice*. *Toxicology and Applied Pharmacology* 63: 409–421. 1982.

13. Payan, J.P., Saillenfait, A.M., Bonnet, P., Fabry, J.P., Langonne, I., and Sabate J.P. *Assessment of the developmental toxicity and placental transfer of the 1,2-dichloroethane in rats*. *Fundamental and Applied Toxicology* 28: 187–198. 1995.

14. Sherwood, R.L., O'Shea, W., Thomas, P.T., Ratajczak, H.V., and Aranyi, C. *Effects of inhalation of ethylene dichloride on pulmonary defenses of mice and rats*. *Toxicology and Applied Pharmacology* 91: 491–496. 1987.

15. U.S. EPA, OPPTS. "Burden Estimates for the Enforceable Consent Agreement for Ethylene Dichloride." (January 31, 2002).

## List of Subjects

Environmental protection, Hazardous chemicals.

Dated: May 13, 2003.

**Stephen Johnson,**

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

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**BILLING CODE 6560-50-S**

## ENVIRONMENTAL PROTECTION AGENCY

[OPPT-2002-0067; FRL-7287-4]

### TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance

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

**ACTION:** Notice.

**SUMMARY:** EPA is hereby finalizing revisions to certain parts of EPA's "Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" (policy statement) issued March 16, 1978, concerning the reporting of "substantial risk" information pursuant to section 8(e) of the Toxic Substances Control Act (TSCA). EPA is making these revisions

after having considered public comments that were solicited in 1993 and 1995. Specifically, the revisions address the reporting of information on the release of chemical substances to, and the detection of chemical substances in, environmental media, the reporting deadline for written "substantial risk" information, and the circumstances under which certain information need not be reported to EPA under section 8(e) of TSCA. EPA is republishing the policy statement in its entirety in this document, including both those portions of the policy statement that are revised and those portions that are not affected by any revisions. Since the policy statement was published in 1978, this republication is intended to ensure that a single reference source for the TSCA section 8(e) policy and guidance is easily available to the regulated community and other interested parties.

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

For technical information contact: Richard Hefter, Chief, High Production Volume Chemicals Branch, Risk Assessment Division, Office Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-7649; e-mail address: hefter.richard@epa.gov.

## SUPPLEMENTARY INFORMATION:

### I. General Information

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

You may be potentially affected by this action if you manufacture, process, import, or distribute in commerce chemical substances and mixtures. Potentially affected entities may include, but are not limited to:

- Chemical manufacturers, processors, and distributors (NAICS 325)
- Petroleum refiners and distributors (NAICS 324)
- Manufacturers of plastic parts and components (NAICS 325211)
- Paints and coatings and adhesive manufacturing (NAICS 3255)
- Cleaning compounds and similar products manufacturing (NAICS 3256)
- Electronics manufacturing (NAICS 334 and 335)
- Automobiles manufacturing (NAICS 3361)