ENVIRONMENTAL PROTECTION AGENCY

[OPPTS-42107E; FRL-5744-3]

RIN 2070-AB94

Testing Consent Order for 1,6-Hexamethylene Diisocyanate (HDI)

AGENCY: Environmental Protection

Agency (EPA).

ACTION: Notice of consent agreement.

SUMMARY: Pursuant to 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 ARCO Chemical Company, Bayer Corporation, and Rhone-Poulenc Inc. (collectively, the Companies). The Companies have agreed to perform certain health effects tests on 1,6-hexamethylene diisocyanate (HDI) (CAS No. 822–06–0). This notice announces the ECA and Order for HDI and summarizes the terms of the ECA. EFFECTIVE DATES: The effective date of the ECA and Order is September 30, 1997.

FOR FURTHER INFORMATION CONTACT:

Susan B. Hazen, Director, **Environmental Assistance Division** (7408), Office of Pollution Prevention and Toxics, Rm. ET-543B, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone: (202) 554-1404; TDD: (202) 554-0551; e-mail: TSCA-Hotline@epamail.epa.gov. For specific information regarding this notice, or the ECA and Order, contact Keith J. Cronin, Project Manager, Chemical Control Division (7405), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone: (202) 260-8157; fax: (202) 260-1096; e-mail: cronin.keith@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

ELECTRONIC AVAILABILITY: 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/).

This notice announces the ECA and Order for HDI and summarizes the terms of the ECA.

I. Introduction

HDI is an aliphatic diisocyanate. HDI is used in the manufacture of higher molecular biuret polyisocyanate resins and trimer polyisocyanate resins used in polyurethane paint systems. The production and use of HDI in polyurethane paint systems result in potential exposures to substantial numbers of workers. The greatest potential for occupational exposure to HDI is coating application operations, with an estimated 153,000 auto body repair workers having a potential for some exposure to paints containing HDI biuret and trimer.

In the Federal Register of May 20, 1988 (53 FR 18196), the Interagency Testing Committee (ITC) designated HDI for health effects testing for chronic toxicity, oncogenicity, and reproductive and developmental effects. EPA responded to the ITC's designation of HDI by issuing a proposed test rule in the Federal Register of May 17, 1989 (54 FR 21240), requiring that HDI be tested for oncogenicity, mutagenicity, reproductive toxicity, developmental toxicity, neurotoxicity, pharmacokinetics, and hydrolysis under section 4 of TSCA. The proposed rule contains a chemical profile of HDI, a discussion of EPA's TSCA section 4(a) findings, and the proposed test standards and reporting requirements. EPA based its proposal on section 4(a)(1)(B) of TSCA, finding that HDI is produced in substantial quantities and that there is or may be substantial human exposure from its manufacture, processing, and use.

EPA has reviewed significant new scientific data developed since publication of the proposed rule in 1989. The new data—which address chronic toxicity, subchronic toxicity, mutagenicity, and hydrolysis—

significantly affect the final scope of testing needs for this chemical substance. In view of the impact of these developments on the scope of needed HDI testing, EPA published a notice on June 12, 1995 (60 FR 30874) (FRL–4938–2) soliciting testing proposals for HDI.

II. Enforceable Consent Agreement Negotiations

In response to EPA's offer to negotiate an ECA, the Chemical Manufacturers Association (CMA) HDI Panel submitted a proposal for a testing program (Ref. 1).

EPA held a public meeting to negotiate an ECA for HDI on September 25, 1996. This meeting was attended by representatives of the Companies and other interested parties. During the public meeting, consensus was reached on the ECA, and on the tests to be included in the ECA. On August 26, 1997, EPA received the ECA signed by the Companies. On September 23, 1997, EPA signed the ECA and accompanying Order.

III. Proposed Test Rule

EPA has decided not to finalize the proposed test rule for HDI (54 FR 21240, May 17, 1989). EPA has instead reached agreement with the Companies that the testing requirements for HDI in the proposed rule will be met by implementing the ECA and Order, and that the issuance of the ECA and Order constitutes final EPA action for purposes of 5 U.S.C. 704. Should EPA decide in the future that it requires additional data on HDI, EPA will initiate a separate action.

IV. Testing Program

The following table 1 describes the required testing, test standards, and reporting requirements under the ECA for HDI. This testing program will allow EPA to characterize further the potential health hazards resulting from exposure to HDI. The appendices referenced in this table are specific to the enforceable consent agreement and are not appendices in 40 CFR part 798.

Table 1.—Required Testing, Test Standards and Reporting Requirements for HDI

Description of test	Test standard	Deadline for final report ¹ (months)	Interim reports ² required (number)
Genotoxicity: 1. Mammalian cells in culture	798.5300 (40 CFR)	12	1
2. Salmonella Typhimurium	798.5265 (40 CFR)	12	1

Table 1.—Required Testing, Test Standards and Reporting Requirements for HDI—Continued

Description of test	Test standard	Deadline for final report ¹ (months)	Interim reports ² required (number)
3. In vivo Cytogenetics	798.5385 (40 CFR) (Appendix I)	12	1
Developmental Toxicity: One species (rat), inhalation	798.4900 (40 CFR) (Appendix II)	21	3
Reproductive developmental screen with functional observational battery; One species (rat), via inhalation	OECD 422 (Appendix III)	21	3
2-generation reproductive study ³	798.4700 as proposed for revision (59 FR 42272, August 17, 1994) (Appendix IV)	244	3

¹ Number of months after the effective date of the testing consent order.

² Interim reports are required every 6 months from the effective date until the final report is submitted. This column shows the

number of interim reports required for each test.

⁴ Figure indicates the reporting deadline, in months, calculated from the date of notification to the test sponsor by certified let-

ter of FEDERAL REGISTER notice that the Agency has determined this required testing must be performed.

V. Export Notification

At a later date EPA will propose to amend 40 CFR 799.5000 by adding HDI to the list of chemicals subject to testing consent orders, thereby subjecting all persons who export or who intend to export HDI, of any purity, to the export notification requirements of section 12(b) of TSCA.

VI. Public Record

EPA has established an official record for this ECA and Order under docket number OPPTS-42107E, which is available for inspection from 12 noon to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located in the TSCA Nonconfidential Information Center in Rm. NE-B607, 401 M St., SW., Washington, DC 20460. Information claimed as Confidential Business Information (CBI), while part of the record, is not available for public review. This record contains the basic information considered in developing this ECA and Order and includes the following information.

A. Supporting Documentation

- (1) Testing Consent Order for HDI, with incorporated Enforceable Consent Agreement and associated testing protocols attached as appendices.
- (2) **Federal Register** notices pertaining to this notice, the Testing Consent Order

and the Enforceable Consent Agreement, consisting of:

- (a) Notice of Proposed Rulemaking for HDI (54 FR 21240, May 17, 1989).
- (b) Notice of Solicitation of Testing Proposals for 1,6-Hexamethylene Diisocyanate for Negotiation of a TSCA Section 4 Enforceable Consent Agreement (60 FR 30874, June 12, 1995).
 - (3) Communications consisting of:
 - (a) Written letters.
 - (b) Meeting summaries.
- (4) Reports—published and unpublished factual materials.

B. References

1. The Hexamethylene Diisocyanate Panel of the Chemical Manufacturers Association. Letter from Langley A. Spurlock to EPA. Enforceable Testing Agreement Proposal for 1,6-Hexamethylene Diisocyanate. Washington, DC (August 11, 1995).

List of Subjects

Environmental protection. Dated: September 23, 1997.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides, and Toxic Substances.

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FEDERAL COMMUNICATIONS COMMISSION

Sunshine Act Meeting; Additional Item To Be Considered at Open Meeting Thursday, September 25, 1997

The Federal Communications Commission will consider an additional item on the subject listed below at the Open Meeting scheduled for 9:30 a.m., Thursday, September 25, 1997, at 1919 M Street, N.W., Washington, D.C.

Item No., Bureau; and Subject

3—Wireless Telecommunications—
Title: Amendment of the
Commission's Rules Regarding
Installment Payment Financing for C
Block Personal Communications
Service (PCS) Licenses. (WT Docket
No. 97–82). Summary: The
Commission will consider action
concerning resumption of installment
payments for PCS C and F Block
licensees and other repayment
options for C Block licensees.

The prompt and orderly conduct of the Commission business requires that less than 7-days notice be given consideration of this additional item.

Action by the Commission September 25, 1997, Chairman Hundt and Commissioners Quello, Ness and Chong voting to consider this item.

³ This study must be conducted if the Agency determines that the results of the reproductive/developmental screening test show statistically or biologically significant adverse reproductive or developmental effects. If the results of the reproductive/developmental screening test are equivocal, the 2-generation reproductive/developmental study will not be required unless the Agency concludes that the use of HDI may present an unreasonsable risk to human health or the environment in light of (1) a weight-of-the-evidence evaluation of HDI's reproductive/developmental effects, and (2) worker exposure practices and/or manufacturer product stewardship activities. The Agency shall, in any event, provide the Panel with an opportunity to meet and discuss the screening test results with the Agency before making a determination under this paragraph.