Dated: May 8, 1989.

Victor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

Therefore, it is proposed that 40 CFR, Chapter I, Subchapter R, be amended as follows:

PART 790—[AMENDED]

1. The authority citation for Part 790 would continue to read as follows:

Authority: 15 U.S.C. 2603.

2. In § 790.42, by adding paragraph (a)(4) to read as follows:

§ 790.42 Persons subject to a test rule.

(a) * * *

(4) While legally subject to the test rule in circumstances described in paragraph (a)(1) of this section, persons who manufacture less than 500 kilograms (1,100 pounds) of the chemical annually during the period from the effective date of the test rule to the end of the reimbursement period, must comply with the requirements of the test rule only if such manufacturers are directed to do so in a subsequent notice as set forth in § 790.48, or if directed to do so in a particular test rule.

* * * * *

3. In § 790.48, by revising paragraphs (a)(2) and (b)(3) to read as follows:

§ 790.48 Procedure if no one submits a letter of intent to conduct testing.

(a) * * *

(2) If no manufacturer subject to the test rule has notified EPA of its intent to conduct one or more of the required tests within 30 days after the effective date of the test rule described in § 790.40, EPA will notify all manufacturers, including those described in § 790.42(a)(4), by certified mail or by publishing a notice of this fact in the **Federal Register** specifying the tests for which no letter of intent has been submitted and will give such manufacturers an opportunity to take corrective action.

* * * * *

(b) * * *

(3) No later than 30 days after the date of publication of the **Federal Register** notice described in paragraph (b)(2) of this section, each person described in § 790.40(a)(4) and each person processing the subject chemical as of the effective date of the test rule described in § 790.40 or by 30 days after the date of publication of the **Federal Register** notice described in paragraph (b)(2) of this section must, for each test specified in the **Federal Register** notice, either notify EPA by letter of his or her intent to conduct testing or submit to EPA an application for an exemption from testing requirements for the test.

* * * * *

4. In § 790.50, by revising paragraph (a)(1) to read as follows:

§ 790.50 Submission of study plans.

(a) * * *

(1) Persons who notify EPA of their intent to conduct tests in compliance with a single phase test rule or consent agreement as described in § 790.40(b)(1) must submit study plans for those tests prior to the initiation of each of these test, unless directed by a particular test rule or consent agreement to submit study plans at a specific time.

* * * * *

[FR Doc. 89-11826 Filed 5-16-89; 8:45 am]

BILLING CODE 6560-50-M

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40 CFR Part 799

[OPTS 42107; FRL-3572-5]

1,6-Hexamethylene Diisocyanate; Proposed Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing a test rule under section 4 of the Toxic Substances Control Act (TSCA) that would require manufacturers and processors of 1,6-hexamethylene diisocyanate (HDI) (CAS No. 822-06-0) to test HDI for oncogenicity, mutagenicity, reproductive toxicity, developmental toxicity, neurotoxicity, pharmacokinetics, and hydrolysis. This proposed rule is EPA's response to the Interagency Testing Committee's (ITC) designation of HDI for health effects consideration in its twenty-second report to the Administrator of EPA.

DATES: Submit written comments on or before July 17, 1989. If persons request an opportunity to submit oral comments by July 3, 1989, EPA will hold a public meeting on this rule in Washington, DC. For further information on arranging to speak at the meeting, see Unit VIII. of this preamble. The incorporation by reference in this rule will be effective on the effective date of the final rule.

ADDRESS: Submit written comments identified by the document Control number (OPTS-42107) in triplicate to: TSCA Public Docket Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Room NE-G004, 401 M Street SW., Washington, DC 20460.

A public version of the administrative record supporting this action is available for inspection at the above address from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Room EB-44, 401 M Street SW., Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: EPA is issuing a proposed test rule under section 4(a) of TSCA in response to the ITC's designation of HDI for health effects testing consideration.

I. Introduction

A. ITC Recommendation

In its twenty-second report to the EPA Administrator, the ITC designated HDI for health effects testing, including chronic toxicity, oncogenicity, and reproductive and developmental effects. The rationale behind this designation is discussed in the **Federal Register** of May 20, 1988 (53 FR 18106). Based on an ongoing carcinogenicity study being conducted in one rodent species, the ITC recommended that chronic toxicity studies with carcinogenicity as an endpoint be conducted in another species in accordance with accepted guidelines.

B. Test Rule Development Under TSCA

Detailed discussions of the TSCA section 4 findings (section 4(a)(1) (A) and (B)) were provided in EPA's first and second proposed test rules which were published in the **Federal Register** of July 18, 1980 (45 FR 48510), and June 5, 1981 (46 FR 30300).

EPA has evaluated the ITC's testing recommendations for HDI, relying heavily on the Information Review (Ref. 1) developed by the ITC in support of their findings, as well as the supplemental information developed by EPA (see Unit IX. of this preamble). Based upon EPA's evaluation of this information, EPA is proposing health effects and chemical fate testing for HDI under TSCA section 4(a)(1)(B). This action completes EPA's statutory response to the ITC.

II. Chemical Profile and Health Effects

The HDI chemical profile, a review of published studies, and an analysis of the health effects, including acute toxicity, subchronic toxicity, chronic toxicity, oncogenicity, mutagenicity, reproductive effects, developmental toxicity, and neurotoxicity, and an analysis of metabolism and pharmacokinetis of HDI are described in the ITC's Information Review (Ref. 1), the HDI technical support document prepared by the Syracuse Research Corporation (Ref. 2),

and in the ITC Report published in the **Federal Register** (53 FR 18201).

III. Findings

Under TSCA section 4(a)(1)(B), EPA finds that HDI is produced in substantial quantities, that there is or may be substantial human exposure to HDI from its manufacture, processing, and use, and that insufficient data and experience exist to reasonably determine or predict: (1) The oncogenic, genotoxic, reproductive, developmental, and neurotoxic effects of human exposure to HDI resulting from its manufacture, processing, and use; (2) The absorption, distribution, metabolism, and excretion of HDI in the body as a result of dermal, oral, and inhalation exposure from HDI manufacture, processing, and use; and (3) the chemical fate of HDI in the atmosphere resulting from HDI manufature, processing, and use. EPA also finds that the testing program proposed in this **Federal Register** notice is necessary to, and will develop such data.

A. Substantial Production

The public portion of the TSCA section 8(b) Inventory data base lists U.S. production of HDI as 1 to 10 million pounds in 1977 (Ref. 1). Mobay reported 1981 production at 9 to 11 million pounds, and has estimated its 1987 production in the area of 11 million pounds (Ref. 1). The actual production and import volumes for 1987 have been submitted as confidential business information. EPA finds that this annual production volume is "substantial" as that term is used in section 4(a)(1)(B) of TSCA.

B. Substantial Human Exposure

EPA finds that the production and uses of HDI-containing resins and trimers in polyurethane paint systems results in potential exposure to substantial numbers of workers. HDI is used in the manufacture of higher molecular weight biuret polyisocyanate resins and trimer polyisocyantate resins used in polyurethane paint systems. The greatest potential for occupational exposures to HDI is in coating application operations, with an estimated 153,000 autobody repair workers having a potential for some exposure to HDI biuret and trimer-containing paints (Ref. 1). Potential exposures to workers supporting EPA's finding are described in the Information Review (Ref. 1). EPA believes that potential exposure of 153,000 workers as well as exposures listed in Reference 1 is "substantial" as that term is used in section 4(a)(1)(B) of TSCA.

C. Insufficiency of Data

On the basis of its review of data, EPA finds that existing data are insufficient or unavailable to reasonably determine or predict oncogenic, genotoxic, reproductive, developmental, and neurotoxic effects on human exposure to HDI resulting from its manufacture, processing, and use.

EPA has reviewed all of the available studies on the carcinogenicity of HDI and has found no current completed studies on the carcinogenicity of HDI in laboratory animals in the available literature, therefore there is insufficient information to predict the carcinogenic potential of HDI. EPA recognizes that HDI is currently undergoing testing in a 2-year rat inhalation toxicity/oncogenicity study (Ref. 5). EPA is, however, proposing that a bioassay be conducted according to TSCA test guidelines. Should this study (scheduled for completion in mid-1989) be completed, reviewed and found acceptable by EPA prior to promulgation of the final test rule, this test standard will not be finalized.

EPA has reviewed all of the available studies and found them insufficient to reasonably predict the mutagenic potential of HDI. There were no studies on the reproductive or developmental toxicology of HDI in laboratory animals in the available literature, therefore assessment of the fetotoxic potential can not be done. There were no studies on the neurotoxic potential of HDI laboratory animals in the available literature, therefore neurotoxic assessment cannot be done. (Ref. 2).

EPA has recently received data on the subchronic toxicity of HDI (Ref. 6). These data have been reviewed by EPA and found to be adequate. Therefore EPA is not proposing subchronic testing of HDI.

EPA also finds that there are insufficient data to reasonably predict and compare the absorption, distribution, metabolism, and excretion of HDI in the body as a result of dermal, oral, and inhalation exposure due to HDI manufacture, prosessing, and use. Data on the pharmacokinetics of HDI were not located in the available literature, therefore the absorption, distribution, metabolism and excretion of HDI cannot be determined. (Ref. 2).

EPA finds that available data are insufficient to reasonably determine or predict the rate of hydrolysis of HDI by water vapor in the gas phase. Identifying the rate of hydrolysis of HDI is necessary to determine the availability of HDI for absorption to humans. (Ref. 2).

D. Testing is Necessary

EPA believes that the testing of HDI for effects noted in Unit III.C. will be relevant to a determination of whether HDI manufacture, processing and use does or does not present an unreasonable risk of injury to human health and the environment. EPA believes that the testing proposed in this proposed test rule will provide data sufficient to make such a determination.

IV. Proposed Rule

A. Proposed testing and Test Standards

EPA is proposing that testing be conducted in accordance with specific test guidelines set forth in 40 CFR Parts 795 and 798. All persons conducting tests would conduct tests in accordance with the TSCA Good Laboratory Practice (GLP) Standards (40 CFR 792). The specific tests EPA is proposing are set forth in proposed § 799.2145 and are identified in the table in Unit IV.D. of this preamble.

The tiered testing schemes for mutagenicity are discussed in detail in the final test rule for the C_9 aromatic hydrocarbon fraction (50 FR 20662; May 17, 1985). Modifications to the MVSL including the option of substitution the MBSL for the MVSL and the MBSL test procedures were proposed in the **Federal Register** notice of December 23, 1988 (53 FR 51847) and are incorporated into this proposed rule.

EPA believes that pharmacokinetics testing is necessary to reduce uncertainties associated with the extrapolation of toxicity test data from high to low doses, from species to species, and from one route of exposure to another. However, EPA is currently reviewing its pharmacokinetics testing guideline and will propose a specific test in a separate **Federal Register** notice.

To assess the chemical fate of HDI in the atmosphere, EPA is proposing hydrolysis testing. In the absence of an existing standard testing protocol for testing gas-phase hydrolysis rates of diisocyanates in the atmosphere, EPA is proposing that the determination of the rate of hydrolysis of HDI in air be conducted in accordance with Holdren et al. (Ref. 4).

B. Test Substance

EPA is proposing that HDI of at least 98 percent purity be used as the test substance. EPA has specified a relatively pure substance for testing because EPA is interested in evaluating the effects attributable to HDI itself. EPA believes that this grade of HDI is readily available for testing purposes.

C. Persons required to test

Because EPA has found that there are insufficient data and experience to reasonably determine or predict the effects on human health of the manufacture, processing, and use of HDI, EPA is proposing that persons who manufacture and/or process, or who intend to manufacture and/or process HDI, other than as an impurity, at any time from the effective date of the final test rule to the end of the reimbursement period be subject to the testing requirements in this proposed rule. This period is defined in 40 CFR 791.3(h). While EPA has not identified any byproduct manufacturers of HDI, such persons would be covered by the requirements of this test rule.

Manufactures, including importers potentially subject to the final rule should consult the procedures in 40 CFR Part 790. Processors subject to the final rule, unless they are also manufacturers, would not be required to submit letters of intent or exemption applications, but should consult 40 CFR Part 790 for additional details.

EPA is not proposing to require the submission of equivalence data as a condition for exemption from the proposed testing for HDI because EPA is interested in evaluating the effects attributable to HDI itself and has specified a relatively pure substance for testing.

D. Reporting Requirements

As required in 40 CFR 799.10, all data developed under the final rule would be reported in accordance with its TSCA GLP Standards which appear in 40 CFR Part 792. In addition 40 CFR Part 790 requires test sponsors to submit individual study plans at least 45 days prior to the initation of each study.

As required by section 4(b)(1)(C) of TSCA, EPA is proposing specific reporting requirements for each of the proposed tests for HDI shown in the following table.

TABLE—PROPOSED TESTING, TEST STANDARDS, AND REPORTING REQUIREMENTS FOR HDI

Test	Test standard (40 CFR citation)	Reporting deadline for final report [1]	Interim (6-month) reports required
Chronic toxicity:			
1. Oncogenicity	§ 798.3300	53	8
Specific organ/tissue toxicity:			
2. Reproduction and fertility effects	§ 798.4700	29	4
3. Developmental toxicity (oral)	§ 798.4900	12	1
Gene toxicity:			
Gene mutations:			
4. *Salmonella typhimurium*	§ 798.5265	9	1
5. Mammalian cells in culture	§ 798.5300	19	2
6. *Drosophila* sex-linked recessive lethal	§ 798.5275	31	4
7. Mouse visible specific locus or Mouse biochemical specific locus test	§ 798.5200 or § 795.5195 [2]	51	8
Chromosomal aberrations:			
8. *In vitro* cytogenetics	§ 798.5375	10	1
9. *In vitro* cytogenetics	§ 798.5385	24	3
10. Dominant lethal assay	§ 798.5450	36	5
11. Heritable translocation assay	§ 798.5460	[3] 25	4
Acute neurotoxicity:			
12. Functional observation battery	§ 798.6050	9	1
13. Motor activity	§ 798.6200	9	1
Subchronic neurotoxicity:			
14. Functional 90-day observation battery	§ 798.6050	21	3
15. Motor activity	§ 798.6200	21	3
16. Neuropathology	§ 798.6400	21	3
Chemical fate:			
17. Hydrolysis	Holdren (Ref. 4)	12	1

[1] Number of months after the effective date of the final rule, except as indicated.
[2] MVSL/MBSL Guideline proposed in 53 FR 51847 (December 23, 1988).
[3] Figure indicates the reporting deadline, in months, calculated from the date of notification of the test sponsor by certified letter of **Federal Register** notice that, following public program review of all of the then existing data for HDI, EPA has determined that the required testing must be performed.

V. Issues for Comment

1. This proposed rule specifies TSCA test guidelines as the test standards for health effects testing of HDI. EPA is soliciting comments as to whether these test guidelines are appropriate and adequate to characterize the health effects of HDI. EPA specifically requests comments on whether EPA's proposed combined chronic toxicity/oncogenicity (40 CFR 798.3320) guideline is appropriate and should be required in place of the oncogenicity guideline (40 CFR 798.3300). The provisions of this guideline are designed primarily for use with the rat as the test species. The use of this combined guideline would reflect EPA's concern for long-term low-dose chronic effects of HDI that may not be adequately characterized by subchronic testing alone. Oncogenicity testing in a second species would also be required.

2. EPA requests comments on the potential for HDI to hydrolyze in the atmosphere. Based on the data reported by Holdren et al. (Ref. 4) for toluene diisocyanate (TDI), EPA believes that the hydrolysis rate of HDI in the gas phase with low to moderate humidity (7 to 70 percent) will be slow relative to the hydrolysis rate in an aqueous phase. EPA solicits comments on the use of the method reported by Holdren (Ref. 4) to assess the hydrolysis rate in a gas phase with moderate to high humidity (70 to 100 percent).

3. EPA requests comments on the route of exposure for testing. EPA is proposing that most of the tests be conducted by inhalation because it is the most relevant route for human exposure to HDI. However, because of technical problems associated with certain TSCA test guidelines (i.e., reproductive effects and developmental toxicity), and the desire to choose a route of administration and vehicle that will assure that the dose is received by the target tissues, EPA is proposing exposure by gavage for reproductive effects and developmental toxicity. EPA requests comments on this approach

and also on the route of exposure for the mutagenicity screens. In addition should the inhalation route of entry be selected for the developmental toxicity study after the completion of the pharmacokinetics study if the pharmacokinetics study reveals significant metabolic differences between inhalation and gavage exposures? EPA also requests comments on an appropriate vehicle (e.g. corn oil) for the gavage studies.

4. EPA requests comments on the adequacy of the genetic toxicity testing scheme, in particular the use of bone marrow assays for a highly reactive substance such as HDI. Would cytogenetic assays such as those involving peripheral blood lymphocytes or lung cells following *in vivo* exposures be useful or be in a sufficient stage of development and validation to provide useful information?

5. Diisocyanates are known to be highly reactive biologically, with HDI known to be a respiratory and dermal irritant and sensitizer. EPA requests comments on the role these properties will pay in selecting an appropriate animal model for testing, and what additional testing may be needed to assess these effects in humans.

6. EPA requests comments on the reporting requirements (schedules) for the cited guidelines.

VI. Economic Analysis of the Proposed Rule

To assess the potential economic impact of this rule, EPA has prepared an economic analysis that evaluates the potential for significant economic impacts on the industry as a result of the proposed testing. (Ref. 3)

Total testing costs for the proposed testing of HDI are estimated to range from $2.3 to 3.3 million. To predict the financial decisionmaking practices of manufacturing firms, these costs have been annualized. Annualized costs are compared with annual revenue as an indication of potential impact. The annualized costs represent equivalent constant costs which would have to be recouped each year of the payback period to finance the testing expenditure in the first year.

The annualized test costs, using a 7 percent cost of capital over a period of 15 years, range from $251,700 to $362,000. The production volume and price information have been claimed confidential and are contained in the economic analysis which is being treated as CBI.

VII. Availability of Test Facilities and Personnel

As required by section 4(b)(1) of TSCA, EPA has conducted a study to assess the availability of test facilities and personnel to handle the additional demand for testing services created by section 4 test rules and found that there will be available test facilities and personnel to perform the testing specified in this proposed rule. Copies of the study, Chemical Testing Industry: Profile of Toxicological Testing, can be obtained through the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161 (PB 82-140773). A copy of this study is contained in the rulemaking record for this proposed rule.

VIII. Public Meeting

If persons indicate to EPA that they wish to present oral comments on this proposed rule to EPA officials who are directly responsible for developing the rule and supporting analyses, EPA will hold a public meeting after the close of the public comment period in Washington, DC. Persons who wish to attend or to present comments at the meeting should call the TSCA Assistance Office (TAO): (202) 554-1404 by July 3, 1989. No meeting will be held unless members of the public indicate that they wish to make oral presentations. While the meeting will be open to the public, active participation will be limited to those persons who arranged to present comments and to designated EPA participants. Attendees should call the TAO before making travel plans to verify whether a meeting will be held.

Should a meeting be held, EPA will transcribe the meeting and include the written transcript in the rulemaking record. Participants are invited, but not required, to submit copies of their statements prior to or on the day of the meeting. All such written materials will become part of EPA's record for this rulemaking.

IX. Comments Containing Confidential Business Information

Any person who submits comments which the person claims as Confidential Business Information (CBI) must mark the comments as confidential. Comments not claimed as confidential at time of submission will be placed in the public file. Any comments marked confidential will be treated in accordance with the procedures in 40 CFR Part 2. EPA requests that any person submitting confidential comments prepare and submit a sanitized version of the comments which EPA can place in the public file.

X. Rulemaking Record

EPA has established a record for this rulemaking (docket number OPTS-42107). This record contains the basic information considered by EPA in developing this proposal and appropriate **Federal Register** notices. EPA will supplement this record with additional relevant information, as necessary.

CBI, while part of the record, is not available for public review. A public version of the record, from which CBI has been deleted, is available for inspection in the OPTS Reading Room, Rm. G-004, NE Mall, 401 M St. SW., Washington, DC 20460, from 8 am to 4 pm, Monday through Friday, except legal holidays. EPA will supplement this record periodically with additional information received.

The record includes the following information:

A. Supporting Documentation

(1) **Federal Register** notices pertaining to this rule consisting of:

(a) Notice containing the ITC designation of HDI to the Priority List (53 FR 18196; May 20, 1988) and all comments on HDI received in response to that notice.

(b) Rules requiring TSCA section 8(a) (53 FR 18211; May 20, 1988) and 8(d) reporting (52 FR 16022; May 1, 1987) on HDI.

(c) Notice of final rule on EPA's TSCA Good Laboratory Practice Standards (48 FR 53922; November 29, 1983).

(d) Notice of final rule on data reimbursement policy and procedures (48 FR 31786; July 11, 1983).

(e) Interim Final Rule: Procedures Governing Testing Consent Agreements and Test Rules Under the Toxic Substances Control Act (40 CFR Part 790).

(2) Support documents consisting of:

(a) Technical support document for proposed rule.

(b) Economic impact analysis of proposed rule for HDI.

(3) TSCA test guidelines cited as test standards for this rule.

(4) Communications before proposal consisting of:

(a) Written public comments and letters.

(b) Contact reports of telephone conversations.

(c) Meeting summaries.

(5) Reports—published and unpublished factual materials including Chemical Testing Industry: Profile of Toxicological Testing (October, 1981).

(6) Data received under section 8(a) of TSCA

B. References

(1) Dynamac Corporation. "Information Review 1,6-diisocyanatohexane," IR-323 Rockville, MD. (June 24, 1988).

(2) Syracuse Research Corporation. "Review of Some Critical Studies on 1,6-

Hexamethyl Diisocyanate," Syracuse, NY. (July 8, 1988).

(3) EPA, "Economic Impact Analysis of Proposed Test Rule—Hexamethylene Diisocyanate, Non Confidential version", Washington, DC (April 13, 1989).

(4) Holdren, M.W., Spicer, C.W., Riggin, R.M. "Gas Phase Reaction of Toluene Diisocyanate with Water Vapor", *American Industrial Hygiene Association Journal*, 45:626–633 (1984).

(5) Letter from F. J. Rattay, Manager, Regulatory Compliance, Mobay Corporation, Pittsburgh, PA, to R. Brink, TSCA Interagency Testing Committee, (January 21, 1988)

(6) Mobay Corporation, "90-day Inhalation Toxicity Study With 1,6 Hexamethylene Diisocyanate (HDI) in Rats," Study Number 81–141–01, (December 28, 1988) (EPA No 86-89000080).

XI. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. EPA has determined that this proposed test rule would not be major because it does not meet any of the criteria set forth in section 1(b) of the Order; i.e., it would not have an annual effect on the economy of at least $100 million, would not cause a major increase in prices, and would not have a significant adverse effect on competition or the ability of U.S. enterprises to compete with foreign enterprises.

This proposed rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB to EPA, and any EPA response to those comments, are included in the rulemaking record.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, Pub. L. 96–354, September 19, 1980), EPA is certifying that this test rule, if promulgated, would not have a significant impact on a substantial number of small businesses because: (1) They would not be expected to perform testing themselves, or to participate in the organization of the testing effort; (2) they would experience only very minor costs, if any, in securing exemption from testing requirements; and (3) they are unlikely to be affected by reimbursement requirements.

C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in this proposed rule under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2070–0033.

Public reporting burden for this collection of information is estimated to average 1027 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The total public reporting burden is estimated to be 17,454 hours for all responses.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM–223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA." The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

List of Subjects in 40 CFR Part 799

Chemicals, Environmental protection, Hazardous substances, Testing, Laboratories, Recordkeeping and reporting requirements, Incorporation by reference.

Dated: May 2, 1989.

Charles Elkins,

Acting Assistant Administrator for Pesticides and Toxic Substances.

Therefore, it is proposed that 40 CFR Part 799 be amended as follows:

PART 799—[AMENDED]

a. The authority citation for Part 799 would continue to read as follows:

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

b. By adding § 799.2145 to read as follows:

§ 799.2145 1,6-Hexamethylene diisocyanate.

(a) *Identification of test substance.* (1) 1,6-Hexamethylene diisocyanate (HDI) (CAS No. 822–06–0) shall be tested in accordance with this section.

(2) HDI of at least 98 percent purity shall be used as the test substance.

(b) *Persons required to submit study plans, conduct tests, and submit data.* All persons who manufacture (including import or byproduct manufacture) or process HDI other than as an impurity from (44 days after the publication date of the final rule in the **Federal Register**) to the end of the reimbursement period shall submit letters of intent to conduct testing, submit study plans, conduct tests, and submit data or submit exemption applications as specified in this section, Subpart A of this part, and Parts 790 and 792 of this chapter for single-phase rulemaking.

(c) *Health effects testing*—(1) *Oncogenicity*—(i) *Required testing.* An oncogenicity test shall be conducted with HDI by inhalation using the Fischer 344 rat and one other rodent species in accordance with § 798.3300 of this chapter.

(ii) *Reporting requirements.* (A) The oncogenicity test shall be completed and the final report submitted to EPA within 53 months of the effective date of the final rule.

(B) Progress reports shall be submitted at 6-month intervals beginning 6 months after the effective date of the final rule until submission of the final report.

(2) *Reproduction and fertility effects*—(i) *Required testing.* A reproduction and fertility effects test shall be conducted by gavage in corn oil with HDI in accordance with § 798.4700 of this chapter.

(ii) *Reporting requirements.* (A) The reproduction and fertility effects test shall be completed and the final report submitted to EPA within 29 months of the effective date of the final rule.

(B) Progress reports shall be submitted at 6-month intervals beginning 6 months after the effective date of the final rule until submission of the final report.

(3) *Developmental toxicity*—(i) *Required testing.* A developmental toxicity test shall be conducted by gavage with HDI in accordance with § 798.4900 of this chapter.

(ii) *Reporting requirements.* (A) The developmental toxicity test shall be completed and the final report submitted to EPA within 12 months of the effective date of the final rule.

(B) Progress reports shall be submitted 6 months after the effective date of the final rule until submission of the final report.

(4) *Mutagenic effects—gene mutations*—(i) *Required testing.* (A) A *Salmonella typhimurium* reverse mutation assay shall be conducted with HDI both with and without metabolic activation in accordance with § 798.5265 of this chapter.

(B) A gene mutation test in mammalian cells shall be conducted with HDI both with and without metabolic activation as specified in § 798.5300 of this chapter if the results from the *Salmonella typhimurium* test conducted pursuant to paragraph (c)(4)(i)(A) of this section are negative.

(C) (*1*) A sex-linked recessive lethal test in *Drosophila melanogaster* shall be conducted with HDI in accordance with § 798.5275 of this chapter except for the provisions in paragraphs (d)(5) (ii) and

(iii) of § 798.5275, unless the results of both the *Salmonella typhimurium* test conducted pursuant to paragraph (c)(4)(i)(A) of this section and the mammalian cells in the culture gene mutation test conducted pursuant to paragraph (c)(4)(i)(B) of this section, if required, are negative.

(2) [*Reserved*]

(D) (1) A mouse visible specific locus test or a mouse biochemical specific locus test shall be conducted with HDI by inhalation in accordance with § 798.5200 of this chapter except for the provisions in paragraph (d)(5)(iii) of § 798.5200, or in accordance with § 798.5195 of this chapter except for the provisions in paragraph (d)(5)(iii) of § 798.5195 of this chapter, if the results of the sex-linked recessive lethal test conducted pursuant to paragraph (c)(4)(i)(B) of this section are positive and if, after a public program review, EPA issues a **Federal Register** notice or sends a certified letter to the test sponsor specifying that the testing shall be initiated.

(2) For the purposes of this section, the following provisions also apply:

(*i*) *Dose levels.* The duration of exposure shall be for 6 hours per day.

(*ii*) *Route of administration.* Animals shall be exposed to HDI by inhalation.

(ii) *Reporting requirements.* (A) The gene mutation tests shall be completed and final report submitted to EPA as follows:

(1) The *Salmonella typhimurium* reverse mutation assay within 9 months of the effective date of the final rule.

(2) The gene mutation in mammalian cells assay within 19 months of the effective date of the final test rule.

(3) The sex-linked recessive-lethal test in *Drosophila melanogaster* within 31 months of the effective date of the final rule.

(4) The mouse visible specific-locus test or mouse biochemical specific locus test within 51 months of the date of EPA's notification of the test sponsor by certified letter or **Federal Register** notice under paragraph (c)(4)(i)(C) of this section that testing shall be initiated.

(B) Progress reports shall be submitted to EPA for the *Drosophila* sex-linked recessive lethal test 6 month intervals beginning 6 months after the effective date of the final rule until the submission of the final report.

(C) Progress reports shall be submitted to EPA for the mouse visible specific locus test or mouse biochemical specific locus test at 6-month intervals beginning 6 months after the date of EPA's notification of the test sponsor that testing shall be initiated until submission of the final report.

(5) *Mutagenic effects—chromosomal aberration*—(i) *Required testing.* (A) An *in vitro* cytogenetics test shall be conducted with HDI in accordance with § 798.5375 of this chapter.

(B) (1) An *in vivo* cytogenetics test shall be conducted with HDI in accordance with § 798.5385 of this chapter except for the provisions in paragraphs (d)(5) (iii) and (iv), if the *in vitro* test conducted pursuant to paragraph (c)(5)(i)(A) of this section is negative.

(2) For the purpose of this section, the following provisions also apply:

(*i*) *Route of administration.* Animals shall be exposed to HDI by inhalation.

(*ii*) *Treatment schedule.* The duration of exposure shall be for 6 hours per day for 5 consecutive days with one sacrifice time or for 6 hours per day for 1 day with 3 sacrifice times.

(C) (1) A dominant lethal assay shall be conducted with HDI in accordance with § 798.5450 of this chapter except for the provisions in paragraphs (d)(5) (ii) and (iii), unless both the *in vitro* and *in vivo* cytogenetics tests conducted pursuant to paragraphs (c)(5)(i) (A) and (B) of this section are negative.

(2) For purposes of this section, the following provisions also apply:

(*i*) *Route of administration.* Animals shall be exposed by inhalation.

(*ii*) *Treatment schedule.* The duration of exposure shall be for 6 hours per day for 5 consecutive days.

(D) (1) A heritable translocation test shall be conducted with HDI in accordance with § 798.5460 of this chapter except for the provisions in paragraphs (d)(5) (ii) and (iii), of the results of the dominant lethal assay conducted pursuant to paragraph (c)(5)(i)(C) of this section are positive and if, after a public program review, EPA issues a **Federal Register** notice or sends a certified letter to the test specifying that the testing shall be initiated.

(2) For the purposes of this section, the following provisions also apply:

(*i*) *Route of administration.* Animals shall be exposed to HDI by inhalation.

(*ii*) [Reserved]

(ii) *Reporting requirements.* (A) The chromosomal aberration tests shall be completed and the final reports submitted to EPA as follows:

(1) The *in vitro* cytogenetics test within 10 months of the effective date of the final rule.

(2) The *in vivo* cytogenetics test within 24 months of the effective date of the final rule.

(3) The dominant lethal assay within 36 months of the effective date of the final rule.

(4) The heritable translocation test within 25 months of the date of EPA's notification of the test sponsor by certified letter or Federal Register notice under paragraph (c)(5)(i)(D) of this section that testing shall be initiated.

(B) Progress reports shall be submitted to EPA for the *in vitro* cytogenetics, the *in vivo* cytogenetics, and the dominant lethal assays at 6-months intervals beginning 6 months after the effective date of the final rule until submission of the applicable final report.

(C) Progress reports shall be submitted to EPA for the heritable translocation assay at 6-month intervals beginning 6 months after the date of EPA's notification of the test sponsor that testing shall be initiated until submission of the final report.

(6) *Neurotoxicity*—(i) *Required testing.* (A)(1) An acute and subchronic functional observation battery shall be conducted with HDI in accordance with § 798.6050 of this chapter except for the provisions in paragraphs (d) (5) and (6) of § 798.6050.

(2) For the purpose of this section, the following provisions also apply:

(*i*) *Duration and frequency of exposure.* For the acute study, animals shall be dosed for 4 to 6 hours once. For the subchronic study, animals shall be dosed for 6 hours per day, 5 days per week for 90 days.

(*ii*) *Route of exposure.* For the acute and subchronic studies, animals shall be exposed to HDI by inhalation.

(B) (1) An acute and subchronic motor activity test shall be conducted with HDI in accordance with § 798.6200 of this chapter except for the provisions in paragraph (d) (5) and (6) of § 798.6200.

(2) For the purpose of this section, the following provisions also apply:

(*i*) *Duration and frequency of exposure.* For the acute study, animals shall be dosed for 4 to 6 hours once. For the subchronic study, animals shall be dosed for 6 hours per day, 5 days per week for 90 days.

(ii) *Route of exposure.* For the acute and the subchronic studies, animals shall be exposed to HDI by inhalation.

(C)(1) A neuropathology test shall be conducted with HDI in accordance with § 798.6400 of this chapter except for the provisions in paragraphs (d) (5) and (6) of § 798.6400

(2) For the purpose of this section, the following provisions also apply:

(*i*) *Duration and frequency of exposure.* Animals shall be dosed for 6 hours per day, 5 days per week for 90 days.

(*ii*) *Route of exposure.* Animals shall be exposed to HDI by inhalation.

(ii) *Reporting requirements.* (A) The subchronic functional observation battery, subchronic motor activity, and neuropathology tests shall be completed and the final reports submitted to EPA within 21 months of the effective date of the final rule.

(B) The acute functional observation battery and acute motor activity tests shall be completed and the final reports submitted to EPA within 9 months of the effective date of the final rule.

(C) Progress reports shall be submitted to EPA for the acute and subchronic functional observation battery, acute and subchronic motor activity, and neuropathology tests at 6-month intervals beginning 6 months after the effective date of the final rule until submission of the applicable final report.

(7) *Pharmacokinetics Testing*—[Reserved]

(d) *Chemical fate testing—Hydrolysis*—(1) *Required testing.* A rate of hydrolysis in the gaseous phase shall be conducted with HDI in accordance with the test guideline by M.W. Holdren, C.W. Spicer, and R.M. Riggens entitled, "Gas Phase Reaction of Toluene Diisocyanate with Water Vapor" and published in: *American Industrial Hygiene Association Journal*, 45:626–633 (1984) which is incorporated by reference. This method is available for inspection at the Office of Federal Register, Rm. 8301, 1100 L St. NW., Washington, DC 20408 and copies may be obtained from the EPA TSCA Public Docket Office, Rm. NE G–004, 401 M Street SW., Washington, DC 20460. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This material is incorporated as it exists on the effective date of this section and a notice of any change in this material will be published in the **Federal Register.** Copies of the incorporated material may be obtained from the Document Control Officer (TS–793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. NE–C004, 401 M Street SW., Washington DC, 20460.

(2) *Reporting requirements.* (i) The hydrolysis in the gaseous phase test shall be completed and the final report submitted to EPA within 12 months of the effective date of the rule.

(ii) A progress report shall be submitted to EPA for the hydrolysis test 6 months after the effective date of the final rule.

(e) *Effective dates.* (1) This rule shall become effective 44 days after date of publication of the final rule in the **Federal Register.**

(2) The guidelines and other test methods cited in this section are referenced as they exist on the effective date of the final rule.

[Information collection requirements have been approved by the Office of Management and Budget under control number 2070–0033]

[FR Doc. 89–11824 Filed 5–16–89; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Parts 10 and 15

[CGD 81–059a]

RIN 2115–AB91

Licensing of Officers and Operators for Mobile Offshore Drilling Units

AGENCY: Coast Guard, DOT.

ACTION: Supplemental Notice of Proposed Rulemaking

SUMMARY: This supplemental notice deals solely with the licensing of officers on mobile offshore drilling units (MODUs) and the manning of these vessels. This proposal would replace the Interim Final Rule published on October 16, 1987 (52 FR 38660). The effective date of that Interim Final Rule was suspended indefinitely on February 28, 1989 (54 FR 8334). The licensing structure implements National Transportation Safety Board (NTSB) recommendations for the establishment of personnel qualifications and manning regulations for this type of vessel. Compliance with these minimum standards will ensure that qualified individuals are on board to deal with marine safety related matters.

DATE: Comments must be received on or before June 16, 1989.

ADDRESSES: Comments should be submitted to: The Executive Secretary, Marine Safety Council (G–LRA–2) [CGD 81–059a] U.S. Coast Guard, Washington, DC 20593–0001. Between 8:00 a.m. and 3:00 p.m., Monday through Friday, comments may be delivered to and will be available for inspection or copying at the Marine Safety Council (G–LRA–2), Room 3600, U.S. Coast Guard Headquarters, 2100 Second Street, SW., Washington, DC 20593–0001, (202) 267–1477.

FOR FURTHER INFORMATION CONTACT: LCDR Gerald D. Jenkins, Project Manager, Office of Marine Safety, Security and Environmental Protection, (G–MVP), phone (202) 267–0224.

SUPPLEMENTARY INFORMATION: Interested persons are invited to participate in this rulemaking by submitting written data, views, or arguments. Written comments should include the name and address of the person making them, identify this notice [CGD 81–059a], the specific section of the proposal to which the comment applies, and the reason for the comment. Persons desiring an acknowledgement that their comment has been received should enclose a stamped, self-addressed postcard or envelope. All comments received before expiration of the comment period will be considered before final action is confirmed.

Drafting Information

The principal drafters of this supplemental notice are: LCDR Gerald D. Jenkins, Office of Merchant Marine Safety, Security and Environmental Protection, and CDR Gerlad A. Gallion, Office of Chief Counsel.

Background

The Notice of Proposed Rulemaking to completely revise licensing regulations in Part 10 of Title 46, Code of Federal Regulations, published on August 8, 1983 (48 FR 35920) included proposed rules which formalized the special industry licenses and extended their application to all mobile offshore drilling units. As a result of comments received, a separate Supplemental Notice of Proposed Rulemaking concerning the licensing of officers on MODUs and the manning of these vessels was published on October 24, 1985 (50 FR 43366). The Coast Guard received generally good support from the mobile offshore drilling industry. Forty-five specific written comments were submitted and the International Association of Drilling Contractors (IADC) provided the detailed MODU On-Board Marine Task Analysis Report. An Interim Final Rule was published on October 16, 1987 (52 FR 38660). The Coast Guard received fifteen written comments to the Interim Final Rule. These comments demonstrate that additional changes were necessary in order to adequately address several subjects. This supplemental notice revises the offshore installation manager qualifications and MODU manning levels. It also provides a procedure by which unlicensed individuals currently serving in positions requiring licenses can obtain the required credentials.

Specific Comment Areas

1. *Effective date of regulations.* The nature of the comments made to the previously published Interim Final Rule demonstrate that extensive changes to the rulemaking are appropriate. To facilitate public comment on these