40 CFR Part 799

[OPTS-42030H; FRL 3883-3]

Testing Consent Order for Mesityl Oxide

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This rule announces that EPA has signed an enforceable testing consent order with four of the manufacturers of mesityl oxide (MO; CAS No. 141-79-7), who have agreed to perform certain health effects tests with MO. MO is added to the list of Testing Consent Orders in 40 CFR 799.5000. Accordingly, the export notification requirements of 40 CFR part 707 apply to MO.

EFFECTIVE DATE: September 5, 1991.

FOR FURTHER INFORMATION CONTACT: David Kling, Acting Director, Environmental Assistance Division (TS-799), Office of Toxic Substances, rm. E-543B, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: Elsewhere in this issue of the **Federal Register**, EPA is proposing to revoke the previous TSCA section 4 test rule for this chemical.

I. Regulatory History

In its Fourth Report to EPA, published in the **Federal Register** of June 1, 1979 (44 FR 31866), the Interagency Testing Committee (ITC) recommended that MO be considered for health effects testing. In response to the ITC, EPA issued a two-phase final test rule under section 4(a)(1)(A) of the Toxic Substances Control Act (TSCA). The first phase of the final test rule was published in the **Federal Register** of December 20, 1985 (50 FR 51857). The second phase--test standards and reporting requirements, was published in the **Federal Register** of May 20, 1987 (52 FR 19088). Testing requirements specified in the rule included subchronic toxicity, mutagenicity, and oncogenicity testing if the mutagenicity testing was positive. Prior to EPA issuing the test standards and reporting requirements for MO, several of the manufacturers (Shell Chemical Company, Eastman Kodak Company, Union Carbide Corporation, and Exxon Chemical Americas) submitted a TSCA section 21 petition requesting that EPA withdraw the test rule. Their request was based upon declining use of MO, voluntary changes made in their manufacturing practices, and cessation of merchant sale--all of which, the manufacturers concluded, reduced human exposure. EPA denied the TSCA section 21 petition, finding that the remaining exposures from manufacturing and processing MO both as an intermediate and as a byproduct were still sufficient to support the need for health effects testing under TSCA section 4 (51 FR 30216; August 25, 1986).

The manufacturers also pursued judicial review of the rule, and on August 19, 1987, the US Court of Appeals, for the Fifth Circuit, remanded the rule for reconsideration in light of new information suggesting that human exposure to MO had declined since EPA promulgated the test rule. The Court

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stayed the test rule pending EPA's reconsideration on remand (Ref. 1).

EPA, several of the manufacturers, and the Chemical Manufacturers Association (CMA) then independently reassessed worker exposure and current manufacturing practices. The manufacturers and CMA conducted additional work place monitoring and user surveys (Refs. 2 and 9); and EPA evaluated exposure from the manufacture of MO as a byproduct (Ref. 3). Based upon the results of these exposure analyses and surveys, four of the manufacturers (Union Carbide Corporation, Shell Chemical Company, Eastman Kodak Company, and General Electric Company) and EPA agreed that screening level health effects testing would be appropriate.

II. Use and Exposure

The use and exposure of MO were characterized in the proposed and final test rules (48 FR 30699, 50 FR 51857, and 52 FR 19088, respectively) and in EPA's response to the section 21 petition (51 FR 30216). After the Court remand, several of the manufacturers conducted additional work place monitoring and together with the other manufacturers sponsored a user survey (Refs. 2 and 9). In addition, EPA reevaluated exposures associated with manufacture of MO as a byproduct (Refs. 3 and 6).

The manufacturers reported that, as of February 1990:

1. Exxon Chemical Americas had dismantled its production unit, leaving only three manufacturers that use MO as an intermediate (primarily to make methyl isobutyl ketone).

2. There are now only three sites where MO is used as an intermediate; there were six at the time the test rule was promulgated.

3. Three of the six companies that produced MO as a byproduct no longer do so, and exposures associated with manufacturing facilities of the remaining three companies are "negligible".

4. Work place monitoring in both intermediate and byproduct manufacturing facilities indicates exposures consistently below 0.1 ppm, the lower detection limit.

5. There are fewer than 350 workers exposed during manufacturing activities (both as an intermediate and as a byproduct).

6. Two of the four companies that processed MO as a pesticide inert ingredient no longer do so. The remaining two companies import less than 1 million pounds annually, and only a few workers may be infrequently exposed to low levels of MO.

Prior to industry submitting their survey and monitoring results, EPA estimated occupational exposures to MO resulting from byproduct manufacture (Refs. 3 and 6). EPA did not independently reevaluate the worker exposure profile from manufacturing MO as an intermediate or as a pesticide inert ingredient since EPA believed that manufacturing practices had not changed substantially since EPA reviewed the section 21 petition.

Based upon EPA's analysis and calculations, approximately 50 workers may be exposed to MO as a byproduct produced during isophorone manufacture. During sampling of isophorone, inhalation of MO is estimated to be 0.4 mg/day and dermal exposure estimates range from 570 to 1,100 mg/day. Inhalation exposure to MO during drumming of isophorone is estimated to range from 13 to 26 mg/day, while dermal exposures may range from 740 to 2,200 mg/day. Additionally, 8 to 16 workers are estimated to be exposed to MO as a byproduct produced during the manufacture of vitamin C. MO exposures during sampling of vitamin C were estimated to be 0.1 mg/day for inhalation and 130 to 390 mg/day for dermal, while drumming of wastes containing MO may result in additional exposures of 80 mg/day for inhalation and 130 to 390 mg/day for dermal. Between 72 to 360 workers may also be exposed to MO as a byproduct produced during the dry extrusion of cellulose acetate. Estimated MO exposures are: 0.001 mg/day for inhalation and 0.06 to 0.19 mg/day for dermal.

III. Health Effects

The known health effects of MO were discussed in the proposed and final test rules (48 FR 30699, 50 FR 51857, and 52 FR 19088 respectively). In summary, exposure to MO may cause mutagenic effects. EPA believes MO may react as an alkylating agent and as such has the potential to interact with the informational molecules of human cells (DNA, RNA, proteins). The reaction products, if not repaired, may result in cellular or genetic damage that may be expressed as mutagenic and possibly carcinogenic effects. MO may also induce leukopenia (reduction of the number of white blood cells in the body) and cause hypertrophy of the liver, kidney, and spleen. There are no studies on the developmental (teratogenic) or reproductive effects of MO.

IV. Testing Consent Order Negotiations

After receipt of the exposure update from the manufacturers, CMA and EPA discussed the need for testing MO. On September 12, 1990, CMA, representing the manufacturers, requested that EPA develop a testing consent order (Ref. 4). EPA agreed to consider negotiating a consent order with the manufacturers and issued a notice, published in the **Federal Register** of October 2, 1990 (55 FR 40234), announcing the decision. This notice also announced the time and location of a public meeting to initiate testing negotiations pursuant to 40 CFR part 790. The notice requested that all "interested parties" who wanted to participate in negotiations identify themselves to EPA by October 18, 1990. Four manufacturers and CMA identified themselves as interested parties. Prior to the public meeting, CMA submitted proposed protocols for three health effects tests. The protocols were modelled after the Organization for Economic Cooperation and Development (OECD) Screening Information Data Set (SIDS) draft guidelines. EPA reviewed CMA's draft protocols and developed a draft consent agreement. Both were discussed during the October 18, 1990 public meeting. On December 27, 1990, the following manufacturers agreed in principle to EPA's proposals regarding the agreement: Eastman Kodak Company, Shell Chemical Company, Union Carbide Corporation, and General Electric Company (Ref. 5). On (insert date) these four manufacturers, and CMA as an interested party, signed the Testing Consent Order for MO. The manufacturers agreed to perform a microbial mutagenesis test in salmonella using the mammalian microsome plate incorporation assay, an *in vivo* mammalian bone marrow assay, and a combined repeat dose and reproductive/developmental toxicity screening test in the rat. The manufacturers developed the test protocols which were reviewed and modified by EPA and incorporated as the test standards for the Consent Order. In the event that testing under the consent order is invalid, not conducted, or EPA determines that additional testing is necessary, EPA will initiate rulemaking procedures. As part of any such rulemaking proceedings, EPA would make statutory findings pursuant to section 4 of TSCA.

V. Testing Program

Four of the manufacturers have agreed to test MO for health effects using test protocols comparable to those developed by the United States and OECD for the SIDS testing program. The three-test battery will screen MO for mutagenic, subchronic, developmental and reproductive effects. MO will be tested for mutagenic activity using five strains of salmonella (with and without exogenous metabolic activation) and the

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in vivo mammalian bone marrow micronucleus assay. For the micronucleus assay, MO will be administered to mice by intraperitoneal injection; bone marrow will be harvested; and the ratio of polychromatic to normochromatic erythrocytes and frequency of micronucleated cells examined. Subchronic (including effects to the blood, liver, spleen and kidneys), developmental, and reproductive effects will be evaluated using a combined test. Rats will be exposed by inhalation to MO for 6 hours per day, 7 days per week. Males will be exposed throughout the entire study, approximately 40 to 53 days. Females will be exposed only until day 20 of gestation; the study will last approximately 35 to 48 days. Full histopathology will be conducted on both male and female rats. EPA has reviewed the three test protocols developed by CMA and the manufacturers and found them acceptable (Refs. 7 and 8). The Salmonella and micronucleus tests should provide equally reliable results as the EPA test guidelines published at 40 CFR part 798. The combined repeat dose developmental/reproductive effects test is a new protocol and is a modification of the test jointly developed by EPA and OECD for the SIDS program. The SIDS protocol calls for oral dosing and histopathology of only one sex. For MO, inhalation was selected as a more relevant route of human exposure and histopathology will be conducted on both sexes. EPA will use the data generated by these tests to evaluate the risk of adverse health effects associated with the manufacture, processing, use, and disposal of MO.

VI. Standards and Methodologies for Conducting Tests

Testing shall be conducted in accordance with the test protocols submitted by the manufacturers and CMA on December 27, 1990 and August 9, 1991 which were set forth as appendices 1, 2, and 3 of the consent order (collectively the "test standards"). Through CMA the four manufacturers will consult EPA in a good faith effort to determine if further test standard modifications are necessary. Modifications to the Consent Order shall be governed by 40 CFR 790.68.

VII. Reporting Requirements

The Salmonella and micronucleus tests shall be submitted to EPA 9 months after the effective date of the consent order. The combined repeat dose and reproductive/developmental toxicity screening test in the rat shall be submitted to EPA 12 months after the effective date of the consent order. In addition, interim status reports for each test are due at 6 month intervals, with the first status report due 6 months from the effective date of the consent order until all three tests are completed under this order.

VIII. Export Notification

The issuance of this Testing Consent Order subjects any person who exports or intends to export MO to the export notification requirements of section 12(b) of TSCA. The specific requirements are listed in 40 CFR part 707. Chemicals subject to consent orders are listed at 40 CFR 799.5000. This listing serves as notification to persons who export or who intend to export chemical substances or mixtures which are the subject of Testing Consent Orders that 40 CFR part 707 applies.

IX. Rulemaking Record

EPA has established a record for this rule under docket no. OPTS–42030H. This record contains the information EPA considered in developing this Consent Order and includes the following information.

A. Supporting Documentation

(1) Testing consent order for MO.

(2) **Federal Register** notices pertaining to this notice and consent order consisting of:

(a) Notice announcing a public meeting for October 18, 1990, and soliciting interested parties to develop a consent order for MO, (55 FR 40234, October 12, 1990).

(b) Final rule for MO (establishing testing requirements) (50 FR 51857, December 20, 1985).

(c) Final rule for MO (establishing test standards and reporting requirements) (50 FR 19088, May 20, 1987).

(d) Section 21 petition response (50 FR 30216, August 25, 1986).

(3) Communications consisting of:

(a) Written letters.

(b) Contact reports of telephone conversations.

(c) Meeting summaries.

B. References

(1) *Shell Chemical Co. v. EPA*, 826 F. 2d 295 (5th Cir. 1987)

(2) Chemical Manufacturers Association (CMA). Results of a worker exposure survey conducted by the Ketones Panel of CMA using mesityl oxide as an intermediate and for operations where mesityl oxide is formed as a byproduct or impurity (non-CBI version). (February 28, 1990)

(3) EPA. Occupational exposure to mesityl oxide resulting from incidental formation. Kin Wong, Chemical Engineering Branch, Economics andTechnology Division, Office of Toxic Substances. (June 10, 1988).

(4) CMA. Letter on proposed mesityl oxide consent agreement. From: Barbara Francis, CMA. Manager, Ketones Panel. Washington, DC 20037. To: Robert Jones, Existing Chemicals Assessment Division, EPA. (September 12, 1990).

(5) CMA. Letter agreeing in principle to test mesityl oxide under a consent order. From: Barbara Francis, CMA. To: Robert Jones, EPA.(December 27, 1990).

(6) PEI Associates, Inc. (PEI). Assessment of incidental production of mesityl oxide. Contract No. 68–02–4248, for EPA, Office of Pesticides andToxic Substances. (December 15, 1987).

(7) EPA. Letter with comments on CMA testing protocols. From Robert Jones, EPA, to Barbara Francis, CMA. (December 6, 1990).

(8) EPA. Letter requesting final protocol changes and letter of agreement in principle to enter into the consent order. From Robert Jones, EPA, to Barbara Francis, CMA. (December 11, 1990).

(9) CMA. Rhone-Poulenc AG Company, Institute Plant, Industrial Hygiene Sampling Results. (March 4, 1991).

Confidential Business Information (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 Rm. NE–G004, 401 M St., SW., Washington, DC, from 8:00 a.m. to 12 noon and 1:00 to 4:00 p.m., Monday through Friday, except legal holidays.

X. Other Regulatory Requirements

OMB has approved the information collection requirements contained in this final rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq., and has assigned OMB control 2070–0033.

Public reporting burden for this collection of information is estimated to average 40 hours per response. The estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

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 Management and Budget, Paperwork Reduction Project (2070–0033), Washington, DC 20503.

List of Subjects in 40 CFR Part 799

Chemicals, Chemical export, Environmental protection, Hazardous substances, Health effects, Laboratories, Reporting and recordkeeping requirements, Testing.

Dated: August 26, 1991.

Vicotor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

Therefore, 40 CFR chapter I, subchapter R, part 799 is amended as follows:

PART 799—[AMENDED]

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

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

2. Section 799.5000 is amended by adding mesityl oxide 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.

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CAS Number	Substance or mixture name	Testing	FR citation
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141-79-7	Mesityl Oxide	Health effects	[Insert FR date]
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