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[OPTS-42017A; PH-FRL 2413-8]

Methyl Isobutyl Ketone and Methyl Ethyl Ketone Decision to Adopt Negotiated Testing Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA published a notice in the Federal Register announcing a preliminary decision not to initiate rulemaking under section 4(a) of the Toxic Substances Control Act (TSCA) to require health effects testing of methyl isobutyl ketone (MIBK) or methyl ethyl ketone (MEK). The basis for the decision was EPA's evaluation of the existing data and the Agency's preliminary acceptance of a program submitted to EPA by the Ketones Program Panel of the Chemical Manufacturers Association. On the basis of its review and consideration of comments received, the Agency finds no reason to alter its preliminary decision not to propose, at this time, a section 4(a) rule to require health effects testing of MIBK or MEK.

FOR FURTHER INFORMATION CONTACT: Jack P. McCarthy, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Room E-547, Washington, D.C. 20460. Toll Free: (800-424-9065), in Washington, D.C. (554-1404), outside the USA (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Background

EPA issued a notice in the Federal Register on December 29, 1982 (47 FR 58025), which announced the Agency's preliminary decision not to propose a rule under section 4(a) of the Toxic Substances Control Act (TSCA) to

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require health effects testing of methyl isobutyl ketone (MIBK) or methyl ethyl ketone (MEK). This decision was based on the Agency's evaluation of a testing proposal submitted by the Ketones Program Panel of the Chemical Manufacturers Association (CMA) and the existence of certain data about these substances.

A draft of the Ketones Panel proposal was included in the public record (docket number OPTS-42017). The Agency requested comments on the tentative decision not to develop a test rule for MIBK or MEK and on the proposed testing scheme.

II. EPA's Response to Public Comments

The Agency received comments from the Natural Resources Defense Council (NRDC) and from the Ketones Panel of CMA; no other comments were received. The Ketones Panel advocated acceptance of the program submitted to EPA. NRDC raised various legal issues about EPA's acceptance of a negotiated testing agreement. They were also concerned about the setting of schedules for testing. Their basic concerns, along with EPA's response to each, are discussed below. NRDC did not raise any concerns about the substance of the testing program proposed by the Ketones Panel.

NRDC criticized EPA's policy of accepting negotiated testing agreements in lieu of rulemaking to require testing under section 4 of TSCA. The Council argued that the "plain language" of TSCA mandates that testing of section 4(e) chemicals must be accomplished by rule. In addition, NRDC contended that negotiated testing has procedural and legal deficiencies: in its comments NRDC particularly cited the lack of enforceability of negotiated testing agreements and their failure to trigger other provisions which would be triggered by a section 4 rule.

EPA has previously addressed NRDC's general concern about negotiated testing in a Federal Register notice issued on January 5, 1982 (47 FR 335), discussing the negotiated testing program for alkyl phthalates. A more detailed analysis of NRDC's arguments was prepared for inclusion in the public record of that action. As was indicated in that notice, EPA believes that neither TSCA nor its legislative history support NRDC's contention that the Congress believed rules were the exclusive means for accomplishing testing. EPA believes that negotiated testing is consistent with the statutory purpose that adequate data on chemicals be developed expeditiously by the involved companies.

EPA agrees that negotiated testing is not legally enforceable, but as the Agency previously indicated, there are strong practical reasons why it expects that the involved companies will live up to their agreements in the vast majority of cases. Furthermore, the Agency disagrees with NRDC's contention that if EPA is forced to develop a rule because of failure of a negotiated program, the entire program will take substantially longer than if EPA had pursued rulemaking from the beginning. Rather, EPA believes that it could conduct an expedited rulemaking which, in many cases, would not substantially lengthen the entire process.

NRDC is correct in asserting that acceptance of a negotiated testing program will not trigger certain other statutory provisions that would have been brought into play if the Agency proposed, and then promulgated, a testing rule for these substances. But EPA believes that NRDC has considerably exaggerated the practical impact of this difference. Although a negotiated testing program does not trigger the obligation of a manufacturer of a new substance subject to a section 4 rule to submit test data under section 5(b)(1), and to delay manufacturing, that particular requirement only relates to EPA actions under section 4 concerning categories of chemical substances and would not be applicable to MIBK or MEK which were submitted to the Agency as individual chemical substances by the ITC.

In addition, contrary to NRDC's claim, EPA has the same authority to disclose health and safety data generated from negotiated testing as it would if the testing were conducted under a rule. Section 14(b) (1)(A) (i) concerns data from any health and safety study on a chemical in "commercial distribution" (which includes all non-category chemicals designated by the ITC) and makes no distinction based upon how the Agency receives the data.

EPA's position that negotiated testing is a legally sufficient alternative to section 4 rulemaking was examined by the General Accounting Office (GAO) during 1982. The GAO concluded that "neither section 4(a) nor 4(e) compels the promulgation of a test rule proceeding where adequate test data may be developed pursuant to voluntary testing agreements." GAO further concluded that "since voluntary agreements are consistent with the significant purposes of section 4, implied authority exists for EPA to negotiate such agreements." (GAO, 1982. EPA Implementation of Selected Aspects of the Toxic Substances Control Act.

General Accounting Office, December 7, 1982. GAO/RCED-83-82 pp. 15).

NRDC stated in their comments that, "in the case of teratology testing for methyl isobutyl ketone, a schedule—has not yet been established." Final schedules had not been set by the time the proposed agreement was published. However, the protocol submitted to the Agency as required for completion of the negotiated testing agreement specified submission of a preliminary summary of results on the probe study on July 15, 1983 with treatment to begin on August 3, 1983 (mice), and August 7, 1983 (rats), following consultation with EPA on the selection of dose levels based on the results of the probe study. The draft of the final report is scheduled for December 1983. EPA met with CMA on July 25, 1983 to recommend doses. The submitted results, schedules and summary of the meeting are in the public record. It is apparent that progress on this testing is far ahead of any testing that would be initiated as a result of a rule.

On the above basis, EPA continues to believe that, where appropriate testing is being undertaken, negotiated testing agreements are an appropriate alternative to expensive, time-consuming rulemaking under section 4 of TSCA.

No new substantive issues have arisen during the comment period and consequently the Agency believes that the final study plan submitted by the Ketones Program Panel of CMA is the best means of meeting all the remaining testing needs for MIBK and MEK.

III. Testing

1. In a notice of a Negotiated Testing Agreement which appeared in the December 29, 1982 Federal Register (47 FR 58027), the Agency described the CMA's proposed program. The final study plans for this program are in the public record (docket number OPTS-42017) and include:

a. An inhalation teratology test of MIBK, to be initiated in mid- to late-1983 and for which a final study report will be submitted by the second quarter of 1984.

b. A 90-day subchronic toxicity study of MIBK, which has been completed and for which the final report will be submitted to EPA in mid-1983.

c. Mutagenicity studies on MIBK and MEK, to be initiated within 30 days of publication of this notice in the Federal Register and for which final reports will be submitted within a year after publication.

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2. EPA has reviewed the study plans on MIBK and MEK and has concluded that:

a. The teratology study will provide sufficient data to establish the potential toxic effects on the fetus as a result of MIBK exposure.

b. The subchronic study is likely to provide sufficient data to assess the potential for chronic effects of MIBK.

As reported in the OTS Workshop on Subchronic Toxicity Testing (EPA-560/11-80-028), subchronic toxicity studies can serve as surrogates for full chronic toxicity tests. Therefore, for the purposes of TSCA section 4, the Agency will accept a properly conducted subchronic 90-day study with full histopathology as a basis for predicting the chemical's chronic effects.

c. The mutagenicity studies will provide sufficient data to establish the potential mutagenic effects of MIBK and MEK.

Dated: September 27, 1983.

William D Ruckelshaus,

Administrator.

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