

8. Shimanouchi, T. Tables of molecular vibrational frequencies. *J. Phys. Chem. Ref. Data* 6: 993-1102, 1977.

9. Stein A.A. and W.E. Kirwan: Chloroacetophenone (tear-gas) poisoning: a clinicopathologic report. *J. Forensic Sci.* 9: 374-382, 1964.

#### V. Administrator's Decision

The petition to initiate a regulatory proceeding under TSCA for control of the manufacture, processing, or distribution in commerce of CN for use as a thermally generated tear gas is denied.

Based upon the review of information available to EPA on the risks posed by CN containing thermal tear gas devices the Agency has concluded that the benefits of using them outweigh the small potential for serious health injuries.

(Sec. 21, 90 Stat. 2042 (15 U.S.C. 2620))

Dated: December 16, 1981.

Anne M. Gorsuch,  
Administrator.

[FR Doc. 82-126 Filed 1-4-82; 9:46 am]

BILLING CODE 6560-31-M

IOPTS-42005A; TSH-FRL-1988-61

#### Alkyl Phthalates and Benzyl Butyl Phthalate; Follow-up Response To The Interagency Testing Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

**SUMMARY:** In a previous notice which appeared in the Federal Register of October 30, 1981 (46 FR 53775), the EPA announced a preliminary decision not to propose a section 4(a) rule to require environmental or health effects testing of alkyl phthalates or benzyl butyl phthalate. This preliminary decision was made pending review of public comment received too late for consideration prior to the statutory deadline for action. On the basis of the now completed review, the Agency finds no reason to alter its preliminary decision. Therefore, the Agency has determined not to propose, at this time, a section 4(a) rule to require environmental or health effects testing of alkyl phthalates or benzyl butyl phthalate.

**FOR FURTHER INFORMATION CONTACT:** Douglas G. Bannerman, Acting Director, Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Room E-511, 401 M St., SW., 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

In a previous notice which appeared in the Federal Register of October 30, 1981 (46 FR 53775), the Agency announced a preliminary decision not to propose, at that time, a section 4(a) rule under the Toxic Substances Control Act (TSCA) to require environmental or health effects testing of alkyl phthalates or benzyl butyl phthalate (BBP). This decision was based on the Agency's acceptance of a comprehensive testing proposal for phthalate esters from the Chemical Manufacturers Association (CMA) on behalf of the Phthalate Esters Program Panel.

Previous to that notice, a public meeting was held on September 15, 1981, to brief the public on the CMA voluntary testing proposal as an alternative to a test rule under TSCA section 4. The briefing was followed by an opportunity for discussion and comment.

At the conclusion of the meeting, and by letter of September 21, 1981, the Natural Resources Defense Council (NRDC) requested additional time to review and comment on the proposed testing scheme for the phthalates.

Although EPA believes that it had provided adequate opportunity for the public to examine the proposed testing scheme and comment upon it, because this is the first time the Agency has considered deferring testing because of a voluntary scheme, EPA agreed to accept NRDC comments up to October 21, 1981. However, because section 4(e) of TSCA requires EPA to publish a response to the ITC within one year from the date a chemical is designated by the Committee and the one year anniversary date for benzyl butyl phthalate was October 24, 1981, EPA did not have an opportunity to consider NRDC's comments so that action could be taken by that date. Instead, EPA elected to issue a preliminary decision not to proceed with development of a test rule, giving the Agency time to consider NRDC's comments before issuing a final decision on the acceptability of the CMA program.

##### Agency's Response To Public Comment

On October 21, 1981, the Agency received NRDC's comments on (1) EPA's proposed decision not to require testing of the alkyl phthalates and BBP; and (2) CMA's proposed testing scheme for those compounds. NRDC raised various concerns, both legal and scientific. Their basic concerns, along with EPA's response to each, are summarized below. More detailed responses to these legal issues and responses to all

scientific issues are included in the public record.

##### A. Legal Concerns

(1) NRDC argues that acceptance of a negotiated testing scheme in place of issuance of a section 4 test rule is contrary to the statutory language and legislative history indicating that Congress intended EPA to issue test rules even if appropriate testing was planned or ongoing.

EPA disagrees with this contention. EPA has found that neither the statutory language nor the legislative history would support NRDC's contention that negotiated testing schemes are an inappropriate response to ITC recommendations. The Agency believes that the purpose of section 4 was to assure that adequate data are developed, that the data are developed in expeditious fashion, and that industry assumes financial responsibility for testing. Because the negotiated scheme will meet these criteria, EPA believes it is consistent with section 4.

(2) NRDC contends that negotiated schemes in general, and this scheme in particular, are not an acceptable alternative to section 4 test rules because of certain specific legal and procedural deficiencies including (1) lack of public participation in their development; (2) lack of deadlines on completion of testing (which result in getting data later than under a rule); (3) lack of public access to data from the tests; and (4) lack of legal enforceability of industry's promise to perform testing.

EPA disagrees with this comment. First, EPA believes that there was adequate opportunity for public comment on the decision to defer testing. A public meeting was held on September 15, 1981, at which the voluntary approach was discussed. A docket containing all the pertinent information was available to the public beginning August 27, 1981. In addition, the basics of the phthalate voluntary testing scheme were presented at the Scoping Workshop on the 7th ITC Report, March 12, 1981, and the NTP/IRGL Phthalate Conference on June 11, 1981. The Agency, however, will continue to work with the public to develop new and better ways of facilitating that review. Comments were requested from the public on how to facilitate this in the tentative phthalates decision (46 FR 53775).

Second, the Agency believes that the schedule of testing provided by the industry in most cases will result in initiation and completion of testing significantly earlier than would result if the Agency pursued a test rule for these

substances. CMA has submitted an approximate schedule for testing to the Agency. Testing under this schedule would begin in November 1981 for some of the tests, no later than July 1982 for the majority of the tests and by February 1983 for the remaining Phase II (environmental) tests. Due to the experimental nature of the health program, the start of long-term testing is uncertain. However, the Agency generally expects any necessary long-term health effects testing to begin by mid-1983. If EPA were to pursue issuance of a test rule on these chemicals, this rule would probably not be final until January 1983 and short-term testing would not actually begin for several months after that. Furthermore, while EPA had not determined that it would pursue a tiered testing scheme for those chemicals, such a scheme, if included in a rule, would have further delayed the start of long-term testing which would occur in the later tiers. Therefore, the Agency believes that the CMA scheme will produce results at least as fast, and in most cases faster than would be obtainable under a test rule. Third, the CMA has agreed that all data on the tests it performs will be made available to the Agency, and that it will assert no claims of confidentiality on the data when they are transmitted to EPA.

Finally, the EPA believes that while the NRDC is correct in asserting that the negotiated test scheme is not enforceable, the importance of this fact is exaggerated. EPA believes that the real issue is whether the testing will actually be done, and EPA is convinced that CMA will not retreat from its commitment. The Agency will monitor the industry's performance, and if the CMA does not follow through, EPA intends to exercise its full legal authority under section 4 to require that all necessary testing be performed.

#### B. Scientific Concerns

(1) NRDC was concerned that the compounds selected for testing may not be truly representative of the alkyl phthalate class of compounds, and that to assume so *a priori* and without a subsequent review of the test data would be unwarranted.

EPA agrees that compound selection for testing should be done throughout the course of the testing program. A thorough review of the test data in regard to its applicability to other (untested) chemicals in the class has been the Agency's and CMA's intent from the start. Scoring systems for chemical selection, as described in CMA's proposal, will not be applied

uncritically but are subject to modification as deemed necessary.

(2) NRDC stated that a significant gap in the CMA testing program is that no explicit criteria are given for making decisions about which higher level or additional tests are to be performed.

Given the large number of testing endpoints, both the EPA and the CMA felt that explicit decision criteria would be exceedingly difficult to formulate. Because the EPA will be involved in making all testing decisions, the absence of explicit decision criteria is not considered by the Agency to be a problem. EPA reserves its right to require industry to perform tests it considers necessary.

(3) NRDC believes that too few tests are being proposed in the CMA program to allow for effective regulation of the phthalate esters.

EPA disagrees with this contention. As discussed in detail in the Agency's preliminary decision not to require testing of the alkyl phthalates and BBP, CMA's program is ultimately expected to satisfy all of the ITC's and the Agency's needs for additional environmental effects of concern for the alkyl phthalates and BBP. CMA's proposal calls for the testing of a wide variety of aquatic species on an acute basis and what are regarded by Agency scientists to be very sensitive species on a chronic basis. CMA's program will also address the biodegradation and bioaccumulation of the phthalates. Based on past phthalate testing, these test data are expected to provide excellent guidance for setting acceptable concentration levels in the environment. Because of the demonstrated low toxicity of the phthalate esters to mammalian, bird and terrestrial plant species, and because the chemical physical properties and (limited) monitoring data indicate very low concentrations in the terrestrial environment; terrestrial toxicity testing was not considered a priority, nor did the ITC recommend such testing. CMA's health effects testing program, admittedly involves an experimental approach in an attempt to screen and prioritize the alkyl phthalates for potential long-term testing. Should the initial tests not prove sufficient to demonstrate a clear dose-response relationship, first with the reference chemicals, and then with all of the chemicals under test, the Agency has requested, and CMA has agreed, to conduct other short-term assays as required both to validate the test battery and allow structure-activity inferences to be made. CMA has also made a commitment to perform additional

testing, including long-term tests, where this appears to be indicated by the initial test results.

#### III. Public Record

EPA has established a public record for this decision not to pursue testing under section 4, docket number OPTS-42005, which is available for inspection from 8:00 a.m. to 4:00 p.m. Monday through Friday, excluding legal holidays, in Rm. E-106, 401 M St., SW., Washington, D.C. 20460. This record includes basic information considered by the Agency in developing this decision. This record includes the following information:

(1) Federal Register notices containing the designation of alkyl phthalates and benzyl butyl phthalate to the Priority List.

(2) Communications:

(a) Public and intra-agency of interagency memoranda, comments and proposals.

(b) Contact reports of telephone conversations.

(c) Meetings.

(3) Public comments on the ITC reports.

(4) Reports—published and unpublished data.

(Sec. 4, 90 Stat. 2003; (15 U.S.C. 2601)).

Dated: December 22, 1981.

Anne M. Gorsuch,  
Administrator.

[FR Doc. 82-127 Filed 1-4-82; 8:45 am]

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[OPTS-51374; TSH-FRL-2018-8]

#### Certain Chemicals; Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

**SUMMARY:** Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) premanufacture notices are discussed in EPA statements of interim policy published in the *Federal Register* of May 15, 1979 (44 FR 28558) and November 7, 1980 (45 FR 74378). This notice announces receipt of seven PMNs and provides a summary of each.

**DATES:** Written comments by:

PMN 81-645, 81-646, 81-647, 81-648, 81-649, 81-650, & 81-651: February 20, 1982.