

## 40 CFR Part 799

[OPTS-42092A; FRL-3503-7]

**Testing Consent Order on Alkyl Phthalates****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

**SUMMARY:** This document announces that EPA has signed an enforceable testing Consent Order with Aristech Chemical Corporation (Aristech), BASF Corporation (BASF), Exxon Chemical Company (Exxon), Eastman Kodak Company (Kodak), and Witco Corporation, Humko Chemical Division (Witco). These companies have agreed to perform certain chemical fate and environmental effects tests on dimethyl phthalate (DMP; CAS No. 131-11-3), di-n-butyl phthalate (DnBP; CAS No. 84-74-2), dihexyl phthalate, (DHP; CAS No. 68515-50-4 and 84-75-3), di-2-ethylhexyl phthalate (DEHP; CAS No. 117-81-7), di-(heptyl, nonyl, undecyl) phthalate (D711P; CAS No. 68515-42-4), diisodecyl phthalate (DIDP; CAS No. 68515-49-1 and 26761-40-0), diundecyl phthalate (DUP; CAS No. 3648-20-2), and dtridecyl phthalate (DTDP; CAS No. 68515-47-9 and 119-06-2). These chemicals are added to the list of testing Consent Orders in 40 CFR 799.5000 for which the export notification requirements of 40 CFR Part 707 apply.

Depending on the results of these tests, two additional chemical substances, diethyl phthalate (DEP; CAS No. 84-66-2) and diisononyl phthalate (DINP; CAS No. 68515-48-0 and 28553-12-0), may also be tested, and if so would also be made subject to export notification requirements.

**EFFECTIVE DATE:** January 9, 1989.

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

**SUPPLEMENTARY INFORMATION:** Under procedures described in 40 CFR Part 790, Aristech, BASF, Exxon, Kodak, and Witco have entered into a testing Consent Order with EPA in which they have agreed to perform certain chemical fate and environmental effects tests for DMP, DnBP, DHP, DEHP, D711P, DIDP, DUP, and DTDP. This rule amends 40 CFR 799.5000 by adding these eight chemical substances to the list of chemical substances and mixtures subject to testing Consent Orders.

**I. ITC Recommendation**

In its Initial Report to EPA, published in the *Federal Register* of October 4, 1977 (42 FR 55026), the ITC recommended that the alkyl phthalates chemical category be considered for environmental effects testing.

The recommended environmental effects testing included chronic and reproductive effects testing with aquatic organisms, especially fish. EPA's health effects testing concerns for these chemicals are being examined separately and are not addressed in this notice.

EPA responded to the ITC's designation of the alkyl phthalates category by issuing a notice in the *Federal Register* (October 30, 1981; 46 FR 53775) announcing that it had decided not to require testing. EPA instead accepted a testing program sponsored by the Phthalate Esters Program Panel (PEPP) of the Chemical Manufacturers Association (CMA). The program included testing for both health and environmental effects; however, in keeping with the subject of this notice, discussion will focus on the environmental effects portion.

CMA proposed phased testing for environmental effects for 13 alkyl phthalates identified as being annually produced in quantities greater than ten million pounds, and for benzyl butyl phthalate (BBP). CMA's proposal included testing for aquatic toxicity, environmental transport and fate, and biodegradation of the alkyl phthalates and BBP. These were the environmental testing areas of concern to the Agency and to the ITC.

The program was designed to complete testing in two phases. Phase I tests were performed to determine acute toxicity to fish, aquatic invertebrates, and algae, and chronic toxicity to aquatic invertebrates. Biodegradation tests and tests to determine vapor pressure, water solubility and Koctanol/water were also performed. Phase I of testing has been completed. All of the data from these studies have been placed in the public file on alkyl phthalates and BBP (OPTS-42005) and are available for public inspection.

In Phase II of the testing, more advanced tests, including early life stage testing with fish, bioconcentration tests with oysters, soil and water biodegradation tests, and tests of soil transport were to be performed, if the results of the Phase I tests indicated a need for further testing. The tests and chemicals selected for Phase II testing were to be determined primarily by the results of the Phase I tests.

Testing under this negotiated testing agreement (NTA) was suspended when, in August 1984, a suit brought against EPA by the Natural Resources Defense Council (NRDC) resulted in the ruling that such negotiated testing programs were not legal substitutes for a test rule under section 4 of the Toxic Substances Control Act (TSCA) [*NRDC and AFL-CIO v. EPA*, 595 F Supp. 1255 (S.D.N.Y. 1984)]. Furthermore, BBP was specifically mandated for rulemaking, or for notice explaining why testing was not necessary. As a result, the Agency published a proposed rule for BBP requiring environmental effects and chemical fate testing (50 FR 36446; September 6, 1985). The proposed testing for BBP was completed and submitted to EPA by Monsanto Company, and the Agency has issued a *Federal Register* notice withdrawing the proposed rule (52 FR 41593; 29 October, 1987).

For the remaining phthalate esters recommended by the ITC, several of the Phase II tests noted in the NTA are still needed; namely, early life stage testing with fish and sediment transport (adsorption). EPA, in this final rule, announces that these environmental and chemical fate testing needs are being addressed by consent order. Health effects testing for this chemical category will be the subject of a future notice.

**II. Testing Consent Order Negotiations**

In the *Federal Register* of December 24, 1986 (51 FR 46718), and in accordance with the procedures established in 40 CFR 790.28, EPA requested persons interested in participating in or monitoring testing negotiations on alkyl phthalates to contact the Agency. EPA held public meetings with interested parties on January 7, 1987, February 12, 1987, June 3, 1987, and September 29, 1987 to discuss the testing appropriate for the alkyl phthalate chemical category. On November 11, 1988, EPA, Aristech, BASF, Exxon, Kodak, and Witco signed a testing Consent Order for certain alkyl phthalate esters. A Consent Order is not based on a formal finding and expedites testing, while retaining the same TSCA penalty provisions applicable under rulemaking. Under the Order, these companies have agreed to conduct or provide for the conduct of fish early life stage toxicity tests and adsorption isotherm tests. The specific test standards to be followed and the testing schedule for each test are included in the Order. Procedures for submitting study plans, modifying the Order, monitoring the testing and other provisions are also included in the Order.

### III. Use and Exposure

The alkyl phthalates are a chemical category consisting of alkyl diesters of 1,2-benzenedicarboxylic acid. They typically are formed by esterifying phthalic acid anhydride with various alcohols. The compounds vary in size, depending on the alcohols used, from the short chain compound dimethyl phthalate to long-chain compounds such as ditridecyl phthalate. Mixed alcohols may also be used in the esterification process giving a combination of unsymmetrical alkyl diester compounds, such as D711 phthalate, whose side chains may consist of alkyl groups of 7, 9, or 11 carbons.

Phthalate esters are used as plasticizers in plastic products at different percentages depending on the mutual compatibilities of each and the degree of flexibility desired in the plastic product (Ref. 1). The chain lengths affect the properties of the compounds in a fairly predictable way; as the chain gets longer, water solubility and vapor pressure decrease, and  $K_{oc}$  increases (Ref. 1).

Many of the alkyl phthalates are produced in large volume, with some individual compounds having annual production volumes well in excess of 100 million pounds. The alkyl phthalates are primarily used as plasticizers in a wide variety of plastic products (although a few, such as diethyl phthalate, are used in such products as cosmetics), and releases into the environment may occur through waste streams from manufacturing facilities or from use and disposal of end products.

The 14 phthalate esters selected for testing in Phase I of the NTA were selected because they have individual annual production volumes of approximately 10 million pounds or greater. The chemicals selected for additional testing in this Consent Order represent a subset of those 14.

### IV. Testing Program; Chemical Fate and Environmental Effects

With regard to untested phthalate esters, EPA believes that it can, for risk assessment purposes, reliably predict values for most of the environmental effects endpoints and chemical fate processes identified as being of concern in the NTA. Bioconcentration potential of the phthalate esters can be predicted from studies performed on a number of these compounds with a variety of fish and aquatic invertebrates. These data indicate bioconcentration values of 112 to 856 in fish and 116 to about 4,000 in invertebrates (Refs. 2 through 11).

Furthermore, EPA has sufficient data based on studies completed during

Phase I of the NTA and other available data to estimate the water solubility, volatility and aerobic biodegradability of the phthalate esters and to sufficiently predict the acute toxicity of the phthalate esters to fish, invertebrates and algae and their chronic toxicity to aquatic invertebrates.

However, the Agency believes it has insufficient data to predict chronic toxicity of the phthalate esters to fish, and to reliably predict adsorption of these chemicals to sediments. EPA intends that testing be conducted under this Consent Order to fill those data deficiencies. EPA believes that these data will, with the earlier data on the alkyl phthalates and BBP, be sufficient to reliably assess current risks that the dialkyl and alkyl benzyl phthalates may present to the environment. The testing will examine chronic toxicity to fish (through early life stage toxicity testing with rainbow trout) and adsorption of these chemicals to sediments. EPA intends to gather data by having manufacturers test a subset of the 14 alkyl phthalates tested under Phase I of the negotiated testing agreement.

EPA will use the data to determine a quantitative structure-activity relationship (QSAR) that it can apply to untested members of the alkyl phthalate ester chemical class. EPA believes, from available data, that this chemical category is amenable to a QSAR approach. However, if the data developed under this Consent Order indicate such is not the case, then the Agency reserves its right to re-examine the testing needs for this chemical category. Also, the use of QSAR estimation does not mean that estimated values take precedence over valid experimental data, where the two differ. Therefore, should manufacturers of untested or new phthalate ester compounds wish, they could develop experimental data, which EPA would then consider in any risk estimation or regulatory context.

Under the Consent Order, DMP, DnBP, DHP, D711P and DUP will all be tested in the fish early life stage toxicity test in accordance with the schedules and test protocols specified in the Order. These five phthalate esters are characterized by having low, medium, or high numbers of carbons in their alkyl side chains ( $n = 1$  to 11). In a more limited way, these five compounds also cover an array of chemicals having an odd or even number of carbons in the alkyl side chains and having either branched or unbranched side chains. Based on available data, phthalate esters of side chain lengths of more than six carbons may not be toxic at the chemical's limit of water solubility. EPA and the

signatory manufacturers have therefore agreed in this Consent Order to double (under the conditions described in the test standard applicable to this Consent Order) the normal length of exposure to the chemical substance in the early life stage toxicity test. Doing so will strengthen any potential conclusion of no toxic response for some or all of the long-chain compounds.

Depending on the results of the testing of these five compounds, additional phthalate esters may be tested. Diethyl phthalate (DEP) may also be tested if its toxicity cannot be reliably estimated from the test data on DMP and DnBP. Furthermore, if D711P produces a toxic response, diisononyl phthalate (DINP) may be tested; positive results for DINP may further lead to testing on diisodecyl phthalate (DIDP). If DUP produces a positive result, ditridecyl phthalate (DTDP) may be tested. Testing of these additional compounds (DEP, DINP, DIDP, and DTDP) would be indicated in a follow-up Federal Register notice for notification purposes, but is considered part of this Consent Order.

EPA and representatives of the industry signatories will consult in a good faith effort to reach agreement on the interpretation of the data and the necessity of testing these additional compounds. Should EPA and the industry signatories ultimately disagree on the interpretation of the results, then EPA reserves its right to issue a section 4 test rule to obtain the necessary data. The process for review of the results is described in more detail in the Consent Order.

Adsorption isotherm testing in sediments shall be first conducted on DHP, DEHP, DIDP and DTDP (Group I); and if necessary, also on D711P and DINP (Group II). The compounds selected for Group I cover a range with respect to the physical/chemical properties expected to affect the sorptive behavior of phthalates. Testing of this group should provide useful information about the effects of structure and associated properties on adsorption. Compounds from Group I are C-6 to C-13 linear and branched phthalate esters. Their selection will complement the existing adsorption isotherm data on DnBP, DNOP, and DEHP. The inclusion of DEHP in Group I will provide an internal standard for the new set of chemicals to be tested. Testing of these chemicals will also provide a small data set for the development of new, or use of existing structure-activity relationships, to attempt to predict the sorptive behavior of the compounds in Group II. Testing for D711P and DINP, if necessary, would

be indicated in a follow-up notice in the Federal Register for notification purposes.

#### V. Export Notification

The issuance of the Consent Order subjects any person who exports or intends to export DMP, DnBP, DEHP, D711P, DIDP, DTDP and DUP to the export notification requirements of section 12(b) of TSCA. The specific requirements are listed in 40 CFR Part 707. In the June 30, 1988 (51 FR 23706), Interim Rule establishing the Testing Consent Order process, EPA added and reserved Subpart C of Part 799 for listing of chemical substances subject to testing consent orders issued by EPA. This listing serves as notification to persons who export or intend to export chemical substances or mixtures which are the subject of testing consent orders, that 40 CFR Part 707 applies.

#### VI. Rulemaking Record

EPA has established a record for this rule and the Consent Order (docket number OPTS-42092A). This record contains the basic information considered by the Agency in developing this rule and the testing Consent Order.

This record includes the following information:

##### A. Supporting Documentation

(1) Testing Consent Order between Aristech, Exxon, Kodak, BASF, and Witco and the Agency.

(2) Federal Register notices pertaining to this notice consisting of:

(a) Notice containing the ITC recommendation of alkyl phthalates to the Priority List (October 12, 1977; 42 FR 55026).

(b) Notice containing the ITC recommendation of BBP to the Priority List (November 25, 1980; 45 FR 78432).

(c) Notice containing the Agency's response to the Interagency Testing Committee for the alkyl phthalates and benzyl butyl phthalate (October 30, 1981; 46 FR 53775).

(d) Notice of proposed rulemaking for BBP (September 6, 1985; 50 FR 36446).

(e) Notice of withdrawal of proposed rulemaking for BBP (October 29, 1987; 52 FR 41593).

(f) Notice soliciting interested parties for developing a consent order for the alkyl phthalates (December 24, 1986; 51 FR 46718).

(g) Notice of interim final rule on procedures for developing enforceable

consent agreements (51 FR 23706; June 30, 1986).

(3) Communications consisting of:

(a) Written letters.

(b) Contact reports of telephone conversations.

(c) Meeting summaries.

(4) Reports—published and unpublished factual materials.

#### B. References

(1) Hirzy, J. W., W. J. Adams, W. E. Gledhill, and J. P. Miere. "Phthalate esters: The environmental issues." Seminar presented to USEPA National Water Quality Laboratory—Duluth. (October 16, 1978).

(2) Karara, A. H. and W. L. Hayton. "Pharmacokinetic model for the uptake and disposition of di-2-ethylhexyl phthalate in sheepshead minnow *Cyprinodon variegatus*." *Aquatic Toxicology* 5:181-195 (1984).

(3) Mehrle, P. M., and F. L. Mayer. "Di-2-ethylhexyl phthalate: residue dynamics and biological effects in rainbow trout and fathead minnows." In: "Trace substances in Environmental Health—X. A Symposium", D. D. Hemphill, ed. University of Missouri, Columbia, Missouri. pp. 519-524. (1976).

(4) Macek, K. J., S. R. Petrocelli, and B. H. Sleight III. "Considerations in assessing the potential for, and significance of biomagnification of chemical residues in aquatic food chains." In: "Aquatic Toxicology, ASTM STP 667." L. L. Marking and R. A. Kimerle, eds. American Society for Testing and Materials, Philadelphia, Pennsylvania. pp. 251-268. (1979).

(5) Gledhill, W. E., R. G. Kaley, W. J. Adams, O. Hicks, P. R. Michael, and V. W. Saeger. "An environmental safety assessment of butyl benzyl phthalate." *Environmental Science and Technology* 14(3): 301-305 (1980).

(6) Gloss, S. P. and G. R. Biddinger. "Comparison of system design and reproducibility to estimate bioconcentration of di-n-hexylphthalate by *Daphnia magna*." In: "Aquatic Toxicology and Hazard Assessment" Seventh Symposium, ASTM STP 854." R. D. Cardwell, R. Purdy and R. Comotto, eds. American Society for Testing and Materials, Philadelphia, Pennsylvania. pp. 202-213 (1985).

(7) Brown, D. and R. S. Thompson. "Phthalates and the aquatic environment: Part I of the effect of di-2-ethylhexyl phthalate (DEHP) and di-isodecyl phthalate (DIDP) on the reproduction of *Daphnia magna* and observations on their bioconcentration." *Chemosphere* 11(4): 417-426 (1982).

(8) Brown, D. and R. S. Thompson. "Phthalates and the aquatic environment: Part II the bioconcentration and depuration of di-2-ethylhexyl phthalate (DEHP) and di-isodecyl phthalate (DIDP) in mussels (*Mytilus edulis*). *Chemosphere* 11(4): 427-435 (1982).

(9) Streufert, J. M., J. R. Jones, and H. O. Sanders. "Toxicity and biological effects of phthalate esters on midges (*Chironomus plumosus*)." *Transactions of the Missouri Academy of Science* 14: 33-40 (1980).

(10) Perez, K. T., E. W. Davey, N. F. Lackie, G. E. Morrison, P. G. Murphy, A. E. Soper, and D. L. Winslow. "Environmental assessment of a phthalate ester, di-(2-ethylhexyl) phthalate (DEHP), derived from a marine microcosm." In: "Aquatic Toxicology and Hazard Assessment: Sixth Symposium, ASTM STP 802." W. E. Bishop, R. D. Cardwell, and B. B. Heidolph, eds. American Society for Testing and Materials, Philadelphia, Pennsylvania. pp. 100-191. (1984).

(11) Brown, D., C. Poels, J. B. Scheubel, and H. Wellens. "An assessment of the occurrence and effects of dialkyl orthophthalates in the environment." ECETOC Technical Report No. 19. L. Turner, ed. European Chemical Industry Ecology and Toxicology Center, Brussels, Belgium, 64 pp. (May 22, 1985).

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 TSCA Public Docket Office, Rm. NE-G004, 401 M St. SW., Washington, DC, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

#### List of Subjects in 40 CFR Part 799

Test procedures, Environmental protection, Hazardous substances, Chemicals, Chemical export, Recordkeeping and reporting requirements.

Dated: December 27, 1988.

Susan F. Vogt,

Acting Assistant Administrator for Pesticides and Toxic Substances.

Therefore, 40 CFR 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 the following chemical substances in Chemical Abstract Service (CAS) Registry Number order to the table, to read as follows:

§ 799.5000 Testing consent orders.

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CAS Number	Substance or mixture name	Testing	FEDERAL REGISTER citation
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84-74-2 Di-n-butyl phthalate ..... Environmental effects ..... (Insert FR date)

CAS Number	Substance or mixture name	Testing	FEDERAL REGISTER citation
84-75-3	Di-n-hexyl phthalate	Environmental effects	(Insert FR date)
		Chemical fate	(Insert FR date)
117-81-7	Di-2-ethylhexyl phthalate	Chemical fate	(Insert FR date)
119-06-2	Ditridecyl phthalate	Chemical fate	(Insert FR date)
131-11-3	Dimethyl phthalate	Environmental effects	(Insert FR date)
3648-20-2	Diundecyl phthalate	Environmental effects	(Insert FR date)
26761-40-0	Dodecyl phthalate	Chemical fate	(Insert FR date)
68515-42-4	Di (heptyl, nonyl, undecyl phthalate (mixed isomers)	Environmental effects	(Insert FR date)
68515-47-9	Ditridecyl phthalate (mixed isomers)	Chemical fate	(Insert FR date)
68515-49-1	Dodecyl phthalate (mixed isomers)	Chemical fate	(Insert FR date)
68515-50-4	Dihexyl phthalate (mixed isomers)	Environmental effects	(Insert FR date)
		Chemical fate	(Insert FR date)

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