

SUPPLEMENTARY INFORMATION: EPA is withdrawing its proposed rule requiring environmental fate and effects testing of benzyl butyl phthalate.

I. Background

The Interagency Testing Committee (ITC), in its Seventh Report, designated benzyl butyl phthalate for priority consideration of environmental and health effects testing under section 4 of the Toxic Substances Control Act (TSCA). In response to that designation, EPA and the Chemical Manufacturers Association (CMA) developed a negotiated testing program for BBP for certain environmental fate and effects testing. Health effects testing of BBP, as noted in the Agency's previous response to the ITC and published in the Federal Register of October 30, 1981 (46 FR 53775), is being addressed adequately by testing conducted by the National Toxicology Program. In August 1984, a suit brought against EPA resulted in the ruling that such negotiated testing programs were not a legal substitute for a test rule under section 4. As a result, EPA issued a proposed rule to obtain all environmental fate and effects testing necessary for the full characterization of BBP.

Based upon its review of the available data, including those developed under the negotiated testing program, EPA concluded that additional environmental fate and effects testing of BBP was warranted under section 4(a)(1)(A). In the Federal Register of September 8, 1985 (50 FR 36446), EPA issued a proposed rule to obtain additional environmental fate and effects testing of BBP. (For a summary of environmental effects tests performed prior to this withdrawal notice, see the preamble to the proposed rule.)

In the proposed rule, EPA found that environmental fate and effects testing was warranted under section 4 of TSCA. This testing was intended to enable the Agency to make a determination whether BBP presents an unreasonable risk of injury to the environment and to establish water quality criteria for protecting aquatic life under section 304(a)(1) of the Clean Water Act. The proposed tests were acute and chronic toxicity tests with marine and freshwater organisms, an oyster bioconcentration test, and a test to determine the fate of BBP in undisturbed sediment. All of this proposed testing has been completed and submitted to EPA by Monsanto Company. The following table summarizes the results of these studies.

40 CFR Part 799

[OPTS-42070A; FRL-3284-5]

Benzyl Butyl Phthalate; Withdrawal of Proposed Environmental Fate and Effects Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; Withdrawal.

SUMMARY: EPA is withdrawing its proposal to require certain environmental fate and effects testing for benzyl butyl phthalate (BBP, CAS No. 85-68-7). EPA proposed acute and chronic toxicity tests in freshwater and saltwater organisms, an oyster bioconcentration test, and a test to determine the fate of BBP in undisturbed sediment. Because these tests have been satisfactorily completed by industry, they do not need to be obtained through a test rule.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. E-543, 401 M St., SW., Washington, DC 20460, (202) 554-1404.

Summary of Environmental Fate and Effects Data for BBP

Organism	Endpoint	Effect level (mg/L)	Ref. No.
Rainbow trout (<i>Salmo gairdneri</i>)	Early life stage MATC	0.095-0.20	1
Hydra (<i>Hydra littoralis</i>)	96-hr EC50	1.1	2
Mayfly (<i>Hexagenia sp.</i>)	96-hr LC50	1.1	3
Crayfish (<i>Procambarus sp.</i>)	96-hr LC50	¹ > 2.4	4
Polychaete (<i>Nereis/Neanthes virens</i>)	96-hr LC50	¹ > 3.0	5
Grass shrimp (<i>Palaemonetes vulgaris</i>)	96-hr LC50	¹ > 2.7	6
Pink shrimp (<i>Penaeus duorarum</i>)	96-hr LC50	¹ > 3.4	4, 7
Mysid shrimp (<i>Mysidopsis bahia</i>)	96-hr LC50	² > 0.74	8
Mysid shrimp (<i>Mysidopsis bahia</i>)	Chronic MATC	0.075-0.17	9
Oyster (<i>Crassostrea virginica</i>)	96-hr EC50	1.3	10
Oyster (<i>Crassostrea virginica</i>)	Bioconcentration factor	135	11
Fate in water/(sediment)	Degradation half life	>1.0 <2.0d/ (<10 d)	12, 13

¹ No mortalities at this limit of solubility.

² 35 percent mortality at this test concentration.

EPA has evaluated the completed studies and has also audited selected studies for adherence to TSCA Good Laboratory Practice Standards in 40 CFR Part 792. EPA considers these studies sufficient to meet the Agency's environmental fate and effects testing needs for BBP at this time. Therefore, the Agency is issuing this notice to withdraw the rule for BBP proposed in the Federal Register of September 6, 1985 (50 FR 35446) because sufficient data are now available to characterize the environmental effects of BBP.

II. Rulemaking Record

A public record, containing the basic information considered by the Agency in developing its decisions on BBP, is available for inspection in the OPTS Reading Room NE-G004, 401 M St., SW., Washington, DC, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays (docket number OPTS-42070A). Confidential Business Information (CBI), while part of the rulemaking record, is not available for public review.

The rulemaking record includes the following information

A. Supporting Documentation

(1) The Federal Register notice containing the ITC designation of BBP to the Priority List (45 FR 78432; November 25, 1980).

(2) The Federal Register notice proposing that EPA require certain environmental fate and effects for BBP (50 FR 36446; September 6, 1985).

(3) Communications consisting of letters, contact reports of telephone conversations, and meeting summaries.

B. References

(1) Analytical Bio-Chemistry Laboratories, Inc. "Early life stage toxicity of ¹⁴C-butylbenzyl phthalate to rainbow trout (*Salmo gairdneri*) in a flow-through system."

Report No. 33996 submitted to Monsanto Co., St. Louis, MO. (September 25, 1986).

(2) Analytical Bio-Chemistry Laboratories, Inc. "96-hour flow-through toxicity study of butylbenzyl phthalate to *Hydra littoralis*." Report No. 34168 submitted to Monsanto Co., St. Louis, MO. (April 29, 1986).

(3) Analytical Bio-Chemistry Laboratories, Inc. "96-hour flow-through toxicity study of butylbenzyl phthalate to the mayfly, *Hexagenia sp.*" Report No. 34187 submitted to Monsanto Co., St. Louis, MO. (September 24, 1986).

(4) Analytical Bio-Chemistry Laboratories, Inc. "96-hour flow-through toxicity study of butylbenzyl phthalate to the freshwater crayfish, *Procambarus sp.*" Report No. 34186 submitted to Monsanto Co., St. Louis, MO. (July 14, 1986).

(5) Springborn Bionomics, Inc. "Acute toxicity of butylbenzyl phthalate to polychaetes (*Nereis/Neanthes virens*) under flow-through conditions." Report No. BW-86-7-2094 submitted to Monsanto Co., St. Louis, MO. (July, 1986).

(6) Springborn Bionomics, Inc. "Acute toxicity of butylbenzyl phthalate to grass shrimp (*Palaemonetes vulgaris*) under flow-through conditions." Report No. BW-86-7-2087 submitted to Monsanto Co., St. Louis, MO. (July, 1986).

(7) Springborn Bionomics, Inc. "Acute toxicity of butylbenzyl phthalate to pink shrimp (*Penaeus duorarum*) under flow-through conditions." Report No. BW-86-7-2083 submitted to Monsanto Co., St. Louis, MO. (July, 1986).

(8) Monsanto Co. Letter from William J. Adams to John Schaeffer. (October 8, 1987).

(9) Springborn Bionomics, Inc. "Chronic toxicity of butylbenzyl phthalate to mysid shrimp (*Mysidopsis bahia*)."

Report No. BW-86-7-2074 submitted to Monsanto Co., St. Louis, MO. (July, 1986).

(10) Springborn Bionomics, Inc. "Acute toxicity of ¹⁴C-butylbenzyl phthalate to eastern oysters (*Crassostrea virginica*)."

Report No. BW-86-7-2063 submitted to Monsanto Co., St. Louis, MO. (August, 1986).

(11) Springborn Bionomics, Inc. "Uptake and elimination of ¹⁴C-residue by eastern oysters (*Crassostrea virginica*) exposed to butylbenzyl phthalate (BBP)." Report No.

BW-86-2114 submitted to Monsanto Co., St. Louis, MO. (August, 1986).

(12) Adams, W.J., W.J. Renaudette, J.D. Doi, M.C. Strepo and M.W. Tucker. "Experimental freshwater microcosm biodegradability study of butyl benzyl phthalate." Report No. MSL-6045, ESC-EAG-86-01. (September 17, 1986).

(13) Monsanto Co. Letter from William J. Adams to John Schaeffer. (April 28, 1987).

Therefore, 40 CFR 799.850 *Benzyl butyl phthalate*, proposed at page 36448 in the Federal Register of September 6, 1985 (50 FR 36448), is hereby withdrawn.

List of Subjects in 40 CFR Part 799

Testing, Environmental protection, Hazardous substances, Chemicals, Recordkeeping and reporting requirements.

Dated: October 22, 1987.

Victor J. Kimm,

Assistant Administrator for Pesticides and Toxic Substances.

[FR Doc. 87-25034 Filed 10-29-87; 8:45 am]

BILLING CODE 5600-50-M

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Based upon its review of the available data, including those developed under the negotiated testing program, EPA concluded that additional environmental fate and effects testing of BBP was warranted under section 4(a)(1)(A). In the Federal Register of September 8, 1985 (50 FR 36446), EPA issued a proposed rule to obtain additional environmental fate and effects testing of BBP. (For a summary of environmental effects tests performed prior to this withdrawal notice, see the preamble to the proposed rule.)

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(OPTS-42070A; FRL-3284-5)

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AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule: Withdrawal.

SUMMARY: EPA is withdrawing its proposal to require certain environmental fate and effects testing for benzyl butyl phthalate (BBP; CAS No. 85-89-7). EPA proposed acute and chronic toxicity tests in freshwater and saltwater organisms, an oyster bioconcentration test, and a test to determine the fate of BBP in undisturbed sediment. Because these tests have been satisfactorily completed by industry, they do not need to be obtained through a test rule.

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Dated: October 22, 1987.

Victor J. Kimm,

Assistant Administrator for Pesticides and Toxic Substances.

[FR Doc. 87-25034 Filed 10-28-87; 8:45 am] BILLING CODE 6560-50-M

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