ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[OPTS-42101A; FRL-3528-3]

Testing Consent Order for Diisodecyl Phenyl Phosphite

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule announces that EPA has signed an enforceable Testing Consent Order with three manufacturers of diisodecyl phenyl phosphite (PDDP; CAS No. 25550-98-5), who have agreed to perform certain neurotoxicity tests with PDDP. This action is in response to the Toxic Substances Control Act (TSCA) Interagency Testing Committee's (ITC) recommendation of PDDP for testing. PDDP is added to the list of Testing Consent Orders for which export notification requirements of 40 CFR Part 707 apply.

EFFECTIVE DATE: February 24, 1989.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, 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, three manufacturers have entered into a testing consent order with EPA in which they have agreed to perform certain neurotoxicity tests with PDDP. This rule amends 40 CFR 799.5000 by adding PDDP to the list of chemical substances and mixtures subject to testing consent orders.

I. ITC Recommendation

In its 17th report to EPA, published in the **Federal Register** of November 19, 1985 (50 FR 47603; Ref. 1), the ITC listed PDDP under Part C (chemicals recommended without designation for response within 12 months) of the section 4(e) priority list. PDDP was recommended for health effects testing, specifically toxicokinetics and subchronic toxicity, including neurotoxicity. The ITC's rationale for the listing was: limited health effects data; the structural relationship between PDDP and a known neurotoxicant, triphenyl phosphite (TPP); high production volume (1-10 million pounds per year); National Institute for Occupational Safety and Health survey data reporting 900 potential workplace exposures; and a dispersive use pattern.

II. Testing Consent Order Negotiations

Prior to the issuance of the Interim Rule establishing the Testing Consent Order Process (51 FR 23706), EPA made findings under TSCA section 4 as the basis for rulemaking in response to the ITC's designation of chemical substances for priority testing. Part 790 now provides for a consent order process to expedite the development of data for risk assessment.

On December 16, 1985, EPA held a public meeting with the manufacturers of PDDP and other interested parties to discuss the ITC listing of PDDP, related health data, and manufacturing and use information (Ref. 1). On February 11, 1988, in accordance with the procedures in 40 CFR 790.22, EPA issued a notice (53 FR 4072) that asked interested parties to participate in consent order negotiations concerning PDDP and announced a public meeting to be held on February 22, 1988 (Ref. 2). At that meeting, EPA presented its tentative testing decisions concerning PDDP and initiated negotiations which led to the adoption of a testing consent order. The identified manufacturers of PDDP, Borg-Warner Chemicals, Inc., Witco Chemicals, and Dover Chemical Corporation, presented their analysis of the existing manufacturing, use, and health data relating to PDDP. Subsequently, negotiation meetings were held on March 10, 1988, and April 6, 1988, to discuss testing options and TSCA testing guidelines. On April 21, 1988, the Phenyl Diisodecyl Phosphite Industry Group, composed of the aforementioned three companies, submitted a letter of intent to perform a testing program for PDDP utilizing specific test standards (Ref. 3). On November 9 and 11, 1988, Borg-Warner Chemicals, Inc., Witco Corporation, and Dover Chemical Corporation signed the Testing Consent Order for PDDP.

Under the Order, the test sponsors agree to conduct or provide for the conduct of the following two health effects tests: a subchronic delayed neurotoxicity test designed for organophosphorus substances and a neurotoxic esterase assay. The specific test standards to be followed and the testing schedule for each test are included in the Order. EPA has concluded that this testing battery is adequate to evaluate PDDP for the concerns identified by the ITC. 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 phosphite chemicals market may be categorized by two major end-uses; insecticide intermediates and plastic stabilizers/antioxidants (Ref. 4). The stabilizer/ antioxidant market consists of the aryl phosphites, aryl alkyl phosphites, and the higher molecular weight alkyl phosphites.

Phosphite stabilizers inhibit the tendency of high-density polyethylene polymers to degrade and discolor during processing. These phosphites are termed secondary antioxidants; they are peroxide decomposing or preventative antioxidants since they reduce hydroperoxides to alcohols, to inhibit the further reaction of free radicals in polymers (Ref. 4). They are also color stabilizers and inhibit the formation of colored quinoid structures by primary phenolic antioxidants (Ref. 4).

PDDP is a dialkyl monophenyl phosphite (aryl-alkyl) and its primary use is as a low cost heat/light stabilizer and secondary antioxidant for polymeric materials, including vinyl polymers and polyurethanes, poly (ether ester) rubbers, and epoxy resins. Its predominant use is in polyvinyl chloride (PVC) as a secondary heat stabilizer, but it is also used in other polymers and elastomers such as polypropylene, polystyrene, high density polyethylene, and ABS rubber as an antioxidant (Ref. 5).

PDDP is a clear liquid that is essentially insoluble in water, with an estimated water solubility of 0.01 to 20 ppb (Refs. 5 and 6). PDDP is soluble in most common aprotic organic solvents, has a vapor pressure of less than 1 mm Hg at 20°C (Ref. 6), and has a calculated log P of greater than 12. (Ref. 7).

The National Occupational Hazard Survey reports 900 potential workplace exposures yearly (Ref. 8). Based on the physical properties of PDDP, EPA believes that dermal exposure to PDDP may occur during manufacture and processing. The potential also exists for inhalation of PDDP by workers during the processing of PDDP. Sampling, cleaning, or replacing of filters and packaging operations are the activities most likely to produce exposures during manufacturing operations. Exposures resulting from PDDP's use as a stabilizer/antioxidant are expected to occur during the milling and bagging of powdered products, from the blending of stabilizers, and from the extrusion of PVC resins.

IV. Testing Program

The only existing neurotoxicity data concerning PDDP is a neurotoxicity

screening study where single doses of 5 g/kg of PDDP were administered by gavage to hens (Ref. 9). Although no signs of ataxia were noted during the 21-day observation period, the study has a major limitation in that the dose, administered only once, may not have been sufficient to elicit an effect. This characteristic is typical of other organophosphorous substances.

EPA is concerned that human exposure to PDDP may result in delayed neurotoxic effects. These concerns are based on test data in cats, rats, and chickens where triphenyl and tricresyl phosphites produced delayed neurotoxic effects including spinal cord and brainstem lesions accompanied by ataxia and paralysis (Ref. 10) in animals exposed by several routes, either acutely or subacutely. The dermal exposure of hens with as little as a single dose of 50 mg/kg of triphenyl phosphite produced severe neurological damage to the central nervous system (Ref. 11). After comparing the chemical structures and expected activities of triphenyl phosphite and PDDP, EPA believes that the potential delayed neurotoxicity of PDDP may be similar to the type observed with triphenyl phosphite (Ref. 7).

In signing the PDDP Consent Order, the manufacturers have agreed to conduct a testing program that EPA believes will identify PDDP's potential to produce delayed neurotoxic effects. The testing program consists of two studies that will be conducted concurrently. The first study is a subchronic delayed neurotoxicity study normally conducted with organophosphorus substances. This study will be conducted according to a modified version of 40 CFR 798.6560, and will use hens as test animals, repeated oral exposures by gavage for 28 days, observations for behavioral effects, and histopathologic examination of tissues (neuropathology). Although the exposure period for this type of test is normally 90 days, EPA expects that any neurologic effect that PDDP may produce will be manifested in 28 days.

The second test is the Neurotoxic Target Esterase Assay, 40 CFR 798.6450, as modified in the Consent Order for PDDP. This test, used in evaluating organophosphorus compounds, measures the inhibition of the esterase activity of a protein called neurotoxic esterase (NTE) in the brain or spinal cord of animals. Animals are sacrificed at regular intervals during repeated exposures and tissues are prepared and chemical activity is measured. NTE measurements provide quantitative data on the first step in the initiation of delayed neurotoxicity.

The Consent Order provides one year for completion and final reporting of the study results to EPA.

Normally, EPA requires that chemical substances to be tested under section 4 of TSCA be 99 percent pure or closely approaching that level of purity. This helps to ensure that any toxic effect produced in a test can be attributed to the activity of the test substance and not a contaminant or confounding factor. However, in the case of PDDP, EPA is accepting a purity level of 92 percent. The PDDP test substance is prepared from an impure intermediate and, after reviewing several attempts by the manufacturers to further purify the compound, EPA believes that the compound is thermally unstable. This instability interferes with the purification of the intermediate and therefore limits the attainable purity of the test substance.

V. Export Notification

The issuance of the Consent Order subjects any person who exports or intends to export PDDP to the export notification requirements of section 12(b) of TSCA. The specific requirements are listed in 40 CFR Part 707. In the Interim Rule of June 23, 1987, (52 FR 23548), EPA added and reserved Subpart C of Part 799 for a listing of chemical substances subject to testing consent orders issued by EPA. 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.

VI. Rulemaking Record

EPA has established a record for this rule (docket number OPTS-42101A). This record contains the information EPA considered in developing this rule and the Consent Order and includes the following information.

A. Supporting Documentation

(1) Testing Consent Order for PDDP.

(2) **Federal Register** notices pertaining to this rule and the Consent Order consisting of:

(a) Notice containing the ITC designation of PDDP to the Priority List (50 FR 47603; November 19, 1985).

(b) Notice soliciting interested parties for developing a Testing Consent Order for PDDP (53 FR 4072; February 11, 1988).

(3) Communications consisting of:

(a) Written letters.

(b) Contact reports of telephone conversations.

(c) Meeting summaries.

(4) Reports—published and unpublished materials.

B. References

(1) USEPA. Seventeenth Report of the Interagency Testing Committee to the Administrator; Receipt of Report and Request for Comments Regarding Priority List of Chemicals (50 FR 47603; November 16, 1985).

(2) USEPA. Testing Consent Agreement; Development for Diisodecyl Phenyl Phosphite (PDDP); Solicitation for Interested Parties (53 FR 4072, February 11, 1988).

(3) Borg-Warner Chemicals. Letter to David Price, Test Rules Development Branch, Office of Toxic Substances, USEPA, from Richard Brooke, Borg Warner Chemicals, advising EPA of manufacturer's intent to agree with testing via Consent Order (April 21, 1988).

(4) Mathtech Inc. Memorandum from J.K. Orrell of Mathtech to Mark Dreyfus, Regulatory Impacts Branch, Office of Toxic Substances, USEPA. Phosphites Market Study (September 30, 1986).

(5) Syracuse Research Corporation. Technical Support Document, Diisodecylphenyl Phosphite. Contract No. 68-02-4209, Task 14 (July 1, 1986).

(6) CRCS Inc. Information Review, Diisodecyl Phenyl Phosphite, IR-377 (April 16, 1984).

(7) USEPA. Memorandum from Pauline Wagner, Toxic Effects Branch, Office of Toxic Substances, USEPA, to Charles Auer, Chemical Risk Evaluation Branch, Office of Toxic Substances, USEPA. SAR Report on Phenyl Diisodecyl Phosphite (PDDP) (August 18, 1987).

(8) NIOSH. National Occupational Hazard Survey (1972-74) [data base]. Department of Health and Human Services, National Institute for Occupational Safety and Health, Cincinnati, OH (1976).

(9) Borg-Warner Chemicals. TSCA section 8(d) Submission 878216267 received January 15, 1986. Study report: Screening Report for Neurotoxicity of Phenyldiisodecyl Phosphite (PDDP) in the Chicken, March 1981. Washington D.C. U.S. Environmental Protection Agency.

(10) Smith et al. The pharmacologic action of the phosphorus acid esters of the phenols. *Journal of Pharmacology and Experimental Therapeutics* 49:78-99, 1933.

(11) Borg-Warner Chemicals. TSCA section 8(e) submission 8EHQ-1282-0451. Follow-up. 88-8300447. Screening test for neurotoxicity of triphenyl phosphite in the chicken following dermal application to the comb. 1982. Washington, DC: Office of Toxic Substances, U.S. Environmental Protection Agency.

List of Subjects in 40 CFR Part 799

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

Dated: February 17, 1989.

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 diisodecyl phenyl phosphite to the table in CAS Number order, 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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25550-98-5	Diisodecyl phenyl phosphite	Neurotoxic effects	February 24, 1989
*	*	*	*

[FR Doc. 89-4304 Filed 2-23-89; 8:45 am]

BILLING CODE 6560-50-M