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40 C.F.R. § 799.4360

Tributyl phosphate.

(a) *Identification of test substance.* (1) Tributyl phosphate (TBP, CAS No. 126-73-8) shall be tested in accordance with this section.

(2) TBP of at least 99 percent purity shall be used as the test substance.

(b) *Persons required to submit study plans, conduct tests, and submit data.* All persons who manufacture (including import and byproduct manufacture) or process or intend to manufacture or process TBP, other than as an impurity, from the effective date of the final rule to the end of the reimbursement period shall submit letters of intent to conduct testing, submit study plans, conduct tests, and submit data, or submit exemption applications as specified in this section, subpart A of this part, and part 790 of this chapter for single-phase rulemaking.

(c) *Health effects testing*—(1) *Neurotoxicity*—(i) *Required testing.* (A)(*1*) An acute and subchronic functional observational battery shall be conducted with TBP in accordance with § 798.6050 of this chapter except for the provisions of paragraphs (d) (5) and (6) of § 798.6050.

(2) For the purpose of this section, the following provisions also apply:

(*i*) *Animal selection.* Testing shall be performed in laboratory rats.

(*ii*) *Duration of testing.* For the acute testing, the substance shall be administered over a period not to exceed 24 hours; for the subchronic testing, test species shall be exposed daily for at least 90 days.

(*iii*) *Route of exposure.* Animals shall be exposed to TBP orally.

(B)(*1*) An acute and subchronic motor activity test shall be conducted with TBP in accordance with § 798.6200 of this chapter except for the provisions of paragraphs (d) (5) and (6) of § 798.6200.

(2) For the purpose of this section, the following provisions also apply:

(*i*) *Animal selection.* Testing shall be performed in laboratory rats.

(*ii*) *Duration of testing.* For the acute testing, the substance shall be administered over a period not to exceed 24 hours; for the subchronic testing, test species shall be exposed daily for at least 90 days.

(*iii*) *Route of administration.* Animals shall be exposed to TBP orally.

(C)(*1*) A neuropathology test shall be conducted with TBP in accordance with § 798.6400 of this chapter except for the provision of paragraphs (d)(1)(i) (5) and (6) of § 798.6400.

(2) For the purpose of this section, the following provisions also apply:

(*i*) *Animal selection.* Testing shall be performed in laboratory rats.

(*ii*) *Duration of testing.* Animals shall be exposed for at least a 90-day period.

(*iii*) *Route of administration.* Animals shall be exposed to TBP orally.

(ii) *Reporting requirements*—(A) The neurotoxicity tests required under paragraph (c)(1)(i) (A), (B), and (C) of this section shall be completed and final reports submitted to EPA within 18 months of the effective date of the final rule.

(B) An interim progress report for these neurotoxicity tests shall be submitted to EPA 6 months after the effective date of the final rule.

(2) *Developmental toxicity*—(i) *Required testing.* (A) A developmental toxicity study shall be conducted with TBP in accordance with § 798.4900 of this chapter, except for the provisions of paragraph (e)(5) of § 798.4900.

(B) for the purpose of this section, the following provision also applies:

(*1*) *Route of administration.* The animals shall be exposed to TBP by gavage.

(2) [Reserved]

(ii) *Reporting requirements.* (A) The developmental toxicity study required under paragraph (c)(2) of this section shall be completed and a final report submitted to EPA by January 27, 1991.

(B) An interim progress report shall be submitted to EPA 6 months after the effective date of the final rule.

(3) *Reproductive and fertility*—(i) *Required testing.* (A) A reproduction and fertility study shall be conducted with TBP in accordance with § 798.4700 of this chapter, except for the provisions of paragraph (c)(5)(i)(A) of § 798.4700.

(B) for the purpose of this section, the following provisions also apply:

(*1*) *Route of administration.* Animals should be exposed to TBP by gavage.

(2) [Reserved]

(ii) *Reporting requirements.* (A) The reproduction and fertility effects study required under paragraph (c)(3) of this section shall be completed and a final report submitted to EPA by August 17, 1992.

(B) Interim program reports shall be submitted to EPA at 6 month intervals, beginning 6 months after the effective date of the final rule, until the final report is submitted to EPA.

(4) *Mutagenic effects—Gene mutation*—(i) *Required testing.* (A) A detection of gene mutation in somatic cells in culture test shall be conducted with TBP in accordance with § 798.5300 of this chapter.

(B)(*1*) If TBP produces a positive result in the assay conducted pursuant to paragraph (c)(4)(i)(A) of this section, a sex-linked recessive lethal test in *Drosophila melanogaster* shall be conducted with TBP in accordance with § 798.5275 of this chapter, except for the provisions of paragraph (d)(5)(iii) of § 798.5275.