

(i) *Duration of exposure.* Animals shall be dosed for 6 hours per day, 5 days per week for 90 days.

(ii) *Route of exposure.* Animals shall be exposed to isopropanol by inhalation.

(D) The developmental neurotoxicity test shall be conducted with isopropanol in accordance with §795.250 of this chapter, except for paragraph (c)(1)(iv).

(J) For purposes of this section, the following provisions also apply:

(i) *Numbers of animals.* The objective is for a sufficient number of pregnant rats to be exposed to ensure that an adequate number of offspring are produced for neurotoxicity evaluation. At least 24 litters shall be used at each dose level.

(ii) [Reserved]

(2) [Reserved]

(ii) *Reporting requirements.* (A) The acute functional observation battery and motor activity tests shall be completed and the final report submitted to EPA within 15 months of the date specified in paragraph (d)(1) of this section. The subchronic functional observation battery, motor activity, and neuropathology tests shall be completed and the final reports submitted to EPA within 18 months of the date specified in paragraph (d)(1) of this section. The developmental neurotoxicity test shall be completed and the final report submitted to EPA within 21 months of the date specified in paragraph (d)(1) of this section.

(B) Progress reports shall be submitted to EPA for the functional observation battery, motor activity, neuropathology, and developmental neurotoxicity tests at 6-month intervals beginning 6 months after the date specified in paragraph (d)(1) of this section until submission of the applicable final report.

(7) *Pharmacokinetics studies*—(i) *Required testing.* An oral and inhalation pharmacokinetics test shall be conducted with isopropanol in accordance with §795.231 of this chapter.

(ii) *Reporting requirements.* (A) The pharmacokinetic test shall be completed and the final report submitted to EPA within 15 months of the date specified in paragraph (d)(1) of this section.

(B) Progress reports shall be submitted to EPA for the pharmacokinetics test at 6-month intervals beginning 6 months after the date specified in paragraph (d)(1) of this section until submission of the final report.

(8) *Oncogenicity*—(i) *Required testing.* An oncogenicity test shall be conducted by inhalation with isopropanol in accordance with §798.3300 of this chapter.

(ii) *Reporting requirements.* (A) The oncogenicity test shall be completed and the final report submitted to EPA by July 5, 1994.

(B) Progress reports shall be submitted at 6-month intervals beginning 6 months after the date specified in paragraph (d)(1) of this section until submission of the final report.

(d) *Effective date.* (1) The effective date of this final rule is December 4, 1989, except for the provisions of paragraphs (c)(5)(i)(C)(J), (c)(5)(ii)(A)(3), (c)(6)(i)(D), and (c)(8)(ii)(A), of this section. The effective date for paragraphs (c)(5)(i)(C)(J), and (c)(5)(ii)(A)(3) of this section is May 21, 1990. The effective date for paragraphs (c)(6)(i)(D) of this section is May 21, 1991. The effective date of paragraph (c)(8)(ii)(A) is September 29, 1995.

(2) The guidelines and other test methods cited in this rule are references as they exist on the effective date of the final rule.

[54 FR 43262, Oct. 23, 1989, as amended at 55 FR 12644, Apr. 5, 1990; 56 FR 23231, May 21, 1990; 58 FR 34205, June 23, 1993; 60 FR 56956, Nov. 13, 1995]

#### § 799.2475 2-Mercaptobenzothiazole.

(a) *Identification of test substance.* (1) 2-Mercaptobenzothiazole (MBT, CAS No. 149-30-4) shall be tested in accordance with this section.

(2) MBT of at least 97.6 percent purity (plus or minus 1.5 percent) shall be used as the test substance.

(b) *Persons required to submit study plans, conduct tests, and submit data.* All persons who manufacture (including byproduct manufacture, and import of MBT and MBT-containing articles) or process or intend to manufacture or process MBT, other than as an impurity, after October 21, 1988, 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 parts 790 and 792 of this chapter for single-phase rulemaking.

(c) *Chemical fate*—(1) *Aerobic aquatic biodegradation*—(i) *Required testing*. Aerobic aquatic biodegradation testing shall be conducted with MBT in accordance with § 796.3100 of this chapter.

(ii) *Reporting requirements*. (A) The aerobic aquatic biodegradation test shall be completed and the final report submitted to EPA within 12 months of the effective date of the final rule.

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

(2) *Indirect photolysis-screening level test*—(i) *Required testing*. Indirect photolysis testing shall be conducted with MBT in accordance with § 795.70 of this chapter.

(ii) *Reporting requirements*. (A) The indirect photolysis test shall be completed and the final report submitted to EPA within 12 months of the effective date of the final rule.

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

(3) *Chemical mobility*—(i) *Required testing*. Chemical mobility testing shall be conducted with MBT in accordance with § 796.2750 of this chapter.

(ii) *Reporting requirements*. (A) The chemical mobility test shall be completed and the final report submitted to EPA within 12 months of the effective date of the final rule.

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

(d) *Environmental effects*—(1) *Fish chronic toxicity*—(i) *Required testing*. (A) Chronic toxicity testing of MBT shall be conducted using rainbow trout (*Salmo gairdneri*.) according to § 797.1600 of this chapter, except for paragraphs (c)(4)(iv)(A), (c)(4)(x)(E) and (c)(4)(x)(F), (c)(6)(iv)(A), (d)(2)(vii)(A)(2), and (d)(3)(iv) of § 797.1600.

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

(I) The first feeding for the fathead and sheepshead minnow fry shall begin

shortly after transfer of the fry from the embryo cups to the test chambers. Silversides are fed the first day after hatch. Trout species initiate feeding at swim-up. The trout fry shall be fed trout starter mash or live newly-hatched brine shrimp nauplii (*Artemia salina*) three times a day *ad libitum*, with excess food siphoned off daily. The minnow fry shall be fed live newly-hatched brine shrimp nauplii (*Artemia salina*) at least three times a day.

(2) All physical abnormalities (e.g., stunted bodies, scoliosis, etc.) shall be photographed and preserved.

(3) At termination, all surviving fish shall be measured for growth. Total length measurements should be used except in cases where fin erosion occurs, then the use of standard length measurements shall be permitted. Standard length measurements should be made directly with a caliper, but may be measured photographically. Measurements shall be made to the nearest millimeter (0.1 mm is desirable). Weight measurements shall also be made for each fish alive at termination (wet, blotted dry, and to the nearest 0.01 g for the minnows and 0.1 g for the trout). If the fish exposed to the toxicant appear to be edematous compared to control fish, determination of dry, rather than wet, weight is recommended.

(4)(i) *Test substance measurement*. Prior to addition of the test substance to the dilution water, it is recommended that the test substance stock solution be analyzed to verify the concentration. After addition of the test substance, the concentration of test substance shall be measured in the test substance delivery chamber prior to beginning, and during, the test. The concentration of test substance should also be measured at the beginning of the test in each test concentration (including both replicates) and control(s), and at least once a week thereafter. Equal aliquots of test solution may be removed from each replicate chamber and pooled for analysis. If a malfunction in the delivery system is discovered, water samples shall be taken from the affected test chambers immediately and analyzed.

(ii) *pH*. It is recommended that a pH of 7 be maintained in the test chambers.

(iii) *Reporting*. An analysis of the stability of the stock solution for the duration of the test shall be reported.

(5) [Reserved]

(6) For brook and rainbow trout, a 16-hour light and 8-hour dark photoperiod shall be provided.

(ii) *Reporting requirements*. (A) The fish chronic toxicity test shall be completed and the final report submitted to EPA within 12 months of the effective date of the final rule.

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

(2) *Daphnid chronic toxicity*—(i) *Required testing*. (A) Daphnid chronic toxicity testing shall be conducted with MBT using *Daphnia magna* according to § 797.1330 of this chapter.

(B) For the purposes of this section, the following provisions also apply:

(1) *Test substance measurement*. Test substance concentration shall be measured in the test substance delivery chamber prior to beginning, and during, the test.

(2) *pH*. It is recommended that a pH of 7 be maintained in the test chambers.

(3) *Reporting*. An analysis of the stability of the stock solution for the duration of the test shall be reported and data comparing trout starter mash with *A. salina* for supporting trout growth should be submitted with the final report.

(ii) *Reporting requirements*. (A) The daphnid chronic toxicity test shall be completed and the final report submitted to EPA within 12 months of the effective date of the final rule.

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

(e) *Health effects*—(1) *Developmental toxicity testing*—(i) *Required testing*. Developmental toxicity testing shall be conducted in two mammalian species with MBT in accordance with § 798.4900 of this chapter, using the oral route of administration.

(ii) *Reporting requirements*. (A) The developmental toxicity test shall be completed and the final report submitted

to EPA within 12 months of the effective date of the final rule.

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

(2) *Reproductive toxicity*—(i) *Required testing*. Reproductive toxicity testing shall be conducted with MBT in accordance with § 798.4700 of this chapter, using the oral route of administration.

(ii) *Reporting requirements*. (A) The reproductive test shall be completed and the final report submitted to EPA within 29 months of the effective date of the final rule.

(B) Progress reports shall be submitted to EPA at 6-month intervals beginning 6 months after the effective date of the final rule until submission of the final report.

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

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

(i) *Duration and frequency of exposure*. For acute study, animals shall be administered MBT over a period not to exceed 24 hours. For subchronic study, animals shall be dosed daily for at least 90 days.

(ii) *Route of exposure*. Animals shall be exposed to MBT orally.

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

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

(i) *Duration and frequency of exposure*. For acute study, animals shall be administered over a period not to exceed 24 hours. For subchronic study, animals shall be dosed daily for at least 90 days.

(ii) *Route of exposure*. Animals shall be exposed to MBT orally.

(C)(1) A subchronic neuropathology test shall be conducted with MBT in accordance with § 798.6400 of this chapter except for the provisions in paragraphs (d)(5) and (6) of § 798.6400.

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

§ 799.2700

40 CFR Ch. I (7-1-04 Edition)

(i) *Duration and frequency of exposure.* Animals shall be dosed daily for at least 90 days.

(ii) *Route of exposure.* Animals shall be exposed to MBT orally.

(ii) *Reporting requirements.* (A) The functional observation battery, motor activity, and neuropathology tests shall be completed and the final reports for each test submitted to EPA within 18 months of the effective date of the final rule.

(B) A progress report shall be submitted to EPA for the functional observation battery, motor activity, and neuropathology tests, respectively, 6 months after the effective date of the final rule.

(4) *Mutagenic effects—Chromosomal aberrations—(i) Required testing.* (A) A dominant lethal assay shall be conducted with MBT in accordance with § 798.5450 of this chapter, using the oral route of administration.

(B) A heritable translocation assay shall be conducted with MBT in accordance with the test guideline specified in § 798.5460 of this chapter if MBT produces a positive result in the dominant lethal assay conducted pursuant to paragraph (e)(4)(i)(A) of this section and if, after a public program review, EPA issues a FEDERAL REGISTER notice or sends a certified letter to the test sponsor specifying that the testing shall be initiated.

(ii) *Reporting requirements.* (A) Mutagenic effects—Chromosomal aberration testing of MBT shall be completed and the final report submitted to EPA as follows: Dominant lethal assay, within 12 months after the effective date of this rule; heritable translocation assay, within 24 months after notification under paragraph (e)(4)(i)(B) of this section that the testing shall be initiated.

(B) For the dominant lethal assay, an interim progress report shall be submitted to EPA 6 months after the effective date of the final rule; for the heritable translocation assay, progress reports shall be submitted to EPA at 6-month intervals beginning 6 months after the date of EPA's notification of the test sponsor that testing shall be initiated until submission of the final report.

(f) *Effective date.* (1) The effective date of this final rule is October 21, 1988, except for paragraphs (a)(2), (d)(1)(i), (d)(2)(i)(B)(3), and (e)(3)(ii)(A) of this section. The effective date for paragraphs (a)(2), (d)(1)(i), (d)(2)(i)(B)(3), and (e)(3)(ii)(A) of this section is March 1, 1990.

(2) The guidelines and other test methods cited in this rule are referenced as they exist on the effective date of the final rule.

[53 FR 34530, Sept. 7, 1988; 53 FR 37393, Sept. 26, 1988, as amended at 55 FR 7326, Mar. 1, 1990; 58 FR 34205, June 23, 1993]

§ 799.2700 Methyl ethyl ketoxime.

(a) *Identification of test substance.* (1) Methyl ethyl ketoxime (MEKO, CAS No. 96-29-7) shall be tested in accordance with this section.

(2) MEKO 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) or process or intend to manufacture or process MEKO, including persons who manufacture or process or intend to manufacture or process MEKO as a byproduct, or who import or intend to import products which contain MEKO, after the date specified in paragraph (e) of this section 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 parts 790 and 792 of this chapter for single-phase rulemaking. Persons who manufacture, import, or process MEKO only as an impurity are not subject to these requirements.

(c) *Health effects testing—(1) Pharmacokinetics testing—(i) Required testing.* Pharmacokinetics testing shall be conducted with MEKO in accordance with paragraph (c)(1)(ii) of this section.

(ii) [Reserved]

(2) *Oncogenicity—(i) Required testing.* Oncogenicity testing shall be conducted in accordance with § 798.3300 of this chapter.

(ii) *Route of administration.* MEKO shall be administered either orally or by inhalation.