

40 C.F.R. § 799.2325

Isopropanol.

- (a) *Identification of test substance.* (1) Isopropanol (CAS No. 67-63-0) shall be tested in accordance with this section.
- (2) Isopropanol of at least 99.8 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 byproduct manufacture) or intend to manufacture or process isopropanol, from the effective date of this 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 parts 790 and 792 of this chapter for single-phase rulemaking.
- (c) *Health effects testing*—(1) *Subchronic inhalation toxicity*—(i) *Required testing.* A subchronic inhalation toxicity test shall be conducted with isopropanol in accordance with § 798.2450 of this chapter.
- (ii) *Reporting requirements.* (A) The subchronic inhalation toxicity test shall be completed and the final report submitted to EPA within 15 months of the date specified in paragraph (d) of this section.
- (B) Progress reports shall be submitted to EPA for the subchronic inhalation toxicity 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.
- (2) Reproduction and fertility effects—(i) Required testing. A reproduction and fertility effects test shall be conducted by gavage with isopropanol in accordance with § 798.4700 of this chapter.
- (ii) *Reporting requirements.* (A) The reproduction and fertility effects test shall be completed and the final report submitted to EPA within 29 months of the date specified in paragraph (d)(1) of this section.
- (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.
- (3) *Developmental toxicity*—(i) *Required testing.* A developmental toxicity test shall be conducted in two mammalian species by gavage with isopropanol in accordance with § 798.4900 of this chapter.
- (ii) Reporting requirements. (A) The developmental toxicity test shall be completed and the final report submitted to EPA within 12 months of the date specified in paragraph (d)(1) of this section.
- (B) A progress report shall be submitted 6 months after the date specified in paragraph (d)(1) of this section.
- (4) Mutagenic effects—gene mutations—(i) Required testing. (A) A gene mutation test in mammalian cells shall be conducted with isopropanol in accordance with § 798.5300 of this chapter.

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