§ 799.1650 2-Ethylhexanoic acid.

(a) *Identification of test substance.* (1) 2-Ethylhexanoic acid (CAS No. 149–57–5) (hereinafter "EHA") shall be tested in accordance with this section.

(2) EHA 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 or process EHA other than as an impurity from the effective date of this section, December 20, 1986, to the end of the reimbursement period shall submit an exemption application, or shall submit a letter of intent to conduct testing, study plans, conduct tests, and submit data as specified in this section, subpart A of this part, and parts 790 and 792 of this chapter. The end of the reimbursement period shall be 5 years after the submission of the last final report required under this test rule.

(c) *Health effects testing*—(1) *Pharmacokinetics*—(i) *Required testing.* Metabolism studies of the oral and dermal routes of exposure shall be conducted with EHA using Fischer 344 rats in accordance with the test standard specified in § 795.223 of this chapter.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 45 days prior to initiating testing.

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

(C) The final report of results shall be submitted to the Agency no later than 1 year from the effective date of the final test rule.

(2) *Subchronic toxicity*—(i) *Required testing.* Subchronic toxicity tests shall be conducted with EHA using Fischer 344 rats and B6C3F1 mice in accordance with the test standard specified in § 795.260 of this chapter.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 45 days prior to initiating testing.

(B) Interim progress reports shall be provided to the Agency 6 months and 12 months after the effective date of the final test rule.

(C) The final report of results shall be submitted to the Agency no later than 18 months from the effective date of the final test rule.

(3) *Administration of test substance.* Dosing for the testing required under paragraphs (c) (1) and (2) of this section shall be by the oral route for both tests, and as specified in § 795.223(c)(2)(ii)(C) and § 795.260(d)(7) of this chapter.

(4) *Development toxicity*—(i) *Required testing.* Developmental toxicity tests shall be conducted with EHA using one rodent and one nonrodent mammalian species in accordance with the OECD guideline entitled "Teratogenicity", No. 414, adopted May 12, 1981. The OECD guideline is available in OECD Publication No. ISBN 92–64–12221–4 and is sold by the OECD Publication and Information Center, Room Number 1207, 1750 Pennsylvania Avenue, NW., Washington, DC. Copies of this document may be inspected at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC, or the OPPTS Reading Room (docket No. OPPTS–42065), Room N.E.–G004, Environmental Protection Agency, 401 M Street, SW., Washington, DC. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. These materials are incorporated as they exist on the effective date of this rule; a notice of any change will be published in the FEDERAL REGISTER.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 45 days prior to initiating testing.

(B) Interim progress reports shall be provided to the Agency 6 months and 12 months after the effective date of the final test rule.

(C) The final report of results shall be submitted to the Agency no later than 18 months from the effective date of the final test rule.

[51 FR 40330, Nov. 6, 1986, as amended at 52 FR 24158, June 29, 1987; 52 FR 32240, Aug. 26, 1987; 58 FR 34205, June 23, 1993]

§ 799.1700 Fluoroalkenes.

(a) *Identification of test substances.* (1) Vinyl fluoride (VF; CAS No. 75–02–5), vinylidene fluoride (VDF; CAS No. 75–38–7), tetrafluoroethene (TFE; CAS No. 116–14–3), and hexafluoropropene (HFP;