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## PART 799—IDENTIFICATION OF SPECIFIC CHEMICAL SUBSTANCE AND MIXTURE TESTING REQUIREMENTS

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- 799.9537 TSCA in vitro mammalian chromosome aberration test.
- 799.9538 TSCA mammalian bone marrow chromosomal aberration test.
- 799.9539 TSCA mammalian erythrocyte micronucleus test.
- 799.9620 TSCA neurotoxicity screening battery.
- 799.9630 TSCA developmental neurotoxicity.
- 799.9748 TSCA metabolism and pharmacokinetics.
- 799.9780 TSCA immunotoxicity.

AUTHORITY: 15 U.S.C. 2603, 2611, 2625.

SOURCE: 49 FR 39817, Oct. 10, 1984, unless otherwise noted.

## Environmental Protection Agency

## § 799.10

### Subpart A—General Provisions

#### § 799.1 Scope and purpose.

(a) This part identifies the chemical substances, mixtures, and categories of substances and mixtures for which data are to be developed, specifies the persons required to test (manufacturers, including importers, and/or processors), specifies the test substance(s) in each case, prescribes the tests that are required including the test standards, and provides deadlines for the submission of reports and data to EPA.

(b) This part requires manufacturers and/or processors of chemical substances or mixtures (“chemicals”) identified in subpart B to submit letters of intent to test, exemption applications, and study plans in accordance with EPA test rule development and exemption procedures contained in part 790 of this chapter and any modifications to such procedures contained in this part.

(c) This part requires manufacturers and/or processors of chemicals identified in subpart B to conduct tests and submit data in accordance with the test standards contained in this part in order to develop data on the health and environmental effects and other characteristics of these chemicals. These data will be used to assess the risk of injury to human health or the environment presented by these chemicals.

(d) This part contains certain TSCA test guidelines which are cross-referenced in the test rules contained in this part.

[49 FR 39817, Oct. 10, 1984, as amended at 62 FR 43824, Aug. 15, 1997]

#### § 799.2 Applicability.

This part is applicable to each person who manufactures or intends to manufacture (including import) and/or to each person who processes or intends to process a chemical substance or mixture identified in subpart B for testing during the period commencing with the effective date of the specific chemical test rule until the end of the reimbursement period. Each set of testing requirements in subpart B specifies whether those requirements apply to manufacturers only, to processors

only, or to both manufacturers and processors.

#### § 799.3 Definitions.

The definitions in section 3 of the Toxic Substances Control Act (TSCA) and the definitions of § 790.3 of this chapter apply to this part.

#### § 799.5 Submission of information.

Information (letters, study plans, reports) submitted to EPA under this part must bear the Code of Federal Regulations section number of the subject chemical test rule (e.g., § 799.1285 for Cumene) and must be addressed to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

[60 FR 34467, July 3, 1995, as amended at 71 FR 33642, June 12, 2006]

#### § 799.10 Test standards.

Testing required under subpart B must be performed using a study plan prepared according to the requirements of parts 790 and 792 of this chapter unless modified in specific chemical test rules in subpart B. All raw data, documentation, records, protocols, specimens and reports generated as a result of a study under subpart B must be developed, reported, and retained in accordance with TSCA Good Laboratory Practice Standards (GLP’s) in part 792 of this chapter. These items must be made available during an inspection or submitted to EPA upon request by EPA or its authorized representative. Laboratories conducting testing for submission to the Agency in response to a test rule promulgated under section 4 of TSCA must adhere to the TSCA GLP’s. Sponsors must notify the laboratory that the study is being conducted pursuant to TSCA section 4. Sponsors are also responsible for ensuring that laboratories conducting the test abide by the TSCA GLP standards. In accordance with § 792.12 of this chapter, a certification concerning adherence to the TSCA GLP’s must be submitted to EPA.