

hens in the control and high-dose groups. Microscopic examination should also be carried out on hens in the low and intermediate dose groups when there is evidence of effects in the high-dose group.

(e) *Data reporting and evaluation*—(1) *Test report*. In addition to the reporting requirements specified under 40 CFR part 792, subpart J the final test report must include the following information:

(i) Toxic response data by group with a description of clinical manifestations of nervous system damage; where a grading system is used the criteria should be defined.

(ii) For each animal, time of death during the study or whether it survived to termination.

(iii) The day of observation of each abnormal sign and its subsequent course.

(iv) Body weight data.

(v) Necropsy findings for each animal, when performed.

(vi) A detailed description of all histopathological findings.

(vii) Statistical treatment of results, where appropriate.

(2) *Treatment of results*. (i) Data may be summarized in tabular form, showing for each test group the number of animals at the start of the test, the number of animals showing lesions or effects, the types of lesions or effects and the percentage of animals displaying each type of lesion or effect.

(ii) All observed results should be evaluated by an appropriate statistical method. Any generally accepted statistical method may be used; the statistical methods should be selected during the design of the study.

(3) *Evaluation of results*. The findings of a subchronic delayed neurotoxicity study should be evaluated in conjunction with the findings of preceding studies and considered in terms of the incidence and severity of observed neurotoxic effects and any other observed effects and histopathological findings in the treated and control groups. A properly conducted subchronic test should provide a satisfactory estimation of a no-effect level based on lack of clinical signs and histopathological changes.

(f) *References*. For additional background information on this test guideline the following references should be consulted:

(1) Abou-Donia, M.B. "Organophosphorus ester-induced delayed neurotoxicity" Annual Review of Pharmacology and Toxicology, 21:511-548 (1981).

(2) Abou-Donia, M.B., Pressing, S.H. "Delayed neurotoxicity from continuous low-dose oral administration of leptophos to hens." *Toxicology and Applied Pharmacology*, 38:595-608 (1976).

(3) Baron, R.L. (ed). "Pesticide Induced Delayed Neurotoxicity." Proceedings of a Conference, February 19-20, 1976, Washington, DC. U.S. Environmental Protection Agency. EPA Report No. 600/1-76-025, Washington, DC (1976).

(4) Cavanaugh, J.B. "Peripheral neuropathy caused by chemical agents" *Critical Reviews of Toxicity*, 2:365-417 CRC Press, Inc. (1973).

(5) Johannsen, F.R., Wright, P.L., Gordon, D.E., Levinskas, G.L., Radue, R.W., Graham, P.R. "Evaluation of delayed neurotoxicity and dose-response relationship of phosphate esters in the adult hen." *Toxicology and Applied Pharmacology*, 41:291-304 (1977).

(6) Johnson, M.K. "Organophosphorus esters causing delayed neurotoxic effects: mechanism of action and structure/activity studies." *Archives of Toxicology*, 34:259-288 (1975).

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

### Subpart A—General Provisions

Sec.	
799.1	Scope and purpose.
799.2	Applicability.
799.3	Definitions.
799.5	Submission of information.
799.10	Test standards.
799.11	Availability of test guidelines.
799.12	Test results.
799.17	Effects of non-compliance.
799.18	Chemicals subject of test rules or consent orders for which the testing reimbursement period has passed.
799.19	Chemical imports and exports.

**Subpart B—Specific Chemical Test Rules**

- 799.1053 Trichlorobenzenes.
- 799.1560 Diethylene glycol butyl ether and diethylene glycol butyl ether acetate.
- 799.1575 Diethylenetriamine (DETA).
- 799.1645 2-Ethylhexanol.
- 799.1700 Fluoroalkenes.
- 799.2155 Commercial hexane.
- 799.2325 Isopropanol.
- 799.2475 2-Mercaptobenzothiazole.
- 799.2700 Methyl ethyl ketoxime.
- 799.3300 Unsubstituted phenylenediamines.
- 799.4360 Tributyl phosphate.
- 799.4440 Triethylene glycol monomethyl ether.

**Subpart C—Testing Consent Orders**

- 799.5000 Testing consent orders for substances and mixtures with Chemical Abstract Service Registry Numbers.
- 799.5025 Testing consent orders for mixtures without Chemical Abstracts Service Registry Numbers.

**Subpart D—Multichemical Test Rules**

- 799.5055 Hazardous waste constituents subject to testing.
- 799.5075 Drinking water contaminants subject to testing.
- 799.5115 Chemical testing requirements for certain chemicals of interest to the Occupational Safety and Health Administration.

**Subpart E—Product Properties Test Guidelines**

- 799.6755 TSCA partition coefficient (*n*-octanol/water), shake flask method.
- 799.6756 TSCA partition coefficient (*n*-octanol/water), generator column method.
- 799.6784 TSCA water solubility: Column elution method; shake flask method.
- 799.6786 TSCA water solubility: Generator column method.

**Subparts F–G [Reserved]****Subpart H—Health Effects Test Guidelines**

- 799.9110 TSCA acute oral toxicity.
- 799.9120 TSCA acute dermal toxicity.
- 799.9130 TSCA acute inhalation toxicity.
- 799.9135 TSCA acute inhalation toxicity with histopathology.
- 799.9305 TSCA Repeated dose 28-day oral toxicity study in rodents.
- 799.9310 TSCA 90-day oral toxicity in rodents.
- 799.9325 TSCA 90-day dermal toxicity.
- 799.9346 TSCA 90-day inhalation toxicity.
- 799.9355 TSCA reproduction/developmental toxicity screening test.

- 799.9365 TSCA combined repeated dose toxicity study with the reproduction/developmental toxicity screening test.
- 799.9370 TSCA prenatal developmental toxicity.
- 799.9380 TSCA reproduction and fertility effects.
- 799.9410 TSCA chronic toxicity.
- 799.9420 TSCA carcinogenicity.
- 799.9430 TSCA combined chronic toxicity/carcinogenicity.
- 799.9510 TSCA bacterial reverse mutation test.
- 799.9530 TSCA in vitro mammalian cell gene mutation test.
- 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.

**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 Protection Agency

## § 799.17

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 (7407), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Room G-099, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

[60 FR 34467, July 3, 1995]

### § 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.

### § 799.11 Availability of test guidelines.

(a) The TSCA and FIFRA guidelines for the various study plans are available from the National Technical Information Service (NTIS). Address and telephone number: National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703-487-4650).

(b) The OECD guidelines for the various study plans are available from the following address: OECD Publication and Information Center, 1750 Pennsylvania Ave., NW., Washington, DC 20006 (202-724-1857).

### § 799.12 Test results.

Except as set forth in specific chemical test rules in subpart B of this part, a positive or negative test result in any of the tests required under subpart B is defined in the TSCA test guidelines published by NTIS.

### § 799.17 Effects of non-compliance.

Any person who fails or refuses to comply with any aspect of this part or part 790 is in violation of section 15 of TSCA. EPA will treat violations of Good Laboratory Practice Standards as indicated in § 792.17 of this chapter.