



Standard Test Method for Determining Subchronic Dermal Toxicity¹

This standard is issued under the fixed designation E 1103; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This test method describes a procedure for the assessment and evaluation of the toxic characteristics of a test substance that is applied daily to the skin of experimental animals for 90 days.

1.2 This test method is not capable of determining effects that have a long latency period (for example, carcinogenicity) or are life shortening.

1.3 This test method is intended primarily to be used with rats, guinea pigs, or rabbits. Other species may be used with appropriate modifications.

1.4 *This standard does not purport to address the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 ASTM Standards:

E 609 Terminology Relating to Pesticides²

E 758 Test Method for Mammalian Acute Percutaneous Toxicity²

2.2 Federal Standards:

Title 21, Code of Federal Regulations (CFR), Food and Drug Administration, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies³

Title 40, Code of Federal Regulations (CFR), Environmental Protection Agency, Part 798, Health Effects Testing Guidelines, Subpart C, Subchronic Exposure, Oral Toxicity³

Title 40, Code of Federal Regulations (CFR), Environmental Protection Agency, Part 798, Health Effects Testing Guidelines, Subpart B, General Toxicity Testing, Acute Oral Toxicity³

Title 40, Code of Federal Regulations (CFR), Environmental Protection Agency, Subchapter E, Pesticide Programs; Part 160, Good Laboratory Practice Standards³

Title 40, Code of Federal Regulations (CFR), Toxic Sub-

stance Control Act, Part 792, Good Laboratory Practice Standards³

3. Terminology

3.1 *Definitions*—For definitions of terms used in this test method, see Terminology E 609.

3.2 Definitions of Terms Specific to This Standard:

3.2.1 *dose, dosage, n*—the quantity of a substance applied per unit treated or applied to or entered into organism. This is expressed as the weight of the test substance per unit weight of test animal (mg/kg).

3.2.2 *no observed adverse effect dose (NOAED), n*—the highest tested dose of a substance at which the measured biological variables of a specific group under test conditions show no statistically significant dose-related adverse difference from the control treatment group.

3.2.3 *nulliparous, adj*—having never borne an offspring.

3.2.4 *test substance, n*—pesticide or other material (element, chemical compound, formulation, known mixture) administered orally for the purpose of determining subchronic oral toxicity.

4. Summary of Test Method

4.1 The test substance is applied daily to the skin in geometrically graduated doses to several groups of animals, one dose per group, for a period of 90 days. Generally at least three dose levels with a control and, where appropriate, a vehicle control group are employed.

4.2 Animals that die during the test are necropsied. At the conclusion of the test, the surviving animals are sacrificed and necropsied and appropriate histopathological examinations performed.

4.3 A limit test with one dose of at least 1000 mg/kg body weight can be conducted using the procedures described for this method if no toxicity would be expected based upon data of structurally related compounds. If this test produces no observable toxic effects, then a full study using three doses is not necessary.

5. Significance and Use

5.1 This test method provides information on health hazards likely to arise from repeated exposure to a pesticide or other chemical by the dermal route over a short time period. It may provide information needed to establish safety criteria for human exposure.

¹ This test method is under the jurisdiction of ASTM Committee E35 on Pesticides and is the direct responsibility of Subcommittee E35.26 on Safety to Man. Current edition approved Oct. 10, 1996. Published December 1996. Originally published as E 1103 – 86. Last previous edition E 1103 – 91.

² *Annual Book of ASTM Standards*, Vol 11.05.

³ Available from U.S. Government Printing Office, Superintendent of Documents, Washington, DC 20402.