



Standard Test Method for Evaluation of Eye Irritation in Albino Rabbits¹

This standard is issued under the fixed designation E 1055; 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 determines the duration and the numerical degree of eye irritation in young, adult albino rabbits. The test is an alternative method to the standard Draize eye irritation method. Experimentation indicates that this procedure provides more realistic data, and therefore a better basis for making predictions of eye responses from accidental exposure in man. This test method is applicable to both liquids and solids; it is not applicable to aerosols or vapors.

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

2. Referenced Documents

2.1 ASTM Standards:

E 609 Definition of Terms Relating to Pesticides²

E 943 Terminology Relating to Biological Effects and Environmental Fate²

2.2 Federal Standards:³

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

Title 21 CFR, Food and Drug Administration, Part 58, Laboratory Practice for Nonclinical Studies

Title 40 CFR, Toxic Substance Control Act, Part 792, Good Laboratory Practice Standards

3. Summary of Test Method

3.1 The test material is placed directly on the cornea of one eye in each of six rabbits while the untreated eye serves as a control. The eyelid is released immediately after instillation without forced blinking or manipulation.

3.2 The eyes are scored in accordance with the method of Draize at 1, 2, 3, 7, 14, and 21 days following treatment. Scoring at other time intervals may be added as deemed necessary for certain materials. Scores are discontinued at any

time during the 21-day observation period if there is no perceivable evidence of irritation or at the end of the 21-day observation period. The daily total score for each eye is calculated, and the daily arithmetic mean score for all eyes in test group is calculated. When the test is completed, the highest average score is determined.

4. Significance and Use

4.1 This test method evaluates the eye irritation elicited by a test substance when introduced into the eye of a rabbit. For terminology see Terminology Standards E 609 and E 943.

4.2 Results of testing by this test method can be used to estimate the potential for eye irritation or injury in humans when this material is accidentally introduced into the eye.

4.3 The dose volume of 0.01 mL is used because this amount provides a very good discrimination between substances of moderate irritancy plus the ability to detect potentially severe irritants or corrosives.^{4,5}

4.4 The dose volume of 0.01 is only one-tenth the volume specified in the Draize rabbit eye irritation test and thereby produces less ocular injury than the latter test.³ This results in a more humane test with better discrimination between moderate irritants than with a 0.1 mL volume.^{6,7}

5. Interpretation of Results

5.1 When the exposure of the eyes to a test material under the specified conditions causes no significant ocular changes at 24 h, the material is considered to produce *no irritation*.

5.2 An eye response is characterized as *moderate irritation* when any of the following responses are present at 24-h and clear within 7 days: opacity of the cornea (other than a slight dulling of the normal luster), hyperemia of the iris, or swelling of the conjunctiva.

5.3 An eye response is characterized as *substantial irritation* when any changes/injuries in the ocular tissues persist for

⁴ Committee for the Revision of NAS Publication #1138, "Principles and Procedures for Evaluating the Toxicity of Household Substances," *National Academy of Sciences*, 1977, pp. 41–54.

⁵ Griffith, J. F., et al., "Dose-Response Studies with Chemical Irritants in the Albino Rabbit Eye as a Basis for Selecting Optimum Testing Conditions for Predicting Hazard to the Human Eye," *Toxicity and Applied Pharmacology*, Vol 55, 1980, pp. 501–513.

⁶ Freeberg, F. E., et al., "Human and Rabbit Eye Responses to Chemical Insult," *Fundamental and Applied Toxicology*, Vol 7, 1986, pp. 626–634.

⁷ Freeberg, F. E., et al., "Correlation of Animal Eye Test Data with Human Experience for Household Products: an Update," *Journal of Toxicology-Cutaneous and Ocular Toxicology*, Vol 5, 1986, pp. 115–123.

¹ This test method is under the jurisdiction of ASTM Committee E-35 on Pesticides and is the direct responsibility of Subcommittee E35.26 on Safety to Man.

Current edition approved March 10, 1999. Published July 1999. Originally published as E 1055 – 85. Last previous edition E 1055 – 90.

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

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