Designation: E640 – 06 (Reapproved 2019)

Standard Test Method for Preservatives in Water-Containing Cosmetics[1]

This standard is issued under the fixed designation E640; 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 covers the determination of the suitability of preservatives for use in cosmetic formulations. It sets minimal requirements for preservative performance in model formulations.

1.2 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

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

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E1054 Test Methods for Evaluation of Inactivators of Antimicrobial Agents

3. Summary of Method

3.1 This test method involves a microbiological challenge test of preservatives incorporated into model formulations at recommended efficacy levels. Routine microbiological procedures are used to determine the antimicrobial activity of preservatives in formulations. This method requires the knowledge of standard microbiological techniques.

4. Significance

4.1 This test method should be used to determine if a preservative or preservative system has application for the preservation of water-miscible cosmetic products.

5. Materials

5.1 *Test Formulations*—Formulations that the submitter feels are appropriate for demonstration of preservative activity shall be included in the test. Non-preserved (control) samples of these formulas shall also be included. Incompatibility of the preservative(s) with any of the formulations or formulation components shall be noted.

5.2 *Test Microorganisms (Suggested Panel):*

5.2.1 Other test microorganisms or equivalent species may be included as appropriate and if standardized cultures from cosmetic isolates become available. The primary function of these cultures is to provide a common basis for comparison of different preservatives.

5.2.1.1 *Pseudomonas aeruginosa* ATCC 9027.
5.2.1.2 *Burkolderia cepacia* ATCC 25416.
5.2.1.3 *Escherichia coli* ATTC 8739.
5.2.1.4 *Staphylococcus aureus* ATCC 6538.
5.2.1.5 *Candida albicans* ATCC 10231.
5.2.1.6 *Enterobacter gergoviae* ATCC 33028.
5.2.1.7 *Aspergillus niger* ATCC 16404.
5.2.1.8 *Eupenicillium levitum* ATCC 10464.

5.2.2 If available, cosmetic spoilage microorganisms and/or microorganisms obtained from the cosmetic manufacturing environment may be used in addition to those microorganisms suggested in 5.2.

5.3 *Culture Maintenance*—The microorganisms listed in 5.2.1 shall be maintained as specified by ATCC.

5.3.1 *Plating Diluents*—Plating diluents are used to disperse the test sample in preparation for plating and, if necessary, aid in neutralizing the preservative present to permit the optimum recovery of surviving microorganisms. The choice of diluents is dependent of the diluents ability to meet the neutralization requirements specified in 5.3.3. The following suggested diluents have been found to be suitable for this purpose:

5.3.1.1 Buffered 1 % Peptone in physiological saline (0.85 % NaCl).
5.3.1.2 Dey/Engley (D-E) neutralizing broth.
5.3.1.3 Eugon Broth.

[1] This test method is under the jurisdiction of ASTM Committee E35 on Pesticides, Antimicrobials, and Alternative Control Agentsand is the direct responsibility of Subcommittee E35.15 on Antimicrobial Agents.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.