



Designation: E 1589 – 94

## Standard Test Method for Evaluation of First Aid Antiseptic Drug Products<sup>1</sup>

This standard is issued under the fixed designation E 1589; 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 ( $\epsilon$ ) indicates an editorial change since the last revision or reapproval.

### 1. Scope

1.1 The tests described in this test method are designed to evaluate antimicrobial agents in formulations intended for use as first aid antiseptic products for their ability to reduce or suppress the growth, or both, of the skin microflora.

1.2 A knowledge of microbiological techniques is required for these procedures.

1.3 In this test method metric units are used for all applications, except for distance, in which case inches are used and metric units follow in parenthesis.

1.4 *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 and health practices and determine the applicability of regulatory limitations prior to use.*

### 2. Referenced Documents

#### 2.1 ASTM Standards:

E 1054 Practices for Evaluating Inactivators of Antimicrobial Agents Used in Disinfectant, Sanitizer, Antiseptic, or Preserved Products<sup>2</sup>

### 3. Summary of Test Methods

3.1 These test methods describe standard *in vivo* techniques to determine the following:

3.1.1 *Effect of the Test Agent to Reduce An Artificially Enhanced Skin Microbial Flora*—The forearms of subjects are occluded for 48 h prior to application of the test agents to increase the microbial population on the skin of the volar forearm surface. At treatment the occlusion material is removed and the skin is allowed to dry, the test agents are then applied to selected sites. At a pre-determined time(s) following application, the sites are microbiologically sampled and the

samples plated for total aerobic bacteria count. The counts obtained from the treated sites are compared to counts obtained from untreated occluded sites.

3.1.2 *Effect of the Test Agent to Suppress the Growth of Normal Skin Flora When Applied As a Dressing*—The dressings are applied to the forearm for 24 h. The density of the resident organisms that develop under the dressings are compared to the population that develops on a similar untreated occluded site. Following 24 h of occlusion, the sites are microbiologically sampled and the samples plated for total aerobic bacteria count.

3.2 The principal of the test is that the microflora of forearm skin is sparse. The impermeable dressing will increase surface moisture by preventing diffusional water loss and thus expand transient resident skin microorganisms. A significant effect by the test agent will be reflected by significantly lower population on the treated site.

### 4. Significance and Use

4.1 The procedures in this test method should be used to evaluate *in vivo* the antimicrobial activity of drug products applied topically to the skin that are intended to help prevent infection in minor cuts, scrapes and burns.

4.1.1 This test method is applicable for testing liquids, ointments, powders, films, or dressing containing or impregnated with an antimicrobial for their effect to reduce an enhanced skin microflora or their effects to suppress the growth of the skin flora, or both.

### 5. Apparatus

5.1 *Colony Counter*—Any of several types may be used, for example, Quebec colony counter.

5.2 *Incubator*—Any incubator capable of maintaining a temperature of  $35 \pm 2^\circ\text{C}$  may be used.

5.3 *Sterilizer*—Any suitable steam sterilizer capable of producing the conditions or sterilization.

5.4 *Timer (Stop-Clock)*—One that can be read for hours and minutes.

<sup>1</sup> This test method is under the jurisdiction of ASTM Committee E-35 on Pesticides and is the direct responsibility of Subcommittee E35.15 on Antimicrobial Agents.

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<sup>2</sup> *Annual Book of ASTM Standards*, Vol 11.05.