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Instant hand sanitizer — Specification —

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EAST AFRICAN STANDARD

Instant hand sanitizers — Specification

EAST AFRICAN COMMUNITY

First Edition 2013

Foreword

Development of the East African Standards has been necessitated by the need for harmonizing requirements governing quality of products and services in the East African Community. It is envisaged that through harmonized standardization, trade barriers that are encountered when goods and services are exchanged within the Community will be removed.

In order to achieve this objective, the Community established an East African Standards Committee mandated to develop and issue East African Standards.

The Committee is composed of representatives of the National Standards Bodies in Partner States, together with the representatives from the private sectors and consumer organizations. Draft East African Standards are circulated to stakeholders through the National Standards Bodies in the Partner States. The comments received are discussed and incorporated before finalization of standards, in accordance with the procedures of the Community.

East African Standards are subject to review, to keep pace with technological advances. Users of the East African Standards are therefore expected to ensure that they always have the latest versions of the standards they are implementing.

EAS 789 was prepared by Technical Committee EAS/TC 074, *Surface active agents*.

Introduction

The alcohol contained within hand sanitizers, when rubbed on the surface of skin is effective in killing 99.9 % of dangerous germs on the skin. The type of alcohol used in most hand sanitizers is ethyl alcohol. Ethyl alcohol is the active ingredient in most hand sanitizers. A concentration of 60 % to 95 % alcohol in hand sanitizing product is recommended. However, there are also non-alcohol based hand sanitizers which can be effective in killing germs. For instance, Benzalkonium Chloride (BAC) has been proven effective in killing 99.9 % of germs. There are also several other non-active ingredients in hand sanitizer, the second most concentrated ingredient is water. Most hand sanitizers also have a form of moisturizer in their sanitizer such as Vitamin E or Aloe. This is to help leave the skin soft after applying. Fragrances and dyes are among some of the other inactive ingredients.

Instant hand sanitizers — Specification

1 Scope

This East African standard specifies the requirements and methods of test for alcohol based instant hand sanitizers. The standard does not cover non-alcohol based hand sanitizers.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EAS 104, *Alcoholic beverages – Method of sampling and test*

EAS 377-1, *Cosmetics and cosmetics products — Part 1: List of substances prohibited in cosmetic products*

EAS 377-2, *Cosmetics and cosmetics products — Part 2: List of substances which cosmetic products must not contain except subject to restrictions laid down*

EAS 377-3, *Cosmetics and cosmetics products — Part 3: List of colourants allowed in cosmetic products*

EAS 377-4, *Cosmetics and cosmetics products — Part 4: List of preservatives allowed in cosmetic products*

EAS 377-5, *Cosmetics and cosmetics products — Part 5: Use of UV filters in cosmetic products*

3 Terms and definitions

For the purposes of this standard terms and definitions given in ISO 862 and the following apply.

hand sanitizers
antiseptic agents used to cleanse the hands when soap and water are unavailable. They are often used to protect and prevent the passage of bacteria, virus and other pathogens that can cause infections.

4 Requirements

4.1 General requirements

4.1.1 The sanitizer shall have an acceptable odour.

4.1.2 The sanitizer shall be clear, colourless and in the form of liquid or gel.

4.1.3 The sanitizer shall not have any disagreeable odour or smell.

4.1.4 The substances used in the sanitizers shall conform to all the parts of EAS 377.

4.2 Specific quality requirements

The hand sanitizer shall also comply with the specific quality requirements given in Table 1 when tested in accordance with the corresponding test method.

Table 1 — Specific quality requirements for instant hand sanitizer

Sl. No	Characteristic	Requirement	Test method
i)	Alcohol content (ethanol and/or isopropanol, n-propanol), %, v/v, min.	60.0	EAS 104
ii)	pH (neat)	6 - 8	—
iii)	Bactericidal efficacy	to pass test	Annex A

5 Packaging and labelling

5.1 Packaging

5.1.1 The sanitizer shall be supplied in suitable well-closed containers/packages.

5.1.2 The containers/packages (including the closures) shall not interact chemically with the sanitizer and shall be strong enough to protect the sanitizer adequately during normal handling, transportation and storage.

5.1.3 Only containers/packages of the same size and bearing the same batch identification shall be packed together in a bulk container.

5.2 Marking

The container/package shall be securely closed and marked legibly and indelibly with the following information:

a) name of the product as “hand sanitizer”

b) manufacturer’s name and physical address

NOTE The name, physical address of the distributor/supplier and trade mark may be added as required

c) batch or code number;

d) net content;

e) list of ingredients used;

f) general instructions for use (be in either English, Kiswahili or French or in combination as agreed between the manufacturer and supplier);

g) date of manufacture and expiry date;

h) country of origin/manufacture;

i) the following cautionary warnings:

i) “Do not allow the sanitizer to come into contact with eyes”;

ii) “Keep Out Reach of Children”;

iii) “If swallowed contact a doctor”; and

iv) “Highly flammable, keep away from fire or flame”.

Annex A
(normative)

Determination of disinfecting efficacy

A.1 Outline of the method

A.1.1 The sanitizer is tested at the recommended 'use'-dilution' and concurrently at 0.5 and 1.5 times that dilution. The test consists of challenging the diluted sanitizer with bacterial inoculum, withdrawing a sample after a given time and culturing the sample in a suitable recovery medium. After this sampling, the mixture is again challenged by a second inoculum and after a second interval, is again sampled for culturing. This process is then repeated to provide a third challenge.

A.1.2 The sample is considered to have passed or failed the test according to the extent of growth shown in the first two cultured samples.

A.2 Apparatus

A.2.1 Facility, for incubation at 37 °C ± 1 °C

A.2.2 Facility, for incubation at 2 °C ± 1 °C

A.2.3 Stop clock, indicating in seconds

A.2.4 Facility, for refrigeration at 4 °C ± 1 °C

A.2.5 Universal containers, made of glass and having metal tops with rubber liners. Plastic containers or glass containers with plastic tops shall not be used.

A.2.6 Test tubes, 19 mm X 150 mm

A.2.7 Filter paper, No. 4 Whatman (sterile) or equivalent

A.2.8 Facility, for autoclaving at 121 °C ± 1 °C

A.2.9 Pipette, capable of dispensing 0.02 mL ± 0.005 mL

A.2.10 pH meter

A.2.11 Facility, to sterilize by filtration

A.2.12 150 µm test sieve

A.2.13 Oven, capable of maintaining temperature at 100 °C ± 1 °C

A.3 Media

A.3.1 Growth media for test organisms

A.3.1.1 The growth media for test organisms shall be Wright and Mundy Broth with Dextrose (WMBD).

A.3.1.2 Dispense 10 mL and 6 mL quantities of the Wright and Mundy Broth into universal bottles, and autoclave at 121 °C ± 1 °C for 12 min.

A.3.1.3 Add to this medium, 10 % (m/V) dextrose solution sterilized by filtration, to give a final dextrose concentration of 0.1 % (m/v), (that is, to 10 mL broth add 0.1 mL dextrose solution and to 6.0 mL broth add 0.06 mL dextrose solution).

A.3.2 Recovery medium

A.3.2.1 Composition

A nutrient broth prepared as follows:

a) beef extract, 10 g;

b) peptone, 10 g;

c) sodium chloride, 5 g; and

d) polyoxyethylene sorbitan mono-oleate, 30 g

A.3.2.2 Preparation

Add the ingredients to 1 000 mL of water. Mix well. Dispense 10 mL quantities into test tubes and autoclave at 121 °C ± 1 °C for 15 min**.**

A.3.3 Hard water

Standard hard water with 342 mg/L (ppm) hardness prepared as follows: dissolve 0.304 g of anhydrous calcium chloride hexahydrate ($MgCl_2.6H_20$) in distilled water and make up the volume to one litre. Sterilize the standard hard water by autoclaving at 121 °C ± 1 °C for 15 min. Allow this to reach room temperature before use.

A.3.4 Yeast suspension

A.3.4.1 Weigh to the nearest gram about 65 g of active dry yeast. Cream by the gradual addition of sterile hard water (A.3.3) using a heavy glass rod for stirring. Decant the creamed portion into a flask, add more hard water to any lumpy residue remaining and repeat the creaming and decantation until no residue remains, and 500 mL of hard water has been used.

A.3.4.2 Shake the contents of the flask vigorously and strain-through a 150 µm sieve (A.2.12) breaking down any remaining lumps.

A.3.4.3 Add 500 mL sterile hard water, shake vigorously.

A.3.4.4 Transfer 50 mL or 100 mL portions into screw-capped bottles, screw the caps tightly and autoclave at 121 °C ± 1 °C for 15 min. Allow the autoclave to cool without releasing the pressure. Store cold but not freezing.

A.3.4.5 Dry two glass petri-dishes to constant mass. Into each of these dishes, pipette 25 mL of sterilized yeast suspension and dry to constant mass at 100 °C. Calculate the average solids content of the suspension.

A.3.4.6 Before use, pipette 25 mL of the sterilized yeast suspension into a beaker. Determine the pH using a glass electrode, and determine the volume of 40 g/L sodium hydroxide solution needed to adjust the pH to 7.0 ± 0.1.

A.3.4.7 Immediately before use, add to each bottle of sterilized yeast suspension a volume of sterile hard water and a volume of 40 g/L sodium hydroxide calculated to adjust the concentration of dry yeast to 5 % (m/v) and the pH to 7.0 ± 0.1. Discard prepared yeast, two weeks after preparation.

A.3.5 Ringers solution, 25 % (v/v)

Dissolve 9.00 g of sodium chloride, 0.42 g of potassium chloride, 0.24 g of anhydrous calcium chloride and 0.20 g of sodium bicarbonate in water and dilute to 1 000 mL. Add one volume of this solution to three volumes of water to give a 25 % solution. Dispense into test tubes fitted with suitable closures and sterilized by auto-claving at 121 °C ± 1 °C for 15 min.

A.4 Selection of the most resistant organism by the minimum inhibitory concentration test

A.4.1 The following organisms shall be used for the test:

a) *Pseudomonas aeruginosa* (NCTC 6749 or equivalent);

b) *Proteus vulgaris* (NCTC 4635 or equivalent); and

c) *Staphyloccus aureus* (NCTC 4163 or equivalent).

These organisms may be obtained as freeze dried cultures. Once sub-cultured, the organisms shall be maintained on agar slopes of suitable nutrient medium at 4 °C ± 1 °C.

A.4.2 Subculture each organism daily into a universal bottle containing 6 mL of growth medium (see A.3.1) and incubate for 24 h ± 2 h at 37 °C ± 1 °C.

A.4.3 Dilute one part of freshly grown sub-culture of each organism, which is at least a fifth sub-culture and not more than a fourteenth, with ten parts of the growth medium (see A.3.1) before dilution, the *P. aeruginosa*, culture shall be filtered using a Whatman No.4 filter paper.

A.4.4 Prepared three sets of ten, doubling dilutions of the sanitizer in universal containers (A.2.5). For this purpose dilute the neat sanitizer in the growth medium (see A.3.1) or the recovery medium (A.3.2) to give a final volume of 5 mL of the diluted sanitizer for each dilution.

A.4.5 Inoculate each dilution in one set with 0.02 mL of a diluted culture of one organism (see A.4.3).

A.4.6 Incubate all the three sets of inoculate dilutions at 37 °C ± 1 °C for 72 h, and examine to determine the organism most resistant to the sanitizer, that is the organism for which the minimum inhibitory concentration is highest.

A.5 Preparation of inoculum

A.5.1 Daily sub-cultures of the test organism selected as in A.4.6 shall be grown in 6 mL quantities of the growth medium (A.3.1) and incubated at 37 °C ± 1 °C for 24 h ± 2 h.

A.5.2 The day before the test, inoculate 10 mL of the growth medium (A.3.1) with the test organism from a daily sub-culture and not more than a fourteenth. Incubate the inoculated, broth at 37 °C ± 1 °C for 24 h ± 2 h.

A.5.3 Add 6 mL of the test organism culture (A.5.1) and (A.5.2) to 4 mL of the yeast suspension (A.3.4) thus making a final concentration of 2 % (m/v) of yeast in the yeast/organism suspension. If a culture of *P. aeruginosa* is used, it shall be filtered using a Whatman No.4 filter paper before addition.

A.5.4 Shake the yeast/organism suspension for one minute with a few sterile glass beads. Immediately before the test, count the number of viable organisms in the inoculum by decimal dilutions in 25 % Ringers solution (see A.3.5) and by the drop plate method. The viable count shall be not less than 10^8 organisms/mL or more than 10^{10} organisms/mL or the test results are considered invalid.

A.6 Preparation of the sanitizer dilutions

Prepare three dilutions of the sanitizer in hard water (A.3.3) based on the recommended 'use dilution' of the sanitizer, as follows:

- A = 0.5 times the recommended 'use-dilution';
- B = 1.0 times the recommended 'use-dilution'; and
- C = 1.5 times the recommended 'use-dilution'.

The sanitizer dilutions shall be prepared and tested on the same day.

A.7 Test procedure

A.7.1 The test shall be carried out at 27 °C ± 1 °C.

A.7.2 Dispense 3 mL of each dilution of sanitizer (A6) into separate universal bottles labelled A, B, and C, then allow to equilibrate to 27 °C ± 1°C.

A.7.3 Add 1 mL of the inoculum to A, B and C at 0, 1 and 5 min respectively and mix by swirling gently.

A.7.4 Eight minutes after the addition of the inoculum, remove a sample of the inoculum/sanitizer mixture and put 0.02 mL into each of the first group of five tubes of recovery broths. Return the remainder of the mixture in the pipette to the universal container.

A.7.5 Ten minutes after the first addition of the inoculum, add another 1 mL of the inoculum to each of the sanitizer dilutions and mix by swirling gently

A.7.6 After 8 min, remove a sample of the mixture as put before (A.7.4) and put 0.02 mL into each of the second group of five tubes of recovery broths.

A.7.7 Twenty minutes after the first addition of the inoculum, add a further 1 mL of inoculum to each of the sanitizer dilutions and mix by swirling gently.

A.7.8 After 8 min, remove a sample of the mixture as before and place 0.02 mL into each of the third group of five tubes of recovery broths.

A.7.9 Swirl the recovery broths and incubate at 37 °C ± 1 °C for 48 h ± 2 h. Examine the growth and record the results.

A.8 Interpretation of results

A.8.1 The instant hand sanitizer, shall be regarded as having passed the test at the recommended 'use dilution' if there is no growth in at least two of the five recovery broths for the first and second additions of the inoculum.

A.8.2 To be acceptable, an instant hand sanitizer shall pass the test on three separate occasions using freshly prepared sanitizer and freshly prepared inoculum on each occasion.

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