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DRAFT EAST AFRICAN STANDARD

Alcohol-based instant hand sanitizer – Specification

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EAST AFRICAN COMMUNITY

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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.

The Community has established an East African Standards Committee (EASC) mandated to develop and issue East African Standards (EAS) and other deliverables. The Committee is composed of representatives of the National Standards Bodies in Partner States, together with the representatives from the public and private sector organizations in the community.

East African Standards are developed through Technical Committees that are representative of key stakeholders including government, academia, consumer groups, private sector and other interested parties. 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 Principles and procedures for development of East African Standards.

East African Standards and other deliverables 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.

The committee responsible for this document is Technical Committee EASC/TC 074, *Surface active agents*

Attention is drawn to the possibility that some of the elements of this document may be subject of patent rights. EAC shall not be held responsible for identifying any or all such patent rights.

This second edition cancels and replaces the first edition (EAS 789:2013), which has been technically revised.

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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.

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Alcohol-based instant hand sanitizer — Specification

1 Scope

This Draft East African standard specifies the requirements, sampling and test methods 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 847-17, *Cosmetics – Analytical methods – Part 17: Determination of pH*

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*

ISO 862, *Surface active agents — Vocabulary*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1 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.

3.2 alcohol
organic compound that carries at least one hydroxyl functional group bound to a saturated carbon atom

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3.3 alcohol-based sanitizer

preparation containing at least 60% ethyl alcohol and/or isopropanol or n-propanol intended for disinfecting hands or surfaces

3.4 disinfecting efficacy

efficiency of the product to kill or reduce microorganisms, such as bacteria, fungi and viruses.

4 Requirements

4.1 General requirements

4.1.1 The alcohol-based instant hand sanitizer shall be a homogeneous mixture in the form of liquid, foam orgel.

4.1.2 The alcohol-based instant hand sanitizer shall contain ethanol, isopropanol or the mixture of the two

4.1.3 The alcohol-based instant hand sanitizer shall not have objectionable odour.

4.1.4 The substances used in the alcohol-based instant hand sanitizers shall conform to all the parts of EAS 377.

4.2 Specific requirements

The alcohol-based instant hand sanitizer shall comply with the specific requirements given in Table 1 when tested in accordance with the corresponding test method.

Table 1 — Specific requirements for alcohol-based 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	6.0 – 8.0	EAS 847-17
iii)	Disinfecting efficacy	to pass test	Annex A

5 Packaging

5.1 The alcohol-based instant hand sanitizer shall be supplied in suitable well-closed containers/packages.

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

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

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6 Labelling

The container/package shall be securely closed, legibly and indelibly labelled either in English, Kiswahili or French or combination or any other language as agreed between the manufacturer and supplier with the following information:

a) name of the product as “alcohol-based instant hand sanitizer”

b) alcohol content manufacturer’s name and physical address

c) batch or code number;

d) net content in litres

e) list of ingredients used;

f) general instructions for use

g) date of manufacture and expiry date;

h) country of origin;

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”.

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

7. Sampling

Sampling shall be done in accordance with EAS 104

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Annex A
(normative)

Determination of disinfecting efficacy

A.1 Outline of the method

A.1.1

The test consists of challenging the alcohol-based instant hand 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 27 °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).

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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 342mg/L (ppm) hardness is prepared as follows: Dissolve 0.301g of calcium chloride dihydrate and 0.336g of magnesium sulfate heptahydrate 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.

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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.

Other options

Ringer's solution or Buffered peptone buffer, or Butterfields phosphate buffer.

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.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.

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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 alcohol-based instant hand sanitizer , shall be regarded as having passed the test at the recommended ‘use dilution’ if there is no growth in 40% (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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