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Non-alcohol based hand sanitizers — Specification

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Contents

Page

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Foreword

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The main task of technical committees is to prepare national standards. Final Draft Rwanda Standards adopted by Technical committees are ratified by members of RSB Board of Directors for publication and gazettment as Rwanda Standards.

DRS 455 was prepared by Technical Committee RSB/TC 024, *Organic and Inorganic Chemicals.*

Committee membership

The following organizations were represented on the Technical Committee on Organic and Inorganic Chemicals (RSB/TC 024) in the preparation of this standard.

Star Construction and Consultancy Ltd

Rwanda Inspectorate, Competition and Consumer Protection Authority

Rwanda Food and Drugs Authority

Rwanda Investigation Bureau

Rwanda Forensic Laboratory

Rwanda Social Security Board

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Introduction

Hand sanitizer, also called hand antiseptic, handrub, or hand rub, agent applied to the hands for the purpose of removing common pathogens (disease-causing organisms). Hand sanitizers typically come in foam, gel, or liquid form. Their use is recommended when soap and water are not available for hand washing or when repeated hand washing compromises the natural skin barrier (e.g., causing scaling or fissures to develop in the skin). Although the effectiveness of hand sanitizer is variable, it is employed as a simple means of infection control in a wide variety of settings, from day-care centres and schools to hospitals and health care clinics and from supermarkets to cruise ships.

Depending on the active ingredient used, hand sanitizers can be classified as one of two types: alcohol-based or alcohol-free. Alcohol-based products typically contain between 60 and 95 percent alcohol, usually in the form of ethanol, isopropanol, or n-propanol. At those concentrations, alcohol immediately denatures proteins, effectively neutralizing certain types of microorganisms.

Alcohol-free products are generally based on disinfectants, such as benzalkonium chloride (BAC), or on antimicrobial agents, such as triclosan. The activity of disinfectants and antimicrobial agents is both immediate and persistent. Many hand sanitizers also contain emollients (e.g., glycerin) that soothe the skin, thickening agents, and fragrance.

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Non-alcohol based hand sanitizers — Specification

1 Scope

This Draft Rwanda Standard prescribes the requirements, sampling and test methods for non-alcohol based hand sanitizers.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

RS EAS 377, *Cosmetic Products (all parts)*

RS ISO 10523, *Water quality — Determination of pH*

3 Terms and definitions

For the purposes of this standard, the following terms and definitions apply.

3.1

hand sanitizer

antiseptic agents used to cleanse the hands with the aim to protect and prevent the passage of bacteria, virus and other pathogens that can cause infections.

3.2

non-alcoholic hand sanitizer

hand sanitizer in which the antiseptic agent is other than alcohol.

3.3

alcohol

ethanol (ethyl alcohol, C_2H_5OH), isopropanol (isopropyl alcohol, $CH_3CHOHCH_3$), n-propanol (1-propanol, $CH_3CH_2CH_2OH$) or the mixture of them.

3.4

antimicrobial efficacy

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

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3.5

dermal irritation

production of reversible damage of the skin following the application of a test substance for up to 4 hours.

4 Requirements

4.1 General requirements

4.1.1 The product shall be in form of foam, liquid or gel.

4.1.2 The product shall be clear and free from visible impurities.

4.1.3 The product shall not have any disagreeable odour or smell. It may be coloured or not.

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

4.1.5 The active ingredient and its proportion in the product shall be approved by competent authority. The formulator should consider WHO recommendations given in Annex A.

4.1.6 The product may be dilutable or ready-to-use. For the dilutable product, the manufacturer shall give clear instruction on dilution ratio.

4.2 Specific requirements

The product shall also comply with the specific requirements given in the table 1 when tested in accordance with the corresponding test method.

Table 1 – Specific requirements for Non-alcohol based hand sanitizers

S/N	Parameters	Requirements	Test methods
1.	pH	6 – 8	RS ISO 10523
2.	Antibacterial efficacy	Pass the test	Annex B
3.	Dermal irritation	Pass the test	Annex C

5 Packaging and labelling

5.1 Packaging

5.1.1 The package shall ensure integrity of the product during handling, storage and transportation.

5.1.2 Bulk packaging: Only products of the same type and the same batch shall be packaged together in one bulk package.

5.1.3 The closure shall not be made of cork or of any other material that contains cork.

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5.2 Labelling

The following information shall appear in legible and indelible labelling on each container or on a label securely attached to each container:

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

b) name and full address of the manufacturer;

c) active ingredient (s) content;

NOTE The tolerance limit from the declared value shall be less than 1% of the active ingredient content.

d) net content;

e) list of ingredients

f) batch identification;

g) manufacture and expiry dates;

h) instructions for use;

i) storage conditions; and

j) warnings.

6 Sampling

6.1 General

The following sampling procedure shall be applied in determining whether a lot submitted for inspection and testing complies with the relevant requirements of this standard. The sample so drawn shall be deemed to represent the lot.

6.2 Sample for inspection

After inspecting the lot for compliance with Clause 4, take, at random, the number of containers, as relevant, shown in column 2 of Table 2, relative to the appropriate lot size shown in column 1.

Table 2 — Samples for inspection and testing

Lot size (number of containers)	**Sample size for physical examination** (number of containers)	**Sample size for microbiological examination** (number of containers)
0 to 5 000	3	3

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5 001 to 12 500	6	3
12 501 to 25 000	9	3
25 001 to 50 000	16	3
50 001 upwards	30	3

6.3 Sample for testing

After inspection of the containers taken in accordance with 6.2,

a) take, at random, half the number of containers and use them for the storage stability test; and

b) thoroughly mix the contents of each of the remaining containers and, take from each container the lesser of the total volume and 250 mL, and obtain a composite test sample by combining and thoroughly mixing these quantities. Use these samples for testing for compliance with the requirements of Clause 4.

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Annex A
(informative)

Methods and selection of products to perform hand hygiene

A.1 According to WHO recommendations, when an alcohol-based handrub is available it should be used as the preferred means for routine hand hygiene in health care.

A.2 To comply with routine hand hygiene recommendations, Health Care Workers should ideally perform hand hygiene where and when care is provided, which means at the point of care and at the moments indicated, and following the recommended technique and time.

A.3 The selection products that are both efficacious and as safe as possible for the skin is the utmost importance.

A.4 Ways to minimize the possible adverse effects of hand hygiene include selecting less irritating products, using skin moisturizers, and modifying certain hand hygiene behaviours such as unnecessary washing.

A.5 The following table gives the antimicrobial activity and summary of the properties of some antiseptics used in hand hygiene.

Table A1 – Antimicrobial activity and summary of properties of some antiseptic products

Antiseptics	Gram-negative bacteria	Gram-negative bacteria	Viruses enveloped	Viruses non-enveloped	Myco-bacteria	Fungi	Spores
Alcohols	+++	+++	+++	++	+++	+++	-
Chloroxylenol	+++	+	+	±	+	+	-
Chlorhexidine	+++	++	++	+	+	+	-
Hexachlorophene[a]	+++	+	?	?	+	+	-
Iodophors	+++	+++	++	++	++	++	±[b]
Triclosan[d]	+++	++	?	?	±	±[e]	-
Quaternary ammonium compounds[c]	++	+	+	?	±	±	-

Antiseptics	Typical concentration (%)	Speed of action	Residual activity	Use
Alcohols	60 – 80	Fast	No	HR
Chlroxylenol	0.5 – 4	Slow	Contradictory	HW
Chlorhexidine	0.5 – 4	Intermediate	Yes	HR, HW
Hexachlorophene[a]	3	Slow	Yes	HW, but not recommended
Iodophors	0.5 – 10	Intermediate	Contradictory	HW
Triclosan[d]	0.1 – 2	Intermediate	Yes	HW; seldom
Quaternary ammonium compounds[c]		Slow	No	HR, HW; seldom; +alcohols

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Good = +++. moderate = ++, poor = +, variable = ±, none = -

HR: handrubbing; HW: handwashing

* Activity varies with concentration.

[a] Bacteriostatic.

[b] In concentrations used in antiseptics, iodophors are not sporicidal.

[c] Bacteriostatic, fungistatic, microbicidal at high concentrations.

[d] Mostly bacteriostatic.

[e] Activity against *Candida* spp., but little activity against filamentous fungi.

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Annex B
(normative)

Determination of disinfecting efficacy

B.1 Outline of the method

B.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.

B.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**.**

B.2 Apparatus

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

B.2.2 Facility, for incubation at 27 ± 1 °C.

B.2.3 Stop clock, indicating in seconds.

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

B.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.

B.2.6 Test tubes — 19 mm X 150 mm.

B.2.7 Filter paper, No. 4 whatman (sterile) or equivalent.

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

B.2.9 Pipette, capable of dispensing 0.02 ± 1°C 0.005 ml.

B.2.10 pH meter

B.2.11 Facility, to sterilize by filtration.

B.2.12 150 µm test sieve.

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

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B.3 Media

B.3.1 *Growth media for test organisms.* Wright and Mundy Broth with Dextrose (WMBD).

B.3.1.1 Dispense 10 ml and 6 ml quantities of the Wright and Mundy Broth into universal bottles, and autoclave at 121 ± 1 °C for 12 minutes.

B.3.1.2 Add to this medium, 10 per cent (m/V) dextrose solution sterilized by filtration, to give a final dextrose concentration of 0.1 per cent (m/v), (i.e. to 10 mL broth add 0.1 dextrose solution and to 6.0 mL broth add 0.06 mL dextrose solution).

B.3.2 Recovery medium — A nutrient broth prepared as follows:

B.3.2.1 Composition

- Beef extract 10 g
- Peptone 10 g
- Sodium chloride 5 g
- Polyoxyethylene sorbitan mono-oleate 30 g

B.3.2.2 Preparation — Add the ingredients to 1000 mL of water. Mix well. Dispense 10 ml quantities into test tubes and autoclave at 121 ± 1°C for 15 minutes**.**

B.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 ($MgCl_2.6H_2O$) in distilled water and make up the volume to one litre. Sterilize the standard hard water by autoclaving at 121 ± 1° C for 15 minutes. Allow this to reach room temperature before use**.**

B.3.4 Yeast suspension

B.3.4.1 Weigh to the nearest gram about 65 g of active dry yeast. Cream by the gradual addition of sterile hard water (B.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.

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

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

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

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B.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.

B.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.

B.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 per cent (m/V) and the pH to 7.0 ± 0.1. Discard prepared yeast, two weeks after preparation.

B.3.5 Ringers solution, 25 per cent (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 1000 ml. Add 1 volume of this solution to 3 volumes of water to give a 25 per cent solution. Dispense into test tubes fitted with suitable closures and sterilized by auto-claving at 121 ± 1°C for 15 minutes**.**

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

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

- *Pseudomonas aeruginosa* (NCTC 6749 or equivalent)
- *Proteus vulgaris* (NCTC 4635 or equivalent)
- *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 ± 1°C.

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

B.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 (B.3.1) before dilution, the P. aeruginosa, culture shall be filtered using a whatman No.4 filter paper.

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

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

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

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B.5 Preparation of inoculum

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

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

B.5.3 Add 6 ml of the test organism culture (B.5.1) and (B.5.2) to 4 ml of the yeast suspension (B.3.4) thus making a final concentration of 2 per cent (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**.**

B.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 per cent Ringers solution (see B.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**.**

B.6 Preparation of the sanitizer dilutions

Prepare three dilutions of the sanitizer in hard water (B.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'

C = 1.5 times the recommended 'use-dilution'

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

B.7 Test procedure

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

B.7.2 Dispense 3 mL of each dilution of sanitizer (B.6) into separate universal bottles labelled A, B, and C, then allow to equilibrate to 27 ± 1°C.

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

B.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**.**

B.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.

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B.7.6 Eight minutes later, remove a sample of the mixture as put before (B.7.4) and put 0.02 mL into each of the second group of five tubes of recovery broths.

B.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.

B.7.8 Eight minutes later, 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.

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

B.8 Interpretation of results

B.8.1 The 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.

B.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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Annex C
(normative)

Determination of dermal irritation

C.1 Test panel

A test panel that consists of three men and three women, none of whom is known to have an abnormally sensitive skin or has an injury or abrasion on the hands.

C.2 Procedure

Place approximately 5 mL of the test sample onto the cupped palm of one hand of each member of the panel, and get him or her to spread the Hand Sanitizer over the back and between the fingers of the other hand, and rub it thoroughly into the skin for 2 min. Repeat this procedure twice, with 30 min intervals between applications. Do not allow a treated hand to be washed until 2 h after the last application of the test sample.

Immediately after the tests, and again 2 h, 24 h and 48 h later, examine the treated hand of each member of the panel for any signs of irritation or inflammation, using the untreated hand as a control.

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[1] World Health Organization (WHO), *Guidelines on Hand Hygiene in Health Care*, 2009

[2] World Health Organization (WHO), *Guide to local production — WHO-recommended Handrub Formulations,* 2009.

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