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SOUTH AFRICAN NATIONAL STANDARD

Disinfectant alcohol-based handrub

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Table of changes

Change No.	Date	Scope
Amdt 1	2013	Amended to update referenced standards and to delete standard conditions for relative humidity.

Foreword

This South African standard was approved by National Committee SABS/TC 1022, *Antiseptics, disinfectants and detergent-disinfectants*, in accordance with procedures of the SABS Standards Division, in compliance with annex 3 of the WTO/TBT agreement.

This document was published in September 2013.

This document supersedes SANS 490:2008 (edition 1).

A vertical line in the margin shows where the text has been technically modified by amendment No. 1.

A reference is made in 6.1.1 to suitable methods of packing as given under "the relevant national legislation". In South Africa this means the Trade Metrology Act, 1973 (Act No. 77 of 1973).

A reference is made in 6.2 to regulations promulgated under "the relevant national legislation". In South Africa this means the Trade Metrology Act, 1973 (Act No. 77 of 1973) and the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972).

Disinfectants for use on skin shall be registered with the Medical Control Council in South Africa.

Annexes A and B form an integral part of this document. Annex C is for information only.

Contents

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Disinfectant alcohol-based handrub

1 Scope

This standard specifies requirements for two types of disinfectant alcohol-based handrub.

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. Information on currently valid national and international standards can be obtained from the SABS Standards Division.

SANS 289, *Labelling requirements for prepackaged products (prepackages) and general requirements for the sale of goods subject to legal metrology control.*

SANS 5261, *Bactericidal efficacy of anti-bacterial liquid toilet soap*. **Amdt 1**

3 Definitions

For the purposes of this document, the following definitions apply.

3.1
acceptable
acceptable to the authority administering this standard, or to the parties concluding the purchase contract, as relevant

3.2
batch
that quantity of sealed containers of handrub that have been filled from one homogeneous blend or, in the case of a continuous production process, that have been filled from one day's production

3.3
disinfectant
chemical agent that kills most vegetative forms of pathogen and other micro-organisms (but not necessarily all bacterial and fungal spores, mycobacteria, rickettsiae or viruses)

3.4
standard conditions
temperature of 23 °C ± 2 °C **Amdt 1**

4 Requirements

4.1 Types

The handrub shall be of one of the following types, as required (see annex A):

type 1: liquid type; or

type 2: gel type.

4.2 Bactericidal efficacy

When the handrub is tested in accordance with 5.2, it shall comply with the requirements for a hygienic handrub as described in SANS 5261. **Amdt 1**

4.3 Storage stability

4.3.1 When a type 1 handrub is tested in accordance with 5.3.1, it shall maintain its bactericidal efficacy.

4.3.2 When a type 2 handrub is tested in accordance with 5.3.2, it shall maintain its bactericidal efficacy and shall not liquefy.

4.4 Freedom from visible impurities

When the handrub is tested in accordance with 5.4, the number of visible specks of impurities shall not exceed five.

4.5 Dermal irritation

When the handrub is tested in accordance with 5.5, it shall not irritate or inflame the skin of any member of the test panel.

5 Inspection and methods of test

5.1 Inspection

Visually examine each container in the sample (see annex B) for compliance with the requirements in 4.1 and 6.2 of the standard for which tests to assess compliance are not given in 5.2 to 5.5 (inclusive).

5.2 Bactericidal efficacy

Carry out the tests for hygienic handrub as described in SANS 5261. Check for compliance with 4.2. **Amdt 1**

5.3 Storage stability

5.3.1 Type 1 handrub

Store each handrub in its original unopened container under standard conditions (see 3.4) for six months. Check for compliance with 4.3.1.

5.3.2 Type 2 handrub

Store each handrub in its original unopened container under standard conditions (see 3.4) for six months. Check for compliance with 4.3.2.

5.4 Freedom from visible impurities

Spread approximately 50 mL of each test sample over the bottom of a 150 mm diameter Petri dish. Check for compliance with 4.4 by viewing at a range of approximately 600 mm.

5.5 Dermal irritation

5.5.1 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.

5.5.2 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 handrub 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. Check for compliance with 4.5.

6 Packing and marking

6.1 Packing

6.1.1 The relevant regulations for suitable methods of packing for the handrub as given under the relevant national legislation (see foreword) shall be complied with.

6.1.2 The containers (including the closures) shall not interact chemically or physically with the handrub and shall be strong enough to protect the handrub adequately during normal handling, transportation and storage.

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

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

6.2 Marking

In addition to the markings required in terms of the regulations promulgated under the relevant national legislation (see foreword), and the relevant requirements given in SANS 289, the following information shall appear in legible and indelible marking on each container or on a label securely attached to each container:

a) the registration number and full name and address of the manufacturer, producer, proprietor or controlling company or, in the case of containers packed for any other person or organization, the full name and address of that person or organization;

b) a statement that the product is a disinfectant alcohol-based handrub;

c) the type (see 4.1), and the percentage and type of alcohol (for example ethanol or methanol);

d) the nominal volume in the case of a liquid-form handrub, or the nominal mass in the case of a gel-form handrub, in plain type and in a colour that contrasts distinctly with that of the container or label;

e) the batch identification and the production date and, if applicable, the expiry date of the batch;

f) general instructions for use;

g) the following warnings:

   1) do not allow the handrub to come into contact with the eyes;

   2) unless recommended by the manufacturer, do not mix the handrub with other substances;

   3) use the contents within 24 months of the date of manufacture;

   4) avoid contamination of foodstuffs with the handrub; and

   5) store the handrub in closed containers in a dry place at a temperature not higher than 30 °C, protected from intense light and away from flammable material.

NOTE The product name should not be misleading to the consumer.

Annex A
(normative)

Note to purchasers

The following requirement shall be specified in tender invitations and in each order or contract:

The type of handrub required (see 4.1).

Annex B
(normative)

Sampling and compliance with this standard

B.1 Sampling

B.1.1 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.

B.1.2 Definitions

B.1.2.1
defective
sample of handrub that fails to comply in one or more respects with the relevant requirements of this standard

B.1.2.2
lot
that quantity of handrub in sealed containers of the same size and bearing the same batch identification, from one manufacturer, and submitted at any one time for inspection and testing

B.2 Sample for inspection

After inspecting the lot for compliance with clause 5, take, at random, the number of containers, as relevant, shown in column 2 of table B.1, relative to the appropriate lot size shown in column 1.

Table B.1 — Samples for inspection and testing

1	2	3
Lot size number of containers	**Sample size for physical examination** number of containers	**Sample size for micro-biological examination** number of containers
0 to 5 000	3	3
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

B.3 Sample for testing

After inspection of the containers taken in accordance with B.2 for compliance with 5.1,

a) take, at random, half the number of containers and use them for the storage stability test (see 5.3); 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 clauses 4.2 to 4.5.

B.4 Compliance with this standard

The lot shall be deemed to comply with the relevant requirements of this standard if, after inspection and testing of the samples taken in accordance with B.1, B.2 and B.3, no defective is found.

Annex C
(informative)

Quality verification of disinfectant alcohol-based handrub

C.1 When a purchaser requires ongoing verification of the quality of disinfectant alcohol-based handrub, it is suggested that, instead of concentrating solely on evaluation of the final product, he also direct his attention to the manufacturer's quality system. In this connection it should be noted that SANS 9001 covers the provisions of an integrated quality system.

C.2 If no information about the implementation of quality control or testing during manufacture is available to help in assessing the quality of a lot and a purchaser wishes to establish, by inspection and testing of samples of the final product, whether a lot (see B.1.2.2) of the handrub complies with this standard, the sampling procedure given in B.2 can be applied.

Bibliography

SANS 9001/ISO 9001, *Quality management systems – Requirements*.

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The objective of the SABS Standards Division is to develop, promote and maintain South African National Standards. This objective is incorporated in the Standards Act, 2008 (Act No. 8 of 2008).

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