CARICOM Regional Standard

HAND SANITIZERS – ALCOHOL-BASED HAND SANITIZERS - SPECIFICATION

DCRS 76:202X

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### AMENDMENTS ISSUED SINCE PUBLICATION

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<th>AMENDMENT NO.</th>
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Committee representation

This CARICOM Regional Standard was developed under the supervision of the Regional Project Team for hand Sanitizers, (hosted by the CARICOM Member State, Antigua and Barbuda), which at the time comprised the following members:

<table>
<thead>
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<th>Members</th>
<th>Representing</th>
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</thead>
<tbody>
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<td>Saint Vincent and The Grenadines Bureau of Standards</td>
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<td>Suriname Alcoholic Beverages, N. V</td>
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<td>Institute for Graduate Studies and Research, Suriname</td>
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<td>ICSC Solutions Limited, Trinidad and Tobago</td>
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<td>Chemistry Food and Drugs Division, Ministry of Health, Trinidad and Tobago</td>
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<td>Ms. Avlon Ramkissoon</td>
<td></td>
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<tr>
<td>Mrs. Gem Reynolds (Technical Secretary)</td>
<td>Antigua and Barbuda Bureau of Standards</td>
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Foreword

This CARICOM Regional Standard _CRS :202X, Hand Sanitizers – Alcohol-based hand sanitizers - Specification_ has been developed under the authority of the CARICOM Regional Organisation for Standards and Quality (CROSQ). It was approved as a CARICOM Regional Standard by the CARICOM Council for Trade and Economic Development (COTED).

Hands are frequently in contact with other surfaces and contaminated hands readily transfer microorganisms to other surfaces. The hands play a significant role in the spread of these microorganisms and to help prevent the spread, proper and regular hygiene is crucial. Hand sanitizers aid in interrupting the spread of microorganisms.

This standard was developed to establish minimum requirements for hand sanitizers and to ensure that the product is safe and suitable for its intended use.

This regional standard is intended for use by all manufacturers, importers, distributors and other entities engaged in the production and/or trade of alcohol-based hand sanitizers.

The following documents were used in the formulation of this regional standard:

— Guide to Local Production: WHO-recommended Handrub Formulations
— Health Canada 2020
— JS 351: 2020 Specification for Instant Hand Sanitizers
— KS EAS 789:2013 Instant hand sanitizers – Specification
— Rwanda FDA Guidelines on preparation of alcohol-based hand sanitizers
— PS: 5453/2020 Pakistan Standard for hand sanitizer and disinfectants
— USP Hand Sanitizer Tool Kit
— Excerpted USP-NF and FCC Standards: A Hand Sanitizer Resource, August 17, 2020
1 Scope

This Regional Standard outlines requirements and test methods for alcohol-based hand sanitizers.

The standard does not include requirements for non-alcohol-based hand sanitizers.

2 Normative references

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

ASTM International

— ASTM E3058, Standard Test Method for Determining the Residual Kill Activity of Hand Antiseptic Formulations

— ASTM E2011, Standard Test Method for Evaluation of Hygienic Handwash and Handrub Formulations for Virus-Eliminating Activity Using the Entire Hand


— ASTM E1838, Standard Test Method for Determining the Virus-Eliminating Effectiveness of Hygienic Handwash and Handrub Agents Using the Fingerpads of Adults

— ASTM E2613, Standard Test Method for Determining Fungus-Eliminating Effectiveness of Hygienic Handwash and Handrub Agents Using Fingerpads of Adults

CARICOM Regional Organisation for Standards and Quality

— CRS 55-1, Labelling of goods – Part 1: General requirements

— CRS 55-2, Labelling of goods — Part 2: Specific requirements for prepackaged goods

European Committee for Standardization

— EN 12791, Chemical disinfectants and antiseptics - Surgical hand disinfection - Test method and requirements (phase 2, step 2)

— EN 14885, Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics

— EN 1500, Hygienic handrub method

— European Pharmacopoeia
3 Terms and definitions

For the purposes of this document, the following terms and definitions apply:

3.1 alcohol-based hand sanitizer
alcohol-containing preparation (liquid, gel or foam) designed for application to the hands to inactivate microorganisms and/or temporarily suppress their growth.

NOTE Such preparations may contain one type of the specified alcohol, other active ingredients with excipients, and humectants.

3.2 ethanol
ethyl alcohol
compound with chemical formula C\text{\textsubscript{2}}H\text{\textsubscript{5}}OH

3.3 isopropyl alcohol
isopropanol
2-propanol
n-propanol
compound with chemical formula C\text{\textsubscript{3}}H\text{\textsubscript{7}}OH

3.4 methanol
methyl alcohol
compound with chemical formula CH\text{\textsubscript{3}}OH

3.5 impurity
constituent of the hand sanitizer not intended to be part of the final formulation

3.6 sterile
free from viable microorganisms

3.7 potable water
water which is intended for direct human consumption

3.8 non-toxic
materials which, under the intended conditions of their use, will not cause the product to be harmful to humans or domestic animals [ISO 14159:2002(en), 3.16]

4 General requirements

4.1 The hand sanitizer shall be in the form of liquid, foam or gel.

4.2 The hand sanitizer shall comply with the requirements outlined in Tables 1 and 2 when tested in accordance with the appropriate methods.

4.3 Alcohol used in the manufacturing of hand sanitizers shall comply with the US Pharmacopeia, EU Pharmacopeia specifications or any other pharmacopeia which provides equivalent requirements and test methods as outlined in Table 2.

4.4 Sterile, potable water shall be used in the production of hand sanitizers.

4.5 Thickening agents and humectants used in the manufacture of hand sanitizers shall be non-toxic.

NOTE See Annex A for recommended guidelines for establishments producing hand sanitizers.

4.6 Containers used for hand sanitizers shall be clean.

Table 1 — Requirements for alcohol-based Hand Sanitizer

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Requirements</th>
<th>Test methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol (v/v) *</td>
<td>60%-80%</td>
<td>US Pharmacopeia Chapter 611</td>
</tr>
<tr>
<td>Isopropanol (v/v) *</td>
<td>70%-80%</td>
<td>US Pharmacopeia Chapter 611</td>
</tr>
<tr>
<td>pH</td>
<td>6-8</td>
<td>ISO 10523</td>
</tr>
<tr>
<td>Bactericidal efficacy</td>
<td>to pass test</td>
<td>ASTM E3058, ASTM E2011, ASTM E2613, ASTM E1838, EN 12791, EN 1500, EN 14885</td>
</tr>
</tbody>
</table>

NOTE 1 Only ONE alcohol shall be used (ethanol or isopropyl alcohol) in the formulation of alcohol-based
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<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Requirements</th>
<th>Test methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>hand sanitizers.</td>
<td></td>
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</tbody>
</table>

NOTE 2  Any one of the test methods referenced for bactericidal efficacy shall be used.

<table>
<thead>
<tr>
<th>Chemical impurity</th>
<th>Limits</th>
<th>Test Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methanol</td>
<td>&lt; 0.02% (200 ppm)</td>
<td>US Pharmacopeia or EU Pharmacopeia monograph on alcohol</td>
</tr>
<tr>
<td>Acetaldehyde and acetal</td>
<td>&lt;0.001% (10 ppm), expressed as acetaldehyde</td>
<td></td>
</tr>
<tr>
<td>Benzene</td>
<td>&lt;0.0002% (2 ppm)</td>
<td></td>
</tr>
<tr>
<td>Sum of all other impurities</td>
<td>&lt; 0.03% (300 ppm)</td>
<td></td>
</tr>
</tbody>
</table>

5  Labelling requirements

In addition to the requirements of CRS 55-1, Labelling of goods – Part 1: General requirements and CRS 55-2, Labelling of goods — Part 2: Specific requirements for prepackaged goods, the following shall apply:

a)  type and percentage of alcohol used;

b)  the following cautionary warnings:

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

ii. “Keep out of reach of children”;

iii. “If swallowed contact a doctor”; and

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

6  Storage

Hand sanitizers and raw materials shall be stored in a cool, dry place and shall be kept out of direct sunlight.
Annex A

(Informative)

Guidelines for establishments producing hand sanitizers

The following document contains the recommended guidelines for establishments producing hand sanitizers: