RWANDA STANDARD

DRS 456-2

First edition

Approved by RSB 2021-mm-dd

Surface disinfectants — Specification —

Part 2:

Disinfectants based on iodophors

ICS 71.100.35

to appear on the last page

Reference number

DRS 456-2: 2021

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Rwanda Standards Board

P.O Box 7099 Kigali-Rwanda

KK 15 Rd, 49

Tel. +250 788303492

Toll Free: 3250

E-mail: info@rsb.gov.rw

Website: www.rsb.gov.rw

ePortal: www.portal.rsb.gov.rw

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Foreword

Rwanda Standards are prepared by Technical Committees and approved by Rwanda Standards Board (RSB) Board of Directors in accordance with the procedures of RSB, in compliance with Annex 3 of the World Trade Organisation/Technical Barrier to Trade (WTO/TBT) agreement on the preparation, adoption and application of standards.

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 456-2 was prepared by Technical Committee RSB/TC 024, *Organic and Inorganic Chemicals*.

In the preparation of this standard, reference was made to the following standard:

US 1709: Disinfectants/sanitizers based on iodophors — Specification

The assistance derived from the above source is hereby acknowledged with thanks.

DRS 456 consists of the following parts, under the general title *Surface disinfectants — Specification*:

— *Part 1: Disinfectants for general use*

— *Part 2: Disinfectants based of iodophors*

— *Part 3: Disinfectants based on glutaraldehyde*

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

Rwanda Environment Management Authority

BARANYUZWE Cosmetics Ltd

SULFO Rwanda Industries Ltd

UBURANGA Natural Products

Divine Hope Company Ltd

University of Rwanda/College of Medicine and Health Sciences

University of Rwanda/College of Sciences and Technology

University of Rwanda/College of Education

Rwanda Polytechnic – IPRC Kigali

Standards for Sustainability (SfS)

Rwanda Standards Board (RSB) – Secretariat

Surface disinfectants — Specification — Part 2: Disinfectants based on iodophors

1 Scope

This Draft Rwanda Standard specifies the requirements, sampling and test methods for disinfectants that contain iodophor(s) as active ingredients and are intended for use on inanimate surfaces. It is applicable to all disinfectants where iodophors are present.

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.

EAS 384, *Disinfectants — Glossary of terms*

ISO 10523, *Water quality — Determination of pH*

DRS 457, *Determination of bacterial efficacy of disinfectants/sanitizers*

3 Terms and definitions

For the purposes of this standard, the terms and definitions given in EAS 384 and the following apply.

3.1

active ingredient

any chemical or biological component that is included in the formulation of a disinfectant/sanitizer product in sufficient concentration to achieve the intended anti-microbial of the specific product

3.2

batch

collection of packages containing a disinfectant/sanitizer of a single type and composition and of a single manufactured blend, or of a single delivery.

3.3

inanimate surface

any surface other than live human or live animal tissue (for example, skin)

3.4

iodophor

combination of iodine and solubilizing agent (or a “carrier”) that contains (and, when diluted with water, slowly liberates) free iodine

3.5

lot

quantity of disinfectant in sealed containers of the same size and bearing the same batch identification, from one manufacturer, submitted at any time for inspection and testing

4 Requirements

4.1 Type

The product shall be of one of the following types:

Type 1: without added acid; or

Type 2: containing an added acid of an acceptable type.

4.2 Raw materials

The product shall not contain ingredients that are recognized as being potentially hazardous or toxic when the product is used in accordance the manufacturer’s recommendations, nor shall it form toxic or potentially toxic reaction products.

4.3 General requirements

4.3.1 The product shall not:

a) leave an objectionable odour on surfaces; and

b) impart any colour, taste, odour or flavour to food contact surfaces (including drinking water contact surfaces) shall not contain perfumes.

4.3.2 The product intended to be used on food contact surfaces, including drinking water, shall not contain perfumes.

4.4 Specific requirements

4.4.1 The product shall comply with the requirements given in table 1 when tested in accordance with the test methods specified therein.

Table 1 — Specific requirements for disinfectants/sanitizers

S/N	Parameters	Requirements		Test method[a]
		Type 1	Type 2	
i)	Water insoluble matter content, g/L, max.	5	5	Annex A
ii)	pH range	4.0 – 7.0	2.0 – 4.0	ISO 10523
iii)	Antimicrobial efficacy[b]	Pass	Pass	DRS 457
iv)	Storage stability	Homogeneous and free-flowing		Annex B
v)	Added colouring matter	Absent		Annex C
[a] The tests shall be carried out at the manufacturer's prescribed concentration [b] It is recommended that the user assesses the efficacy and suitability of the product for specific targeted surfaces under local conditions.				

5 Packaging and labelling

5.1 Packaging

The container, including the closure, in which the product is packaged shall not interact chemically or physically the content and shall be strong enough to protect the product adequately during normal handling, transportation and storage.

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

Only packs of the same size and bearing the same batch number shall be packaged together in a bulk pack.

5.2 Labelling

The following information shall appear prominently, legibly and indelibly on each container or on a label securely attached to each container:

c) manufacturer's name or trademark, or both;

d) name of the product as "disinfectant/sanitizer based on iodophor";

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

e) nominal volume or mass of the content in metric units;

f) an indication of the intended use areas for which the product is claimed to be suitable;

NOTE Intended use areas may include one or more of the following: general residual settings, industrial/institutional settings (such as commercial settings, schools, and offices), hospitals (for non-critical medical devices), food processing/food handling areas and equipment, barns/animal housing settings and any other specific area.

g) general instructions for use. The instructions shall include the recommended concentration, dilution level and the minimum exposure period for each purpose;

h) hazard and toxic warnings, where relevant;

i) statement about the safety precautions to be taken when using the product and the first ait steps to be taken in case of direct ingestion or skin contact;

j) batch number;

k) production and expiry dates;

l) adequate draining, rinsing and/or drying requirements from surfaces after use; and

m) a warning to avoid contact with known incompatible substances, items and foodstuffs.

NOTE The manufacturer should substantiate any virucidal claim made about the product

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
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.

Annex A
(normative)

Determination of water-insoluble matter content

A.1 Procedure

A.1.1 Pipette 5.0 mL of the undiluted disinfectant/sanitizer into a beaker and add 250 mL of standard hard water.

A.1.2 Heat in a steam bath with frequent stirring until the sample is completely dispersed.

A.1.3 Filter the solution immediately, under suction, through a tarred 1.6 µm glass fibre filter and ensure that the insoluble matter is quantitatively transferred to the filter.

A.1.4 Allow the solution to drain completely and dry the residue at 105 °C ± 2 °C until constant mass is attained. Cool in a desiccator and weigh.

A.2 Calculation

The water-insoluble matter content in the solution, expressed in grams per litre (g/L), shall be calculated using the following formula:

$$\text{Water-insoluble matter content} = \frac{m}{V}$$

Where,

m is the mass, in grams, of the residue after it has been dried; and

V is the volume, in litres, of the test solution.

Annex B
(normative)

Determination of storage stability

B.1 Reagents

C.1.1 **Sodium thiosulphate ($Na_2S_2O_3$) solution**, 0.02N, accurately standardized.

C.1.2 **Starch solution**, 10 g/L

B.2 Procedure

B.2.1 Transfer 200 ml of the sample to a 250-ml stoppered measuring cylinder. Cool to 10 °C ± 1 °C. maintain at this temperature for 24h and then examine the test sample visually for signs of separation.

B.2.2 If visible separation has not occurred, allow the test sample to return to ambient temperature and then take from it two test specimens, one from near the surface and one from near the bottom of the contents of the cylinder.

B.2.3 Determine the available iodine content of each of these test specimens as follows:

Pipette accurately 1 ml of the test specimen into a 250-ml Erlenmeyer flask, add 100 ml of distilled or demineralized water and titrate with the 0.02N sodium thiosulphate solution until a straw coloured titration mixture has been reached. Add a small amount of the starch indicator and carry on with the titration until the end point at a starch indicator colour change, from blue to colourless.

NOTE As some iodophors release iodine very slowly as the end point is neared, a reasonable time should be allowed before the titration is regarded as completed.

B.2.4 Repeat the test with another 200-m test sample. From the stage described in B.2.1, warm and maintain the test sample at a temperature of 40 °C ± 1 °C for 24h instead of cooling it.

B.3 Calculation

The available iodine content of each of the four test specimens, expressed as a percentage (%), shall be calculated using the following formula:

Available iodine content = $A \times N \times 126.9$

Where,

A is the volume, in millilitres, of the $Na_2S_2O_3$ solution use in the titration, and

N is the normality of the $Na_2S_2O_3$ solution.

B.4 Results

B.4.1 No visible separation shall occur during either the 24h cooling period or 24h warming period, and

B.4.2 The highest of the four values of the available iodine content (see C.3) shall not differ from the lowest by more than 10%.

Annex C
(normative)

Determination of added colouring matter

C.1 Reagent

Sodium thiosulphate, 50 g/l aqueous solution.

C.2 Procedure

Using a pipetted, transfer 5 ml of the test sample to a clean test tube. Using a separate pipette, add 5 ml of the sodium thiosulphate solution and mix well.

C.3 Interpretation of results

If the colour of the mixture in the tube is no darker than pale straw 30 s after mixing, deem the product to comply with 4.4.4.

Bibliography

[1] ISO/IEC Directives, Part 2, *Rules for the structure and drafting of International Standards*, 2016

[2] ISO/IEC TR 10000-1, *Information technology — Framework and taxonomy of International Standardized Profiles — Part 1: General principles and documentation framework*

[3] ISO 10241 (All parts), *Terminological entries in standards*