



**RWANDA
STANDARD**

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Surface disinfectants — Specification

Part 3:

Disinfectants based on glutaraldehyde

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Reference number

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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 456-3 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 1710: Disinfectants/sanitizers based on glutaraldehyde for general use — 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

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BARANYUZWE Cosmetics Ltd

SULFO Rwanda Industries Ltd

UBURANGA Natural Products

Divine Hope Company Ltd

University of Rwanda/College of Medicine and Health Sciences

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University of Rwanda/College of Education

Rwanda Polytechnic – IPRC Kigali

Standards for Sustainability (SfS)

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Surface disinfectants — Specification — Part 3: Disinfectants based on glutaraldehyde

1 Scope

This Draft Rwanda Standard specifies the requirements, sampling and test methods for two types of disinfectants/sanitizers based on glutaraldehyde and intended for general use on inanimate surfaces.

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*

DRS 457, *Determination of bactericidal 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

batch

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

3.2

inanimate surface

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

3.3

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

3.4

glutaraldehyde

chemical that is **used as** a cold sterilant to disinfect and clean heat-sensitive medical, surgical and dental equipment.

4 Requirements

4.1 Types

The product shall be of one of the following types, as required:

- a) **Type 1:** a homogeneous liquid; or
- b) **Type 2:** a homogeneous liquid that has to be mixed with either a solid or a liquid activator before use as a disinfectant.

4.2 Raw materials

The product shall not contain ingredients that are recognized as being potentially hazardous or toxic when the products are used in accordance with the manufacturer's recommendations, nor shall 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 products of drinking water, when used in accordance with the manufacturer's recommendations.

4.3.2 The product intended for use on food contact surfaces shall not contain perfumes.

4.3.3 Stability after dilution of type 1 product and after activation of type 2 product

After a type 1 product has been diluted to the prescribed concentration or after the two components of a type 2 product have been mixed in accordance with the manufacturer's instructions and the product has been stored in closed dark containers at 25 °C for the effective life as stated on the label, the resulting dilution shall still comply with the requirements.

4.4 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 surface disinfectants based on glutaraldehyde

S/N	Characteristic	Requirement	Test method
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		Type 1	Type 2	
i)	Corrosiveness	No evidence of pitting, etching or discolouration		Annex A
ii)	Water insoluble matter content, g/L, max.	1		Annex B
iii)	Storage stability	Homogeneous and free-flowing	Free flowing	Annex C
iv)	Bactericidal efficacy ^a	To pass the test		DRS 457

^a It is recommended that the user assesses the efficacy of the disinfectant and suitability for purpose for the specific target surfaces under local conditions.

5 Packaging and Labelling

5.1 Packaging

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

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

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

5.2 Labelling

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

- a) Name and full address of the manufacturer, and trademark if any;
- b) Name of the product as “disinfectant/sanitizer based on glutaraldehyde”;

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

- c) A statement of the nominal volume or mass of the contents in metric units;
- d) A description of how the components of a type 2 disinfectant/sanitizer are to be mixed;
- e) general instructions for use of the product. The instructions shall include the recommended concentration, dilution level and the minimum exposure period for each purpose;
- f) hazard and toxicity warnings, where relevant;
- g) hazard and toxicity warnings, where relevant;
- h) statement about the safety precautions to be taken when using the product and the first aid steps to be taken in case of direct ingestion or skin contact;

- i) the batch identification number;
- j) manufacture and expiry dates;
- k) adequate draining, rinsing and/or drying requirements from surfaces after use;
- l) appropriate instructions for the storage of the product, including a warning to store away from children;
- m) when the prescribed end-use concentration of the product is above 0.2% glutaraldehyde, warnings that:
 - 1) the product can be detrimental to the skin, and that gloves should be used; and
 - 2) the product should not be used on surfaces that will come into contact with food.

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.

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Annex A (normative)

Determination of corrosiveness

A.1 Test strips

Use two strip, each of size approximately 75 mm x 19 mm x 1.5 mm, of bright-finished uncoated aluminium Type EN AW 1050A

A.2 Procedure

A.2.1 Degrease the aluminium test strips by washing in a mixture of equal volumes of ethanol and acetone. Allow the strips to air-dry, then heat them for 15 min in an oven at $105\text{ °C} \pm 5\text{ °C}$ and allow them to cool in a desiccator.

A.2.2 Prepare the test solution of the product under test, at the highest concentration recommended by the manufacturer, and transfer 250 ml of the freshly prepared solution to a suitably stoppered glass bottle.

A.2.3 Completely immerse the test strips in the solution in the glass bottle. Stopper the bottle and maintain the bottle at $25\text{ °C} \pm 2\text{ °C}$ for 16h.

A.2.4 Remove the test strips from the test solution, rinse them thoroughly with water and then acetone and allow them to air-dry. Then heat the test strips for 30 min in an oven at $105\text{ °C} \pm 5\text{ °C}$ and cool them again in a desiccator.

A.2.5 Remove the test strips from the desiccator and examine them for compliance with 4.4.1.

Annex B (normative)

Determination of water-insoluble matter

B.1 Procedure

Pipette 5.0 ml of the undiluted product into a beaker and add 250 ml of standard hard water.

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

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.

Wash the beaker and the residue five times with 20-ml volumes of hot standard hard water. Wash the filter with distilled water (to remove salts from the hard water).

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

B.2 Calculation

The water-insoluble matter content in the test 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 C

(normative)

Determination of storage stability

C.1 Store type a product and the liquid component of type 2 product in their original unopened containers at $5\text{ °C} \pm 1\text{ °C}$. inspect the contents of half the packages in the sample for compliance with the relevant requirements of 4.4.3.

C.2 Store the solid component of type 2 product in its original unopened containers under ambient conditions for six months. The liquid component of the product does not have to be stored under these conditions. Inspect the contents of half of the containers in the sample for compliance with 4.4.3.2 and test the solid component, in conjunction with the type 2 product that it activates, for compliance with 4.4.5.

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Bibliography

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