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Disinfectants/sanitizers based on glutaraldehyde for general use — Specification

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Compliance with this standard does not, of itself confer immunity from legal obligations

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Foreword

Uganda National Bureau of Standards (UNBS) is a parastatal under the Ministry of Trade, Industry and Cooperatives established under Cap 327, of the Laws of Uganda, as amended. UNBS is mandated to co-ordinate the elaboration of standards and is

(a) a member of International Organisation for Standardisation (ISO) and

(b) a contact point for the WHO/FAO Codex Alimentarius Commission on Food Standards, and

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Draft Uganda Standards adopted by the Technical Committee are widely circulated to stakeholders and the general public for comments. The committee reviews the comments before recommending the draft standards for approval and declaration as Uganda Standards by the National Standards Council.

The committee responsible for this document is Technical Committee UNBS/TC 5, *[Chemicals and environment].*

Disinfectants/sanitizers based on glutaraldehyde for general use — Specification

1 Scope

This draft Uganda standard specifies the requirements and methods of sampling and test for two types of disinfectants/sanitizers based on glutaraldehyde and intended for general use on inanimate surfaces.

2 Normative references

The following referenced documents 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.

DUS 1692, *Determination of bactericidal efficacy of disinfectants/sanitizers*

US EAS 384*, Disinfectants — Glossary of terms*

3 Terms and definitions

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

3.1
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

3.2
defective
a sample of disinfectant/sanitizer that fails in one or more respects to comply with the relevant requirements of this standard

3.3
inanimate surface
any surface other than live human or live animal tissue (for example skin)

3.4
lot
that quantity of disinfectant/sanitizer in sealed containers of the same size and bearing the same batch identification, from one manufacturer, submitted at any one time for inspection and testing

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

4 Requirements

4.1 Type

The disinfectant/sanitizer 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/sanitizer.

4.2 Raw materials

Raw materials used in the formulation of the disinfectant/sanitizer shall be such as to be suitable for the intended use. Products 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 they form toxic or potentially toxic reaction products.

4.3 Bactericidal efficacy and suitability for purpose

When the bactericidal efficacy of a disinfectant/sanitizer is tested in accordance with DUS 1692, at the prescribed concentration, the disinfectant/sanitizer shall pass the test.

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

4.4 Stability after dilution of a type 1 disinfectant/sanitizer and after activation of a type 2 disinfectant/sanitizer

After a type 1 disinfectant/sanitizer has been diluted to the prescribed concentration (see 6.2(e)) or after the two components of a type 2 disinfectant/sanitizer have been mixed in accordance with the manufacturer's instructions (see 6.2(d)) and the disinfectant/sanitizer has been stored in closed dark containers at 25 °C for the effective life as stated on the label (see 6.2(i)), the resulting dilution shall still comply with the requirements of 4.3.1.

4.5 Corrosiveness

When the disinfectant/sanitizer is tested in accordance with Annex B, it shall not cause more than slight dulling of the surface of the test strip and the test strip shall show no evidence of pitting, etching or discoloration. In addition, there shall be no change in the appearance of the disinfectant/sanitizer.

4.6 Water-insoluble matter content

The water-insoluble matter content of the disinfectant/sanitizer, determined in accordance with Annex C, shall, in the case of both a type 1 disinfectant/sanitizer and a type 2 disinfectant/sanitizer (after mixing of the two components), not exceed 1 g/L.

4.7 Storage stability

4.7.1 When tested in accordance with D.1 (see Annex D), a type 1 disinfectant/sanitizer and the liquid component of a type 2 disinfectant/sanitizer shall remain homogeneous and free-flowing.

4.7.2 When tested in accordance with D.2 (see Annex D), the solid component of a type 2 disinfectant/sanitizer shall remain free-flowing and the type 2 disinfectant/sanitizer that it activates shall still comply with 4.3.1.

4.8 Odour, taste and colour

4.8.1 Disinfectants/sanitizers shall not leave an objectionable odour on surfaces.

4.8.2 A disinfectant/sanitizer intended for use on food contact surfaces (including drinking water contact surfaces) shall not contain perfumes. It shall not impart any colour, taste, odour or flavour to food products or drinking water, when used in accordance with the manufacturer's recommendations.

5 Packaging and labelling

5.1 Packaging

5.1.1 The container (including the closure) in which the disinfectant/sanitizer is packaged shall not interact chemically or physically with the disinfectant/sanitizer and shall be strong enough to protect the disinfectant/sanitizer 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 durably on each disinfectant/sanitizer container or on a label securely attached to each container:

a) the manufacturer's name or trademark, or both;

b) a statement that the product is a disinfectant/sanitizer based on glutaraldehyde;

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) a 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;

h) the batch identification number; or the production date of the batch or both;

i) the expiry date of the product, where relevant, and the effective life of the product;

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

k) appropriate instructions for the storage of the product, including a warning to store away from children;

l) a warning to avoid contact with known incompatible substances, items and foodstuffs; and

m) when the prescribed end-use concentration of the disinfectant/sanitizer is above 0.2% glutaraldehyde, warnings that:

    i. the disinfectant/sanitizer can be detrimental to the skin, and that gloves should be used; and

ii. the disinfectant/sanitizer should not be used on surfaces that will come into contact with food.

NOTE 1 The product name should not be misleading to the consumer.

NOTE 2 The manufacturer should substantiate any virucidal claim made about the product.

Annex A
(normative)

Sampling and compliance with this standard

A.1 Sampling

A.1.1 General

The following sampling procedure shall be applied to determine 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.

A.1.2 Sample for inspection

From the lot, draw at random the relevant number of containers in accordance with table A.1.

Table A.1 — Samples for inspection

Lot size, containers	Sample size, containers
5 — 20	2
21 — 50	3
51 – 90	5
91 – 150	8
151 – 280	13
281 – 500	20
501 – 1200	32
1201 – 3200	50
3201 - 10000	80

A.1.3 Sample for testing

A.1.3.1 After inspection of the containers drawn in accordance with A.1.2,

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

b) take the remaining number of containers and from each of these containers take the smallest of the following:

1) all the contents of the container, or

2) 0.25 L in the case of liquids, or

3) 0.25 kg in the case of solids.

A.1.3.2 Combine these samples and mix them thoroughly to make up a composite sample for testing for compliance with the requirements of this standard.

A.2 Compliance with this standard

Deem the lot to comply with the relevant requirements of this standard if:

a) on inspection of the containers and on testing of the samples taken in accordance with A.1.2 and A.1.3, no defective is found;

b) the manufacturer satisfies the certification body as to the safety of all materials used in the manufacture of the product, and of the safety of the final product when used in accordance with the manufacturer's recommendations.

Annex B
(normative)

Determination of corrosiveness

B.1 Test strips

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

B.2 Procedure

B.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 °C ± 5 °C and allow them to cool in a desiccator.

B.2.2 Prepare the test solution of the disinfectant/sanitizer 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.

B.2.3 Completely immerse the test strips (see B.1) in the solution in the glass bottle. Stopper the bottle and maintain the bottle at 25 °C ± 2 °C for 16 h.

B.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 °C ± 5 °C and cool them again in a desiccator.

B.2.5 Remove the test strips from the desiccator and examine them for compliance with 4.5.

Annex C
(normative)

Determination of water-insoluble matter

C 1 Procedure

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

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

C.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.

C.1.4 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).

C.1.5 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.

C.2 Calculation

Calculate the content of water-insoluble matter in the test solution, expressed in grams per litre, using the formula:

$$\frac{m}{V}$$

where

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

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

Annex D
(normative)

Determination of storage stability

D.1 Store type 1 disinfectants/sanitizers and the liquid component of type 2 disinfectants/sanitizers in their original unopened containers at 5 °C ± 1 °C for 24 h. Inspect the contents of half of the packages in the sample (see Annex A) for compliance with the relevant requirements of 4.7.1.

D.2 Store the solid component of type 2 disinfectants/sanitizers in its original unopened containers under ambient conditions for 6 months. The liquid component of type 2 disinfectants/sanitizers does not have to be stored under these conditions. Inspect the contents of half of the containers in the sample for compliance with 4.7.2 and test the solid component, in conjunction with the type 2 disinfectant/sanitizers that it activates, for compliance with 4.3.1.

Annex E
(informative)

Quality verification of disinfectants/sanitizers for use on food contact surfaces

E.1 General

When a purchaser requires ongoing verification of the quality of disinfectants/sanitizers for use on food contact surfaces, it is suggested that, instead of concentrating solely on evaluation of the final product, attention should also be directed to the manufacturer's quality system. In this connection it should be noted that US ISO 9001 covers the provisions of an integrated quality system.

E.2 Quality system requirements

E.2.1 When assessed in accordance with E.3, the quality system of a manufacturer of disinfectants/sanitizers for use on food contact surfaces shall comply with the requirements of E.2.2 to E.2.12.

NOTE Some or all of these requirements might be relaxed by the authority administering this standard if an appropriate source verification and inspection is being used by the manufacturer.

E.2.2 Responsibility for the quality system shall be delegated to an officer who has sufficient authority, and is sufficiently qualified, to ensure compliance with the relevant requirements of this standard.

E.2.3 The responsibilities of all persons who have direct or indirect responsibility for quality shall be so defined and documented as to ensure that there is no overlap of functions or responsibilities.

E.2.4 Quality system documentation, and the amendment and revision of such documentation (including formulations, test methods and product standards), shall be written and authorized only by duly designated officers who have written authority to perform these functions.

E.2.5 A documented quality system shall exist and be implemented to ensure that only disinfectants/sanitizers that comply with the relevant requirements of this standard are delivered for use on food contact surfaces. Such documentation shall include, but not be limited to:

a) procedures for the manufacture of the respective products,

b) standards for all the raw materials used,

c) standards for the finished products,

d) standards for the testing of raw materials, packaging, work in progress and finished products,

e) standards for packaging, labelling and storage of the finished products, and

f) systems to ensure that personnel involved in activities that affect the manufacture and quality of the disinfectants/sanitizers have available only current and suitably authorized documented procedures and standards, and that such documentation can be recalled and updated when necessary.

E.2.6 Systems shall exist and be implemented to ensure that only raw materials and packaging that comply with the relevant requirements of this standard are used in the manufacture of disinfectants/sanitizers meant for food contact surfaces.

E.2.7 The manufacturer shall implement a system of product identification to ensure that a product in its original packaging can be traced back to the relevant records of manufacture and sources of raw materials.

E.2.8 Products shall be manufactured in appropriate premises, using appropriate equipment and in accordance with appropriate documented manufacturing procedures (see E.2.4), by appropriately trained employees. Process control procedures shall be such as to ensure a consistent quality of the end product.

E.2.9 The formulations of the disinfectants/sanitizers shall be submitted for approval to a certification body, together with sufficient safety data that cover both raw materials and the finished product, to satisfy the certification body with respect to the safety of the product when used in accordance with the manufacturer's recommendations. Material safety data sheets shall form an integral part of such safety data. Formulations, once approved, shall not be altered without the approval of the certification body. The certification body shall impose such reappraisal requirements as it considers necessary to ensure the continued safety of the product.

E.2.10 Testing of raw materials, packaging, work in progress and finished product shall be carried out by appropriately qualified and trained personnel who have access to suitable equipment and facilities and in accordance with documented procedures. Test records shall be maintained and appropriate samples (see annex A) shall be retained for a period that is sufficient to comply with the requirements of the customer and the certification body or the regulatory or inspection authority.

NOTE A sample retention time of at least six months and a record retention time of at least two years are recommended.

E.2.11 Test equipment shall be calibrated periodically to ensure reliability and accuracy. Records of calibration shall be kept. The period between successive calibrations shall not exceed one year.

E.2.12 Systems shall exist and be implemented to ensure that only disinfectants/sanitizers that comply with the relevant quality standards are dispatched to the customer.

E.3 Assessment of quality system

NOTE See note to E.2.1

The quality system shall be assessed by auditors who are trained, qualified and experienced in the evaluation of quality systems in accordance with recognized quality system standards such as US ISO 9001. Audits shall be carried out in accordance with the generally accepted criteria for assessing compliance with such standards.

Bibliography

[1] SANS 1615, *Disinfectants based on glutaraldehyde for general use*

[2] SANS 1853, *Disinfectants and detergent-disinfectants for use in the food industry*

[3] US ISO 9001*, Quality management systems — Requirements*

Certification marking

Products that conform to Uganda standards may be marked with Uganda National Bureau of Standards (UNBS) Certification Mark shown in the figure below.

The use of the UNBS Certification Mark is governed by the Standards Act, and the Regulations made thereunder. This mark can be used only by those licensed under the certification mark scheme operated by the Uganda National Bureau of Standards and in conjunction with the relevant Uganda Standard. The presence of this mark on a product or in relation to a product is an assurance that the goods comply with the requirements of that standard under a system of supervision, control and testing in accordance with the certification mark scheme of the Uganda National Bureau of Standards. UNBS marked products are continually checked by UNBS for conformity to that standard.

Further particulars of the terms and conditions of licensing may be obtained from the Director, Uganda National Bureau of Standards.

ICS 71.100.35

Price based on nn pages