DUS 1693

DRAFT UGANDA STANDARD

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Disinfectants/sanitizers — Specification

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DUS 1693:2017

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

A Uganda Standard does not purport to include all necessary provisions of a contract. Users are responsible for its correct application

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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

(c) the National Enquiry Point on TBT Agreement of the World Trade Organisation (WTO).

The work of preparing Uganda Standards is carried out through Technical Committees. A Technical Committee is established to deliberate on standards in a given field or area and consists of key stakeholders including government, academia, consumer groups, private sector and other interested parties.

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]*.

This standard cancels and replaces US 653:2006 which has been technically revised.

Disinfectants/sanitizers — Specification

1 Scope

This draft Uganda standard specifies requirements, methods of sampling and test for disinfectants/sanitizers intended for general use on inanimate surfaces including food contact and non-food contact surfaces. This standard is applicable to disinfectants/sanitizers represented for use on non-critical medical devices, environmental surfaces and other inanimate objects. This standard does not apply to disinfectants/sanitizers containing iodophor(s) and aldehydes as active ingredients.

NOTE 1 Using this standard, it is not possible to determine the bactericidal activity of the undiluted product. Some dilution is always produced by the addition of inoculum, standard hard water and sterile skimmed milk.

NOTE 2 If a product complies with the test requirements, it can be considered to be bactericidal, but it should not necessarily be inferred that the product is a suitable disinfectant/sanitizer for a defined purpose.

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*

DUS ISO 15510, *Stainless steels — Chemical composition*

US 852, *Cleaning chemicals for use in the food industry*

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
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 purpose 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
certification body
impartial body, governmental or non-governmental, in which the interests of all the parties concerned with the functioning of a certification system are represented, and that possesses the necessary competence and authority to operate such a system

3.4
defective
a sample of disinfectant/sanitizer that fails in one or more respects to comply with the relevant requirements of this standard

3.5
inanimate surface
any surface other than live human or live animal tissue (for example, skin)

3.6
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.

3.7
main active ingredient
active ingredient present in highest quantity or concentration in a disinfectant/sanitizer product

3.8
standard conditions
temperature of 25 °C ± 2 °C and a relative humidity of 50 % ± 5 %.

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 one of the following types:

a) **type 1**: a homogeneous liquid/gel; or

b) **type 2**: a solid, supplied in form of tablets, free-flowing beads, granules, or powder.

4.2 Active ingredients

The disinfectant/sanitizer shall contain active ingredients such as quaternary ammonium compounds, phenolic compounds or any other known active ingredients or a mixture of active ingredients which permit the disinfectant/sanitizer to comply with the requirements of this standard.

NOTE A mixture of active ingredients is permitted provided that the ingredients are compatible and do not interact in a manner that reduces the disinfectant/sanitizer activity.

4.3 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. The safety of raw materials shall be assessed and established in accordance with 5.2.

4.4 Bactericidal efficacy and suitability for purpose

4.4.1 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.

4.4.2 Suitability for purpose shall be a matter of agreement between the supplier and the purchaser (see Annex F).

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.

4.5 Corrosiveness

4.5.1 Corrosiveness to corrosion-resistant steel

When the disinfectant/sanitizer is tested in accordance with B.1 (see Annex B) at the highest prescribed concentration, any loss in mass of the corrosion-resistant test strip shall not exceed 0.05 mg/100 mm^2 of surface area of the test strip, and the test strip shall show no evidence of pitting, etching or discolouration.

4.5.2 Corrosiveness to aluminium

4.5.2.1 When the disinfectant/sanitizer is tested in accordance with B.2 (see Annex B) at the highest prescribed concentration, the disinfectant/sanitizer shall not cause more than a slight dulling of the surface of the aluminium test strip and the test strip shall show no evidence of pitting, etching or discolouration.

4.5.2.2 If a claim is made of non-corrosiveness to a specific material, the manufacturer shall substantiate this claim.

4.6 Odour, taste and colour

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

4.6.2 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.

4.7 Storage stability

4.7.1 When a type 1 disinfectant/sanitizer is tested in accordance with C.1 (see Annex C), the disinfectant/sanitizer shall remain homogeneous and free-flowing.

4.7.2 When a type 2 disinfectant/sanitizer is tested in accordance with C.2 (see Annex C), the disinfectant/sanitizer shall not cake into lumps.

4.8 Freedom from visible impurities (type 2 disinfectant/sanitizer)

When a type 2 disinfectant/sanitizer is tested in accordance with Annex D, not more than five specks of impurities shall be visible.

4.9 Water insoluble matter content

When the disinfectant/sanitizer is tested in accordance with Annex E, at the concentration recommended by the manufacturer, the water insoluble matter content shall not exceed the appropriate of the following:

a) **type 1**: 5 g/L; or

b) **type 2**: 2.5 % (by mass).

5 Inspection and assessment of safety of raw materials

5.1 Inspection

Visually, or otherwise, inspect each container taken in accordance with A.1 (see annex A) for compliance with the requirements set out in sub clause 4.6 and Clause 6.

5.2 Assessment of safety of raw materials

The manufacturer of the disinfectant/sanitizer product shall make available, whenever required by the certification body or purchaser, sufficient evidence to establish the safety of all raw materials used in the formulation of the product, and the freedom of the raw materials from contaminants or trace components in quantities that could prove harmful to human beings or leave toxic residues on surfaces, when the product is used in accordance with the manufacturer's recommendations. Evidence to this effect shall include one or more of the following:

a) proof of certification by a recognized authority;

b) material safety data;

c) certificates of analysis; and

d) any other relevant information.

6 Packaging and labelling

6.1 Packaging

6.1.1 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.

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

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

6.2 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 and the main active ingredient used in its formulation;

c) a statement of the nominal volume or mass of the contents in metric units;

d) 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 residential 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.

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) when so authorized by the relevant authority, a certification mark that indicates compliance with this and with other relevant standards;

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

j) the expiry date of the product, where relevant;

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

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

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

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 Corrosiveness to corrosion-resistant steel

B.1.1 Test strips

Use one strip, of size approximately 80 mm × 25 mm × 1 mm, of a hot-rolled, annealed and polished stainless steel that complies with the requirements for standard grade X2CrNi18-9 as specified in DUS ISO 15510.

B.1.2 Procedure

B.1.2.1 Accurately determine the total area of the surfaces of the steel test strip and degrease it by washing in a mixture of equal volumes of ethanol and acetone. After allowing the strip to air-dry, heat it for 30 min in an oven maintained at 105 °C ± 5 °C, cool it in a desiccator and immediately determine its mass to the nearest 0.1 mg.

B.1.2.2 Prepare the test solution of the disinfectant/sanitizer under test, at the concentration recommended by the manufacturer, and transfer 250 mL of the freshly prepared solution to a suitably stoppered glass bottle.

B.1.2.3 Completely immerse the test strip (see B.1.1) in the solution in the glass bottle. Stopper the bottle and maintain it at 25 °C ± 2 °C for 16 h.

B.1.2.4 Remove the test strip from the test solution, rinse it thoroughly, first with water, then with acetone, and allow it to air-dry. Then heat the test strip for 30 min in an oven maintained at 105 °C ± 5 °C, cool it in the desiccator, and immediately determine its mass to the nearest 0.1 mg.

B.1.2.5 Calculate the loss in mass in mg/100 mm^2 of surface area as follows:

$$M = \frac{100}{A} \times (m_1 - m_2)$$

where,

M is the loss in mass of the steel test strip, in milligrams per 100 square millimetres;

A is the total surface area, in square millimetres;

m_1 is the mass of the test strip before the test, in milligrams;

m_2 is the mass of the test strip after the test, in milligrams.

B.1.2.6 Examine the test strip for compliance with 4.5.1.

B.2 Corrosiveness to aluminium

B.2.1 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.2.2 Procedure

NOTE Should the mass loss evaluation method be required for the corrosiveness to aluminium, use the procedure given in B.1.2.

B.2.2.1 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.2.2.2 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.2.2.3 Completely immerse the test strips (see B.2.1) in the solution in the glass bottle. Stopper the bottle and maintain the bottle at 25 °C ± 2 °C for 16 h.

B.2.2.4 Remove the test strips from the test solution, rinse them thoroughly with water and then acetone and allow to air-dry. Then heat the test strips for 30 min in an oven at 105 °C ± 5 °C and cool in a desiccator.

B.2.2.5 Remove the test strips, and visually inspect them for evidence of pitting, etching or discoloration.

B.2.2.6 Examine the test strips for compliance with 4.5.2.

Annex C
(normative)

Determination of storage stability

C.1 Type 1 disinfectant/sanitizer

C.1.1 Store each disinfectant/sanitizer in its original unopened container at 5 °C ± 1 °C for 24 h.

C.1.2 Check for compliance with 4.7.1.

C.2 Type 2 disinfectant/sanitizer

C.2.1 Store each disinfectant/sanitizer in its original unopened container under standard conditions for six months.

C.2.2 Check for compliance with 4.7.2.

Annex D
(normative)

Determination of freedom from visible impurities (type 2 disinfectant/sanitizer)

D.1 Spread approximately 50 g of each test sample over the bottom of a 150 mm diameter Petri dish.

D.2 Check for compliance with 4.8 by viewing at a range of approximately 600 mm.

Annex E
(normative)

Determination of water insoluble matter content

E.1 Procedure

E.1.1 Pipette 5.0 mL of a type 1 disinfectant/sanitizer, or place 2 g of a type 2 disinfectant/sanitizer into a beaker and add 250 mL of standard hard water.

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

E.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.

E.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).

E.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.

E.2 Calculation

E.2.1 Type 1 disinfectant/sanitizer

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.

E.2.2 Type 2 disinfectant/sanitizer

Calculate the water insoluble matter content, S as a percentage by mass, using the formula:

$$S = \frac{m_2}{m_1} \times 100$$

where

m_1 is the mass of the test sample taken, in grams; and

m_2 is the mass of the residue after it has been dried, in grams.

Annex F
(normative)

Notes to purchasers

F.1 The following requirements shall be specified in tender invitations and in each order or contract:

a) the purpose (or intended area of use) for which the disinfectant/sanitizer is required, and the soils to be removed in case of detergent-disinfectants; and

b) materials with which the product might come into contact, and with which it shall be compatible (see 6.2(m)).

NOTE The above requirements may be specified by reference to a manufacturer's data sheet, where available.

F.2 The following requirement shall be agreed upon between the supplier and the purchaser:

— whether the disinfectant/sanitizer is still required to comply with all requirements of the standard after storage (see 4.4.2).

Annex G
(informative)

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

G.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.

G.2 Quality system requirements

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

G.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.

G.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.

G.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.

G.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.

G.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.

G.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.

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

G.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.

G.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.

G.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.

G.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.

G.3 Assessment of quality system

NOTE See note to G.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] *Hard surface disinfectants monograph, Health Canada, June 26, 2015, accessed at http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/disinfect-desinfect/hsd-rev-dsd-eng.php. Access date: 24th/01/2017*

[2] SANS 636, *Disinfectants based on quaternary ammonium compounds*

[3] SANS 643, *Disinfectants based on stabilized inorganic chlorine compounds*

[4] SANS 1082, *Detergent-disinfectants based on phenolic compounds*

[5] SANS 1673, *Disinfectants based on organic halogen compounds (other than iodine compounds), such as fluorine, bromine or chlorine*

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

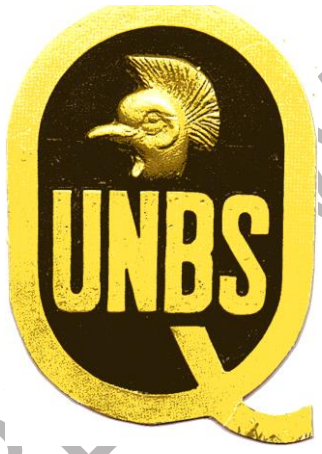
[7] US ISO 9001*, Quality management systems — Requirements*

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