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Disinfectants/sanitizers based on iodophors — Specification

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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].*

Disinfectants/sanitizers based on iodophors — Specification

1 Scope

This draft Uganda standard specifies the requirements and methods of sampling and test for two types of disinfectants/sanitizers that contain iodophor(s) and compatible surface agents that are miscible with water and intended for use on inanimate surfaces. This draft standard is applicable to disinfectants/sanitizers containing iodophor(s) as the sole active ingredient(s), and those containing two or more active ingredients, where iodophors are present. An example of an iodophor is povidone-iodine.

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*

US ISO 10523, *Water quality — Determination of pH*

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
acceptable
acceptable to the authority administering this standard, or to the parties concluding the purchase contract, as relevant

3.3
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

3.4
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
iodophor
a combination of iodine and solubilizing agent (or a "carrier") that contains (and, when diluted with water, slowly liberates) free iodine

3.7
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:** without added acid; or

b) **type 2:** containing an added acid of an acceptable type.

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 pH value

When the disinfectant/sanitizer is tested in accordance with US ISO 10523, at the manufacturer’s prescribed concentration, the pH value shall comply with the appropriate of the following:

a) **type 1:** 4.0 – 7.0 ; and

b) **type 2:** 2.0 – 4.0.

4.5 Water-insoluble matter content

When the disinfectant/sanitizer is tested in accordance with Annex B, at the prescribed concentration, the water-insoluble matter content shall not exceed 5 g/L.

4.6 Storage stability

When the disinfectant/sanitizer is tested in accordance with Annex C,

a) no visible separation shall occur during either the 24 h cooling period or the 24 h warming period; and

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

4.7 Odour, taste and colour

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

4.7.2 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.

4.8 Added colouring matter

The disinfectant/sanitizer shall not contain any added colouring matter and shall pass the test given in Annex D.

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 iodophor(s);

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.

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 water-insoluble matter content

B 1 Procedure

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

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

B.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.

B.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).

B.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.

B.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 C
(normative)

Determination of storage stability

C.1 Reagents

C.1.1 0.02 N sodium thiosulfate ($Na_2S_2O_3$) solution, accurately standardized

C.1.2 Starch solution, 10 g/L

C.2 Procedure

C.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 24 h and then examine the test sample visually for signs of separation.

C.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.

C.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 0.02 N sodium thiosulfate 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.

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

C.3 Calculation

Calculate, as follows, the available iodine content (as a percentage) of each of the four test specimens:

$$A \times N \times 126.9\%$$

where

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

N is the normality of the $Na_2S_2O_3$ solution.

Annex D
(normative)

Determination of added colouring matter

D.1 Reagent

Sodium thiosulphate, 50 g/L aqueous solution.

D.2 Procedure

Using a pipette, 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.

D.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 disinfectant/sanitizer to comply with 4.8.

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 1674, *Disinfectants based on iodophors*

[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