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Disposable wet wipes — Specification

EAST AFRICAN COMMUNITY

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Foreword

Development of the East African Standards has been necessitated by the need for harmonizing requirements governing quality of products and services in the East African Community. It is envisaged that through harmonized standardization, trade barriers that are encountered when goods and services are exchanged within the Community will be removed.

The Community has established an East African Standards Committee (EASC) mandated to develop and issue East African Standards (EAS). The Committee is composed of representatives of the National Standards Bodies in Partner States, together with the representatives from the public and private sector organizations in the community.

East African Standards are developed through Technical Committees that are representative of key stakeholders including government, academia, consumer groups, private sector and other interested parties. Draft East African Standards are circulated to stakeholders through the National Standards Bodies in the Partner States. The comments received are discussed and incorporated before finalization of standards, in accordance with the Principles and procedures for development of East African Standards.

East African Standards are subject to review, to keep pace with technological advances. Users of the East African Standards are therefore expected to ensure that they always have the latest versions of the standards they are implementing.

The committee responsible for this document is Technical Committee EASC/TC 061, Textiles, textile products and accessories.

Attention is drawn to the possibility that some of the elements of this document may be subject of patent rights. EAC shall not be held responsible for identifying any or all such patent rights.

Introduction

Non-woven wet wipes are disposable sanitary products used for light rubbing in order to remove dirt and germs on the skin. In this standard, wet wipes have been classified into personal hygiene and sanitizing wet wipes based on their intended use. Personal hygiene wet wipes are used for baby or adult hygiene (hand, facial, mucous membrane) cleansing purposes. Sanitizing wipes have a double benefit of providing the sanitizing solution used for killing germs as well as removing dirt, grease and other particles off the skin.

Disposable wet wipes — Specification

1 Scope

This Draft East African Standard specifies requirements, sampling and test methods for non-woven disposable wet wipes applicable for general personal hygiene and sanitizing purposes

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 377-1, *Cosmetics and cosmetic products — Part 1: List of substances prohibited in cosmetic products*

EAS 377-2, *Cosmetic and cosmetic products — Part 2: List of substances which cosmetic products must not contain except subject to the restrictions laid down*

EAS 377-4, *Cosmetics and cosmetics products — Part 4: List of preservatives allowed in cosmetic products*

ISO 1833-11, *Textiles — Quantitative chemical analysis — Part 11: Mixtures of certain cellulose fibres with certain other fibres (method using sulfuric acid)*

ISO 3071, *Textile materials; Method for determination of pH value of aqueous extracts*

ISO 9073-1, *Test methods for nonwovens — Part1: Determination of mass per unit area*

ISO 9073-18, *Test methods for nonwovens — Part 18: Determination of breaking strength and elongation of nonwoven materials using the grab tensile test*.

ISO 18416, *Cosmetics — Microbiology — Detection of Candida albicans*

ISO 20743, *Textiles — Determination of antibacterial activity of textile products*

ISO 21149, *Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria*

ISO 21150, *Cosmetics — Microbiology — Detection of Escherichia coli*

ISO 22198, *Textiles — Fabrics — Determination of width and length*

ISO 22717, *Cosmetics — Microbiology — Detection of Pseudomonas aeruginosa*

ISO 22718, *Cosmetics — Microbiology — Detection of Staphylococcus aureus*

3 Terms and definitions

For the purposes of this document, the following terms and definitions shall apply.

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

3.1
non-woven
structures of textile materials, such as fibres, continuous filaments, or chopped yarns of any nature or origin, that have been formed into webs by any means, and bonded together by any means, excluding the interlacing of yarns as in woven fabric, knitted fabric, laces, braided fabric or tufted fabric

3.2
wipe
disposable non-woven material treated with a cleansing or sanitizing agent, rubbed on the skin to remove dirt or germs

3.3
active ingredient
chemical and/or biological component that is included in the formulation of cleaning/sanitizing agents used to treat wipes to achieve their intended purposes

4 Requirements

4.1 General

Disposable wet wipes shall:

a) be in accordance with good manufacturing practices;

b) be of a non-woven construction;

c) be of acceptable uniform make and finish;

d) in case of general personal hygiene wet wipes, they shall be pre-moistened with a non-toxic, hypoallergenic and alcohol free cleansing solution that is completely air dried when applied onto the skin;

e) in case of sanitizing wipes, they shall be pre-soaked with a non-toxic and hypoallergenic concentrated sanitizing solution

f) be made from ingredients complying with EAS 377-1, EAS 377-2 and EAS 377-4;

g) leave no lint on the wiped surface, be free from any foreign matter or any other defect that might impair their appearance or serviceability

4.2 Specific requirements

4.2.1 Fibre composition

When tested in accordance with ISO 1833-11, non-woven disposable wet wipes shall consist of at least 20 % cellulose fibres.

4.2.2 Dimensions

When tested in accordance with ISO 22198 the nominal dimensions of the wipes shall be as declared subject to a tolerance of ± 2 % of the declared dimensions

4.2.3 Performance requirements

Personal hygiene and sanitizing wet wipes shall comply with the performance requirements given in Table 1 when tested in accordance with the test methods specified therein.

Table 1 — Performance requirements for disposable wet wipes

S/N	Parameter		Requirement	Test method
i	Mass per unit area, g/m^2, min.		36	ISO 9073-1
ii	[a]Breaking strength, N, min.	Machine direction (Wet)	30	ISO 9073-18
		Cross direction (Wet)	2.5	
iii	pH of extracted cleansing solution		4.5 – 8.5	ISO 3071
iv	Moisture content, %, min.		50	Annex A
v	[b] Flushability		Pass the test	Annex B
[a] Immerse each sample before testing for at least 60 s in distilled water and test each specimen immediately after removal from the water. [b] Flushability test shall be subjected to wipes that are declared as flushable				

Note Continuous flushing of wipes is liable to cause clogging of sewer systems over time. It is advisable for manufacturers to include warnings for flushable wipes.

4.2.4 Chemical requirements

Personal hygiene and sanitizing wet wipes shall comply with the chemical requirements given in Table 2 when tested in accordance with the test methods specified therein.

Table 2 — chemical requirements for disposable wet wipes

S/N	Parameter mg/kg, max.	Requirement	Test method
i	Lead,	10	EAS 786
ii	Arsenic	2	
iii	Mercury	2	
iv	Cadmium	5	
v	Chlorinated organic compounds	150	ISO 11480

4.2.5 Microbiological requirements

Personal hygiene and sanitizing wet wipes shall comply with the microbiological requirements given in Table 3 when tested in accordance with the test methods specified therein.

Table 3 — microbiological requirements for disposable wet wipes

S/N	Parameter	Requirement		Test method
		Personal hygiene wipes	Sanitizing wipes	
i	Anti-bacterial activity (A) (if declared), min.	2		ISO 20743

ii	Total viable count, cfu/ 1g or 1 mL, max.	100	Not detected	ISO 21149
iii	Pseudomonas aeruginosa, cfu/g	Not detected		ISO 22177
iv	Staphylococcus aureus, cfu/g	Not detected		ISO 22718
v	Candida albicans, cfu/g	Not detected		ISO 18416
vi	Escherichia coli, cfu/g	Not detected		ISO 21150

4.2.6 Active ingredient for sanitizing wipes

Sanitizing wipes shall conform to the active ingredient requirements specified in Table 4 when tested in accordance with the test methods prescribed therein.

Table 4 — Requirements of active ingredients

S/N	Parameter	Requirement	Test method
i	[a]Alcohol content (ethanol and/or isopropanol, n-propanol), %, v/v, min.	60.0	EAS 104
ii	Bacterial efficacy	To pass test	Annex C
[a] Alcohol is the most commonly used active agent. However, other suitable disinfecting agents in appropriate concentrations may be used as substitute agents.			

4.2.7 Biocompatibility

When tested in accordance with the relevant parts of ISO 10993, the sanitizing wipes shall not cause any harmful effect to the skin.

5 Packaging

5.1 Disposable wet wipes shall be packaged in a suitable resealable material presenting no defects that can affect its serviceability

5.2 The primary packaging shall be designed to easily dispense a single towelette at a time keeping the remaining towelettes unexposed to contamination and prevent loss of the moisture or other active ingredients

5.3 Only wipes of the same size shall be packed together in both primary and secondary packages.

6 Labelling

6.1 Primary packaging

a) The primary packaging shall be legibly and indelibly labelled either in English, Kiswahili or French or a combination with the following information:

a) manufacturer’s name, address and/or trade mark;

b) importer/distributors name, address (if applicable);

c) product name and intended use such as “baby wet wipes”, “adult wet wipes” or “sanitizing/disinfection wipes”

d) for sanitizing wipes, the active ingredient used and its percentage composition

e) if anti-bacterial, the declaration, “Anti-bacterial”

f) number of wipes in a package;

g) size of wipes in the package;

h) fibre composition;

i) list of ingredients used;

j) instruction for use, storage and disposal;

k) date of manufacture and expiry; or best before;

l) batch number; and

m) country of origin/manufacture;

6.2. Secondary packaging

The outside of each secondary package shall be legibly and indelibly labelled either in English, Kiswahili or French or a combination with the following information:

a) manufacturer’s name, address and/or registered trade mark;

b) product name and intended use such as “baby wet wipes”, “adult wet wipes” or “sanitizing/disinfection wipes”

c) number of packages;

d) date of manufacture and expiry;

e) batch or lot number; and

f) country of origin/manufacture.

7 Sampling

Random samples of the product shall be drawn for test in accordance with ISO 2859-1.

Annex A
(normative)

Determination of moisture content

A.1 Principle

A specimen of specified mass of filler material of the non-woven disposable wet wipe is dried in an oven at specified temperature and the moisture content is determined.

A.2 Apparatus

A.2.1 **Balance**, with an accuracy of 0.05 % of the weighed mass.

A.2.3 **Sample container,** waterproof when sealed, will be used for transfer of analyzed material and during weighing.

A.2.4 **Oven**, well ventilated with a temperature of 102 ºC to 105 ºC.

A.3 Sample preparation

A.3.1 Take a sufficient number of dry sample containers, number them and take their masses after they are held open for a short period of time so that they will have the same air pressure as the surrounding atmosphere. Then leave them open until you take the test piece.

A.3.2 Take 5 random pieces of the wet wipe. The test pieces shall weigh 5 g.

A.3.3 If the surrounding atmosphere is hot and humid, prevent water condensation on the internal and external surfaces of the container.

A.3.4 Handle the test pieces gently to prevent dirt or changes in water content. Do not touch the test pieces with your bare hands. Put the test pieces in a container just after taking them and close the container immediately.

A.4 Procedure

A.4.1 Dry the test pieces in an oven with a temperature of 102 ºC to 105 ºC. Open the containers lid and dry the specimen inside the container. Open the container for a moment, to balance the air pressure inside the container with the surrounding pressure, weigh the container that holds the specimen again and calculate the weight of the specimen.

A.4.2 First cycle of drying will last at least 30 min. Return the container with the test pieces to the oven, for at least half the first cycles drying time. Take the container out and take the mass with the test pieces inside. Repeat the drying and weighing cycles. When the drying time on every cycle is at least half of the total previous drying cycle times. Continue the process until the difference between two consecutive masses does not exceed 0.1 % of the original mass of the specimen.

A.5 Calculations

Calculate the moisture content using the following formula and round the results up to the nearest 0.1 %.

$$V = 100\ \frac{(a-b)}{a}$$

where,

a is weight of the container with the specimen before drying (in grams);

b is weight of the container with the specimen after drying (in grams); and

V *is water content (in weight %)*

Annex B
(normative)

Determination of flushability

B.1 Apparatus

Use the flushing toilet equipment as described in Figure B.1. The pipes to the septic tank should be transparent acryl tubes to allow the sanitary end of the tube to an open tank so as to collect the products.

B.2 Test method

Throw three wipes into the chamber pot, and flush water (8 to 12 litres per time) from the flush tank.

Dimensions in millimetres

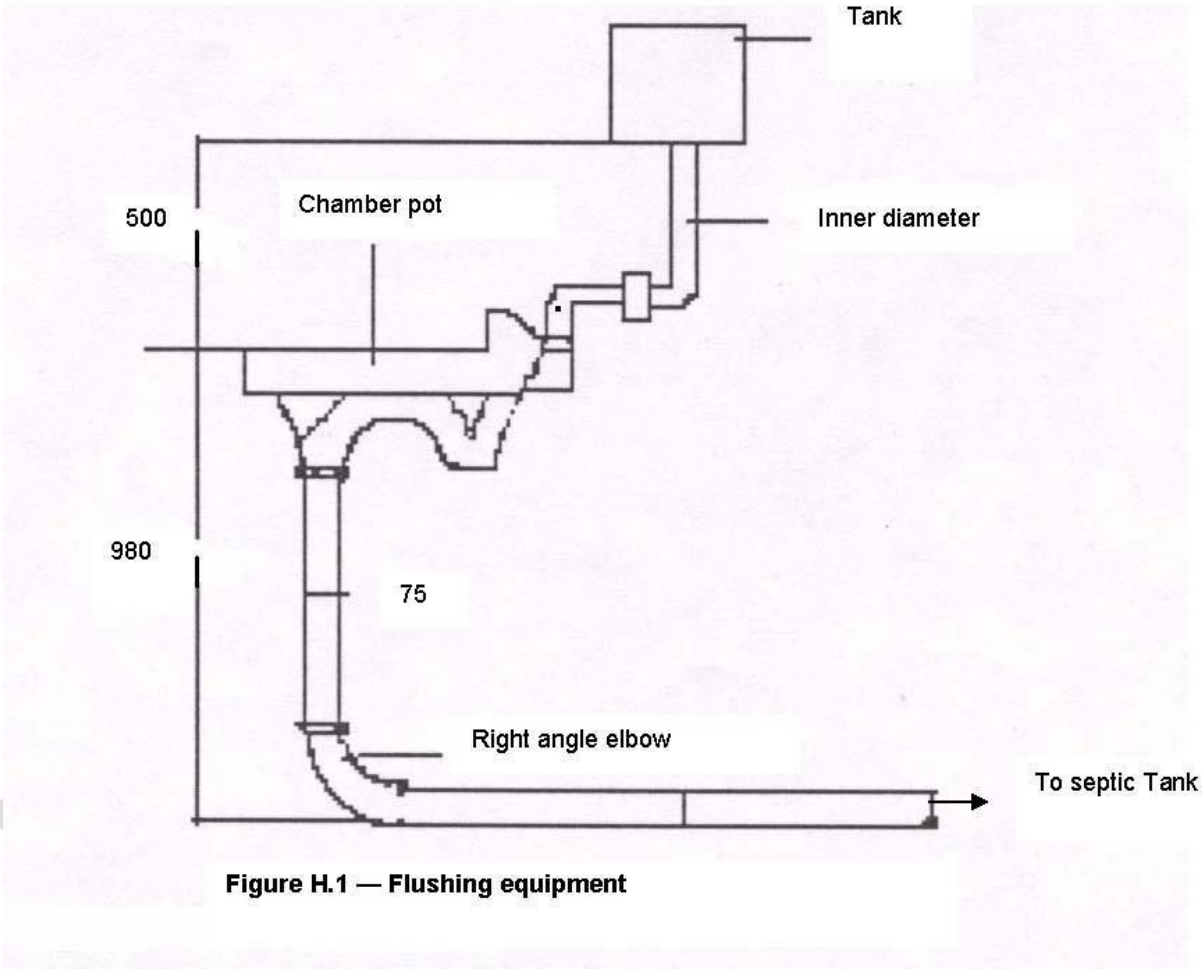

Figure H.1 — Flushing equipment

B.3 Test report

Report whether the wipes are completely flushed down or not.

Annex C
(normative)

Determination of disinfecting efficacy

C.1 Outline of the method

C.1.1 A sanitizing wipe is pressed to obtain the sanitizing solution. The sanitizing solution is tested at the recommended 'use-dilution' and concurrently at 0.5 and 1.5 times that dilution. The test consists of challenging the diluted sanitizer with bacterial inoculum, withdrawing a sample after a given time and culturing the sample in a suitable recovery medium. After this sampling, the mixture is again challenged by a second inoculum and after a second interval, is again sampled for culturing. This process is then repeated to provide a third challenge.

C.1.2 The sample is considered to have passed or failed the test according to the extent of growth shown in the first two cultured samples.

C.2 Apparatus

C.2.1 Facility, for incubation at 37 °C ± 1 °C

C.2.2 Facility, for incubation at 2 °C ± 1 °C

C.2.3 Stop clock, indicating in seconds

C.2.4 Facility, for refrigeration at 4 °C ± 1 °C

C.2.5 Universal containers, made of glass and having metal tops with rubber liners. Plastic containers or glass containers with plastic tops shall not be used.

C.2.6 Test tubes, 19 mm X 150 mm

C.2.7 Filter paper, No. 4 Whatman (sterile) or equivalent

C.2.8 Facility, for autoclaving at 121 °C ± 1 °C

C.2.9 Pipette, capable of dispensing 0.02 mL ± 0.005 mL

C.2.10 pH meter

C.2.11 Facility, to sterilize by filtration

C.2.12 150 µm test sieve

C.2.13 Oven, capable of maintaining temperature at 100 °C ± 1 °C

C.3 Media

C.3.1 Growth media for test organisms

C.3.1.1 The growth media for test organisms shall be Wright and Mundy Broth with Dextrose (WMBD).

C.3.1.2 Dispense 10 mL and 6 mL quantities of the Wright and Mundy Broth into universal bottles, and autoclave at 121 °C ± 1 °C for 12 min.

C.3.1.3 Add to this medium, 10 % (m/V) dextrose solution sterilized by filtration, to give a final dextrose concentration of 0.1 % (m/v), (that is, to 10 mL broth add 0.1 mL dextrose solution and to 6.0 mL broth add 0.06 mL dextrose solution).

C.3.2 Recovery medium

C.3.2.1 Composition

A nutrient broth prepared as follows:

a) beef extract, 10 g;

b) peptone, 10 g;

c) sodium chloride, 5 g; and

d) polyoxyethylene sorbitan mono-oleate, 30 g

C.3.2.2 Preparation

Add the ingredients to 1 000 mL of water. Mix well. Dispense 10 mL quantities into test tubes and autoclave at 121 °C ± 1 °C for 15 min**.**

C.3.3 Hard water

Standard hard water with 342 mg/L (ppm) hardness prepared as follows: dissolve 0.304 g of anhydrous calcium chloride hexahydrate ($MgCl_2.6H_20$) in distilled water and make up the volume to one litre. Sterilize the standard hard water by autoclaving at 121 °C ± 1 °C for 15 min. Allow this to reach room temperature before use.

C.3.4 Yeast suspension

C.3.4.1 Weigh to the nearest gram about 65 g of active dry yeast. Cream by the gradual addition of sterile hard water (C.3.3) using a heavy glass rod for stirring. Decant the creamed portion into a flask, add more hard water to any lumpy residue remaining and repeat the creaming and decantation until no residue remains, and 500 mL of hard water has been used.

C.3.4.2 Shake the contents of the flask vigorously and strain-through a 150 µm sieve (C.2.12) breaking down any remaining lumps.

C.3.4.3 Add 500 mL sterile hard water, shake vigorously.

C.3.4.4 Transfer 50 mL or 100 mL portions into screw-capped bottles, screw the caps tightly and autoclave at 121 °C ± 1 °C for 15 min. Allow the autoclave to cool without releasing the pressure. Store cold but not freezing.

C.3.4.5 Dry two glass petri-dishes to constant mass. Into each of these dishes, pipette 25 mL of sterilized yeast suspension and dry to constant mass at 100 °C. Calculate the average solids content of the suspension.

C.3.4.6 Before use, pipette 25 mL of the sterilized yeast suspension into a beaker. Determine the pH using a glass electrode, and determine the volume of 40 g/L sodium hydroxide solution needed to adjust the pH to 7.0 ± 0.1.

C.3.4.7 Immediately before use, add to each bottle of sterilized yeast suspension a volume of sterile hard water and a volume of 40 g/L sodium hydroxide calculated to adjust the concentration of dry yeast to 5 % (m/v) and the pH to 7.0 ± 0.1. Discard prepared yeast, two weeks after preparation.

C.3.5 Ringers solution, 25 % (v/v)

Dissolve 9.00 g of sodium chloride, 0.42 g of potassium chloride, 0.24 g of anhydrous calcium chloride and 0.20 g of sodium bicarbonate in water and dilute to 1 000 mL. Add one volume of this solution to three volumes of water to give a 25 % solution. Dispense into test tubes fitted with suitable closures and sterilized by auto-claving at 121 °C ± 1 °C for 15 min.

C.4 Selection of the most resistant organism by the minimum inhibitory concentration test

C.4.1 The following organisms shall be used for the test:

a) *Pseudomonas aeruginosa* (NCTC 6749 or equivalent);

b) *Proteus vulgaris* (NCTC 4635 or equivalent); and

c) *Staphyloccus aureus* (NCTC 4163 or equivalent).

These organisms may be obtained as freeze dried cultures. Once sub-cultured, the organisms shall be maintained on agar slopes of suitable nutrient medium at 4 °C ± 1 °C.

C.4.2 Subculture each organism daily into a universal bottle containing 6 mL of growth medium (see C.3.1) and incubate for 24 h ± 2 h at 37 °C ± 1 °C.

C.4.3 Dilute one part of freshly grown sub-culture of each organism, which is at least a fifth sub-culture and not more than a fourteenth, with ten parts of the growth medium (see C.3.1) before dilution, the *P. aeruginosa*, culture shall be filtered using a Whatman No.4 filter paper.

C.4.4 Prepared three sets of ten, doubling dilutions of the sanitizer in universal containers (C.2.5). For this purpose dilute the neat sanitizer in the growth medium (see C.3.1) or the recovery medium (C.3.2) to give a final volume of 5 mL of the diluted sanitizer for each dilution.

C.4.5 Inoculate each dilution in one set with 0.02 mL of a diluted culture of one organism (see C.4.3).

C.4.6 Incubate all the three sets of inoculate dilutions at 37 °C ± 1 °C for 72 h, and examine to determine the organism most resistant to the sanitizer, that is the organism for which the minimum inhibitory concentration is highest.

C.5 Preparation of inoculum

C.5.1 Daily sub-cultures of the test organism selected as in A.4.6 shall be grown in 6 mL quantities of the growth medium (C.3.1) and incubated at 37 °C ± 1 °C for 24 h ± 2 h.

C.5.2 The day before the test, inoculate 10 mL of the growth medium (C.3.1) with the test organism from a daily sub-culture and not more than a fourteenth. Incubate the inoculated, broth at 37 °C ± 1 °C for 24 h ± 2 h.

C.5.3 Add 6 mL of the test organism culture (C.5.1) and (C.5.2) to 4 mL of the yeast suspension (C.3.4) thus making a final concentration of 2 % (m/v) of yeast in the yeast/organism suspension. If a culture of *P. aeruginosa* is used, it shall be filtered using a Whatman No.4 filter paper before addition.

C.5.4 Shake the yeast/organism suspension for one minute with a few sterile glass beads. Immediately before the test, count the number of viable organisms in the inoculum by decimal dilutions in 25 % Ringers solution (see C.3.5) and by the drop plate method. The viable count shall be not less than 10^8 organisms/mL or more than 10^{10} organisms/mL or the test results are considered invalid.

C.6 Preparation of the sanitizer dilutions

Prepare three dilutions of the sanitizer in hard water (C.3.3) based on the recommended 'use dilution' of the sanitizer, as follows:

- A = 0.5 times the recommended 'use-dilution';
- B = 1.0 times the recommended 'use-dilution'; and
- C = 1.5 times the recommended 'use-dilution'.

The sanitizer dilutions shall be prepared and tested on the same day.

C.7 Test procedure

C.7.1 The test shall be carried out at 27 °C ± 1 °C.

C.7.2 Dispense 3 mL of each dilution of sanitizer (C.6) into separate universal bottles labelled A, B, and C, then allow to equilibrate to 27 °C ± 1°C.

C.7.3 Add 1 mL of the inoculum to A, B and C at 0, 1 and 5 min respectively and mix by swirling gently.

C.7.4 Eight minutes after the addition of the inoculum, remove a sample of the inoculum/sanitizer mixture and put 0.02 mL into each of the first group of five tubes of recovery broths. Return the remainder of the mixture in the pipette to the universal container.

C.7.5 Ten minutes after the first addition of the inoculum, add another 1 mL of the inoculum to each of the sanitizer dilutions and mix by swirling gently

C.7.6 After 8 min, remove a sample of the mixture as put before (C.7.4) and put 0.02 mL into each of the second group of five tubes of recovery broths.

C.7.7 Twenty minutes after the first addition of the inoculum, add a further 1 mL of inoculum to each of the sanitizer dilutions and mix by swirling gently.

C.7.8 After 8 min, remove a sample of the mixture as before and place 0.02 mL into each of the third group of five tubes of recovery broths.

C.7.9 Swirl the recovery broths and incubate at 37 °C ± 1 °C for 48 h ± 2 h. Examine the growth and record the results.

C.8 Interpretation of results

C.8.1 The sanitizing wipe, shall be regarded as having passed the test at the recommended ‗use dilution' if there is no growth in at least two of the five recovery broths for the first and second additions of the inoculum.

C.8.2 To be acceptable, the sanitizing wipe shall pass the test on three separate occasions using freshly prepared sanitizing solution and freshly prepared inoculum on each occasion.

Bibliography

[1] FDKS 2720:2021, Non-woven disposable wet wipes — Specification

[2] DRS 439:2020, Non-woven skin care wet wipes– Specification

