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Disposable adult diapers — 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

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Disposable adult diapers — Specification

1 Scope

This draft East African Standard specifies requirements and test methods for disposable adult absorbent products for managing incontinence including adult diapers, adult briefs, adult under pads (inserted in pants) and others.

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.

ISO 139, *Textiles — Standard atmospheres for conditioning and testing*

ISO 3071, *Textiles — Determination of pH of aqueous extract*

ISO 4833-2, *Microbiology of the food chain — Horizontal method for the enumeration of microorganisms — Part 2: Colony count at 30 C by the surface plating technique*

ISO 7218, *Microbiology of food and animal feeding stuffs — General requirements and guidance for microbiological examinations (2nd Edition)*

ISO 11948-1, *Urine-absorbing aids — Part 1: Whole-product testing*

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

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 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

Incontinence products

hygienic products specifically developed to help manage bladder or bowel control problems with the capability to absorb urine and prevent stool and fluid from leaking out

- 3.2**
absorbent filler material
the material at the core of the diaper that absorbs fluids
- 3.3**
Top sheet run-off
The unabsorbed volume of test solution while running across the surface of inclined specimen
- 3.4**
Rewet
The mass of test solution which returns to surface under specific pressure after a certain amount of that being absorbed by the specimen
- 3.5**
Leakage
The mass of test solution which penetrates the leak-proof carrier film under specific pressure after a certain amount of that being absorbed by specimen
- 3.6**
Rate of Absorbency (ROA)
Time required to fully absorb test fluid into the test product. A specified quantity of simulated urine is discharged at a prescribed rate under specified conditions onto a test specimen of an absorbent article with a nonwoven cover. The time taken for the entire liquid dose to penetrate the nonwoven is measured
- 3.7**
Retention Capacity
A measure of a product's capacity to hold fluid without leaking and rewetting the skin
- 3.8**
disposable adult diaper
disposable hygienic pad for adults having capability to absorb urine and prevent stool and fluid from leaking out

4 Requirements

4.1 Materials

All materials used for making absorbent products shall not harm the skin in contact. None of the components in the products, including additives, should be listed in any Regulatory Agency as being “unsafe”

4.1.1 Absorbent filler

- a) it shall allow for air circulation and be comfortable for the baby.
- b) it shall be clean, free from harmful foreign materials, lumps, splits, holes and protruding points when visually examined; and
- c) it shall be arranged in a manner that will draw in and trap all moisture rapidly and efficiently and keeps it away from the adult’s skin.

4.1.2 Top Sheet (the layer which contacts adult’s skin)

- a) shall be of material that helps absorption, and shall have no harmful effect; and
- b) shall cover the absorbent filler completely and prevent the filler from reaching the adult’s skin or clothes under normal handling.

4.1.3 Back sheet

There shall be an outer cover to prevent direct contact of the absorbent filler with the adult’s clothing and to prevent liquid leakage out of the absorbent product.

4.1.4 Fastening device (closure system)

There shall be a suitable device for fastening the absorbent products for secure use. The closure system regardless of how its functionality is achieved should allow for multiple fastening and unfastening. This promotes better fit and allows for easy check of wetness without having to dispose off and replace soiled product

4.1.5 Breathability

There should be a minimum air flow sufficient to release trapped body heat or gaseous body perspiration in the pelvic region

4.2 Key performance requirements

Adult absorbent products shall comply with the performance requirements given in Table 1 when tested in accordance with the methods specified therein.

Table 1 — Characteristics of disposable adult absorbent products

Characteristics	All size categories	Test methods
Rate of absorption, s, (max)	85	Annex A
Rewet under load, g, (max)	5	Annex A

Absorptive capacity (min)	1200	ISO 11948-1
pH	6 – 8.5	ISO 3071

4.3 Microbiological requirements

- a) the total viable bacterial count, when determined in accordance with B.4.1 shall not exceed 100 CFU / g; and
- b) when tested in accordance with ISO 21149, disposable diapers shall be free from *E. coli*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa* and *C. albicans* in 1 g of product

5 Packaging and marking

5.1 Packaging

Disposable adult absorbent products shall be packed in a suitable waterproof package that shall protect them from any form of contamination and damage. Packaging for shipment shall be in accordance with the manufacturer's standard practice and in a manner readily accepted by the market. Within the shipping carton, units shall be packed in manner designed to minimize damage during shipment due to rough or improper handling.

5.2 Marking

On both the primary and secondary packages, the disposable adult absorbent product packs shall be marked with legible and indelible pre-printed marking or a securely affixed and durable label bearing the following information:

- a) name of products;
- b) name and address of the manufacturer and/or importer/distributor (if applicable);
- c) number of pieces in the pack;
- d) instruction for use, storage and disposal;
- e) date of manufacture and expiry;
- f) batch/ lot number; and
- g) country of origin.

6 Sampling

6.1 Lot

In any consignment, all packages of the adult absorbent product belonging to one batch of manufacture or supply shall constitute a lot.

6.2 Scale of sampling

6.2.1 Samples shall be tested from each lot ascertaining its conformity to the requirements of this specification.

6.2.2 The number of packages to be selected from a lot shall be in accordance with Table 2.

Table 2 –scale of sampling

Number of packages in a lot	Number of packages to be selected
Up to 250	6
251-500	8
501-1000	11
1001-2500	15
2501-5000	20
5001 and above	30

6.2.3 The bulk packages and packages shall be selected at random

6.3 Number of tests

6.3.1 Each package selected as per table 2 shall be inspected for packaging and marking requirements

6.3.2 Disposable adult diapers selected as per table 2 shall be examined for requirements stipulated in clause 4

Annex A (normative)

Rate of absorption and rewet test

A.1 Scope and Purpose:

- a) To measure the ability of an absorbent products to accept and retain synthetic urine (saline solution) under simulated in-use conditions of load and pressure.
- b) To determine amount of time required for an absorbent article to absorb a fixed quantity of a test solution

A.2 Principle

The method measures the ability of the absorbent products to accept and retain 0.9% saline solution under simulated in-use conditions of load and pressure

A.3 Apparatus and materials

- a) a rigid cover plate with a weight as shown below. Dimensions of the plate (200 mm \pm 2 mm) x (70 mm \pm 2 mm). Inner diameter of cylinder 40 mm \pm 2 mm, total Weight: 6300 g \pm 10 g representing a pressure of 4.41 kPa \pm 0.05 kPa (0.64 psi \pm 0.007 psi) for all sizes
- b) tray;
- c) filter paper; having a diameter of 110 mm and conditioned together with the test samples
- d) graduated cylinder (1 ml graduation);
- e) stopwatch;
- f) ruler (at least 2 cm longer as absorbent core of the sample, 1mm graduation); and
- g) a pen.

A.4 Saline solution

Add 9 g sodium chloride, and 1 g of blue dye into 200 mL distilled water at ambient temperature after which the solution is made up to 1 Liter. The pH shall be between 6.2 – 6.7. When not within this range, adjust by using 0.1 mol/L sodium hydroxide solution or acetic acid as relevant. The temperature of the solution shall be 37 °C \pm 2 °C, and shall be maintained in a water bath during testing.

A.5 Saline dosage

Measure out the volume of saline solution for each of the products being tested as follows:

- a) adult disposable diaper (brief) of size: Medium to XX-Large, Single dose of 200 ml

- b) adult disposable diaper (brief) of size: Small, Single dose of 100 ml
- c) all sizes of adult disposable under-pads/ underpants: Single dose of 100 ml

A.6 Sample preparation and Set-up

- a) conditioning: Bring samples to moisture equilibrium in the standard atmosphere for testing nonwovens in accordance with ISO 139. Equilibrium is considered to have been reached when the increase in mass of the specimen in successive weighings made at intervals of not less than 2 hours does not exceed 0.25 % of the mass of the specimen;
- b) take 5 test specimens randomly from the test samples;
- c) weigh a stack of dry filter paper and record as weight W1. The stack should have a dry weight of about 10.0 grams;
- d) mark the loading point in the middle of the absorbent core. Note that the absorbent core does not cover the full length of the diaper but it is more concentrated in the front of the diaper. Therefore, the middle of the absorbent core will not be the same as the middle of the diaper: Measure the length and width of the absorbent core. Mark the midpoint, which will be the loading point;
- e) place core with top sheet facing upward on the tray;
- f) place rigid cover plate, ensure the plate is centered towards the width of the diaper core and the cylinder opening is placed over marked loading point. Diaper should be stretched showing minimum amount of wrinkles;
- g) gently place weights on the plate (ideally use weight in a ring form to allow for equally applied pressure);
- h) fill the measuring cylinder with respective amount of saline solution;
- i) gently pour the saline onto the diaper starting the stop watch at the same time with the pouring;
- j) stop the stopwatch as soon as the saline solution has been absorbed by the diaper (all the wet sheen has disappeared) and record the result in seconds as the rate of absorption;

Rewet test

- a) leave the diaper undisturbed for 10 min;
- b) lift the weight and cover plate and place the filter paper stack on the absorption point of the diaper;
- c) replace the cover plate and the weight for 2 min on top of the filter paper stack;
- d) after 2 min, remove the weight and cover plate and immediately determine and record the weight of the wet filter paper stack as W2; and
- e) repeat the procedure on the remaining test specimens recording each result separately;

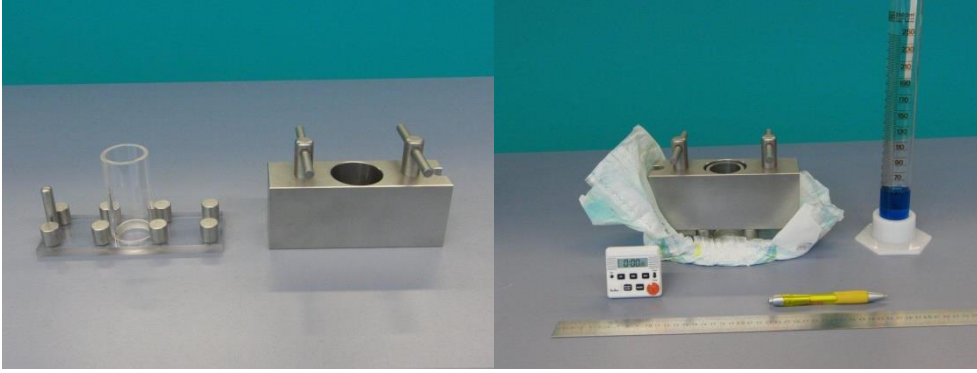


Fig A.3: apparatus and set up

A.7 Calculation of results

A.7.1 Calculate as the rate of absorption in s, the mean time for absorption recorded in (j) above.

A.7.2 $REWET (g) = W2 (Wet\ filter\ paper\ weight) - W1 (Dry\ filter\ paper\ weight)$. Report the average of the 5 products tested

Annex B (normative)

Microbiological Examination

B.1 Apparatus and equipment

Use apparatus and equipment complying with the relevant requirements of ISO 7218.

B.2 Media and reagents

B.2.1 General

Ensure compliance with the general requirements for the ingredients and for the preparation of media and reagents given in ISO 7218

B.2.2 Bacteriological peptone

Peptone	10 g
Disodium phosphate dodecahydrate	1 g
Sodium chloride	5 g
Mono-potassium phosphate	1.5 g

Dissolve the ingredients in distilled water and make up to 1 L. Adjust the pH value to be 7.0 ± 0.1 after sterilization. Dispense 300 mL volumes into flasks of capacity 500 mL and sterilize by autoclaving at $121 \text{ }^\circ\text{C} \pm 2 \text{ }^\circ\text{C}$ for 20 min.

B.2.3 Plate count agar

Agar	15 g
Glucose	1 g
Tryptone	5 g
Yeast extract	2.5 g

Dissolve the ingredients in distilled water, made up to 1 litre, and adjust the pH value to 7.2 ± 0.2 . Dispense 15 mL volumes into bottles and sterilize by autoclaving at $121 \text{ }^\circ\text{C} \pm 2 \text{ }^\circ\text{C}$ for 20 min.

B.2.4 Neutral red-bile salt peptone glucose medium

Peptone	20 g
Glucose	10 g
Bile salts No. 3	1.5 g

Sodium chloride	5 g
Neutral red	0.03 g
Crystal violet	0.002 g

Dissolve the ingredients in 400 mL of distilled water and make up to 500 mL boiling to aid solution. Adjust the pH value to 7.4 and filter to a clear solution. Dispense 10 mL volumes into bottles each containing a Durham tube and sterilize by autoclaving at $121 \text{ }^{\circ}\text{C} \pm 2 \text{ }^{\circ}\text{C}$ for 20 min

B.2.5 Fluid soybean-casein digest medium

Pancreatic digest of casein	17 g
Papaic digest of soybean meal	3 g
Sodium chloride	5 g
Dibasic potassium phosphate	2.5 g
Dextrose	2.5 g

Dissolve the ingredients in distilled water and make up to 1 litre, warming slightly to aid solution. Cool the solution to room temperature and adjust the pH value to be 7.3 ± 0.2 after sterilization. Filter to clarify (if necessary), dispense into suitable containers, and sterilize by autoclaving at $121 \pm 2 \text{ }^{\circ}\text{C}$ for 20 min.

B.2.6 Centrimide agar medium

Pancreatic digest of gelatine	20 g
Magnesium chloride	1.4 g
Potassium sulphate	10 g
Agar	13.6 g
Cetyltrimethylammonium bromide (Cetrimide)	0.3 g
Glycerine	10 mL

Dissolve all the solid ingredients in distilled water, make up to 1 L, and then add the glycerine. Heat, agitating frequently, and boil for 1 min. Adjust the pH value to be 7.2 ± 0.2 after sterilization. Dispense into suitable containers and sterilize by autoclaving at $121 \text{ }^{\circ}\text{C} \pm 2 \text{ }^{\circ}\text{C}$ for 20 min.

B.2.7 *Pseudomonas* agar medium for detection of fluorescein

Pancreatic digest of casein	10 g
Peptic digest of animal tissue	10 g
Anhydrous dibasic potassium phosphate	1.5 g
Magnesium sulphate (MgSO ₄ .7H ₂ O)	1.5 g
Glycerine	10 mL
Agar	15 g

Dissolve all the solid ingredients in distilled water, make up to 1 L, and then add the glycerine. Heat, agitating frequently, and boil for 1 min. Adjust the pH value to be 7.2 ± 0.2 after sterilization. Dispense into suitable containers and sterilize by autoclaving at $121 \text{ }^\circ\text{C} \pm 2 \text{ }^\circ\text{C}$ for 20 min.

B.2.8 *Pseudomonas* agar medium for detection of pyocyanin

Pancreatic digest of casein	20 g
Anhydrous magnesium chloride	1.4 g
Anhydrous potassium sulphate	10 g
Agar	15 g
Glycerine	10 MI

B.3 Preparation of Test Suspension

Transfer 300 ml of the sterile solution of bacteriological peptone (B.2.2) to a sterile wide-mouthed jar of capacity not less than 1 litre and not more than 2 litres. The jar shall have a mouth of diameter not less than 150 mm and not more than 250 mm, and is fitted with a hermetically closing glass or metal-and-glass lid. Aseptically place the towel under test in the solution in the jar, fit the lid, agitate the contents of the jar for 2 min and then allow the jar to stand for 10 min. Repeat this agitating and standing procedure twice more. Aseptically remove about 100 ml of the test suspension for testing as described in B.4 below.

B.4 Procedure

B.4.1 Total viable bacterial count

Into each of three sterile petri dishes aseptically pipette a 1 mL portion of the test suspension. To each dish add 15 mL of freshly melted plate count agar that has been cooled to $45 \text{ }^\circ\text{C}$, and mix well. Incubate, count and calculate the total count as described in ISO 4833 Part 2. From the total viable bacterial count and the mass of the sanitary towel, calculate the total viable bacterial count per gram of sanitary towel.

B.4.2 Examination for the presence of *Enterobacteriaceae*.

Aseptically add 10 mL of the test suspension to a bottle that contains neutral red-bile salt peptone glucose medium (B.2.4). Incubate the bottle for 24 h to 36 h at $37 \pm 0.5^\circ\text{C}$ and examine for the presence of *Enterobacteriaceae*s evidenced by the formation of acid and gas.

B.4.3 Examination for the presence of *Staphylococcus aureus*.

Use the media, reagents and procedure described in ISO 22718 to examine the test suspension (see B.3). As a control, pipette 0.1 mL of a 1:1000 dilution of an 18 h to 24 h culture of *Staphylococcus aureus* SATCC Sta 10 into *Staphylococcus* medium and proceed as with the test suspension.

B.4.4 Examination for the presence of *Pseudomonas aeruginosa*

- a) Use the media, reagents and procedure described in ISO 22717. Aseptically pipette 10 mL of the test suspension into 90 mL of fluid soybean-casein digests medium (B.2.5) and mix well. Incubate for 24 h at $30 \text{ }^\circ\text{C}$ to $35 \text{ }^\circ\text{C}$. By means of an inoculating loop transfer a portion from the 24 h incubated sample tube of fluid soybean-casein digest medium to the dry surface of petri dishes each containing approximately 20 mL of Cetrimide agar medium (B.2.6). Incubate at $30 \text{ }^\circ\text{C}$ to $35 \text{ }^\circ\text{C}$ and examine after 24h, and again after 48 h incubation, for suspect colonies, bearing in mind that in general greenish

fluorescent colonies are typical of *Pseudomonas aeruginosa* and that in its presence a gram stain examined microscopically will reveal gram-negative slender rod-shaped cells.

- b) As a control, add 0.1 ml of a 1:1 000 dilution of an 18 h to 24 h culture of *Pseudomonas aeruginosa* SATCC Pse 11 mL to 100 mL of fluid soybean-casein digest medium (B.2.5), and proceed as with the test suspension.
- c) If none of the colonies obtained from the test suspension conforms to the description given in i) above and the control culture has been satisfactorily recovered, deem the test sample to be free from *Pseudomonas aeruginosa*.
- d) If colonies conforming to the description given in i) above are found, streak representative suspect colonies from the Cetrimide agar onto the surfaces of *Pseudomonas agar* medium for the detection of fluorescein (B.2.7) and *Pseudomonas agar* medium for the detection of pyocyanin (B.2.8) to obtain isolated colonies. Cover and invert the petri dishes and incubate at 30 – 35 °C for at least 3 days. Examine the streaked surfaces under ultraviolet light for suspect colonies, as described in Table B.1.

Table B.1 — Description of colonies

Medium	Description of colonies
<i>Pseudomonas agar</i> for the detection of fluorescein	Generally colourless to yellowish Yellowish fluorescence in ultra violet light
<i>Pseudomonas agar</i> for the detection of pyocyanin	Generally greenish. Blue fluorescence in ultraviolet light

If any further doubt exists as to the identity of the colonies, obtain final confirmation by inoculating the suspect colonies to the wells on commercially available diagnostic kits in accordance with the manufacturer's instructions.

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