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DRAFT EAST AFRICAN STANDARD

Disposable baby diapers — Specification

EAST AFRICAN COMMUNITY

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Contents

Page

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. XXXXXX.

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

Baby diapers and pants are personal hygiene products that are designed to contain the baby's urine and faeces in order to avoid soiling the baby's clothing, beddings and the surrounding environment. They are fastened around the baby's legs and bottom to help prevent leakage. These products aim to provide maximum comfort for the baby and maximum convenience to the care giver.

A disposable diaper consists of an absorbent core sandwiched between two or more sheets of nonwoven fabric. The core is specifically designed to absorb and retain urine and contain faeces, and the nonwoven fabric may be soft and cut in such a way that it is comfortable to wear and prevents leakage. When properly fitted, the diaper will retain the body fluids which pass through the top sheet and are absorbed into the core.

The baby diapers are generally available according to size and weight of the baby. Typical functions of baby diapers include:

- Absorb and retain urine
- Contain faeces/stool to prevent soiling of the baby's environment (clothes, bedding)
- Isolate wetness from the baby's skin

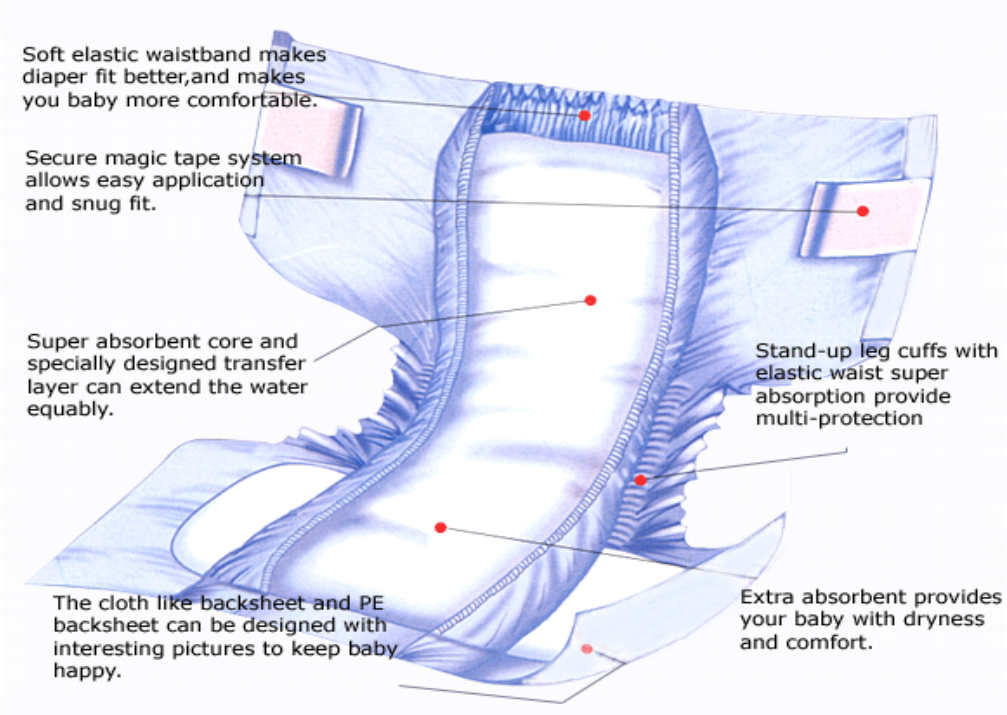

Figure 1 — Baby diaper

Disposable baby diapers — Specification

1 Scope

This draft East African Standard specifies the requirements and test methods for disposable baby diapers.

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 217-1, *Methods for the microbiological examination of foods — Part 1: General procedures and technique*

EAS 217-5:2001, *Methods for the microbiological examination of foods — Part 5: Enumeration of coagulase-positive staphylococci in foods*

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 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
disposable baby diapers
disposable hygienic pad for babies having capability to absorb urine and prevent stool and fluid from leaking

3.2
Super Absorbent Polymer (SAP)
granular cross-linked sodium polyacrylates material used as absorbent core with high retention capacity in disposable diapers

3.3
Acquisition/Distribution Layer (ADL)
component of an absorbent hygiene product through which the fluid is transferred and distributed within the absorbent core

3.4
top sheet (coverstock)
the outer layer of an absorbent hygiene product that is in direct intimate contact with the user's skin. It allows gradual transfer of the fluid from the point of contact to the inside of the product

3.5
back sheet
impermeable layer of an absorbent hygiene product made of either polymer film or nonwoven film designed to prevent wetness transfer from the wearer to their bed or clothes

4 Requirements

4.1 Classification

Diapers shall be classified according to the weight of the baby. The intended baby weight shall be declared on the label.

4.2 General Requirements

Baby diapers shall be manufactured, stored and packed under hygienic conditions to minimise contamination of the product and shall be disposable. The diapers shall present a neat, well finished appearance and shall be free from all defects which might affect the functionality of the diaper.

4.3 Materials

The materials used for making the diapers shall be free from harmful foreign materials and shall not harm the baby's skin.

4.3.1 The absorbent core shall:

a) consist of cellulose fibres fluff pulp and superabsorbent polymer for absorption of fluids

b) be clean and free from lumps, splits, holes, and protruding points when visually examined; and

c) be arranged in a manner that will speed up the absorption of urine and keep it away from the baby's skin.

4.3.2 The top sheet (the layer which contacts the baby's skin) shall:

a) be of material capable of allowing fluid to pass readily through to the next layer and shall resist moisture return to the skin. It shall have no harmful effects;

b) cover the absorbent core completely and prevent the core from reaching the baby's skin or clothes under normal handling; and

c) be soft and shall cause no irritation to the skin.

4.3.3 The back sheet (outer cover) shall

a) prevent direct contact of the absorbent core with the baby's clothing and there shall be no liquid leakage out of the diapers; and

b) allow for air circulation and be comfortable for the baby.

4.3.4 There shall be a device e.g. elastic band or sticky fasteners for ensuring a good fit of the diapers on the baby's femurs and to prevent leakage at the femurs without causing rubefacient effects.

4.3.5 There shall be a suitable device for fastening the diaper at the waist for secure use without causing rubefacient effects.

4.3.6 Adhesive used shall prevent shifting of the absorbent core.

4.3.7 Each material component of the diaper should be bound to the adjacent component to enhance strength and prevent shifting of the absorbent core

4.4 Other physical characteristics

Other physical characteristics of the diapers shall comply with the requirements given in Table 1.

Table 1 — Characteristics of disposable diapers

Characteristics	Weight[a] kg					Test methods
	Up to 4	4.1 - 6	6.1 - 9	9.1 – 15	Above 15	
Rate of absorption per gush, min, (max)	2.5	2.5	2.5	2.5	2.5	Annex A
Absorptive capacity, mL (min)	3 x 20	3 x 35	3 x 50	3 x 60	3 x 70	Annex A
Rewet under load,g (max)	5	5	5	5	5	Annex A
pH[b]	6 – 8.5	6 – 8.5	6 – 8.5	6 – 8.5	6 – 8.5	ISO 3071

NOTE Re-wet test: the purpose of this test is to examine the ability of diapers' top sheet to resist transportation back on to the skin of a liquid which has already penetrated the top sheet. The rewet under load simulates the effect of a baby sitting on a wet diaper. The lesser the rewet value, the better the performance of the diaper.

[a] The weight is the upper limit of the declared weight by the manufacturer.

[b] For products containing SAP or jelly forms, dilute with more distilled water before determining the pH.

4.5 Microbiological requirements

The microbiological limits shall be as defined below;

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 Packing and/or packaging

Diapers shall be packed in a suitable 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

The diaper 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 contents;

b) name and address of the manufacturer;

c) number of diapers;

d) intended baby weight in kilograms ;

e) instruction for storage and disposal;

f) instruction for use;

g) date of manufacture and expiry;

h) batch/ lot number;

i) country of origin; and

j) any perfume, lotion , powder and any other substance added on to the diaper shall be declared.

Annex A
(normative)

Determination of rate of absorption, absorptive capacity and rewet under load

A.1 Principle

The intention of this method is to test the minimum fluid handling performance requirement of diapers; the outcome of the test will be a “Pass” or “Fail” result.

This test simulates the introduction of urine into a diaper under the following conditions;

a) The diaper is tested under pressure to simulate real wearing conditions i.e. to mimic the pressure that the baby applies onto the diaper when wearing it.

b) Specific loading volumes are used for each diaper size

A.2 Apparatus and materials

A.2.1 A rigid cover plate with a weight as shown in Figure A.1

Dimensions of the plate (200 mm ± 2 mm) x (70 mm ± 2 mm). Inner diameter of cylinder 40 mm ± 2 mm, total Weight: 6300 g ± 10 g representing a pressure of 4.41 kPa ± 0.05 kPa (0.64 psi ± 0.007 psi) for all sizes

A.2.2 Tray

A.2.3 Filter paper, having a diameter of 110 mm and conditioned together with the test samples.

A.2.4 Graduated cylinder (1 ml graduation)

A.2.5 Stopwatch

A.2.6 Ruler (at least 2 cm longer as absorbent core of the sample, 1mm graduation)

A.2.7 Pen

A.2.8 Weighing scale

A.2.9 0.9% Saline solution (22 – 24 ºC): 9 g sodium chloride, and 1 g of blue dye added into 200 mL distilled water at ambient temperature after which the solution is made up to 1 L. 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 required.

Depending on the size of the diaper, the following amount of saline solution shall be used

Table A.1: Volume of saline solution per size of Diaper

Category (informative)	**Baby weight,** Kg	**Volume of saline solution (mL)**

Newborn / Extra small	Up to 4	3 x 20
Small	3 – 6	3 x 35
Medium	4 – 9	3 x 50
Large	7 and above	3 x 60

A.3 Sample preparation and set-up

A.3.1 Condition the test samples in accordance with ISO 139 before taking the test specimens required for the tests

A.3.2 Take 5 test specimens randomly from the test samples

Determination of absorption capacity

A.3.3 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.

A.3.4 Place core with top sheet facing upward on the tray

A.3.5 Place the rigid cover plate onto the diaper ensuring that the plate is centered towards the width of the diaper core and the cylinder opening is placed over marked loading point as per Figure A.1. The diaper should be stretched showing minimum number of wrinkles.

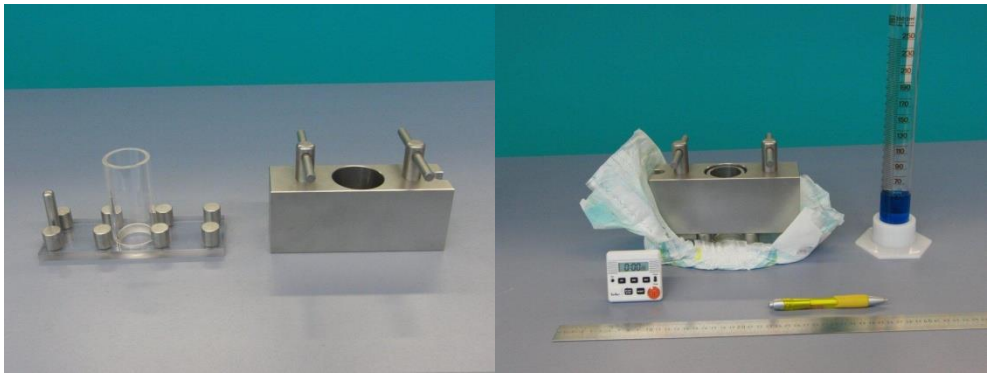

Fig A.1: apparatus and set up

A.3.6 Gently place weights on the plate (ideally use weight in a ring form to allow for equally applied pressure)

A.3.7 Fill the measuring cylinder with respective amount of saline solution

A.3.8 Set the stopwatch to 5 minutes

A.3.9 Gently pour the saline solution onto the diaper via cylinder and immediately start the stopwatch.

A.3.10 If the saline solution is absorbed after 5 minutes (i.e. no more liquid observed in the cylinder and no liquid on the tray outside the diaper), then proceed to the next step.

A.3.11 Leave the diaper undisturbed for 5 min

A.3.12 Repeat step A.3.7 to A.3.11 twice more on the same diaper (i.e. a total of 3 loads of saline solution with 5-minute intervals between successive loads) and observe for any liquid leaking out of the absorbent core.

Note your observations after a total of 3 loads of the specified amount of fluid and score the diaper based on the minimum volumes specified in Table A.1

A.3.13 Acceptance criteria

Pass: No fluid observed leaking out of the diaper

Report the time it takes for the fluid to be completely absorbed.

Determination of rewet under load

A.3.14 Weigh a stack of 5 dry filter papers and record as weight “W1”.

A.3.15 Lift the weight and cover plate and place the filter paper stack on the absorption point of the diaper.

A.3.16 Place the cover plate and weight on top of the stack of filter paper and leave undisturbed for 2 min.

A.3.17 After 2 min, remove the weight and cover plate and immediately determine and record the weight of the wet filter paper stack as “W2”.

A.3.18 Repeat A.3.13 to A.3.16 on the remaining 4 test specimens and record each result separately.

A.3.19 Calculation of results

A.3.18.1 Rewet (g) = W2 (Weight of stack of wet filter paper) - W1 (Weight of stack of dry filter paper).

Record the average rewet of the 5 samples tested and score the samples as follows:

Pass: Average rewet weight is less than or equal to the maximum limit specified in Table 2.

Fail: Average rewet weight exceeds the maximum limit specified in Table 2.

Annex B
(normative)

Microbiological examination

B.1 Apparatus and equipment

Use apparatus and equipment complying with the relevant requirements of EAS 217-1.

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 EAS 217-1.

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 °C ± 2 °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 1litre, and adjust the pH value to 7.2 ± 0.2. Dispense 15 mL volumes into bottles and sterilize by autoclaving at 121 °C ± 2 °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 °C ± 2 °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 L, 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 °C ± 2 °C for 20 min.

B.2.6 Cetrimide agar medium

Pancreatic digest of gelatine	20 g
Magnesium chloride	1.4 g
Potassium sulphate	10 g
Agar	13.6 g
Cetyl trimethylammonium 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 °C ± 2 °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 ($MgSO_4.7H_2O$)	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 °C ± 2 °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 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 °C ± 2 °C for 20 min.

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 L and not more than 2 L. 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 diaper 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 (B.2.3) that has been cooled to 45 °C, and mix well. Incubate, count and calculate the total count as described in ISO 4833 Part 2

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 °C ± 0.5°C and examine for the presence of *Enterobacteriaceae* as 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*

B.4.4.1 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 digest medium (B.2.5) and mix well. Incubate for 24 h at 30 °C to 35 °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 °C to 35 °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 aureginosa* and that in its presence a gram stain examined microscopically will reveal gram-negative slender rod-shaped cells.

B.4.4.2 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.

B.4.4.3 If none of the colonies obtained from the test suspension conforms to the description given in (B.4.4.1) above and the control culture has been satisfactorily recovered, deem the test sample to be free from *Pseudomonas aeruginosa.*

B.4.4.4 If colonies conforming to the description given in (B.4.4.1) above are found, streak representative suspect colonies from the Cetrimide agar onto the surfaces of *Pseudomonas agar* medium for the detection of flourescein (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 °C – 35 °C for at least three days. Examine the streaked surfaces under ultraviolet light for suspect colonies, as described in Table C.1.

Table B.1 — Description of colonies

Medium	Description of colonies
Pseudomonas agar for the detection of fluorescein	Generally colourless to yellowish Yellowish fluorescence in ultra violet light
Pseudomonas agar 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.

Bibliography

[1] US 950:2011, Disposable baby diapers (First Edition)

