



EAST AFRICAN STANDARD

Toothpaste — Specification

EAST AFRICAN COMMUNITY

Draft for comments only — Not to be cited as East African Standard

Foreword

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

In order to achieve this objective, the Partner States in the Community through their National Bureaux of Standards, have established an East African Standards Committee.

The Committee is composed of representatives of the National Standards Bodies in Partner States, together with the representatives from the private sectors and consumer organizations. 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 procedures of the Community.

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.

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Introduction

The need for the development of an East African Standard on toothpaste has arisen from the fast expanding toothpaste industry within the region. Toothpaste assists in the removal of daily accumulation of debris and deposits from the exposed surface of the teeth without causing injury to the teeth and mucous membrane of the mouth. In addition it may remove stain and odour but it shall not remove enamel of the teeth.

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Contents

1	Scope	1
2	Definitions.....	1
3	Requirements for toothpaste	1
4	Prohibition or restrictions on clinical claims.....	3
5	Sampling, testing and compliance with the standard.....	3
6	Packing and marking requirements.....	4

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Toothpaste — Specification

1 Scope

This East African Standard specifies the requirements for toothpaste (fluoridated and non-fluoridated) for use with a brush in the cleaning of natural teeth.

2 Definitions

For the purpose of this standard the following definitions apply.

2.1

dentine

The calcified tissue, tubular in structure that forms the bulk of a tooth.

2.2

Enamel

The highly calcified tissue, prismatic in structure, that covers the crown of a tooth.

2.3

product unit

One unit of the final product consisting of the closed tube filled with toothpaste. The tube may be contained in a box (usually carton).

2.4

bulk pack

A pack containing two or more product units of the same nominal volume.

2.5

lot

Collection of product units of the same size, type and style which have been manufactured under essentially the same conditions.

2.6

defective

A product unit that fails to meet one or more of the requirements as set out in 3 and 5.2

3 Requirements for toothpaste

3.1 Composition

3.1.1 The toothpaste shall not contain sucrose or other readily fermentable carbohydrates. Artificial sweeteners, if used, shall comply with the relevant East African Standard

3.1.2 Colouring matter, if used, shall comply with the requirements of EAS 103.

3.1.3 All ingredients shall be of acceptable quality and shall meet the requirements of the relevant East African Standards

3.2 Consistency

The toothpaste shall be smooth and free from lumps or particles, which are palpable in the mouth as separate or discrete particles.

3.3 Homogeneity

The paste shall extrude from the tube at $27^{\circ}\text{C} \pm 2^{\circ}\text{C}$ in the form of a homogeneous mass with the application of normal force starting from one end of the tube.

EAS 187:2000

3.4 Toxicity

The toothpaste shall not contain ingredients in sufficient concentration to cause a toxic or irritant reaction when used in the oral cavity, nor shall it be otherwise harmful in normal use.

3.6 Stability

The toothpaste shall not ferment, segregate or otherwise deteriorate, during normal conditions of storage and use. When tested in accordance with ISO 11609, the fore mentioned defects shall not occur.

3.7 Effect of container

3.7.1 Tooth paste shall be packed in suitable tubes of material which shall not corrode, deteriorate, or cause contamination of the tooth paste during normal conditions of storage and use. The paste shall be examined visually by extruding part of the contents. The internal surface of the tube when examined in accordance with ISO 11609 shall show no visible signs of corrosion or deterioration and the toothpaste shall show no sign of contamination.

3.7.2 The lead content of the paints on the tube shall not exceed 250 mg/kg, when tested in accordance with ISO 11609.

3.7.3 The toothpaste shall extrude to the extent of 94 % of the nominal volume, when tested in accordance with ISO 11609.

3.8 Fluorine derivatives

The total fluorine derivative and water-soluble fluorine derivative in fluoridated toothpaste (both determined as fluoride ion) shall comply with the requirements given in Table 1. The values given in the table are considered acceptable for toothpaste formulated to contain 1000 mg/kg expressed as fluoride ion.

NOTE The therapeutic effectiveness of a fluoride toothpaste may be influenced by the combination of fluorine containing additive, abrasive agent and other constituents in toothpaste. Combinations additional to those in the table are acceptable provided that the product complies with all requirements of this standard with specific reference to clause 3.

Table 1 — Total and water soluble fluorine derivatives

Predominant abrasive agent in toothpaste	Permitted range of total fluorine derivatives as fluoride ion, mg/kg	Minimum soluble fluorine derivative as fluoride ion, mg/kg
Fluoride agent: Stannous fluoride Insoluble sodium metaphosphate Silica Calcium pyrophosphate	900 to 1120	500 500 108
Fluoride agent: Sodium Monofluorophosphate Alumina Calcium carbonate) Dicalcium phosphate) Insoluble sodium) metaphosphate) Silica)	850 to 1120))) 600)))
Fluoride agent: Sodium fluoride High betaphase calcium Pyrophosphate Polymethacrylate spheres)) 900 to 1150))	403 600

Test methods specified in Annex F are suitable for sodium monofluorophosphate formulations. If formulations involving other fluoride agents are used, then the test methods have to be approved by the respective partner states National Standards Bodies.

3.9 Other requirements

The toothpaste shall also comply with requirements given in Table 2.

Table 2 – Requirements for toothpaste

S/N	Characteristic	Requirements	Method of test
1	Lead (Pb) mg/kg, max	0.5	ISO 11609
2	pH	5.5 to 10.5	
3	Fineness	0.1	
	Particles retained on a 150 micron sieve, per cent by mass, max		
	Particles retained on a 75 micron sieve, per cent by mass, max	2.0	
4	Arsenic (As ₂ O ₃) mg/kg, max	2	

4 Prohibition or restrictions on clinical claims

The toothpaste shall not be claimed to control the amount of dental plaque, remove calculus, reduce dentine hypersensitivity, reduce the incidence of or treat caries or periodontal disease or any other oral diseases, unless such benefits have been clearly demonstrated by clinical trials or other scientific evidence that are acceptable to the respective partner states National Standards Bodies.

5 Sampling, testing and compliance with the standard

5.1 Sampling

Select at random sixty bulk packs. From each bulk pack thus selected, draw at random, one product unit. Divide, in a random manner the sample thus selected into two portions of ten and fifty product units.

EAS 187:2000

5.2 Testing

5.2.1 The portion of ten units shall be used to test for the requirement of 5.2.3
The rest of the sample shall be used to test for the requirements of 4 and 5.2.2

5.2.2 The toothpaste recovered from the extrusion test shall be well-mixed into a composite sample that will be used for all relevant tests on toothpaste.

5.2.3 A suitable number of empty tubes shall be taken from the sample to test for lead in paint.

6 Packing and marking requirements

6.1 Packing

6.1.1 Toothpaste shall be packaged in containers that shall neither show defects nor contaminate the toothpaste during the normal shelf life of the product.

6.1.2 The containers shall be further packed in individual carton boxes or other protective materials.

6.2 Labelling

The primary container (i.e. tube) and outer container shall be legibly and indelibly marked with the following information:

- a) name of the toothpaste and registered trade mark if any
- b) the name, in chemical nomenclature, of any ingredient for which special therapeutic are claimed, together with the concentration present in the toothpaste
- c) the name, in chemical nomenclature, of any ingredient, together with the concentration present in the toothpaste .
- d) nominal volume of contents or weight of contents;
- e) lot/ batch (in Code or number)
- f) name and address of manufacturer;
- g) in the case of fluoridated toothpaste, the words "FLUORIDATED TOOTHPASTE" shall be given in letters of height at least 3 mm in a colour which affords a distinct contrast with the background and the levels.
- h) manufacturing date and expiry date(year,month,day)
- i) Storage conditions
- j) Country of origin
- k) instructions for use on outer container or inserted paper

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