DRAFT EAST AFRICAN STANDARD

Lip balm (Lip salve) — Specification

EAST AFRICAN COMMUNITY
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East African Community
P.O. Box 1096,
Arusha
Tanzania
Tel: + 255 27 2162100
Fax: + 255 27 2162190
E-mail: eac@eachq.org
Web: www.eac-quality.net

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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, 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 071, Cosmetics and related products.

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Introduction

Lip balm (Lip salve) consists of a homogeneous suspension of ingredients which are petroleum or vegetable oil based. It is useful in protecting the lips against chapping and cracking in extremes of temperature by forming a thin protective layer.
Lip balm (Slave) — Specification

1 Scope

This Draft East African Standard specifies requirements, sampling and test methods for lip balm which are petroleum or vegetable oil based.

This standard does not cover lip balm for which therapeutic claims are made, lipsticks, lip gloss and emulsion types.

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 346, Labelling of cosmetics — General requirements

EAS 377 (all parts), Cosmetics and cosmetic products

EAS 846, Glossary of terms relating to the cosmetic industry

EAS 847-16, Cosmetics — Analytical methods — Part 16: Determination of heavy metal content

EAS 847-18, Cosmetics — Analytical methods — Part 18: Determination of thermal stability

ISO 3960, Animal and vegetable fats and oils — Determination of peroxide value — Iodometric (visual) endpoint determination

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

ISO 22716, Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices

ISO 24153, Random sampling and randomisation procedures

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

lip balm (lip salve)
formulation applied onto the lips to prevent drying and protect against adverse environmental factors
4 Types
The lip balm shall be of the following three types:
   a) Type 1 - based on vegetable oils and waxes;
   b) Type 2 - based on petroleum products; and
   c) Type 3 - based on a mixture of petroleum products, vegetable oils and waxes.

5 REQUIREMENTS

5.1 Ingredients
All ingredients used including dyes, pigment and colours shall comply with the requirements of EAS 377.

5.2 General requirement
5.2.1 The lip balm shall
   a) be in the form of solid or soft unctuous mass,
   b) not have harmful effect on the lips and skin around the lips when used as intended by the manufacturer, and
   c) not have any objectionable odour except the characteristic odour from the main ingredient.

5.2.2 The lip balm may be coloured or perfumed.

5.2.3 The product shall be produced, prepared and handled in accordance with ISO 22716.

5.3 Specific quality requirements
5.3.1 Lip balm shall comply with the specific quality requirements given in Table 1 when tested in accordance with the test methods specified therein.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Requirement</th>
<th>Test method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peroxide value, meq/kg, max.</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Stability</td>
<td>To pass test</td>
<td>To pass test</td>
</tr>
</tbody>
</table>

5.3.2 The lip balm shall uniformly spread and shall not stick, fragment, deform or break during application when tested in accordance with Annex A.

6 Heavy metal requirements
Lip balm shall comply with the heavy metal requirements given in Table 2 when tested in accordance with the test methods specified therein.
Table 2 — Heavy metal requirements for lip balm

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Requirement</th>
<th>Test method</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Type 1</td>
<td>Type 2</td>
</tr>
<tr>
<td>Arsenic (as As), mg/kg, max.</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Mercury (as Hg), mg/kg, max.</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Lead (as Pb), mg/kg, max.</td>
<td>10</td>
<td>10</td>
</tr>
</tbody>
</table>

\[ a \] The total amount of heavy metals as lead, mercury and arsenic, in combination in the finished product shall not exceed 10 mg/kg.

7 Microbiological requirements

Lip balm shall comply with the microbiological requirements given in Table 3 when tested in accordance with the test methods specified therein.

Table 3 — Microbiological limits for lip balm (lip salve)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Requirement</th>
<th>Test method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total viable count for aerobic mesophyllic microorganisms per g, max.</td>
<td>1000</td>
<td>1000</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>Not detectable in 0.5 g of cosmetic product</td>
<td>Not detectable in 0.5 g of cosmetic product</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td></td>
<td>ISO 22718</td>
</tr>
<tr>
<td>Candida albicans</td>
<td></td>
<td>ISO 18416</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td></td>
<td>ISO 21150</td>
</tr>
</tbody>
</table>

9 Packaging

The product shall be packaged in suitable well-sealed containers that shall protect the contents and shall not cause any contamination or react with the product.

10 Labelling

In addition to the labelling requirements in EAS 346, the package shall be legibly and indelibly marked with the following information:

- a) product name as “Lip balm” or Lip salve”;
- b) manufacturer’s name and physical address;
- c) batch number;
- d) list of ingredients
- e) type of product “vegetable oil and waxes, petroleum products or mixture of petroleum products, vegetable oils and waxes”;
- f) net content of the material when packed;
g) country of origin;

h) month and year of manufacture and expiry; and

i) recommended storage conditions.

11 Sampling

Sampling shall be carried in accordance with ISO 24153
Annex A
(normative)

Test of spreadability

Apply the lip balm (at room temperature of 25 ºC ± 3 ºC) repeatedly onto a glass slide and visually observe the uniformity in the formation of the protective layer and whether the stick fragments, deforms or breaks during application.
Bibliography

[1] CD/TRADE/01: 2018,


