DRAFT EAST AFRICAN STANDARD

Baby oils — 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, 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.

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.
Baby oils

1 Scope

This Draft East Standard specifies requirements, sampling and test methods for baby oils intended for use on the babies.

Products for which therapeutic claims are made are not covered by this standard. Such products shall be registered with the Ministry of Health.

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 846, Glossary of terms relating to the cosmetic industry
EAS 847-2, Oils for cosmetic industry — Methods of test — Part 2: Determination of moisture content
EAS 847-4, Cosmetics — Analytical methods — Part 4: Determination of acid value and free fatty acids
EAS 847-7, Oils for cosmetic industry — Methods of test — Part 7: Determination of specific gravity
EAS 847-13, Cosmetics — Analytical methods — Part 13: Determination of rancidity
EAS 847-16, Oils for cosmetic industry — Methods of test — Part 16: Determination of heavy metal content
EAS 847-18, Cosmetics — Analytical methods — Part 18: Determination of thermal stability
EAS 847-22, Cosmetics — Analytical methods — Part 22: Determination of sulphur and sulphides in oils
EAS 346, Labelling of cosmetics — General requirements
EAS 377 (all parts), Cosmetics and cosmetic products
ISO 3960, Animal and vegetable fats and oils -- Determination of peroxide value -- Iodometric (visual) endpoint determination
ISO 18416, Cosmetics — Microbiology — Detection of Candida albicans
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
ISO 24153, Random sampling and randomization procedures
ISO 22716, Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EAS 846 and the following 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 acid value
number of milligrams of potassium hydroxide (KOH) required to neutralize 1 g of a sample under specified test conditions

3.2 peroxide value
quantity of those substances in the sample, expressed in terms of active oxygen, that oxidize potassium iodide under the specified conditions

3.3 rancidity
decomposition of fats or oils by oxidation or hydrolysis

4 Types

Baby oil shall be one of the following types:

a) Type 1 - based on refined vegetable oil;

b) Type 2 - based on mineral oil; and

c) Type 3 - based on a mixture of mineral oils and refined vegetable oils.

5 Requirements

5.1 General requirements

5.1.1 All raw materials used shall conform to all parts of EAS 377. The perfume used shall be of refined cosmetic grade.

5.1.2 The product shall:

a) be a clear oily liquid;

b) be free from sediment, suspended matter and separated water;

c) be insoluble in water; and

d) not have any objectionable odour.

5.1.3 The product shall be produced, prepared and handled in accordance with ISO 22716.
5.3 Specific requirements

The oil shall also conform to the requirements specified in Table 1 when tested in accordance with the test methods prescribed therein.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Requirement</th>
<th>Test method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moisture content, % m/m, max.</td>
<td>0.5</td>
<td>EAS 847-2</td>
</tr>
<tr>
<td>Acid value, max.</td>
<td>1.0</td>
<td>EAS 847-4</td>
</tr>
<tr>
<td>Specific gravity 25 °C</td>
<td>0.800 - 0.960</td>
<td>EAS 847-7</td>
</tr>
<tr>
<td>Rancidity</td>
<td>Shall be free from rancidity</td>
<td>EAS 847-13</td>
</tr>
<tr>
<td>Thermal stability</td>
<td>To pass test</td>
<td>EAS 847-18</td>
</tr>
<tr>
<td>Sulphur and sulphides</td>
<td>To pass test</td>
<td>EAS 847-22</td>
</tr>
<tr>
<td>Peroxide value, mg/1 000 g, max.</td>
<td>7.5</td>
<td>ISO 3960</td>
</tr>
</tbody>
</table>

6 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>
<thead>
<tr>
<th>Microorganism</th>
<th>Limit</th>
<th>Test method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total viable count for aerobic mesophilic micro-organisms per g, max.</td>
<td>1000</td>
<td>ISO 21149</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td></td>
<td>ISO 22717</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>
</tbody>
</table>

7 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>
<thead>
<tr>
<th>Heavy metals</th>
<th>Limit mg/kg, max.</th>
<th>Test method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead</td>
<td>10</td>
<td>EAS 847-16</td>
</tr>
<tr>
<td>Arsenic</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Mercury</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

Note: The total amount of heavy metals as lead, mercury and arsenic, in combination in the finished product shall not exceed 10 mg/kg
8 Packaging

The product shall be packed in suitable containers that are securely closed, are impervious to the product or shall not be corroded by the product, and shall be sufficiently strong to prevent contamination of the product arising from the ordinary risks of transportation, handling and storage.

9 Labelling

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

a) manufacturer's name and physical address;

b) product name as “Baby oil”;

c) net content of the material when packed;

d) batch number;

e) instructions for use;

f) ingredients;

g) country of origin;

h) date of manufacture and expiry;

i) storage conditions; and

j) precaution/warning, where applicable.

10 Sampling

Random samples of the product shall be drawn for test in accordance with ISO 24153 from the market, factory or elsewhere.
Bibliography
