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**Cosmetics — General requirements for
Safety of Cosmetic Products —
Specification**



**Kenya Bureau of
Standards**

Standards for Quality life

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REVISION OF KENYA STANDARDS

In order to keep abreast of progress in industry, Kenya Standards shall be regularly reviewed. Suggestions for improvements to published standards, addressed to the Managing Director, Kenya Bureau of Standards, are welcome.

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Cosmetics — General requirements for Safety of Cosmetic Products — Specification

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Foreword

This Kenya Standard was prepared by the Cosmetics and related products Technical Committee (TC) under the guidance of the Standards Projects Committee, and it is in accordance with the procedures of the Kenya Bureau of Standards.

The cosmetics industry is a very vibrant sector. New products and innovations are developed continuously, and there are no standards to cover such products. One such range of products is the make-up range (foundation, concealers, eye shadow, glitters, etc). The Cosmetics TC identified the need to have a general standard, against which all cosmetics products that do not have specific product standards can be tested. This standard will enable manufacturers have a basis to gauge the quality of their products, as well as enable importers to trade. This standard will be very useful for purposes of trade facilitation, while ensuring the products are safe for use by the consumer. Cosmetic products should also function as intended. The Standard ensures the quality, fitness for use and safety of the products to the consumers by having general/specific requirements addressing these aspects. The standard prescribes specific crucial parameters such as raw material requirements, limits for heavy metal contaminants, and microbiological limits. The standard also makes reference to the labelling standard, thereby ensuring labelling requirements are adhered to. The standard also requires that the product shall be produced, prepared and handled under Good Manufacturing Practices (GMP) thus further assuring stakeholders of the quality and safety of the product.

The standard will be used by stakeholders in the cosmetics sector, including manufacturers, importers, traders, testing bodies, research bodies, institutions of higher learning and regulatory bodies. The standard will also be used for purposes of Quality Assurance, Product Certification, Inspection and Market Surveillance.

During the preparation of this standard, reference was made to the following documents.

Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of the European Union. (2009): Cosmetic Products. Brussels.

KS ISO 17516 Cosmetics — Microbiology — Microbiological limits

Acknowledgement is hereby made for the assistance derived from these sources.

Cosmetics — General requirements for Safety of Cosmetic Products — Specification

1 Scope

This Kenya Standard specifies the general requirements for safety of cosmetic products.

This standard applies to all cosmetic products falling within the definition of a cosmetic product in clause 3 and all products as listed in KS EAS 334.

This standard does not apply to the medicated cosmetic products which claim therapeutic value.

This Standard only covers products for which there are no specific Kenya standards.

2 Normative references

The following referenced documents 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.

KS EAS 334, Kenya Standard — *Illustrative list by category of cosmetic products*

KS EAS 377, Kenya Standard — *Cosmetics and cosmetic products*

- *Part 1: List of substances prohibited in cosmetic products*
- *Part 2: List of substances which cosmetic products must not contain except subject to the restrictions laid down*
- *Part 3: List of colorants allowed in cosmetic products*
- *Part 4: List of preservatives allowed in cosmetic products*
- *Part 5: Use of UV filters in cosmetic products*

KS EAS 846, Kenya Standard — *Glossary of terms relating to the cosmetic industry*

KS ISO 22716, Kenya Standard — *Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices*

KS EAS 847-16, Kenya Standard — *Cosmetics — Analytical methods — Part 16: Determination of lead, mercury and arsenic content*

KS ISO 16212, Kenya Standard — *Cosmetics — Microbiology — Enumeration of yeast and mould*

KS ISO 17516, Kenya Standard — *Cosmetics — Microbiology — Microbiological limits*

KS ISO 18416, Kenya Standard — *Cosmetics — Microbiology — Detection of candida albicans*

KS ISO 21149, Kenya Standard — *Cosmetics -- Microbiology -- Enumeration and detection of aerobic mesophilic bacteria*

KS ISO 21150, Kenya Standard — *Cosmetics — Microbiology — Detection of Escherichia coli*

KS ISO 22717, Kenya Standard — *Cosmetics — Microbiology — Detection of Pseudomonas aeruginosa*

KS ISO 22718, Kenya Standard — Cosmetics — Microbiology — Detection of *Staphylococcus aureus*

KS EAS 346, Kenya Standard — Labelling of cosmetics — General requirements

KS ISO 24153, Kenya Standard — Random sampling and randomization procedures.

3 Terms and definitions

For the purposes of this standard, the terms and definitions given in KS EAS 846 and the following shall apply.

3.1 cosmetic

any preparation intended for placing in contact with various external parts of the human body (epidermis, hair, nails, or lips) or with the teeth and mucous membranes of the oral cavity with a view to exclusively or principally cleaning them, perfuming them, or protecting them in order to keep them in good condition, change their appearance or correct body odours.

4 Requirements

4.1 Ingredients

- 4.1.1 All ingredients used including dyes, pigments and colour shall conform to all parts of KS EAS 377.
- 4.1.2 The cosmetic product shall contain acceptable amounts of the ingredients necessary to effect the intended end use performance as stipulated on the label.

4.2 General Requirements

- 4.2.1 Products for which a specific Kenya standard is in place shall be tested against that specific product standard.
- 4.2.2 All products containing therapeutic claims shall be registered with the Ministry of Health
- 4.2.3 The final product shall not be harmful to the user when used as intended by the manufacturer; and
- 4.2.4 The product shall be produced, prepared and handled in accordance with KS ISO 22716.

4.3 Specific requirements

The skincare creams, lotions and gels shall comply with the specific requirements given in Table 1 when tested in accordance with the test methods specified therein.

Table 1 — Specific requirements for cosmetic products

S/No.	Characteristic	Requirement	Test Method
i)	Thermal stability	To pass test	EAS 847-18
ii)	pH range	3.5 - 8.5	EAS 847-17

5 Heavy metal contaminants

The cosmetic product shall comply with the heavy metal limits given in Table 1 when tested in accordance with the test methods specified therein.

Table 1 — Heavy metal limits for cosmetic products

S/N	Heavy metal	Maximum limit ^a mg/kg	Test method
i.	Lead (as Pb)	20	KS EAS 847-16
ii.	Arsenic (as As)	2.0	
iii.	Mercury (as Hg)	2.0	
^a The total amount of heavy metals as lead, mercury and arsenic, in combination in the finished product shall not exceed 20 mg/kg.			

6 Microbiological limits

6.1 The cosmetic product shall comply with the requirements outlined in KS ISO 16212.

6.2 Microbiological criteria shall be determined using ISO 17516:2014

6.3 In addition to this, the microbial risk of the product shall be assessed based on ISO 29621:2010 to establish if the product is a low risk and therefore excluded from the need for microbiological analysis.

6.4 The cosmetic product shall also comply with the microbiological limits given in Table 2 when tested in accordance with the test methods specified therein

Table 2 — Microbiological limits for cosmetic products

S/N	Types of microorganisms	Products specifically intended for children under three years of age, the eye area or the mucous membranes	Other products	Test method
i.	Total Viable Count for Aerobic Mesophilic Microorganisms	≤ 100 CFU per g or ml	≤ 1,000 CFU per g or ml	KS ISO 21149
ii.	<i>Escherichia coli</i>	Not detectable in 1 ml or 1 g of cosmetic product	Not detectable in 1 ml or 1 g of cosmetic product	KS ISO 21150
iii.	<i>Pseudomonas aeruginosa</i>			KS ISO 22717
iv.	<i>Staphylococcus aureus</i>			KS ISO 22718
v.	<i>Candida albicans</i>			KS ISO 18416
vi.	<i>Yeasts and moulds</i>			KS ISO 16212
NOTE When colonies of bacteria are detected on Sabouraud Dextrose agar, Sabouraud Dextrose agar containing antibiotics may be used.				

8 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.

9 Labelling

The product shall comply with the labelling requirements outlined in KS EAS 346, Labelling of cosmetic products.

10 Sampling

Sampling shall be done in accordance with KS ISO 24153.

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