



## DRAFT EAST AFRICAN STANDARD

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Skincare special purpose product— Specification — Part 2: Sunscreen

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](mailto:eac@eachq.org)  
Web: [www.eac-quality.net](http://www.eac-quality.net)

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## Contents

Page

Foreword .....	iv
1 Scope .....	1
2 Normative references .....	1
3 Terms and definitions .....	2
4 Types .....	2
Requirements .....	3
4.1 Ingredients .....	3
4.2 General requirements .....	3
4.3 Specific requirements .....	3
4.4 Microbiological limits .....	4
4.5 Heavy metal contaminants .....	4
5 Packaging .....	5
6 Labelling .....	5
7 Sampling .....	5
Bibliography .....	6

## 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.

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*.

WDEAS/TC 071-2 consists of the following parts, under the general title *Skincare special purpose product— Specification*:

– *Part 1: Anti-aging*

– *Part 2: Sunscreen*

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.

EAS 1205 consists of the following parts, under the general title *Skincare special purpose product—*

*Specification:*

- *Part 1: Anti-aging*

- *Part 2: Sunscreen*

## Introduction

Sunscreen products are used by consumers to help protect the skin from UV radiations and reduce the risk of skin cancer and premature skin aging. Increasing concerns over the effectiveness of sunscreen products available in the market for protection against harmful Ultraviolet (UV) radiations of sunrays led to the need for the formulation of this East African Standard to ensure that the sunscreen products are safe and effective in achieving their purpose of protection against harmful UV radiation of sunrays as per the claim made.



## Skincare special purpose product — Specification — Part 2: Sunscreen

### 1 Scope

This Working Draft East African Standard specifies requirements, sampling and test methods for sunscreens skincare leave-on products.

This standard does not apply to skincare products covered by EAS 786, anti-wrinkle products, anti-aging products, aromatherapy substances and hair creams, lotions and gels.

### 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 786, *Skincare creams, lotions and gels — Specification*

EAS 846, *Glossary of terms relating to the cosmetic industry*

EAS 847-1, *Cosmetics — Analytical methods — Part 1: Glossary of terms*

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

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

ISO 16217, *Cosmetics — Sun protection test methods — Water immersion procedure for determining water resistance*

ISO 18416, *Cosmetics — Microbiology — Detection of *Candida albicans**

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

ISO 21150, *Cosmetics — Microbiology — Detection of *Escherichia coli**

ISO 22717, *Cosmetics — Microbiology — Detection of *Pseudomonas aeruginosa**

ISO 22718, *Cosmetics — Microbiology — Detection of *Staphylococcus aureus**

ISO 24153, *Random sampling and randomization procedures*

ISO 24443 *Cosmetics — Determination of sunscreen UVA photo protection in vitro*

ISO 24442, *Cosmetics — Sun protection test methods — In vivo determination of sunscreen UVA protection*



ISO 24444, *Cosmetics — Sun protection test methods In vivo determination of the sun protection factor (SPF)*

### 3 Terms and definitions

For the purposes of this document, the terms and definitions given in EAS 846 and EAS 847-1 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  
sunscreen**  
any leave-on preparation (such as creams, Lotions, oils, gels, sprays, lip products etc.) exclusively or mainly for UV protection / sun protection and is intended to be placed in contact with the human skin or lip for the purpose of absorbing, reflecting, or scattering radiation in the ultraviolet (UV) range at wavelengths from 290 nm to 400 nm

**3.2  
Ultraviolet A (UVA) radiation**  
electromagnetic radiation in the range of 320 nm to 400 nm

**3.3  
Ultraviolet B (UVB) radiation**  
electromagnetic radiation in the range of 290 nm to 320 nm

**3.4  
Sun Protection Factor of a product (SPF)**  
ratio of minimum erythematous dose on skin protected by a sunscreen product to the minimum erythematous dose on the same unprotected skin

**3.5  
UVA Protection Factor of a product (UVA PF)/(PA)**  
ratio of the minimum UVA dose necessary to induce a persistent pigment darkening on the skin protected by a sunscreen product to the minimal UVA dose necessary to induce the minimal darkening effect on the same unprotected skin

**3.6  
critical wavelength ( $\lambda_c$ )**  
wavelength at which the integral of the absorption spectrum curve starting at 290 nm reaches 90% of the integral between 290 and 400 nm; for the type "Broad spectrum Protection"

### 4 Types

Sunscreen products shall be based on the following types:

- a) sunscreen products with UVA protection — based on UVA Protection Factor
- b) sunscreen products with UVB Protection — based on Sun Protection Factor
- c) sunscreen products with broad spectrum protection — based on UVA PF/SPF Ratio and critical wavelength
- d) water resistant sunscreen products — based on water resistance

## Requirements

### 4.1 Ingredients

4.1.1 Sunscreens shall contain an active ingredient that has sun protection effect.

4.1.2 All ingredients used including dyes, pigments and colours shall comply with all parts of EAS 377.

### 4.2 General requirements

4.2.1 Standard specifications are available for a number of cosmetics. In case, such cosmetics which claim to have sun protection properties, they shall conform to the requirements of this standard along with the relevant East African Standard.

4.2.2 Sun protection products shall generally be divided into the following four protection classes based on the level of their SPF label claims as given in Table 1.

**Table 1 — Protection classes for sunscreen products based on the level of SPF label claims**

S/N.	Label SPF	Protection Class
i.	10	Low Protection
ii.	15, 20, 25	Medium Protection
iii.	30, 40,50	High Protection
iv.	50+	Very High

### 4.3 Specific requirements

4.3.1 Sunscreen product with Sun Protection Factor claim shall also comply with requirements given in Table 1 when tested in accordance with the test methods specified therein.

**Table 2 — Sun Protection Factor (SPF) labelling ranges for sunscreen products**

S/N	SPF Label	Measured SPF	Test method
i.	10	10.0 - 14.9	ISO 24444
ii.	15	15.0 - 19.9	
iii.	20	20.0 – 24.9	
iv.	25	25.0 – 29.9	
v.	30	30.0 – 39.9	
vi.	40	40.0 – 49.9	
vii.	50	50.0 – 59.9	
viii.	50+	≥60.0	

4.3.2 Sunscreen products with UVA Protection Factor claim shall comply with the specific requirements given in Table 3 when tested in accordance with the test methods specified therein.

Table 3 — UVA Protection Factor labelling ranges for sunscreen products

S/N	UVA Protection Factor Label	Measured UVA Protection Factor	Test method
i.	PA+	2.0 – 3.9	ISO 24442
ii.	PA++	4.0 – 7.9	ISO 24443
iii.	PA+++	8.0 – 15.9	
iv.	PA++++	≥16.0	

**4.3.3** Sunscreen products with water resistance claim shall be tested for water resistance of 40 minutes or 80 minutes when tested in accordance with ISO 16217

**4.3.4** For sunscreen products with Broad Spectrum protection claims, the UVA PF/SPF ratio shall be at least 1/3 and the critical wavelength shall be at least 370 nm. The UVA PF measure from the in-vivo, SPF from the in-vivo, critical wavelength shall be tested in accordance with ISO 24442, ISO 24444 and ISO 24443 respectively.

#### 4.4 Microbiological limits

Sunscreen products shall comply with the microbiological limits given in Table 4 when tested in accordance with the test methods specified therein.

Table 4 — Microbiological limits for sunscreen products

S/N	Micro-organism	Limit <sup>a</sup>	Test method
i.	Total viable count for aerobic mesophilic microorganisms CFU/g or CFU/ml, max. <ul style="list-style-type: none"> <li>Products for children below three years</li> <li>Products for humans above three years</li> </ul>	100 1 000	ISO 21149
ii.	<i>Pseudomonas aeruginosa</i>	Not detected in 1 ml or 1 g of cosmetic product	ISO 22717
iii.	<i>Staphylococcus aureus</i>		ISO 22718
iv.	<i>Candida albicans</i>		ISO 18416
v.	<i>Escherichia coli</i>	Not detected in 1 g of cosmetic product	ISO 21150

<sup>a</sup> applicable to sunscreen products which do not have specific product standards.

#### 4.5 Heavy metal contaminants

Sunscreen products shall comply with the heavy metal limits given in Table 5 when tested in accordance with the test methods specified therein.

**Table 5 — Heavy metal limits for sunscreen products.**

S/N	Heavy metal	Maximum limit <sup>a b</sup> mg/kg	Test method
i.	Lead	10	EAS 847-16
ii.	Arsenic	2	
iii.	Mercury	2	
<sup>a</sup> The total amount of heavy metals as lead, mercury and arsenic, in combination in the finished product, shall not exceed 10 mg/kg. <sup>b</sup> applicable to sunscreen products which do not have specific product standards.			

## 5 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.

## 6 Labelling

In addition to the labelling requirements given in EAS 346, each package shall be legibly and indelibly labelled with the following:

- a) product name as “Sunscreen”. For products with specific standards, the product name shall be as per the product standard and the wording sunscreen shall be indicated.
- b) type;
- c) UVA PF value, if applicable;
- d) SPF value;
- e) water resistant in minutes, if applicable; and
- f) for Broad Spectrum protection the label shall carry both SPF and UVA PF.

## 7 Sampling

Sampling shall be carried out in accordance with ISO 24153.

## Bibliography

- [1] Donglikar, M. M., & Deore, S. L. (2016). Sunscreens: A review. *Pharmacognosy Journals*, 8(3).
- [2] Geoffrey, K., Mwangi, A. N., & Maru, S. M. (2019). Sunscreen products: Rationale for use, formulation development and regulatory considerations. *Saudi Pharmaceutical Journal*, 27(7), 1009-1018
- [3] PCD 19 (15096) WC, sunscreen cosmetics products — Specification

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