



## DRAFT EAST AFRICAN STANDARD

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**Cosmetics and cosmetic products — Part 1: List of substances prohibited in cosmetic**

**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.

This third edition cancels and replaces the second edition (EAS 377-1:2013), which has been technically revised.

DEAS 377 consists of the following parts, under the general title, *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, preservatives and UV filters allowed in cosmetic products

## Introduction

Cosmetic products should be safe under normal or reasonably foreseeable conditions of use. In particular, a risk-benefit reasoning should not justify a risk to human health. The safety of finished cosmetic products can already be ensured on the basis of knowledge of the safety of the ingredients that they contain. The European Regulation (EC) No 1223/2009 on cosmetics to which this East African Standard refers, aims at ensuring the safety of cosmetics.

The general principle of the responsibility of the manufacturer or importer for the safety of the product should be supported by restrictions of some substances in Annexes II and III of the Regulation. Moreover, substances which are intended to be used as colorants, preservatives and UV-filters should be listed in the Annexes IV, V and VI respectively of the Regulation in order to be allowed for these uses.

The Regulation relates only to cosmetic products and not to medicinal products, medical devices or biocidal products. The delimitation follows in particular from the detailed definition of cosmetic products, which refers both to their areas of application and to the purposes of their use.

The information contained in the annexes II – VI of the Regulation has been developed through risk assessment of these substances by the Scientific Committee for Consumer Safety (SCCS) set up by Commission Decision 2008/721/EC of 5 September 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment.

Given the hazardous properties of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A, 1B and 2, their use in cosmetic products should be prohibited.

The safety of cosmetic products and their ingredients may be ensured through the use of alternative methods which are not necessarily applicable to all uses of chemical ingredients. Therefore, the use of such methods by the whole cosmetic industry should be promoted and their adoption at Community level ensured, where such methods offer an equivalent level of protection to consumers.

Therefore use of alternatives is encouraged where the substances are prohibited and, in the exceptional case that these substances comply with food safety requirements, *inter alia* as a result of their naturally occurring in food, and that no suitable alternative substances exist, may be used under prescribed conditions when found safe by SCCS in accordance to Annex III.

To minimise the risk and assure the safety of cosmetic products in the region, EAS 377-1 has been adapted from the EU Directive (EC) No 1223/2009 on Cosmetics from Annex II taking into consideration the research done and the constant expert review.

# Cosmetics and cosmetic products — Part 1: List of substances prohibited in cosmetic products

## 1 Scope

This Draft East African Standard prescribes the chemical name, state and formulation under which specific use as substance, is prohibited in the cosmetic products.

This Draft East African Standard applies only to cosmetic products and not to medicinal products, medical devices or biocidal products.

## 2 Normative references

There are no normative references in this document.

## 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>

### 3.1 colorants

substances which are exclusively or mainly intended to colour the cosmetic product, the body as a whole or certain parts thereof, by absorption or reflection of visible light; in addition, precursors of oxidative hair colorants shall be deemed colorants

### 3.2 cosmetic product

substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours

### 3.3 eye product

cosmetic product which is intended to be applied in the vicinity of the eyes

### 3.4 face product

cosmetic product which is intended to be applied on the skin of the face

- 3.5**  
**hair product**  
cosmetic product which is intended to be applied on the hair of head or face, except eyelashes
- 3.6**  
**leave-on product**  
cosmetic product which is intended to stay in prolonged contact with the skin, the hair or the mucous membranes
- 3.7**  
**lip product**  
cosmetic product which is intended to be applied on the lips
- 3.8**  
**mixture**  
preparation or solution composed of two or more substances
- 3.9**  
**nail product**  
cosmetic product which is intended to be applied on nails
- 3.10**  
**oral product**  
cosmetic product which is intended to be applied on teeth or the mucous membranes of the oral cavity
- 3.11**  
**preservatives**  
substances which are exclusively or mainly intended to inhibit the development of micro-organisms in the cosmetic product
- 3.12**  
**product applied on mucous membranes**  
cosmetic product which is intended to be applied on the mucous membranes of the oral cavity, on the rim of the eyes, or of the external genital organs
- 3.13**  
**professional use**  
application and use of cosmetic products by persons in the exercise of their professional activity
- 3.14**  
**rinse-off product**  
cosmetic product which is intended to be removed after application on the skin, the hair or the mucous membranes
- 3.15**  
**serious undesirable effect**  
undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death
- 3.16**  
**skin product**  
cosmetic product which is intended to be applied on the skin
- 3.17**  
**substance**  
chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition

### **3.18**

#### **undesirable effect**

adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product

### **3.19**

#### **UV-filters**

substances which are exclusively or mainly intended to protect the skin against certain UV radiation by absorbing, reflecting or scattering UV radiation

## **4 Requirements**

Cosmetic products shall not contain any of the prohibited substances listed in Annex II of Regulation (EC) No. 1223/2009 on cosmetic products of the European parliament and of the Council (as amended from time to time).



## Bibliography

Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30th November 2009 on cosmetic products

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