

SAFEGUARDS

CONSUMER GOODS AND RETAIL

COSMETICS, PERSONAL CARE AND HOUSEHOLD

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COSMETICS PRODUCT SAFETY REPORT GUIDELINES

Cosmetics are regulated in the European Union by Regulation (EC) No 1223/2009. Since 11 July 2013 it has been mandatory that, before any product is placed on the market, a safety assessment must be carried out and a cosmetic product safety report prepared. On 25 November 2013 the European Commission published guidelines on this legislation to help with the points which should be considered when assessing the safety of cosmetic products.¹

PART A OF COSMETIC PRODUCT SAFETY INFORMATION

1. Quantitative and Qualitative composition of the cosmetic product

- Exact quantitative and qualitative composition of the cosmetic product starting from raw materials.
- CAS Number, EINECS/ELINCS number of raw materials.
- All substances including preservatives, antioxidants, chelating agents, buffering agents, solvents, and additives which are in any of the raw ingredients should be included in the quantitative and qualitative composition of the product.
- For fragranced products the name of the fragrance, fragrance reference number, fragrance manufacturer, allergen declaration and IFRA statement are required.
- Allergens should be listed in the formulation if they exceed 0.001% in the formulation for a leave-on product and 0.01% for a rinse-off product.



PART A OF COSMETIC PRODUCT SAFETY INFORMATION

2. Physical/Chemical Characteristics and Stability of Cosmetic Product

- Physical and chemical specification of raw material and cosmetics products
- Stability of cosmetics product
- Evaluate and determine the minimum durability and period-after-opening

¹ [Commission Implementing Decision of 25 November 2013 on guidelines on Annex I to regulation \(EC\) No 1223/2009 of the European Parliament and the Council on cosmetic products \(2013/674/EU\)](#)

3. Microbiological Quality

- Microbiological specification of cosmetic product required.
- For products with a low microbiological risk a preservative challenge test is not required but justification will be required.
- For single use products which cannot be opened and do not come into contact with air a preservative challenge test is not required, but justification for not carrying out a preservative challenge test and microbiological quality testing will be required.
- For all other products a preservative challenge test and microbiological quality test will be required.

4. Impurities, Traces, Information about Packaging Material

Impurities are unintended substances in raw ingredients and traces are small quantities of unintended substances in the finished product. These can be assessed in the following ways:

- Specification and technical data sheet of each raw material and packaging material to be checked
- Physico-chemical analysis of impurities in raw material and final product
- Evaluate toxicological impact if prohibited substances are present as trace impurities
- Evidence of technical unavailability from manufacturer
- Suitability of packaging to be considered including migration of substances from packaging into product.

5. Normal and Reasonably Foreseeable Use

- The cosmetic product safety report needs to consider the normal and foreseeable use of the product e.g. a shampoo being used as a shower gel.

6. Exposure to the Cosmetics Product

The cosmetic product safety report needs to take the following parameters into consideration to calculate the amount of product coming into contact with the human body:

- Product type
- Applicable area
- Amount of application
- Duration and Frequency of use
- Routes of exposure
- Relevant exposure scenario
- Target age group
- Particle size if necessary

7. Exposure to Individual Substances

- Determine the amount of each individual substance in contact with external parts of human body, teeth or mucous membrane of oral cavity

8. Toxicological Profile of Substances

- Toxicological profile of substances in the formulation.
- Consideration of toxicological endpoints and routes of absorption to determine if a substance is safe.
- Calculation of margin of safety

9. Undesirable Effects and Serious Undesirable Effects

- The responsible person is required to monitor the safety of their product after it is placed on the market and to take any necessary corrective actions.
- Data on undesirable and serious undesirable effects to be collected by the responsible person and shared with the cosmetic safety assessor.

10. Information on the Cosmetic Product

- Any other information that is relevant to the cosmetic safety assessment e.g. studies on human volunteers

PART B OF COSMETIC PRODUCT SAFETY INFORMATION

The cosmetics safety assessor is required to consider all hazard identified with the exposure information to draw a conclusion with reasoning on whether the cosmetics product is safe, safe with restriction, or not safe for human health when it is used under normal and reasonably foreseeable conditions of use.

SGS SOLUTION:

It is crucial for all cosmetic and personal care products to be safe, effective and stable. SGS can perform Cosmetic Product Safety Reports as well as providing the supporting testing, inspection, auditing and consulting services to manufacturers, distributors and importers to ensure a high level of product safety and quality in every area. Our state of the art laboratories offer custom-made solutions for chemical, biophysical, microbiological, stability and biological aspects. We also have extensive capabilities in performance testing, claim support studies and consumer panels. Our testing is conducted according to customer specific or recognised standard methods, some of which were developed by SGS. Our technical experts can support customers in making sure new products comply with regulatory requirements. For more information, please feel free to contact us or visit our website.

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