

# Factsheets: Annex I to Cosmetics Regulation 1223/2009

## THE DATABOOK 2018

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### ANNEX I

## COSMETIC PRODUCT SAFETY REPORT

The cosmetic product safety report shall, as a minimum, contain the following:

PART A – Cosmetic product safety information

#### 1. Quantitative and qualitative composition of the cosmetic product

The qualitative and quantitative composition of the cosmetic product, including chemical identity of the substances (incl. chemical name, INCI, CAS, EINECS/ELINCS, where possible) and their intended function. In the case of perfume and aromatic compositions, description of the name and code number of the composition and the identity of the supplier.

#### 2. Physical and chemical characteristics and stability of the cosmetic product

The physical and chemical characteristics of substances or mixtures as well as the cosmetic product.

The stability of the cosmetics product under reasonably foreseeable storage conditions.

#### 3. Microbiological quality

The microbiological specifications of the substance or mixture and the cosmetic product. Particular attention shall be

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Annex I of Cosmetics Regulation 1223/2009, which governs cosmetic products in Europe since 11 July 2013, is a fundamental section of the text. It is indeed it that describes the content of the RSPC, the Cosmetic Product Safety Report, which must be included in the Product Information File (PID), with many obligations, particularly in terms of the data to be collected. Point by point, this dossier takes the various chapters of Annex I from a practical point of view, in order to understand the safety report properly and avoid the most frequent errors in its constitution.

## ANNEX I: THE TEXT

An article and an annex of the Cosmetics Regulation 1223/2009 display the principles of requirements in terms of the assessment of the safety of cosmetic products. The CPSR (Cosmetic Product Safety Report) is thus rigorously codified and must be prepared (and updated) in accordance with these provisions.

Article 10 of the Regulation 1223/2009 is dedicated to the safety assessment. It states that:

*“1. The Responsible Person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product has undergone a safety assessment on the basis of the relevant information and that a cosmetic product safety report is set up in accordance with Annex I.*

*The Responsible Person shall ensure that:*

- (a) the intended use of the cosmetic product and the anticipated systemic exposure to individual ingredients in a final formulation are taken into account in the safety assessment;*
- (b) an appropriate weight-of-evidence approach is used in the safety assessment for reviewing data from all existing sources;*
- (c) the cosmetic product safety report is kept up to date in view of additional relevant information generated subsequent to placing the product on the market.”*

Article 11.2.b adds that *“the cosmetic product safety report referred to in Article 10(1) shall be contained in the PIF, the Product Information File.”*

**Its content is detailed in the Annex I, and comes as underneath:**

The cosmetic product safety report shall, as a minimum, contain the following:

### **PART A – Cosmetic product safety information**

#### **1. Quantitative and qualitative composition of the cosmetic product**

The qualitative and quantitative composition of the cosmetic product, including chemical identity of the substances (incl. chemical name, INCI, CAS, EINECS/ELINCS, where possible) and their intended function. In the case of perfume and aromatic compositions, description of the name and code number of the composition and the identity of the supplier.

#### **2. Physical/chemical characteristics and stability of the cosmetic product**

- The physical and chemical characteristics of the substances or mixtures, as well as the cosmetic product.
- The stability of the cosmetic product under reasonably foreseeable storage conditions.

#### **3. Microbiological quality**

- The microbiological specifications of the substance or mixture and the cosmetic product. Particular attention shall be paid to cosmetics used around the eyes, on mucous membranes in general, on damaged skin, on children under three years of age, on elderly people and persons showing compromised immune responses.
- Results of preservation challenge test.

#### **4. Impurities, traces, information about the packaging material**

- The purity of the substances and mixtures.
- In the case of traces of prohibited substances, evidence for their technical unavoidability.
- The relevant characteristics of packaging material, in particular purity and stability.

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