Information from producer (importer) for the elaboration of Cosmetic product safety report (CPSR) in compliance with the Regulation (EC) No. 1223/2009

Name of the product:

Responsible person (name, address, identification number):

1. Quantitative and qualitative composition of the cosmetic product

INCI list of ingredients and their contents in the cosmetic product in%

INCI name	CAS No.	**Content (%)**
AQUA	7732-18-5	do 100
PARAFFINUM LIQUIDUM	8012-95-1	7
MYRISTYL MYRISTATE	3234-85-3	1

In the case of perfume compositions: the name and code number of the composition, the identity of the supplier and allergen content.

2. Physical/chemical properties and stability of the cosmetic product

- *Physical and chemical properties*

Type: greasy balm

Viscosity:

Density:

pH: xy

Thermal stability: stable at normal temperature

- *Organoleptic properties*

Appearance: solid, semi liquid, liquid

Colour: xy

Aroma: menthol

Product photo (from the front or from multiple pages)

3. Specifications and raw material safety data sheets **(requirements for raw material supplier)**

Particulars specifications (TDS - technical data sheet)

- Requirements based on the COMMISSION IMPLEMENTING DECISION of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

Cosmetics manufacturers should ensure that the specifications of raw materials are properly documented by their suppliers. (3.2.1)

The content of the technical data sheet raw material:
Business name of the raw materials
INCI name
CAS and EINECS
Manufacturer of raw material (Name, Address)

The specification should include: physical form, molecular weight, solubility, partition coefficient, substance purity, other parameters relevant for the characterisation of specific substances and mixtures, and, for polymers, the average molecular weight and range. (3.2.1)

Specifications should be available for each raw material actually used in the product. Based on function, additional specifications may be needed. For UV absorbers, for instance, the absorption spectra should be provided. (3.2.1)

Where relevant, the particle-size distribution curve of substances should be included in the physico-chemical characteristics, especially for nanomaterials. (3.2.1)

Purity of substances and mixtures ... the presence of unwanted substances such as impurities and trace amounts, based on knowledge of the production process of the raw material (the origin of the material, manufacturing process, the method of synthesis, the process of acquiring, solvent, etc.), (3.4.1)

For each description of physico-chemical properties and specifications (for each substance and mixture contained in the product), the reference methods should be stated in the safety report. (3.2.1)

Qualitative and quantitative information about regulated substances in the fragrance (or flavour) compound and information relevant for a safety assessment should be disclosed to the responsible person and the safety assessor, and should be included in the safety report. (3.1)

All substances entering into the composition of commercial mixtures supplied as raw materials (including directly added preservatives, antioxidants, chelators, buffering agents, solvents, other additives, etc.) are to be identified and quantified in the formula of the finished product. (3.1)

When chemically well-defined substances are present, their quantity and molecular formula should be given together with their analytical specifications (degree of purity, identification of major impurities, criteria and test methods used). (3.1)

When complex ingredients are present, their nature and quantity together with a clear definition of the mixture and the material(s) used should be given in order to identify the substances with regard to their composition and effects (manufacturing and purification processes, including physical, chemical, enzymatic, biotechnological and microbiological steps). The purity criteria and test methods used should be provided. Examples of complex ingredients include those of mineral, botanical, animal or biotechnological origin. The scope of the information needed on complex ingredients, depending on their nature and origin, is explicitly listed in the Scientific Committee for Consumer Safety (SCCS) Note of Guidance. (3.1)

Particulars of safety data sheets (MSDS - material safety data sheet)

- Requirements based on the COMMISSION IMPLEMENTING DECISION of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

Safety Data Sheets should be prepared in accordance with Commission Regulation (EU) No 453/2010.

Particular attention should be paid to Section 11 focussing on the toxicological profile of the substance.

Section 11 should include the following information (3.8.2):

(1) acute toxicity via relevant routes of exposure;

(2) irritation and corrosivity;

(3) skin irritation and skin corrosivity;

(4) mucous membrane irritation (eye irritation);

(5) skin sensitisation;EN 26.11.2013 Official Journal of the European Union L 315/93

(6) dermal/percutaneous absorption;

(7) repeated dose toxicity (normally 28- or 90-day studies);

(8) mutagenicity/genotoxicity;

(9) carcinogenicity;

(10) reproduction toxicity;

(11) toxicokinetics (ADME studies);

(12) photo-induced toxicity;

And even if the data is not available.

For some cosmetic ingredients e.g. of mineral, animal, botanical and biotechnological origin (see also Substances of Unknown or Variable composition, Complex reaction products or Biological materials or ‘UVCB substances’ under REACH), their identification

should carefully address source, process, organisms involved, etc., in order to evaluate their toxicological profile. (3.8.2)

4. Stability of the cosmetic product

Time declared minimum shelf life: 36 months and 12 months PaO

PAO = period after opening

Storage (conditions and temperature):

5. Microbiological quality

Send drawn a preservation challenge test or min. 100 ml sample of a cosmetic product for its implementation (not all products are required to perform a preservation challenge test - you will obtain samples only when necessary and to evaluate the composition and type of packaging cosmetic product)

6. Information about packaging material

Statement packaging manufacturer of safety packaging material (or its suitability for a particular type of cosmetic product), or a description of a test result of compatibility with the product packaging material

Description of the packaging material, for example: 200 ml Tuba (tuba + flip top) - tuba 50% HDPE Liten BB 29 + 50% LDPE Bralen RB 0,3-23; cap - PP

Manufacturer: ADA Zlín, Czech Republic

7. Normal and reasonably foreseeable use

Text inner and possibly outer packaging or leaflet - the best graphical form

(all texts listed on the product label and leaflet including formulation indicated on the packaging)

- in particular: the name of the product, shelf life, composition, content, responsible person, use instruction …

8. Exposure of the cosmetic product

- application site: skin t
- he estimated amount of product applied in grams and a description of how it was found: 2 g
- frequency of use per day/week etc.: 1x daily

9. Additional information on the cosmetic product

Another study reports on the implementation of dermal tests, etc.