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/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 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 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.

5. **Normal and reasonably foreseeable use**

The normal and reasonably foreseeable use of the product. The reasoning shall be justified in particular in the light of warnings and other explanations in the product labelling.

6. **Exposure to the cosmetic product**

Data on the exposure to cosmetic product taking into consideration the findings under Section 5 in relation to

1) The site(s) of application;

2) The surface area(s) of application;

3) The amount of product applied;

4) The duration and frequency of use;

5) The normal and reasonably foreseeable exposure route(s);

6) The targeted (or exposed) population(s). Potential exposure of a specific population shall also be taken into account.

The calculation of the exposure shall also take into consideration the toxicological effects to be considered (e.g. exposure might need to be calculated per unit area of skin or per unit of body weight). The possibility of secondary exposure by routes other than those resulting from direct application should also be considered (e.g. non-intended inhalation of sprays, non-intended ingestion of lip products, etc.).

Particular consideration shall be given to any possible impacts on exposure due to particle sizes.

7. **Exposure to the substances**

Data on the exposure to the substances contained in the cosmetic product for the relevant toxicological endpoints taking into account the information under Section 6.

8. **Toxicological profile of the substances**

Without prejudice to Article 18, the toxicological profile of substance contained in the cosmetic product for all relevant toxicological endpoints. A particular focus on local toxicity evaluation (skin and eye irritation), skin sensitisation, and in the case of UV absorption photo-induced toxicity shall be made.

All significant toxicological routes of absorption shall be considered as well as the systemic effects and margin of safety (MoS) based on a no observed adverse effects level (NOAEL) shall be calculated. The absence of these considerations shall be duly justified.

Particular consideration shall be given to any possible impacts on the toxicological profile due to

— particle sizes, including nanomaterials,

— impurities of the substances and raw material used, and

— interaction of substances.

Any read-across shall be duly substantiated and justified.

The source of information shall be clearly identified.

9. **Undesirable effects and serious undesirable effects**

All available data on the undesirable effects and serious undesirable effects to the cosmetic product or, where relevant, other cosmetic products. This includes statistical data.

10. **Information on the cosmetic product**

Other relevant information, e.g. existing studies from human volunteers or the duly confirmed and substantiated findings of risk assessments carried out in other relevant areas.

PART B – Cosmetic product safety assessment

1. **Assessment conclusion**

Statement on the safety of the cosmetic product in relation to Article 3.

2. **Labelled warnings and instructions of use**

Statement on the need to label any particular warnings and instructions of use in accordance with Article 19(1)(d).

3. **Reasoning**

Explanation of the scientific reasoning leading to the assessment conclusion set out under Section 1 and the statement set out under Section 2. This explanation shall be based on the descriptions set out under Part A. Where relevant, margins of safety shall be assessed and discussed.

There shall be inter alia a specific assessment for cosmetic products intended for use on children under the age of three and for cosmetic products intended exclusively for use in external intimate hygiene.

Possible interactions of the substances contained in the cosmetic product shall be assessed.

The consideration and non-consideration of the different toxicological profiles shall be duly justified.

Impacts of the stability on the safety of the cosmetic product shall be duly considered.

4. **Assessor's credentials and approval of part B**

Name and address of the safety assessor. Proof

of qualification of safety assessor. Date and

signature of safety assessor.