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EFfCI GUIDANCE PAPER REGARDING QUESTIONNAIRES FOR INGREDIENTS TO BE USED IN EU COSMETIC PRODUCTS

Purpose: to provide assistance to EFfCI members in dealing with customers' requests for ingredient information to enable these customers to fulfill their obligations according to EU Cosmetics Legislation.

Manufacturers of cosmetic products to be marketed in the EU need to comply with the EU Cosmetics Regulation EC/1223/2009.

These legislations apply primarily to **finished cosmetic products.**

Suppliers of ingredients used in cosmetic products are subject to the **chemicals legislation** (e.g. REACH) As such they have to comply with their respective legal obligations, where applicable – such as those requirements regarding Safety Data Sheets (SDS), and Classification & Labelling.

Raw materials used as ingredients in cosmetic products are affected by the **cosmetics legislation**, regarding certain elements to be taken into account, such as Annex I to Regulation EC/1223/2009 and purity requirements under the relevant Annexes.

In consequence, manufacturers of cosmetic products contact their suppliers with various questions.

There is a clear trend for customer questionnaires to address not only information required by the EU cosmetics legislation but also further items of information, such as quality certification and/or private eco-labels, or even patent status. This clearly exceeds the scope of data needed for the purpose of compliance with the cosmetics legislation which is to ensure the safety in use of the finished cosmetic product.

Some of these needed data are covered by other regulatory requirements (e.g. SDS, Classification & Labelling) and so this information is already supplied to cosmetic manufacturers.

Hence, EFfCI has developed a set of information in support of ingredients used in cosmetic products.

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Cosmetic Ingredient information set

I. INFORMATION ON THE SUPPLIER

Company Name, address, contact.

II. INFORMATION ON THE INGREDIENT

II.A IDENTIFICATION

a) Trade Name of the Ingredient:

b) Intended function: (e.g. *surfactant, solubiliser, colorant, preservative, rheology modifier)*

c) Ingredient description

d) Brief description of the manufacturing process

II.B COMPOSITION OF INGREDIENT

List all the components of the ingredient relevant for labelling of the finished cosmetic product, including additives (preserving agents, antioxidants/stabilizers, solvents, other)

Component name	Concentration/ range(§)	INCI Name EU / USA	CAS N°	EC number

(§) Composition breakdown to allow cosmetic products manufacturer to label the ingredients in the right order. For pure substance Concentration = 100%, only one component is present

For positive lists substances (Cosmetic Regulation 1223/2009) the exact concentration has to be given.

II.C IMPURITIES

Name any known significant impurity of the ingredient, due to nature and process, such as: residual reaction chemicals, residual solvents, residual monomers, pesticides residues, heavy metals, PCBs, nitrosamines…..[1]

[1] see EFfCI Guidance document on Traces

II.D SPECIFIC INFORMATION RELATED TO ORIGIN

II.D.1 Ingredient *of Botanical origin*

- Component name.
- Common name.
- Botanical name of the plant used.
- Part of the plant used: *(e.g. fruit, flower, root, seed, other)*.
- Extraction solvent *(if applicable)*
- If applicable, information with respect to Regulation (EC) n° 338/97 (CITES) as amended concerning *the protection of species of wild fauna and flora*.
- If applicable, information with respect to EU Regulation 511/2014 as amended concerning *compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union*[2]
- Origin GMO

II.D.2 Ingredient *of vertebrate ANIMAL origin*

- Component name.
- Animal species.
- Part of animal used.
- If applicable, information with respect to Regulation (EC) n° 338/97 (CITES) as amended concerning *the protection of species of wild fauna and flora*.
- If applicable, information with respect to EU Regulation 511/2014 as amended concerning *compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union*[2]
- In case of bovine, ovine or caprine origin, certify BSE/TSE absence.

II.D.3 Ingredient *of MICROBIOLOGICAL and BIOTECHNOLOGICAL origin (e.g. yeast* **fermentation***)*

- Component name
- Latin Name of microorganism
- Origin GMO
- If applicable, information with respect to EU Regulation 511/2014 as amended concerning *compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union*[2]

[2] see Joint CE / EFfCI Guidance Document on Best Practice

III. SPECIFICATION AND PRODUCT CHARACTERISTICS

Physical-chemical characteristics: if not available in Technical Data Sheet and/or Safety Data Sheet (SDS)

Specifications and analytical methods: if specification data sheet is not available.

Microbiological information: if not part of the specifications.

IV. REGULATORY INFORMATION

1. Statement about CMR(*) substances, as defined according to Regulation EC/1272/2008 and Cosmetic Regulation (1223/2009) as amended.
   (*) Carcinogenic, mutagenic, toxic for reproduction
2. Statement about *«Allergens» listed in Annex III of the Cosmetic Regulation 1223/2009/EC*
3. Statement about presence of nanomaterial in the sense of Cosmetic Regulation 1223/2009/EC
4. Other pertinent regulatory information, if available.

V. TOXICOLOGICAL INFORMATION

Refer to relevant section in safety data sheet (SDS) or report available.

(See also SCCP *Note for guidance for testing of cosmetic ingredients and their safety evaluation*, 9th revision, 2015)

VI. ENVIRONMENTAL INFORMATION

(not specifically required by cosmetics legislation)

Refer to relevant section in SDS

VII. STORAGE, PACKAGING, HANDLING, TRANSPORT

Shelf life of the ingredient.
Refer to relevant sections in SDS and/or indicate conditions of storage – limitation of use respect to risks of instability.