Cosmetics Europe
the personal care association

COSMETICS EUROPE:

EXCHANGE OF INFORMATION BETWEEN FRAGRANCE SUPPLIERS AND COSMETIC MANUFACTURERS

2011

GUIDELINES ON EXCHANGE OF INFORMATION BETWEEN FRAGRANCE SUPPLIERS AND COSMETIC MANUFACTURERS

COMPLIANCE WITH THE PRODUCT INFORMATION REQUIREMENTS OF ARTICLE 7
OF THE EC COSMETICS DIRECTIVE 76/768
AS LAST AMENDED BY THE SEVENTH AMENDMENT (DIRECTIVE 2003/15) AND ITS ADAPTATIONS TO TECHNICAL PROGRESS

EUROPEAN COSMETIC, TOILETRY AND PERFUMERY ASSOCIATION (COLIPA)
AND
INTERNATIONAL FRAGRANCE ASSOCIATION (IFRA)

Revised Version 2011 Final

I. INTRODUCTION AND SCOPE

These guidelines are intended for the exchange of safety related product information between fragrance suppliers and manufacturers of cosmetic products needed to meet the Cosmetics Directive requirements.

This document needs to be reviewed in accordance with the mandatory requirements of any new regulation, e.g. EU Cosmetic Regulation 1223/2009.

The guidelines consist of the following sections:

I. Introduction
II. An overview of the information on the fragrance compound that needs to be exchanged
III. An explanation of the importance of a reasoned safety evaluation and the status of the safety evaluator
IV. An explanation of the background and meaning of the IFRA Code of Practice and its safety standards for consumer exposure to certain fragrance ingredients.
V. Further information that can be exchanged.
VI. Appendix 1A, 1B, 1C: Examples of the product information for a fragrance compound.

The information as described in paragraph II needs to be available to the cosmetic company when a fragrance compound is selected for a cosmetic product.

The examples provided in the appendices 1A, B and C are not to be regarded as formal requirements regarding the format used for information exchange. Especially for Appendix 1A, B and C, where the information in points 1 – 5 is identical, one joint format should be able to be used to communicate the information in one document, if so agreed by the fragrance supplier and its customer.

For the purpose of this document and especially with regard to labelling requirements of the EU Cosmetics Directive a fragrance compound is a mixture of fragrance ingredients and functional components with olfactory, odour-enhancing, odour-protecting or blending properties, formulated and intentionally added to a cosmetic product to impart a scent or cover a malodour.

II. THE INFORMATION

Confidentiality: The information provided by the fragrance supplier must be handled by the cosmetic company in a way, which respects the intellectual property of the supplier. For example, unless otherwise agreed, commercially sensitive data (e.g. quantitative formulation data) should only be available to regulatory and safety personnel for the purposes of determining the correct labelling of the final product and for meeting the requirements of the Cosmetics Directive or for other safety or regulatory purposes.

Confidentiality of the fragrance formula is implicit. The Cosmetics Directive acknowledges the confidentiality of the fragrance formula and, therefore, a full disclosure of the fragrance ingredients is not legally required. However, the fragrance compound must still be considered in the safety assessment of the finished cosmetic product, as required in *Article 7a1. (d).*

As a minimum, the fragrance supplier must provide the following information:

- The identity of the customer
- The name and address of the supplier
- The identity of the fragrance compound with its name (if any) and code number
- The product classes, use pattern and use concentration for which the fragrance compound has been assessed. Broad and multiple product categories can be considered in one declaration, as long as the assessor is satisfied that the fragrance compound is suitable for all products, which may come under those categories, up to a maximum level considered.
- A reasoned evaluation of the safety of the fragrance compound for its intended use (see paragraph III below)
- A certificate of compliance with IFRA Standards currently in place, given the commitment of COLIPA members to adhere to these Standards. In case of an update of IFRA Standards, information about a changed status of the fragrance compound (e.g. no longer compliant) needs to be issued within the time frame as stipulated by IFRA and forwarded to the cosmetic manufacturer.
- A statement of compliance of the fragrance ingredients used in the compound with relevant EU chemical control legislation
- A Safety Data Sheet in compliance with current relevant EU regulation
- Accurate information on the presence and concentration of substances, regulated in the Annexes of the Cosmetics Directive, based on reliable sources of the fragrance compound or its ingredients
- Where appropriate, additional information (please refer to section V, Further Information)
- The date
- The name, qualification and signature of the safety evaluator

All information can be supplied either via separate documents or via aggregated documents.

III. THE SAFETY EVALUATION AND THE ROLE OF THE SAFETY EVALUATOR

In addition to the certificate of compliance with current IFRA Standards, a reasoned evaluation of the safety of the fragrance compound for its intended use should be carried out by the fragrance supplier.

This safety evaluation should be based on a thorough analysis, evaluation and interpretation of available data and conditions of exposure. To this end the cosmetic manufacturer shall communicate to the fragrance supplier adequate information on product category and use pattern for which the fragrance compound is intended.
Ideally, the development of the fragrance compound should take into account these elements from the start by a close collaboration between the safety evaluator and the perfumer.

The selection of ingredients at an adequate concentration level might be sufficient to minimize risk resulting of the presence of certain potential hazardous materials. The safety evaluation should also consider the level of purity of the ingredients.

Additional information on the nature of potential health hazard(s) of the undiluted fragrance compound, according to the rules of the Dangerous Preparations Directive (and in future the CLP) can be retrieved from the Safety Data Sheet (SDS) for the selected fragrance compound. The SDS will identify the ingredient(s) responsible for the hazard(s) and leading to the classification of the fragrance compound.

If new information comes to light, or if there are changes in IFRA Standards or in legislation, the impact on existing fragrances must be considered and, if necessary, new assessments must be issued.
The safety evaluator in charge of assessing the safety of the fragrance compound should be qualified similar to a safety assessor of a cosmetic product, i.e. holding a diploma, or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline, or a course recognized as equivalent by a Member State.

The role and responsibility of the safety evaluator must be emphasised. It is in the interest of the fragrance company to select a person with appropriate expertise.

As an alternative to the above reasoned evaluation of the fragrance compound, the fragrance supplier and the cosmetic manufacturer may agree that the cosmetic manufacturer will carry out the safety evaluation at the level of the safety assessment carried out on the finished cosmetic product. In this case and under appropriate terms of confidentiality, the fragrance supplier would provide a breakdown of the fragrance compound according to agreements between the supplier and manufacturer, together with any necessary information on components.

The safety evaluator is responsible for determining:

- whether the ingredients present in the fragrance compound meet the requirements of the cosmetics and chemical legislations, the current IFRA Code of Practice as well as the current COLIPA Recommendations when applicable;
- whether the toxicological data on ingredients are relevant and sufficient;
- the safety of the fragrance compound considering the type of the product and its use conditions
- whether additional information supporting the safety (e.g. market experience) can be considered for a given ingredient or the finished fragrance compound;

The safety evaluator must:

- have recognised competence in analysis, evaluation and interpretation of toxicological data;
- have access both to the toxicological and analytical information relevant for the safety of the fragrance compound;
- consider the safety of the fragrance compound independently of commercial considerations and would generally be expected to report to the senior management of a company.

The judgement of the safety evaluator relies on:

- the knowledge of the physico-chemical properties of the ingredients and QSAR studies available;
- the knowledge and experience of toxicological properties and safety-in-use of the ingredients;
- the history of safety-in-use of fragrance compounds containing the same or similar ingredients;
- the expert assessment of the appropriate data available on a new or novel ingredient
- if necessary, the results of additional data obtained either on one or more ingredients or on the finished fragrance compound itself.

IV. THE IFRA STANDARDS FOR THE SAFE USE OF FRAGRANCES

The IFRA Code of Practice prescribes Standards for the safe use of certain fragrance ingredients in consumer products and is based on an evaluation by an independent expert panel (REXPAN) of the safety data and profiles of these fragrance ingredients.

A certificate of compliance with current IFRA Standards is an integral basic part of the safety information to be supplied by the fragrance manufacturer. However, the certificate does not replace a reasoned evaluation of the safety of the fragrance compound for its intended use.
The suppliers may either declare the IFRA compliance of the fragrance compound in the product class provided by the cosmetic manufacturer (option 1, Appendix 1A) based on the intended use concentration of the compound in the finished product or disclose the maximum limit of the fragrance compound in the product class given by the cosmetic manufacturer or disclose the maximum limit in several product classes (up to the maximal number of classes identified by IFRA – option 2, Appendix 1A).

In case of an update of IFRA Standards, information about the status of the fragrance compound with regard to the new Standard(s) needs to be issued within two months after the amendment enters into force for new creations (which generally is 4 months after the date of the letter of notification) and forwarded to the cosmetic manufacturer for inclusion in the product information.
COLIPA recognizes the IFRA/RIFM safety process, the resulting Standards and the IFRA Code of Practice as central elements in the safety assessment of a fragrance compound and strongly recommends its members to ensure IFRA compliance of all its compounds in use in marketed finished products.

V. FURTHER INFORMATION

Further to the information on presence and levels of substances regulated in the Annexes to the Cosmetics Directive, information on specific ingredients that are commonly subject to enquiries may be provided with the product information at the request of the cosmetic manufacturer. This will facilitate the safety assessment of the cosmetic product and dealing with consumer concerns in the marketplace (e.g. in case of sensitisation).

There may be occasions where further information is required to aid investigation of consumer complaints or adverse effects in the marketplace (Art. 7a 1. (f)). In such cases, the fragrance supplier will collaborate in any investigations and supply, in confidence, any information necessary for the investigation. This information may be supplied as necessary to the regulatory authorities, medical personnel investigating the incident as well as to the toxicologist or equivalent safety person in the cosmetic company.

Nothing in these guidelines prevents more comprehensive exchange of information between the fragrance supplier and the customer, as part of their commercial agreement.

Appendix 1A

EXAMPLE OF AN IFRA CONFORMITY CERTIFICATE

1. Identity of customer: COLIPA Hair Company
15 A Hermann-Debroux
1160 Brussels

2. Product category: Shampoo

3. Identity of fragrance supplier: Company xyz
49 Avenue de la Parfumerie
06130 Grasse

4. Identity of fragrance compound: Name (if any): Amber Flower
Code Number: ABC 6789

5. Assessment Concentration of the fragrance compound in cosmetic product: 0.5%

6. Conformity with current IFRA Standards

1st option:
When used in a shampoo at 0.5%, Fragrance compound ABC 6789 conforms to Amendment xx, the currently applicable Standards of the International Fragrance Association (IFRA).

This safety evaluation applies only to the use of fragrance ABC 6789 in the product stated. Use in other product types or at higher concentrations should be the subject of a separate safety evaluation by the supplier.

2nd option:
In order to be in compliance with the xx IFRA Amendment to the IFRA Code of Practice, this fragrance compound should not be used at levels exceeding the following ones per category:
Class 1: x %
Class 2: x%
……
……
Class 11B: x %

The presence and concentration in the fragrance compound of ingredients listed in the current IFRA Standards are as follows:

CAS	Substance	Concentration (mg/kg)
6728-263	trans-2-hexenal	200
8016-20-4	Grapefruit oil expressed	8500

Evaluator **Name:**

Qualification:

Signature:

Date:

Appendix 1B

EXAMPLE OF AN EXCHANGE OF REGULATORY INFORMATION FOR A FRAGRANCE COMPOUND (IN EUROPE)

1. **Identity of customer:** COLIPA Hair Company
   15 A Hermann-Debroux
   1160 Brussels

2. **Product category:** Shampoo

3. **Identity of fragrance supplier:** Company xyz
   49 Avenue de la Parfumerie
   06130 Grasse

4. **Identity of fragrance compound:** Name (if any): Amber Flower
   Code Number: ABC 6789

5. **Assessment Concentration of the fragrance compound in cosmetic product:** 0.5%

6. Regulatory Information

The ingredients used in Fragrance compound ABC 6789 are in compliance with current European chemical control legislation.

Fragrance compound ABC6789 is formulated in accordance with the requirements of Annex II of Dir. 76/768/EEC (Cosmetics Directive).
The presence and concentration in the fragrance compound of ingredients listed in the Annexes III, IV, VI, VII to the Cosmetics Directive (76/768/EEC) are as follows:
For practical reasons, substances considered as “allergens” (26) within Annex III will be provided on a distinct list.

Annex III

The following substances considered as “allergens” in annex III are present:

CAS N°	**Substance Name (e.g.: INCI)**	**Cosmetics Directive Annex/N°**	**Concentration (mg/kg) in the compound**
105-13-5	Anisyl Alcohol (4-Methoxybenzyl alcohol)	III / 80	2
78-70-6	Linalool	III/ 84	30.000

The following other substances regulated in the annexes of the Cosmetics Directive are present:

CAS N°	**Substance Name (e.g. : INCI)**	**Cosmetics Directive Annex/N°**	**Concentration (mg/kg) in the compound**
93-89-0	Ethyl benzoate	VI/1/1	20
1506-02-1 21145-77-7	AHTN	III/182	200

7. Other information on specific ingredients [1]

The presence and concentration in the fragrance compound of the following specific ingredients are as follows

CAS	Substance	Concentration (mg/kg)
123-45-6	Material ABC	200

Evaluator **Name:**

Qualification:

Signature:

Date:

[1] To be decided by individual companies on a case-by-case basis.

Appendix 1C

EXAMPLE OF A SAFETY EVALUATION OF THE FRAGRANCE COMPOUND

1. Identity of customer: COLIPA Hair Company
15 A Hermann-Debroux
1160 Brussels

2. Product category: Shampoo

3. Identity of fragrance supplier: Company xyz
49 Avenue de la Parfumerie
06130 Grasse

4. Identity of fragrance compound: Name (if any): Amber Flower
Code Number: ABC 6789

5. Assessment Concentration of the fragrance compound in cosmetic product: 0.5%

6. Reasoned Safety Evaluation of Fragrance Compound ABC 6789

Fragrance compound ABC 6789 has been evaluated for safety when used at 0.5% in shampoo.

Company xyz only uses ingredients for which a safety clearance procedure is carried out by appropriately qualified people. The safety clearance takes into account the following information:

1. Safety data generated by RIFM, the suppliers or in the open scientific literature. This data is evaluated in accordance with the principles laid down in Appendix 5 to the IFRA Code of Practice. *Appendix 5 requires consideration of possible effects on the skin, including skin irritation and sensitisation with special attention paid to the effect of sunlight, should ingredients absorb ultra-violet radiation. Systemic toxicity should be considered in relation to the quantities of fragrance material used and likelihood of entry into the body.*
2. A history of safe-use of the ingredients at the levels proposed, taking into account in particular any reports of adverse effects reported by Dermatologists or other medical professionals.
3. Restrictions on the use of the ingredient published in the IFRA Standards.
4. In the absence of adequate data, structural relationships between the proposed ingredient and ingredients already cleared for inclusion in the product concerned or comparable product.
5. Impurities in the ingredients used, where necessary imposing purity specifications.

The creative perfumery procedures in company xyz ensure that the end use and concentration of the fragrance in the product are taken into account when deciding the concentration of each ingredient to be used. This ensures that any restrictions are not exceeded, and that there are appropriate margins of safety for each ingredient with regard to relevant toxicological endpoints.

I confirm that Fragrance compound ABC 6789 is composed only of ingredients approved by the safety clearance procedure, and that all ingredients are used within the restrictions relevant to the use of this fragrance in a shampoo at 0.5%.

Conclusion

The conclusion of the safety evaluation is that this fragrance compound satisfies, according to the current state of knowledge, the safety requirements for the intended application under normal and reasonably foreseeable conditions of use.

Evaluator **Name:**

Qualification:

Signature:

Date:

COSMETICS EUROPE IS THE EUROPEAN TRADE ASSOCIATION REPRESENTING THE INTEREST OF THE COSMETICS, TOILETRY AND PERFUMERY INDUSTRY

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