



Cosmetics Europe Nano Guidance Package

Part III: Labelling of products containing nanomaterials

Colipa Cosmetic Product Labelling Guidelines

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**COMPLIANCE WITH REGULATION 1223/2009 ON
COSMETIC PRODUCTS**

COLIPA GUIDELINES ON COSMETIC PRODUCT LABELLING

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I. INTRODUCTION

Regulation 1223/2009 of the European Parliament and the Council of 30 November 2009 on cosmetic products (the “Cosmetics Regulation” or the “Regulation”) was published in the Official Journal of the European Union on 22 December 2009 (OJEU, L 342, p. 59). The Regulation will replace Directive 76/768/EC (the “Cosmetics Directive” or the “Directive”), which has been governing the composition, labelling and packaging of finished cosmetic products in the European Union since 1976. This replacement will be fully effective on 11 July 2013 when all provisions of the Regulation become enforceable.

The Regulation is a recast of the Cosmetics Directive and does not introduce fundamental changes to the regulatory framework of the Directive.

Being in the form of a Regulation and no longer a Directive, it applies to all Member States and does not need to be transposed into national legislation. Any cosmetic products placed on the EU market before 11 July 2013 may comply either with the Cosmetics Directive or with the Cosmetics Regulation. After that date, products must comply with the Regulation.

The information that must be printed on cosmetic product labels (containers and packaging) is regulated under Article 19 of the Cosmetics Regulation. New requirements introduced by the Regulation are the symbol for “date of minimum durability” (Annex VII, point 3) and the indication of ingredients present in the form of nanomaterials. The Regulation also acknowledges that the “period after opening” is not required when the concept of durability after opening is not relevant: for single-use products, products presented in containers that do not allow contact between the product and the external environment and products for which there is no risk of deterioration that could lead to non-conformity of the product with the safety requirements of the Regulation.

These guidelines are intended to provide information and guidance on the labelling requirements of the Regulation. They consist of three main parts: a quick guide for cosmetic product labelling in the EU, specific guidance on the individual requirements and references to labelling requirements in other, horizontal regulations that apply to cosmetic products.

II. QUICK GUIDE FOR COSMETIC PRODUCT LABELLING IN THE EUROPEAN UNION

II.a. Which products?

The Cosmetics Regulation applies to cosmetic products. Article 2.1 a defines cosmetic products as any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.

This definition applies to all cosmetic products, be they sold in shops, through vending machines, by mail order, via the internet, applied by professionals, or made available in hotels, spas etc.

II.b. When?



The labelling requirements of the Regulation become mandatory as of 11 July 2013 (Article 40). All cosmetics products made available on the market on or after 11 July 2013 have to comply with the new Cosmetics Regulation.

However, companies can voluntarily comply with the labelling requirements of the Regulation from 11 January 2010, which is the date when the Regulation entered into force (Article 39). As the Regulation only introduces few new labelling elements, and as these are not relevant for the vast majority of cosmetic products, most products which were labelled in line with the Cosmetics Directive will already comply with the labelling provisions of the Regulation.

II.c. What?

The following table contains an overview of the compulsory labelling requirements of the Regulation. Please see Chapter III for more detailed information on each of these requirements.

Cosmetics Regulation Article	Requirement
Art 19.1(a)	Name or registered name and the address of the responsible person
Art 19.1(a)	Country of origin for cosmetic products imported into the EU
Art 19.1(b)	Nominal content at the time of packaging by weight or by volume. <i>Exceptions: for pre-packaged items, number of items if weight or volume are not relevant; packaging containing less than five grams or five millilitres, free samples and single-application packs</i>

<p>Art 19.1(c)</p>	<p>Date of minimum durability preceded by the symbol  or the words: 'best used before the end of'.</p> <p>Indication of the date of minimum durability is not mandatory for products with a minimum durability of more than 30 months. For such products except where the concept of durability after opening is not relevant an indication of the period of time after opening has to be indicated for which the product is safe and can be used without any harm to the consumer. This information shall be indicated by the symbol  followed by the period (in months and/or years, but usually in months as "x M");</p>
<p>Art 19.1(d)</p>	<p>Information regarding possible precautions to be observed in use. Note especially the compulsory information listed in Annexes III to VI.</p>
<p>Art 19.1(e)</p>	<p>Batch number or reference to identify the final cosmetic product. When products are too small, such information need appear only on the packaging.</p>
<p>Art 19.1(f)</p>	<p>Function of the cosmetic product, unless it is clear from its presentation</p>
<p>Art 19.1(g)</p>	<p>List of ingredients (INCI). May be indicated on the packaging only. Must be preceded by the term 'ingredients'.</p>

Please note that for cosmetic products packaged in aerosol dispensers there are additional requirements specified by Directive 75/324/EEC (for further details, please see section IV.a).

II.d. Where?

The Regulation refers to two types of packaging for cosmetic products:

- the **container** (also known as primary package or inner package) is the packaging designed to come into direct contact with the product;
- The **packaging** (also known as secondary package or outer package) is the packaging designed to contain one or more containers, including protective materials, if any.

The information required by Article 19.1, items (a) to (f) of the Regulation must appear on the label of both the container and the packaging of each individual cosmetic product.

The list of ingredients (Article 19.1 item (g)) may be printed on the packaging only.

In particular cases, the information may not have to be indicated or shall be made available to the consumer by other means. For further details, please see section II.f below.

II.e. How?

Lettering (Article 19.1)

The lettering used for cosmetic product labelling must be indelible, easily legible and visible (e.g. in terms of contrast with the background, size, etc.) under normal conditions of presentation.

Specific requirements apply for the size of lettering used for the indication of the nominal content (for further details, please see section III.b).

Abbreviation/highlighting (Article 19.1(a))

The name and the address of the responsible person may be abbreviated as far as it remains possible to easily identify the responsible person and his address.

In case of multiple addresses, the one where the Product Information File is made readily available by the responsible person shall be highlighted. This is usually done by underlining the address.



Language/nomenclature (Article 19.5 and 19.6)

Except for the ingredient list, the language of the information printed on a cosmetic product's label shall be determined by the law of the Member State where the product is made available to the end user.



The list of ingredients shall be expressed by using the common ingredient name set out in the glossary provided for in Article 33 and to be published in the Official Journal of the European Union. In the absence of a common ingredient name, a term as contained in a generally accepted nomenclature shall be used (please see section III.g for further details).

II.f. Particular cases (small products, non-pre-packaged products, free / trade, samples, etc.)

	<u>NAME OF RESPONSIBLE PERSON, ADDRESS, COUNTRY OF ORIGIN</u>	<u>NOMINAL CONTENT</u>	<u>DATE OF MINIMUM DURABILITY/PAO</u>	<u>PARTICULAR PRECAUTIONS</u>	<u>BATCH N°</u>	<u>FUNCTION OF THE COSMETIC PRODUCT</u>	<u>LIST OF INGREDIENTS</u>
<u>SMALL PRODUCTS</u>	✓	Exempted, if the product contains	✓	The information shall appear on	✓	✓	The information shall appear on

	<u>NAME OF RESPONSIBLE PERSON, ADDRESS, COUNTRY OF ORIGIN</u>	<u>NOMINAL CONTENT</u>	<u>DATE OF MINIMUM DURABILITY/PAO</u>	<u>PARTICULAR PRECAUTIONS</u>	<u>BATCH N°</u>	<u>FUNCTION OF THE COSMETIC PRODUCT</u>	<u>LIST OF INGREDIENTS</u>
		less than 5 ml or 5 g		<p>an enclosed or attached leaflet, label, tape, tag or card. Unless impracticable, a reference to this information shall be made by the symbol given in Annex VII:</p>  <p>or by an abbreviated indication.</p>			<p>an enclosed or attached leaflet, label, tape, tag or card. Unless impracticable, a reference to this information shall be made by the symbol given in Annex VII:</p>  <p>or by an abbreviated indication.</p> <p>Unless impracticable to place this information on an enclosed or attached leaflet, label, tape, tag or card, it shall appear on a notice in immediate proximity of the product.</p>

	<u>NAME OF RESPONSIBLE PERSON, ADDRESS, COUNTRY OF ORIGIN</u>	<u>NOMINAL CONTENT</u>	<u>DATE OF MINIMUM DURABILITY/PAO</u>	<u>PARTICULAR PRECAUTIONS</u>	<u>BATCH N°</u>	<u>FUNCTION OF THE COSMETIC PRODUCT</u>	<u>LIST OF INGREDIENTS</u>
<u>SINGLE APPLICATION ON PRODUCTS</u>	✓	Exempted	PAO is not relevant but date of min. durability shall be indicated if durability is less than 30 months	✓	✓	✓	✓
<u>FREE SAMPLES / TESTERS</u>	✓	Exempted	✓	✓	✓	✓	✓
<u>NON PRE-PACKAGED PRODUCTS</u>	Labelling of the information in accordance with the rules adopted by Member States						
<u>IMPRACTICABLE PACKAGING</u>	✓	✓	✓	The information shall appear on an enclosed or attached leaflet, label, tape, tag or card. Unless impracticable,, a reference to this informati	✓	✓	The information shall appear on an enclosed or attached leaflet, label, tape, tag or card. Unless impracticable, this information shall be referred to by the symbol in

	<u>NAME OF RESPONSIBLE PERSON, ADDRESS, COUNTRY OF ORIGIN</u>	<u>NOMINAL CONTENT</u>	<u>DATE OF MINIMUM DURABILITY/PAO</u>	<u>PARTICULAR PRECAUTIONS</u>	<u>BATCH N°</u>	<u>FUNCTION OF THE COSMETIC PRODUCT</u>	<u>LIST OF INGREDIENTS</u>
				<p>on shall be made by the symbol given in Annex VII:</p>  <p>or by an abbreviated indication</p>			<p>Annex VII:</p>  <p>or by an abbreviated indication.</p>
<u>MULTI-PACKS</u>	✓	The N° of items shall appear on the packaging except if it is visible from the outside.	✓	✓	✓	✓	✓

In the table above:

- Single application products are products intended to be used only once immediately after opening.
- Free samples are products that are made freely available to the end user.
- Impracticable packaging refers to products where it is impossible for practical reasons to label the information on the packaging or container.
- Non-pre-packaged products are products that are packaged at the point of sale, containing similar or different products with similar or different functions.
- Multi-packs regulated by Article 19.1(b) are “pre-packages normally sold as a number of items, for which details of weight or volume are not significant”. Further national regulations for multi-packs and pre-packages made up of individual packages which are not intended to be sold individually may apply on the basis of Article 5¹ of Directive 2007/45/EC.

¹ Art 5 of Directive 2007/45/EC reads:

Multipacks and prepackages made up of individual packages which are not intended to be sold individually

- In some cases, a combination of the above may apply.

1. For the purposes of Article 3, where two or more individual prepackages make up a multipack, the nominal quantities listed in section 1 of the Annex shall apply to each individual prepackage.

2. Where a prepackage is made up of two or more individual packages which are not intended to be sold individually, the nominal quantities listed in section 1 of the Annex shall apply to the prepackage.

III. SPECIFIC GUIDANCE FOR EACH LABELLING REQUIREMENT

III.a. Name and address of responsible person; country of origin

Article 4 of the Cosmetics Regulation provides that, "*only cosmetic products for which a legal or natural person is designated within the Community as 'responsible person' shall be placed on the market*".

The responsible person can be one of the following:

- Manufacturer² within the EU;
- Person designated by a manufacturer from outside the EU;
- Distributor if he modifies a product already on the market in such a way that compliance with the Regulation may be affected (according to Articles 4 to 6);
- Importer (According to Articles 4 and 5);
- Third party with a written mandate from the manufacturer or the importer.

Additional information on the identification of the responsible person can be found in Colipa Guidance Document on Roles & Responsibilities along the supply chain.

The following information must be printed on both the container and the packaging:

- Name & address of the responsible person. The name and address must be sufficient to allow the identification of and to the access to the undertaking. The address may be abbreviated to a well-known city or town such that the normal postal service will deliver a letter to that address.
- If the product is manufactured outside the EU, the country of origin must also be labelled.

III. b. Nominal content

The nominal quantities are expressed in units of weight or volume except in specific cases (packaging containing less than five grams or five millilitres, and others - see chapter II section f)

Rules regarding labelling of the nominal content at the time of packaging are set by:

- Directive 76/211/EEC of 20 January 1976 relating to the making-up by weight or by volume of certain pre-packaged products³
- and its amendments: Directive 78/891/EEC⁴ and Directive 2007/45/EC⁵

² Definition of the Manufacturer according to Article 2.1 (d)

³ Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain prepackaged products (OJ L 46, 21.2.1976, p. 1)

⁴ Commission Directive 78/891/EEC of 28 September 1978 adapting to technical progress the Annexes to Council Directives 75/106/EEC and 76/211/EEC on pre-packaging (OJ L 311, 04/11/1978, p. 21)

⁵ Directive 2007/45/EC of the European Parliament & of the Council of 5 September 2007 laying down rules on nominal quantities for prepacked products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC (OJ L 247, 21.9.2007, p.17)

According to Directive 76/211/EC, Annex I, point 3.1, the nominal quantity (nominal weight or nominal volume) is expressed in kilograms, grams, litres, centilitres or millilitres. The minimum height of the figures is given in the following table:

Contents	Minimum height of figures
Not exceeding 50 g or 50 ml	2 mm
Exceeding 50 g or 50 ml but not exceeding 200 g or 200 ml	3 mm
Exceeding 200 g or 200 ml but not exceeding 1 kg or 1 l	4 mm
Exceeding 1 kg or 1 l	6 mm

The figures must be followed by the symbol for the unit of measurement used or, where appropriate, by the name of the unit in accordance with Directive 80/181/EEC and its modifications.

If the pre-package meets the requirements of Directive 76/211/EEC, a small 'e', at least 3 mm high, may be placed in the same field of vision as the indication of the nominal quantity.

For products which are sold in aerosol dispensers, additional requirements are specified in:

- Directive 75/324/EEC (article 8) and its amendments
- Directive 2007/45/EC (article 4)

For further details, please see chapter IV.a.

III.c. Date of minimum durability (DOMD) and period after opening (PAO)

On the basis of finished product physicochemical and microbiological stability studies, two different situations have to be considered:

a) The finished product has a minimum durability of less than or equal to 30 months

➔ The date of minimum durability shall be clearly expressed and preceded by the mention 'best used before the end of' or by the following symbol, specified in Annex VII of the Regulation:



The date consists either of the month and year (MMYYYY or MMY) or the day, month and year (DDMMYYYY or DDMMYY), in that order.

If the date is not located next to the symbol or next to the "best used before the end of" sentence, its location has to be clearly explained.

If necessary, the information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.

b) The finished product has a minimum durability of more than 30 months

→ A date of minimum durability is not required. However, an indication of the period of time after opening for which the product is safe and can be used without any harm to the consumer must be labelled using the symbol representing an open cream jar

shown in point 2 of Annex VII:



The symbol must be accompanied by an indication of the period of time in months or years shown as a number, which can be located inside or outside the symbol. The European Commission and Member States have agreed on the use of **M** to represent months, but a shortened version to represent the number of years has not been agreed. In practice, the indication is usually given in months as “x M”.

It must be borne in mind that for some products the period of time after opening is not relevant:⁶

- Single use products;
- Products where the packaging does not allow physical opening of the products, as is the case for products presented in containers where there is no possibility of contact between the product in the container and the external environment, such as aerosol dispensers, airless containers...;
- Products with a low microbiological risk such as those with: pH \geq 10.0, pH \leq 3.5, high alcohol content (e.g. perfumes, eau de cologne, ...) [see EN ISO 29621:2010 *Cosmetics – Microbiology – Guidelines for the risk assessment and identification of microbiologically low-risk product*]

III.d. Particular precautions / warnings

Article 19.1(d) requires that specific precautions to be observed during the use of cosmetic products must be indicated on cosmetic product labels. Warnings required by the Regulation are laid down in Annexes III to VI column i).

Example:

- *all toothpastes containing sodium fluoride must be labelled with the following wording: “contains sodium fluoride”;*
- *any toothpaste containing 0.1 to 0.15% fluoride, unless it is already labelled as contra-indicated for children (e.g. “for adult use only”) the following labelling is mandatory: “Children under 6 years and younger: use a pea-sized amount for supervised brushing to minimise swallowing. In case of intake of fluoride from other sources consult a dentist or doctor”.*

In addition to these legal requirements, other precautionary statements or warnings (referring e.g. to certain aspects of product liability/safety or recommendations made

⁶ See Recital 48 of the Cosmetics Regulation and the Commission Guidance on the practical implementation of Article 6(1)(c) of the Cosmetics Directive: the PaO is not required for single-use products; products presented in containers that do not allow a contact between the product and the external environment and products for which there is no risk of deterioration that could lead to non conformity of the product with the safety requirements of the Regulation. See also Commission guidelines “Practical implementation of Article 6(1)(c) of the Cosmetics Directive (76/768/EEC): labeling of product durability: “period of time after opening” (04/ENTR/COS/28)

by the safety assessor) may be printed on the label, under the responsibility of the responsible person.

Where additional recommendations from the European Commission are available, they should also be taken into consideration. For example, the European Commission published a recommendation on 22 September 2006 (2006/647/EC) “on the efficacy of sunscreen products and the claims made relating thereto” giving recommendations on labelling.

Specific precautions for use must be mentioned in the language(s) required by the Member States in which the products are made available to end users (see Annex I of this document).

The precautions and warnings need to appear on both the container and the packaging.

Where it is impossible for practical reasons to print this information on the label, the information shall be mentioned on an enclosed or attached leaflet, label tape, tag or card.

This shall be referred to either by abbreviated information or by the “hand-in-book” symbol which must appear on the container or packaging:



Where it is impracticable to label the symbol, this may be omitted.

III.e. Batch number

The batch number of manufacture or the reference for manufacturing identification of the cosmetic product is a combination of letters and/or figures. The Regulation does not specify the format for the batch number; the decision belongs to the responsible person. The purpose of the batch number is to ensure identification of a certain batch of a cosmetic product throughout the whole supply chain, in particular in the rare case of a recall.

The batch number has to be printed on both the container and the packaging. Where this is impossible for practical reasons because the products are too small, it can be printed only on the packaging.

The batch number should not be confused with the “notification number” which is an administrative number obtained in the context of Article 13 and which is not required to appear on the product label.

III.f. Product function

A cosmetic product⁷ is dedicated to exclusively or mainly clean, perfume, change the appearance, protect or keep in good condition external parts of the human body

⁷ Cosmetic products may include, for example: creams, emulsions, lotions, gels and oils for the skin, face masks, tinted bases (liquids, pastes, powders), make-up powders, after-bath powders, hygienic powders, toilet soaps, deodorant soaps, perfumes, toilet waters and eau de Cologne, bath and shower preparations (salts, foams, oils, gels), depilatories, deodorants and anti-perspirants, hair colorants, products for waving, straightening and fixing hair, hair-setting products, hair-cleansing products (lotions, powders, shampoos), hair-conditioning products (lotions, creams, oils), hairdressing products (lotions, lacquers, brilliantine), shaving products (creams, foams, lotions), make-up and products removing make-up, products intended for application to the lips, products for care

(epidermis, hair system, nails, lips and external genital organs) or the teeth and the mucous membranes of the oral cavity or to correct body odours.

The function of the cosmetic product should be clearly printed on the container and on the packaging, unless it can be spontaneously and obviously deduced from a combination of:

- the product presentation (shape, size and volume) e.g. lipstick;
- its name (e.g. cream), trademarks;
- its claims (including the use of certain foreign terms that are generally accepted, e.g. “waterproof mascara”), pictures, logos and figurative or other signs (e.g. the picture of an eye on an eye-shadow).

Although the language in which the function should be stated on the label is determined by the law of the Member State(s) where the product is made available to the end user, some terms used on labels are internationally accepted (e.g. “eyeliner”, eau de toilette, etc.).

III.g. List of ingredients

The purpose of ingredient labelling is to ensure transparency to the consumer, giving adequate information about the product, for example allowing him or her to avoid ingredients that he/she may be allergic to. It also helps control authorities in their market surveillance activities.

All cosmetic products marketed in any part of the EU have to be labelled with a list of their ingredients, irrespective of the channel of distribution. This requirement therefore applies to products defined under Article 2.1(a) of the Cosmetics Regulation, including imported products, professional products, free samples, tester samples, multi-component products, products sold by mail order or via the internet, products provided in hotels and other public facilities.

Labelling Rules:

1. Nomenclature

To achieve transparency, it is essential to ensure uniformity throughout the EU in the labelling names used for the ingredients in cosmetic products. This helps the consumer identify the same ingredient across different EU countries.

The common name for ingredient labelling referred to in the EU regulation is known as the **International Nomenclature Cosmetic Ingredient** name or INCI name. The relevant regulatory text listing the INCI names is the Glossary, to be published in the Official Journal of the EU. In the meantime, the reader is referred to the current Inventory⁸ of Cosmetic Ingredients, or to the Commission’s Cosmetic Ingredients Database (CosIng)⁹.

2. Position and legibility

The ingredients list must be visible to the consumer at the time of purchase.

of the teeth and the mouth, products for nail care and make-up, products for external intimate hygiene, sunbathing products, products for tanning without sun, skin-whitening products and anti-wrinkle products.

⁸ Commission Decision 2006/257/EC of 9 February 2006 amending Decision 96/335/EC establishing an inventory and a common nomenclature for ingredients employed in cosmetic products; OJEU L97, 5.04.2006

⁹ <http://ec.europa.eu/consumers/cosmetics/cosing/>

Therefore, it can be placed on the packaging only. However, if there is no packaging, it must be indicated on the container. It is sufficient to declare ingredients in any place on the external side of the packaging of any cosmetic product, provided that the information is in indelible, easily legible and visible lettering.

If a multi-product pack is sold as a whole and not opened before selling to the consumer, the ingredient declaration may appear only once on the whole pack. Obviously, the declaration should show a separate list for every non-identical product in the pack.

Where, for practical reasons, it is impossible to indicate the ingredients on the packaging, the information shall be mentioned on an enclosed or attached leaflet, label, tape, tag or card and shall be referred to by abbreviated information or the following symbol which must appear on the container or packaging:



Where it is impracticable to label that abbreviated information or the symbol, they may be omitted.

For soap and small products, where it is impossible for practical reasons to provide ingredient information as detailed above, the information may be given on a notice or leaflet in close proximity to the product offered for sale. In this case, the hand-in-book symbol is not needed on the package.

3. Ingredients to be labelled

All ingredients have to be labelled on the packaging. An incomplete listing of ingredients is considered to be misleading.

However, there is a provision whereby certain materials are not considered as ingredients. The relevant extract from Article 19.1(g) states:

“For the purpose of this Article, an ingredient means any substance or mixture intentionally used in the cosmetic product during the process of manufacturing.

The following shall not, however, be regarded as ingredients:

(i) Impurities in the raw materials used;

(ii) Subsidiary technical materials used in the mixture but not present in the final product.”

These definitions are reasonably clear. Subsidiary materials not present in the final product would include filtration aids and decolourising agents, both of which could be added during manufacturing but would subsequently be removed.

Regarding perfume and aromatic compositions¹⁰, it should be highlighted that under the Cosmetics Directive, *“materials used in strictly necessary quantities as solvents or as carriers for perfume and aromatic compositions”* did not need to be labelled. These are no longer specifically exempted from the requirements of Article 19.1(g) of the Regulation. Consequently:

¹⁰ as bought from the supplier and described by their name and code number in the Cosmetic Product Safety Report.

- in the ingredient list, the INCI names “Parfum” or “Aroma” shall be used for perfume and aromatic compositions and their raw materials, as applicable. These names usually include functional components, e.g. solvents or carriers; in such cases the solvents or carriers do not need to appear separately in the ingredient list;
- whenever perfumes or aromatic compositions require the addition of solvents or carriers to the product, these solvents or carriers must be listed in the ingredients list.

In addition, 26 specific substances listed in Annex III of the Regulation shall be indicated if their concentration is above the threshold concentration mentioned column h) of this Annex, irrespective of the substances’ function and/or source (i.e. whether added directly or as component of a complex cosmetic ingredient such as botanical extracts, essential oils, fragrance compositions, aroma compositions, etc.). The thresholds are 0.001% for leave-on products and 0.01% for rinse-off products. For cosmetic products consisting of different components that are mixed immediately prior to use, these thresholds refer to the concentration of the substances in the final mix, as applied to the body.

The purpose of this additional labelling is to inform those sensitised individuals who have been tested and know which ingredients to avoid; it will tell them whether the substance to which they are sensitised is present in the product. There is no requirement to remove these substances and no need to consider reformulating out of these ingredients; the overwhelming majority of cosmetic users will not experience any undesirable effects associated with the presence of these substances.

Practical guidance:

- Companies should obtain reliable information from their ingredient suppliers on the presence and levels of the 26 substances in the materials they sell.
- Common Colipa/EFFA (European Fragrance and Flavour Association) Guidelines for information exchange between fragrance raw material suppliers and cosmetic manufacturers have been agreed (Annex 2). Suppliers of other raw materials may need to be aware of this requirement as their materials may also provide a source of some of the ingredients that have to be labelled.
- Ingredient labels may need to be changed by inclusion of the substance (when present above the threshold) following the normal ingredient nomenclature (INCI) and labelling rules of Article 19.1(g).
- When present at a concentration >1%, the ingredients should be listed at the position corresponding to that concentration; for a concentration of <1%, they can be listed in any order in the remainder of the ingredient list.
- The INCI names of the 26 specific substances are attached (Annex 3).

4. Order of the declaration

The ingredient list shall be preceded by the common term “ingredients”. This does not require translation, in line with Articles 19.5 and 19.6. However, in some language versions of the Regulation, the term was translated into the national language. Colipa has required the Commission to issue a corrigendum for these.

The term “ingredients” can be used alone or as part of a box enclosing the list of ingredients.

The relevant extracts from article 19.1 (g) requiring ingredient labelling are:

- *“The list of ingredients shall be established in descending order of weight of the ingredients at the time they are added to the cosmetic product. Ingredients in concentrations of less than 1 % may be listed in any order after those in concentrations of more than 1 %.”*
- *“Colorants other than colorants intended to colour the hair may be listed in any order after the other cosmetic ingredients”*

The wording of the legal text does not make it clear where in the ingredient list substances present at exactly 1% should appear. Colipa advises that any such ingredient be declared at the end of the list of ingredients present at more than 1% (i.e. the wording in the text should be interpreted as “1% or more”).

If solutions of ingredients are used, the ingredients are to be listed based on their concentration as active matter. The solvents must also be listed.

If a raw material is supplied as an intentional mixture, each individual ingredient must be declared separately, taking into account its concentration in the finished product.

For decorative cosmetic products, the Regulation requires:

“Colorants other than colorants intended to colour the hair may be listed in any order after the other cosmetic ingredients. For decorative cosmetic products marketed in several colour shades, all colorants other than colorants intended to colour the hair used in the range may be listed, provided that the words ‘may contain’ or the symbol ‘+/-’ are added. The CI (Colour Index) nomenclature shall be used, where applicable.”

This will allow the use of a common ingredient labelling for a whole colour range of similar products.

Colipa recommends that the wording “may contain” be replaced by the sign “+/-” (to avoid translations for products sold in several countries) followed by the relevant INCI names, all enclosed in square brackets.

5. Nanomaterials

A new requirement introduced by the Regulation is the obligation to inform the consumer when nanomaterials, as defined under Article 2.1(k), are used in cosmetic products. To this end, the suffix “nano” shall be placed after the INCI name of the ingredient concerned.

The official text reads: *“All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word ‘nano’ in brackets.”*

Most language versions of the Regulation do not specify the type of brackets to be used however, some do. In Colipa’s view, all types of brackets should be allowed on the basis of the following:

- all language versions of the Cosmetics Regulation are equally valid;
- Member States shall not refuse, prohibit or restrict the making available on the market of cosmetic products which comply with the requirements of this Regulation (Article 9).

Examples:

- titanium dioxide (nano) or TITANIUM DIOXIDE (NANO)
- titanium dioxide [nano] or TITANIUM DIOXIDE [NANO]

- titanium dioxide {nano} or TITANIUM DIOXIDE {NANO}
- titanium dioxide <nano> or TITANIUM DIOXIDE <NANO>

Based on the two arguments above, and in line with Articles 19.5 and 19.6, the suffix “nano” should be accepted throughout the EU regardless of national language or alphabet.

6. Glossary

Article 33 of the Regulation requires the European Commission to compile, update and publish in the Official Journal of the European Union a Glossary of common ingredient names. The Glossary is not a “closed” listing and will be updated periodically. There is no requirement to register cosmetic ingredients with EU authorities or EU Member States for inclusion into the Glossary and the latter does not constitute a list of substances authorised for use in cosmetic products.

The use of the INCI name in the common nomenclature is of prime importance as it helps to ensure transparency. Therefore, if such a name exists for a particular ingredient through its listing in the EU inventory (see footnote 6), it must be used. If there is no such name an alternative name may be used, but this must be regarded as a temporary expedient.

The manufacturer of the cosmetic product should take the necessary steps to ensure that an INCI name is applied for and allocated, and, when it becomes available, it should be used in the ingredient declaration without unnecessary delay: the Cosmetic Regulation (Article 33) requires that *the common ingredient name shall be applied for the purpose of labelling cosmetic products placed on the market at the latest twelve months after publication of the Glossary in the Official Journal of the European Union.*

IV. RELATED HORIZONTAL LABELLING REQUIREMENTS

IV.a. Aerosols

The Aerosol Dispensers Directive 75/324/EEC and its adaptations to technical progress 94/1/EC and 2008/47/EC include the following labelling requirements for aerosols with a capacity of more than 50 ml:

- The name and address or trade mark of the person responsible for marketing the aerosol dispenser.
- The symbol ϵ (so-called 'inverted epsilon') certifying conformity with the requirements of this Directive; the size of the symbol is not specified, but it is normally 3 mm high and usually placed in the same field of vision as the volume (and weight) declaration.
- Code markings enabling the filling batch to be identified.
- Whatever its contents, the phrase "Pressurized container: protect from sunlight and do not expose to temperatures exceeding 50 °C. Do not pierce or burn, even after use." and any additional operating precautions which alert consumers to the specific dangers of the product; if the aerosol dispenser is accompanied by separate instructions for use, the latter must also reflect such operating precautions.
- Where the aerosol is classified as "flammable" or "extremely flammable": the flame symbol, in accordance with the model in Annex II to Directive 67/548/EEC.
- The indication "flammable" or "extremely flammable" depending on the classification of the aerosol as "flammable" or "extremely flammable".
- The safety phrases S2 and S16 laid down in Annex IV to Directive 67/548/EEC.
- The phrase "Do not spray on a naked flame or any incandescent material".
- Where the aerosol contains flammable ingredients but is not classified as "flammable" or "extremely flammable", the sentence "X% by mass of the contents are flammable".
- The nominal quantity ('net contents') by weight and by volume. However the Nominal Quantities Directive 2007/45/EC states that, by derogation to Directive 75/324/EEC, aerosol dispensers do not need to be labelled with the nominal weight of their contents. The practice is only to label the nominal quantity by volume (in ml).
- Directive 2007/45/EC additionally requires that aerosol dispensers shall indicate the nominal total capacity of the container. The indication shall be such as not to create confusion with the nominal volume of the contents. Usually, the nominal total capacity of the container is shown by a number without unit in a square box.

IV.b. Flammable products

Flammability labelling of non-aerosol dispenser cosmetic products is recommended but not regulated (cosmetics which are in the finished state and intended for the final user are not covered by Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures – see point 5 of Article “Purpose and Scope”).

Therefore, it is under the manufacturer’s responsibility to assess the flammability hazards associated with his product when used under normal or reasonably foreseeable conditions.

Several documents may be used to perform a risk analysis such as:

- Colipa recommendation issued on 1994 (“Flammability labelling of cosmetic products 94/267) – *To be updated according to the new requirements defined in GHS.*
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

In case a warning is considered appropriate by the manufacturer, it has to follow the labelling rules laid down by the Cosmetics Regulation, namely to be printed using indelible, easily legible and visible lettering, on the primary and secondary packaging.

c. Nominal Content Directive

Directive 76/211/EEC on the making up by weight or by volume of certain pre-packaged products, as well as its amendments Directive 78/891/EEC and Directive 2007/45/EC are laying down the rules for indicating the nominal content of products, at the time of packaging, on the products’ labels. For further details on how these Directives apply to the labelling of cosmetic products, please see chapter III section b).

d. Packaging and Packaging Waste

The Directive on Packaging and Packaging Waste (94/62/EC) was brought in to harmonise the differing requirements in national legislation. There are no specific labelling requirements. The Directive foresees a voluntary identification system for packaging materials. This system is established by the Commission Decision 97/129/EC of 28 January 1997. The Decision aims to establish the numbering and abbreviations on which the identification system is based, indicating the nature of the packaging material(s) used and specifying which materials shall be subject to the identification system.

A number of countries have introduced national packaging recycling and recovery schemes that may require the use on packaging of a membership logo, e.g. the

Green Dot. Further details of which countries use this logo may be found at:
<http://www.pro-e.org/>

Some countries have guidelines and recommendations for industry to encourage consumers to recycle packaging or to give advice on how to recycle safely. Any labelling guidelines are purely voluntary.

V. LIST OF REFERENCES

- Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products, 76/768/EEC, OJ L 262, 27.9.1976
- Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ L 342, 22.12.2009
- Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers, OJ L 147, 09.06.1975, p. 40 – 47
- Commission Directive 94/1/EC of 6 January 1994 adapting some technicalities of Council Directive 75/324/EEC on the approximation of the laws of the relating Member States to aerosol dispensers, OJ L 23, 28.01.1994, p. 28 – 29
- Commission Directive 2008/47/EC of 8 April 2008 amending, for the purposes of adapting to technical progress, Council Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosol dispensers, OJ L 96, 09.04.2008, p. 15 – 28
- Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain pre-packaged products, OJ L 046, 21.02.1976, p. 1 – 11
- Commission Directive 78/891/EEC of 28 September 1978 adapting to technical progress the Annexes to Council Directives 75/106/EEC and 76/211/EEC on pre-packaging, OJ L 311, 04.11.1978
- Directive 2007/45/EC of the European Parliament & of the Council of 5 September 2007 laying down rules on nominal quantities for prepacked products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC, OJ L 247, 21.9.2007
- Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC, OJ L 039, 15.02.1980, p. 40 – 50
- Directive 2007/45/EC of the European Parliament and the Council of 5 September 2007 laying down rules on nominal quantities for prepacked products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC, OJ L 247, 21.09.2007
- EN ISO 29621:2010 Cosmetics – Microbiology – Guidelines for the risk assessment and identification of microbiologically low-risk product
- Commission Recommendation of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto, OJ L 265, 26.09.2006

- Commission Decision of 9 February 2006 amending Decision 96/335/EC establishing an inventory and a common nomenclature of ingredients employed in cosmetic products, OJ L 97, 05.04.2006
- Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ L 196, 16.08.1967, p. 1 – 98
- Colipa Recommendation: Flammability Labelling of Cosmetic Products, September 1994
- European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste, OJ L 365, 31.12.1994, p. 10 – 23

VI. ANNEXES

Annex 1: Labelling compulsorily expressed in national language¹¹

This overview reflects Colipa's current knowledge on the basis of the national implementations of Cosmetics Directive 76/768/EEC.

COUNTRY	LANGUAGE
AUSTRIA	German
BELGIUM	Dutch and French and German
BULGARIA	Bulgarian
CZECH	Czech
CYPRUS	Greek/English
DENMARK	Danish
ESTONIA	Estonian
FINLAND	Finnish and Swedish
FRANCE	French
GERMANY	German
GREECE	Greek
HUNGARY	Hungarian
IRELAND	English
ITALY	Italian
LATVIA	Latvian
LITHUANIA	Lithuanian
LUXEMBURG	French or German or
MALTA	Maltese/English
NETHERLANDS	Dutch
NORWAY	Norwegian
POLAND	Polish
PORTUGAL	Portuguese
ROMANIA	Romanian
SLOVAKIA	Slovak
SLOVENIA	Slovenian
SPAIN	Spanish
SWEDEN	Swedish
UNITED	English

¹¹ Courtesy of FEBEA (*Fédération des Entreprises de la Beauté*)



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 ¹²

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:

¹² 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:

Annex 3

INCI NAMES FOR 26 SUBSTANCES ADDED TO ANNEX III OF THE COSMETICS DIRECTIVE

Annex III ref.	Directive Description	INCI Name	Other Name	CAS No	EINECS No.
67	Amyl Cinnamal	Amyl Cinnamal		122-40-7	204-541-5
68	Benzyl Alcohol	Benzyl Alcohol ¹		100-51-6	202-859-9
69	Cinnamyl Alcohol	Cinnamyl Alcohol ¹		104-54-1	203-212-3
70	Citral	Citral ¹		5392-40-5	226-394-6
71	Eugenol	Eugenol ¹		97-53-0	202-589-1
72	Hydroxy-citronellal	Hydroxycitronellal		107-75-5	203-518-7
73	Isoeugenol	Isoeugenol ¹		97-54-1	202-590-7
74	Amylcin-namyl Alcohol	Amylcinnamyl Alcohol		101-85-9	202-982-8
75	Benzyl Salicylate	Benzyl Salicylate ¹		118-58-1	204-262-9
76	Cinnamal	Cinnamal ¹		104-55-2	203-213-9
77	Coumarin	Coumarin ¹		91-64-5	202-086-

Annex III ref.	Directive Description	INCI Name	Other Name	CAS No	EINECS No.
					7
78	Geraniol	Geraniol ¹		106-24-1	203-377-1
79	Hydroxy-methylpentylcyclohexenecarboxaldehyde	Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde	Lylal	31906-04-4	250-863-4
80	Anisyl Alcohol	Anise Alcohol ¹		105-13-5	203-273-6
81	Benzyl Cinnamate	Benzyl Cinnamate ¹		103-41-3	203-109-3
82	Farnesol	Farnesol ¹		4602-84-0	225-004-1
83	2-(4-tert-butylbenzyl) Propionaldehyde	Butylphenyl Methylpropional	Lilial	80-54-6	201-289-8
84	Linalool	Linalool ¹		78-70-6	201-134-4
85	Benzyl Benzoate	Benzyl Benzoate ¹		120-51-4	204-402-9
86	Citronellol	Citronellol ¹		106-22-9	203-375-0
87	Hexyl cinnam-aldehyde	Hexyl Cinnamal		101-86-0	202-983-3
88	d-Limonene ^{1,2}	Limonene ^{1,2}		5989-27-5	227-813-5
89	Methyl heptin carbonate	Methyl 2-Octynoate		111-12-6	203-836-

Annex III ref.	Directive Description	INCI Name	Other Name	CAS No	EINECS No.
					6
90	3-Methyl-4-(2,6,6-tri-methyl-2-cyclohexen-1-yl)-3-buten-2-one	Alpha-Isomethyl Ionone ⁵		127-51-5	204-846-3
91	Oak Moss extract	Evernia Prunastri ⁴	Evernia Prunastri (Oak Moss) Extract (US INCI name)	90028-68-5	289-861-3
92	Treemoss extract	Evernia Furfuracea ⁴	Evernia Furfuracea (Treemoss) Extract (US INCI name)	90028-67-4	289-860-8

Notes

- These ingredients are also found in some natural essential oils and extracts.*
- DL-Limonene is a mixture of the D and L isomers. If used in the cosmetic product, strictly speaking the relative proportions of the isomers would have to be worked out to determine whether the concentration requires d-Limonene to be labelled under its new INCI name 'Limonene'. In practice, because of the technical difficulty of the analysis, the total level of both isomers will be used to establish whether the threshold is exceeded and labelling is required.*
- The Directive specifies the restrictions for each ingredient as:*
The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds:
 - 0.001 % in leave-on products
 - 0.01 % in rinse-off products

This applies if these ingredients are present in the product for any reason – not just as constituents of fragrances.
- Evernia Prunastri: as listed in 1996 inventory, we expect this to change to Evernia Prunastri extract in a future update. Evernia Furfuracea: for consistency we have used the format that would have appeared in the 1996 inventory. We expect this to change to Evernia Furfuracea extract in a future update.*

5. *Alpha-Isomethyl Ionone is the name which appears in the current CTFA On-line listing of the INCI name for 3-Methyl-4-(2,6,6-tri-methyl-2-cyclohexen-1-yl)-3-buten-2-one. Previous hard copy listings omitted 'iso' from the name.*