

ข้อมูลเกี่ยวกับเครื่องสำอาง (PRODUCTS INFORMATION FILE : PIF)

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COSMETICS EUROPE:
COSMETIC INGREDIENT LABELLING
IN THE EUROPEAN UNION

Updated Guidelines for the Cosmetics Industry
based on the 7th Amendment to the
Cosmetics Directive

SEPTEMBER 2006

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INTRODUCTION

The 6th Amendment to the Cosmetics Directive (published as Council Directive 93/35/EEC in the Official Journal of the European Communities n° L151 of 23 June, 1993) introduced several requirements for those marketing cosmetics in the European Union (EU). One of the major items directly concerning such marketing is the mandatory labelling, for any product introduced onto the EU market as from 1 January, 1997, of ingredients on the outer packaging of all cosmetic products.

The 7th Amendment to the Cosmetics Directive (published as Directive 2003/15/EC in the Official Journal of the European Communities n° L 66 on 11 March 2003) introduced further labelling requirements with regard to ingredients listed in Annex III of the Directive. Furthermore, three aspects of ingredient labelling (the “+/-” sign for “may contain”, “parfum” for fragrance materials and “aroma” for flavours) which were already accepted by Member States when implementing the 6th Amendment, are now confirmed in the 7th Amendment¹.

These guidelines are intended to provide information on the requirements of the Cosmetics Directive concerning ingredient labelling and on those aspects of the EU inventory of cosmetic ingredients related to such ingredient labelling.

The wording of the Directive on ingredient labelling does not always give clear guidance. These guidelines try to clarify such matters, with the overall objective of harmonising labelling in practice throughout all of the EU Member States.

These guidelines consist of two parts:

- Firstly, a summary which identifies the key provisions of the EU ingredient labelling requirement. It serves as a quick “how to...” guide.
- Secondly, a description of the legal requirements in detail and additional background information.

¹ Companies are reminded that “Parfum” and “Aroma” are INCI names and do not need translation into national languages.

INGREDIENT LABELLING IN THE EUROPEAN UNION: QUICK GUIDE

WHEN

- Ingredient labelling, according to the 6th Amendment: in force since January 1, 1997;
- Additional ingredient labelling requirements, introduced by the 7th Amendment: in force since March 11, 2005.

WHAT

All cosmetics products marketed anywhere in the European Union

WHICH PRODUCTS

All types of products supplied to consumers in whatever way

WHERE

On outer packaging only. Of course, it will be indicated on the inner container, if there is no outer packaging.

WHICH INGREDIENTS

all ingredients must be listed, except:

- Impurities in raw materials used;
- Subsidiary technical materials used in the preparation but not present in the final product;
- Materials used in strictly necessary quantities as solvents or as carriers for perfume and aromatic compositions.

HOW

- In decreasing order of concentration of the ingredient in the finished cosmetic product;
- Those ingredients with a concentration below 1% at random after other ingredients;
- Colorants in any order after all other ingredients.

NOMENCLATURE:

- INCI names (previously known as CTFA names)
- published in the EU Inventory by the European Commission (Decision 96/335/EC and Decision 2006/257/EC)

EU SPECIAL NOMENCLATURE FOR:

- Cosmetic colorants: CI number (not for hair dyes)
- Perfume ingredients: all as "PARFUM" (except those listed in Annex III of the Cosmetics Directive, see the chapter "Additional labelling requirements introduced by the 7th Amendment")
- Flavouring ingredients: all as "AROMA" (except those listed in Annex III of the Cosmetics Directive, see the chapter "Additional labelling requirements introduced by the 7th Amendment")
- Plant materials: Latin name under "LINNÉ" system (genus and species), followed by the part of the plant (when applicable) and type of derivative (if a plant material contains one or more ingredients listed in Annex III of the Cosmetics Directive, see the chapter "Additional labelling requirements introduced by the 7th Amendment", the latter need to be listed accordingly)
- Trivial names: based on the EUROPEAN PHARMACOPOEIA (Latin name)
- Denatured ethanol: as "ALCOHOL DENAT"
- The term "ingredients": as "INGREDIENTS"
- The term "may contain": as [+/-... ...], only for decorative cosmetics products marketed in several colour shades (see also Annex 1, page 13).

See example of labelling in Annex 1

ADDITIONAL LABELLING REQUIREMENTS INTRODUCED BY THE 7TH AMENDMENT TO THE COSMETICS DIRECTIVE

The legal requirement, under Article 6.1(g), reads:

[(....) Perfume and aromatic compositions and their raw materials shall be referred to by the word “perfume” or “aroma”.] However, the presence of substances, the mention of which is required under the column “other limitations and requirements” in Annex III, shall be indicated in the list irrespective of their function in the product.

This new provision extends the existing ingredient labelling to ensure that 26 specific substances¹ are labelled by their individual INCI name, even if they are introduced in the cosmetic product as part of a complex ingredient.

The labelling requirement is linked to the presence of the substance above the threshold concentration mentioned in Annex III, irrespective of the substance's function and irrespective of its 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 application, 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.

¹ Identified in Annex III of the Cosmetics Directive with the sentence “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”.

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 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 6(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 should be printed in any chosen order at the end of the ingredient list.
- The INCI names of the 26 specific substances are attached (Annex 3).
- This requirement applies to cosmetic products placed on the market by the producer or importer into the EU on or after 11th March 2005.

INGREDIENT LABELLING CAN ONLY WORK WITH A COMMON INTERNATIONAL NOMENCLATURE

The purpose of ingredient labelling is to ensure transparency to the consumer, giving adequate information about the product to enable him or her, for example, to avoid purchasing a product which contains an ingredient that he or she does not wish to use.

Mandatory ingredient labelling was included in the Cosmetic Directive as the result of a voluntary industry proposal; this demonstrates industry's strong support for ingredient labelling as a way to ensure transparency to the consumer. At the same time, the cosmetic industry represented by Colipa was concerned that the procedures adopted be practicable and workable.

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

If not, the consumer will be confused and not benefit from the information provided. To this end, Colipa, with the support of the European Commission, has developed a common

ingredient nomenclature for use in ingredient labelling of cosmetic products. Used in conjunction with the EU cosmetic ingredient Inventory, published in 1996 (Commission Decision 96/335/EC) and updated in 2006 (Commission Decision 2006/257/EC), which is indexed by these names, it will be possible for ingredients to be rapidly and correctly identified from the information given on product labels. To ensure transparency and that ingredient labelling is practicable, Colipa finds it essential that a particular ingredient have the same label name in every cosmetic product that contains it, no matter where it is sold in the EU.

Colipa has taken advantage of the experience on ingredient labelling from other countries where this has been mandatory for some years.

WHICH PRODUCTS HAVE TO CARRY INGREDIENT LABELLING?

All cosmetic products marketed in any part of the EU have to be labelled with their ingredients. The current requirement therefore applies to products covered under Article 1 of the Cosmetics Directive, including imported products, professional products, free samples, tester samples, multi-component products, products sold by mail order, products provided in hotels and other public facilities. For free samples and tester samples, it is possible to use off-pack labelling according to the rules existing for small packs. Soaps are also to be labelled, which is not the case in the USA.

LABELLING RULES

A summary and commentary regarding these rules, as they are currently expressed in the text of the Cosmetic Directive, follows.

1. Order of declaration

The relevant extracts from article 6.1(g) requiring ingredient labelling are:

“... a list of ingredients in descending order at the time they are added. That list shall be preceded by the word ‘ingredients’.”

“Ingredients in concentrations of less than 1% may be listed in any order after those in concentrations of more than 1%.”

“Colouring agents may be listed in any order after the other ingredients, in accordance with the colour index or denomination adopted in Annex IV.”

Colipa advises that the word “ingredients” should be used throughout the EU. This word can be used alone or as part of a box enclosing the list of ingredients (see Annex 1).

The wording of the legal text does not make it clear where in the ingredient list substances present at exactly 1% should appear. Industry 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 read 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.

2. Materials not regarded as ingredients

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 6.1(g) states:

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

- impurities in the raw materials used;***
- subsidiary technical materials used in the preparation but not present in the final product;***
- materials used in strictly necessary quantities as solvents, or as carriers for perfume and aromatic compositions.”***

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

3. Position and legibility of the declaration

The relevant extract from Article 6.1 is:

“Member States shall take all measures necessary to ensure that cosmetic products may be marketed only if the container and the packaging bear the following information in indelible, easily legible and visible lettering; the information mentioned in point (g) may, however, be indicated on the packaging alone.”

This means it is sufficient to declare ingredients in any place of the external side of the outer packaging of any cosmetic product.

4. Off-pack labelling - provision for limited pack or label size

A provision for ingredient labelling to be made not directly on the outer packaging is foreseen in some cases. The relevant regulatory text reads:

“Where that is impossible for practical reasons, an enclosed leaflet, label, tape or card must contain the ingredients to which the consumer is referred either by abbreviated information or the symbol given in Annex VIII.”

“In the case of soap, bath balls, or other small products where it is impracticable, for reasons of size or shape, for the particulars referred to in point (g) to appear on a label, tag, tape or card or in an enclosed leaflet, those particulars shall appear on a notice in immediate proximity to the container in which the cosmetic product is exposed for sale.”

If a pack is too small or has a difficult shape, the necessary ingredient declaration can be given on a label, tag, tape, or card fixed to, or enclosed with, the cosmetic product. If it is impossible to do this, the information may appear in a notice next to the display in which the product is offered, e.g. for samples.



The symbol of Annex VIII is a hand inside an open book:

5. Products sold by mail order

Ingredient labelling has to appear on the outer packaging also for products sold by mail order. It is at the discretion of each company whether ingredient labelling is also listed in the catalogue.

6. Multi-product packs

If a multi-product pack is sold as a whole and not broken up 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 product in the pack.

7. Ingredients to be labelled as warning

There are several ingredients regulated under Annexes III, VI and VII of the Cosmetics Directive which have to be labelled as a warning by listing their name (i.e. contains X). For such ingredients there has to be a double labelling.

They have to be listed:

- as part of the ingredients list, using the INCI name;
- separately, as a warning, in the **national** language.

NOMENCLATURE TO BE USED

Information on the requirements for nomenclature is given in several parts of the Cosmetics Directive as follows:

Article 6.1(g)

“An ingredient must be identified by the common name referred to in Article 7.2 or failing that, by one of the names referred to in article 5a (2), first indent.”

Article 7.2

“... they (Member States) may also require that the particulars provided for in Article 6.1(g) be expressed in a language easily understood by the consumer. To that end, the Commission shall adopt a common ingredients nomenclature in accordance with the Article 10 procedure.”

Article 6.1(g)

“... perfume and aromatic compositions and their raw materials shall be referred to by the word ‘perfume’¹ or ‘aroma’.”

“Colouring agents may be listed in any order after the other ingredients, in accordance with the colour index number or denomination adopted in Annex IV.”

The common name for ingredient labelling referred to in the EU regulations is known as the International Nomenclature Cosmetic Ingredient name or INCI name. It is based on a nomenclature developed jointly by the EU and US cosmetic industries. The INCI name was previously known as the CTFA (the US Cosmetic, Toiletry and Fragrance Association) name.

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, 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.

If a cosmetic ingredient which does not have an INCI name is used, such a name should be applied for by the supplier of this ingredient. This can be done either by connecting, free of charge, to the website <http://www.ctfa-inciacapplication.org> or by using a paper standard form (reference TN), obtainable from Colipa or its Member Associations, which, however, implies a cost of 100 USD for handling the submission. CTFA publishes all INCI names in its “International Cosmetic Ingredient Dictionary and Handbook” (www.ctfa.com).

Once a cosmetic ingredient has obtained an INCI name, this will be added, via Colipa, to the EU Inventory.

¹ Companies are reminded that “Parfum” and “Aroma” are INCI names and do not need translation into national languages.

THE EU INVENTORY OF COSMETIC INGREDIENTS

Article 5a of the 6th Amendment to the Cosmetics Directive requires the establishment of an EU Inventory of cosmetic ingredients. The purpose of the Inventory is to provide a reference document to satisfy the requirements for ingredient labelling using a common international nomenclature.

The relevant regulatory text (extract) reads:

“The Inventory shall contain information on:

- the identity of each ingredient;***
- the chemical name;***
- the CTFA name*** (now known as INCI name, see page 8);
- the European Pharmacopoeia name;***
- the international non-proprietary names recommended by the World Health Organisation;***
- the EINECS/IUPAC/CAS and colour index numbers;***
- the common name referred to in Article 7.2.;***
- the usual function(s) of the ingredient in the final product;***
- where appropriate, restrictions and conditions of use and warnings which must be printed on the label by reference to the Annexes.”***

The Inventory 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 Inventory. The Inventory is published by the European Commission in the Official Journal of the European Union. Updates to the Inventory are handled in the same way.

Colipa has prepared the EU Inventory in collaboration with the European Commission. A special Liaison Committee on Labelling Nomenclature (known as LCLN) existed within the association to co-ordinate this activity, including the updating of the Inventory. The LCLN is now replaced by the Project Team INCI. The Inventory consists of an alphabetical listing of the INCI name for each cosmetic ingredient which is to be used for ingredient labelling purposes. The other information on each ingredient, required under the 6th Amendment, is listed under the entry of the INCI name, as far as it is available. Trade or commercial names are not included in the EU Inventory and are never to be used for ingredient labelling.

The EU Inventory of cosmetic ingredients is also available through the DG Enterprise website at the following address:

http://europa.eu.int/comm/enterprise/cosmetics/html/cosm_inci_index.htm

The EU Inventory consists of Section 1 (cosmetic ingredients other than perfume and aromatic materials) which is handled by the Commission in cooperation with Colipa, and

Section 2 (perfumery and aromatic materials) which is handled in cooperation with EFFA, the European Flavour and Fragrance Association.

The first update of the EU Inventory was published by the European Commission as Commission Decision 2006/257/EC, in the EU Official Journal L97 of 5 April 2006.

INGREDIENT LABELLING: EU SPECIFICITIES

1. Cosmetic colorants

For the EU, it is mandatory to use the nomenclature listed in Annex IV to the Cosmetics Directive (colour index number, e.g. CI 19149, or denomination, e.g. Bromocresol Green).

If an ingredient that is a colorant is used for other purposes, the alternative INCI name, and not the name listed in Annex IV, should be used (e.g., titanium dioxide).

2. Botanicals

Cosmetic ingredients directly derived from plants are designated as botanicals. For botanicals, the INCI nomenclature is based on the LINNÉ system, whereby the genus and species of the plant in Latin are used. The 1st Update of the EU Inventory of cosmetic ingredients (published by the European Commission as Decision 2006/257/EC) on the Official Journal L97 on April 5, 2006) introduces additional information to be labelled as part of a botanical's INCI name (the part of the plant, if applicable, and the type of the derivative). This is a step toward a closer harmonisation of plant INCI names as used in the European Union and in the USA, respectively.

If a plant material contains one or more ingredients listed in Annex III of the Cosmetics Directive (see the chapter "Additional labelling requirements introduced by the 7th Amendment") the latter need to be listed accordingly.

Cosmetic ingredients derived from plants which have undergone chemical modification are named according to the normal INCI nomenclature. Their names are not based on the LINNÉ system.

The following reference books have been used to establish the LINNÉ-derived names for botanicals, in order of priority:

(1) Penso, G. *Index plantarum medicinalium totius mundi eorumque synonymorum*, O.E.M.F.

Milano (1983) - ISBN n° 88-7076-027-8;

(2) Steinmetz, E.F. *Codex vegetabilis*. Amsterdam (1957);

(3) Hoppe, H.A. *Drogenkunde*, 8th edition, Walter de Gruyter. Berlin. Volume 1 (1975) - ISBN n° 3-11-003849-8. Volume 2 (1977) - ISBN n° 3-11-006660-2;

- (4) Mabberley, D.J. *The plant book - a portable dictionary of the higher plants*. Cambridge (1992)
- ISBN n° 0-521-34060-8.
- (5) Hoppe H.A., Levring T., Tanaka Y., *Marine Algae in Pharmaceutical Science*, Walter de Gruyter, Berlin, New York, 1979.

3. Trivial names

“Trivial names” is the term used for names of ingredients which should be well known to consumers. The INCI names for such ingredients are based on those used in the European Pharmacopoeia (e.g. Aqua, Mel, Cera Alba, etc.) and they are different from those used in the USA.

4. Ethanol

For products containing denatured ethanol there are two solutions for ingredient labelling:

- (1) use the single INCI name “ALCOHOL DENAT”; (this is the preferred option)
- (2) use the INCI name “ALCOHOL” for ethanol plus the specific INCI name for the denaturant; in this case the name of the denaturant may not appear next to “alcohol”, since ingredients have to be listed in decreasing order of concentration.

For products containing undenatured ethanol, use the INCI name “ALCOHOL”.

5. Labelling for products also sold outside the EU

Companies who wish to market the same product inside and outside the EU (for example in the USA) should make use of double labelling for those ingredients which have a different nomenclature (such as colorants, botanicals, biologicals, trivial names, alcohol). If double labelling is applied, the alternative names for each ingredient should follow one another. There is no absolute legal guarantee that such double labelling will not be contested, but, up to now, this approach has not been challenged by controlling bodies.

INGREDIENTS NOT PRESENT IN ALL PRODUCTS IN A RANGE

The text of Article 6.1(g)(part) of Cosmetic Directive states:

“For decorative cosmetic products marketed in several colour shades, all colouring agents in the range may be listed, provided that the words ‘may contain’ or the symbol +/- are added.”

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

Colipa advises that the wording “may contain” can be replaced by the sign “+/-” followed by the relevant INCI names, all enclosed in square brackets. For clarification see also Annex 1.

CONFIDENTIALITY

The relevant text of article 6.1(g) states:

“In accordance with the procedure laid down in article 10, the Commission shall, no later than 14 December 1994, adopt the criteria and conditions under which a manufacturer may, for reasons of trade secrecy, apply not to include one or more ingredients on the abovementioned list.”

The procedure how to apply for, to receive and to make use of an exemption from ingredient labelling for a raw material, is laid down in a Commission Directive (Directive 95/17/CEE)

ANNEX 1

INGREDIENT LABELLING EXAMPLE

INGREDIENTS

Aqua, Cyclohexasiloxane, Mica, Polybutene, Triisostearin, Quaternium-18 Hectorite, Polymethylmethacrylate, Persea Gratissima Leaf Extract, Cera Alba, Propylene Carbonate, Methylparaben, Phenoxyethanol, Propylparaben, Linalool, Benzyl Alcohol, Lecithin, BHT, Parfum, [+/- CI 77491, CI 77492, CI 77499, CI 77891]

**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)

EUROPEAN FLAVOUR AND FRAGRANCE ASSOCIATION (EFFA)
AND
EUROPEAN COSMETIC, TOILETRY AND PERFUMERY ASSOCIATION (COLIPA)

Revised Version 2003

I. INTRODUCTION

This document is an addendum to the Colipa/EFFA guidelines on Product Information Requirements pursuant to the requirements of EU Directive 76/768/EEC (hereafter referred to as the Cosmetics Directive). The document has been developed together with EFFA. The guidelines herein 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 and in particular its Article 7.

This document needs to be reviewed in accordance with the mandatory requirements of any new regulation.

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 A: An example of a declaration for the product information for a fragrance compound

The declaration and the Safety Data Sheet need to be available to the cosmetic company when a fragrance compound is selected for a cosmetic product.

II. THE INFORMATION

Confidentiality: This information should only be provided 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.

The Cosmetics Directive provides for 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 a declaration with information consisting of:

- 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 product category, 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
- a certificate of compliance with IFRA standards currently in place. 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 two months and forwarded to the cosmetic manufacturer.
- a statement of compliance of the fragrance ingredients with relevant EU Chemical legislation
- accurate information on the presence and concentration of substances regulated in the Annexes of the Cosmetics Directive, based on chemical analysis of the fragrance compound or its ingredients.
- where appropriate, additional information (please refer to page 3)
- the date
- the name, qualification and signature of the safety evaluator

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.

A proper choice of ingredients at an adequate concentration level is sufficient to avoid risk of the hazards (e.g. genotoxicity, carcinogenicity, teratogenicity, systemic toxicity and in particular sensitisation and phototoxicity). The safety evaluation should also consider the level of purity of the ingredients.

Additional information on the nature of potential health hazard of the undiluted fragrance compound, according to the standards of the Dangerous Preparations Directive can be obtained from the Safety Data Sheet (SDS) for the selected fragrance compound. The SDS will identify the ingredient(s) responsible for the hazard(s) (see Annex 2).

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, holding a diploma in the field of pharmacy, toxicology, dermatology, medicine or a similar discipline, and equally important, should have adequate experience in their chosen field.

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, the fragrance supplier would provide a full quantitative breakdown of the fragrance compound (under appropriate terms of confidentiality), together with any necessary information on purity of components.

The safety evaluator is responsible for determining whether:

- the ingredients present in the fragrance compound meet the requirements of the cosmetics legislation and the currently applicable IFRA Code of Practice and Colipa Recommendations;
- the toxicological data on ingredients are relevant and sufficient;
- the safety of the fragrance compound will be affected by the nature of the product containing it;
- 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 physicochemical 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 judgement of the set of 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 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 experts of the safety profiles of these fragrance ingredients.

A certificate of compliance with current IFRA Standards is an integral 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.

In case of an update of IFRA Standards, information about the status of the fragrance compound with regard to the new standard needs to be issued within two months and forwarded to the cosmetic manufacturer for inclusion in the product information.

V. FURTHER INFORMATION

Further to the information on presence and levels of substances regulated in the Annexes of 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 fuller exchange of information between the fragrance supplier and the customer, as part of their commercial agreement.

Appendix A
EXAMPLE OF A DECLARATION

***FRAGRANCE SAFETY EVALUATION FOR THE PRODUCT INFORMATION REQUIRED
UNDER DIRECTIVE 76/768/EEC***

- | | |
|---|--|
| 1. Identity of customer: | COLIPA Hair Company 5-7 Rue du Congrès 1000 Brussels |
| 2. Product category and relevant use pattern: | Shampoo Once daily application of 8 grams, rinse-off |
| 3. Identity of fragrance supplier: | EFFA Fragrances Ltd 49 Square Marie Louise 1000 Brussels |
| 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 and
Colipa Recommendations**

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

Fragrance compound ABC 6789 is in compliance with current Colipa Recommendations, up to Recommendation N° _____.

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.

7. Regulatory Information

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

| CAS | Substance | Cosmetics Directive Annex/N° | Concentration (mg/kg) |
|-----------|--|------------------------------|-----------------------|
| 78-70-6 | Linalool | III / 84 | 30.000 |
| 91-64-5 | Coumarin | III / 77 | 1 |
| 97-53-0 | Eugenol | III / 71 | 280 |
| 100-51-6 | Benzyl Alcohol | III / 68 VI/1/34 | 5 |
| 105-13-5 | Anisyl Alcohol (4-Methoxybenzyl alcohol) | III / 80 | 2 |
| 106-22-9 | Citronellol | III / 86 | 14.000 |
| 106-24-1 | Geraniol | III / 78 | 94.000 |
| 107-75-5 | Hydroxycitronellal | III / 72 | 230 |
| 118-58-1 | Benzyl salicylate | III / 75 | 4600 |
| 120-51-4 | Benzyl benzoate | III / 85 | 4600 |
| 4602-84-0 | Farnesol | III / 82 | 460 |
| 5392-40-5 | Citral | III / 70 | 230 |
| 93-89-0 | Ethyl benzoate | VI/1/1 | 20 |

Directive (76/768/EEC) are as follows:

8. Other information on specific ingredients¹

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 |
| ? | Menthadienyl formate | 100 |
| ? | Amylcyclopentenone | 150 |

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

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

| CAS | Substance | Concentration (mg/kg) |
|---------------------------------------|----------------|-----------------------|
| 101-41-7 140-11-4 | Benzyl acetate | 200 |
| 8007-75-8 68648-33-9 85049-52-1 | Bergamot oil | present |
| 140-67-0 | Estragol | 10.000 |
| 1506-02-1 21145-77-7 | AHTN | 60.000 |
| 1222-05-5 | HHCB | 80.000 |
| 68647-73-4 | Tea Tree oil | 1000 |

9. Reasoned Safety Evaluation of Fragrance Compound ABC 6789

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

EFFA Fragrances Ltd. 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 Annex I to the IFRA Code of Practice.
Annex I requires consideration of possible effects in 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 used and likely to enter 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 ingredients published in the IFRA Standards.
4. In the absence of adequate data, structured relationships between the proposed ingredient and ingredients already cleared for inclusion in the authorised ingredients list.
5. Impurities in the ingredients used, where necessary imposing purity specifications.

The creative perfumery procedures in the EFFA Fragrances Ltd 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.

10. *Evaluator Name :*

Qualification :

Signature:

Date :

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

| Annex III reference | Directive Description | INCI Name | CAS N° | EINECS N° |
|--------------------------------|---|--|---------------|------------------|
| 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 | Amylcinnamyl 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 | 202-086-7 |
| 78 | Geraniol | Geraniol ¹ | 106-24-1 | 203-377-1 |
| 79 | Hydroxy-methylpentylcyclohexenecarboxaldehyde | Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde | 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 | 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 | 203-836-6 |
| 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 | 90028-68-5 | 289-861-3 |
| 92 | Treemoss extract | Evernia Furfuracea ⁴ | 90028-67-4 | 289-860-8 |

Notes

1. These ingredients are also found in some natural essential oils and extracts.
2. 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.

3. *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.

4. *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.*

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