ข้อมูลเกี่ยวกับเครื่องสำอาง (PRODUCTS INFORMATION FILE : PIF)

เลขที่จดแจ้ง: 1026300003493
ชื่อทางการค้าเครื่องสำอาง: แอนนัว ANUA
ชื่อเครื่องสำอาง: ฮาร์ทลีฟ 77 เปอร์เซ็นต์ ซูทธิ่ง โทนเนอร์ HEARTLEAF 77% SOOTHING TONER
ประเภทของเครื่องสำอาง: ใช้แล้วไม่ล้างออก
วันที่จดแจ้ง: 28/1/2563
วันที่ใบอนุญาตหมดอายุ:27/1/2569
จุดประสงค์การใช้: บำรุงผิว
ลักษณะทางกายภาพ: ผิวหน้า
ชื่อผู้ผลิต: บริษัท เจ เอส ดับเบิ้ลยู แอสเสท จำกัด
ชื่อผู้ผลิตต่างประเทศ: MEGACOS CO.,LTD. 37, CHEONGWONSANDAN 5-GIL, MADO-MYEON, HWASEONG-SI, GYEONGGI-DO , KOREA, SOUTH
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Cosmetics Europe
the personal care association

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

CONTENTS

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 Amendment[1].

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 substances[1] 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 **I**nternational **N**omenclature **C**osmetic **I**ngredient 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-inciapplication.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]

ANNEX 2

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

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

8. Other information on specific ingredients[1]

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	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	202-086-7
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.*

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

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ใบรับจดแจ้งนำเข้าเพื่อขายเครื่องสำอาง

ใบรับจดแจ้งเลขที่ : 10-2-6200013222

ใบรับจดแจ้งฉบับนี้ออกให้ ณ วันที่ : 28 มีนาคม 2562 **ให้ใช้ได้จนถึงวันที่ :** 27 มีนาคม 2568

ชื่อการค้าและชื่อเครื่องสำอาง (ไทย) : มาย์แคร์ โรส เลิฟเวอร์ คลีนซิ่ง มูส

ชื่อการค้าและชื่อเครื่องสำอาง (อังกฤษ) : MY CARE ROSE LOVER CLEANSING MOUSSE

ชื่อเครื่องสำอางแนบท้าย : รายการตามเอกสารแนบท้าย

ประเภทของเครื่องสำอาง : ทำความสะอาด/ผิวหน้า/ล้างออก

ลักษณะทางกายภาพของเครื่องสำอางและภาชนะบรรจุ : ครีม (Cream) / ขวด/หลอด

รูปแบบของเครื่องสำอาง : ผลิตภัณฑ์เดี่ยวชนิดเดียวกันที่มีส่วนประกอบและการใช้เหมือนกันแต่แตกต่างกันที่สีหรือกลิ่น

ชื่อผู้นำเข้า : บริษัท วิมา แพ็คเกจจิ้ง จำกัด

ที่ตั้งสถานที่นำเข้า : เลขที่ 60/7 หมู่ 1 ถนน พระราม 2 ตำบล บ้านบ่อ อำเภอ เมืองสมุทรสาคร จังหวัด สมุทรสาคร 74000 โทรศัพท์ 091-404-7388

ที่ตั้งสถานที่เก็บ : เลขที่ 60/7 หมู่ 1 ถนน พระราม 2 ตำบล บ้านบ่อ อำเภอ เมืองสมุทรสาคร จังหวัด สมุทรสาคร 74000 โทรศัพท์ 091-404-7388

ชื่อผู้ผลิตต่างประเทศ : GUANGZHOU AROMATIC COSMETICS CO.,LTD

ที่ตั้งสถานที่ผลิต : GUANGZHOU HUADU DISTRICT ROAD NO.35 RED PLANT A PLANT B GUANGZHOU CITY,GUANGDONG PROVINCE,

ประเทศผู้ผลิต : CHINA

ใบรับจดแจ้งนี้ออกให้โดยมีเงื่อนไข ดังนี้

๑. สำนักงานคณะกรรมการอาหารและยามีสิทธิ์ที่จะเพิกถอนใบรับจดแจ้งนี้ เมื่อปรากฏว่ามีการกระทำอันฝ่าฝืนพระราชบัญญัติเครื่องสำอาง พ.ศ. ๒๕๕๘

๒. สำนักงานคณะกรรมการอาหารและยามีสิทธิ์ที่จะเพิกถอนใบจดแจ้งนี้ เมื่อปรากฏว่ามีการฝ่าฝืนพระราชบัญญัติวิธีปฏิบัติราชการทางปกครอง พ.ศ. ๒๕๓๙

๓. ใบรับจดแจ้งเครื่องสำอางออกให้ เพื่อแสดงว่าผลิตภัณฑ์นี้ได้จดแจ้งแล้ว มิใช่เป็นการรับรองคุณภาพมาตรฐานของผลิตภัณฑ์

ออกโดย สำนักงานคณะกรรมการอาหารและยา
กระทรวงสาธารณสุข

รายชื่อเครื่องสำอางแนบท้าย

เลขรับที่ : 62038311 **ใบรับจดแจ้งเลขที่ :** 10-2-6200013222

รายการแนบท้าย

เครื่องสำอาง : มีจำนวน 5 รายการดังนี้

1. มาย์แคร์ โรส เลิฟเวอร์ คลีนซิ่ง มูส สีเหลือง
   MY CARE ROSE LOVER CLEANSING MOUSSE YELLOW
2. มาย์แคร์ โรส เลิฟเวอร์ คลีนซิ่ง มูส สีฟ้า
   MY CARE ROSE LOVER CLEANSING MOUSSE BLUE
3. มาย์แคร์ โรส เลิฟเวอร์ คลีนซิ่ง มูส สีขาว
   MY CARE ROSE LOVER CLEANSING MOUSSE WHITE
4. มาย์แคร์ โรส เลิฟเวอร์ คลีนซิ่ง มูส สีชมพู
   MY CARE ROSE LOVER CLEANSING MOUSSE PINK
5. มาย์แคร์ โรส เลิฟเวอร์ คลีนซิ่ง มูส สีเขียว
   MY CARE ROSE LOVER CLEANSING MOUSSE GREEN

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Annex II : Financial Guidelines

The purpose of this document is to enable applicants to prepare their grant applications.

Please be sure to read these guidelines carefully before replying to the current call for proposals.

MAIN FINANCIAL AND MANAGEMENT RULES

Disclaimer: this document provides the applicants with a quick summary of the main legal and financial rules contained in the Financial Regulation applicable to the general budget of the European Communities[1] and its Implementing Rules[2]. The information given is not exhaustive and beneficiaries are therefore asked to carefully read the agreement sent to them, as it will constitute the legal basis for the grant.

1. General principles

Grants are subject to the principles laid down in the Financial Regulation, in particular the principles of co-financing, prohibition of double financing and no-profit.

Co-financing principle

Union grants may not finance the entire cost of the action to be subsidised. The applicant must contribute to the implementation of the action either by way of own resources or by financial contribution from third parties (in the form of public or private assistance obtained elsewhere)[3].

No double financing rule

Each action may give rise to the award of only one grant, there can be no duplicate Union funding of the same expenditure. The applicant must indicate the sources and amounts of any other funding received or applied for in the same financial year for the same action or for any other action and for routine activities[4].

No-profit rule

The Union grant may not have the purpose or effect of producing a profit for the beneficiary. Profit is defined as a surplus of total actual receipts over the total actual costs of the action.

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1 Council Regulation (EC, Euratom), n° 1605/2002 of 25.06.2002 (OJ L 248, 16.09.2002), as amended by Regulation n° 1995/2006 (OJ L 390, 30.12.2006) (http://eur-lex.europa.eu/LexUriServ/site/en/consleg/2002/R/02002R1605-20070101-en.pdf)

2 Commission Regulation (EC, Euratom) n° 2342/2002 of 23.12.2002, (OJ L 357, 31.12.2002) and subsequent amendments: Commission Regulation (EC, Euratom) n° 1261/2005 of 20.07.2005 (OJ L 201, 02.08.2005), Commission Regulation (EC, Euratom) n° 1248 of 07.08.2006 (OJ L 227, 07.08.2006) and Commission Regulation n° 478/2007 (OJ L 111, 28.04.2007) (http://eur-lex.europa.eu/LexUriServ/site/en/consleg/2002/R/02002R2342-20070501-en.pdf)

3 Art. 113 FR and 172 IR

4 Art. 111 FR and 173(5) IR

Any income of the action must be indicated in the estimated budget and the final financial statement. The amount of the grant will be reduced by the amount of any surplus.[5].

2. Rules related to the grant requested

- The Union grant will not exceed 80% of the total eligible costs.

  - The applicant organisation and/or other fund providers are required to make financial (cash) contribution(s) to the proposal of at least 20% of the total eligible costs.
  - The grant does not cover ineligible costs (see below for definition).
  - Contributions in kind (unpaid charity work by a private individual or corporate body, etc.) cannot be accepted.
  - Signed letters of commitment from the applicant organisation and/or other sources must be provided stating the precise amount of each financial (cash) contribution to the budget. If other institutions or organisations (partners) are involved in carrying out the action, the letter of commitment/partnership, from each of the partners, should also provide the name, address and person responsible and explain the nature of their involvement.
  - The partial or total withholding by the applicant of any information that may have an impact on the Commission's final decision concerning the application will entail the automatic disqualification of the application or, if discovered at a later stage, will entitle the Commission to impose financial and administrative penalties[6].

3. The estimated budget of the action

3.1. The budget must be detailed and balanced

Grant applications must include a detailed estimated budget presented in Euro (see application form). Applicants established in countries outside the Euro zone must use the conversion rates published in the Official Journal of the European Union (http://ec.europa.eu/budget/inforeuro/index.cfm?Language=en). Applicants should be aware that they fully carry the exchange rate risk.

The budget estimate must be properly balanced: the two totals (income and expenditure) must be the same, since the available income (including the grant requested from the Commission) will have to finance the planned expenditure[7]. Please make sure that all the items related to the implementation of the action are included and not just those for which financing is being sought.

3.2. Expenditure

Expenditure must include the estimated costs exclusively for the implementation of the action.

3.2.1. General criteria for eligibility of costs

In order to be eligible for Union-funding, costs must meet the following criteria[8]:

[5] Art. 109(2) FR and 165(1) IR
[6] Art. 175 IR
[7] Art. 173(3) IR
[8] Art. 172a IR

(a) be incurred during the duration of the action, with the exception of costs relating to final reports and audit certificates;

(b) be indicated in the estimated overall budget of the action attached to the grant agreement;

(c) be necessary for the implementation of the action which is the subject of the grant;

(d) be identifiable and verifiable, in particular being recorded in the accounting records of the beneficiary and determined according to the applicable accounting standards of the country where the beneficiary is established and according to the usual cost-accounting practices of the beneficiary;

(e) comply with the requirements of applicable tax and social legislation;

(f) be reasonable, justified, and comply with the requirements of sound financial management, in particular regarding economy and efficiency.

The successful applicant must take care to avoid any unnecessary or unnecessarily high expenditure.

The beneficiary's internal accounting and auditing procedures must permit a direct reconciliation of the costs and revenue declared in respect of the action with the corresponding accounting statements and supporting documents.
Documentation justifying costs must be kept by the beneficiary for **five years** following final payment by the Commission.

Expenditure eligible for financing may not have been incurred before the grant application was lodged.
Extra costs associated with the participation of people with disabilities are also eligible. These costs may be required to cover the use, for example, of special means of transport, personal assistants or sign language interpreters.

3.2.2. Eligible direct costs

The eligible direct costs for the action are those costs which, provided that they satisfy the criteria of eligibility set out above, are identifiable as specific costs directly linked to the performance of the action and which can therefore be booked to it directly.
In particular, the following direct costs may be considered eligible:

Staff costs

The costs of staff (permanent or temporary staff employed by the beneficiary or the partners) assigned to the implementation of the action, comprising actual salaries plus social security charges and other statutory costs included in the remuneration, are eligible. The salary costs should not exceed the average rates corresponding to the beneficiary's usual policy on remuneration. In addition, they should not be higher than the generally accepted market rates for the same kind of task.

The costs of personnel of national administrations may be considered as eligible to the extent that they relate to the cost of activities which the relevant public authority would not carry out if the action concerned were not undertaken.

Please, fill in the form reserved for these costs in the budget estimate (see application form) indicating the persons to be remunerated (full-time/part-time), the number of days of work to be performed and the daily rate calculated on the basis of an average of 20 days per month, up to a maximum total of 220 working days per year.

When submitting the request for final payment, the beneficiary may have to provide pay slips **and timesheets** justifying the actual staff costs declared.

Warning: the cost of any work to be performed by external experts by means of subcontracting must not be included in staff costs but under services.

If members of the staff are recruited after the submission of the application, the beneficiary must send the names and complete CVs of these persons to the European Commission for approval as soon as possible.

Travel, accommodation and subsistence allowances

Travel costs must not exceed the most reasonable rates available on the market. Accommodation and subsistence costs related to the participants to the action are eligible provided that they are in line with the beneficiary's usual practices on travel costs or do not exceed the scales approved periodically by the Commission which are set out in the table below.

Journeys must be carried out by the most direct and economic route. Economy class fares will be used as the benchmark for analysing air travel costs. Air travel is acceptable only for distances above 400 km, i.e. return flight above 800 km. For other modes of transport, the benchmark is the first-class rail fare. Car journeys: equivalent of corresponding first-class train ticket. Please bear in mind that receipts, boarding passes and used tickets must always be kept as supporting evidence of travel costs paid.

The *Daily subsistence allowances (DSA*) are paid in addition to costs for accommodation as a flat-rate amount and are considered to cover breakfast and two main meals, local transport, the cost of telecommunications and all other sundries. Daily subsistence allowances are to be calculated as follows according to the length of the mission:

- stays less or equal to 6 hours: reimbursement of actual costs (on production of supporting documents);
- more than 6 hours up to 12 hours inclusive: 0.5 DSA;
- more than 12 hours up to 24 hours inclusive: 1 DSA;
- more than 24 hours up to 36 hours inclusive: 1.5 DSA;
- more than 36 hours up to 48 hours inclusive: 2 DSA;
- more than 48 hours up to 60 hours inclusive: 2.5 DSA, etc.

The maximum amounts (in Euro per calendar day) accepted for each country are set out in the table below, and applicants are advised to adhere to these rates in their budget estimates[9]:

[9] The daily allowance rates are subject to periodic review by the Commission.

Destinations		*DSA in EUR*	*Maximum hotel price in EUR*
AT	Austria	95,00	130,00
BE	Belgium	92,00	140,00
BG	Bulgaria	58,00	169,00
CY	Cyprus	93,00	145,00
CZ	Czech Republic	75,00	155,00
DE	Germany	93,00	115,00
DK	Denmark	120,00	150,00
EE	Estonia	71,00	110,00
EL	Greece	82,00	140,00
ES	Spain	87,00	125,00
FI	Finland	104,00	140,00
FR	France	95,00	150,00
HR	Croatia	60,00	120,00
HU	Hungary	72,00	150,00
IC	Iceland	85,00	160,00
IE	Ireland	104,00	150,00
LI	Liechtenstein	80,00	95,00
RS	Serbia	80,00	140,00

Destinations		*DSA in EUR*	*Maximum hotel price in EUR*
IT	Italy	95,00	135,00
LT	Lithuania	68,00	115,00
LU	Luxembourg	92,00	145,00
LV	Latvia	66,00	145,00
MK	F.Y.R. of Macedonia	50,00	160,00
MT	Malta	90,00	115,00
NL	The Netherlands	93,00	170,00
NO	Norway	80,00	140,00
PL	Poland	72,00	145,00
PT	Portugal	84,00	120,00
RO	Romania	52,00	170,00
SE	Sweden	97,00	160,00
SI	Slovenia	70,00	110,00
SK	Slovakia	80,00	125,00
TR	Turkey	55,00	165,00
UK	United Kingdom	101,00	175,00

Please note that the Commission and the other European Institutions cover the travel and subsistence costs of their own officials when they participate in an event organised by the beneficiary and these should therefore not be included in the budget estimate.

Catering

The total amount calculated according to the above mentioned rules regarding Daily subsistence allowances shall constitute a maximum. If catering services are provided by the organisers, the DSAs directly paid to participants must be reduced accordingly.

Costs of services

Information dissemination, publications costs can be taken into account provided that they are directly related to the action. Please give, for each publication and/or other materials, a description, an estimate of the number of pages and copies planned, the frequency and language of publication, an indication of the production costs per copy as well as an estimate of the distribution costs where appropriate.

Translation costs must include the following details: the number of languages, the number of pages to be translated, the rate applied per page. These rates may not exceed the most reasonable market rates.

Interpretation: the different components must be specified. In particular, the number of languages, the number of interpreters, the number of days and the daily rates must be specified. The accepted daily fee of an interpreter may not exceed 700 EURO (including VAT). Interpreters should be hired locally. For their travel and subsistence expenses to be covered by the grant, it must be impossible to hire them locally and it must be explained why this is so.

Evaluation: if the proposal supported requires some form of evaluation, monitoring and evaluation methods, as well as tools to assess, on an on-going basis, the progress of the action in relation to the objectives defined at the beginning and to benchmark the results, the cost of such work will be regarded as eligible expenditure.

Subcontracting

Any service undertaken by an external party in connection with the implementation of the action is considered to be **subcontracting.**[10].

Applicants should have the operational capacity to complete the action to be supported. However, when justified and necessary, parts of the action(s) may be subcontracted to another person or organisation. In this case, the beneficiary shall ensure that some[11] of the terms applicable to itself under the agreement are also applicable to the subcontractors.

It must be clearly specified in the description of the project which tasks it is intended to subcontract and why this subcontracting is necessary.

Main rules related to subcontracting activities

When concluding external contracts in order to implement the action, the beneficiary must seek competitive tenders from potential contractors and award the contract to the bid offering **the best value for money, i.e. the best price-quality ratio**. In doing so, the beneficiary shall observe the principles of transparency and equal treatment of potential contractors and shall take care to avoid any conflict of interests.

Contracts as referred above may be awarded only in the following cases:

a) They may only cover the execution of a limited part of the action;
b) Recourse to the award of contracts must be justified having regard to the nature of the tasks necessary for the implementation of the action;
c) The tasks to be subcontracted and the corresponding estimated costs must be set out in detail in the budget estimate;
d) Any recourse to the award of contracts while the action is underway shall be subject to prior written authorisation by the Commission;
e) The beneficiary shall retain sole responsibility for the implementation of the action and for compliance with the provisions of the agreement. The beneficiary must undertake the necessary arrangements to ensure that the subcontractor waives all rights in respect of the Commission under the agreement;
f) The beneficiary must undertake to ensure that the terms, mentioned above, applicable to him under the agreement are also applicable to the subcontractor.

Where the value of the procurement contract awarded exceeds EUR 60 000, the beneficiary shall, in addition to the above general rules, apply the following procedures:

Estimated value of contract	Minimum procedure applicable
> € 60 000 but less than € 125 000	Restricted procedure following a call for expression of interest
≥ € 125 000	Open or restricted procedure

Administration costs

Depreciation for purchase of equipment[12]: the purchase cost of equipment (new or second-hand) is eligible provided that it is written off in accordance with the tax and accounting rules

[10] Art. 120FR, 184 IR
[11] The terms related to liability, conflict of interests, confidentiality, publicity, evaluation, assignment and checks and audits
[12] Art. 172 IR

applicable to the beneficiary and generally accepted for items of the same kind. Only the portion of the equipment's depreciation corresponding to the period of eligibility for Union funding covered by the grant agreement and the rate of actual use for the purposes of the action may be taken into account by the Commission. A justification for the need of purchasing such equipment is to be annexed to the budget estimate.

Other eligible administrative costs are: rent of meeting rooms (coffee breaks included), rent of interpretation booths, communications' costs, charges for financial services, costs relating to a bank guarantee and to external audits, etc. Indicative amounts for rental of booths, excluding technical equipment: 750€ (excluding VAT) per day. Rental of booths with equipment and technical assistance: 1200€ (excluding VAT) per day.

3.2.3. Eligible indirect costs - Overheads

Indirect costs are general administrative costs – overhead costs incurred in connection with the eligible direct costs for the action. They are limited to a maximum flat-rate of 7% of the total eligible direct costs for the action. These can include maintenance, stationery, photocopying, mailing postage, telephone and fax costs, heating, electricity or other forms of energy, water, office furniture, insurance and any other expenditure necessary for the successful completion of the action(s). Postage costs are considered as overhead costs and cannot be accepted under the headings "publications" or "administration".

If the accepted budget includes provision for flat-rate funding in respect of indirect costs, they need not to be supported by accounting documents.

Indirect costs are not eligible for an action where the beneficiary already receives an operating grant from the Union budget during the period in question.

3.2.4. Non-eligible costs

The following expenses are ineligible and not accepted:

- contributions in kind: these are contributions that are not invoiced, e.g. voluntary work, equipment or premises made available free of charge;
- return on capital;
- debt and debt service charges;
- doubtful debts;
- provisions for losses or potential future liabilities;
- interest owed;
- exchange losses;
- VAT, unless the beneficiary can show that he/she is unable to recover it according to the applicable national legislation.

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It should be noted that VAT paid by a public body to operators who are subject to VAT (when purchasing goods or supplying services within the framework of the implementation of the co-financed action) is not eligible. The VAT thus collected by operators liable for tax will in fact be returned to accounts of the Member State of the public body. Considering this VAT as an eligible cost would lead to double financing (by the European Union and by the fiscal revenue).

- excessive or reckless expenditure;
- costs declared by the beneficiary and covered by another action or work programme receiving a grant from the European Union.

3.3. Income

Total income must be identical to total expenditure. The income side of the budget must show:

- The beneficiary's contribution in cash: the direct monetary (cash) contribution from the applicant's own resources and/or the contribution from any other fund providers. This means a financial flow that can be traced in the written accounts of the beneficiary.
- The revenue generated by the action: any income expected to be generated by the implementation of the action should be detailed (e.g. the yield from sales of publications or the fees charged to participants attending a conference, etc.).
- The Union grant: the grant requested from the Commission.

4. How the grant will be calculated ?

If the proposal is selected for a grant, the Commission will calculate the Union contribution as a percentage of the total eligible costs as shown in the estimated budget for the implementation of the action.

The Commission reserves the right to reduce the grant requested if the proposal is acceptable but considered too expensive, and to reduce individual unit costs if these are estimated to be too high.

Determination of the final amount of the grant

The Union final grant is calculated on the basis of the **actual** eligible expenditure by applying the "double ceiling" rule and verifying compliance with the no-profit rule.

- Application of the **"double ceiling" rule** limiting the grant both to the percentage of the eligible costs and to the maximum amount mentioned in the grant agreement

The Union final grant is calculated by applying the percentage for the co-financing of the eligible costs laid down in the grant agreement to the total of the actual eligible costs. This amount must not exceed the maximum amount for the Union grant laid down in the grant agreement.

As a result, if the actual expenditure turns out to be lower than the expenditure you budgeted, the actual grant will also be reduced in application of the percentage contribution which will remain the same. If the actual expenditure turns out to be higher than the expenditure budgeted, the Union grant will not be increased. It is therefore in the applicant's interest to submit a realistic estimate of expenses.

- Verification of compliance with the **no-profit rule**

The grant may not have the purpose or effect of producing a profit for the beneficiary[13]. On the basis of the above rule if the total income of the action is higher than the total costs, the final grant amount will be reduced accordingly so that it will not produce a profit.

A mere forecast of expenditure does not give entitlement to a grant. This is why the final grant amount cannot be calculated until the Commission has received the final activity report and

[13] Art. 109(2) FR

the final statement of expenditure. The expenditure that is committed to the implementation of the action must be justified by invoices or equivalent supporting documents, in order to be accepted as actual expenditure. It must also relate to actual rather than inputted costs.

5. Agreement governing the grant

Should the Commission award a grant, a standard grant agreement for an action setting out the conditions and maximum level of funding will be concluded with the beneficiary.

Successful applicants will receive two original copies of the grant agreement for acceptance and signature. Both of these copies must be sent back to the Commission, which will then return one of them once it has been signed by both parties.

6. Payment procedures

The payment arrangements will be laid down in the grant agreement.
Payment of the grant will be made in two instalments (a pre-financing payment and a final payment under the following conditions:

- A pre-financing payment of 50 % at the signature of the grant agreement.
- The balance will be paid upon acceptance by the Commission of the final technical implementation report and final financial statement.

7. Bank account and interest generated by pre-financing payments[14]

Payment shall be made to the beneficiary's bank account or sub-account denominated in Euro. This account or sub-account indicated by the beneficiary must make it possible to identify the funds transferred by the Commission.

If the funds paid to their account yield interest or equivalent benefits under the law of the State on whose territory the account is opened, such interest or benefits, if they have been generated by pre-financing payments which remain the property of the European Union, shall not be treated as a receipt for the action.

The beneficiary shall, as specified in the grant agreement, inform the Commission of any interest or equivalent benefits yielded by pre-financing payments higher than EUR 50 000, it has received from the Commission. Notification must be made when the request is introduced for interim payment or for payment of the balance that clears the pre-financing.

Interests yielded by pre-financing payments between € 50 000 and € 750 000 will be directly deducted from payments.

Interests shall not be due to the Union for pre-financing paid to Member States, to their regional or local authorities including organisms and administrative and instrumental structures under their control or paid in the framework of joint management with international organisations.

All costs related to these requirements (such as the cost for opening and closing accounts) are eligible and may be submitted in the budget estimate.

[14] Art. 5(a) FR, Art. 3, 4 , 4(a) IR

8. Submission of reports and other documents

The final report on the implementation of the action along with a final financial statement of all actual expenditure and actual revenue are to be sent within three months from the closing date of the action.

The final report should answer at least to the following questions:

1) How was the action performed? Was it performed in accordance with the description of the action annexed to the grant agreement? (Describe the action, its results and methodology, planned activities, timetable, partners, participants, etc.).
2) To what extent did the action meet the objectives set?
3) What was the European added value of the implementation of the action?
4) How was the action presented to the public and how were the results disseminated?
5) What lessons have been learned from this experience?
6) Describe the results of the evaluation (internal/external) of the implementation of the action.

The final activity report must be completed using the template annexed to the grant agreement.

These templates will be an essential part of performance monitoring of PROGRESS which is strongly committed to results-based management, which is the continuous measurement of the programme's achievements towards its objectives, reporting and taking action to fine-tune the programme in order to improve its performance.

Please also attach to the final report a copy of the documents produced during the action (publications, press articles, manuals, leaflets, posters…).

Should the final report be deemed to be inadequate and of low quality, the Commission reserves the right to request additional information within 60 days of reception of the final report, and, if necessary, to suspend the final payment until the requested information is provided.

9. Publicity

Beneficiaries of the grant are required to mention clearly the fact that they have received funding from the Union in any publication and/or in other materials, or in the occasion of activities (conferences or seminars, etc.), for which the grant is used, using the following wording: "**With support from the European Union** ". The logo of the EU, given at the following web address: http://europa.eu/abc/symbols/emblem/ and the logo of the "For Diversity. Against discrimination campaign" should also be visible.

Any communication or publication by the beneficiary, in any form and medium, including the Internet, shall indicate that sole responsibility lies with the author and that the Commission is not responsible for any use that may be made of the information contained therein.
In addition to these minimum requirements, references specified in the text of the call for proposals must also be indicated (see Point 17 of the guidelines).

All grants awarded in the course of a financial year shall be published on the Internet site of the Union institutions during the first half of the year following the closure of the budget year in respect of which they were awarded.

By signing the grant agreement for an action, the beneficiary authorises the Commission to publish the following information in any form and medium, including via the Internet site of the Union[15]:

- the beneficiary's name and the address
- the subject of the grant,
- the amount awarded and the rate of funding of the costs of the action.

Upon a duly substantiated request by the beneficiary, publication of this data can be waived if it threatens the safety of the beneficiary or harms his business interests.

Publication of information related to partner(s) in PROGRESS-funded projects
In order to increase the visibility of transnational partnerships established under PROGRESS and to facilitate networking between organisations involved in actions covered by PROGRESS grants, the Commission intends to publish the name and address of partners in PROGRESS-funded projects together with the name and address of the beneficiary, the reference of the call for proposals and the title and description of the project. To that purpose, the Beneficiary will be asked to seek the partners' agreement to authorise the Commission to publish this data. This written agreement should be included in the letters of commitment sent to the Commission with the application form.

10. Evaluation

If the proposal should include a specific evaluation component for ongoing monitoring and final evaluation of the action, these costs can be taken into account as eligible in the budget estimate.

Successful proposals could be the subject of an ongoing and ex-post evaluation led by the Commission and/or by independent experts selected by the European Commission. Therefore, the beneficiaries of the grant undertake to make available to the Commission and/or persons authorised by it, all such documents or information as will allow the evaluation to be successfully completed and give them the rights of access required.

11. CHECKS AND AUDITS

The beneficiary undertakes to provide any detailed information requested by the Commission or by another qualified outside body chosen by the Commission for the purposes of checking that the action and the provisions of the agreement are being properly implemented. The beneficiary must enable the Commission and/or the Court of Auditors to verify the organisation's accounting documents, if they deem this appropriate. To this end, documentation justifying items of expenditure must be retained by the applicant's organisation for five years following final payment by the Commission.

[15] Art. 110(2) FR, 169(2) IR

12. Procedure: Electronic means of submission - SWIM

The Internet Web application called "SWIM" (SAGA Web Input Module) allows applicants/beneficiaries to introduce, edit, validate, print and submit grant applications, request for payments and request for modifications on the budget estimate. SWIM can be accessed in the following web address[16]: https://webgate.ec.europa.eu/swim.

12.1. Introduction of grant applications

The grant application form has to be electronically filled in as follows: first, access the system at the address mentioned above and click on the link "New grant application", then, select the number of the call for proposals you wish to apply for and, eventually, fill in your application. Once your application is completed, click on the "submission" button in order to finalise the submission procedure.

Please note that after having submitted your application form electronically no changes to the application are possible.

After being submitted electronically, the application form must also be printed out, signed by the legal representative of the organization submitting the proposal and sent by post to the responsible Unit, as specified in the text of the call for proposals.

Failure to respect this procedure will render the application ineligible.

12.2. Requests for payments and budgetary modifications

In addition to the documents specified in the grant agreement, financial documents required in support for payment of the balance, as well as requests for modifications of the budget estimate to be made by addendum must also be electronically submitted using SWIM.

To be allowed to log on into SWIM and access its grant file, the beneficiary will be asked to enter on the login page the same file number and Access code assigned by the system to the grant application when it was created.

13. Data Protection

The grant application will be processed by computer. All personal data (such as names, addresses, CVs, etc.) will be processed in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data[17]. Replies to the questions in the application form are necessary in order to assess the grant application and they will be processed solely for that purpose by the department responsible for the Union grant programme concerned. On request, applicants may be sent personal data and correct or complete them. For any question relating to these data, please contact the Commission department to which the form must be returned. Beneficiaries may lodge a complaint against the processing of their personal data with the European Data Protection Supervisor at any time.

[16] For more technical details on SWIM utilisation, a user's manual is available on line

[17] Official Journal L 8, 12.1.2001.

14. WARNING SYSTEM AND CENTRAL EXCLUSION DATABASE

Grant applicants and, if they are legal entities, persons who have powers of representation, decision-making or control over them, are informed that, should they be in one of the situations mentioned in:

- the Commission Decision of 16.12.2008 on the Early Warning System (EWS) for the use of authorising officers of the Commission and the executive agencies (OJ, L 344, 20.12.2008, p. 125), or

- the Commission Regulation of 17.12.2008 on the Central Exclusion Database – CED (OJ L 344, 20.12.2008, p. 12),

their personal details (name, given name if natural person, address, legal form and name and given name of the persons with powers of representation, decision-making or control, if legal person) may be registered in the EWS only or both in the EWS and CED, and communicated to the persons and entities listed in the above-mentioned Decision and Regulation, in relation to the award or the execution of a procurement contract or a grant agreement or decision.