



LABELLING GUIDELINES FOR COSMETIC & BEAUTY PRODUCTS IN EUROPE

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Article 33 of the Regulation requires the European Commission to compile, update and publish in the Official Journal of the European Union. It is updated periodically as asked by European Commission.



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DECLARATION:

This is just a guidance document prepared by the author for information purpose only. Although every effort has been made to ensure that the document and guidance is in line with European Cosmetics Regulation (EC) No. 1223/2009 and/or its rulings issued by the EU Courts, we do not accept any responsibility of any actions taken on basis of this information. The legal text of Cosmetics Product Regulations (EC) No. 1223/2009 must be used as it is bound to EU Courts ruling.

Introduction

In Europe Cosmetics Regulation (EC) No. 1223/2009 replaced the Cosmetics Directive 76/768/EC in 2013. The European Parliament and the Council of 30 November 2009 published Regulations in Journal of the European Union on 22 December 2009 (OJEU, L 342, p. 59). The replacement came into effect on 11 July 2013 and all provisions of the Regulation become enforceable.



The above regulation applies to all Member States of European Union and does not need to be transposed into national legislation. Any Cosmetic products placed on market on 11 July 2013 or after must comply with the Regulation.

Article 19 of the Cosmetics Regulation governs the information that must be printed on cosmetic product labels (containers & packaging). The guidelines intend to provide clear information and guidance on the labelling requirements under the Regulation.

A Cosmetic Product

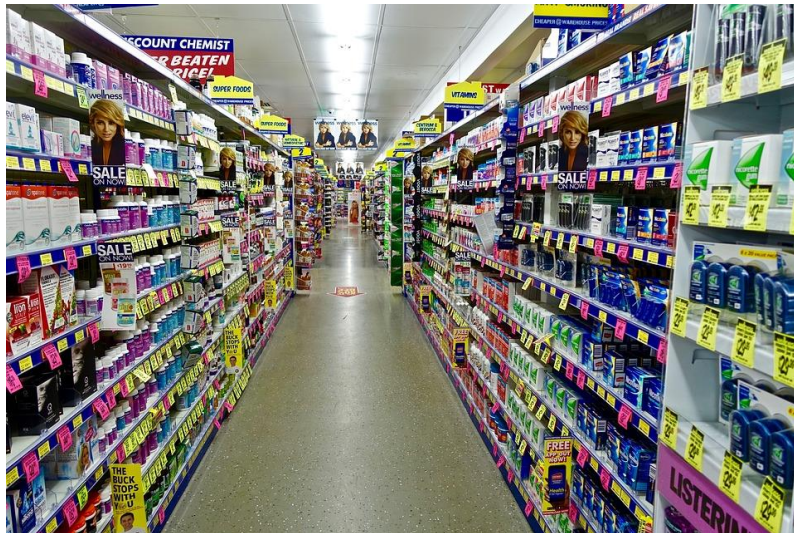
According to Article 2.1 of the Cosmetics Regulation, A cosmetic Product means any substance or mixture intended to be placed in contact with the external parts of the human body (Epidermis, Hair System, Nails, Lips and External genital organs) or with the teeth and the mucous membranes of the oral cavity with the view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.

The definition applies to all cosmetic products including but not limited to retail products, salon products, sold on internet, by mail order or made available in hotels, spas, etc.

Primary & Secondary Packaging

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

1. The Container (Primary Package) is designed to be in direct contact with the product
2. The Packaging (Secondary Packaging) is designed to contain one or more containers, including any other materials like leaflets, instructions, etc.



Compulsory Labelling Requirements

The following list overviews the cosmetic labelling requirements (except Aerosol as it has additional requirements) as per the Regulation (EC) No. 1223/2009.

- 1. Product Name & Function**
- 2. Nominal content**
- 3. Name/Registered Name/Address of the Responsible Person**
- 4. Shelf Life/ Period After Opening/ Date of Durability**
- 5. Precautions/Warnings**
- 6. Batch Number**
- 7. Country of Origin**
- 8. List of Ingredients (INCI)**

All the above points are explained under section ‘LABELLING EXPLANATION

The points from 1. to 7. above must appear on the label of both primary & secondary packaging of each cosmetic product.

The point 8. may be printed only on the secondary packaging with specific condition.

Font & Letters

The lettering must be legible, not easily erasable and clearly visible. The font must be readable under normal conditions of presentation.

Language

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

The list of Ingredients shall be used as set out in the glossary of Article 33 and published in the Official Journal of European Union. In the absence of a common ingredient name, a term as contained in a generally acceptable nomenclature shall be used.

LABELLING EXPLANATION

Product Name & Function

Product Name includes the Brand Name and the commercial name of the product.

The function of the cosmetic product should be clearly printed on the container and on packaging, unless it can be determined by various factors:

- a. Name [Shampoo, Conditioner and so on]
- b. Product presentation [Shape, Size, Volume, Weight]
- c. Claims [Mascara, Waterproof mascara, lip picture and so on]

The language stated on the label is determined by the law of Member State(s) where product is made available to the end user.

Some terms are internationally accepted on label, like Eu De Parfum, and so on.

Nominal content

Except packaging less than five grams or 5 millilitres, the nominal content is expressed in Units of weight or volume.

Directive 76/211/EEC of 20 January 1976 and its amendment Directive 78/891/EEC and Directive 2007/45/EC sets the rules of the nominal content at the time of packaging.

As per Directive 76/211/EC, Annex 1, point 3.1, the nominal quantity (nominal weight or nominal volume) is expressed in Kilograms, grams, litres, centilitres, or millilitres.

The minimum height of figures is:

Contents	Minimum height of figures
Up to and including 50g or 50ml	2mm
Above 50g or 50ml up to and including 200g or 200 ml	3mm
Above 200g or 200ml up to and including 1 Kg or 1 litre	4mm
Above 1 Kg or 1 Litre	6mm

A small ‘e’ of minimum height 3mm representing ‘estimate fill’ may also be placed in the same field of vision as the indication of the nominal quantity as per Directive 76/211/EC.

Aerosols have few additional requirements which see our Aerosol Packaging requirements.

Name/Registered Name/Address of the Responsible Person

Only Cosmetic Products for which legal or natural person is designated with the Community as ‘Responsible Person’ shall be placed on the market as stated by Article 4 of the Cosmetics Regulation.

The Responsible person must be in Europe and has been classified under three categories:

- a. The European Manufacturer or the 'Company/Person' designated by written mandate by European or Non-European Manufacturer [Art. 4.3., 1223/2009/EC, L 342/65-66, 22.12.2009]

- b. The European Importer or the 'Company/Person' designated by written mandate by the Importer [Art. 4.5., 1223/2009/EC, L 342/66, 22.12.2009]

- c. The Distributor shall be the responsible person where he places a cosmetic product on the market under his name or trademark or modifies a product already existing in the market affecting compliance. [Art. 4.6., 1223/2009/EC, L 342/66, 22.12.2009]

The name and the address of the responsible person must be easily identifiable, although it could be abbreviated if required.

In case of multiple addresses, the one where the Product Information File (PIF) is available must be highlighted, mostly by either making text bold or by underlining the address.

Shelf Life/ Period After Opening

Date of Minimum Durability (DOMD) and Period After Opening (PAO)

Physical, chemical & Microbiological stability studies divide the situation into following:

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

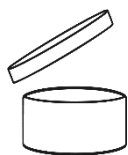
Date of minimum durability is clearly expressed and preceded by either 'Best Before the end of' or



Symbol with either MMYYYYY or MMY. It could also be DDMMYYYY or DDMMYY. It is best to place the date next to the symbol.

- b. The finished product has minimum durability of more than 30 months

A date of minimum durability is replaced by an indication of 'Period After Opening' for which the product is safe and can be used without any harm to the consumer must be labelled using the below symbol as per point 2 of Annex VII



The symbol is accompanied by an indication of the period in months or years shown as a number which can be located inside or outside of the symbol.

M represents months, but shortened version of years has not been agreed, so it is written as ‘x M’, for instance 3 Years is written as 36M.

PAO is not relevant in certain cases like:

1. Single use products
2. Products where packaging does not allow physical opening of the products. These are products presented in containers where there is no possibility of contact between the product and the external environment, such as aerosol dispensers, airless containers and so on.
3. Products with low microbiological risk, especially with pH.10.5 or higher and pH 3.5 or lower. It applies to high alcohol content products such as perfumes, Eau de colognes and so on.

Precautions/Warnings

Article 19.1(d) requires the specific precautions to be observed during the use of cosmetic products which must be indicated on cosmetic product labels.

Warnings required by the Regulation are laid down in Annexes III to VI.

Specific precautions for use must be mentioned in the language(s) required by the member States in which the products are made available to end users.

24 Languages are spoken within Europe.

Languages in Europe	
<i>Language</i>	<i>On pack Abb.</i>
Bulgarian	bg
Croatian	hr
Czech	cs
Danish	da
Dutch	nl
English	en
Estonian	et
Finnish	fi
French	fr
German	de
Greek	el
Hungarian	hu
Irish	ga

Italian	it
Latvian	lv
Lithuanian	lt
Maltese	mt
Polish	pl
Portuguese	pt
Romanian	ro
Slovak	sk
Slovenian	sl
Spanish	es
Swedish	sv

The precautions and warnings need to appear on both the container and the packaging. If it is impossible to print this information on the label, the information shall be mentioned on an enclosed or attached leaflet, label tape, tag or card.

This shall be abbreviated or by the 'Hand-In-Book' symbol which must appear on the container or packaging:



If it is impossible to label the symbol, it may be omitted.

Batch Number

Batch Number ensures identification of a certain batch of a cosmetic product throughout whole supply chain, especially in case of any recall.

The Batch number of manufacture or reference for manufacturing identification of the cosmetic product could be written in any format as Regulation does not specify a format.

The batch number must be printed on both the primary packaging as well as secondary packaging. Where it is impossible for practical reasons because the product is too small, it can be printed only on the packaging.

Country of Origin

The ‘Country of Origin’ must be labelled for the products manufactured outside Europe.

The ‘Country of Origin’ label is not mandatory for the products manufactured with the European Community.

List of Ingredients (INCI)

Ingredient list ensures transparency to the consumer, giving adequate information about the product.

All cosmetic products marketed in any part of the EU have to be labelled with a list of their ingredients, irrespective of the channel of distribution.

As stated under Article 2.1(a) of the Cosmetics Regulation, including imported products, professional products, free samples, tester samples, multi-component products, products sold by mail order or via internet, products provided in hotels and other public facilities.

Rules

a. Nomenclature

To achieve transparency, uniformity should be followed throughout Europe in the labelling across different EU countries.

International Nomenclature Cosmetic Ingredient, also termed as INCI name should be a common ground to be followed.

b. Order

The Ingredient list shall be preceded by the common term ‘Ingredients’ and no translation is required in line with Articles 19.5 & 19.6.

The list of ingredients shall be established in the descending order of weight of the ingredients at the time they are added to the cosmetic product. Ingredients in concentrations of less than 1% may be listed in any order after those in concentrations of more than 1%.

Colorants other than colorants intended to colour the hair may be listed in any order after the cosmetic ingredients.

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, considering its concentration in the finished product.

For Decorative cosmetics other than hair colorants, all colorants used in the range may be listed, provided that the words ‘may contain’ or the symbol ‘+/-’ are added. The CI (Colour Index) nomenclature shall be used, wherever applicable.

c. Position

The ingredient list must be visible during the time of purchase, so it could be written on packaging only. It could be placed on any side of packaging if it is indelible, easily legible and lettering is visible.

Multi pack could have individual Ingredient declaration on one place on outer of the pack.

If it's impossible to indicate the ingredients on the packaging, the information shall be mentioned on an enclosed leaflet, label, tag, tape or card and Book-In-Hand symbol must be used.



If it is still impossible to label, it may be omitted.

In case of soaps, Book-In-Hand symbol is not required. The information may be given on a notice or leaflet near the product offered for sale.

d. Ingredients on packaging

An incomplete listing of ingredients is considered misleading.

According to Article 19.1(g), an ingredient means any substance or mixture intentionally used in the cosmetic product during the process of manufacturing.

The following shall not be considered ingredients, if:

1. Impurities in the raw materials used;
2. Subsidiary technical materials used in the mixture but not present in the final product.

It may include filtration aids and decolorizing agents.

e. Parfum/Aroma

In the ingredient list, the INCI names ‘Parfum’ or ‘Aroma’ must be used to summarise and add up all functional components, e.g. solvents or carriers.

26 specific substances listed in Annex III of the Regulation shall be indicated if their concentration is above threshold concentration. The thresholds are 0.001% for leave-on products and 0.01% for rinse off products. These thresholds refer to concentrations in the final mix as applied to the body.

This labelling helps the sensitised individuals identify and avoid material they are allergic to, if any.

If present at the concentration >1%, the ingredients should be listed at the position corresponding to that concentration

The INCI names of 26 specific substances are:

Amyl cinnamal
Anise alcohol
Amyl cinnamyl alcohol
Benzyl benzoate
Benzyl alcohol
Benzyl cinnamate
Benzyl salicylate
Citronellol

Cinnamyl alcohol
Farnesol
Cinnamal
Hexyl cinnamal
Citral
Butylphenyl methylpropional
Coumarin
Limonene
Eugenol
Linalool
Geraniol
Methyl 2-octynoate
Hydroxycitronellal
Alpha-isomethyl ionone
Hydroxyisohexyl-3-Cyclohexene-Carboxaldehyde
Evernia Prunastri Extract
Isoeugenol
Evernia Furfuracea Extract

f. Nanomaterials

It is an obligation to inform the consumer when nanomaterials, as defined under Article 2.1(k) are used in cosmetic products.

The materials present in the form of nanomaterials must be clearly indicated and shall be followed by the word 'Nano' in the bracket.

In line with Articles 19.5 and 19.6, the suffix 'Nano' is accepted throughout Europe regardless of national language or alphabet.

Summary of Amendment on Nanomaterial is available separately.

REFERENCE

1. Colipa Guidelines on Cosmetic Product Labelling, 2011



Further Information

If you require further assistance on the regulations, or would like to discuss your products further, please us at:

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