

# Rules & Regulations for Legally Selling Cosmetic Products



If you sell cosmetic products, they must be safe; there are specific requirements for composition and labelling

## **This guidance is for England, Scotland and Wales**

Cosmetics are subject to legal definition; products used solely as medicines are excluded. Regulation (EC) No 1223/2009 *on cosmetic products* makes it an offence to supply a cosmetic product that may cause damage to human health or contains specific restricted or prohibited substances.

It is an offence to supply an incorrectly labelled cosmetic product. The labelling requirements include the name and address of the manufacturer / importer, the ingredients, durability marking, function and precautions.

Finally, it is an offence not to undertake certain safety assessments and not to compile technical documentation.

The Regulation is enforced by trading standards services in the UK by the Cosmetic Products Enforcement Regulations 2013, which have been amended by the Product Safety and Metrology etc (Amendment etc) (EU Exit) Regulations 2019. The Regulation sets out requirements that must be met before cosmetics products can be placed on the market in Great Britain. There are also restrictions on animal testing of products.

## **What is a cosmetic product?**

Regulation (EC) No 1223/2009 (referred to in this guide as 'the Regulation') defines a cosmetic product as "any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours".

The Regulation relates only to cosmetic products and not to medicinal products, medical devices or biocidal products.

A substance or mixture intended to be ingested, inhaled, injected or implanted into the human body is not a cosmetic product.

## **What about aromatherapy products?**

These can be medicines, cosmetic products or neither of these, depending on their intended use. If they are not medicines or cosmetic products, they are governed by the General Product Safety Regulations 2005.

Please ask your local trading standards service if you require more guidance on aromatherapy products.

## **Main provisions**

It is an offence for a UK responsible person to supply a cosmetic product that may cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking into account:

its presentation (and in particular, its form, odour, colour, appearance, packaging, labelling, volume or size) should not endanger the health and safety of consumers due to confusion with foodstuffs

its labelling

any instructions for its use and disposal

any other information provided by the responsible person

The UK responsible person can be any of the following:

the manufacturer within the UK (or they can nominate someone else in writing to be the responsible person)

a person in the UK designated by written mandate by a manufacturer that is outside the UK

a distributor, where they place a cosmetic product on the market under their name or trademark, or modify a product already placed on the market in such a way that

compliance with the applicable requirements may be affected - for example, repackaging or relabelling

the importer (established in the UK who places a product from a country outside the UK on the UK market)

### **Rules on animal testing**

It is an offence to test a finished cosmetic product or an ingredient on an animal in order that the product may comply with the requirements of the Regulation.

The Regulation also restricts the supply of cosmetic products whose final formulation, or any ingredient or combination of ingredients, have been tested on animals.

### **Composition**

The rules on what may and may not be used as an ingredient, and the rules on restricted use and special precautions, are too detailed to be included here. If you require this information, you should refer to the Regulation's annexes (see link in '**Key legislation**' below) or you should seek specialist advice.

### **Marking / labelling**

The following information must be given on the packaging or labelling.

#### **NAME AND ADDRESS**

The name and address of the UK responsible person must be on the container (such as a tube, bottle or jar) and the packaging (for example, the box or outer carton). Where the product is manufactured outside the UK, the country of origin must also be given. For the purposes of enabling existing stock to make its way through the supply chain, and reflecting the typical shelf-life of a cosmetic, there will be a two-year transition period from 1 January 2021 before businesses have to include the details of the UK responsible person on product labels (as long as the details of the EU responsible person are included).

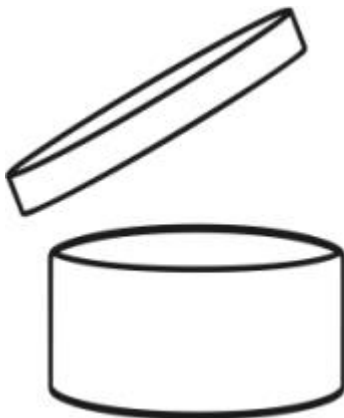
#### **DURABILITY**

Where a cosmetic product has a minimum durability of 30 months or less, it must be marked on the container and the packaging with a best-before date or the symbol shown below.



The indication must be in the form 'Best used before the end of', followed by the date (day / month / year or month / year) or an indication of where the date appears on the packaging. If any particular conditions must be observed to guarantee the stated durability, these must also be described.

Where a product has a shelf life of more than 30 months, it must instead be marked with the symbol shown below together with an indication (in months, or years and months) of the period after opening for which the product can be used without harming the consumer.



## **PRECAUTIONS**

Precautions to be observed in use, as shown in the annexes to the Regulation, must be printed on the label. Special precautionary information on cosmetic products for professional use, such as in hairdressing, must appear on the container and packaging.

## **BATCH CODE**

The batch number of manufacture or the reference for identifying the goods.

## **FUNCTION**

If not otherwise obvious from design and packaging.

## **INGREDIENTS**

The package in which the cosmetic product is supplied must bear a list of ingredients, headed 'Ingredients' (see note below), in descending order of weight, determined at the time the ingredient was added to the product.

All cosmetic products marketed in any part of the UK have to be labelled with a list of their ingredients, irrespective of the channel of distribution. This requirement also applies to professional products, free samples, tester samples, multi-component products, products sold by mail order or online, and products provided in hotels and other public facilities.

You do not need to include any of the following as ingredients:

impurities in the raw materials

materials used in the preparation of, but not present in, the final product

materials used as solvents or carriers for perfumes and aromatic compositions

Perfume and aromatic compositions and their raw materials must be referred to as 'perfume' (see note below) or 'aroma' unless a more specific indication of their presence is required in Annex III to the Regulation (see link in **'Key legislation'** below).

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

Colouring agents may be listed in any order after the other ingredients. For decorative cosmetics marketed in various colours, all colouring agents in the range may be listed so long as the words 'may contain' or the symbol '+/-' is also used.

The ingredient name must be that listed in the International Nomenclature of Cosmetic Ingredients (INCI) or, if no such name is listed, one of the following:

chemical name

European Pharmacopoeia name

International Non-proprietary Name (INN), as recommended by the World Health Organisation

European Inventory of Existing Commercial chemical Substances (EINECS), International Union of Pure and Applied Chemistry (IUPAC), or Chemical Abstracts Service (CAS) identification reference

colour index number

A [database of INCI names](#) is available on the Europa website.

All ingredients present in the form of nanomaterials must be clearly indicated in the list of ingredients. The names of such ingredients must be followed by the word 'nano' in brackets.

There is a procedure detailed in the Regulation that, subject to agreement, allows the confidentiality of some ingredients to be maintained.

For consistency the following conventions have been agreed by the Cosmetic, Toiletry and Perfumery Association (CPTA), the UK cosmetics industry trade association. Firstly, the word 'ingredients' should be given in capital letters, and secondly, the word 'perfume' should be replaced by 'parfum'. Although these conventions do not have the force of law, their use will be accepted by UK enforcement authorities. If you are exporting cosmetic products to countries in the European Economic Area (EEA), you should confirm that the authorities in those countries also accept this convention.

#### ADDITIONAL INFORMATION

Additional information must be given where certain ingredients, such as preservatives and UV filters, are present. This information is specified in Annexes III, IV, V, and VI to the Regulation (see link in **'Key legislation'** below).

#### PRESENTATION

All required information must be visible, indelible and easily legible. The ingredients list must be given in a language that is easily understood by the consumer. All of the other information must be in English and can be supplemented by other languages.

There is one set of rules about presentation for ingredients lists and another set for the other information.

#### **Ingredients list**

The ingredients list must appear on the packaging or, if it is impossible to do so or there is no packaging, on the container. If the product is sold loose, the ingredients list can be given on the container in which the product is exposed for supply or on a notice. If this is not possible, the list can be given on a leaflet, label, tag, tape or card enclosed with or attached to the product, along with an indication referring the consumer to it (either by way of abbreviated information or the 'hand and book' symbol below). For small products such as soap and bath balls, a notice can be used instead of a leaflet, label, etc.



### **Other information**

The other information must normally appear on both the container and the packaging. However, if it is not possible for the batch code to appear on the container, it can appear on the packaging only. Similarly, where there are practical constraints, the conditions for use may appear on a leaflet, label, tag, tape or card enclosed with or attached to the product, again with an indication referring the consumer to it.

For 'unpackaged' loose cosmetic products (such as soap, bath balls and other small products) it may be impossible for practical reasons for the ingredients list to be attached on a tag, tape or card. If that is the case, all the relevant information that would be required on the packaging, and as outlined above, must be given on a notice adjacent to the container in which the cosmetic product is exposed for sale.

### **Claims**

Regulation (EU) No 655/2013 *laying down common criteria for the justification of claims used in relation to cosmetic products* states that claims should be legal, truthful, supported by evidence, honest, fair, and clear and understandable to the end user.

In particular 'free from' claims should not be used where they refer to an ingredient that is typically not used in that kind of cosmetic - for example, 'free from preservatives' in a perfume that already contains alcohol. Also free-from claims should not be used where the ingredient is legal for use. This means claims such as 'free from parabens' are not allowed.

For more information on claims, please see the European Commission's *Technical Document on Cosmetic Claims*.

### **The requirements on the responsible person**

The manufacturer of cosmetic products must comply with good manufacturing practice. Compliance with good manufacturing practice can be presumed where the manufacture is in accordance with the relevant designated standards\*.

[\*'Designated standards' are those approved by the Secretary of State and published by the British Standards Institution (BSI).]

In order to demonstrate that a cosmetic product is safe, the UK responsible person must ensure that the cosmetic product has undergone a safety assessment and that

a cosmetic product safety report is produced. This safety assessment must be carried out by a person in possession of a diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline.

Where a cosmetic product is supplied or manufactured in the UK, the responsible person is required to keep certain product information at the registered office address or the address detailed on the product. This information must be easy for the nominated authorities (generally the responsible person's local trading standards service) to access and can be requested in the case of medical emergency. The information must be in English or another language easily understood by the nominated authority.

The product information file (PIF) must include all of the following:

the qualitative and quantitative composition of the product. For perfume or perfume compositions in the product, you are only required to keep the name, code number and supplier identity. Qualitative information for all composites, and the quantitative information in relation to dangerous substances, must also be made easily available to the general public

the physico-chemical and microbiological specifications of the raw materials and the finished product, and the purity and microbiological control criteria of the cosmetic product

the method of manufacture, which must be in accordance with good manufacturing practice

an assessment of safety for human health of the finished product, in the form of a 'cosmetic product safety report' (CPSR) signed by a qualified safety assessor, according to the criteria stipulated in the Regulation. In addition, a specific safety assessment is required for cosmetic products intended for use on children under the age of three, and for cosmetic products intended exclusively for use in external intimate hygiene

the presentation of the cosmetic product must take into account the requirements of the Food Imitations (Safety) Regulations 1989, which concern dangerous imitations. See 'Food imitations' for more information on these Regulations

existing data on the undesirable effects on human health resulting from use of the product. This information must also be made easily available to the general public

evidence to justify any claims made by the product

data on any animal testing performed by the manufacturer, their agents or suppliers, relating to the development or safety evaluation of the product or its ingredients

The PIF must be maintained in English at the UK address, and made available to market surveillance and enforcement authorities, which includes the Secretary of State and local authority trading standards services in GB (also known as local weights and measures authorities).



Prior to placing the cosmetic product on the market the responsible person must submit the following information to the UK Government through the UK's Submit Cosmetic Product Notifications service (SCPN):

the category of cosmetic product and its name or names, enabling its specific identification

the name and address of the responsible person (if the PIF is made readily accessible)

the contact details of a physical person to contact in the case of necessity (if the cosmetic product has been imported into the UK)

the presence of substances in the form of nanomaterials and their identification

the frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties

When the cosmetic product is placed on the market, the responsible person must notify to the UK Government the original labelling, and, where reasonably legible, a photograph of the corresponding packaging.

Responsible persons who consider or have reason to believe that a cosmetic product that they have placed on the market is not in conformity with the Regulation must immediately take the corrective measures necessary to bring that product into conformity, withdraw it or recall it, as appropriate. Where the cosmetic product presents a 'serious undesirable effect' (SUE) or risk to human health, responsible persons and/or distributors must immediately inform their local trading standards service, giving details of the non-compliance and of the corrective measures to be taken.

An importer (which must by definition be based in the UK) that places a product on the GB market is the responsible person in respect of that product.

### **Microbeads**

Legislation prohibits the manufacture and sale of rinse-off personal care products containing plastic microbeads. For more information see 'Microbeads'.