This guidance is for England, Scotland & Wales

Cosmetics are subject to legal definition and products used solely as medicines are excluded. EU 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 that contains specific restricted or prohibited substances.

It is also 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.

There are also restrictions on animal testing of products.

The EU Regulation is enforced by trading standards in the UK by the Cosmetic Products Enforcement Regulations 2013.
What is a cosmetic product?

EU 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 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 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 responsible person can be one of the following:

- the manufacturer within the EU (or they can nominate someone else in writing to be the responsible person)
- a person in the EU designated by written mandate by a manufacturer that is outside the EU, but has the product manufactured in the EU
- 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 EU who places a product from a country outside the Union on the Union 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.

Where a claim is made that a cosmetic product has not been tested on animals, this must be correct. In particular, the manufacturer or supplier must not have tested or commissioned tests on animals of the finished product, its prototype or any of their ingredients. The cosmetic product must also not contain any ingredients that have been tested on animals by others for the purpose of developing new cosmetic products.

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 make reference to the Regulation's annexes (see 'Key legislation' below for link) or you should seek specialist advice.

Marking / labelling

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

Name & address

The name and address of the responsible person established within a Member State must be on the container and the packaging. Where the product is manufactured outside the European Economic Area (EEA), the country of origin must also be given.

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 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 EU have to be labelled with a list of their ingredients, irrespective of the channel of distribution. This requirement also applies to imported products, professional products, free samples, tester samples, multi-component products, products sold by mail order or via the internet, 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.
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 across the EEA, the following conventions have been agreed by Cosmetics Europe (the European 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 other EEA countries, 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.

**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.

In the case of loose cosmetic products other than soap, all of the information must be given on the container in which the product is exposed for supply, or on a notice in immediate proximity to the container.

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 harmonised standards, the references of which have been published in the *Official Journal of the European Union*.

In order to demonstrate that a cosmetic product is safe the 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, or a course recognised as equivalent by a Member State.

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 easily accessible to the nominated authorities, generally the responsible person’s local trading standards service, 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, including the criteria as stipulated in the Regulation. There are additional criteria where the product is intended for use on children under three years old or exclusively for use in external intimate hygiene (see above)

- the name and address of the person or persons - with the minimum qualifications as detailed in the Regulation - who carried out the assessments
- 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

Prior to placing the cosmetic product on the market the responsible person must submit the following information to the European Commission through the Cosmetic Products Notification Portal (CPNP):

- the category of cosmetic product and its name or names, enabling its specific identification
- the name and address of the responsible person where the product information file is made readily accessible in the country of origin
- in the case of import into the Member State in which the cosmetic product is to be placed on the market, the contact details of a physical person to contact in the case of necessity
- 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 Commission 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 this 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 risk to human health, responsible persons must immediately inform their local trading standards service giving details, in particular, of the non-compliance and of the corrective measures taken.

Microbeads

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

Penalties

Failure to comply with trading standards law can lead to enforcement action and to sanctions, which may include a fine and/or imprisonment. For more information please see 'Trading standards: powers, enforcement & penalties'.

Key legislation

EU Regulation (EC) No 1223/2009 on cosmetic products
Cosmetic Products Enforcement Regulations 2013

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Please note

This information is intended for guidance; only the courts can give an authoritative interpretation of the law.

The guide’s 'Key legislation' links may only show the original version of the legislation, although some amending legislation is linked to separately where it is directly related to the content of a guide. Information on amendments to UK legislation can be found on each link's 'More Resources' tab; amendments to EU legislation are usually incorporated into the text.

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