Cosmetic Products
Safety, composition and labelling

Guidance Information provided by the Trading Standards Institute

The **Cosmetic Product (Safety) regulations 2004** came into force on 11th September 2004. The Regulations consolidate earlier Regulations and implement current European Directives.

What is a cosmetic product?

The Regulations define a cosmetic product as being:

"Any substance or preparation intended to be placed in contact with any part of the external surfaces of the human body (that is to say, the 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 except where such cleaning, perfuming, protecting, changing, keeping, or correcting is wholly for the purpose of treating or preventing disease."

The last part of this definition means that products used solely as medicines are not covered by these Regulations.

The Regulations further define "cosmetic product intended to come into contact with the mucous membranes" as:

"A cosmetic product intended to be applied in the vicinity of the eyes, on the lips, in the oral cavity or to the external genital organs, and does not include any cosmetic product which is intended to come only into brief contact with the skin.

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.

Main Provisions

- It is an offence to supply cosmetic products that are liable to cause damage to human health when applied under normal conditions of use, or reasonably foreseeable conditions of use, taking into account all circumstances such as presentation, labelling, instructions for use and disposal, and any other information provided by the manufacturer, his agent or first supplier in the UK.
- There are many substances that are either prohibited or restricted for use in cosmetic products. Reference should be made to the legislation itself for detailed information. There are some substances that are not subject to the Regulations, if the product was placed on the market before 24 March 2005 and was supplied before 24th September 2005.
- There are restrictions on animal testing of cosmetic products and ingredients
- Certain labelling is required.
- Certain information is required to be held by `the responsible person`, who must also notify the competent authority (The DTI) of the types of product that they are manufacturing or importing into the EC.

Rules on animal testing

The regulations make it an offence to supply a cosmetic product where the final formulation or any of the ingredients were tested on animals, other than using the authorised alternative method (where such a method exists), after 11th September 2004.

From 11th March 2013, it will be an offence to supply any cosmetic product where the final formulation or ingredients have been tested on animals, other than using the authorised alternative method, where the tests involve repeated dose toxicity, reproductive toxicity or toxicokinetics. For all other tests, the same restriction on supply applies from 11th march 2009.

Where a claim is made that a cosmetic product has not been tested on animals in general, this must be correct but, specifically, for any cosmetic product placed on the market in any Member State from 11th September 2004, the manufacturer or supplier must not have tested or commissioned tests on animals of either the finished product or any 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 and ingredient, and the rules on restricted use and special precautions, are too detailed to be summarised.Refer to the Regulations for more detail.

Marking/Labelling

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

1. **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.

   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.

   For products placed on the market after 11th March 2005, perfume and aromatic compositions and their raw materials will be referred to as `perfume` (see note below) or `aroma` unless:
   - It is listed in column 2 of Schedule 4, and
   - It is required to be mentioned specifically by virtue of column 5 of schedule 4.

   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 `+/-` are also used.

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

   - Chemical name;
   - CTFA name;
   - European Pharmacopoeia name;
   - International Non-proprietary Name (INN), as recommended by the World Health Organisation;
   - EINECS identification
   - Colour index number.

   A database of INCI names is available on the Europa website:
   http://ec.europa.eu/enterprise/cosmetics/html/cosm_inci_index.htm
   There is a procedure detailed in the Regulations that, subject to agreement, allows the confidentiality of some ingredients to be maintained.

   NOTE: For consistency across the EU, the following conventions have been agreed by COLIPA (the European cosmetics industry trade association). Firstly, the word `ingredients` should be given in capital letters, and secondly, the word `perfume` should be replaced with `parfum`. Although these conventions

do not have the force of law, UK enforcement authorities will accept their use. If you are exporting cosmetic products to other EU Member States, you should confirm that the authorities in those states also accept this convention.

2. Name and Address

Name, or trade name, and address, or registered office address, of the manufacturer or the supplier in the EC.

3. Function

If not otherwise obvious from design or packaging

4. Batch Code

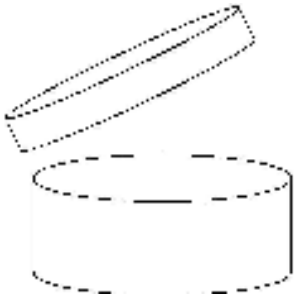
Some means of identifying the production batch, normally a code or date.

5. Durability

Where a cosmetic product is likely, within 30 months of the date of manufacture, to deteriorate to the extent that it no longer meets the safety requirements of the Regulations or is no longer fit for purpose, it must be marked with a `Best Before` date that reflects the earliest likely date that this is likely to happen.

The indication must be in the form `Best Before (date)` or, where the date appears elsewhere on the labelling, `Best Before (position of date on the labelling)`. If any particular precautions are required to ensure the shelf-life of the product, these must be also described.

Where a product has a shelf-life of more than 30months, but is liable to deteriorate after it is opened to the extent that it no longer meets the safety requirements of the Regulations or is no longer fit for purpose, it must be marked with the following symbol together with an indication of its expected life after opening:



6. Additional Information

Additional information must be given where certain ingredients, such as preservatives and UV filters, are present. This information is specified in Schedules 4, 6 and 7 to the Regulations.

7. Presentation

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

There is one set of rules about presentation for ingredient lists, and another set for the other information:

Ingredient 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). For small products such as soap and bath-balls, a notice can be used instead of a leaflet, label, etc.

Other Information

The name/address and `best before` date must always appear on both the container and the packaging. The batch code must also appear on the container and packaging, if this is not possible for the reasons of size, it can appear on the packaging only. All the remaining information must also appear on the container and packaging or, where this is impossible, 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 soap, soap the name, address and batch number must be given on the soap itself (in which case it need be indelible until the soap is first used), or on the container in which the soap is exposed for sale. All other information must be given on a leaflet that is supplied with the soap.

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.

8. The requirements on the "responsible person"

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 Regulations define "responsible person" as any of the following:

- The manufacturer of the product
- The manufacturers agent
- The person to whose order the product is manufactured, for example a supermarket chain, which has an `own brand` item, produced by an independent manufacturer.
- The person who first supplies the cosmetic product in the UK, if all of the above are established outside of the EC

The product information must include all of the following:

- The quantitative and qualitative 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
- An assessment of safety for human health of the finished product, including the criteria as stipulated in the Regulations. For products first placed on the market on or after 11th September 2004, 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.
- Details of the person or persons, with the minimum qualifications as detailed in the Regulations, who carried out the assessments.
- Existing data on the undesirable effects on human health resulting from use of the product. This information shall also be made easily available to the general public.
- Evidence to justify any claims made by the product.
- For products placed on the market from 11th September 2004, data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety evaluation of the product or its ingredients.

Where the "responsible person" is established in the UK and is the manufacturer or first importer into the EC, he/she/it must possess an appropriate level of experience or qualifications in accordance with UK legislation and practice. They must also notify the

competent authority (the DTI) of the address of the place of manufacturer or initial importation into the EC for each type of product they place on the market (but not for each individual product).

Where the product is manufactured in the UK and another EC country, the product information can be retained outside the UK, as long as the UK nominated authority is directed to the correct address and the information is available in English or other language easily understood by the UK authority.

This information is relevant in the following nations only:

- England
- Scotland
- Wales
- Northern Ireland