Cosmetic Products Enforcement Regulations 2013

A guide for small and medium business enterprises
This advice is designed to provide basic guidance to traders. It is not a complete or authoritative statement of the law.


The Regulations apply to all cosmetic products that are made available on the EU market after 11 July 2013.

Main provisions
- It is an offence to supply cosmetic products which may cause damage to human health when applied under normal or reasonably foreseeable conditions of use.
- The use of certain substances in cosmetic products is prohibited.
- The use of certain substances is restricted - e.g. some fragrances, colouring agents, preservatives and UV filters.
- The use of 'specified risk material' (e.g. products derived from certain animals that may carry a risk of BSE) as an ingredient is prohibited.
- Specific labelling is required.
- Certain information is required to be held by the 'responsible person'.

What is a cosmetic product?
The EC Regulation defines a 'cosmetic product' as being:

"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".

Who is a responsible person?
The responsible person is the manufacturer, manufacturer’s agent, person for whom the manufacturer is making the product or the first importer into a member state.

**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, then they are controlled by the *General Product Safety Regulations 2005*. Please ask your local Trading Standards Service if you require more guidance on aromatherapy products.

**Composition**

The rules on what may or may not be used as an ingredient, and the rules on restricted use and special precautions, are too detailed to be summarised in a leaflet like this, therefore reference will need to be made to the EC regulation.

**Labelling requirements:**

The container and packaging of cosmetic products should state the following information in indelible, easily legible and visible lettering.

1. **Name and address details**

   The name or registered name and address of the responsible person is required. This information may be abbreviated as long as it is possible to identify the responsible person. The address must be sufficient for the normal postal service to deliver a letter to that address. Consider setting up a PO Box address, if you only have a residential address.

   If several addresses are indicated, the one where the responsible person makes readily available the product information file should be highlighted, for example, underlined.

   The country of origin needs to be specified for imported cosmetic products.

2. **Nominal content**

   The nominal content at the time of packaging needs to be given by weight or volume. Exemptions are; packaging containing less than five grams or five millilitres, free samples and single-application packs.

3. **Durability**

   Any precautions required to keep the product in a satisfactory condition need to be stated (e.g. store in a cool dry place).

   ![](image)

   The *Date of minimum durability* symbol as specified in Annex VII (3) of the EC Regulation should preceed the date itself or details of where it appears on the packaging.
Less than 30 month period

If the product is likely to either become unsafe or not fulfil its intended purpose within 30 months of manufacture, it should carry the words "Best used before the end of ..." followed by day/month/year or month/year format on which it is likely to cease to perform satisfactorily.

More than 30 month period

If the product is likely to either become unsafe or not fulfil its intended purpose more than 30 months after manufacture, it should carry the Period-after-opening symbol as specified in Annex VII (2) of the EC Regulation.

An indication of the period after opening when the above conditions will occur should also be stated, followed by month or month/year format. The use of 'M' to represent months is acceptable.

4. Precautions

Any relevant information contained in the Schedules to the EC Regulation regarding certain restricted ingredients needs to be included in the labelling. Any particular precautions for cosmetics for professional use (especially in hairdressing products) must be stated.

5. Batch number/reference identification

The batch number of manufacturer or reference for identification is required. This is to allow sufficient identification and traceability.

6. Product function

If it is not obvious from the presentation of the product, its function needs to be stated (e.g. "conditioning shampoo").

7. Ingredients

A list of ingredients may be indicated on the packaging alone and preceded by the word 'ingredients'. The list is required to be in descending order of weight. The weights are determined at the time the ingredients are added to the product.

An ingredient must be identified by its common name, as listed in the International Nomenclature of Cosmetic Ingredients (INCI). This list can be obtained from the Stationery Office or online at the Europa Website

In the absence of an INCI name, any of the following may be used:

- Chemical name
• European Pharmacopoeia name
• International Non-proprietary name (INN) as recommended by the World Health Organisation
• EINECS, IUPAC or CAS identification reference; or
• Colour index number.

Where ingredients constitute less than 1% of the product, they may be listed in any order after those that constitute 1% or more.

Certain fragrance compounds have been found to be allergens that can produce allergic reactions to individuals sensitive to these compounds. The presence of any of these listed fragrances exceeding 0.001% (leave-on products) or 0.01% (rinse-off products) must be declared in the main part of the ingredients list. (eg. the presence of linalool in lavender.)

Colouring agents can be listed in any order after the other ingredients.

What does not have to be listed as an ingredient

Some items are not regarded as cosmetic ingredients, e.g. impurities, solvents, carriers (but the latter two only if used in quantities that are strictly necessary for their purpose), and these do not have to be listed.

Language
The date of minimum durability, particular precautions to be observed in use and the function of the product should be in English.

Where Should the Labelling Appear?

Non pre-packaged products
Packaged at the point of sale at the purchaser’s request.

The information must appear on the container in which the product is exposed for supply or a notice in immediate proximity to that container.

Pre-packed for immediate sale
The information must appear on an attached label, tag, tape or card, or in an enclosed leaflet. Where this is impossible for practical reasons this information must appear on a notice in immediate proximity to the container in which the cosmetic product is exposed for sale.

The ‘Hand and book’ symbol is specified in Annex V II (1) of the EC Regulation. This symbol can be used to refer users to enclosed or attached information.
**Information to be kept by the responsible person**

The responsible person is required to keep and make a product information file readily accessible in electronic or other format, at the address indicated on the label, to the competent authority (usually the UK 'Home/Primary' Trading Standards Service).

The product information file is required to be kept for a period of ten years following the date on which the last batch of the cosmetic product was placed on the market.

The product information file requires the following information/data and needs to be updated as necessary. It should be available in a language which can be easily understood by the competent authority:

- A description of the cosmetic product which enables the product information file to be clearly attributed to it.
- The cosmetic product safety report.
- A description of the method of manufacturing and a statement on compliance with good manufacturing practice.
- Where justified by the nature or effect of the cosmetic product, proof of the effect claimed.
- Data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries.

**Trade secrecy**

If the responsible person does not wish to list all the ingredients of a product, so that it's full composition remains a secret, they can make a request for confidentiality to BIS. The responsible person may be allowed to omit certain ingredients from the list. These omitted ingredient(s) can be listed as a registration number instead of a name.

For more detailed advice on the manufacture and supply of cosmetic products, please contact your local Trading Standards Service.

**Cosmetic Products Notification Portal (CPNP)**

A significant new duty on importers and manufacturers of cosmetic products, brought in by this EC Regulation, is the duty to notify the Commission in detail about all the products marketed by the responsible business.

This requires economic operators to first register with the European Commission Authentication Service (ECAS) to obtain a unique login. Then to notify details of all products via the CPNP, including images of the packaging and details of labelling and formulations.

The basic premise of the new notification duty is that poison centres across Europe should have access to details of cosmetic products on the EU market in the event of poisoning and medical incidents involving cosmetic products.

**The Cosmetic, Toiletry and Perfumery Association (CTPA)**
You may wish to consider joining the **The Cosmetic, Toiletry and Perfumery Association.** The CTPA represents members worldwide through its wide network of contacts within government, national associations, European and International organisations.

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