Argyll and Bute Council
Comhairle Earra Ghàidheal agus Bhòid

Head of Planning and Regulatory Services : Angus Gilmour

Cosmetic Products – Safety, Composition and Labelling
Cosmetic Products (Safety) Regulations 2008
Business Advice

Legislation

The **Cosmetic Products (Safety) Regulations 2008** came in to force on 18th June 2008. The Regulations consolidate earlier Regulations and implement current European Directives.

The **Cosmetic Products (Safety) (Amendment No 2) Regulations 2009** implement 2 EC Directives. Directive 2008/13 amends the base Directive by banning the use of 4-amino-benzoic acid (PABA) previously allowed in sunscreens, and Directive 2009/6 bans the use of diethylene glycol and phytoadione, as well as setting levels of restriction for toluene and various glycol ethers in all cosmetics.

What is a cosmetic product?
The Regulations define a cosmetic product as:

"Any substance or preparation intended to be placed in contact with the various 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, correcting body odours, protecting them, or keeping them in good condition 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. Please ask us if you require more guidance on aromatherapy products.

Main provisions

- It is an offence to supply a cosmetic product which may cause damage to human health when applied under normal conditions of use, or reasonably foreseeable conditions of use, taking into account in particular its presentation, its labelling, any instructions for its use and disposal, and any other information provided by the manufacturer, his authorised agent or the first supplier in the European Economic Area (EEA)

- 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 restrictions on animal testing of cosmetic products and ingredients

- Certain labelling is required

- Certain information is required to be held by 'the responsible person' (see point 9, below), who must also notify the competent authority Department of Business, Innovation and Skills (BIS) of the types of product which they are manufacturing or importing into the EEA.

Rules on animal testing

It is an offence to test a finished cosmetic product on an animal in order that the product might comply with the requirements of the Regulations. The Regulations also restrict the supply of cosmetic products whose final formulation, or any ingredient or combination of ingredients, have been tested on animals. There are also similar restrictions on carrying out any such tests. These restrictions apply where there are authorised alternative methods of test (from 11 March 2013 where the tests involve repeated dose toxicity, reproductive toxicity or toxicokinetics).

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 or 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 summarised in a leaflet such as this. If you require this information, you should make reference to the Schedules to the Regulations or you should seek specialist advice.

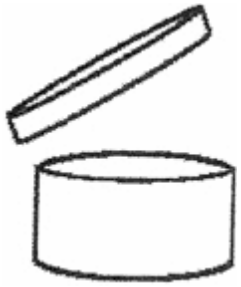
Marking/labelling

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

1. Name and address
Name or trade name, and address or registered office address, of the manufacturer or the person responsible for marketing the product who is established in the EEA. Where the product is manufactured outside the EEA, the country of origin must also be given.

2. Durability
Less than 30 months
Where a cosmetic product has a minimum durability of 30 months or less, it must be marked with a 'best-before' date. 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.

More than 30 months
Where a product has a shelf life of more than 30 months, it must be marked with the symbol, as shown right, 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.



3. Precautions

Precautions to be observed in use, as shown in the schedules to these Regulations must be printed on the label. Special precautionary information on cosmetic products for professional use, particularly in hairdressing, must appear on the container and packaging.

4. Batch code

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

5. Function

If not otherwise obvious from design and packaging.

6. 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.

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 column (e) 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 must be that listed in the International Nomenclature of Cosmetic Ingredients (INCI) or, if no such name is listed, the:

- 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 (http://ec.europa.eu/enterprise/sectors/cosmetics/cosing/).

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 EEA, 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 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.

7. 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, 5, 6 and 7 to the Regulations.

8. 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 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). 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.

9. 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 manufacturer's 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 EEA, if the manufacturer and (where applicable) the person to whose order the product is manufactured are outside the EEA, and the manufacturer has no agent in the EEA or that agent did not supply the product.

The product information 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 shall 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 Regulations - 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
- the name and address 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 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, his agents or suppliers, relating to the development or safety evaluation of the product or its ingredients.

The responsible person must also notify the competent authority (BIS) of the address of the place of manufacture or initial importation into the EEA (where this is in the UK) for each type of product they place on the market, before they place it on the market.

Where the product is manufactured in the UK and also in one or more other EEA countries, the product information can be retained in one of those other EEA countries so 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.

Where can I get further help?
This leaflet is not an authoritative document on the law and is only intended for guidance.

For further information and advice contact your local area Trading Standards Office

Telephone	01546 605519
Email	tradingstandards@argyll-bute.gov.uk

Bute and Cowal - 22 Hill Street, Dunoon, PA23 7AP
Helensburgh and Lomond - Blairvadach, Shandon, Helensburgh, G84 8ND
Mid Argyll, Kintyre and Islands - Area Office, Manse Brae, Lochgilphead, PA31 8QU
Oban, Lorn and the Isles - Municipal Buildings, Albany Street, Oban, PA34 4AW

Office Hours: 9.00am-5.00pm Monday-Friday