

STR Guidance Leaflet

The Cosmetic Products (Safety) Regulations

LEGISLATION

On the 11th September 2004 The Cosmetic Products (Safety) Regulations 2004 came into force. The Regulations bring together the old cosmetic regulations and their amendment regulations, and implement the Seventh Amendment to the EC Cosmetics Directive. This legislation now forms The Cosmetic Products (Safety) Regulations 2004.

In the Regulations a cosmetic product is defined 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 Regulations establish an offence for supplying, offering to supply, agreeing to supply, exposing for supply or possessing to supply cosmetic products which are liable to cause damage to human health when applied under normal or reasonably foreseeable conditions of use. In addition the regulations prohibit a number of substances from use in cosmetic products and also restrict certain substances including preservatives, colouring agents, and UV filters.

PRODUCT INFORMATION

It is a requirement that the supplier of the cosmetic within Europe keeps a Product Information Package. This must be readily accessible to the enforcement authorities (e.g. Trading Standards). It must contain the following information: -

1 Product Composition

This is the formulation of the product giving the identity of the ingredients and their concentration. Typically this would be the INCI name, CAS number and concentration.

2 Physico-chemical and Microbiological specifications of the Raw Materials and Finished Products

The specifications and any related control criteria of both raw materials and the finished product will be determined by the type of raw material and product concerned. The appropriate grade of raw material for inclusion in a cosmetic grade must be assured. The incorrect grade may contribute to incidences of adverse reactions, toxicological effects and formulation problems. There are many control criteria that could be considered relevant.

These include: microbiological quality, the concentration of metal elements not permitted within schedule 1 of The Cosmetic Products (Safety) Regulations 1996 and a range of possible organic contaminants. The finished product specification should also contain the relevant quality data obtained from each batch product, such as batch release microbiological results.

3. Method of Manufacture

This will be in the form of a brief summary of the processes used in the method of manufacture including storage and filling. Use of flow diagrams could be used to display the information. The manufacture of cosmetics should be carried out in accordance with the principles of Cosmetic Good Manufacturing Practice. This information must be evident within the Product information Package.

4. Safety Assessment

This is recommended to be in the form of a signed statement of opinion by a suitably experienced person or persons within the field of cosmetic science. Under the Regulations it must be a Medical Practitioner, Pharmacist, Chartered Chemist or Chartered Biologist who is registered to practice in the EU.

5. Name and Address of the Safety Assessor

There are specific requirements with respect to qualifications of the safety assessor. The relevant qualifications held by the safety assessor must also be included in the Product Information Package.

6. Existing data on undesirable effects on Human Health

Professionally substantiated reports of any recorded adverse reaction should be included. This information should be updated whenever such adverse reactions occur.

7. Proof of effect

Any claimed effect must be substantiated with supporting data. This only applies to claims which are not supported by virtue of the ingredients present.

For example: A shampoo with the claim "to clean hair"

No proof of effect is required, the claim is considered obvious from the formula and product presentation, although it must still fulfil the function.

For example: A sunscreen, the sunscreen itself is not a claim, the SPF value is the actual claim.

This would require performance data relating to its Sun Protection Value (SPF) and any UVA or UVB claims.

8. Animal testing data

Any data relating to the testing of the product or its ingredients during product development or as an aspect of safety substantiation must be documented. This includes any testing on animals used for legislative or regulatory purposes for countries not within the European Union to ensure certification to their specific requirements.

PUBLIC ACCESS TO INFORMATION

Information on the qualitative composition of a cosmetic product including its quantitative composition (limited only to those ingredients included in the Dangerous Substances Directive 67/548/EEC) and on adverse effects is to be easily available to the public.

For this requirement following a request from the public, the supplier would be obliged to provide the following information:

- The list of ingredient (as displayed on the outer packaging).
- The name, concentration and hazard of any substance classified under the Dangerous Substances Directive.
- Any reported adverse reactions to the product (typically stated as the number of adverse reactions reported per 1,000,000 units distributed).

ANIMAL TESTING

The Regulations prohibit the supply of cosmetic products, which contain any ingredients or combinations of ingredients, which have been tested on animals (where such testing takes place after 30th June 2000).

A further requirement is that any reference to testing on animals in the labelling or advertising must state clearly whether the reference to testing involves the cosmetic product itself or its ingredients.

INGREDIENTS

Packaging in which cosmetic products are supplied must bear lettering which is visible, indelible and easily legible. It must be in a language easily understood by the consumer, it is required that you list of this cosmetic ingredients (preceded by the word "INGREDIENTS") in descending order of weight.

For products that have no packaging or it is impossible for practical reasons to list the ingredients on the packaging and the list of ingredients must appear on the container. Where this is impossible for practical reasons the list of ingredients must appear on a leaflet, label, tag, tape, or card enclosed with the product to which the consumer is referred either by abbreviated information or by a symbol.

An ingredient must be identified by its common name as provided for in the common ingredients nomenclature (INCI list), or in the absence of the nomenclature or of a common name, by its chemical name, its CTFA name, its European Pharmacopoeia name, its International Non-proprietary Name as recommended by the World Health Organisation, its EINECS, IUPAC or CAS identification reference or its colour index number.

A number of items are not regarded as cosmetic ingredients including materials strictly used in necessary quantities as solvents or as carriers for perfumes and aromatic compositions.

Perfume and aromatic compositions should be referred to by the words "parfum" and "aroma" respectively.

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

Fragrance Labelling

26 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 26 fragrances above certain threshold limits must be declared in the ingredient list. All sources of these fragrances must be taken into account. Normal ingredient labelling rules apply, with the fragrances listed in the main body of the ingredient list.

The threshold limits are as follows:

Leave on products	0.001%
Rinse-off products	0.01%

To assess whether these declaration limits are exceeded a technical specification declaring the concentration of these potential fragrance allergens would be required from the supplier of the fragrance or natural extract.

The 26 ingredients are to be listed in the regulations as follows:

<u>Ingredient Number</u>	<u>CAS</u>
Amyl Cinnamal	122-40-7
Benzyl Alcohol	100-51-6
Cinnamyl Alcohol	104-54-1
Citral	5392-40-5
Eugenol	97-53-0
Hydroxy-citronellal	107-75-5
Isoeugenol	97-54-1
Amylcinnamyl Alcohol	101-85-9
Benzyl Salicylate	118-58-1
Cinnamal	104-55-2
Coumarin	91-64-5
Geraniol	106-24-1
Hydroxymethylpentylcyclohexecarboxaldehyde	31906-04-4
Anistyl Alcohol	105-13-5
Benzyl Cinnamate	103-41-3
Farnesol	4602-84-0
2-(4 tert Butylbenzyl) Propionaldehyde	80-54-6
Linalool	78-70-6
Benzyl Benzoate	120-51-4
Citronellol	106-22-9
Hexyl Cinnam-aldehyde	101-86-0
d-Limonene	5989-27-5
Methyl Heptin Carbonate	111-12-6
3-Methyl-4-(2,6,6-trimethyl-2-cyclohexen-yl)-3-buten-2-one	127-51-5
Oak Moss and Tree Moss extract	90028-68-5
Treemoss extract	90028-67-4

This requirement will apply to cosmetic products placed on the market **on or after 11th March 2005**.

It should be noted that this requirement will not only apply to conventional fragrances, but will also apply to other sources of these ingredients (for example natural plant extracts).

LABELLING REQUIREMENTS - Other

Containers and packaging in which a cosmetic product is supplied must bear, in lettering which is visible, indelible and easily legible: -

1. The name or trade name and the address or registered office of the manufacturer of the product or of the supplier established within a member state of the European Community (this information may be

abbreviated providing this does not prevent the person concerned from being identified).

2. If the product is likely within 30 months from manufacture to cease to either:

- (i) Comply with the requirement that it shall not cause damage to human health when applied under normal or reasonably foreseeable conditions of use; or
- (ii) Fulfil the purpose for which it was intended.

Then the product must be marked 'Best Before' immediately followed by:

- (i) The earliest date on which it is likely to cease; or
- (ii) An indication of where that date appears on the labelling and any particular precautions to be observed to ensure that the product does not so cease before that date.

The date shall include the month and the year - the month preceding the year.

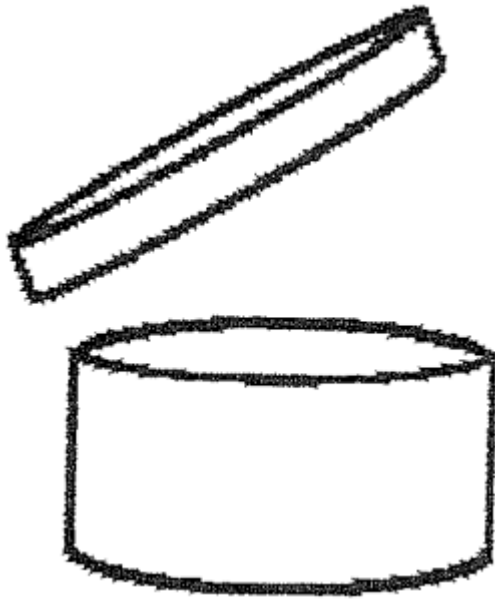
If a product does not require a best before date, it may require a period after opening declaration. An indication of the period of time that a product can be safely used after opening would be required unless:

- The product is a single use application (for example a sachet)
- No opening of the product occurs (for example an aerosol)
- The product would not represent a hazard to human health irrespective of the period of time after initial opening by the consumer.

The period after opening commences when the consumer uses the product for the first time. There is no single scientific test to determine the period after opening and it is the companies' responsibility to decide the period after opening to be printed on their products. To determine the period after opening the following sources of information can be used:

- Microbiological challenge tests
- Assessment for the potential for micro-organism introduction
- Analytical data (e.g. preservative analysis)
- Type of packaging
- Experience with similar formulations and products
- Consumer habits and practices

The following symbol should be used where appropriate along with the time period in months (denoted by the capital M) e.g. 12M



This symbol must be present on the product itself and the outer packaging if required. This requirement will apply to cosmetic products placed on the market **on or after 11th March 2005**.

3. Reference to any restrictions required by the Regulations on certain ingredients and any particular precautions to be observed in use and any special precautionary information on a cosmetic for professional use (in particular hairdressing) must be stated.

4. A means of identifying the batch in which the product was manufactured (or if the product was not manufactured in a batch a reference from which the date and place of manufacture can be identified). Where it is impossible for reasons of size for these particulars to appear on the container and packaging the said particulars shall appear on the packaging.

5. The function of the product unless it is clear from its presentation.

If there is insufficient space to display the warnings and instructions on the product itself or the outer labelling, this information may be displayed on an enclosed leaflet or tag. To alert the consumer to the location of this information, the following symbol must be displayed on the product and packaging:

Symbol declaring that required information is present on an enclosed leaflet or card.

