

BALLYMENA BOROUGH COUNCIL

GUIDANCE LEAFLET

THE COSMETIC PRODUCTS (SAFETY) REGULATIONS

LEGISLATION

Legislation controlling cosmetic products has recently been consolidated and expanded making controls more onerous to the manufacturer. The Cosmetic Products (Safety) Regulations 1996 came into force on the 16th December 1996, with the majority of requirements for the manufacturer or importer into the UK coming into force either on the 16th December 1996 or the 1st January 1997, an extension of a year being given for retailers, (with some exceptions). The Regulations consolidate the old cosmetic regulations and their amendment regulations, and implement current European Directives.

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".

They establish an offence for supplying, offering to supply, agreeing to supply, exposing for supply or possessing for supply cosmetic products which are liable to cause damage to human health when applied under normal or reasonably foreseeable conditions of use.

They also prohibit certain substances from use in cosmetic products and restrict certain substances including colouring agents, preservatives and UV filters.

The regulations also lay down certain labeling requirements, including the following:-

ANIMAL TESTING

Since 1/1/97 any reference to testing on animals in the labeling/advertising must state clearly whether the reference to testing involves the cosmetic product itself or its ingredients.

INGREDIENTS

From 1/1/97 the packaging in which the cosmetic product is supplied must bear in lettering which is visible, indelible and easily legible, in a language easily understood by the consumer a list of its cosmetic ingredients (preceded by the word "INGREDIENTS") in descending order of weight, the weight to be determined at the time the ingredients are added to the product.

If the product has no packaging or it is impossible for practical reasons for the list of ingredients to appear on the packaging, then the list of ingredients must appear on the container. Where it is impossible for practical reasons for the list of ingredients to appear on the container, they 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.

There are a number of items which are not regarded as cosmetic ingredients including materials used in strictly 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.

Members states have also agreed that the words "may contain" can be replaced by (+/-...).

OTHER LABELLING REQUIREMENTS

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

1. The name of 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 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 either to:
 - (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.

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.

Where it is impossible for practical reasons for these particulars to appear on the container and packaging, they shall appear on an enclosed leaflet label, tag, tape or card to which the consumer is referred to either by abbreviated information or by a symbol, which must appear on the container and packaging; and where it is impracticable by way of shape or size for the particulars to so appear, they shall appear on a label, tag, tape, or card attached to the product.

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.

Note that 2, 3 & 5 must be in English, but this does not prohibit the use of other languages.

PRODUCT INFORMATION

From 1/1/98 first suppliers in the EEA (European Economic Area):- manufacturers, their agents or importers into the EEA, (known as the "responsible person") must keep readily accessible to their 'home authority' detailed information on:-

- * The qualitative and quantitative composition of the product, except for perfume product or ingredient, where the name and code number and identity of supplier is sufficient.
- * The physio-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.
- * Assessment of the safety for human health of the finished product.

- * The name and address of the person responsible for assessments must be kept. Assessments must be undertaken by persons who are registered pharmacists or registered medical practitioners or doctors or pharmacists holding specific qualifications or persons holding specific diplomas to practice as chartered biologists or chartered chemists.

The responsible person must possess appropriate experience or an appropriate level of professional qualification. The responsible person must notify the Department of Trade and Industry, 1 Victoria Street, London, SW1H 0ET, (Telephone : 020 7215 0371 - contact Bill Trott), of the address of the place of manufacture of the product before its first supply. Existing data on undesirable effects on human health resulting from use of the cosmetic product. Proof of any effect claimed for the cosmetic product, where justified by the nature of the effect or product.

STATUS OF AROMATHERAPY PRODUCTS

The Medicines Control Agency and the Aromatherapy Trade Council have jointly considered the range of aromatherapy products on the market. The view reached with respect to their 'status' was that:-

"provided no medicinal claims are made, aromatherapy products do not satisfy the definition of a medicinal product. Essential oils which are mixed and administered, or sold, by aromatherapists in the course of their business, and which satisfy the definition of a herbal remedy in section 132 of the Medicines Act, would be medicinal products but be exempt from the requirement to have a marketing authorization".

One approach suggested to the industry as a result of this interpretation is to treat aromatherapy products as instead falling within the cosmetic products controls. However, there appears to be a difference of view between DTI and the Medicines Control Agency regarding the classification of aromatherapy products and, as yet, the DTI has not produced any guidance notes which could provide certainty in this area to manufacturers.

In view of the growing number of aromatherapy products on the market, and the confusion over the legislative requirements applicable to them the Local Authorities Coordinating Body on Food and Trading Standards (LACOTS), was asked to give a view on the matter. The view taken was that aromatherapy products fall within the scope of the General Product Safety Regulations 1994, unless they are intended to perform a medicinal or cosmetic function or are presented as performing such a function. Each product will have to be considered on an individual basis taking into account its presentation, its stated function, the ingredients used and any claims that are made.

The above advice is merely a summary of the legislation, compiled in the light of current available information, and may be subject to change. As always we must advise that only the courts can give an authoritative opinion on statute law.

For further information on advice contact the Environmental Health Department of Ballymena Borough Council on 028 2566 0300.