



AFP CHEMICAL CONSULTANCY

What is a Cosmetic: Legal Definition

Directive 93/35/EEC, the Sixth Amendment to the original Cosmetic Directive of 1976, incorporates the following definition of a cosmetic product:

A "cosmetic product" shall mean 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 and/or correcting body odours and/or protecting them or keeping them in good condition.

There are three preliminary questions which should be addressed when deciding whether a product could legally be classified as a cosmetic.

Purpose

Is the purpose of the product wholly or mainly cosmetic i.e. is it intended to:

- clean
- perfume
- change appearance
- correct body odour
- protect
- keep in good condition

If the main purpose of the product is not to perform one of these functions it is unlikely to be a cosmetic.

Example

- a product intended to be applied to a spot in order to treat that spot is not a cosmetic.
- a product intended to be applied to a spot in order to conceal it is a cosmetic.
- a product offered to conceal a spot but having a secondary purpose of preventing the formation of further spots is a cosmetic.

Site of application

Is the product intended to be applied to the:

- epidermis
- hair system
- nails
- lips
- external genital organs
- teeth
- mucous membrane of the oral cavity

If it is not, the product is unlikely to be a cosmetic.

Example

Eye drops, vaginal douches, nose drops and orally ingested tablets intended to improve appearance, are not cosmetics.

Composition

Does the composition of the product conform with the Cosmetic Directive and the Cosmetic Products (Safety) Regulations.

- ingredients which are prohibited in cosmetic products
- ingredients which are restricted in cosmetic products
- preservatives, UV filters and colourants which are permitted in cosmetic products
- (preservatives, UV filters and colourants not listed in the Schedules to the Regulations are not permitted in cosmetic products).

If the composition of the product is not in accord with these Regulations it cannot be marketed as a cosmetic, regardless of claims made or the absence of such claims.

Example

Toothwhitening products are cosmetics. However, there is a limit of 0.1% of Hydrogen Peroxide present in the product or released in use. A toothwhitener with hydrogen peroxide in excess of the limit is an illegal cosmetic. If a product is not a cosmetic, it may fall under another regulatory regime such as that for foods, biocides or general product safety. However, care must be taken to ensure that what is, at first sight, a cosmetic does not become a medicine by virtue of its presentation, its claims or its composition.

The CTPA provides advice to its members on how to classify a product.

It should be noted that EU legal cases and EU agreements can alter the legal status of products, particularly those for which the legal classification is not harmonised across the community. The legal status of these products should be reviewed regularly.

See also:

- European Commission Manual on the scope of application of the Cosmetics Directive 76/768/EEC (Version 3.0) - December 2006