

General background

The Council of Europe's Committee of Experts on Cosmetic Products (the Committee) has observed that many ingredients used in cosmetics have potential pharmacological effects. Of these ingredients, some are used in all the partial agreement states and some are used in only some of these states. Typically these ingredients are used to confer a specific cosmetic property on the product.

Examples of conditions that the products are intended to be used for include dry skin, unclean skin, photo-aged skin, "fine lines" (wrinkles), "orange-peel" skin (so called from its surface resemblance to orange peel), age spots, blotches, freckles, brittle nails, hair loss, dandruff, plaque, sensitive teeth, discoloured teeth, unpleasant odours, sweating, unpleasant conditions of the skin after sunbathing, and hygiene in the outer genital region (intimate products) or the feet.

There is a consensus that cosmetic products containing certain active ingredients may pose a health risk both because of their potential toxicity and because they can mask underlying serious diseases in an early phase and consequently cause a dangerous delay in diagnosis.

Some of these ingredients, when present in sufficient quantities, are capable of exerting pharmacological and toxicological effects – for instance, they may eliminate or reduce:

- pain (camphor, menthol, methylsalicylate, ibuprofen),
- symptoms such as bulging veins, varicose veins, "spider" veins, swollen legs (escin, esculin, rutin),
- symptoms of immune system deficiency being manifested in the form of various fungus infections (the azoles discussed below),
- inflammatory symptoms (glycyrrhetic acid and various xanthines, used to counteract orange-peel skin),
- slight gum bleeding, which may be a precursor of serious gingivitis (tranexamic acid).

The substances in question could rightly be called active ingredients, by analogy with active principles in medicinal products. Nearly all of them are, or have been, used for medical purposes also. In those cases, their evaluation takes into account their medicinal properties as well as their toxicological profiles. The evaluation of the benefit/risk ratio is not acceptable for cosmetics. Moreover the complete safety assessments as regards their use in cosmetics use may be missing.

In this survey the Committee has only considered these active ingredients for which no specific regulations regarding their cosmetic use exist in any partial agreement member state.

The Committee therefore thought it worthwhile to identify these ingredients and any potential safety concerns.

Definition of an active ingredient (AI)

In the context of this publication, "active ingredient" is defined as:

"a substance used in cosmetic products with the aim of conferring specific cosmetic properties on them. Certain of these active ingredients may have pharmacological and/or toxic effects under certain conditions of use (e.g. concentration, formulation, frequency of use, site and mode of application)."

Included under this definition are not only ingredients conferring properties relating to some pharmacological potential, as mentioned, but also ingredients used for biocidal purposes in cosmetics making secondary claim.

Other sorts of "active" ingredients used in cosmetic products include ultraviolet (UV) absorbers, colourants for external parts of the body, and odorant molecules meant to provide a pleasant bodily odour. The active ingredients in question are either rigorously regulated (UV filters, colourants), are the subject of EU programmes to introduce their stricter regulation (hair dyes) or are being actively

studied by organs within the EU Commission with a view to regulating them better (perfumes). Because those active ingredients are being considered by other European bodies, the Committee has not included them in this study.