



Review

Positive lists of cosmetic ingredients: Analytical methodology for regulatory and safety controls – A review



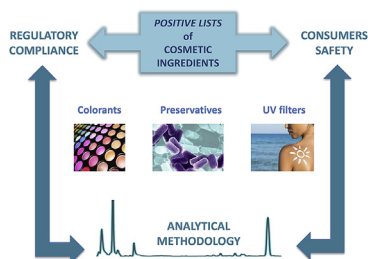
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HIGHLIGHTS

- Extraction and determination of allowed ingredients in cosmetic and personal care products.
- Analytical methodology (2005–2015) for colorants in cosmetics.
- Analytical methodology (2005–2015) for preservatives in cosmetics.
- Analytical methodology (2005–2015) for UV Filters in cosmetics.
- Updated regulatory issues (Regulation 1223/2009) for cosmetic ingredients in *positive lists*.

GRAPHICAL ABSTRACT



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ABSTRACT

Cosmetic products placed on the market and their ingredients, must be safe under reasonable conditions of use, in accordance to the current legislation. Therefore, regulated and allowed chemical substances must meet the regulatory criteria to be used as ingredients in cosmetics and personal care products, and adequate analytical methodology is needed to evaluate the degree of compliance. This article reviews the most recent methods (2005–2015) used for the extraction and the analytical determination of the ingredients included in the *positive lists* of the European Regulation of Cosmetic Products (EC 1223/2009): comprising colorants, preservatives and UV filters. It summarizes the analytical properties of the most relevant analytical methods along with the possibilities of fulfilment of the current regulatory issues. The cosmetic legislation is frequently being updated; consequently, the analytical methodology must be constantly revised and improved to meet safety requirements. The article highlights the most important advances in analytical methodology for cosmetics control, both in relation to the sample pretreatment and extraction and the different instrumental approaches developed to solve this challenge.

Cosmetics are complex samples, and most of them require a sample pretreatment before analysis. In the last times, the research conducted covering this aspect, tended to the use of green extraction and microextraction techniques. Analytical methods were generally based on liquid chromatography with UV detection, and gas and liquid chromatographic techniques hyphenated with single or tandem mass spectrometry; but some interesting proposals based on electrophoresis have also been reported, together with some electroanalytical approaches. Regarding the number of ingredients considered for analytical control, single analyte methods have been proposed, although the most useful ones in the real life cosmetic analysis are the multianalyte approaches.

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1. Introduction

Laws regulating cosmetics are diverse in different parts of the world, and cosmetic ingredients can be subjected to various levels of regulation even within the same regulatory framework. Thus, in the European Regulation of Cosmetic Products (EC 1223/2009) [1] there are prohibited, regulated and allowed chemical substances that must meet the regulatory criteria to be used as ingredients in cosmetics and personal care products. In particular, allowed compounds are those listed as the only colorants (Annex IV), preservatives (Annex V) and UV filters (Annex VI) permitted as ingredients with the corresponding functions: colouring, preserving, and protection from UV radiation, either the user or the cosmetic product itself. These annexes are commonly known as *positive lists* and cover, as a whole, close to 250 compounds belonging to very different chemical families, which further have to be used in accordance with the conditions laid down in the Annexes.

Moreover, some compounds that have belonged to these lists in the near past, have been moved to the category of regulated or even prohibited substances in the various amendments to the Cosmetics Regulation. The relative large number of such amendments is quite surprising, considering its recent entry into force; which it is proof of the enormous raised concern to guarantee consumer safety in relation to cosmetics and personal care products, leading in turn to a permanent updating of the legislation.

On the other hand, cosmetic companies and government control laboratories are urged to guarantee that the products placed on the market and their ingredients are safe under reasonable conditions of use, in accordance to the current legislation. Therefore, the large number of substances to be controlled, the wide range of chemical structures, and the variety of complex matrices containing them, pose a great challenge for the development of reliable analytical methodologies.

Thus, in the present contribution, the updated regulatory issues related with compounds in the three *positive lists* are considered, as the core idea to opportunely revise the analytical methodology developed on the basis of compliance with such aspects. The paper is an overall view of the state-of-the-art and the technical know-how concerning the extraction and chromatographic techniques for the determination of allowed ingredients in cosmetic products.

Each section (colorants, preservatives and UV filters) contains aspects related to sample preparation and determination methods, without forgetting the legislative topics. The three sections have unequal size, reflecting the real state of methodological possibilities to control the different families of chemicals considered in the three positive lists.

2. Positive lists of cosmetic ingredients

2.1. Colorants

Colour plays an important role in consumer products to make them attractive. At present, about 10,000 chemicals, including organic and inorganic compounds, are employed as colorants in the formulation of massive consumer products like food, toys, plastics, medicines or cosmetics [2].

In cosmetics and personal care products formulations, colouring agents are added in order to colour the product itself or to colour the skin, nails, hair, and eyelashes for decorative purposes. These agents can be natural substances obtained from minerals, plants, and animals, or of synthetic origin. The former have been employed in cosmetics since ancient times; however, due to the scarce variety of compounds and their high production costs, from mid XIX century, synthetic dyes are the preferred choice for most of cosmetic manufacturers.

The colouring agents are classified in two main groups: pigments and dyes. Pigments, divided into organic or minerals, are insoluble so they remain in particulate form in the product. They are found especially in shadow eyes, toothpastes or decorative makeup. Dyes are synthetic organic compounds mainly employed in personal care products like creams or shampoos, among others. According their solubility, we refer to oil- or hydro-soluble dyes, which are very sensitive to UV light, pH, as well as oxidative or reducing chemicals [3]. Based on their chemical structure, synthetic colorants can be further divided in azo, triarylmethane, xanthene, indigo and quinoline classes; and they are usually used as the water-soluble sodium salts. The colouring agents intended to colour the hair (hair dyes) are cosmetic ingredients with specific features; they are not included in the *positive list*, and consequently they are not reflected in this review.

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