

Safety Issues in the Cosmetics Industry

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The use of cosmetic products is very extensive and therefore large population groups, as well as the environment, are exposed to them. Although cosmetic products have been rarely associated with serious health problems, they cannot be considered safe per se. Both rigorous testing of the product before entering the market, as well as stringent quality control during manufacture and storage, play a vital part in ensuring that the assumption of safety holds.

The safety of a cosmetic product in the EU is the responsibility of the manufacturer (or first importer) and is based on the safety of its ingredients. The legal basis for the safety evaluation of cosmetic products is laid down in Directive 76/768/EEC and the safety evaluation in the EU is carried out by the Scientific Committee on Cosmetic Products and Non-Food Products intended for consumers (SCCNFP). Although some non-animal safety tests are accepted by the SCCNFP, no alternatives to the classical animal assays have been validated yet for many toxicological endpoints. This does not mean that no scientific advances are being made in this field, and these activities are being stimulated by the recent adoption of the 7th amendment to the cosmetics directive (2003/15/EC).

New in vitro technologies for safety assessment of cosmetics

Over the last years, several non-animal toxicity tests have been validated and are being applied in a regulatory setting. In vitro assays now exist for the assessment of skin corrosion and phototoxicity of chemical compounds, while various in vitro genotoxicity tests have been accepted already for decades. Although in vitro / ex vivo assays for eye irritation have not been formally validated, the enucleated eye test and BCOP are often used for in-house screening purposes and for labeling of irritants [1].

For decades, research has been carried out in order to develop in vitro methods to predict skin irritation [2]. Despite the fact that none of these methods have been formally validated, they already are often used to compare the irritative potential of cosmetic products. In 1999 and 2000, several of these methods have been tested in an international pre-validation study [3,4] and this activity will be followed up this year by a formal validation study in which three in vitro assays will be included. It can be expected that the availability of a validated method will lead to further use of these models.

The new methodologies described above are predominantly focused on the assessment of local effects. However, cosmetic ingredients should also be tested for their potential to cause skin sensitization, genotoxicity and systemic toxicity after single and repeated exposure. Some studies on systemic toxicity are part of a minimal base set requirements. When considerable oral intake is expected or when data indicate considerable skin absorption, more complex animal studies (e.g. carcinogenicity and reproductive toxicity) may become necessary. It is therefore of great importance to obtain reliable, quantitative data on the amounts of cosmetic ingredients that can enter the systemic circulation after in-use dermal application. A general description of the in vitro method is given in OECD guideline 428, while basic criteria for the in vitro assessment of dermal absorption of cosmetic ingredients are provided by the SCCNFP (last updated in October 2003). Using this in

