

# Cosmetic Safety Assessment

C I Betton, Product Safety Assessment Ltd. UK.

## Introduction

The regulatory control of cosmetics in the European Union is more advanced than in most countries. Some materials are proscribed, while others such as colours, sunscreens and preservatives may only be used subject to certain controls and with labelling requirements to guide the consumer. Other regulatory environments such as in the USA, have restrictions on some ingredients e.g. colours but with a general requirement that the cosmetic product is “demonstrably safe”.

The requirement for safety is also paramount within the European Union and is enshrined in legislation and all cosmetics must be assessed for safety by a qualified individual before it can be sold legally within the European Union.

In this paper I will outline the safety assessment of cosmetic products within the European Union and identify some of the many pitfalls and problems inherent in the process.

**A cosmetic product** as defined by European Law is: “Any substance or preparation intended to be placed in contact with any part of the external surfaces of the human body or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to clean them, perfume them, change their appearance, protect them, keep 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.”

**The safety assessment** of cosmetics is a risk based process. Risk is a product of the intrinsic properties of the material (physical, chemical, toxicological – the hazard) and the exposure to that material, whether it be by ingestion, inhalation or via the skin and whether the exposure time is short as with a shower gel or long term as with a perfume.

$$\text{Risk} = \text{Hazard} \times \text{Exposure}$$

## What is Safety?

With Cosmetic products, the ultimate arbiter of what is acceptable is the consumer. Market forces determine whether

the degree of risk associated with a product is acceptable. A depilatory cream may have a degree of irritancy that would not be accepted with a foundation cream: for obvious reasons. Where long term effects are involved, and the consequence of exposure may not be noted for days, months or even years, a more proactive safety assessment process, based on professional expertise, is needed.

Men, women and babies, of all ages and states of health use cosmetics that are applied to the face, skin, hair, eyes, teeth and mouth or inhaled and then either rinsed off or left in place for extended periods. A safety assessment must take all of these potential users and exposure patterns into account when determining what is “safe”.

## Cosmetics Regulations in Europe

The safety of cosmetic products in the EU is controlled by the Cosmetic Products Directive, 76/768/EEC and its amendments. This is incorporated into UK Law as The Cosmetic Products (Safety) Regulations 2003 [SI 2003 No.835].

These regulations specify what materials may and may not be used in cosmetics either as raw materials, or as ingredients of fragrances. Materials that may be used subject to specific controls such as maximum concentrations, type of product, warning labels or restricted lists are also specified e.g. preservatives, colours, UV filters.

## Safety Assessment

The safety assessment process is governed by the 6th Amendment to the Cosmetics Directive and requires “the assessment of the safety for human health of the finished product. To that end the manufacturer shall take into consideration the general toxicological profile of the ingredient, its chemical structure and its level of exposure.”

Guidance is given by the Commission on how the required assessment should be carried out and specifies the qualifications that an assessor must have.