

## Assuring the Safety of Cosmetics

Cosmetic and personal care products include a wide range of product types that we rely on every day, including deodorants, shower gels, shampoos, toothpastes, sunscreens, hand sanitisers, moisturisers and make-up.

Personal care products contain many different ingredients that perform a variety of functions (e.g. structurants, preservatives, surfactants, moisturisers, colours, emulsifiers and fragrances) and it is important that everyone who uses them can be confident of their safety.



The safety assessment of cosmetics and personal care products and their ingredients is regulated differently around the globe. In 2009 and 2013, [EU Cosmetics Regulation](#) banned animal testing to assess the safety of ingredients in cosmetic products. Similar bans now exist in many other countries around the world, such as Israel, New Zealand and India.

Before the safety assessment of an ingredient begins, all the relevant information will be collected. It is important to understand whether there are any impurities in an ingredient and some cosmetic ingredients can be chemically complex e.g. plant extracts. As with all toxicological risk assessments, the safety of a cosmetic ingredient is evaluated using data on how much a consumer will be exposed to and how (e.g. through the skin or lungs) as well as information on the inherent hazard posed to consumers i.e. what an ingredient could do to the body (its bioactivity). The key to a thorough safety assessment is to understand whether the biological effect would occur to a consumer at a reasonable worst-case level of exposure to the ingredient.

### Assessing exposure

The most common route of exposure to cosmetics is via the skin, although for some product types other routes also need to be considered, such as oral ingestion of toothpastes; potential inhalation of ingredient aerosols; exposure to the eyes for many products used in the shower. The level of consumer exposure to each ingredient can be calculated from knowledge of the concentration in the formulation and data on how consumers use different types of product. This includes understanding how regularly consumers use the product and how much they use. Industry surveys publish these data distributions in different parts of the world (habits and practice surveys).

### Types of safety assessment

To ensure that the ingredients in cosmetic products do not cause adverse effects to consumers, safety assessments for local effects (at the site of application) and systemic effects (those elsewhere in the body) are conducted.

Historically, local effects that ingredients might cause on the eye or skin were evaluated using experimental animals. Any such data generated before the animal testing ban can still be used in an overall safety assessment, but all new data is generated using non-animal approaches e.g. testing using human skin cells grown in a laboratory, is routinely used to assess the potential for an ingredient to cause skin irritation.

It is also important to assess whether exposure to an ingredient will lead to skin allergy. Skin allergy (allergic contact dermatitis; ACD) is a serious health effect that can be caused by some ingredients applied to the skin and it is the most prevalent form of immunotoxicity in humans. Historically, animal tests used guinea pigs or mice exposed to different amounts (concentrations) of ingredients to assess their ability to cause ACD. Now, due to advances in mechanistic understanding, several non-animal approaches [can be integrated](#) to classify skin allergens and ensure that a new ingredient in cosmetic products will not cause ACD in consumers.

As well as ensuring that an ingredient is safe for use at the site of application, it is also important to understand whether any of an ingredient which might be absorbed into the bloodstream could have the potential to cause any adverse effect elsewhere in the body.

Several approaches exist to estimate the amount of an ingredient that may pass through the skin. These include computer predictions based on the physical and chemical properties of the ingredient as well as experimental data from studies using human skin to monitor how ingredients can move through different layers of the skin. This information can then be combined mathematically with other data (e.g. on the way the ingredient is metabolised by the body) to predict what level of the ingredient might end up in the bloodstream or in different organs of the body. This is called physiologically-based kinetic modelling.

If an ingredient is predicted to be absorbed into the bloodstream, a large number of approaches can be used to understand the level of exposure which is likely be safe. These include use of human clinical/epidemiological data, use of historical animal data for either the ingredient itself or from a very similar chemical, use of computational approaches to predict the systemic toxicity of the ingredient (e.g. Quantitative Structural Activity Relationships) and increasingly, novel biological and chemical methods are being used to characterise bioactivity.

The cosmetics industry is starting to investigate and apply so called “new approach methodologies” (NAMs) to characterise the bioactivity of ingredients, as described in the 2007 landmark publication from the US National Academies of Sciences ‘[Toxicity Testing in the 21st Century: A Vision and a Strategy](#)’. These ideas have been developed and extended for cosmetic risk assessment in key publications such as the [International Cooperation on Cosmetics Regulation \(ICCR\) principles](#) and [the Notes of Guidance \(12<sup>th</sup> Revision\)](#) from the European Commission’s Scientific Committee on Consumer Safety. Importantly, these new methods, based on in vitro (cells cultured in the lab) testing and computational biology do not try to predict the results of historical toxicity studies that

used animals. Instead they characterise the effect that an increasing concentrations of the ingredient would have on key biological processes or pathways (including Adverse Outcome Pathways) as well as using so called 'omics' techniques, such as high throughput transcriptomics (gene expression profiling) to define the dose of the ingredient that would not cause a biological effect.

### **Safety assessment of products**

The final safety assessment of ingredients prior to marketing in new cosmetic products compares the level of consumer exposure with the level of the ingredient that has been demonstrated to be a no effect level (this maybe from historical animal data or, for new ingredients from non-animal methods). Ingredients are only included into products when there is a large enough 'safety margin' between these two values.

The safety of cosmetics and personal care products does not end with the pre-market safety assessment. Once products are marketed, companies must have procedures in place to enable them to record and react to all reports of undesirable effects (cosmetovigilance). This post-marketing surveillance of cosmetic products in the marketplace is an important component to ensuring that everyone can rely on the safety of cosmetic products they buy and use.

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