



SAFE COSMETIC PRODUCTS IN THE EUROPEAN UNION

Know-how and tools for safety assessment

THE EUROPEAN UNION REGULATION

At present, several requirements exist for documentation of the composition and safety of cosmetics and personal care products. These requisites pose a significant challenge to cosmetics suppliers and producers.

In the European Union (EU), all cosmetics must be notified via the Central Products Notification Portal (CPNP) with detailed information submitted on all substances in a product. This applies to new and existing products on the market.

The regulation requires cosmetics to be safe by normal and foreseeable use. Furthermore, the safety of each product must be documented by a named responsible professional with relevant experience and a recognised diploma in pharmacy, toxicology, medicine or similar. In addition to the EU regulation, many markets need to comply with national requirements such as labelling.

CLIENT

Producers, importers and distributors of cosmetics and body care products and raw materials

CHALLENGE

Complying with national and international regulations while fulfilling the responsibilities imposed on the industry in terms of assessing and communicating the safe use of cosmetics

SOLUTION

- Toxicological assessment of ingredients and formulated products (for instance, safety assessments in dossiers)
- Preparation of the full dossier (PIF)
- Declaration of ingredients in accordance with International Nomenclature of Cosmetic Ingredients (INCI)
- Review of cosmetics labelling, including claims
- Notification pursuant to national executive orders on cosmetics, including Central Products Notification Portal (CPNP) notification
- Safety data sheets (SDS) of cosmetics for professional use
- Strategic counselling on legal requirements
- Software for chemicals management of ingredients, toxicological profiles and safety assessments

VALUE

- Cost-efficient development
- Compliance with all regulatory requirements
- Up-to-date documentation for product dossiers (PIFs)
- Complete assistance with the different notification processes
- Updated data on ingredients and safety assessments by use of our web-based software

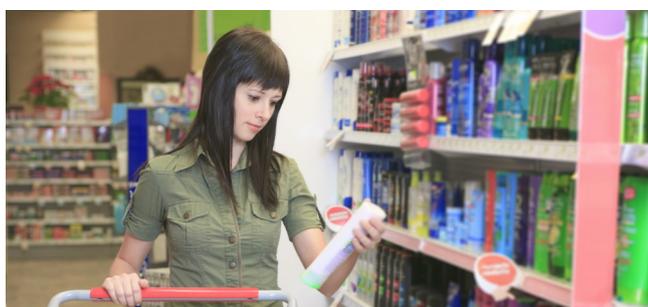
YESTERDAY	TODAY
SAFETY	
 Obligation for a manufacturer to prepare an information file on his products with a safety assessment	 Clearer requirements for safety assessment, for example, new obligation to include reasoning leading the safety assessor to a particular conclusion
ON THE LABEL	
 Name and address of the manufacturer or the person responsible for marketing the product	 Name and address of a responsible person for compliance with the rules. Clear outline of obligations.
 Date of minimum durability or period when product is safe after opening	 Pictogram indicating the date of minimum durability or period when product is safe after opening
	 All nanomaterials are to be declared with 'nano' in the list of ingredients.
NOTIFICATIONS	
 Manufacturer notifying information on its products to each EU country, for example, for the purpose of medical treatment	 Faster notification through the Cosmetic Products Notification Portal. Information can be retrieved within seconds by anti-poison centres in EU-28.
CLAIMS	
 General requirements in line with the legislation on unfair commercial practices	 Additional common criteria for claims, which may be used on cosmetics. Possibility for national authorities to verify claims. For example, if the claim says '48h efficacy', it has to be proven scientifically.

Comparison of former and current requirements. © DHI

EXPERT KNOWLEDGE OF TOXICOLOGY FOR SAFETY ASSESSMENTS

Our expert staff is up-to-date on the many regulatory amendments and possess in-depth knowledge of human toxicology. We can assist you in the retrieval and assessment of toxicological data and we possess all the qualifications required by authorities to carry out and compile safety assessments of cosmetics.

Moreover, our expertise in the legislation concerning related products (such as herbal medicines, medical devices and food supplements) makes us an indispensable partner. We can also assist you in case you need information on requirements for cosmetics for other markets. For instance, China has set requirements for the registration of cosmetic ingredients, and the Food and Drug Administration (FDA) in the United States has a Voluntary Cosmetic Registration Program.



Our in-depth knowledge of human toxicology and regulatory requirements ensures that cosmetic products have been assessed meticulously before they reach the shops. Photo: © Shutterstock / Lopolo

TAILOR-MADE SERVICES

We offer tailor-made solutions to fit your professional needs. After clarifying if a given cosmetic product is safe and legal, we prepare the required documents, including the Product Information File (PIF). Moreover, we can assist with the notification according to the CPNP, and we check if the declaration of ingredients is in accordance with the International Nomenclature of Cosmetic Ingredients (INCI).

COSMESAFE – SOFTWARE TOOL

As part of our chemical management software portfolio, we offer a software module to create and store safety assessments of cosmetic ingredients and products. The module assists you in keeping track of toxicological endpoints and data or raw materials from multiple suppliers, as well as doing the calculations of the Margin of Safety (MoS). Please contact us for a demonstration.

RESEARCH EXPERTISE IN NANOSUBSTANCES

Nanosubstances are used increasingly in personal care products and must be marked 'nano' on the labelling after the substance name. However, little is known of their effects on humans and the environment. Nevertheless, specific data relevant for risk assessment purposes needs to be

Contact: reach@dhigroup.com

For more information, visit: www.tox.dhigroup.com

SAFETY ASSESSMENTS FOR MULTI-NATIONAL MANUFACTURERS

Many cosmetics manufacturers have their own in-house experts to carry out safety assessments and toxicological evaluations of cosmetics and personal care products.

In case of large workloads or bottlenecks, additional help from external experts can support your marketing efforts. When one of the world's leading cosmetics manufacturers needed help with the safety assessment of cosmetic products and toxicological evaluation of cosmetic ingredients, they requested that we assist them.

100 INGREDIENTS IN TWO MONTHS

We assessed and verified nearly 100 toxicological profiles of cosmetics ingredients within a time span of just two months. We brought our in-depth knowledge of toxicology and the relevant regulatory requirements to the table. Furthermore, we quickly assigned a team of experts to undertake the task and carry out the safety evaluations of the many ingredients within the tight deadline.

We completed the documentation and assessment within a short timeframe and up to the expected high standards. The client was very pleased with our work— especially our profound knowledge of toxicology.

provided and scientific knowledge about the safety of nanomaterials is increasing.

We have participated in several nano-related research projects. As a result, we are capable of guiding you in making the right choice for a nanosubstance. In the EU, whenever a nanosubstance is used in a cosmetic product, the appropriate notification must be submitted to the competent EU authorities.

QSAR TOOLBOX HELPS TO PREDICT TOXICOLOGICAL ENDPOINTS

The OECD QSAR Toolbox is a fast and economical way to get access to and generate data and fill data gaps. We can predict a large variety of toxicological and ecotoxicological endpoints. Data mining and QSAR models are applied for risk assessments, regulatory decisions and for the optimisation of existing products.

ADDITIONAL MODELS, TOOLS AND KNOW-HOW

- advanced models for exposure scenarios
- advanced simulation methods
- a thorough knowledge of endocrine disruptors and sensitising substances
- safety assessment tools
- an ingredients database