

## COSMETIC

Cosmetic products are directly applied to the human body. Thus, the demands for the safety assessment of cosmetic products, their manufacturing, and duties of notification for manufacturers and importers are high.

Before marketing cosmetic products, a detailed and comprehensive safety assessment is required. The safety of the cosmetic product for human health must be proved by a toxicological evaluation of all ingredients taking into consideration the exposure under normal and reasonably foreseeable conditions of use.

We assist you to fulfil the requirements of the Cosmetic Regulation.

## OUR SERVICE IN DETAIL

- ✓ Competent and comprehensive consultancy
- ✓ assistance with selection and coordination of required tests (microbiological tests, etc.)
- ✓ cosmetic safety assessments according to Regulation (EC) 1223/2009, Art. 10
- ✓ assistance with the establishment of the product information file according to Regulation (EC) 1223/2009, Art. 11
- ✓ assistance with the notification according to Regulation (EC) 1223/2009, Art. 13
- ✓ consultancy and auditing of compliance with Good Manufacturing Practice (Cosmetic GMP) DIN EN ISO 22716
- ✓ data collection and notification of serious undesirable effects
- ✓ assistance in communication with authorities
- ✓ assistance with inclusion of new ingredients in the INCI list
- ✓ training in topics related to the Cosmetic regulation and cosmetic GMP



CONSULTANTS FOR  
**CFCS**  
CHEMICAL SAFETY

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## SAFETY ASSESSMENT OF COSMETIC PRODUCTS / PRODUCT INFORMATION FILE

To perform a safety assessment of your products, we require the following data:

- responsible person, name and contact details
- manufacturer, name and contact details if different from above
- product name and product code
- intended use, target group
- ingredients: INCI name, CAS number, amount in final product (as weight %), manufacturer
- colourants: CI index
- fragrances: code and manufacturer, IFRA certificate of the manufacturer, a list of the concentrations of the 26 allergens that have to be declared in the EU
- safety data sheets and certificates of analysis of all ingredients
- details on packaging (e.g. pump spray, tube, wide-mouthed jar), packaging material (ideal: suitable for food contact), package size(s)
- microbial test, preservation challenge test, if required
- final product specifications, e.g. pH, appearance, colour, viscosity, etc.

- stability testing (including stability in the final packaging)
- data on cosmetovigilance, if available
- reports of any available dermatological or clinical testing, if available

For the compilation of the product Information File we will additionally need the following data:

- description of the product
- description of the manufacturing process
- declaration of GMP conformity
- efficacy tests, if required
- data on animal tests (performed by manufacturers / suppliers of raw materials)

