Fraunhofer
ITEM

FRAUNHOFER INSTITUTE FOR TOXICOLOGY AND EXPERIMENTAL MEDICINE ITEM

COSMETICS – ASSESSMENT AND REGISTRATION


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In the EU, cosmetic ingredients as well as cosmetic products are regulated by the European Cosmetics Directive 1223/2009/EC. Manufacturers are obligated to generate data on their cosmetic ingredients or products before placing them on the market. Both cosmetic products ready for the market and new substances for use in cosmetic products need to undergo safety evaluation. Manufacturers need to provide a product information file (PIF) for their cosmetic products, before they can place these on the market.

Over the past 20 years, we have prepared substance assessments and safety evaluations at national and international levels for different regulatory purposes. Fraunhofer ITEM supports clients with all scientific and regulatory issues. This includes the evaluation of all data available, identification and assessment of critical hazards, and preparation of PIFs. We furthermore support our clients with safety evaluations of fragrances and aromas, taking into account relevant safety standards of the International Fragrance Association.

Fraunhofer Institute for Toxicology and Experimental Medicine ITEM

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Our services

We support you with regulatory affairs in the authorization of your cosmetics.

- Scientific and regulatory advice
- Consulting on the registration strategy and the implementation of regulatory requirements
- Services for cosmetic products:
    - Evaluation of existing data
    - Study monitoring (e.g. stability of cosmetic products)
    - Exposure assessment
    - Safety evaluation
    - Preparation of a product information file
- Services for fragrances:
    - Evaluation of existing data
    - Safety assessment
    - Preparation of IFRA standards
- Further services:
    - Training courses
    - Assistance with strategic decisions and production development
    - In-house exposure measurements and analytics (focus on release estimation of spray products)

Expertise

Our team of experienced human and environmental toxicologists offers:

- Long-term experience in dossier preparation for chemicals and biocides and other legislation
- Exposure assessment and risk assessment for human health and the environment
- Consulting and support in related regulatory areas including biocides, human and veterinary medicinal products, and food additives
- Qualification through DGK seminars (safety assessor DGK)
- Evaluation and development of concepts and methods for chemical risk assessment including development of (Q)SAR/read-across, exposure models, and risk mitigation measures