

**Workshop: Principles of the Safety Assessment for Cosmetic Products in Europe**

Welcome & Introduction

Part I: Key Aspects for the Safety Assessment in the EU

Legislative Background for the Safety Assessment

- The EU Cosmetics Regulation
- Status on Guidance Document Update towards Annex I
- Responsibility for the Safety Assessment
- Risk Management and Risk Communication
- EU Control and Enforcement Policies for Cosmetic Products
- Qualification of the Safety Assessor
- Training and Advanced Education for Safety Assessors in Europe

Practical Aspects for the Design, Preparation and Maintenance of a Product Information File

- Borderline Products
- The Components of the Product Information File [PIF]
  - Description of the Cosmetic Product
  - Manufacturing Method / GMP Statement
  - Proof of the Claimed Effect
  - Data on any Animal Testing Performed
  - The Cosmetic Product Safety Report
    - Part A – Cosmetic Product Safety Information
    - Part B – Cosmetic Product Safety Assessment
- Maintenance of the PIF
- Notification
- Cosmetic Products-GMP DIN EN ISO 22716 and Cosmetic Ingredient GMP
- Two Channels Function in the Safety Assessments of Cosmetic Ingredients
- The Annexes of Evaluated Substances

General Principles of the Safety Assessment of Cosmetic Ingredients in the EU

- SCCS Notes of Guidance and Opinion
- General Aspects of Hazard Identification
- Toxicological Tests
- Weight of Evidence Approach/ In Vitro/Dermatological Data

Q&A

Break

Part II: Individual Safety Assessment of Cosmetic Ingredients

General Toxicological Requirements for Ingredients Evaluated by Individual Safety Assessors

- Test Requirements from EU Guidance Documents (SCCS Notes) & Annex I/CosmReg
- Test Examples
- The Impact of REACH
- Animal Testing Ban and Availability of Alternative Methods

General Information Requirements for Ingredients Evaluated by Individual Safety Assessors

- Identification and Issues of Mineral, Animal, Botanical and Biotechnological Ingredients
- Work Status of the new EU Guidance Document
- Chemical and Physical Properties
- Impurities, Traces
- Cooperation with Ingredient Suppliers – SDS, CoA, Supplier Dossiers, etc.

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### Specific Ingredient Requirements – Fragrances

- IFRA Standards - IFRA Code of Practice
- Specific Regulatory Provisions for Fragrance Ingredients
- Reactivity of Aroma Chemicals and related Safety Aspects

### Risk Characterization of Ingredients

- Exposure vs NOAEL
- The Margin of Safety
- TTC - Threshold of Toxicological Concern

### Q&A

### Break

### Part III: Safety Assessment of Cosmetic Products

#### Exposure Criteria for Cosmetic Products

- New Colipa Cosmetic Exposure Study
- Categories of Cosmetic Products and Exposure Use Levels
- Target Group Specifics: Baby & Child Products / Intimate Hygiene Products

#### Microbiological Aspects in the Safety Assessment of Cosmetic Products

- Legal Requirements
- Microbiological Quality of Raw Materials
- Microbiological Quality of Finished Products
- Purity: Bioburden
- Stability: Preservative Efficacy Test (Microbiological Challenge Test)
- Microbiological Aspects in the Phases of Product Development
- Microbiological Aspects in the Phases of Production

#### General Information Requirements for Finished Cosmetic Products

- Work Status of the new EU Guidance Document
- Identification Issues
- Chemical and Physical Properties, Stability
- Data from Clinical Testing

### Q&A

### Concluding Summary