Safety assessment Proposition 65



Notifications CPNP et PCN Statement BioCID

### **EXPERTISE-REACTIVITY**







Microbiology

**Toxicology** 

INSTITUT SCIENTIS is a scientific service provider specializing in regulatory affairs, microbiology, toxicology, and the design of cosmetic, biocidal, detergent, disinfectant, candle, and ambient fragrance products. Its core activity is the safety assessment of cosmetic products (with an in-house ERT toxicologist).

In the field of cosmetic products, its areas of expertise extend to formulation, pre-toxicological assessment, drafting of Product Information Files (DIP), their auditing, CPNP notification, label verification, normative and regulatory monitoring, international compliance (ingredient list checks, Proposition 65), and industrial transposition.

In the field of biocidal products (detergents-disinfectants-repellents), the company offers formulation, verification of regulatory compliance of formulas, microbiological testing strategies, label creation, BioCID declarations, and PCN notifications. It also assists its clients with the market placement of biocidal products during transitional periods in various European countries and ensures the registration of "same product" submissions.

Research Tax Credit (CIR).

Research Tax Innovation (CII).

Training organization registered n° 11 75 54659 75

Activities presentation slideshow

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### **REGULATION**

## **COSMETICS - EUROPEAN REGULATION N°1223/2009**

- > Safety assessment. French and/or English version.
- > Ingredients list to label (INCI).
- > Product Information File (PIF). French and/or English version.
- Audit of your product information files.
- > Electronic notification on the CPNP.
- Theoretical determination of PAO.
- > Toxicological pre-expertise of a formula.
- > Updates of the safety assessments / Product Information Files.

### **COSMETICS-INTERNATIONAL**

Regulatory compliance assessment (prohibitions, restrictions ...) of raw materials incorporated in the cosmetic products outside Europe, proposition 65.

# **BIOCIDAL PRODUCTS - EUROPEAN REGULATION N° 528/2012**

Assistance in placing your biocidal products on the market.

- > Regulatory compliance checking in transitional period, same product
- Marketing strategy to adopt in perennial period,
- Data Gap Analysis,
- > Full market approval file.
- BioCid Statements-PCN Notification.

## SAFETY DATA SHEETS - REACH REGULATION N°1907/2006 AND CLP N°1272/2008

- Edition of FDS. Sheet provided in French and in English in PDF format.
- PCN Notification.

# SCIENTIFIC AND REGULATORY ASSISTANCE

- Regulatory and normative watch including transmission by regular e-mails of relevant regulatory information
- > Consulting/Scientific and Regulatory specific assistance : labels verification, notices, responses to targeted issues, CIR files, links with competent authorities.

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### FORMULATION-CONCEPTION-R&D

We create galenic forms according to your specifications. We have the approval of the Ministry of Research for the research tax credit (CIR) and for innovation tax credit (CII). Our clients can benefit from these Tax Credits.

### PRODUCTS CONCERNED

Cosmetics - Detergents - Biocidal products - Topical and oral medical devices - Candles.

### **BENEFITS**

- > Scientific Marketing: Writing Aid for development specifications.
- Formulation: Development of a new product in accordance with the specifications and optimization existing formulations.
- > Stability and content/container compatibility: Control of organoleptic, physico-chemical and microbiological properties after storage for a defined time at different temperatures.
- > Physico-chemistry: pH, density, viscosity, dry matter and determination of the closed cup flash point.

### **TRAINING**

Registered training organization number 11 75 54659 75, we offer scientific and regulatory training, theoretical and hands-on in connection with our areas of expertise. Our trainees can ask us questions and we ensure follow-up of the training provided.

Certified by <u>Qualiopi</u> as the "training actions" category, our courses are recognized for their quality and could be supported by joint bodies.

All our webinars and formations are available in "Replay" after the date.

The offices and the laboratory are located in Montmartre.



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