SIGILLUM
KNOWLEDGE
SOLUTIONS

Cosmetic & Household products

Sustainability, Health & Safety Compliance

Who we are?

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SOLUTIONS

SIGILLUM KNOWLEDGE SOLUTIONS

Who we are?

Sigillum Knowledge Solutions is an international consultancy service provider focused on Health, Safety and Sustainability of consumer products.

From design to end of life cycle we cover the full production process in order to ensure that any consumer good meets all legal requirements before it is placed on the market.

Skills

Sigillum KS has highly skilled safety assessors with specific training and demonstrated experience in the field of international regulations of cosmetics products, in particular against the European Regulation of Cosmetic Products (CE) No 1223/2009 and the procedures related to drafting and revision of Product Information Files.

Our partners

USC UNIVERSIDADE DE SANTIAGO DE COMPOSTELA

CiQUS Centro Singular de Investigación en Química Biolóxica e Materiais Moleculares

amslab.

Mestrelab Research chemistry software solutions

Scientific and technical knowledge

What do we do?

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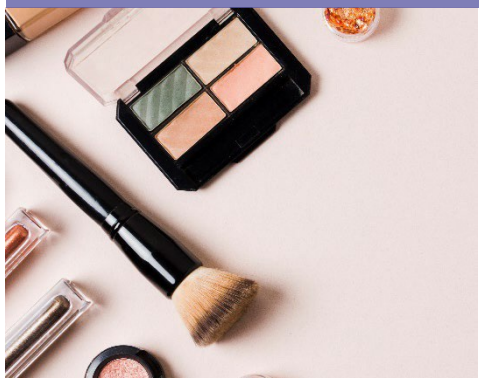
Cosmetics



Household products

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What do we do?

What do we do for cometic & household industry?

I. Regulatory compliance

II. Drafting of technical documentation

III. Risk Assessment and risk management

IV. Evaluation and control programs

V. Responsible Person EU & UK

VI. Sustainability

VII. Ad Hoc Training

VIII. Software development

IX. R&D

Services focused on improving competitiveness of our clients in their target markets

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I. Regulatory compliance

What do we do?

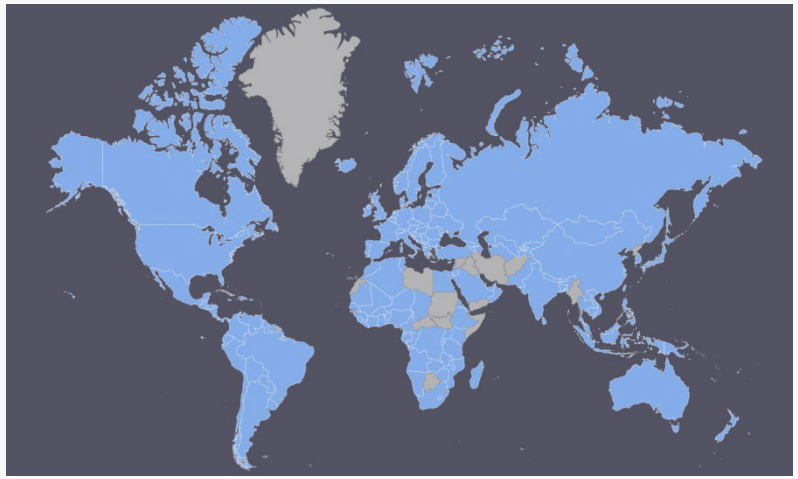
- Studies of regulatory requirements by countries and markets.
- Scientific-technological surveillance on aspects related to product health and safety (normative and of socioeconomic repercussion).
- Observatory of international regulations and standards: Continuous monitoring of international regulations in more that 50 countries (5 continents), including early warnings about drafts of new regulations.
- Substances Data Base, detailed and updated regulatory information of more than 2500 regulated substances including, but no limited :

RAPEX
KEEPING EUROPEAN CONSUMERS SAFE

U. S. Consumer Product Safety Commission

AQSIQ

- **Colorants**
- **Preservatives**
- **UV filter**
- **Allergenic Fragances**
- **Phtalates**
- **Metals and its compounds**
- **Nitrosamines**
- **etc**



Risk reduction due to non-compliance

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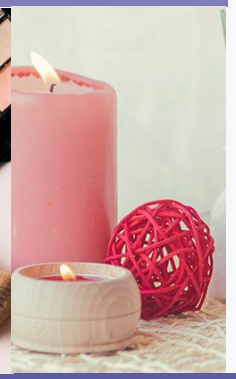
II. Drafting of technical documentation

What do we do?

Cosmetics & Household Products



- **Technical Documents**
  - Drafting and assessment of **Product Information File (PIF).**
  - Drafting and approval of the **Cosmetic Product Safety Report assessment (CPSR)**
  - Notification to the European Cosmetic Product Notification Portal (CPNP)
  - **PCN + ECHA Submission Portal**
  - Labelling
  - Safety Data Sheets (SDS). Review and drafting
- **Compliance:**
  - **Regulation (EC) No 1223/2009 for cosmetics products**
  - **REACH & CLP regulation**
  - **Regulation (EC) No 648/2004** on **detergents**
  - **Regulation (EU) No 528/2012 on biocidal products** (BPR)

Legal & Reputational risk control

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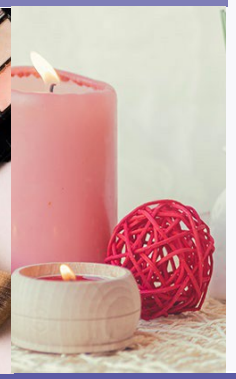
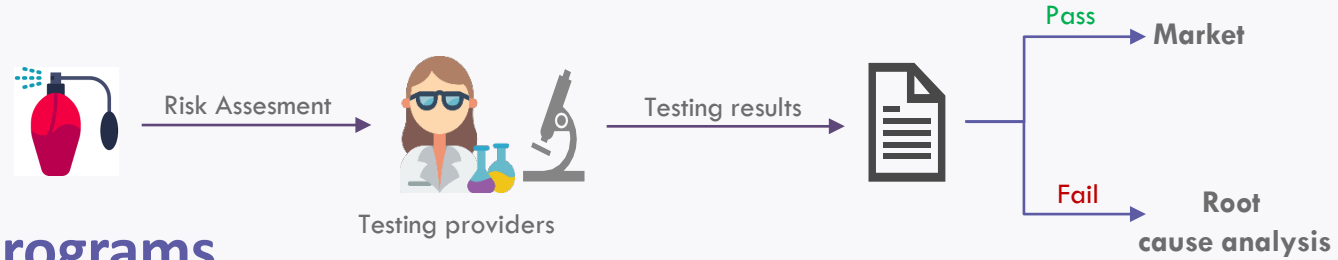
What do we do?

Cosmetics & Household Products



III. Risk Assessment and risk management

- Development and implementation of **Restricted Substances List** (RSL)
- Claims and labelling guidelines.
- Development of **Market surveillance** protocols.
- Root cause analysis of not compliance.



IV. Evaluation and control programs

- **VOCs, allergenic fragances, etc,** Design of control strategies.
- Design of control strategies for cosmetic industries.
- Development of chemical management programs.
- Advising in the selection and control of testing providers: Supervision and audits of control laboratories and compliance tests.

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V. Reponsible Person EU & UK

What is a Responsible Person in the EU?

Since Regulation (EC) No. 1223/2009 for cosmetic products came into effect, it has been necessary to designate a Responsible Person for cosmetic products sold in the European Union. The Responsible person, who must have a presence in the EU, guarantees compliance with the Regulation to European authorities, and ensures that the product is safe for human health under normal and reasonably foreseeable conditions of use.

What is a Responsible Person in the UK?

Since Brexit and due to “The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, Schedule 34”, it has been necessary to designate a Responsible Person for cosmetic products sold in the UK. The Responsible person, who must have a presence in the UK, guarantees compliance with UK regulation and authorities, and ensures that the product is safe for human health under normal and reasonably foreseeable conditions of use.

The importer may, by written mandate, designate a person established within the Community and UK the responsible person who shall accept in writing.

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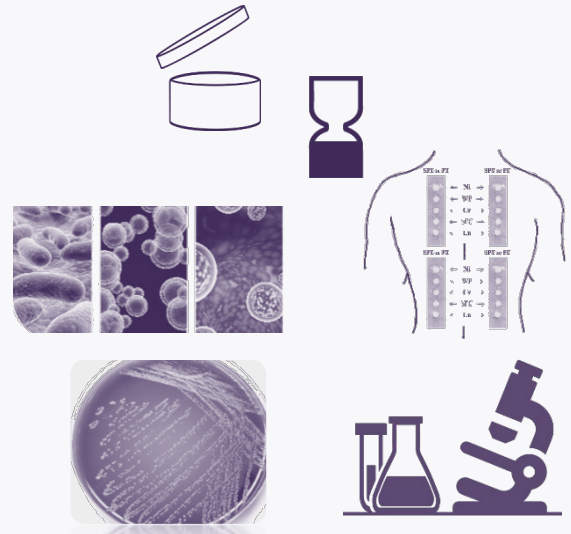
V. Reponsible Person EU & UK service

1. GUARANTEE THE SAFETY OF THE COSMETIC PRODUCT

The Responsible Person will assess the safety of the cosmetic product and is responsible for preparing the product information file (PIF), keeping it and maintaining it for 10 years after the last batch is placed on the market.

2. GUARANTEE THE COMPLIANCE OF THE COSMETIC FORMULA

- Drafting of Product Information File
- Advice and manage testing process and clinical trials
- Ensure compliance of packaging and labelling
- Notification to CPNP portal



3. MAIN POINT OF CONTACT WITH AUTHORITIES REGARDING SAFETY OF PRODUCT

4. MARKET SURVELLAINCE

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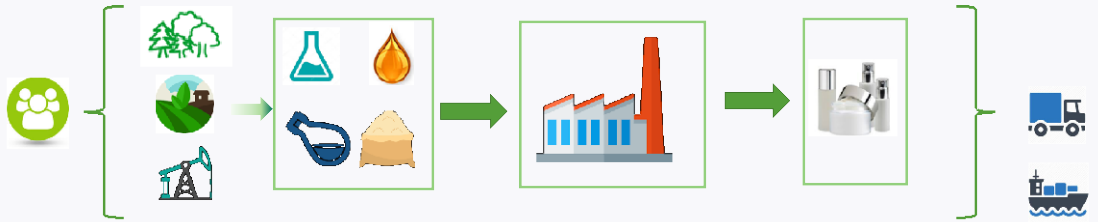
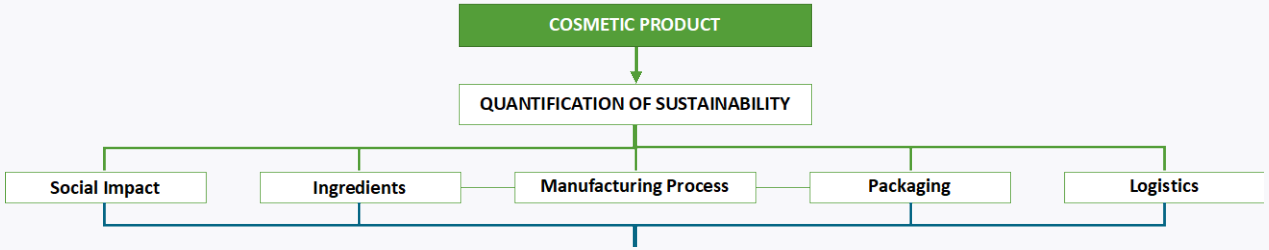
VI. Sustainability

What do we do?

- Definition of corporate strategies for sustainable cosmetic products.
- Evaluation and improvement of cosmetic products sustainability.
- Creation of indicators for the evaluation of the sustainability of products.
- Advisement on natural, organic or vegan cosmetics products
- Sustainability, claims and labelling.
- Cosmetic packaging sustainability

- Process efficiency
- Waste reduction
- Recycling
- Enviromental protection
- Human Rights
- Fair Trade





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VII. Training

What do we do?

- Training in regulatory aspects for technical and production units staff .
- Requirements for compliance with international product health and safety standards.
- Responsible person and PIF requirements.
- Risk management.
- Sustainability in the cosmetic industry.

Corporate Values: Health, Safety & Sustainability

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VIII. Software development

What do we do?

Cloud DB

- Updated regulated substances
- Positive lists
- Toxicological properties

Multi Device

Client access

- Licence
- Customize

- Development of cloud data base of regulated substances to an easy analysis of compliance by markets, group of substances, positive lists, toxicological properties, etc. Partnership with software development company.

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IX. R&D

TACTICS

MIP-20201046

NUEVAS TÉCNICAS ANALÍTICAS DE CONTROL PARA LA TRANSICION INDUSTRIAL HACIA UNA ECONOMÍA CIRCULAR SEGURA

MINISTERIO DE CIENCIA E INNOVACION · CDTI · UNIÓN EUROPEA · amslab. · torusware · SIGILLUM KNOWLEDGE SOLUTIONS

To test the feasibility and suitability of a new chemical analysis technique based on low-field nuclear magnetic resonance (NMR), to facilitate the incorporation of recycled or recovered materials in the value chain of the circular industry 4.0, simplifying and saving costs of the control processes of raw materials and products, providing guarantees on their composition and quality in all steps of the supply chain

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