Product Safety Regulatory Compliance Product Stewardship

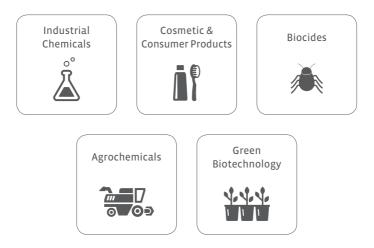
# Toxminds Product Safety & Regulatory Affairs

www.toxminds.com

#### About Us Toxicologists with a Business Mind

ToxMinds BVBA is a product safety and regulatory affairs firm located in Brussels, Belgium. Our passion and motivation is the use of good science, but we also understand the reality of our tightly regulated chemicals world. With our broad industry experience, we support our customers in bringing safe, regulatory compliant and publicly acceptable products to the market.

We provide chemical safety, regulatory and product stewardship support to the following industries:



Thanks to the international nature of our team we interact with our clients in various languages including English, German, French, Italian, Spanish, Portuguese or Hindi.



## Chemical & Product Safety

ToxMinds is composed of a core team of industry-experienced (eco)toxicology and regulatory affairs consultants that is supported by a group of highly motivated research analysts.

Our wide range of chemical and product safety services includes:

- Literature and desktop searches using public and commercial databases
- Quality analysis, study summaries and accurate presentation of information related to the effects of chemicals on human health and the environment
- Structure activity analysis ((Q)SAR)
- Analogue identification and chemical similarity assessments
- Data gap analysis under full consideration of non-testing approaches
- Identification of intelligent hazard assessment and testing approaches ('IATA') to fill information gaps including:
  - └● Non-testing hazard and safety assessment strategies
  - └ Hypothesis and mechanism-based in chemico and *in vitro* testing
  - └• *In vivo* testing strategies
- Study monitoring and management
- Exposure modelling using for example REACH, BPR or PPPR recommended modelling tools
- Tiered human & environmental risk assessments
- Green chemistry and R&D candidate evaluations

# Regulatory Strategy & Compliance

The ToxMinds team of regulatory experts supports and guides our clients through all necessary steps to achieve regulatory compliance with European regulations for industrial chemicals, consumer and cosmetic products, biocides and agrochemicals. Our science and regulatory experience paired with our established relationships with regulatory authorities enable us to fulfil client needs and provide valuable and timely advice. We combine independent scientific expertise with pragmatic regulatory solutions and business practice.

Our regulatory services include:

- Portfolio review and regulatory strategy consulting
- Registration dossier preparation under
  - └• REACH Regulation (EC) No 1907/2006
  - └● Biocidal Product Regulation (EU) No 528/2012 ('BPR')
  - └● Plant Protection Product Regulation (EC) No 1107/2009 ('PPPR')
- Preparation of SCCS-compliant cosmetic ingredient dossiers
- Post-submission support including the preparation of responses to authority requests or advocating and defending scientific approaches with public authorities
- Cosmetic product information files (PIF)





### **Product Stewardship**

Product stewardship is the practice of making health, safety and environmental protection an integral part of the life cycle of chemicals. It is a shared responsibility between chemical producers, their suppliers and customers. It provides the platform for companies to identify risks at an early stage and manage those risks along the value chain.

We facilitate and support clients in their product stewardship activities with the following services:

- Development of REACH-compliant extended Safety Data Sheets
- Generation of ICCA-compliant product safety summaries
- Tailored trainings to PS&RA or product stewardship staff, for example on
  - Principles of human & environmental hazard, exposure and risk assessment of chemicals
  - └ (Q)SAR modeling and hazard-specific endpoint training (e.g., skin sensitization, endocrine disruption, aquatic toxicity)
  - └● Regulatory frameworks and related IT tools (e.g., IUCLID software package)
  - └• REACH exposure modelling & CSR/CSA creation software
  - └● Creation of REACH-compliant extended safety data sheets (eSDS)
- Establishment and moderation of scientific review panels
- Science-based advocacy and client representation with regulatory authorities
- Hazard and risk communication to various audiences





ToxMinds BVBA Avenue de Broqueville, 116 | 1200 Brussels, Belgium Tel +32 (0)2 762 91 45 | info@toxminds.com www.toxminds.com