YOUR PARTNER FOR PRODUCT SAFETY AND COMPLIANCE

toxminds.com

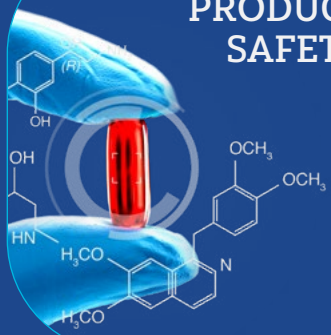
ToxMinds

THINKING AHEAD IN TOXICOLOGY

Since our foundation in 2007 and through our work with large multinationals, industry associations as well as small and medium-sized businesses, ToxMinds has grown in size and expertise with professionals located in various regions around the world. Our team is composed of experienced toxicology, environmental and regulatory affairs specialists supported by a scalable group of motivated research analysts. They closely follow the developments in science and regulatory toxicology to provide state-of-the-art **Product Safety**, **Regulatory Compliance** and **Product Stewardship** services.

REGULATORY COMPLIANCE

PRODUCT SAFETY



PRODUCT STEWARDSHIP

CHEMICALS

ToxMinds' toxicology, environmental and regulatory specialists provide innovative, scientifically sound and compliant solutions for chemical safety and regulatory compliance.

We support our clients from the chemical industry on all scientific and regulatory issues related to human health and the environment

Our dedicated services for commodity and specialty chemicals businesses include:

- REACH registration services and post-submission support with ECHA
- State-of-the art human health and environmental risk assessments
- (Q)SAR modelling and ECHA RAAF conform analogue- and grouping-based read-across justifications
- Design and management of (eco)toxicology testing programmes
- Science advocacy and product defence
- Hazard screening and prioritisation of chemical pallets and R&D developments ('safe and sustainable by design')
- Consortium management, 3rd party representation and LoA cost determinations

BIOCIDES

We support our clients with preparation of the registration package required for biocidal actives or products under the EU Biocidal Product Regulation

ToxMinds is experienced in identifying and implementing the most suitable BPR registration strategy for biocidal products. Our experts have substantial experience with complex (eco)toxicological profiles and assessment of actives and co-formulants for endocrine disrupting properties.

Our dedicated services related to supporting biocidal actives, substances or product families include:

- Compilation of information and data gap analysis against the requirements of the BPR
- Scientific advice on filling data gaps and testing strategies to deal with complex toxicological or environmental profiles
- Compilation of ECHA/EFSA guideline-compliant endocrine disruptor (ED) assessments for active substances and ED screening of co-formulants
- Assessment of relevancy and risk of impurities in the biocidal active substances
- Building of registration packages (IUCLID datasets, human and environmental risk assessments, efficacy, supporting documentation)
- Dossier submission via R4BP; pre-and post-submission support with ECHA and the evaluating competent authorities
- Technical equivalence dossiers
- Support for Article 95 inclusion

COSMETICS & CONSUMER PRODUCTS

ToxMinds are passionate about ensuring the safety of ingredients present in cosmetics and consumer products. We integrate information provided by the so-called New Approach Methodologies (NAMs) for biology-based safety support of cosmetic ingredients or products.

Our team of experienced safety assessment specialists provide science-based solutions for ongoing and new business initiatives

Our dedicated services for cosmetics & consumer products include:

- Feasibility and safety screening of new technologies including botanicals, peptides and nanomaterials
- Development of SCCS Notes of Guidance-compliant safety assessment dossiers for cosmetic ingredients
- Ingredient screening and assessment for endocrine disrupting properties
- (Q)SAR modelling, analogue identification and analogue- and grouping-based read-across justifications
- Advice on biology- and mechanism-based *in vitro* testing programmes to determine biological activity and/or to reduce read-across uncertainties
- Assessment of impurities present in cosmetic products
- Development of product information files (PIF) and notification via the Cosmetic Product Notification portal (CPNP) for cosmetic products

PHARMA, VETERINARY MEDICINES & MEDICAL DEVICES

ToxMinds' toxicologists and environmental specialists support companies from the life-science industry on many different aspects related to product safety.

We have many years experience in helping clients from the pharmaceutical industry to establish safe exposure levels for residues, E&L or impurities in their medicinal products

Our dedicated services for the pharmaceutical, veterinary medicines or medical device sector include:

- (Q)SAR modelling to predict bacterial mutagenicity using ICH M7 recommended tools (e.g., Derek Nexus and Sarah Nexus)
- Derivation of Permissible Daily Exposure (PDE) levels for extractables & leachables (E&L), impurities or for API's
- Derivation of acceptable intake (AI) values for carcinogenic impurities (e.g., nitrosamines) based on data from Lhasa or Gold TD50 values
- Metabolic pathway evaluation for impurities including nitrosoamine formation potential
- Derivation of Occupational Exposure Limits (OELs)
- Establishment of safe exposure or maximum residue levels of excipients
- Environmental risk assessment of APIs and non-actives
- EU chemical regulatory compliance support as applicable (e.g. REACH, CLP)

NEW APPROACH METHODOLOGIES (NAMs)

ToxMinds are specialists in identifying testing and assessment strategies to fill safety information gaps without any further animal testing. We have an excellent track record for successful submissions of read-across justifications under existing chemicals, cosmetics or medicinal product regulatory frameworks.

We are passionate about finding opportunities to reduce animal testing by using information provided by *in silico* and *in vitro* bioactivity testing approaches in the safety assessment process

Our dedicated NAMs services include:

- (Q)SAR-based hazard profiling and metabolism prediction using a range of public and commercial OECD, ECHA and ICH recommended tools
- Identification of suitable analogues and development of guideline-compliant analogue- and grouping-based read-across justifications
- Establishment of NAM-based testing programmes to reduce read-across uncertainties or verify MoA hypotheses
- Advice on biology- and mechanism-based *in vitro* testing strategies to determine biological activity
- Exposure and systemic bioavailability predictions

At ToxMinds, we are passionate about toxicology and how emerging scientific developments can be utilised to support our customers in bringing safe, regulatory compliant and sustainable products to the marketplace.

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