



**Product Safety
Regulatory Compliance
Product Stewardship**

toxminds.com

CHEMICAL & PRODUCT SAFETY

Ensuring chemical and product safety using emerging technology and state-of-the-art risk assessment practices

ToxMinds is composed of a core team of experienced (eco)toxicology consultants, supported by a group of highly motivated research analysts. We closely follow the developments in regulatory toxicology, focusing specifically on predictive toxicology, endocrine disruption and new risk assessment concepts. Our motivation is to apply emerging methodologies in the chemical risk assessment process to avoid animal testing.

Our **chemical & product safety** services include:

- Comprehensive literature searches using public or proprietary databases
- QSAR-based (eco)toxicological hazard profiling and metabolism prediction
- Toxicological data gap analysis under consideration of non-animal testing approaches
- Weight-of-evidence based hazard assessments and characterisations
- Assessment of endocrine disrupting properties
- Design and management of (eco)toxicology testing programmes
- Human & environment exposure and risk assessments in compliance with regulatory frameworks
- Development of strategies to resolve complex health or environmental issues
- Feasibility screening of new technologies and R&D developments

"Ensuring chemical safety and compliance is at the core of what we do."

REGULATORY STRATEGY & COMPLIANCE

Maintaining compliance with EU regulations and regulatory requirements

Based in Brussels, the heart of European decision-making, the regulatory experts of ToxMinds stay abreast of the regulatory developments applicable to the industry sectors we support. Our experience and in-depth knowledge is the basis of our registration services, and we guide our clients through the necessary steps to achieve compliance with the regulations for chemicals, biocides, cosmetics and consumer products, pharmaceuticals and green biotechnology.

Our **regulatory** services include:

- Portfolio review and regulatory strategy consulting
- Data compilation, evaluation of non-testing approaches and waiving opportunities, final data gap analysis
- Design and management of testing programmes
- Preparation of robust study summaries of physico-chemical, environmental fate, ecotoxicology and human toxicology studies
- Development of Regulation-compliant registration dossiers
 - REACH Regulation: IUCLID dossiers; Chemical safety assessment and reports
 - Biocidal Product Regulation: Development of product authorisation dossiers and supporting documents for all product types
 - Cosmetics Regulation: Cosmetic ingredient dossiers for SCCS submission; Product information files (PIF)
- Post-submission support (e.g., client representation with – and response to – authorities)



PRODUCT STEWARDSHIP

Supporting safety, environmental protection
and regulatory compliance within your
chemicals life cycle

Product stewardship is the practice of making safety, environmental protection and regulatory compliance an integral part of the life cycle of chemicals. ToxMinds supports companies by helping them to characterise the risks associated with the manufacture and use of their products. We provide client-tailored trainings on topics related to safety and regulatory compliance and develop the documentation to support and communicate the safety of your product.

Our **product stewardship** services include:

- Development of science-based strategies and documentation to support chemicals or products under regulatory or public scrutiny
 - Client tailored trainings on topics related to product safety & regulatory compliance
 - Principles of human & environmental hazard, exposure and risk assessment of chemicals
 - Hazard-specific endpoint training (e.g., skin sensitisation, endocrine disruption, aquatic toxicity)
 - Regulatory frameworks and related IT tools (e.g., IUCLID software package)
 - QSAR & REACH/BPR specific exposure modelling tools
- Development of REACH-compliant extended Safety Data Sheets (eSDS)
- Science advocacy and product defence
- Communication of (eco)toxicology and risk assessment findings to various audiences with different levels of scientific knowledge

"Communicating
the safety of your
products to the
public."

QSAR MODELLING

Predicting toxicity, identifying suitable analogues for read-across, and selecting lead candidates through combined use of public and commercial structure activity modelling tools

ToxMinds has substantial experience in applying QSAR modelling tools to support the safety evaluation and risk assessment of chemicals, food contact materials, cosmetic ingredients or impurities present in pharmaceuticals. We routinely identify analogue compounds and utilise a range of public and proprietary QSAR tools including Derek Nexus, Sarah Nexus and Meteor Nexus from Lhasa Ltd in the context of structure activity predictions.

Our services include:

- **QSAR-based (eco)toxicological hazard profiling and/or metabolism prediction**
- **Quantitative prediction of physico-chemical and ecotoxicological properties**
- **Identification of analogues for read-across purposes**
- **SAR-based chemical and biological similarity assessments**
- **ECHA guideline compliant read-across justification for (eco)toxicology endpoints and analogue-based derivation of safe exposure levels**
- **ICH-guideline compliant mutagenicity assessment of manufacturing impurities, extractables and leachables**
- **Identification of low toxicity molecules and lead candidate selection in comparative toxicity screens**



NEW APPROACH METHODOLOGIES

Identifying and applying new methodologies and risk assessment approaches to support chemical safety without animal testing

Our team members are very passionate about identifying and applying new approach methodologies in chemical risk assessment. We are routinely confronted with clients' queries on how to evaluate the safety of a newly developed cosmetic ingredient or a non-intentionally added substance (NIAS) in a food contact material without any new animal testing. ToxMinds has a track record for analogue identification and the successful submission of QSAR-supported read-across justifications under the REACH regulation.

We offer a range of options to **evaluate chemical safety**:

- Thorough desktop research to identify, collate and appraise relevant toxicological information
- QSAR-based (eco)toxicological hazard profiling and metabolism prediction
- Exposure and systemic bioavailability prediction (target organs, internal concentration)
- SAR-based analogue identification and justification
- Suitability evaluation of TTC and read-across approaches
- Advice on integrated testing strategies using non-animal methodologies
- Development of tiered testing programme(s) to reduce read-across uncertainties or verify MoA hypotheses
- Integration of in silico, Toxcast, transcriptomics, metabolomics and PBPK modelling data to identify potential AOP's, support read across and/or derive MOIE for safety assessment purposes

"Applying the latest scientific developments to ensure safety and animal welfare."

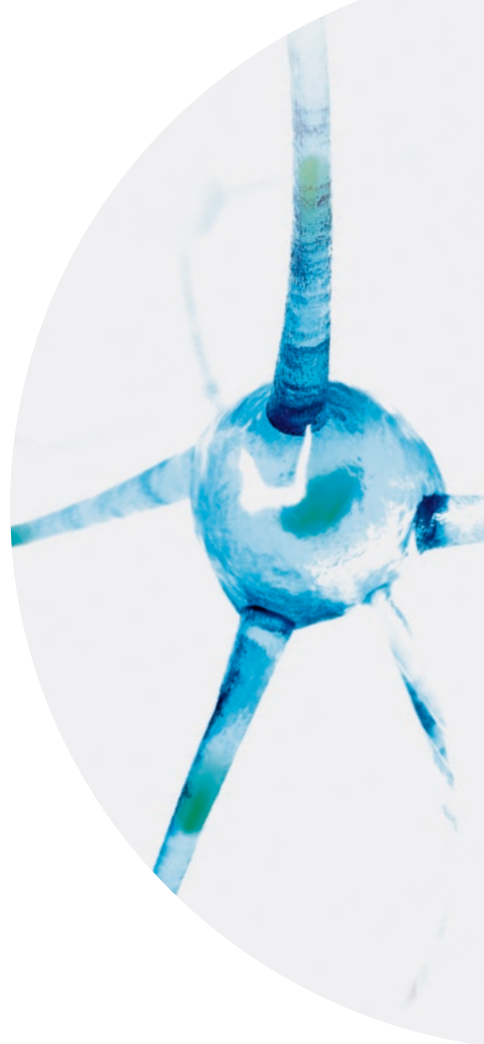
ENDOCRINE DISRUPTION

Assessing the potential endocrine disrupting properties of a chemical for humans and the environment

ToxMinds scientists have followed the debate surrounding endocrine disruption at the technical and regulatory level for numerous years. We have been involved in the evaluation of toxicological and ecotoxicological data as evidence for the potential endocrine activity of industrial chemicals, biocides or agrochemicals. If deemed necessary, we recommended testing strategies to confirm possible modes of actions (MoA) and strategic options from a client's business point of view.

Our services to identify and assess chemicals with potential **endocrine disrupting effects** in humans or the environment include:

- Comprehensive literature searches using public or proprietary databases
- Topline screening and feasibility assessment of lead candidates from an ED perspective
- QSAR modelling to predict endocrine activity based on chemical structures
- Systematic review of collected data based on pre-defined criteria
- Matrix-based collation of identified data based on relevance, reliability and lines of evidence
- Assessment of endocrine-mediated adversity and Mode of Action (MoA) analysis
- Design and management of testing programmes to evaluate or verify endocrine activity
- ECHA/EFSA-guideline compliant ED assessment reports



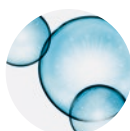
ToxMinds are specialised in ensuring product safety and compliance.

We are passionate about toxicology and how emerging developments can be utilised to provide our customers with a competitive advantage in the marketplace.

INDUSTRIES FOR WHICH WE WORK



Chemicals



Biocides



**Cosmetic &
Consumer
Products**



**Pharmaceuticals
& Medical
Devices**



**Green
biotechnology**