Fraunhofer
ITEM

FRAUNHOFER INSTITUTE FOR TOXICOLOGY AND EXPERIMENTAL MEDICINE ITEM

INDUSTRIAL CHEMICALS – ASSESSMENT AND REGISTRATION


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Industrial chemicals need to be registered at ECHA according to the European REACH chemicals regulation (EU 1907/2006). Depending on the manufactured or imported quantity, defined data have to be provided. For chemicals produced or imported in quantities of more than ten tonnes per year, potential risks have to be assessed in addition in a chemical safety report. After registration, companies are required to keep their dossiers up to date, respond to additional data requirements, e.g. from Member State evaluations, and integrate new data. Over the past 20 years, we have prepared substance documentations and assessments for new and existing substances at national (GDCh BUA activity) and international levels (OECD ICCA HPV program). Based on this expertise, we support clients with all scientific and regulatory issues. This includes the evaluation of all data available, identification and assessment of critical hazards, and dossier preparation and submission. For questions beyond standard toxicology, we create tailored solutions: read across/bridging principles, integrated testing strategies and custom-fit in-vitro methods. Our aim is to identify and reduce risks to health and the environment, while not losing sight of the desired reduction of animal testing to a realistic minimum.

Fraunhofer Institute for Toxicology and Experimental Medicine ITEM

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Our services

We support you with regulatory affairs in the registration of your chemical substances.

- Assistance with strategic decisions
  - Consulting on the registration strategy and the implementation of regulatory requirements
  - Communication with competent authorities
  - Assistance during substance evaluation, CoRAP and SVHC as well as RAC discussions on CLH
  - Tonnage band update strategies including letter of access negotiations (LoA)
- Data collection and study monitoring
  - Identification of data gaps
  - Development of testing strategies and use of (Q)SAR/read-across
  - Commissioning and monitoring of experimental studies for toxicological and ecotoxicological endpoints
  - Collection of exposure information and consultancy on downstream users
- Risk assessment of existing and new substances
  - Assessment of the hazard profile including classification and labeling
  - Evaluation of specific concern: PBT/vPvB assessment and endocrine disrupting properties
  - Exposure assessment and risk assessment for humans and the environment
- Dossier preparation and submission
  - Dossier preparation for registration of new substances according to the REACH regulation (including IUCLID file; chemical safety report)
  - Dossier update to new tonnage band
  - Response to further inquiries and additional data requests by the authorities
- Miscellaneous services
  - Training courses
  - Development of models for exposure and emission evaluation
  - Assistance with strategic decisions and production development
  - In-house exposure measurements and analytics
  - Toxicological assessment of residues and contaminants

Expertise

Our team of experienced human and environmental toxicologists offers:

- Long-term experience in dossier preparation for existing and new chemical substances
- Exposure estimation and modelling and risk mitigation measures
- Risk assessment for human health and the environment
- Consulting and support in related regulatory areas including biocides, human and veterinary medicinal products, food additives, and cosmetic products
- Evaluation and development of concepts and methods for chemical risk assessment including development of (Q)SAR, read-across and in-silico methods