Fraunhofer ITEM

FRAUNHOFER INSTITUTE FOR TOXICOLOGY AND EXPERIMENTAL MEDICINE ITEM

BIOCIDES – ASSESSMENT AND AUTHORIZATION


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Biocidal products are used on a daily basis to protect human health, improve hygiene, extend the shelf life of a variety of products, or help sustain smooth production processes. This is achieved by targeted use of biocides against harmful organisms, such as fungi, bacteria, algae, viruses, insects, or other organisms. The authorization of biocidal products and their active substances is subject to a systematic but complex authorization procedure according to the Biocidal Product Regulation (EU) 528/2012 (BPR).
Over the past 20 years, we have prepared dossiers for biocidal active substances and for biocidal products of different product types. Fraunhofer ITEM supports its clients with all scientific and regulatory issues. This includes the evaluation of all available data, identification and assessment of critical substances, and dossier preparation and submission. For questions beyond standard toxicology, we create tailor-made solutions for our clients by applying read-across/bridging principles or integrated testing strategies, such as in-vitro methods. Our aim is to point out risks to health and the environment and to reduce these, while not losing sight of the desired efficacy against the targeted harmful organisms.

Fraunhofer Institute for Toxicology and Experimental Medicine ITEM

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Our services

We support you with regulatory affairs in the context of biocide authorization.

- Assistance with strategic decisions
  - Consulting on the registration strategy and the implementation of regulatory requirements
  - Communication with competent authorities
  - Letter of access negotiations (LoA)
  - Notification of biocides in all EU countries

- Data collection and study monitoring
  - Identification of data gaps
  - Development of testing strategies and use of (Q)SAR
  - Commissioning and monitoring of analytical, in-vitro, and in-vivo studies
  - Efficacy assessment and consultancy on label claims

- Risk assessment of active substances and biocidal products/families
  - Assessment of the hazard profile including classification and labeling
  - Substance of concern evaluation (SoC)
  - Evaluation of endocrine disrupting criteria (ED assessment)
  - Exposure assessment and risk assessment for man and the environment
  - In-house exposure measurements and analytics

- Dossier preparation and submission
  - Dossier preparation for authorization of active substances and biocidal products according to BPR (including IUCLID file, draft risk assessment (DRA), and summary of product characteristics (SPC))
  - Dossier submission via R4BP
  - 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 product development
  - In-house exposure measurements and analytics

Expertise

Our team of experienced human and environmental toxicologists offers:

- Many years of experience in dossier preparation for biocidal active substances and biocidal products
- Exposure assessment and risk assessment for human health and the environment
- Consulting and support in related regulatory areas including REACH, veterinary medicinal products, food additives, and cosmetics
- Evaluation and development of concepts and methods for chemical risk assessment including development of (quantitative) structure-activity relationships ((Q)SAR), exposure models, and risk mitigation measures