



1 *The environmental effects of nanomaterials are investigated in different organisms including aquatic macrophytes.*

NANOMATERIALS

Behavior, fate and toxic effects of nanomaterials: risks to human health and the environment

Conditions for safe use of nanomaterials in various applications. Aspects to be taken into account to prevent harm to exposed humans and the environment. Successful registration of nanoforms under REACH and other regulations.

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Nanomaterials are capturing the European market in a rapidly increasing number of products, available both for industry and private consumers. They offer a wide spectrum of technical and commercial opportunities, e.g. as ingredients of foods, pharmaceuticals and cosmetics. Evidence published in scientific literature during the past few years, however, suggests that some nanomaterials, due to hazardous properties, might give reason for health and safety concerns with regard to humans and organisms in the environment.

European authorities meanwhile recommend that manufacturers and downstream users adequately assess and manage the potential risks from exposure of workers and consumers and ensure the safe use

of these new forms of materials under different regulations. While draft guidance of competent authorities is still under development, we are able to provide a full spectrum of experimental methods to test and assess the behavior, fate and effects of nanomaterials in a way that fully complies with regulatory requirements. Further services based on our broad expertise include dossier preparation and registration, and we can act as a Third-Party Representative under REACH and other regulatory regimes.

Target group

Companies looking for targeted assessment of the fate, behavior and effects of their nanomaterials and nano-containing products based on sound experimental data, where necessary in compliance with regulatory requirements.

Key issue

We assess your isolated nanomaterials or products containing nanomaterials as functional ingredients.

- Investigation of the environmental fate of nanomaterials and their effects on exposed organisms
- Toxicological testing of nanomaterials in vivo and in vitro
- Potential exposure of workers, end users, consumers and the environment
- Hazard and risk evaluation for humans and relevant environmental compartments

Our services

All experimental services offered are conducted in compliance with international standards (e.g. OECD, ISO), taking into account also regulatory rules and guidelines of European authorities and agencies (e.g. ECHA, EFSA, EMA), with a focus on human health and the environment and, if required, under GLP conditions.

We offer characterization of nanomaterials and their agglomerates with regard to size (MMAD, hydrodynamic diameter) and surface of agglomerates (ζ potential) using standardized dispersion protocols. We have experience in optimization of hydrophobic nanoparticles in liquid dispersion in stock dispersions and during the test.

We closely cooperate with other Fraunhofer institutes (e.g. IST, ICT, IFAM, IPA, ISE, ISC, FEP) capable of developing nano-containing products for various applications and performing tailored characterization of specific nanomaterials.

Human health – in-vivo and in-vitro studies

Based on our broad expertise in inhalation toxicology and our special devices developed for particle and fiber aerosol generation, we can offer experimental setups fulfilling highest scientific demands.

Wide experimental experience with the nanocarbon family (carbon black, carbon nanotubes and graphenes) results from a considerable number of projects. For addressing the very high length/diameter aspect ratio and the low density, special equipment is available to assure high-quality aerosol generation.

We offer highly efficient aerosol generation systems for acute, subacute and subchronic inhalation tests. Carbon nanotubes are either aerosolized from highly dispersed liquid formulations or using an acoustic feeder system, the current state-of-the-art solution for dry dispersion. Specific expertise exists

in genotoxic assays with nanomaterials in optimized dispersion media. An air-liquid interface system is available to simulate physiological lung conditions. Cultivated epithelial cell lines can be exposed to well-defined aerosols.

Environmental safety – fate and effects

Using tests originally developed for chemicals and adapted for testing of nanomaterials, we investigate the fate of nanomaterials in soils, water and sediments, their impact on aquatic and terrestrial organisms and their fate and effect in sewage treatment plants.

Our strengths include performance of standard tests such as leaching in soil columns and ecotoxicological tests with algae, daphnids, fish, earthworms, plants, microorganisms, and sediment organisms. Beyond these approaches, we offer the use of further test organisms such as *Hyallela azteca*, which is able to ingest nanomaterials bound to organic matter, and application of more realistic and complex test systems such as model sewage treatment plants, aquatic microcosms and terrestrial lysimeters.

We provide specific investigation programs considering the whole life cycle of nanomaterials and potential transformations in the environment.

2 Carbon nanotubes (CNT), visualized by electron microscopy here, can be tested at the Fraunhofer ITEM for fiber-specific toxic effects.