



DHI SOLUTION

ECOTOXICOLOGY AND CHEMICAL SAFETY ASSESSMENT

Intelligent generation of data to save time and money

ENVIRONMENTALLY SAFE? – MEET THE REGULATION

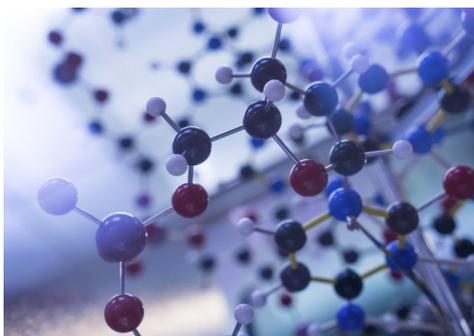
A number of regulations require ecotoxicological testing in order to fulfil the need for documentation. Requirements for documentation of environmental safety exist, including in OSPAR, in the European REACH regulation and the Biocidal Product Directive (BPR). United States Food and Drug Administration (FDA) and European Medicines Agency (EMA) regulations also require ecotoxicological testing.

At DHI, we offer a wide range of standardised ecotoxicological tests and tailor-made studies to generate the data to meet the documentation needs of the relevant regulation. Existing data from published studies as well as data from non-testing methods should be used to the largest extent possible. Further laboratory studies will address substance properties which cannot be evaluated without new experimental data.

EFFICIENT DATA COLLECTION AND TESTING

We can assist manufacturers of chemical substances with an optimal approach to meet ecotoxicological information requirements including for example:

- efficient use of existing data and literature search
- use of non-test alternatives such as QSAR and read-across
- waiving of data requirements
- exposure based waiving
- new experimental studies in our ecotoxicology lab



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EXPERTISE AND FACILITIES

Our ecotoxicological laboratory staff carry out standardised and specialised tests concerning biodegradability, toxicity and bioaccumulation of chemical substances, products and complex mixtures.

Our laboratories are accredited according to ISO 17025 by the Danish Accreditation Fund (DANAK) in Denmark or Singapore Laboratory Accreditation Scheme (SINGLAS) in Singapore. Our European lab is also authorised to carry out studies

SUMMARY

CLIENT

Manufacturers and importers of chemicals

CHALLENGE

Meeting the requirements for documentation of an environmentally safe production, use and handling of chemical substances

SOLUTION

Identification and generation of data to support information on substance properties required by relevant regulations

VALUE

- Provides support with a focused and effective testing strategy
- Minimises test requirements
- Decrease the amount of testing on animals
- Lowers expenses and shorter test cycles
- Uses alternatives to tests (QSAR and read-across)
- Ensures compliance with REACH
- Ensures compliance with the OECD Principles of Good Laboratory Practice (GLP)

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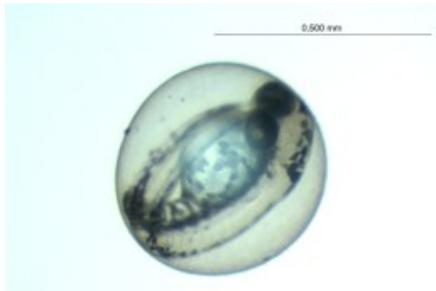
A close collaboration with other laboratories will support tests on physico-chemical properties and toxicology. Moreover, we can serve as the project manager of joint studies in collaboration with sub-contractors.

CHEMICALS TESTING

Our environmental laboratories offer a wide range of base set and higher tier tests required by chemicals regulation such as Globally Harmonised System of Classification and Labelling of Chemicals (GHS) and REACH (listed in Annex VII-X, for example). Additionally, we are trained in conducting tailor-made studies designed to suit any special needs of our clients.

For REACH, the extent of the test requirements relates to the yearly tonnage of substance manufactured or imported by the European Member States. To meet requirements according to your future plans on the market it is useful to review your test strategy in order to maximise the output of test data.

EFFICIENT TESTING OF CHEMICALS USING NEW ENVIRONMENTAL STUDIES AND QSAR



Zebra fish (Danio rerio) embryo 48h after fertilisation

European chemical legislation approaches the desire to reduce the use of animal testing, opening the opportunity to conduct alternative tests in the laboratory.

We have developed considerable experience conducting these alternative test methods, which are both time- and cost-efficient. Please see below for a number of examples that address this need.

THE FISH EMBRYO TOXICITY TEST

- The Fish Embryo Toxicity Test (OECD 236) is considered a promising alternative to the classical fish acute toxicity test (OECD 203)
- The test defines lethal effects of a chemical on embryonic stages of the Zebra fish (*Danio rerio*) after 96 hours of exposure
- The test has already been implemented as a mandatory component of whole effluent testing in Germany (DIN, 2001)

CALANOID COPEPOD EARLY-LIFE STAGE TEST WITH ACARTIA TONSA

- An early-life stage test on a very common marine planktonic crustacean, *Acartia tonsa*
- Starting with eggs, the method investigates the hatching and development of the organism
- Exposure to different concentrations of the test substance for six days
- The method is well-suited for the testing of chemicals, effluents and complex mixtures
- We have been involved in developing the standard for this test (ISO/DIS 16778)



Acartia tonsa, a marine crustacean used in early-life stage testing

QUANTITATIVE STRUCTURE ACTIVITY RELATIONSHIP (QSAR)

Using QSAR models to fill in data gaps within ecotoxicity is a very cost-efficient and fast alternative to performing tests.

- Chemicals are grouped based on mechanism of action and/or structural similarity and existing experimental data of the grouped chemicals is used to fill the data gaps, for example via read-across and/or trend analysis
- Data on most of the regulatory end-points can be predicted
- QSAR predictions, especially the OECD QSAR Toolbox, are accepted by regulatory authorities (for example, REACH registration)
- The Toolbox can be used in parallel with IUCLID software for data exchange
- Indicates whether a chemical is included in national regulatory inventories or chemical categories



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For more information visit: www.tox.dhigroup.com