

Ecotoxicology and Environmental Fate Services

## Comprehensive services by SynTech Research Group

SynTech Research Group is a globally recognized Contract Research Organization providing services from Research to Registration.

Discover how our regulatory consultancy and GLP-compliant experimental studies can help you navigate the complex regulatory landscape and bring your substances and chemicals to the global market with confidence.

At SynTech Research Group, we specialize in top-tier consultancy and testing services across a wide range of sectors - including agrochemicals, biopesticides, biocides, industrial chemicals (REACH), and human and veterinary pharmaceuticals. With strategic locations across key regions, we are dedicated to helping your products meet regulatory requirements efficiently, effectively, and on time.



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#### Regulatory services for plant protection products, biocides and REACH

Our international team brings over 25 years of hands-on experience, including previous roles within regulatory authorities. We have been directly involved in numerous active substance approvals, renewals, and the ongoing support of established compounds and related product registrations.

We also have a dedicated team specializing in biologicals, with in-depth expertise in semiochemicals such as pheromones.

Across all areas, our expert teams work closely with evaluators - providing strategic guidance on emerging regulatory topics, EFSA tenders, IUCLID dossiers, OECD methods, and more.

#### Services provided include:

- Preparation, submission and defense of dossiers, including data gap analysis, expert statements, efficient exchange with Member States, study supervision.
- Expertise in higher-tier approaches and risk assessment for complex active substances such UVCBs, inorganics, and naturally derived substances, as well as industrial chemicals.
- Risk assessment approaches and study designs compliant with EU, US and national specific requirements.
- Modelling customized exposure scenarios, screening to optimize use conditions.

#### Regulatory services for pharmaceuticals

Our regulatory experts have over 20 years of experience in Pharmaceuticals in the environment through active participation in key research projects such as ERAPharm, iPiE, and PREMIER.

We have authored more than 40 scientific, peer-reviewed publications on various aspects of pharmaceuticals in the environment are (co)authored by our experts, demonstrating broad experience and scientific knowledge. In addition, test methods for the assessment of parasiticides on dung organisms were developed in our laboratory and standardized as OECD test guidelines.

#### The following services are provided:

- Data gap analysis, development of assessment strategy, literature search, evaluation of relevance & reliability of literature data.
- Performing GLP studies required for environmental risk assessment.
- Environmental risk assessment according to the current EMA guideline.

#### Ecotoxicity testing with aquatic and sediment-dwelling organisms

We offer an extensive range of ecotoxicity tests under GLP according to OECD, ISO and EPA guidelines using aquatic micro-organisms, cyanobacteria, algae, aquatic plants, crustaceans, insects, oligochaetes, and fish. Our test organisms are raised in-house under controlled, standardized conditions. With our significant contributions to the development and standardization of numerous international test guidelines, we are exceptionally prepared to tailor test designs or exposure scenarios to meet the specific requirements of each test substance or establish test systems using non-standard test species. Our study directors have between 7 and 25 years of experience in their roles.

Activated sludge respiration inhibition OECD 209

Freshwater algae and cyanobacteria OECD 201

Lemna, growth inhibition OECD 221

Myriophyllum spicatum toxicity OECD 238, 239

Water-sediment Glyceria maxima toxicity Ring-test protocol

Daphnia magna, acute test and reproduction OECD 202, 211

Ceriodaphnia cf. dubia, reproduction OECD 211, EPA-821-R-02-013

Chironomus sp., acute toxicity OECD 235

Acute toxicity in fish and fish embryos OECD 203, 236

Fish, early-life stage and juvenile growth OECD 210, 215

Sediment-water toxicity with *Chironomus riparius* OECD 218, 219, 233

Sediment-water toxicity with Lumbriculus variegatus OECD 225

Sediment-water toxicity with *Tubifex tubifex* ASTM E1706

Sediment-water toxicity with *Hyalella azteca*US EPA 600/R-99/064, OECD

225

Fish, short-term reproduction assay OECD 229

21-Day fish assay OECD 230

Fish, sexual development test OECD 234

Fish, partial life-cycle test OECD DRP 95

Analytical verification of actual test concentrations is crucial to robust ecotoxicity studies. We offer this essential service on various matrices, including water, sediment, and soil.

Our analytical services are available under GLP, including validation of analytical methods according to SANTE guidelines (e.g., SANTE/2020/12830). Raw analytical data are stored in our GLP archive.

#### **Ecotoxicity testing with soil and dung organisms**

We offer a comprehensive range of soil ecotoxicity tests with microorganisms, plants and invertebrates under GLP according to OECD, ISO and EPA guidelines. Our team has made significant contributions to the development and standardization of numerous international test guidelines. We frequently perform custom-designed studies with modified exposure scenarios or alternative test species. For the environmental risk assessment of veterinary medical products, particularly parasiticides, we perform laboratory tests with dung organisms in cattle dung, as well as other beetle species and sheep or horse dung. Additionally, we have extensive experience performing higher-tier tests (field studies) with dung organisms throughout Europe.

Soil microorganisms: nitrogen and carbon transformation OECD 216, 217

Terrestrial plants, seedling emergence and growth OECD 208; OCSPP 850.4100

Terrestrial plants, vegetative vigour OECD 227; OCSPP 850.4150

Terrestrial plants, early seedling growth toxicity test OCSPP 850.4230

Chronic toxicity in higher plants ISO 22030

Earthworms, acute and reproduction tests OECD 207, 222

Enchytraeid reproduction test OECD 220

Collembolla reproduction test OECD 232

Predatory mite reproduction test OECD 226

Avoidance tests with earthworms and collembolans ISO 17512-1 and -2

Dung beetles, laboratory tests OECD GD 122

Dung flies, laboratory tests OECD 228

Earthworm and soil micro-fauna field studies NF EN ISO 11268-3: 2015-11; ISO

23611-2: 2006-02

Dung organism field study

EMA/CVMP/ERA/409350/2010

(draft)



#### PBT screening and bioaccumulation testing

We are highly experienced in determining log Kow to screen for bioaccumulation potential as well as conducting bioaccumulation studies with aquatic, sediment-dwelling and soil organisms with radio-labelled and non-labelled test substances. All studies are conducted in compliance with GLP and adhere to national and international guidelines. Our expertise includes adapting test designs to meet specific scientific or regulatory needs.

| Determination octanol-partition coefficient           | OECD 107, 123 |
|---|---------------|
| Bioaccumulation in fish: aqueous and dietary exposure | OECD 305      |
| Hyalella azteca bioconcentration test (HYBIT)         | OECD 321      |
| Bioaccumulation in sediment-dwelling oligochaetes     | OECD 315      |
| Bioaccumulation in terrestrial <i>oligochaetes</i>    | OECD 317      |

#### **Ecotoxicity testing with non-target arthropods**

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We perform laboratory, extended laboratory, aged residues, semi-field and field studies on a wide range of non-target arthropod species under GLP according to OECD, ISO, EPPO and EPA guidelines. We can also perform custom-designed studies, e.g. with modified exposure scenarios or alternative test species. Field studies can be performed in all our global locations.

IODO/MDDO 0000, Marad Dalara 0040

| Aphid parasitoids                                       | IOBC/WPRS, 2000; Mead-Briggs, 2010     |
|---|--|
| Predatory mites   | IOBC/WPRS, 2000                        |
| Green lacewings   | IOBC/WPRS, 2000                        |
| Ladybirds   | IOBC/WPRS, 2000                        |
| Predatory hemipteran                                    | IOBC/WPRS, 2000                        |
| Rove and ground beetles                                 | IOBC/WPRS, 2000                        |
| Lycosid spiders   | IOBC/WPRS, 2000                        |
| Egg and whitefly parasitoids                            | IOBC/WPRS, 2000; EPPO 1/142            |
| Terrestrial mesocosm field study (arthropod full fauna) | IOBC/WPRS, 2000; De Jong et al. (2010) |

#### **Ecotoxicity testing with pollinators**

We provide complete pollinator ecotoxicity services under GLP according to OECD, EPPO, EFSA, CEB and EPA guidelines. The pollinator testing package includes acute and chronic laboratory tests, semi-field and field studies on adult and larvae of honeybees, bumble bees and solitary bees. Semi-field and field studies can be performed in all our global locations.

Honey bee adult acute oral and contact toxicity OECD 213, 214; OPPTS 850.3020

Honey bee adult acute contact toxicity (aged residues) OCSPP 850.3030

Honey bee adult 10-day chronic toxicity OECD 245

Honey bee larval 7-day acute toxicity OECD 237

Honey bee larval 8-day chronic toxicity OECD GD 239 modified

Honey bee larval 22-day chronic toxicity OECD GD 239

Bumble bee adult acute oral and contact toxicity OECD 246, 247

Solitary bee adult acute oral and contact toxicity ICPPR/OECD Ring Test, 2016, 2017

Residue study in bee matrices (tunnel or field) EFSA, 2023

Honey MRL study (tunnel or field) SANTE/11956/2016 rev.9

Honey bees higher tier side effect studies (tunnel or field)

EFSA, 2023; EPPO 170; OECD 75; CEB 170; Oomen et al., 1992

Analytical verification of actual test concentrations is also a need in pollinators studies. We provide this important part of our studies for various matrices (water, sucrose solution, royal jelly).

All analytical services can be offered under GLP conditions, including validation of analytical methods according to SANTE guidelines (e.g., SANTE/2020/12830).



#### E-fate field testing

We conduct terrestrial field dissipation (TFD) studies throughout the EU according to OECD and EPA guidelines. All analytical services can be offered under the conditions of GLP, including validation of analytical methods according to SANTE guidelines (e.g., SANTE/2020/12830). Analytical raw data are stored under GLP in our electronic archive. We also offer study monitoring services by our regulatory experts for these complex studies. TFD studies can also be performed at our global locations.

Terrestrial field dissipation study

OECD 232 / 82; OPPTS 835.6100

#### **Biosolutions Laboratory Services**

For testing microbial substances, we perform laboratory, extended laboratory, aged residues, semi-field and field studies on a wide range of non-target arthropod species under GLP according to OECD and EPA guidelines.

Ecotoxicity testing with non-target arthropods following guidelines OECD 67; PPTS 885.
 4000; OPPTS 885.4340

We provide complete pollinator ecotoxicity services under GLP according to OECD and EPA guidelines. Our pollinator testing package includes acute and chronic laboratory tests, semifield and field studies on adult and larvae of honeybees, bumble bees and solitary bees.

 Ecotoxicity testing with pollinators following guidelines OECD 67; OPPTS. OPPTS 885.4380

Our microbiological laboratory is experienced in performing analytical verification of actual test concentrations for microbial organisms for various matrices, such as water, sucrose solution, royal jelly. All analytical services can be offered under GLP conditions, including validation of analytical methods according to international guidelines, as e.g., SANTE/2020/12830; ISO 6887-1:2017; ISO 11133:2014; ISO 7218:2007.

#### **Microbiology Laboratory Services**

With our extensive microbiological expertise on different matrices and on specific microorganisms we conduct customized microbiocidal studies according to customers' demands and specifications.

#### We offer the following services:

- Microbiology lab validation and analytical determination, including quantification of the active ingredient content by colony forming units (CFU) count for ecotoxicology studies.
- GLP analysis of 5-batches using validated analytical methods for active ingredient content and impurities (microbial contaminants) to check product quality.
- Estimation of in vitro levels of susceptibility or resistance to antibiotics to determine Minimal Inhibitory Concentration calculation (MIC).
- Morphological characterization of colonies (phenotypes) under different growth conditions to determine growth characteristics.





# Research to Registration

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