eurofins | Regulatory Science Services

Proven track record

- Decades of experience in performing simple and complex physical chemistry, biodegradation, toxicology and ecotoxicolgical testing
- Established relationships with regulatory bodies

State of the art equipment

- Custom designed state of the art apparatus and equipment
- Unparalleled analytical support
- Modern laboratories equipped to the highest standards

Study design

- Excellent experience in consideration of difficult test substances (UVCBs)
- Customized study designs
- Understand ECHA decisions and will design studies to specifically answer request

Cost effective

- Consideration of reduction of vertebrate testing inherent in our approach

Studies conducted within the Eurofins network and via approved partners

Tests on Endocrine Disruption - *in vitro* (OECD CF Level 2)

- Androgen receptor binding assay (OPPTS 890.1150)
- Estrogen receptor binding assay (OECD 493 OPPTS 890.1250)
- Androgen receptor transcriptional activation assay (OECD 458)
- Estrogen receptor transcriptional activation assay (OPPTS 890.1300, OECD 455)
- Steroidogenesis assay (OPPTS 890.1550, OECD 456)
- Aromatase assay (OPPTS 890.1200)
- Thyroid disruption assays (e.g. thyroperoxidase inhibition, sodium idode uptake (NIS))

Tests on Endocrine Disruption - (OECD CF Level 3)

- Hershberger bioassay, rat (OECD 441, OPPTS 890.1400)
- Uterotrophic bioassay, rat (OECD 440, OPPTS 890.1600)
- Amphibian metamorphosis assay (AMA) (OECD TG 231)
- Fish short-term reproduction assay (FSTRA) (OECD TG 229)(b)
- 21-day fish assay (OECD TG 230)
- Androgenised female stickleback screen (AFSS) (GD 148)*
- Xenopus Eleutheroembryonic Thyroid Assay (XETA) OECD TG 248
- Juvenile Medaka Anti-Androgen Screening Assay (JMASA) (draft OECD GD)
- Short-Term Juvenile Hormone Activity Screening Assay Using Daphnia magna (OECD 253)

* Under development

Tests on Endocrine Disruption - assays providing ED related adverse effects data (OECD CF Level 4)

- Pubertal development and thyroid function in female rat (OPPTS 890.1450)
- Pubertal development and thyroid function in male rat (OPPTS 890.1500)
- Repeated dose 28-day (OECD 407) and 90 day studies (OECD 408)
- Prenatal developmental toxicity study (OECD TG 414)
- Combined chronic toxicity and carcinogenicity studies (OECD TG 451-3)
- Reproduction/developmental toxicity screening test (OECD TG 421)
- Combined repeated dose toxicity study with reproduction/ developmental toxicity screening test (OECD TG 422)
- Developmental neurotoxicity study (OECD TG 426)
- Subchronic dermal toxicity: 90-day study (OECD TG 411)
- Fish sexual development test (FSDT) (OECD TG 234)
- Larval amphibian growth & development assay (LAGDA) (OECD TG 241)
- Avian reproduction test (OECD TG 206)
- Fish early life stage (ELS) toxicity test (OECD TG 210)
- Chironomid toxicity test (OECD TG 218-219)(d)
- Daphnia magna reproduction test (OECD TG 211)
- Earthworm reproduction test (OECD TG 222)
- Enchytraeid reproduction test (OECD TG 220)(d)
- Sediment water Lumbriculus toxicity test using spiked sediment (OECD TG 225)
- Predatory mite reproduction test in soil (OECD TG 226)
- Collembolan reproduction test in soil (TG OECD 232)(d)

Tests on Endocrine Disruption - *in vivo* assays providing comprehensive data on ED endpoints over more extensive life cycle of the organism (OECD CF Level 5)

- Extended one-generation reproductive toxicity study (EOGRTS) (OECD TG 443)
- 2-Generation reproduction toxicity study (OECD TG 416)
- Fish lifecycle toxicity test (FLCTT) (US EPA TG OPPTS 850.1500)
- Medaka extended one-generation reproduction test (MEOGRT) (OECD TG 240)
- Avian Two-generation toxicity test in Japanese quail (ATGT) (US EPA TG OCSPP 890.2100/740-C-15-003)
- Sediment water chironomid life cycle toxicity test (OECD TG 233)
- Daphnia multigeneration test for assessment of endocrine disrupting chemicals (draft OECD TG)

Please get in touch via email if you can't see the test you are looking for - new capabilities are always in the pipeline.

Eurofins Regulatory Science Services

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One-stop service - world-class, worldwide

Endocrine Disruptor Assessment

Helping you fulfil the global regulatory requirements for assessment of potential endocrine disrupting substances.

An emerging area of concern, with impact on human and environmental health, is endocrine disruption, the potential for chemical substances and mixtures to affect the endocrine systems of mammalian, vertebrate and invertebrate species.

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Global requirements

The effects of certain substances and compounds which disrupt the actions of naturally occurring hormones have become a central point of focus for the scientific community and an area of concern for the wider public. Globally, endocrine disruptors are being tackled by authorities all over the world - discussions are taking place to establish the policies that will regulate the future of ED testing.

In recent years the potential impact of endocrine disruptors has been increasingly regulated on a global scale with a variety of legislative implementations such as one of the first extensive endocrine screening programs, namely the US Endocrine Disruptor Screening Program (EDSP), with specific regulatory triggers highlighted in the Food Quality Protection Act (FQPA) in 1996.

More recently European legislation has come into force which specifically mandates that potential disruption of mammalian and non-mammalian endocrine systems need to be considered.

In response to these concerns, we have been at the forefront of developing specific tests to address the questions that concern the chemical industry, government and non-government organisations and the wider public; Eurofins is the go-to Contract Research Organisation for complex multigenerational and long term studies with vertebrates and invertebrates.

We are ready to support your risk assessment, performing endocrine testing to characterize the endocrine effects of your product

Our offer

Eurofins Regulatory Science Services is in full compliance with the latest OECD guidelines. We offer a variety of endocrine disruption studies ranging from physical chemical data to *in vitro* testing through to complex multi-generational and long-term studies with vertebrates and invertebrates. With a network of laboratories across the globe, we have a team of experts ready to confirm and characterize the endocrine effects of your product.

Example testing strategy and considerations - Fish Short Term Reproduction Assay - OECD 229

1 — *In vitro* Testing or lack of data initiates request for study

Regulatory authority and/or submitter indicates requirements for Endocrine Disruptor assessment

2 — Species selection

Fathead minnow, Japanese medaka and Zebrafish are fully validated for this guideline. Regulatory preference should be considered such as US EPA preference for fathead minnow

3 — Chemical Analysis

Consider analytical methods in water at relevant concentrations. A method will need to be developed and validated at test dose concentrations. Also need to consider stability of samples prior to analytics

4 — Preliminary work

Solubility and stability trials in flow-through testing systems is a key part of the study, as well as very early analytical method development especially with difficult substances

5 — Physical chemical parameters of substance

Water solubility, abiotic degradation (hydrolysis) profile and other parameters play a key part in the study design. Both organic solvents and saturator columns available to dissolve test substances as required

6 — Range finding studies

Range finding to determine Maximum Tolerated Concentration (MTC). Aim is to produce minimum classical toxic effect but ensure potential endocrine disruption is properly investigated

7 — FSTRA

Execution of the test using in house fish cultures, high precision flow-through systems and swift chemical analysis for control and verification of chemical exposure

8 — Weight of evidence assemblage

EATS modalities information from historical data, literature reviews and *in vitro* data studies already completed. Assemble lines of evidence for adverse effects and endocrine activity

Consider Timelines

When agreeing to study schedules with Regulatory Authorities and your CRO, take into account that a FSTRA study normally takes 10 months from contract signature to final report - it's important to take into account the test substance supply chain.