

Substances characterization & (eco)toxicity **(according to REACH, CLP, BPR, CPR, PPP)**

Because you care about consumers' health



Mérieux NutriSciences group offers a complete package of analytical services suitable for the identification and (eco)toxicological evaluation of substances subjected to authorization and/or registration according to international regulation as REACH, Biocidal Products, Cosmetics Products and Plant Protection Products Regulations.

Specific physico-chemical or (eco)toxicological studies could be performed in order to define the correct Classification & Labeling of substances and mixtures according to CLP Regulation or GHS criteria.



Substances Identity & Physico-Chemical Properties

Accurate identification of substances and sameness verification are prerequisites for the registration process of many substances according to international regulations. Mérieux NutriSciences can support its customers in the full characterization of well-defined substances and UVCB substances applying an integrated testing strategy approach thanks to the availability of several analytical techniques in the same laboratory.

The assessment of physical hazards of substances and mixtures is performed in compliance with Good Laboratory Practice (GLP) and worldwide recognized quality standards.

Spectral data

- UV/Vis Spectra
- FT-IR Spectra
- NMR Spectra
- MS/HRMS Spectra
- XRPD Spectra

Other identifiers

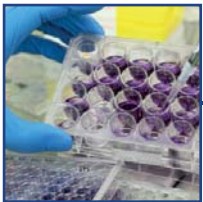
- XRF Spectra
- GC Profile
- HPLC Profile
- ICP Spectra
- Aminogram
- Enantioselective Chromatography
- Enzymatic Activity
- Physico-chemical properties

Physico-chemical properties

- Melting/freezing point
- Boiling point
- Relative density
- Vapour pressure
- Surface tension
- Hydrosolubility
- Partition coefficient (log Kow)
- Flashpoint
- Flammability
- Self-ignition temperature
- Granulometry

Analytical techniques for spectral & compositional characterisation of substances

Spectral Analysis SPFT, SPFL, XRD, MS, FTIR, NIR, TOF, NMR	Elemental Analysis ICP-MS, ICP-OES, XRF, AAS, SEM-EDX	Mass Spectrometry LCI-MS/MS, LC-Q/TOF, LC-ESI/TOF, GC-MS, LC-Orbitrap, GC-MS/MS, GC-HRMS
Liquid Chromatography HPLC-DAD, HPLC-ELSD, HPLC-RID, IEX, IC, SEC/GPC, Amino Analyzer	Gas Chromatography GC-FID, GC-ECD, HS-GC, Chiral GC	Other Separative Techniques TLC, SDS-PAGE, EC
Titrimetry Acid-base, Colorimetric, Complexometric, Potentiometric, Redox, K-F	Morphology Optical Microscopy, SEM, Laser Granulometry, Sieve Granulometry, DLS	Other Techniques DSC, TOC, TGA, Polarimetry, Refractometry



Toxicology



Mérieux NutriSciences can assess the potential health hazards of chemicals in accordance with good laboratory practices (GLP) and all worldwide quality and safety standards.

***In Vitro/Ex Vivo* tests**

Skin Irritation/Corrosion Test

- Skin Irritation: Reconstructed Human Epidermis Test Method (OECD 439)
- Dermal Irritation: Dermal Irritection® Assay System (DB-ALM 157 - OECD Accepted)
- Skin Corrosion: Human Skin Model Test (OECD 431)
- Corrositex: Corrositex® Kit (OECD 435)

Skin Sensitization

- Direct Peptide Reactivity Assay (DPRA) (OECD 442 C)
- Keratinsens™ - ARE-Nrf2 Luciferase Test Method (OECD 442D)
- Human Cell Line Activation Test (hCLAT) (OECD 442E)
- U937 Skin Sensitization Test (U-SENS™) (OECD draft 2016)

Eye Irritation Test

- Eye Irritation STE Test (OECD 491)
- Eye Irritation on Reconstructed Human Corneal Epithelia (OECD 492)
- Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants (OECD 437)
- Isolated Chicken Eye Test Method for Identifying Ocular Corrosives and Severe Irritants (OECD 438)
- Ocular Irritation: Ocular Irritection® Assay System (DB-ALM 157 - OECD Accepted)

Dermal Absorption

- Skin Absorption (OECD 428)

Phototoxicity Test

- *In Vitro* 3T3 NRU Phototoxicity Test (OECD 432)

Mutagenicity Studies

- *In Vitro* Mammalian Cell Micronucleus Test (OECD 487)
- *In Vitro* Mammalian Cell Gene Mutation Tests Using the Thymidine Kinase Gene (MLA) (OECD 490)
- Bacterial Reverse Mutation Test (Ames Test) (OECD 471)

***In Vivo* tests**

Skin Irritation/Corrosion Test: Skin Sensitization

- Skin Sensitization (OECD 406) - Guinea Pig Maximization Test (GPMT) (OECD 406)
- Skin Sensitization - Local Lymph Node Assay (LLNA) (OECD 429)

Acute toxicity

- Acute Inhalation Toxicity (OECD 403)
- Acute Dermal Toxicity (OECD 402)
- Acute Dermal Irritation/Corrosion (OECD 404)
- Acute Eye Irritation/Corrosion (OECD 405)
- Acute Oral Toxicity - Acute Toxic Class Method (OECD 423)
- Acute Oral Toxicity: Up-and-Down (OECD 425)
- U937 Skin Sensitization Test (U-SENS™) (OECD draft 2016)

Mutagenicity Studies

- *In Vivo* Mammalian Erythrocyte Micronucleus Test (OECD 474)





Endocrine Disruption Testing

The advantage of an *In Vivo* test at an *In Vitro* scale

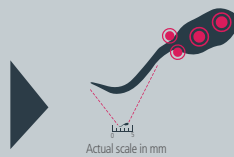
Mérieux NutriSciences can offer an innovative and alternative approach to OECD Test Guidelines, based on the use of larvae at early stages for demonstrating effects on living organisms whilst keeping an ethical approach. This new detection method designed to identify and measure potential effects of endocrine disruptors in a **wide range of ingredients, products and packaging** to simplify regulatory approval.



CHARACTERISTICS OF THE METHOD	ESTROGENIC EFFECT		THYROID EFFECT		ANDROGENIC EFFECT	
	Estrogenic disruptor identification test	Mechanistic characterization of the estrogenic disruptive potential	Thyroid disruptor identification test	Mechanistic characterization of the thyroid disruptive potential	Androgenic disruptor identification test	Mechanistic characterization of the androgenic disruptive potential
Level of characterization						
Availability of results	15 days	1 month	15 days	1 month	15 days	1 month
TEST FEATURES						
Absence of false positive	✓	✓	✓	✓	✓	✓
Hormone equivalent	✓	✓	✓	✓	✓	✓
Results interpreted in accordance with OECD criteria	✓	✓	✓	✓	✓	✓
Elucidation of disruption mechanism		✓		✓		✓
Data contributing to risk assessment		✓		✓		✓
Data required for scientific publication		✓		✓		✓
Data to support substance replacement strategy		✓		✓		✓
REFERENCES FOR ASSESSED CRITERIA	OECD TEST GUIDELINE 229/230		OECD TEST GUIDELINE 231		OECD GUIDANCE DOCUMENT No.148	

A validated alternative to laboratory animal testing

All of tests use larvae and fry at "post-egg" stages (D0 to D8) which are prior to developmental stages considered as laboratory animals.



THE SENTINELS:
fish fry and tadpoles
possessing **FLUORESCENT BIOMARKERS**

AN EXPOSURE TO SUBSTANCES OR MIXTURES OF SUBSTANCES, EVEN AT LOW DOSES, CAN HAVE SIGNIFICANT CONSEQUENCES ON LIVING ORGANISMS.

An example of a known consequence of exposure is a modification to the sexual characteristics of animals. Until now, in order to demonstrate this, it has been necessary to expose laboratory animals until their sexual maturity.



Ecotoxicology & Environmental Fate

Mérieux NutriSciences offers a comprehensive range of GLP compliant testing services to assess the environmental hazards of products, provided in compliance with worldwide recognized quality standards.

Aquatic Toxicity

- Short-term toxicity testing on invertebrates (Daphnia Magna) (OECD 202)
- Growth inhibition study on aquatic plants (algae) (OECD 201)
- Short-term toxicity testing on fish (OECD 203)
- Activated sludge respiration inhibition test (OECD 209)
- Long-term toxicity testing on invertebrates (OECD 211)
- Juvenile growth test on fish (OECD 215)
- Bioaccumulation in aquatic species, preferably fish (OECD 305)

Effects on Terrestrial Organisms

- Earthworm acute toxicity test (OECD 207)
- Earthworm reproduction test (OECD 222)
- Soil microorganisms - Nitrogen test (OECD 216)
- Soil microorganisms - Carbon test (OECD 217)
- Honeybees acute oral toxicity test (OECD 213)
- Honeybees acute contact toxicity test (OECD 214)
- Avian acute oral toxicity test (OECD 223)
- Avian dietary toxicity test (OECD 205)

Fate and Behaviour in the Environment

- Estimation of the adsorption coefficient (Koc) on soil and on sewage sludge using HPLC (OECD 121)
- Adsorption/desorption screening (OECD 106)
- Ready biodegradability (OECD 301)
- Inherent biodegradability (aerobic) (OECD 304)
- Anaerobic soil metabolism (OECD 307)
- Leaching in soil columns (OECD 312)





Consulting services

Mérieux NutriSciences is working with qualified partners to provide customers with a close partnerships and a complete range of regulatory and consulting services, thus creating a customized and seamless service.

Our services include:

- Information and training
- Regulatory consultancy
- Registration strategy
- Registration dossier

Mérieux NutriSciences can offer a specific focus for the following topics:

- CLP/SDS , Biocides, REACH, Pharmaceuticals
- extra-European regulatory assistance for USA, Canada, Mexico, Brazil, Argentina, Australia, New Zealand.

This expertise is available to issue specific customer requirements and the working group offer the best solution.

Top Level Accreditations and Certifications:

- Good Laboratory Practices (GLP) certificate granted by the Italian Ministry of Health
- Good Manufacturing Practices (GMP) certificate granted by AIFA (Italian Medicines Agency)
- US FDA registration as Testing Facility in compliance with cGMP requirements
- ISO/IEC 17025:2005 accreditation granted by Accredia (Italian Accreditation Body)
- ISO 9001:2008 certificate granted by Certiquality srl
- ISO 14001:2004 certificate granted by Certiquality srl

Mérieux NutriSciences offers its scientific excellence in chemical, biocide, cosmetic, food and pharmaceutical products' testing and consulting to ensure support, optimal reactivity and flexibility to its customers all over the world.

Mérieux NutriSciences

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