



# Biocidal Products Services

Because you care about consumers' health



# WHY MÉRIEUX NUTRISCIENCES?

*Mérieux NutriSciences is a multinational Corporation that provides a full range of analytical services and regulatory support to its clients around the world. Mérieux NutriSciences is the leader in chemical, biological and microbiological analysis and it is one of the leaders in the agrochemicals and biocides laboratory services.*

*Thanks to more than 40 years of experience and 6.000 employees in 80 laboratories, Mérieux NutriSciences supports biocides, agrochemicals and chemicals companies during the authorization process of their products.*

*We offer a complete range of regulatory and analytical services in compliance with ISO 17025 and GLP to support our clients in the authorization process of Active Substances or Biocidal Products, pursuant to the European Biocidal Products Regulation (BPR).*

## **B**IOCIDAL PRODUCTS REGULATION

The Biocidal Product Regulation Nr. 528/2012/EC:

- Concerns the placing on the market and use of biocidal products and treated articles, which are used to protect humans, animals, materials or articles against harmful organisms, like pests or bacteria, by the action of the active substances contained in the biocidal product;
- Establishes a list of active substances which may be used on biocidal products;
- Provides a mutual recognition of authorisation within Europe.

## **R**EGULATORY SUPPORT

In collaboration with qualified partners, Mérieux NutriSciences assists your company during the registration of an active substance and/or biocidal product offering a tailor-made regulatory support.

### Our services include:

- Communication with regulatory authorities
- Advice on regulatory requirements
- Testing strategy evaluation
- Human and environmental risk assessment
- Exposure assessment
- Dossier preparation



# PHYSICO CHEMICAL TESTS

Mérieux NutriSciences performs a whole set of tests suitable for the evaluation of physical, chemical and technical properties of Active Substances and Biocide Products. All the tests are performed in compliance with official (e.g. CIPAC, OECD, etc.) or in-house validated methods.

- GLP 5 Batch Analysis (5BA) & Technical Equivalence studies on Active Substances
- Analytical methods set-up and validation
- **Physical and chemical properties:**
  - Spectral data (UV/Vis, IR, NMR, MS/HRMS, XRD, SEM-EDX)
  - Appearance & seepage data
  - Acidity/Alkalinity
  - Relative Density and Bulk Density
  - Physical and Chemical Compatibility with other products
  - Surface tension
  - Viscosity
  - Melting, freezing, boiling point
  - Solubility in water and organic solvents
  - Partition coefficient
  - Dissociation constant
- **Physical Hazards:**
  - Flash point
  - Flammability of solids
  - Corrosivity to metals
- **Technical properties of Biocidal Products:**
  - Wettability
  - Suspensibility, spontaneity and dispersion stability
  - Wet & dry sieve analysis
  - Emulsifiability, re-emulsifiability and emulsion stability
  - Disintegration time
  - Particle size distribution, friability
  - Flowability, pourability, dustability
  - Burning rate and completeness
  - Degree of dissolution and dilution stability
  - Technical properties of aerosols

# STABILITY

Stability studies following different guidelines such as CIPAC or ICH are performed to evaluate the effects of temperatures, relative humidity and light on active substances and biocidal products and their containers. All conditions are continually monitored with a validated software ensuring a totally secure and controlled environment. Accesses, alarms and changes are under audit trail and electronic signature.

The following storage conditions can be applied:

- Long-term, accelerated and intermediate conditions according to ICH requirements
- Accelerate conditions according to CIPAC MT 46.3
- Low temperature according to CIPAC MT 39.3
- Photostability according to ICH Q1B Options 1 & 2



# EFFECTIVENESS AGAINST TARGET ORGANISMS

Efficacy studies against microorganisms and viruses on Biocidal Products belonging to Product Types 1-5 are performed according to international standards (e.g. EN, ISO, ASTM, AOAC, SANS). Tests are performed on formulated products, treated materials (e.g. polymers, textiles) and disinfection devices/equipments.

Efficacy tests against insects are provided in collaboration with qualified partners.

We support our clients in the definition of the proper testing strategy for the substantiation of the efficacy claims of the products.

- Efficacy tests against target microorganisms:
  - Virucidal activity
  - Bactericidal activity
  - Fungicidal activity (molds and yeasts)
  - Mycobactericidal activity
  - Sporicidal activity
  - Legionellicide activity
  - Bacteriocidal and phagocidal activity
  - Microbicidal activity of treated materials (e.g. polymers and textiles)



- Efficacy tests against insects:
  - Insecticidal activity
  - Insects repellent activity

Target insects: Cockroaches, Ants, Mosquitos, Flies, Wasps, Mites, Ticks, Fleas, Louses, etc.

Other specific efficacy tests can be performed or customized in function of the product/application considered.

# TOXICOLOGICAL & ECOTOXICOLOGICAL STUDIES

Toxicological and Ecotoxicological studies are performed according to Good Laboratory Practice.

- Toxicological Studies:
  - Skin Irritation
  - Skin Corrosion
  - Eye Irritation
  - Skin sensitization
  - Mutagenicity
    - Ames test
    - Micronucleus Assay
    - Mammalian Cell Gene Mutation assay (MLA)
- Ecotoxicological studies:
  - Growth inhibition study on algae
  - Short term toxicity testing on *Daphnia Magna*
  - Short term toxicity testing on fishes
  - Long term toxicity testings
  - Bioaccumulation in aquatic or terrestrial organisms
- Environmental Fate and Behaviour:
  - Adsorption/desorption studies
  - Identification of metabolites and degradation products



## COMPATIBILITY TESTS

Compatibility tests on disinfectants and cleaning agents are performed according to official standards (e.g. EN ISO 21530, EN ISO 11981, NF S94-402-1, ASTM D543, etc.) in order to evaluate the physico-chemical resistance of specific materials and articles (e.g. medical devices) in contact with the test product.

The final visual evaluation can be integrated with an physico-chemical instrumental verification on the treated material. For example:

- Morphological and chemical modification by means of SEM-EDX (performed on the sample as is without metal coating)
- Reological properties modification by means of physico-mechanical tests (traction, tearing, impact, etc.)

## EQUIPMENTS

A non exhaustive list of the analytical techniques applied by Mérieux NutriSciences for active substances and biocidal products testings is reported below:

Atomic Absorption Spectroscopy (AA-FIAS)

Atomic Absorption Spectroscopy (AA-Flame)

Atomic Absorption Spectroscopy (AA-GF)

Cell Culture Techniques

Densimetry

Differential Scanning Calorimetry (DSC)

FT-IR Spectroscopy

Gas Chromatography (GC-FID)

Gas Chromatography (Head-Space)

Granulometry (Analytical Sieving) (microscale)

Granulometry (Dynamic Light Scattering) (nanoscale)

Granulometry (Laser Light Diffraction) (microscale)

Gravimetry

ICP Atomic Emission Spectroscopy (ICP-OES)

ICP Atomic Mass Spectroscopy (ICP-MS)

Ionic Chromatography (ED)

Ionic Chromatography (PAD)

Liquid Chromatography (HPLC-UV/DAD)

Liquid Chromatography (HPLC-ELSD)

Liquid Chromatography (HPLC-RID)

Mass Spectrometry (GC-MS & GC-MS/MS)

Mass Spectrometry (MALDI-TOF/TOF)

Mass Spectrometry (LC-MS/MS)

Mass Spectrometry (LC-Q/ORBITRAP)

Microscopy (Optical)

Microscopy (SEM-EDX)

pH-metry

Polarimetry

Reology (traction, tearing, impact, etc.)

Rifractometry

Spectrofluorimetry

Spectrophotometry (UV-Visible)

Tensiometry

Thin Layer Chromatography (TLC)

Titrimetry

TOC

Viscosimetry (capillary)

Viscosimetry (rotational)

Water Determination (coulometric, micro)

Water Determination (K-F, semi-micro)



*A worldwide presence*



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