**TOXIKON AT A GLANCE**

**Services**
- In Vivo
- In Vitro
- Acute/Subchronic/Chronic Toxicology
- Irritation
- Cytotoxicity
- Genotoxicity

**Capabilities**
- In Vivo
- In Vitro
- Acute/Subchronic/Chronic Toxicology
- Irritation
- Cytotoxicity
- Genotoxicity

**Locations:**
**Corporate Headquarters**
Toxikon Corporation
15 Wiggins Avenue
Bedford, MA 01730
USA
800.458.4141
info@toxikon.com
www.toxikon.com

**Toxikon Europe N.V.**
Romeinsestraat 12
B-3001 Leuven
Belgium
+32-16-400484
info@toxikon.be
www.toxikon.be

---

**Biocompatibility Assessment Overview**

**Acute Systemic Toxicity**
- Material mediated pyrogenicity in rabbits
- Systemic injection

**Subacute/Subchronic/Chronic Toxicity**
- 14, 28, 90 day
- Range finding, recovery groups
- Dose routes: IV, IP, IM, subcutaneous, dermal, oral and nasal
- Customized studies
- Single dose, repeat dose or continuous infusion
- Chronic studies in rodents/dogs

**In Vivo Mutagenicity / Genotoxicity**
- Chromosomal aberration
- Mouse micronucleus (blood/bone marrow)
- COMET assay

**Animal Models**
- Mouse, hamster, gerbil, rat, guinea pig, ferret, rabbit, cat, dog, swine, sheep and goat

**In Vivo Laboratory Support**
- Analytical chemistry
- Clinical chemistry
- Hematology
- Histopathology
- Radiography
- Surgical research
- Microbiology
- Micro surgery
- Carcinogenicity
- 6 month transgenic mouse model
- 2 year carcinogenicity rodents
- 2 year toxicity/carcinogenicity rodents
- 18 month carcinogenicity rodents

**Toxicokinetics / Metabolism**
- Elucidation of metabolic pathway
- Single / multiple dose

**Reproductive Toxicity**
- Multigeneration studies
- Developmental toxicology

**Irritation**
- Bladder
- Dermal
- Intracutaneous
- Nasal
- Ocular
- Oral/mucosal
- Penile
- Rectal
- Vaginal
- Vascular

**Implants**
- Bone
- Brain
- Custom implants
- Dental
- Dermal
- Intraperitoneal
- Muscle
- Ocular
- Subcutaneous
- Vascular

**Cytotoxicity**
- Agar overlay
- Clonal assay
- Direct contact
- Inhibition of cell growth assay
- MEM elution
- MTT, NRU, XTT

**In Vitro Mutagenicity / Genotoxicity**
- Ames assays-salmonella and E. coli
- Cell transformation in BALB/c-3T3 cells

www.toxikon.com
Services at a Glance

Toxikon is an ISO/IEC 17025-accredited Contract Research Organization (CRO) registered with the FDA for drug, biologic, and medical device testing. With approximately 200 employees, Toxikon is committed to staying at the forefront of life science product development. Toxikon's safety services include toxicology (acute, subchronic, and chronic toxicity, reproductive toxicity, genetic toxicology, carcinogenicity), pharmacokinetics, toxicokinetics, bioavailability, ADME, chemical characterization, impurities analysis and synthesis, bioanalysis, and microbiology. Additionally, full IND/NDA enabling studies are performed with a multidisciplinary approach to program management. Toxikon’s extensive certifications and licenses allow it to meet international regulatory requirements for data acceptability and harmonization.

To meet all applicable international GxP requirements, Toxikon’s facilities are fully registered with FDA and USDA, and accredited with the Association for the Assessment and Accreditation of Laboratory and Animal Care International (AAALAC), and the International Organization for Standardization (ISO). Toxikon also has assurance with the National Institutes of Health so federally funded work can be performed at our facilities in compliance with NIH's Public Health Service Policy on Human Care and Use of Laboratory Animals (PHS Policy).

In Vitro Mutagenicity / Genotoxicity
- CHO/chromosomal aberration assay
- CHO/HGPRT gene mutation assay
- CHO/sister chromatid exchange
- Chromosomal aberration in human lymphocytes
- Rat lymphocyte cytogenetic assay
- SCE assay in human lymphocytes
- UDS assay in primary rat hepatocytes

Chemistry Services
- Material characterization
- Physicochemical and other compendia analysis
- Extractables and leachables
- Degradation profile
- Metals analysis, including biological matrices
- Residual analysis
- Particulate analysis

Microbiology Support
- Antimicrobial effectiveness
- Endotoxin testing

Sterility-direct transfer, membrane filter, package integrity and penetration
- Total bioburden – AAMI, ISO

Sensitization
- Buehler sensitization
- Kligman maximization
- Murine local lymph node assay

Enhanced
- ISO Class 7 (Class 10,000) sterility suites
- Continuous IV infusion studies
- In vivo efficacy testing
- Surgical suites
- Reusable device processing
- Virology

Special Services
- Customized studies
- Neurotoxicity
- Pharmacokinetics/Toxicokinetics
- Reproductive toxicity and teratology
- Specialized surgical procedures
- Wound healing

Regulatory and Technical Capabilities
- FDA, ISO, EMEA, MHLW, WHO

Biocompatibility Assessment Overview

**In Vitro Mutagenicity / Genotoxicity**

- PT assay
- Thrombogenicity assay in dogs
- UPTT assay

Chemistry Services

- Material characterization
- Physicochemical and other compendia analysis
- Extractables and leachables
- Degradation profile
- Metals analysis, including biological matrices
- Residual analysis
- Particulate analysis

Sensitization

- Buehler sensitization
- Kligman maximization
- Murine local lymph node assay

Enhanced

- ISO Class 7 (Class 10,000) sterility suites
- Continuous IV infusion studies
- In vivo efficacy testing
- Surgical suites
- Reusable device processing
- Virology

Special Services

- Customized studies
- Neurotoxicity
- Pharmacokinetics/Toxicokinetics
- Reproductive toxicity and teratology
- Specialized surgical procedures
- Wound healing

Regulatory and Technical Capabilities

- FDA, ISO, EMEA, MHLW, WHO

To learn more about Toxikon and our development capabilities, please visit us at www.toxikon.com

Toxikon Corp.
Midwest Regional Office
13911 Ridgedale Drive
Minneapolis, MN 55305
USA
800.425.4044
jay.mctaggart@toxikon.com

Toxikon India
21, Parmeshwar
353/20 R B Mehta Marg
Ghatkopar East
Mumbai 400 077
+91.22.67983604
rajiv.desai@toxikon.com

Toxikon Asia
Moriya Sangyo K.K.
3-36-7 Wada.Sugimani-Ku
Tokyo, Japan 166-0012
+011.813.5306.6267
sangyo@morisan.com

To learn more about Toxikon and our development capabilities, please visit us at www.toxikon.com