Maxxam
A Bureau Veritas Group Company

EMEA

Ecotoxicology services that help to assess the toxicity potential of effluent, sediment, soil and chemical substances.

Overview

Ecotoxicology testing is an essential tool for evaluating the effects of pharmaceuticals on the environment. Maxxam offers a variety of environmental testing services in support of data generation for various regulatory bodies.

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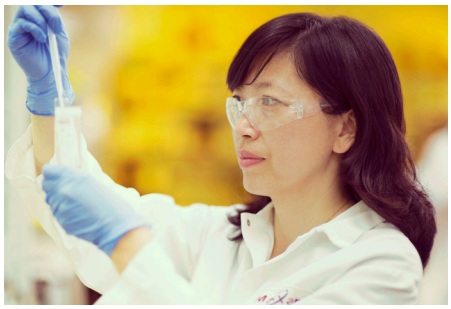
The European Medicines Agency (EMEA) is the European Union body responsible for coordinating the existing scientific resources by Member States for the evaluation, supervision and pharmacovigilance of medicinal products. In January, 2005, the EMEA published guidelines entitled The Environmental Risk Assessment of Medicinal Products for Human Use (London CHMP/SWP/4447/00 draft).

Maxxam is the only full-service environmental laboratory in Canada that provides Phase II (Tier A and B) physico- chemical, ecotoxicology and eco-fate testing tests required to meet EMEA risk assessment guidelines. Maxxam is recognized by the Standards Council of Canada as an OECD-GLP compliant laboratory.



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Maxxam can provide assistance with the data and test requirements specified in tables 1-3 below.

Table 1: The phased approach in environmental risk assessment

Stage in regulatory evaluation	Stage in risk assessment	Objective	Method	Test / Data Requirement
Phase I	Pre-screening	Estimation of exposure	Action limit	No test requirement
Phase II Tier A	Screening	Initial prediction of risk	Risk assessment	Base set aquatic toxicology and fate
Phase II Tier B	Primary	Standard approach to ensure consistent decision making	Risk assessment	Extended data set on emission, fate and effects
	Secondary	Substance and site specific refinement	Risk assessment	Case-by-case; alternative approaches; TGD approach

Table 2: Physico-chemical, fate and effects studies required in Phase II Tier A

Data Requirement/Test	Guideline to be used
n-Octanol/Water Partition Coefficient (Kow)	OECD 107 or 117
Adsorption - Desorption Using a Batch Equilibrium Method	OECD 106 or OECD 121 or OPPTS 835.1110
Aerobic and Anaerobic Transformation in Aquatic Sediment Systems	OECD 308
Algae, Growth Inhibition Test	OECD 201
Daphnia sp. Reproduction Test	OECD 211
Fish, Early Life Stage Test	OECD 210
Activated Sludge, Respiration Inhibition Test	OECD 209

Table 3: Tier B Terrestrial risk assessment studies

Data Requirement/Test	Guideline to be used
Aerobic and Anaerobic Transformation in Soil	OECD 307
Soil Microorganisms: Nitrogen Transformation Test	OECD 216
Terrestrial Plants, Growth Test	OECD 208
Earthworm, Acute Toxicity Tests	OECD 207
Collembola Reproduction	ISO 11267

*Guidelines are noted as per the EMEA's "Environmental Risk Assessment of Medicinal Products for Human Use" (London CHMP/SWP/4447/00 draft)

Maxxam is the Canadian market leader in analytical services and solutions to the energy, environmental, food and DNA industries and a member of the Bureau Veritas Group of companies – a world leader in testing, inspection and certification services. We support critical decisions made by our customers through the application of rigorous science and the knowledge and expertise of our over 2500 employees.

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