



Environmental Risk Assessment (ERA)

An Environmental Risk Assessment aims to identify potential risks to the environment following prescribed use of a medicinal product. Charles River has extensive experience in environmental risk assessments, including those for veterinary pharmaceuticals (Environmental Impact Assessment). Our track record includes numerous successful ERAs and EAs that were accepted by the EMA and FDA, including several for endocrine-active ingredients.

	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12	Month 13	Month 14	Month 15
Phase I															
Model calculations	•	•													
PBT screening	•	•													
Phase I ERA report	•	•	•												
Phase II Tier A															
Development and validation of an analytical method			•	•	•										
Water solubility (OECD 105)						•	•								
Dissociation constant in water (OECD 112)						•	•								
UV-VIS adsorption spectrum (OECD 101)						•									
Melting point (OECD 102)						•									
Vapour pressure (OECD 104)						•									
Octanol/water partition coefficient OECD (107/117/123)						•	•								
Synthesis of 14C labeled material			•	•	•										
Soil adsorption/desorption (OECD 106)						•	•	•	•						
Soil biodegradation (OECD 307)						•	•	•	•	•	•	•	•	•	
Aerobic degradation in water/sediment systems (OECD 308)						•	•	•	•	•	•	•	•		
Photolysis (OECD 316)						•	•	•	•	•					

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Abiotic degradation/hydrolysis (OECD 111)						•	•	•	•						
Terrestrial plants toxicity (OECD 208)			•	•	•										
Earthworm reproduction (OECD 222)			•	•	•	•	•								
Nitrogen transformation (OECD 216)*			•	•	•	•									
Algae study (OECD 201)						•	•	•							
Acute toxicity to Daphnia (OECD 202)						•	•	•							
Acute toxicity to fish (OECD 203)						•	•	•							
Toxicity to dung organisms (OECD 228, OECD GD 122)*			•	•	•	•									
Risk Assessment									•	•	•	•	•		
Phase II ERA report													•	•	•

- study requiring radiolabelled compound
- study requiring sample analyses
 - study without analyses
 - reporting
- optional
- * Subcontracted