Australian Government

Australian Pesticides and Veterinary Medicines Authority

Appendix B

Aquatic species

April 2020

Comments and enquiries regarding copyright:

Assistant Director, Communications
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001 Australia

Telephone: +61 2 6770 2300

Email: communications@apvma.gov.au.

This publication is available from the APVMA website.

CONTENTS

LIST OF TABLES

INTRODUCTION

The general protection goal is to protect biodiversity and ecosystems. The protection goal for aquatic species aims to protect aquatic plants and animals at the population level in surface water, and aquatic vertebrates at the individual level so that mortality and suffering due to acute toxicity is avoided.

USES THAT DON'T REQUIRE ASSESSMENT

If the product is used exclusively indoors (including glasshouses) and cannot reach surface by an indirect route (eg vegetable washings), then it is assumed aquatic organisms will not be exposed and assessment is not required. Veterinary medicine products that stop in the VICH phase I level of assessment do not require an assessment of risks to aquatic species.

TOXICITY DATA

Core data requirements:

- OECD guideline 203: Fish acute LC_{50}
- OECD guideline 210: Fish chronic NOEC or EC_{10}
- OECD guideline 202: Invertebrate acute EC_{50}
- OECD guideline 211: Invertebrate chronic NOEC or EC_{10}
- OECD guideline 201: Alga chronic E_rC_{50}
- OECD guideline 221: Macrophyte chronic EC_{50}

Insecticides and insect growth regulators

Data on an additional arthropod species are required for active constituents with an insecticidal mode of action (eg OECD guideline 235 or OCSPP 850.1035). *Chironomus* species are preferred for insect growth regulators. If Daphnia is an order of magnitude more sensitive than algae or fish, then a second arthropod species is also required since this might also indicate insecticidal activity.

Herbicides and plant growth regulators

Data on an additional algal species are required for active constituents with a herbicidal mode of action or plant growth regulators (OECD guideline 201). If *Lemna* is not sensitive or there is expected intake by the roots of submerged macrophytes, then data on an additional macrophyte species are required for herbicides and plant growth regulators (OECD guideline 229, 238 or 239).

Endocrine active substances

For active constituents that are identified as an endocrine active substances where the mode of action may be expected to impact fish sexual development and/or reproduction, fish development and/or reproduction assays are required (OECD guideline 230 or 234). Should the active constituent exhibit endocrine activity in any of these tests, then the fish full life cycle toxicity test is required (OECD guideline).

Sediment dwelling species

Data on sediment dwelling species are required if accumulation of the active constituent in sediment is indicated or is predicted from fate studies (ie if the water/sediment study showed >10 per cent of applied radioactivity in the sediment on day 14 or onwards) and the chronic NOEC or EC_{10} for *Daphnia* is <0.1 mg/L. *Chironomus* is recommended for insecticides and *Lumbriculus* is recommended for fungicides (OECD guideline 218, 219, 233 or 225).

Fish bioconcentration study

A log K_{ow} > 3 is used as a general trigger to require a fish bioconcentration study according to OECD 305. Where it can be justified that exposure leading to bioconcentration is not likely to occur, a study is not necessary. Where bioconcentration is not expected because a substance is not stable in water, the study is not required. Where the DT_{90} in the whole system is <10 days (as determined in a water-sediment study), a fish bioconcentration study is not necessary, unless the proposed use of the active substance includes multiple applications at intervals short enough to result in significant long-term exposure.

RISK ASSESSMENT

The major potential routes of exposure of aquatic species are considered to be spray drift or runoff from the treatment area. The acute and chronic risks to aquatic species are assessed using a tiered approach. Although the product is not applied to water, a screening level risk assessment assumes the worst-case scenario of a direct overspray of shallow aquatic habitat in order to identify those substances and associated uses that do not pose a risk to aquatic species. A regulatory acceptable concentration (RAC) for acute and chronic exposure scenarios is first calculated as indicated in Table B1.

Screening level assessment

A screening level assessment is undertaken considering direct application to a 3 m wide × 15 cm deep body of water (Table B2). When acceptable risks cannot be concluded at the screening level, spray drift and runoff risk assessments are conducted.

Spray drift assessment

A spray drift risk assessment is conducted on the lowest RAC when acceptable risks cannot be determined at the screening level. Please refer to APVMA spray drift policy for details.

Runoff assessment

A runoff risk assessment is conducted on the lowest RAC when acceptable risks cannot be determined at the screening level. Please refer to Attachments B1 and B2 for details on the methodology.

- Tier 1 (screening level): This is a worst-case assessment where slope is fixed at 8 per cent, which is considered protective of 95 per cent of agricultural activities in Australia. The rainfall value is set at 8 mm, which results in the maximum receiving water concentration using the standard water body of 1 ha and 15 cm initial depth when the clay dominated Queensland soil profile is used; the catchment is 10 ha. Further, for this worst-case scenario, a fallow/bare soil runoff profile is assessed.
- Tier 2 (state-specific): State-based soil profiles are considered such that composite runoff curves were developed for each state. Further, slopes in the growing regions are considered. This level of assessment maintains the standard water body (1 ha, 15 cm initial depth) and rainfall values are established as those that will result in the peak water concentration based on the runoff curve for each state.
- Tier 3 (in-stream analysis): Appropriate rainfall values are applied based on stream flow percentiles being assessed. The assessment is performed on both a spatial and temporal scale. Further, the assessment assumes that 20 per cent of the catchment is treated at the same time and all the treated area contributes to runoff. Consequently, the mean slope values are applied. Acceptable risks can be concluded if biodiversity is predicted to be protected in >90 per cent of receiving waters in the region.

RISK ASSESSMENT TABLES

Table B1: Regulatory acceptable concentrations for aquatic species

Group	Exposure	Endpoint	Assessment factor	RAC
Fish	Acute	LC_{50} XX mg ac/L	10	XX mg ac/L
	Chronic	NOEC XX mg ac/L	1	XX mg ac/L
Invertebrates	Acute	EC_{50} XX mg ac/L	10	XX mg ac/L
	Chronic	NOEC XX mg ac/L	1	XX mg ac/L
Sediment dwellers	Acute	LC_{50} XX mg ac/L	10	XX mg ac/L
	Chronic	NOEC XX mg ac/L	1	XX mg ac/L
Algae	Chronic	E_rC_{50} XX mg ac/L	10	XX mg ac/L
Aquatic plants	Chronic	EC_{50} XX mg ac/L	10	XX mg ac/L

RAC = regulatory acceptable concentration = endpoint/assessment factor.

Table B2: Screening level assessment of risks to aquatic species

Group	Exposure	Cumulative rate (g/ha)	PEC (mg/L)	RAC (mg/L)	RQ
Fish	Acute				
	Chronic				
Invertebrates	Acute				
	Chronic				
Sediment dwellers	Acute				
	Chronic				
Algae	Chronic				
Aquatic plants	Chronic				

Cumulative application rate is based on maximum single application rate, number of applications, interval between applications and water/sediment DT50 value.

PEC (water) = predicted environmental concentration in 15-cm water depth (mg/L) = cumulative rate (g/ha) / 1500.

*PEC (sediment) = predicted environmental concentration in sediment (mg/kg ds) = cumulative rate (g/ha) / 1500 * (0.8+(0.2*KP/1000*2400))/1280*1000.*

RAC = regulatory acceptable concentration from Table B1.

RQ = risk quotient = PEC/RAC, where acceptable RQ ≤1.

Table B3: Assessment of runoff risks to aquatic species—Tier 1 (screening level)

Parameter	Value
Cumulative rate (g/ha)	
Interception value—F_{int} (fraction)	
Soil DT_{50} (d)	
K_d (L/kg)	
Rainfall—P (mm)	8.00
Runoff—Q (mm)	1.34
$Cr_{soil\ surface}$ (fraction)	
slope factor—F1 (fraction)	0.26
Deposited fraction—F2 (fraction)	
Runoff (% applied)	
PEC (µg/L)	

Parameter	Value
RAC (µg/L)	
Risk quotient (fraction)	

Cumulative application rate is based on maximum single application rate, number of applications, interval between applications and soil DT50 value.
Interception value as for specific situation from EFSA 2014.
Rainfall P value is default for Tier 1.
Runoff Q value = (((-0.000196(rain^3))+(0.0232*(rain^2)))+(-0.00520*rain)); runoff curve for Queensland (clay dominated) soil profile.*
*Crsoil surface = EXP(-3*ln(2)/DT50soil)*(1/(1+KF).*
*Slope factor F1 = (0.02153 * slope + 0.001423 * slope2), where default screening level slope is 8%.*
Deposited fraction F2 = 1-(Fint / 2).
*Runoff (% applied) = Q/P * F1 * F2 * Crsoil surface * 0.5.*
*PEC = application rate * %runoff * 10/(1500+134).*
RAC = regulatory acceptable concentration from Table B1.
RQ = risk quotient = PEC/RAC, where acceptable RQ ≤1.

RISK MITIGATION AND LABELLING

All products required the following under the heading ‘PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT’.

- DO NOT contaminate wetlands or watercourses with this product or used containers.

If the lowest LD/EC_{50} value is between 1 and 10 mg ac/L, then the following statement applies:

- Toxic to aquatic life.

If the lowest LD/EC_{50} value is <1 mg ac/L, then the following statement applies:

- Very toxic to aquatic life.

If a runoff assessment was required, then the following statements apply under the heading ‘RESTRAINTS’.

- DO NOT apply if heavy rains or storms are forecast within three days
- DO NOT irrigate to the point of runoff for at least three days after application.

REFERENCES

EPHC (Environment Protection and Heritage Council), 2009. *Environmental risk assessment guidance manual for agricultural and veterinary chemicals*, ISBN 978-1-9221173-38-7, available at nepc.gov.au/resource/chemical-risk-assessment-guidance-manuals.

EFSA (European Food Safety Authority), 2013, *Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters*, EFSA Journal 12(7):3290, 268 pp. doi:10.2903/j.efsa.2013.3290, available at efsa.europa.eu/en/efsajournal.

EFSA (European Food Safety Authority), 2014, *EFSA guidance document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil*, EFSA Journal 12(5):3662, 37 pp. doi:10.2903/j.efsa.2014.3662, available at efsa.europa.eu/en/efsajournal.

CVMP/VICH (Committee for Medicinal Products for Veterinary Use/International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products), 2000, *Guideline on environmental impact assessment (EIAs) for veterinary medicinal products (VMPs)—Phase I*, VICH GL 6. CVMP/VICH/592/1998, available at ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500004394.pdf.