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Environmental Risk Assessments for Topical Antiseptic Ingredients: Chloroxylenol



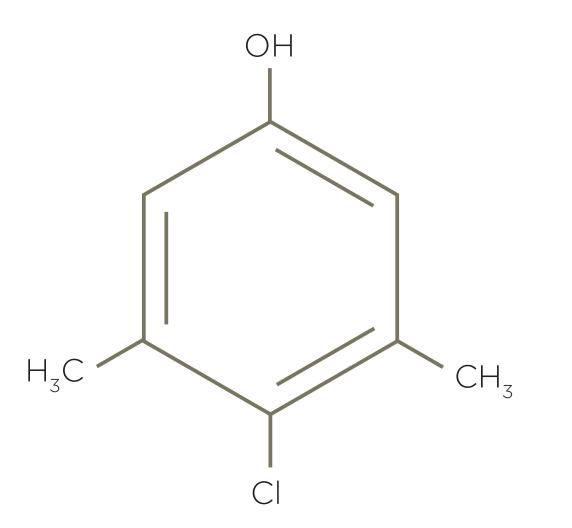
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INTRODUCTION

Since withdrawal of triclosan and triclocarban, chloroxylenol is one of several replacement compounds being used in topical antimicrobial products.

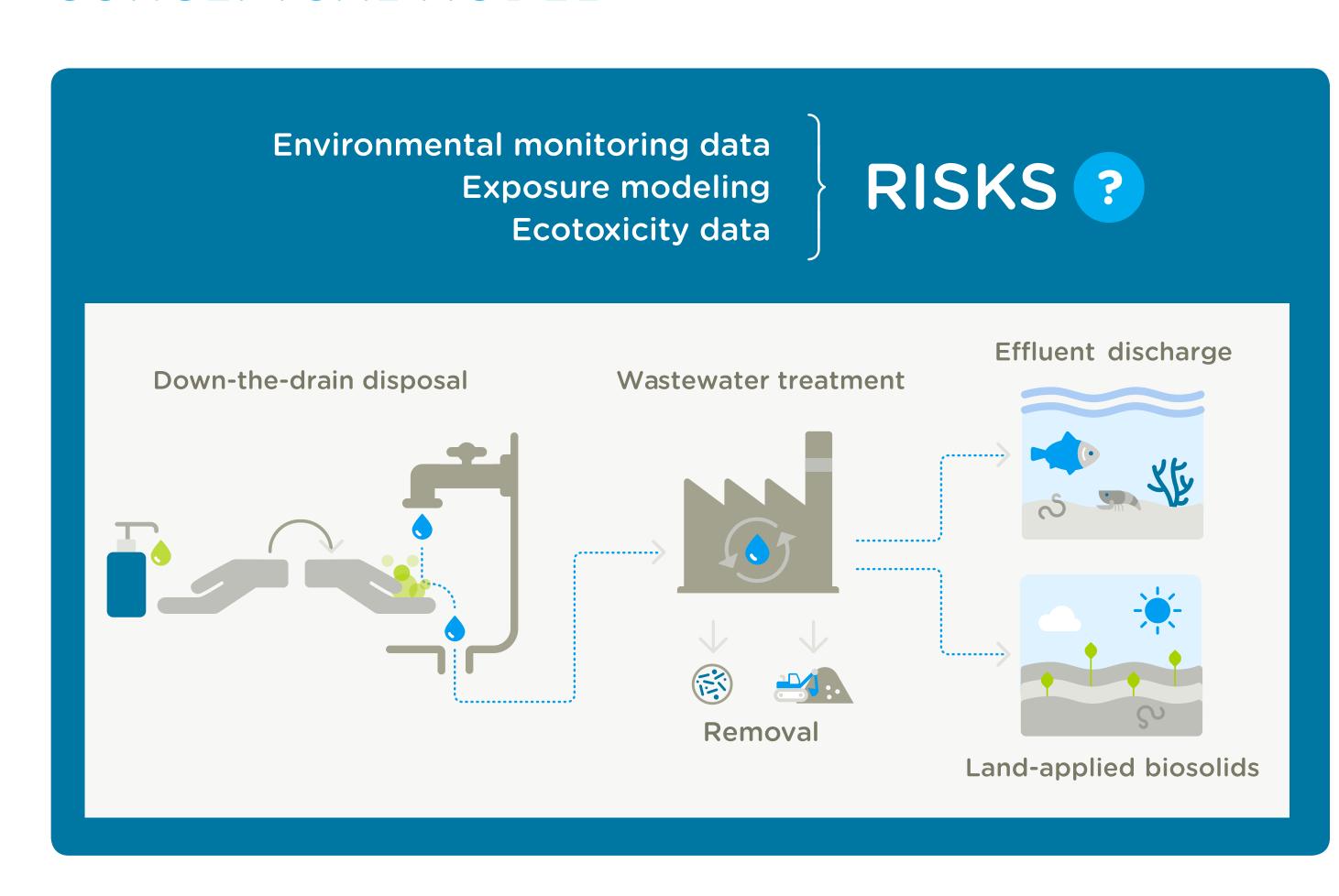
Chloroxylenol is a non-surfactant compound with a high pKa (9.21).



Objectives

- Identify and compile choloroxylenol occurrence, fate and effects data
- Develop hazard and risk profiles for surface water, sediment and soil for 2 scenarios:
- Recent past
- Future where chloroxylenol replaces triclosan use
- Identify uncertainties and options to refine assessment

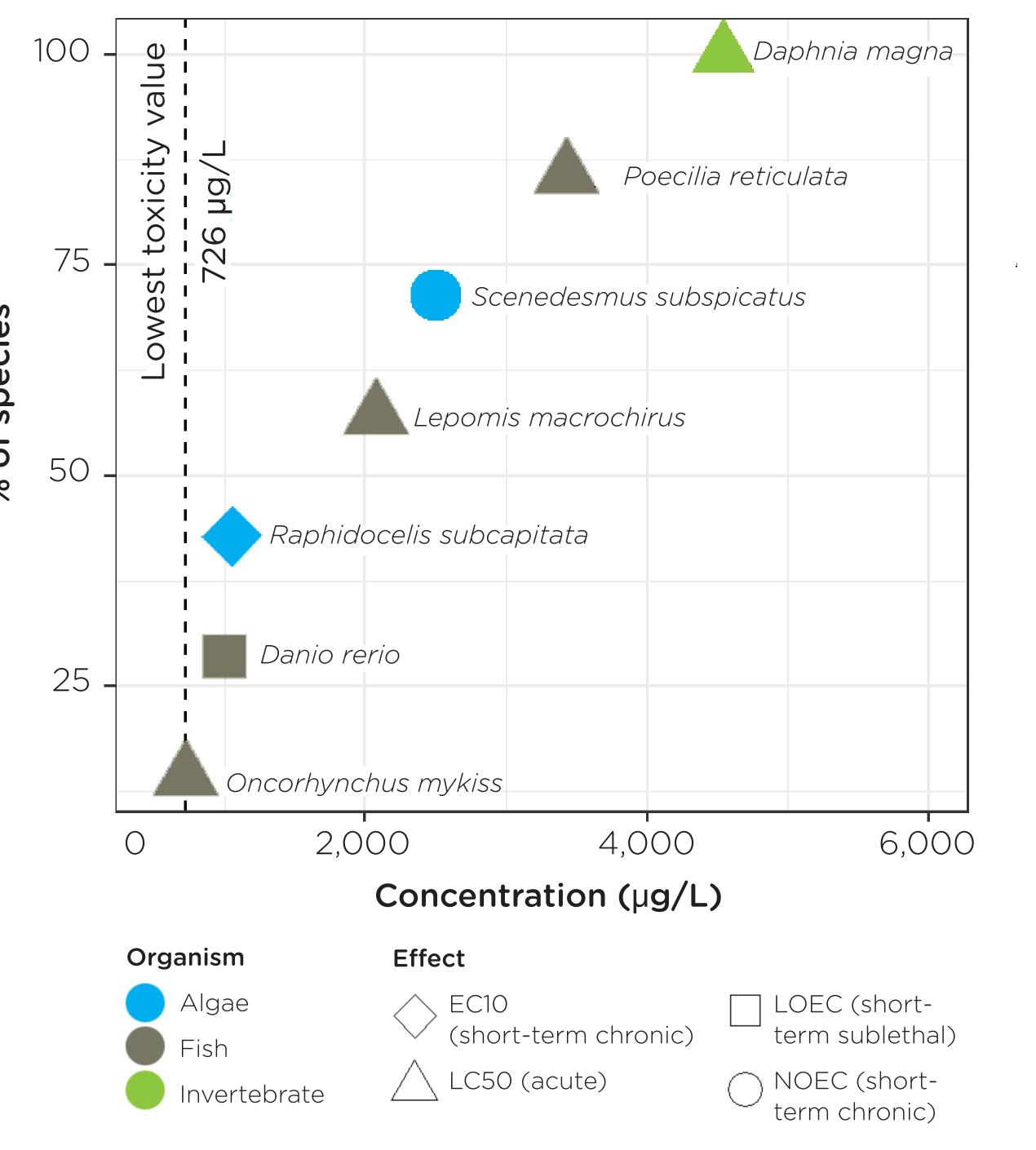
CONCEPTUAL MODEL



EFFECTS

- Toxicity data for chloroxylenol are limited to short-term aquatic toxicity studies for algae, invertebrates and fish
- The LTV was 726 μ g/L, based on the rainbow trout (*O. mykiss*) 96-hour LC50
- LTVs for sediment and soil were determined using equilibrium partitioning with Koc of 800
- Organic carbon fraction of 0.01 in sediment
- Organic carbon fraction of 0.047 in soil

726
$$\frac{\mu g}{L} \times 800 \frac{L}{kg} \times 0.01 \times \frac{mg}{1000 \, \mu g} = 5.8 \, \frac{mg}{kg} / \frac{sediment}{kg}$$
726 $\frac{\mu g}{L} \times 800 \frac{L}{kg} \times 0.047 \times \frac{mg}{1000 \, \mu g} = 27.3 \, \frac{mg}{kg} / \frac{soil}{kg}$





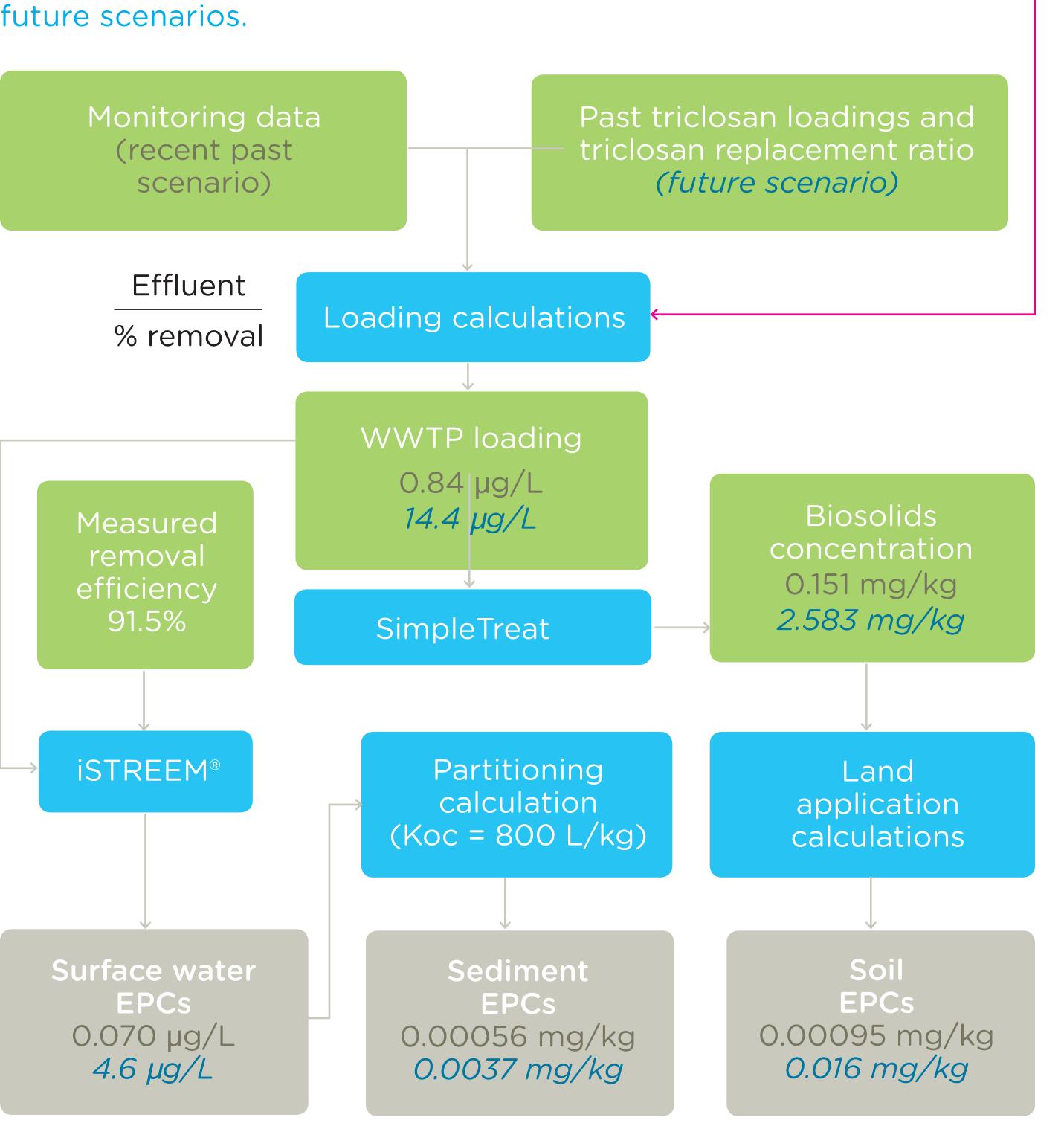
O. mykiss (rainbow trout)

EXPOSURE ASSESSMENT

Chloroxylenol monitoring data were mainly available for surface water and effluent data. Because influent data were sparse (n=1), WWTP loading was estimated based on effluent and removal data.

Matrix	Units	Frequency of detection	Estimate	Value
Surface water	µg/L	31 / 132	95th pctl	0.070
Effluent	µg/L	14 / 14	95th pctl	0.77
Influent	µg/L	1/1	Median	0.35
Removal	%	NA	Median	91.5

Figure 1. Exposure modeling approach for recent past and



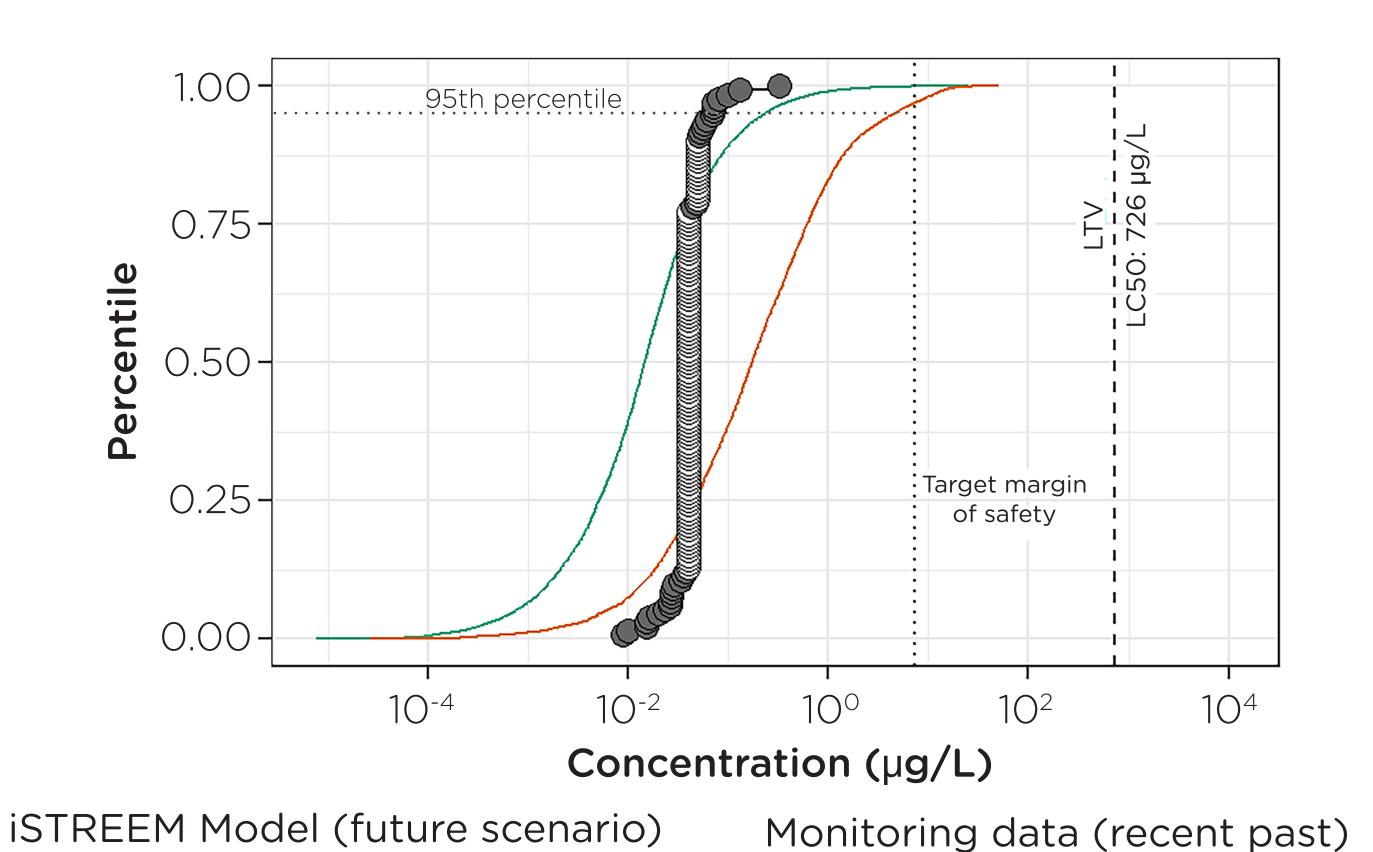
Because sufficient surface water data were available, the recent past surface water EPC is the 95th percentile of monitoring data. Additionally, the 95th percentile of effluent concentrations is used in the loading data used to calculate recent past soil concentrations.

In the future scenario, a central tendency loading estimate is used based on the conservative assumption that chloroxylenol will replace all triclosan use. The 95th percentile of modeled surface water concentrations is used to determine future scenario surface water and sediment EPCs. Because the soil EPC is calculated directly from the same loading, it is a conservative central tendency estimate.

RISK EVALUATION

Surface water

- Because only acute data are available for the most sensitive trophic group, the target margin of safety is 100
- No risk to aquatic species in recent past or at the 95th percentile in the future scenario



Soil and sediment

Low flow

Mean flow

No risk based on conservative soil or sediment exposure in recent past or future scenarios.

Scenario	Medium	EPC (mg/kg)	LTV (mg/kg)	Margin of safety	Target margin of safety	
Recent	Sediment	0.00056	5.81	10,400		
past	Soil	0.00095	27.3	28,700	100	
Projected	Sediment	0.037	5.81	157	100	
future	Soil	0.016	27.3	1,710		

KEY FINDINGS

Confident in low-risk conclusion

High margins of safety

iSTREEM model output is conservative (model is inherently conservative (Kapo et al 2016); in-river loss mechanism not accounted for).

Detect

Non-detect

Chronic toxicity data: potential for refinement

No chronic toxicity data for fish - weak endocrine toxicity shown *in vitro*, but none in *in vivo* mammalian studies. Endocrine toxicity in fish unlikely, but data would help resolve uncertainty.

Soil/sediment occurrence data

Lack of soil or sediment monitoring data not a major uncertainty, because low Koc suggests low occurrence of chloroxylenol in soil and sediment.

