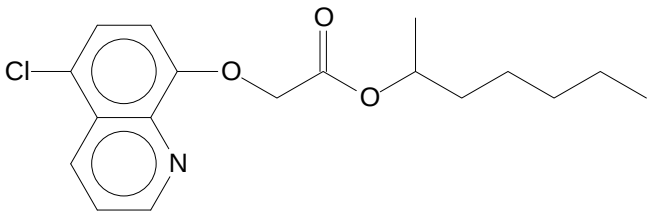
Evaluation Report for Category A Subcategory 1.1 Application

Application Number:	2008-5404
Application:	New Active Ingredient
Product:	Cloquintocet-mexyl Technical
Registration Number:	30527
Active ingredients (a.i.):	Cloquintocet-mexyl
PMRA Document Number:	2367300

Purpose of Application

The purpose of this application was to register a manufacturing concentrate containing the safener, cloquintocet-mexyl.

Chemistry Assessment

Active substance	Cloquintocet-mexyl
Function	Herbicide Safener
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	1-methylhexyl (5-chloroquinolin-8-yloxy)acetate
2. Chemical Abstracts Service (CAS)	1-methylhexyl [(5-chloro-8-quinolinyl)oxy]acetate
CAS number	99607-70-2
Molecular formula	$C_{18}H_{22}ClNO_3$
Molecular weight	335.8
Structural formula	
Purity of the active ingredient	96.7 %

Physical and Chemical Properties of the Active Ingredient and End-Use

Product

Technical Product — Cloquintocet-mexyl Technical

Property	Result
Colour and physical state	Colourless to light brown solid
Odour	Odourless
Melting range	61.4 – 69.0
Boiling point or range	Not applicable to solids
Density	1.05 g/cm^3
Vapour pressure at 25°C	5.31 x 10^{-3} mPa
Henry's law constant at 20°C	2.279 X 10^{-8}
Ultraviolet (UV)-visible spectrum	Methanol / 1M HCl (90/10) λ = 255.8 nm ε = 39.7 x 10^3 λ = 364.0 nm ε = 2.56 x 10^3 Methanol λ = 243.8 nm ε = 36.0 x 10^3 λ = 317.6 nm ε = 4.04 x 10^3 Methanol / 1M NaOH (90/10) λ = 244.0 nm ε = 36.4 x 10^3 λ = 319.4 nm ε = 4.18 x 10^3 Minimal absorbance above 370 nm in neutral and basic solution, considerable absorbance between 300 and 420 nm in acidic solution.
Solubility in water at 20°C	0.59 mg/L
Solubility in organic solvents at 25°C (g/100 mL)	Solvent — Solubility toluene 36 acetone 34 ethanol 19 n-octanol 1.1 n-hexane 0.014
n-Octanol-water partition coefficient (K_{OW})	log K_{ow}= 5.03 at 25°C
Dissociation constant (pK_a)	pK_a estimated to be 3.5–4
Stability (temperature, metal)	Stable on storage in glass at 54°C (3 months), at 35°C (24 months) and 20-25°C (36 months). Thermally stable in air to at least 150°C by DSC. Not corrosive to tin plate, steel and stainless steel.

Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and the impurities in cloquintocet-mexyl technical have been validated and assessed to be acceptable for the determinations.

Methods for Residue Analysis

High-performance liquid chromatography methods utilizing either ultraviolet (HPLC-UV) or tandem mass spectrometry (HPLC-MS/MS) detection were developed and proposed for data generation and enforcement purposes. These methods fulfilled the requirements with regards to selectivity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70–120%) were obtained in plant and animal matrices and environmental media. Methods for residue analysis are summarized in Appendix Table 1.

Health Assessments

No new data were submitted. Previously established endpoints were revisited to ensure they met current Pest Control Products Act (PCPA) standards.

No new residue data were submitted to support the registration of Cloquintocet-mexyl Manufacturing Concentrate. Data on file support the use of cloquintocet-mexyl as a safener in the formulations of Horizon, Axial and Simplicity brand herbicides in/on wheat and barley. The proposed use of Cloquintocet-mexyl Manufacturing Concentrate will not result in the residues of cloquintocet-mexyl and metabolite exceeding the established maximum residue limits (MRLs) on wheat and barley. Therefore, the dietary exposure is not expected to increase and the use of cloquintocet-mexyl will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

What Happens When Cloquintocet-Mexyl Is Introduced Into the Environment?

Cloquintocet-mexyl enters the environment when used as an herbicide safener which protects wheat or barley from the phytotoxic effects of herbicides. Once in the terrestrial environment, cloquintocet-mexyl binds to soil particles and has a low potential for leaching. In aquatic systems, cloquintocet-mexyl will move from the water column into the sediment where it will degrade. Residues of cloquintocet-mexyl are not expected to be found in air due to low volatility. Cloquintocet-mexyl is non-persistent in soil and aquatic systems, and both sorption and biotransformation are contributing factors to this non-persistence.

Cloquintocet-mexyl is toxic to aquatic organims, however, based on the use of cloquintocet-mexyl at low rates as a safener, the potential for effects on non-target organisms is expected to be low. Risks to both non-target terrestrial and aquatic organisms from the use of cloquintocet-mexyl were found to be acceptable.

Fate and Behaviour in the Environment

Based on its physical-chemical properties, cloquintocet-mexyl is sparingly soluble in water, is not likely to volatilize from moist soil or water surfaces under field conditions, and is likely to bioconcentrate or bioaccumulate in organisms. However, a laboratory study on bioaccumulation in fish shows the rapid metabolism of cloquintocet-mexyl to its major transformation product followed by rapid depuration.

The environmental fate data for cloquintocet-mexyl are summarized in Appendix Table 1. Biotransformation is a major route of dissipation of cloquintocet-mexyl in aerobic soil and aquatic systems. Cloquintocet-mexyl is non-persistent with one major transformation product (cloquintocet; CGA 153433) observed under aerobic conditions. Both sorption and biotransformation are contributing factors to this non-persistence. Although photodegradation in soil can occur, it is not expected to be a significant route of dissipation. Laboratory studies on adsorption/desorption indicate that cloquintocet-mexyl and its major degradation product strongly adsorb to soil and, therefore, have a low mobility in soil. Cloquintocet-mexyl was found to a soil depth of 30 cm in a field study in Saskatchewan. At other field sites, however, cloquintocet-mexyl and its transformation product could only be detected in the top 10 cm soil layer. The leaching potential of cloquintocet-mexyl in the field is expected to be limited.

Phototransformation in water is not expected to be a significant route of dissipation of cloquintocet-mexyl. Although cloquintocet-mexyl can undergo hydrolysis, it is not expected to be important routes of cloquintocet-mexyl transformation under most conditions. The only hydrolysis transformation product identified is the same as that from aerobic biotransformation. Cloquintocet-mexyl can enter the aquatic environment through spray drift or surface runoff.

Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (i.e. protection at the community, population, or individual level).

For characterizing acute risk, acute toxicity values (e.g. LC_{50}, LD_{50}, and EC_{50}) are divided by an uncertainty factor. The uncertainty factor is used to account for differences in inter- and intra-species sensitivity as well as varying protection goals (e.g. community, population, individual). Thus, the magnitude of the uncertainty factor depends on the group of organisms that are being evaluated (e.g. 10 for fish, 2 for aquatic invertebrates). The difference in value of the uncertainty factors reflects, in part, the ability of certain organisms at a certain trophic level (i.e., feeding

position in a food chain) to withstand, or recover from, a stressor at the level of the population. When assessing chronic risk, the NOEC or NOEL is used and an uncertainty factor is not applied.

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (e.g. direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the RQ is then compared to the level of concern (LOC = 1). If the screening level risk quotient is below the LOQ, the risk is considered negligible and no further risk characterization is necessary. If the screening level RQ is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

Risks to Terrestrial Organisms

A risk assessment of cloquintocet-mexyl to terrestrial organisms was based upon an evaluation of toxicity data to earthworms (acute contact), bees (acute oral and contact), birds (two acute oral, two dietary, and two chronic) and mammals (acute oral and chronic). A summary of terrestrial toxicity data for cloquintocet-mexyl is presented in Appendix Table 2. For the assessment of risk, toxicity endpoints chosen from the most sensitive species were used as surrogates for the wide range of species that can be potentially exposed following treatment with cloquintocet-mexyl.

Earthworms: Cloquintocet-mexyl is not acutely toxic to earthworms (*Eisenia foetida*) up to the highest concentration tested (1000 mg a.i./kg soil). Earthworm survival was reduced in the presence of cloquintocet-mexyl. The screening level risk assessment was determined based on the EECs for the highest use rate scenario of cloquintocet-mexyl (44.1 g a.i./ha). The LOC was not exceeded for bees (Appendix Table 3).

Bees (pollinators): No adverse effects were observed when bees were exposed to cloquintocet-mexyl on an oral or contact basis. The screening level risk assessment was determined based on the EECs for the highest use rate scenario of cloquintocet-mexyl (44.1 g a.i./ha). The LOC was not exceeded for earthworms (Appendix Table 3).

Birds and small wild mammals: Based on acute and dietary toxicity testing on bobwhite quail (*Colinus virginianus*) and mallard duck (*Anas platyrhynchos*), cloquintocet-mexyl is not toxic to birds up to the highest concentration tested. No clinical effects were observed in the reproduction study with cloquintocet-mexyl. The toxicity of cloquintocet-mexyl to rats was used to determine risk to small terrestrial mammals.

The screening level risk assessment was undertaken based on the EECs for the highest use rate scenario of cloquintocet-mexyl (44.1 g a.i./ha). The LOC was not exceeded for birds and mammals (Appendix Table 4).

Risks to Aquatic Organisms

A risk assessment of cloquintocet-mexyl to freshwater aquatic organisms was based upon the evaluation of toxicity data on cloquintocet-mexyl to *Daphnia magna* (acute and chronic), four fish species for acute and one fish species for chronic effects, three algal (acute), and amphibian (using fish as a surrogate). A summary of the freshwater toxicity data for cloquintocet-mexyl is presented in Appendix Table 2. Toxicity endpoints from the most sensitive species were used in the assessment of risk for the wide range of aquatic species that can be potentially exposed following treatment with cloquintocet-mexyl.

The potential for adverse effects on aquatic organisms was assessed based on EECs from a direct application at the highest use rate scenario of cloquintocet-mexyl (44.1 g a.i./ha) to water. The result of the screening level risk assessment for aquatic organisms is presented in Appendix Table 5.

Freshwater invertebrates: Acute exposure of *Daphnia magna* to cloquintocet-mexyl resulted in significant mortality. Adverse effects on reproduction and mortality were also observed in *D. magna* upon chronic exposure to cloquintocet-mexyl. The screening level risk assessment shows no acute risk to freshwater aquatic invertebrates, but that the LOC was exceeded for a 21-day chronic exposure. It was, however, not exceeded for a 7-day chronic exposure. Considering the conservative nature of the screening level risk assessment (direct overspray) and that cloquintocet-mexyl is typically applied once and has an aquatic half-life of <1day, the 21-day chronic exposure endpoint is not considered relevant to the current use pattern. A 7-day chronic exposure scenario would be more relevant, and LOC is not exceeded for that scenario.

Freshwater fish and amphibians: The toxicity of cloquintocet-mexyl to four species of fish was assessed for acute exposure (rainbow trout, bluegill sunfish, common carp, and common catfish), while toxicity from chronic exposure was assessed using results from a study on rainbow trout. Cloquintocet-mexyl was acutely toxic to all four fish species in the range of concentrations tested (Appendix Table 2). Chronic exposure of cloquintocet-mexyl to rainbow trout resulted in significant reductions in survival and several growth parameters when compared to the corresponding controls. The screening level risk assessment was performed with the rainbow trout. The LOC for exposure to cloquintocet-mexyl was not exceeded for the acute and the chronic exposure to fish (Appendix Table 5).

The risk to aquatic life stages of amphibians was assessed using fish toxicity values as surrogate endpoints. Risk was based on results from the acute and chronic rainbow trout studies. The amphibian screening level risk quotients for both acute and chronic exposure to cloquintocet-mexyl did not exceed the LOC (Appendix Table 5).

Freshwater algae: The toxicity of cloquintocet-mexyl to three species of algae was assessed for acute exposure (green algae, blue algae and diatom). Cloquintocet-mexyl was acutely toxic to all three species in the range of concentrations tested (Appendix Table 2). The screening level LOC was not exceeded for all species (Appendix Table 5).

Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e. persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the Canadian Environmental Protection Act].

During the review process, cloquintocet-mexyl and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03 and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Cloquintocet-mexyl does not meet all Track 1 criteria, and is not considered a Track 1 substance.

- Cloquintocet-mexyl transforms into a product which is more soluble in water than cloquintocet-mexyl, therefore the log K_{ow} value is expected to be lower than the parent. As such, the transformation products do not meet the Track 1 criteria.

Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the List of Pest control Product Formulants and Contaminants of Health or Environmental Concern maintained in the Canada Gazette. The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including: DIR99-03; and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the Canadian Environmental Protection Act (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

Cloquintocet-mexyl does not contain any formulants of health or environmental concern identified in the Canada Gazette.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

Environmental Risk

Cloquintocet-mexyl is non-persistent in most soils and aquatic systems. Cloquintocet-mexyl has a low potential to leach into ground water. As cloquintocet-mexyl is used as broadcast spray, it is subject to run-off or drift into surface water. Cloquintocet-mexyl does not pose a risk to non-target aquatic and terrestrial organisms based on the current use pattern.

Value Assessment

A value assessment was not required for this application.

Conclusion

The PMRA has reviewed the information provided in support to this application and has determined that it is acceptable to register a manufacturing concentrate containing the safener, cloquintocet-mexyl.

Appendix

Table 1. Residue Analysis

Matrix	Method ID	Analyte	Method Type	LOQ		Reference (PMRA Number)
Plant	REM 199.03/ 117-01	CGA-153433	LC/MS/MS	0.1 mg/kg	barley fractions	714628 925617
				0.1 mg/kg	wheat grain	714634
				0.2 mg/kg	other wheat fractions	714638
Animal	REM138.15	parent	LC/UV	0.02	meat, liver, milk, eggs	1993963 1993965
	REM138.14	CGA-153433	LC/UV	0.02	meat, milk, eggs	1993961 1993962
				0.05	beef liver	
Soil	REM138.01	parent	LC/MS/MS	0.5 ppb		717725
		CGA-153433		0.5 ppb		717726 717728
Water	2851-03	parent	LC/MS/MS	0.05 ppb		1993958
		CGA-153433		0.05 ppb		1993959

Table 2. Fate and Behaviour in the Terrestrial and Aquatic Environments

Study type	Test material	Study conditions	Value or Endpoint	Interpretation	Major transformation products	References (PMRA Number)
Abiotic transformation						
Hydrolysis	Cloquintocet-mexyl	30min-30d, pH 1, 5, 7, 9 and 13 at 25, 50 and 70ºC	pH 5: $T^{1/2}$= 1606 d pH 7: $T^{1/2}$= 134d pH 9: $T^{1/2}$= 6.6d	Limited susceptibility to hydrolysis at relevant pH (5-7)	CGA 153 433	1128815
	CGA153433	30min-30d, pH 1 and 7 at 50ºC	Stable	Not a major route of transformation	NA	1128815

Study type	Test material	Study conditions	Value or Endpoint	Interpretation	Major transformation products	References (PMRA Number)
Phototransformation - soil	Cloquintocet-mexyl	Dry sterile soil, pH7.3, continuous lightning at 23.37W/m^2	DT_{50} = 4.2d	Not a major route of transformation	Bound residues	1128771
	CGA153433		Unknown	Unclear if it does transform or not	Bound residues	1128771
Phototransformation - water	Cloquintocet-mexyl	Calculations	DT_{50}=30min	NA	NA	1157874
	CGA153433	Calculations	DT_{50}=10min	NA	NA	1157874
	Cloquintocet-mexyl	pH 5.36, continuous artificial light	Apparent: DT_{50}=9.3h Corrected[a]: DT_{50}=4.62h With solvent: DT_{50}=4.3h	Significant route of transformation	Unidentified products of higher polarity	1128772
Biotransformation						
Soil -aerobic	Cloquintocet-mexyl	336d, two soils; pH 6.2-7.4, %OC 1.12-1.79	DT_{50}=1.25d to 2.8d	Non-persistent	CGA153433 Non-extractables CO_2	1128780
		329d, one soil; 10 and 20°C, 38 and 60% moisture; pH 7.0, %OC 1.26	DT_{50}=1.45d to 1.58d	Non-persistent	CGA153433 Non-extractables CO_2	1128782
		350d, two soils; pH 6.5-7.3, %OC 2.3-3.2	DT_{50}=1.34d to 1.6d Sterile soil: DT_{50}=2300d	Non-persistent Persistent in sterile soil		1128779

Study type	Test material	Study conditions	Value or Endpoint	Interpretation	Major transformation products	References (PMRA Number)
	CGA153433	336d, two soils; pH 6.2-7.4, %OC 1.12-1.79	DT_{50}=97.4d to 312d	Moderately persistent to Persistent	Non-extractables CO_2	1128780
		329d, one soil; 10 and 20°C, 38 and 60% moisture; pH 7.0, %OC 1.26	DT_{50}=125d to 185d	Moderately persistent to persistent	Non-extractables CO_2	1128782
		350d, two soils; pH 6.5-7.3, %OC 2.3-3.2	DT_{50}=144d to 170d Sterile soil: DT_{50}=2300d	Moderately persistent		1128779
	Total Residues	336d, two soils; pH 6.2-7.4, %OC 1.12-1.79	DT_{50} = 117 to 243 d	Persistent	NA	1128780
		329d, one soil; 10 and 20°C, 38 and 60% moisture; pH 7.0, %OC 1.26	DT_{50}=894d to 1230d	Persistent	NA	1128782
Soil - anaerobic	Cloquintocet-mexyl	350d, two soils; pH 6.5-7.3, %OC 2.3-3.2	Degraded before test initiation	Unknown	Unknown	1128779
Water/sediment - aerobic	Cloquintocet-mexyl	280d, water:pond sediment, 20ºC; pH 6.8, %OC 9.4	DT_{50} = 0.49d (whole system[b])	Non-persistent	CGA153433 Non-extractables CO_2	1128783

Study type	Test material	Study conditions	Value or Endpoint	Interpretation	Major transformation products	References (PMRA Number)
	CGA153433	280d, water:pond sediment, 20ºC; pH 6.8, %OC 9.4	DT_{50} = 120d (whole system[b])	Moderately persistent	NA	1128783
	Total Residues	280d, water:pond sediment, 20ºC; pH 6.8, %OC 9.4	DT_{50} = 1836d (whole system[b])	Persistent	NA	1128783
Water-sediment - anaerobic	Cloquintocet-mexyl	280d, water:pond sediment, 20ºC; pH 6.8, %OC 9.4	Degraded before test initiation	Unknown	NA	1128783
	CGA153433	280d, water:pond sediment, 20ºC; pH 6.8, %OC 9.4	DT_{50} = 94d (whole system[b])	Moderately persistent	NA	1128783
Mobility						
Adsorption/desorption	Cloquintocet-mexyl	Five soils (pH 6.5-7.2, 0.7-19.6%OC)	Koc = 10 557 to 25 685	Low mobility	NA	1128775
Soil column leaching	Cloquintocet-mexyl	Eight soils (fresh and aged)	Parent and transformation product not found below 6 cm.		CGA153433	1128778 1128776 1128777
Bioconcentration/Bioaccumulation						

Study type	Test material	Study conditions	Value or Endpoint	Interpretation	Major transformation products	References (PMRA Number)
Bioconcentration	Cloquintocet-mexyl		BCF = 123 (edible tissue) BCF = 621 (whole fish)	High potential to bioconcentrate	CGA153433	1128793
	CGA153433		Log K_{OW}<0; DT_{50}<0.6 d	Bioconcentration is unlikely; rapidly depurated	NA	1128793
Field studies						
Field dissipation	Cloquintocet-mexyl	Eight sites relevant to Canadian conditions (Saskatchewan, Manitoba and Alberta)	DT_{50} < 15 days. No radioactivity found below 10 cm, except for one site at up to 30 cm.		CGA153433	1136133 1136132
	CGA153433	Eight sites relevant to Canadian conditions (Saskatchewan, Manitoba and Alberta)	DT_{50} < 10 days. No radioactivity found below 10 cm.		NA	1136133 1136132

[a]Corrected for adsorption-desorption to glass
[b]58% of total radioacticvity was in the water phase at test initiation; 0.57% at test termination.
NA – not applicable

Table 3. Toxicity to Non-target Species

Organism	Study type	Species	Test material	Endpoint	Value (effect)	Classification *	Reference (PMRA #)
Freshwater Organisms							
Invertebrates	Acute	*Daphnia magna*	Cloquintocet-mexyl	48-h EC_{50}	>8.7 mg a.i./L	Slightly to highly toxic	1807685
			CGA153433	48-h EC_{50}	>9.7 mg a.i./L	Moderately toxic	1157877
	Chronic	*Daphnia magna*	Cloquintocet-mexyl	7-d NOEC	0.27 mg a.i./L	Highly to very highly toxic	1807686
				14-d NOEC	0.070 mg a.i./L		
				21-d NOEC	0.002 mg a.i./L		
			Cloquintocet-mexyl	7-d NOEC	0.27 mg a.i./L	Highly to very highly toxic	
				14-d NOEC	0.003 mg a.i./L		
				21-d NOEC	0.002 mg a.i./L		
Fish	Acute	Rainbow trout (*Oncorkynchus mykiss*)	Cloquintocet-mexyl	96-h LC_{50}	>0.59 mg a.i./L	Slightly to highly toxic	1807679
			CGA153433	96-h LC_{50}	90 mg a.i./L	Slightly toxic	1128789
		Bluegill sunfish (*Lepomis macrochirus*)	Cloquintocet-mexyl	96-h LC_{50}	>0.59 mg a.i./L	Moderately to highly toxic	1807681
			CGA153433	96-h LC_{50}	83 mg a.i./L	Slightly toxic	1128791
		Catfish (*Ictalurus punctatus*)	Cloquintocet-mexyl	96-h LC_{50}	>0.59 mg a.i./L	Slightly to highly toxic	1807678
			CGA153433	96-h LC_{50}	>100 mg a.i./L	Practically non-toxic	1128788

Organism	Study type	Species	Test material	Endpoint	Value (effect)	Classification *	Reference (PMRA #)
		Common carp (*Cyprinus carpio*)	Cloquintocet-mexyl	96-h LC_{50}	>0.59 mg a.i./L	Slightly to highly toxic	1807680
			CGA153433	96-h LC_{50}	>100 mg a.i./L	Practically non-toxic	1128790
	Chronic (Early Life Stage)	Rainbow trout (*Oncorkynchus mykiss*)	Cloquintocet-mexyl	21-d NOEC	>1.26 mg a.i./L	Moderately to highly toxic	1807682
Algae	Acute	Green algae (*Scenedesmus subspicatus*)	Cloquintocet-mexyl[a]	72-h EC_{50}	0.19 mg /L	Highly toxic	1807687
				96-h EC_{50}	0.24 mg/L	Highly toxic	1128795
			CGA153433		>100 mg/L	Practically non-toxic	1128798
		Blue algae (*Microcystis aeruginosa*)	Cloquintocet-mexyl	96-h EC_{50}	2.5 mg a.i./L	Moderately to highly toxic	1128797
			CGA153433	120-h EC_{50}	1.9 mg/L	Moderately toxic	1128800
Diatom	Acute	Diatom (*Navicula pelliculosa*)	Cloquintocet-mexyl[b]	96-h EC_{50}	0.86 mg a.i./L	Moderately to very highly toxic	1128796
			CGA153433		5.3 mg/L	Moderately toxic	1128799

*The classification takes into account the reported endpoint as well as the measured concentrations when appropriate.

[a] The measured concentration of cloquintocet-mexyl decreased over test duration to undetected amounts by 96 h.

[b] The measured concentration of cloquintocet-mexyl decreased over test duration to 0.01 – 0.05 mg/L by 96 h.

Table 4. Screening Level Risk to Terrestrial Organisms Other Than Birds and Small Wild Mammals

Organism	Exposure	Test substance	Endpoint value	EEC	RQ[2]
Terrestrial invertebrates					
Earthworm	Acute	Cloquintocet-mexyl	½ LC_{50}: > 500 mg a.i./kg dw	0.0196 mg a.i./kg[1]	<0.001
			NOEC: 60 mg a.i./kg dw		<0.001
Bees	Contact/Oral	Cloquintocet-mexyl	LD_{50}: > 112 000 g a.i./ha	44.1 g a.i./ha	<0.001

[1]Estimated Environmental Concentration (Soil: calculated based on a soil density of 1.5 g/cm^3, soil depth of 15 cm and the maximum label rate for potatoes.
[2]Risk Quotient (RQ) = exposure/toxicity. RQ > 1 indicates exceedance of LOC (Level of Concern)

Table 5. Screening Level Risk for Birds and Small Wild Mammals

	Toxicity (mg ai/kg bw/d)	Feeding Guild (food item)[a]	EDE[b] (mg ai/kg bw)	RQ[c]
Small bird (0.02 kg)				
Acute	200.00	Insectivore (small insects)	2.22	0.01
Reproduction	28.00	Insectivore (small insects)	2.22	0.08
Medium sized bird (0.1 kg)				
Acute	200.00	Insectivore (small insects)	1.73	0.01
Reproduction	28.00	Insectivore (small insects)	1.73	0.06
Large sized bird (1 kg)				
Acute	200.00	Herbivore (short grass)	1.81	0.01
Reproduction	28.00	Herbivore (short grass)	1.81	0.06
Small mammal (0.015 kg)				
Acute	200.00	Insectivore (small insects)	1.28	0.01
Reproduction	36.4	Insectivore (small insects)	1.28	0.04
Medium sized mammal (0.035 kg)				
Acute	200.00	Herbivore (short grass)	4.00	0.02
Reproduction	36.4	Herbivore (short grass)	4.00	0.11
Large sized mammal (1 kg)				
Acute	200.00	Herbivore (short grass)	2.14	0.01
Reproduction	36.4	Herbivore (short grass)	2.14	0.06

[a] Large insects not considered to be a relevant food source for small birds and mammals.

[b] EDE = Estimated dietary exposure. It is calculated using the following formula: (FIR/bw) x EEC. At the screening level, food items representing the most conservative EEC are used. FIR is the Food Ingestion Rates (Nagy, 1987). For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight greater than 200 g, the "all birds" equation was used:
Passerine Equation (body weight < or =200 g): FIR (g dry weight/day) = 0.398(BW in g) $^{0.850}$
All birds Equation (body weight > 200 g): FIR (g dry weight/day) = 0.648(bw in g) $^{0.651}$. For mammals, the "all birds" equation was used: FIR (g dry weight/day) = 0.235(bw in g) $^{0.822}$

[c] Risk quotient (RQ) = exposure/toxicity. Shaded cells indicate that the RQ exceeds the level of concern (LOC = 1)

Table 6. Screening Level Risk for Aquatic Organisms

Organism	Exposure	Endpoint value[1] (mg a.i./L)	EEC[2] (mg a.i./L)	RQ[3]
Cloquintocet-mexyl Technical				
Freshwater crustacean	Acute	½ EC_{50}: > 4.4	0.006	<0.001
	Chronic	21-d NOEC: 0.002	0.006	3
		7-d NOEC: 0.27	0.006	0.02
Rainbow trout	Acute	$^1/_{10}LC_{50}$: 0.059	0.006	<0.10
	Chronic	21-d NOEC: 1.26	0.006	0.005
Amphibian	Fish Acute	$^1/_{10}LC_{50}$: 0.059	0.029	<0.5
	Fish chronic	21-d NOEC: 1.3	0.029	0.05
Freshwater Alga	Acute	½ EC_{50}: 0.095	0.006	0.06
Major transformation product (CGA153433)				
Freshwater crustacean	Acute	½ EC_{50}: >4.8	0.006	0.001
Bluegill	Acute	$^1/_{10}EC_{50}$: 8.3	0.006	0.0007
Amphibian	Fish Acute	$^1/_{10}LC_{50}$: 8.3	0.029	0.004
Shaded cells indicate that the RQ exceeds the level of concern (LOC =1)				

[1]Endpoints used in the acute exposure risk assessment are derived by diving the EC_{50} or LC_{50} from the appropriate laboratory study by a factor of 2 for aquatic invertebrates and plants, and by a factor of 10 for fish and amphibians.

[2]Estimated Environmental Concentration (EEC) based on a 15 cm water body depth for amphibians and a 80 cm water depth for all other aquatic organisms.

[3]Risk Quotient (RQ) = exposure/toxicity. RQ > 1 indicates exceedance of LOC (Level of Concern)

Table 7. Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion Value		Active Ingredient Endpoints
CEPA toxic or CEPA toxic equivalent[1]	Yes		Yes
Predominantly anthropogenic[2]	Yes		Yes
Persistence[3]:	Soil	Half-life ≥ 182 days	Half-life < 15 days
	Water	Half-life ≥ 182 days	Half-life < 1 day
	Sediment	Half-life ≥ 365 days	Half-life < 1 day
	Air	Half-life ≥ 2 days or evidence of long range transport	Half-life or volatilisation is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on the vapour pressure (5.31×10^{-6} Pa) and Henry's law constant (2.279×10^{-8}).
Bioaccumulation[4]	Log $K_{OW} \geq 5$		5.03
	BCF ≥ 5000		621
	BAF ≥ 5000		Not available
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No, does not meet TSMP Track 1 criteria.

[1]All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (i.e., all other TSMP criteria are met).
[2]The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.
[3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.
[4]Field data (e.g., BAFs) are preferred over laboratory data (e.g., BCFs) which, in turn, are preferred over chemical properties (e.g., log K_{OW}).

List of Abbreviations

μg	micrograms
a.i.	active ingredient
BAF	bioaccumulation factor
BCF	bioconcentration factor
bw	body weight
CEPA	Canadian Environmental Protection Act
cm	centimetres
d	day(s)
DT_{50}	dissipation time 50% (the time required to observe a 50% decline in concentration)
DSC	differential scanning calorimetry
dw	dry weight
EC_{25}	effective concentration on 25% of the population
EC_{50}	effective concentration on 50% of the population
EEC	estimated environmental concentration
EDE	estimated dietary exposure
ELS	early life stage
FIR	food ingestion rate
g	gram
h	hour
ha	hectare(s)
HCl	hydrochloric acid
HPLC	high-performance liquid chromatography
kg	kilogram
K_{oc}	organic-carbon partition coefficient
K_{ow}	octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOC	level of concern
LR_{50}	lethal rate 50%
mg	milligram
mL	millilitre
MRL	maximum residue limit
MS	mass spectrometry
NA	not applicable
NOEC	no observed effect concentration
NOEL	no observed effect level
NOER	no observed effect rate
OC	organic carbon content
p*K*a	dissociation constant
PCPA	Pest Control Products Act
PMRA	Pest Management Regulatory Agency
ppb	parts per billion
RQ	risk quotient

$t_{1/2}$	half-life
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet spectrometry

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