

Evaluation Report for Category B, Subcategories 3.1, 3.5, 3.11, 3.12 Application

Application Number: 2023-6459
Application: Changes to Product Labels – Application Rate Increase or Decrease, Rotational Crops/Plantback Interval, New Pests, New Site or Host
Applicant: Valent Canada, Inc.
Product: S-2399 SC Master Fungicide
Registration Number: 34520
Active ingredient (a.i.): Inpyrfluxam
PMRA Document Number: 3687457

Purpose of Application

The purpose of this application was to amend the label of S-2399 SC Master Fungicide to add in-furrow application to potatoes and foliar application to specific crops from Crop Subgroups 15-21A (Wheat) and 15-21B (Barley), expand the use pattern from apples to additional crops from Crop Group 11-09 (Pome Fruit), increase the maximum application rate for all labelled crops from Crop Group 11-09 (including apples), revise adjuvant statements for labelled crops from Crop Subgroups 15-21A and 15-21B and Crop Group 11-09, and revise the crop rotation restrictions.

Health Assessments

The amendments of S-2399 SC Master Fungicide represent an expansion of use of inpyrfluxam. Quantitative mixer/loader/applicator, postapplication worker, and non-occupational/residential exposure risk assessments were updated. No health risks of concern were identified, provided that workers wear the appropriate personal protective equipment and follow all label directions.

Residue data from field trials conducted in Canada and the United States were submitted to support the use of S-2399 SC Master Fungicide on Asian pear, barley, canarygrass, Chinese quince, crabapple, Japanese quince, loquat, medlar, pear, potato, quince, rye, triticale, and wheat. Inpyrfluxam was applied to wheat, barley, pears, and potatoes at labelled or exaggerated rates, and harvested according to label directions. Previously reviewed residue data from field trials conducted in/on apple were reassessed in the framework of this application. In addition, processing studies in treated wheat, potato and apples were reviewed or reassessed to determine the potential for concentration of residues of inpyrfluxam into processed commodities.

Maximum Residue Limits

The recommendation for proposed maximum residue limits (MRLs) for inpyrfluxam was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of inpyrfluxam in/on crops are proposed as shown in Table

1. Residues in processed commodities are covered under the proposed MRLs for the raw agricultural commodities (RACs).

TABLE 1. Summary of Field Trial and Processing Data Used to Support Maximum Residue Limits (MRLs)

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Proposed MRL (ppm)
			LAF T	HAF T			
Apple	Foliar application/ 190-206	111- 185	<0.01	<0.01	Apple juice: 0.1x Apple wet pomace: 2.9x	0.01	0.01 (Asian pear, Chinese quince, crabapple, Japanese quince, loquat, medlar, pear, and quince)
Pear	Foliar application/ 198-206	86- 147	<0.01	<0.01	Not required	Not established	
Wheat	Foliar application/ 97-107	42-94	<0.01	<0.01	No quantifiable residues observed at exaggerated rates	0.01 (Cereal grains - Crop Group 15)	-
Barley	Foliar application/ 97-105	33-92	<0.01	<0.01	Not applicable	0.01 (Cereal grains - Crop Group 15)	-
Potato	In-furrow application/ 95-113	78- 141	<0.01	0.012	No quantifiable residues observed at exaggerated rates	Not established	0.03

g a.i./ha = grams of active ingredient per hectare; ppm = parts per million; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial

Following the review of all available data, the MRLs proposed in Table 1 are recommended to cover residues of inpyrfluxam in/on potato, Asian pear, Chinese quince, crabapple, Japanese quince, loquat, medlar, pear, and quince. Residues of inpyrfluxam in/on wheat, barley, rye, triticale, canarygrass, apple, and animal commodities as a result of the added uses will be covered under the MRLs currently established (i.e., 0.01 ppm in/on cereal grains – Crop Group 15; apples; fat, kidney, liver, meat, and meat byproducts of cattle, goats, horses, hogs, sheep, and poultry; eggs; and milk). Dietary risks from exposure to residues of inpyrfluxam in these crop/livestock commodities at the proposed and established MRLs were shown to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors.

Thus, the foods that contain residues as listed above are considered safe to eat. A toxicological assessment was not required for this assessment.

Environmental Assessment

Since this application was associated with a rate increase in foliar application on pome fruit crops, updated estimated environmental concentrations and exposures were needed to characterize risks to terrestrial and aquatic habitats from increased exposure to inpyrfluxam. Ecotoxicity studies reported in the original decision (PRD2020-10 and RD2020-11) were used in the revised risk assessment.

The increased application rate from 75 g a.i./ha to 99 g a.i./ha in pome fruit using airblast technology resulted in a slight increase in aquatic and terrestrial risk quotient values relative to those presented in PRD2020-10 (see Table 2). However, no new organism groups exceeded the risk quotient levels of concern.

Spray buffer zones calculated for airblast technology using the increased application rate resulted in increases to spray buffer zones for freshwater habitats of depths greater than 1 metre, estuarine habitats of depths less than 1 metre, and terrestrial habitats (for late growth stage only) (see Table 3).

Overall, there was no new risk to non-target organisms that could not be mitigated through existing label statements and updated spray buffer zones. Therefore, the risk is acceptable when S-2399 SC Master Fungicide is used in accordance with the label, which includes statements to mitigate risks to the environment.

TABLE 2. Comparison Between PRD2020-10 and Current Application Risk Quotients (RQs) for Terrestrial (Except Birds and Mammals) and Aquatic Organisms Associated with the Pome Fruit Airblast Scenario

Organism	Exposure	Endpoint Value (mg a.i./L)	Current RQ	PRD2020-10 RQ	Current Drift (74%) RQ	PRD2020-10 (74%) Drift RQ
Terrestrial organisms						
Earthworm	Acute	LC ₅₀ /2 = 118 mg a.i./kg soil	< 0.001	< 0.001	< 0.0007	NR
	Chronic	NOEC = 6.3 mg a.i./kg soil	0.014	0.013	0.01	NR
Springtail	Chronic	NOEC = 100 mg a.i./kg soil	0.001	0.001	0.0007	NR
Honey bee	Adult contact acute	LD ₅₀ > 100 µg a.i./bee	< 0.002	< 0.002	< 0.001	NR
	Adult oral acute	LD ₅₀ > 111.3 µg a.i./bee	< 0.025	< 0.019	< 0.019	NR
	Adult oral chronic	NOEL = 116.6 µg a.i./bee	0.024	0.018	0.018	NR
	Larvae oral acute	LD ₅₀ > 100 µg a.i./larva	< 0.012	< 0.009	< 0.009	NR
	Larval oral chronic	NOEL = 1.15 µg a.i./larva	-	0.79	0.77	NR
		NOED = 30 mg a.i./kg diet ¹	0.32	NR	N/A	NR
Predatory mite (foliar exposure)	Acute contact	LR ₅₀ > 1000 g a.i./ha (glass)	< 0.197	< 0.09	N/A	NR
	Chronic	NOER = 1000 g a.i./ha	0.197	0.09	N/A	NR
Predatory mite (soil exposure)	Acute	LC ₅₀ > 100 mg a.i./kg soil	< 0.001	< 0.001	N/A	NR
	Chronic	NOEC = 100 mg a.i./kg soil	0.001	0.001	N/A	NR
Parasitic wasp	Acute contact (glass)	LR ₅₀ > 1000 g a.i./ha (glass)	< 0.20	< 0.09	N/A	NR
	Chronic (barley)	NOER = 1000 g a.i./ha	0.20	0.09	N/A	NR

Vascular plant	Seedling emergence	LOER (42% effects)/2 = 6.65 g a.i./ha	29.69	27.77	21.98	16.65
		ER ₂₅ = 151 g a.i./ha	1.31	1.22	0.97	0.73
	Vegetative vigour	ER ₂₅ = 151 g a.i./ha	< 0.95	0.89	0.70	NR
Freshwater Invertebrate						
Water flea	Acute 48-h	LC ₅₀ /2 = 0.55	0.05	0.04	N/A	NR
	Chronic 21-d	NOEC/1 = 0.14	0.18	0.16	N/A	NR
Midge	Chronic 62-d	NOEC/1 = 1.1	0.02	0.02	N/A	NR
Amphipod	Chronic 42-d	NOEC/1 = 0.21	0.12	0.11	N/A	NR
Freshwater Fish						
Rainbow trout	Acute 96-h	LC ₅₀ /10 = 0.0031	8.07	7.42	5.97	4.52
Bluegill sunfish	Acute 96-h	LC ₅₀ /10 = 0.0055	4.55	4.18	3.37	2.54
Common carp	Acute 96-h	LC ₅₀ /10 = 0.0065	3.85	3.54	2.85	2.15
Fathead minnow	Acute	LC ₅₀ /10 = 0.0047	5.32	4.89	3.93	2.98
	Chronic 28-d	NOEC/1 = 0.0016	15.63	14.37	11.57	2.98
Guppy	Acute 96-h	LC ₅₀ /10 = 0.035	0.71	0.66	N/A	NR
Japanese medaka	Acute 96-h	LC ₅₀ /10 = 0.08	0.31	0.29	N/A	NR
Zebrafish	Acute 96-h	LC ₅₀ /10 = 0.031	0.81	0.74	N/A	NR
Amphibian						
Rainbow trout ²	Acute 96-h	LC ₅₀ /10 = 0.0031	42.58	40.00	31.51	23.87
Fathead minnow ²	Chronic 28-d	NOEC/1 = 0.0016	82.50	77.50	61.06	46.25
Freshwater Algae						
Green alga	Acute 96-h	EC ₅₀ /2 = 3.55	< 0.01	0.006	N/A	NR
Cyanobacteria	Acute 96-h	EC ₅₀ /2 > 13.5	< 0.01	< 0.002	N/A	NR
Freshwater diatom	Acute 96-h	EC ₅₀ /2 = 1.965	0.01	0.01	N/A	NR
Freshwater Plant						
Duckweed	Acute 7-d	EC ₅₀ /2 = 5.7	0.01	0.004	N/A	NR
Marine and Estuarine Invertebrate						
Mysid shrimp	Chronic 30-d	NOEC/1 = 0.18	0.07	0.13	N/A	NR
Atlantic oyster	Acute 96-h	EC ₅₀ /2 > 0.495	< 0.03	< 0.05	N/A	NR
Amphipod	Chronic 28-d	NOEC/1 = 0.42	0.03	0.05	N/A	NR
Marine and Estuarine Fish						
Sheepshead minnow	Acute 96-h	LC ₅₀ /10 = 0.015	0.83	1.53	0.62	0.47
	Chronic 28-d	NOEC/1 = 0.009	1.39	2.56	1.03	0.78
Marine and Estuarine Algae						
Diatom	Chronic 96-h	EC ₅₀ /2 = 0.28	0.09	0.06	N/A	NR

Bold and shaded values indicate that the level of concern (LOC) is exceeded.

µg = Microgram; d = Day(s); EC₅₀ = Half maximal effective concentration; ER₂₅ = Effective rate for 25% of the population; g = Gram; h = Hour(s); ha = Hectare; kg = Kilogram; L = Litre; LC₅₀ = Lethal concentration 50%; LD₅₀ = Lethal dose 50%; LOER = Lowest observed effect rate; LR₅₀ = Lethal rate 50%; mg = Milligram; N/A = Not applicable if RQ < LOC, NOEC = No observed effect concentration; NOED = No observed effect dose; NOEL = No observed effect level; NOER = No observed effect rate; NR = Not reported

¹ The original study was re-reviewed following the most recent guidance, which resulted in the selection of a different endpoint that is considered to be more relevant to the pollinator risk assessment.

² Fish surrogate for amphibians.

TABLE 3. Comparison Between Existing Spray Buffer Zones and Those Determined in the Current Application

	Method of application	Crop		Spray Buffer Zones (Metres) Required for the Protection of:				
				Freshwater Habitat of Depths:		Estuarine/Marine Habitat of Depths:		Terrestrial Habitat:
				Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Existing Spray Buffer Zones	Field sprayer	Soybean, sugar beet		1	1	NR	NR	1
	Airblast	Apple	Early growth stage	30	4	NR	NR	20
			Late growth stage	20	2	NR	NR	10
Spray Buffer Zones Determined in the Current Application	Field sprayer	Wheat, rye, triticale, barley, canary grass, soybean and sugar beet		1	1	0	0	1
	Airblast	Pome fruit (apple, crabapple, loquat, pear, Asian pear, quince, Chinese quince, Japanese quince and medlar)	Early growth stage	30	5	1	0	20
			Late growth stage	20	3	1	0	15

NR = Not required

Value Assessment

Claims to control several important and common diseases on potato and certain small grain cereal and pome fruit crops were added to the label of S-2399 SC Master Fungicide. Field efficacy trials, scientific rationales and use history information supported disease management claims, a higher application rate for certain diseases on pome fruit and amendments to adjuvant use directions.

The amendments to the S-2399 SC Master Fungicide label will provide growers with an additional option for management of diseases that pose a significant threat to the production of small grain cereal, pome fruit and potato crops in Canada. For scab and powdery mildew control on pome fruit, the broadened application rate range will provide higher levels of efficacy compared to the previously registered rates, particularly under conditions of high disease

pressure, and a greater potential to manage fungicide resistance.

Chemistry Assessment

A chemistry assessment was not required for this assessment.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to amend the label of S-2399 SC Master Fungicide.

References

PMRA Document Number	Reference
2819541	2017, Appendix 2: Trial Reports for "S-2399 2.84 SC Fungicide: Annex IIA Tier II Summary, Efficacy Data and Information on S-2399 2.84 SC Fungicide, Containing Inpyrfluxam, for Use on Apple, Corn (Field, Pop, and Sweet), Soybean, and Sugar beet", DACO: 10.1
3523965	2023, Value Summary for S-2399 SC Master Fungicide, Containing Inpyrfluxam, for Use on Additional Crops, DACO: 10.1,10.2.1,10.2.2, 10.2.3.1,10.2.3.3,10.3,10.3.1,10.4,10.5.1,10.5.2,10.5.3,10.5.4
3523966	2023, MS Excel Spreadsheet for: Value Summary for S-2399 SC Master Fungicide, containing Inpyrfluxam, for Use on Additional Crops, DACO: 10.1,10.2.1,10.2.2,10.2.3.1,10.2.3.3,10.3,10.3.1,10.4,10.5.1,10.5.2, 10.5.3,10.5.4
3523967	2023, Appendix 1: Trial Reports for "Value Summary for S-2399 SC Master Fungicide, Containing Inpyrfluxam, for Use on Additional Crops", DACO: 10.1,10.2.1,10.2.2,10.2.3.1,10.2.3.3,10.3,10.3.1,10.4,10.5.1,10.5.2, 10.5.3,10.5.4
3523968	2023, Appendix 2: References for "Value Summary for S-2399 SC Master Fungicide, Containing Inpyrfluxam, for Use on Additional Crops", DACO: 10.1,10.2.1,10.2.2,10.2.3.1,10.2.3.3,10.3,10.3.1,10.4,10.5.1,10.5.2, 10.5.3,10.5.4
3523969	2023, Agricultural Use History Template for S-2399 SC Master Fungicide (Containing Inpyrfluxam) Use on Apples, DACO: 10.2.4
3524698	2023, S-2399: Magnitude of Residues on Potatoes After Application of S-2399 2.84 SC in-Furrow or to Potato Seed Pieces at Planting, DACO: 7.2.1, 7.3,7.4.1,7.4.2,7.4.5
3524702	2021, S-2399: Magnitude of the Residues on Wheat After Application of S-2399 2.84 SC to Wheat Grown from Seed Treated with S-2399 3.2 FS (Canadian Trials), DACO: 7.2.1,7.3,7.4.1
3524718	2022, S-2399: Magnitude of the Residues on Barley After Application of S-2399 2.84 SC to Barley Grown from Seed Treated with S-2399 3.2 FS (US Trials), DACO: 7.2.1,7.3,7.4.1
3524726	2022, S-2399: Magnitude of the Residues on Barley After Application of S-2399 2.84 SC to Barley Grown from Seed Treated with S-2399 3.2 FS (Canadian Trials), DACO: 7.2.1,7.3,7.4.1
3524743	2021, S-2399: Magnitude of the Residues on Wheat After Foliar Application of S-2399 2.84 SC to Wheat Grown from Seed Treated with S-2399 3.2 FS (US Trials) Amended Report #1, DACO: 7.2.1,7.3,7.4.1,7.4.2,7.4.5

3524744	2023, Magnitude of the Residues of Inpyrfluxam in/on Pear After Two Foliar Applications of Excalia Fungicide (S-2399 2.84 SC), DACO: 7.2.1,7.3,7.4.1, 7.4.2
3524745	2019, S-2399: Magnitude of Residues on Potatoes After Application of S-2399 2.84 SC in-Furrow or to Potato Seed Pieces at Planting (Canadian Trials), DACO: 7.2.1,7.3,7.4.1
3524746	2023, Inpyrfluxam: Analyte Selection for the Potato RAC Program, DACO: 7.4.1
3524747	2019, Addendum to S-2399: Freezer Storage Stability of S-2399 and Metabolites in Crops, DACO: 7.3
3524748	2019, Addendum to S-2399: Freezer Storage Stability of S-2399 and Metabolites in Processed Fractions, DACO: 7.3
3548131	2016, Trial Report 2016AWALS051, DACO: 10.2.3.3B 2023-

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