

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2014-1857
Application: New or Changes to Product Labels-New Site or Host
Product: Velum Prime
Registration Number: 32108
Active ingredients (a.i.): Fluopyram
PMRA Document Number : 2577718

Purpose of Application

The purpose of this application was to register a new end-use product to be used against nematodes and fungi on food crops.

Chemistry Assessment

Apart from the statement of the product specification form (SPSF) for the new alternate formulation no new chemistry data were submitted for this product.

Health Assessments

No toxicology assessment was required.

The occupational exposure and risk from in-furrow application to potatoes, tuberous and corm vegetables and low growing berries was assessed for Velum Prime. No health risks of concern are expected from the new use, provided that workers follow the label directions and wear the personal protective equipment identified on the label.

Residue data for fluopyram from field trials conducted in the United States, including Canadian representative growing regions, were submitted to support the domestic use of Velum Prime on tuberous and corm vegetables, and low-growing berries. Fluopyram was applied to potatoes at label rates, and harvested according to label directions. Previously reviewed residue data from field trials conducted in/on potatoes and strawberries were reassessed in the framework of this petition. In addition, processing data in treated potatoes and strawberries were reassessed to determine the potential for concentration of residues of fluopyram into processed commodities.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for fluopyram was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of fluopyram in/on crops and processed commodities are proposed as shown in Table 1. Residues in processed commodities not listed 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 ai/ha)	PHI (days)	Fluopyram Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT			
Potato tubers	In furrow application to bare soil at planting/ 490-520	7	<0.01	0.069	No concentration was observed in food commodities	0.02 (CSG 1C: Tuberous and Corm Vegetables)	0.1 (CSG 1C: Tuberous & Corm Vegetables)
Strawberry	Direct broadcast/ 491-519	0	0.196	1.012	Not required	1.5 (Strawberries)	2 (CSG 13-07G: Low growing berry) ¹

LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial

¹ Except lowbush blueberries and lingonberries, which are also in CSG 13-07B, and will be covered with the MRL of 7 ppm proposed on CSG 13-07B (Sub No 2014-1827).

Based on the dietary burden and residue data, MRLs of 10 ppm in meat by-products of cattle, goats, horses and sheep, 2 ppm in milk, 1.5 ppm in fat and meat of cattle, goats, horses and sheep, 0.15 ppm in meat byproducts of poultry, 0.06 ppm in meat byproducts of hogs, and 0.05 ppm in fat of poultry to cover residues of fluopyram including the metabolite fluopyram-benzamide (expressed as parent equivalent) are also proposed.

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of fluopyram. Residues in these crop/livestock commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

Velum Prime is similar to the currently registered Luna Privilege Fungicide (PCP # 30509) with fluopyram as the technical active. In addition, the application rates for the control of fungal diseases in small berries and for the control of nematodes in potatoes and other tuberous crops are same as those currently registered for Luna Privilege. The proposed use of Velum Prime by chemigation (through drip irrigation system) for small berries and by soil application (with ground equipment) for potato and tuberous and corm vegetables are, therefore, not expected to result in additional environmental concerns.

Value Assessment

Efficacy data from a total of 13 North American and international trials conducted between 2010 and 2012 were reviewed to assess the efficacy of fluopyram in Velum Prime in suppressing root lesion nematode, root knot nematode, and potato cyst nematode. At the labelled rate, fluopyram was shown to reduce numbers of nematodes, infested tubers, and cysts. Registration of Velum Prime as a nematicide for use on potatoes and other tuber vegetables will provide Canadian growers with a new mode of action among currently very limited options for the management of commercially important pests. Registration of Velum Prime could also lead to a reduction in the amount of soil fumigation applied in fields with established nematode populations. Support for the claim against powdery mildew in strawberry and low growing berries when Velum Prime is applied through drip irrigation was derived from extrapolation from a precedent claim registered in Canada for an equivalent product.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and is able to support the registration of the new end-use product, Velum Prime.

References

PMRA Document Number	Reference
2474412	2014, BCS response to Value deficiency notice - 10.2.3.1 Summary, DACO: 10.2.3.1
2427424	2014, Luna Privilege 500 SC (500 g a.i./L fluopyram) for suppression of major nematodes in potatoes in Canada, DACO: 1.1, 10.2.2, 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.3.2,5.2, IIIA 3.1, IIIA 3.3.3, IIIA 6.1.2, IIIA 6.2.1
2427425	2014, Value assessment Luna Privilege 500 SC (500 g a.i./l fluopyram) for suppression of major nematodes in potatoes in Canada, DACO: 10.2.3.3, 10.2.3.4, 10.3.2, 10.4, 10.5.1, 10.5.2, 10.5.4, IIIA 6.1.2, IIIA 6.1.3, IIIA 6.2.1, IIIA 6.3, IIIA 6.4.1, IIIA 6.4.2, IIIA 6.4.3
1599582	2008, AE C656948 500 SC - Magnitude of the residue in/on fruiting vegetables (crop group 8), DACO: 7.2.1,7.2.4,7.4.1,7.4.2,7.4.6,IIA 4.3,IIA 6.3.3
1599583	2008, AE C656948 500 SC - Magnitude of the residue in/on tomato processed commodities, DACO: 7.4.5,IIA 6.5.3
1599672	2008, Determination of the residues of AE C656948 in/on tomato fruit and the processed fractions (raw juice; washings; fruit, washed; juice; peel; ...) after spraying of AE C656948 (500 SC) in the field in Portugal, Italy and Southern France, DACO: 7.4.5,IIA 6.5.3

1599673	2008, Determination of the residues of AE C656948 in/on tomato fruit and the processed fractions (raw juice; washings; fruit, washed; juice; peel; preserve; fruit, peeled; peeling water; puree; raw puree; strain rest) after spraying of AE C656948 (500 SC) in the field in Italy, DACO: 7.4.5,IIA 6.5.3
1654362	2008, AE C656948 500 SC - Magnitude of the residue in/on root vegetables except sugar beet (crop subgroup 1B), DACO: IIA 6.3.6,IIA 6.3.7
1661265	2008, AE C656948 500 SC - Magnitude of the residue in/on root vegetables except sugar beet (crop subgroup 1B), DACO: IIA 6.3.6,IIA 6.3.7
1654377	2008, AE C656948 500 SC - Magnitude of the residue in/on orange processed commodities, DACO: 7.4.5,IIA 6.5.3
1661284	2008, AE C656948 500 SC - Magnitude of the residue in/on orange processed commodities, DACO: 7.4.5,IIA 6.5.3
1654381	2008, AE C656948 500 SC - Magnitude of the residue on sunflower processed commodities, DACO: 7.4.5,IIA 6.5.3
1661289	2008, AE C656948 500 SC - Magnitude of the residue on sunflower processed commodities, DACO: 7.4.5,IIA 6.5.3
1654382	2008, AE C656948 500 SC - Magnitude of the residue on plum processed commodities, DACO: 7.4.5,IIA 6.5.3
1661290	2008, AE C656948 500 SC - Magnitude of the residue on plum processed commodities, DACO: 7.4.5,IIA 6.5.3
1654389	2008, Determination of the residues of AE C656948 and tebuconazole in/on round cabbage head and the processed fractions (washings; cooking water; head, cooked; head, washed) after spraying of AE C656948 & HWG 1608 (400 SC) in the field in Souther, DACO: 7.4.5,IIA 6.5.3
1661292	2008, Determination of the residues of AE C656948 and tebuconazole in/on round cabbage head and the processed fractions (washings; cooking water; head, cooked; head, washed) after spraying of AE C656948 & HWG 1608 (400 SC) in the field in Souther, DACO: 7.4.5,IIA 6.5.3
1654397	2007, Determination of the residues of AE C656948 and tebuconazole in/on round cabbage head and the processed fractions (washings; cooking water; head, cooked; head, washed) after spraying of AE C656948 & HWG 1608 (400 SC) in the field in Norther, DACO: 7.4.5,IIA 6.5.3
1661297	2007, Determination of the residues of AE C656948 and tebuconazole in/on round cabbage head and the processed fractions (washings; cooking water; head, cooked; head, washed) after spraying of AE C656948 & HWG 1608 (400 SC) in the field in Norther, DACO: 7.4.5,IIA 6.5.3
1661147	2008, AE C656948 500 SC + trifloxystrobin 500 SC - Magnitude of the residue in/on globe artichoke, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661154	2008, AE C656948 500 SC - Magnitude of the residue in/on dry bulb onions, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661159	2008, AE C656948 500 SC - Magnitude of the residue in/on green onions, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661174	2008, AE C656948 500 SC and trifloxystrobin 500 SC - Magnitude of the residue in/on leafy vegetables (crop subgroup 4), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1

1669960	2008, AE C656948 500 SC and trifloxystrobin 500 SC - Magnitude of the residue in/on leafy vegetables (crop subgroup 4), DACO: 7.4.1,7.4.2,7.4.6,IIA 8.3.2
1983751	2010, AE C656948 500 SC and trifloxystrobin 500 SC - Magnitude of the residue in/on leafy vegetables (crop subgroup 4), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661180	2008, AE C656948 500 SC and trifloxystrobin 500 SC - Magnitude of the residue in/on head and stem brassica (crop subgroup 5A), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1669962	2008, AE C656948 500 SC and trifloxystrobin 500 SC - Magnitude of the residue in/on head and stem brassica (crop subgroup 5A), DACO: 7.4.1,7.4.2,7.4.6,IIA 8.3.3
1661199	2008, AE C656948 500 SC - Magnitude of the residue in/on leafy brassica greens (crop subgroup 5B), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661209	2008, AE C656948 500 SC - Magnitude of the residue in/on succulent shelled pea and bean (crop subgroup 6B), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661210	2008, AE C656948 500 SC - Magnitude of the residue in/on edible-podded legume vegetables (crop subgroup 6A), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661221	2008, AE C656948 500 SC - Magnitude of the residue on citrus (crop group 10), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661236	2008, AE C656948 500 SC + pyrimethanil 600 SC - Magnitude of the residue in/on caneberry, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661237	2008, AE C656948 500 SC + pyrimethanil 600 SC - Magnitude of the residue in/on bushberry (crop subgroup 13B), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661249	2008, AE C656948 500 SC - Magnitude of the residue in/on grass forage, fodder, and hay (crop group 17) and grass for seed, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661250	2008, AE C656948 500 SC + trifloxystrobin 500 SC - Magnitude of the residue in/on globe herbs (crop subgroup 19A), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661251	2008, AE C656948 500 SC + trifloxystrobin 500 SC - Magnitude of the residue in/on spices, except black pepper (crop subgroup 19B), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661252	2008, AE C656948 500 SC - Magnitude of the residue in/on peanuts, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661258	2008, AE C656948 500 SC: Magnitude of the residue on hops, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
1661259	2008, AE C656948 500 SC - Magnitude of the residue in/on sunflower, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2427018	2013, Fluopyram 500 SC and fluopyram 400 SC - Magnitude of the residue in/on potato, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2427239	2013, Fluopyram 500 SC and fluopyram 400 SC - Magnitude of the residue in/on potato, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2427021	2013, Fluopyram 500 SC and fluopyram 400 SC - Magnitude of the residue in cotton (Amended) - (i-MRL), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.2

2427022	2014, Fluopyram 500 SC and fluopyram 400 SC - Magnitude of the residue in/on citrus - Fluopyram 500 SC (short code - 129306) - Fluopyram 400 SC (short code - 151196) (i-MRL), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.2
2427023	2013, Fluopyram 500 SC and Fluopyram 400 SC - Magnitude of the residue in/on peanut (i-MRL), DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.2
2427035	2012, BYI 02960, fenamidone, fluopyram, and spiromesifen - Magnitude of the residue in sugarcane processed commodities in Florida (rotational crop regional tolerance) - (Amended) (i-MRL), DACO: 7.4.5,IIA 6.5.3
2427043	2013, Fluopyram 500 SC and fluopyram 400 SC - Magnitude of the residue in/on cotton processed commodities (i-MRL), DACO: 7.4.5,IIA 6.5.3
2427044	2012, BYI 02960, fenamidone, fluopyram, and spiromesifen - Magnitude of the residue in sugarcane in Florida (rotational crop regional tolerance) (Amended) (i-MRL), DACO: 7.4.4,IIA 6.6.3
2535486	2015, Fluopyram- Proposal to Modify Petition for tolerances-version#4 (final), DACO: 7.1,7.8,IIA 6.7.2
2572513	2015, Waiver request: AE C656948 500 SC - Magnitude of the residue in/on barley (as part of crop groups 15 and 16, except rice): Bayer CropScience response to the PMRA deficiency note for fluopyram on barley, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2572514	2015, Waiver request: AE C656948 500 SC - Magnitude of the residue in/on canola (crop group 20A): Bayer CropScience response to the PMRA deficiency note for fluopyram on canola, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2572515	2015, Waiver Request: AE C656948 500 SC - Magnitude of the residue in/on wheat (as part of crop groups 15 and 16, except rice): Bayer CropScience response to the PMRA deficiency note for fluopyram on wheat, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2572518	2015, Waiver request: AE C656948 500 SC - Magnitude of the residue in/on small-sized tomatoes (as part of crop groups 8-09A): Bayer CropScience response to the PMRA deficiency note for fluopyram on tomatoes, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
2577848	2015, Fluopyram - Projected Percent Crop Treated - Canada, DACO: 7.1,7.8,IIA 6.7.2

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