

Evaluation Report for Category B, Subcategory 3.3, 3.4, 3.6, 3.7, 3.11, 3.12 Application

Application Number: 2014-1827

Application:

- B.3.3 New or Changes to Product Labels-Application Number or Frequency
- B.3.4 New or Changes to Product Labels-Application Method
- B.3.6 New or Changes to Product Labels-Pre- Harvest/Slaughte|With-Holding
- B.3.7 New or Changes to Product Labels-Pre-Grazing Interval
- B.3.11 New or Changes to Product Labels-New Pests
- B.3.12 New or Changes to Product Labels-New Site or Host

Product: Luna Privilege

Registration Number: 30509 **Active ingredients (a.i.):** Fluopyram **PMRA Document Number:** 2577452

Purpose of Application

The purpose of this application was to add crops to the label, to add a disease claim on potatoes, add in-furrow and drench application on some crops and to change rotational crop statement.

Chemistry Assessment

No chemistry review was required for this product.

Health Assessments

No toxicology assessment was required.

The occupational exposure and risk from the addition of the uses on artichokes, brassica (cole) leafy vegetables, bulb vegetables, carrot and other root vegetables, cereal grains, cucurbit vegetables, fruiting vegetables, grapes and small vine fruits, herbs and spices, hops, leafy vegetables, legume vegetables, oilseed crops (including the rapeseed and sunflower subgroups) pome fruits, tuberous and corm vegetables, small berries, stone fruit, and almonds to the Luna Privilege label was assessed. No health risks of concern are expected from the new uses, 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 Canada and the United States, including Canadian representative growing regions, were submitted to support the domestic use of Luna Privilege on various crops. Fluopyram was applied to carrots, radish, potatoes, dry bulb



onions, green onions, leaf lettuce, head lettuce, spinach, celery, cabbage, broccoli, cauliflower, mustard greens, snap beans, snow peas, lima beans, garden peas, tomatoes, bell peppers, chili peppers, raspberries, blackberries, highbush blueberries, grass, basil, chives, dill seed, sunflowers, globe artichokes, hops and peanuts at label rates, and harvested according to label directions. Previously reviewed residue data from field trials conducted in/on potatoes, sugar beets, dry beans, dry peas, cucurbits, pome fruits, stone fruits, strawberries, grapes, tree nuts, peanuts, soybeans, cereals, canola and alfalfa were reassessed in the framework of this petition. In addition, processing studies in treated tomatoes, plums, peaches and sunflowers were reviewed, and processing data in treated potatoes, sugar beet, soybeans, apples, grapes, strawberries, wheat, field corn, canola and peanut 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 in Table 1 are covered under the proposed MRLs for the raw agricultural commodities (RACs).

TABLE 1. Limits (MRL	TABLE 1. Summary of Field Trial and Processing Data Used to Support Maximum Residue Limits (MRLs).						
Commodity		PHI (days)	Fluopyram Residues (ppm)		Experiment al Processing	Currently Established MRL	Recommende d MRL (ppm)
	Application Rate (g ai/ha)		LAFT	HAF T	Factor	(ppm)	
Carrot roots	Foliar spray/ 487- 517	0	0.017	0.088	Not required	None	0.3 (CSG 1B: Root
Radish roots	Foliar spray/ 495- 510	0	0.047	0.160	Not required	None	Vegetables, except sugarbeet)
Sugar beet roots	Foliar spray/ 492- 511	5-7	0.018	0.046	Refined sugar (1.3x)	0.1	None
Potato tubers	In furrow application to bare soil at planting/ 490-520	7	<0.01	0.069	No concentratio n was observed in food commoditie s	0.02 (CSG 1C: Tuberous and Corm Vegetables)	0.1 (CSG 1C: Tuberous & Corm Vegetables)
Turnip tops	Foliar spray/ 500- 510	7	0.495	3.816	Not required	None	30 (CG 2: Leaves of
Sugar beet tops	Foliar spray/ 492- 511	5-7	0.279	16.51	Not required	None	Root & Tuber Vegetables)

Commodity	Application Method/ Total	PHI (days)	Fluopy Residu (ppm)		Experiment al Processing	Currently Established MRL	Recommende d MRL (ppm)
	Application Rate (g ai/ha)		LAFT	HAF T	Factor	(ppm)	
Radish tops	Foliar spray/ 495- 510	0	10.53	25.31	Not required	None	
Dry bulb onions	Foliar spray/ 482- 501	0	0.016	0.186	Not required	None	0.4 (CSG 3-07A: Bulb Onion Subgroup)
Green onions	Foliar spray/ 488- 521	0	1.745	6.182	Not required	None	15 (CSG 3- 07B: Green Onion Subgroup) ¹
Chives, whole plant w/o roots	Foliar spray/ 503- 517	0	6.051	19.80	Not required	None	50 (Fresh chive leaves)
Head lettuce	Foliar spray/ 494- 513	0	0.583	5.286	Not required	None	40 (CSG 4A: Leafy Greens)
Leaf lettuce	Foliar spray/ 495- 506	0	1.239	9.048	Not required	None	
Spinach	Foliar spray/ 494- 514	0	8.214	22.03	Not required	None	
Celery	Foliar spray/ 492- 515	0	0.024	10.58	Not required	None	20 (CSG 4B: Leaf Petioles)
Cabbage	Foliar spray/ 492- 526	0	0.059	1.266	Not required	None	4 (CSG 5A: Head and
Broccoli	Foliar spray/ 492- 526	0	1.058	1.179	Not required	None	Stem Brassica)
Cauliflower	Foliar spray/ 492- 526	0	0.02	0.835	Not required	None	
Mustard greens	Foliar spray/ 490- 509	0	8.99	25.62	Not required	None	50 (CSG 5B: Leafy <i>Brassica</i> Greens)
Snap beans	Foliar spray/ 497- 512	0	0.128	0.698	Not required	None	4 (CSG 6A: Edible-podded
Snow peas	Foliar spray/ 500- 528	0	0.784	1.240	Not required	None	legume vegetables)
Lima beans	Foliar spray/ 498- 503	0	0.011	0.070	Not required	None	0.2 (CSG 6B: Succulent

TABLE 1. Summary of Field Trial and Processing Data Used to Support Maximum Residue Limits (MRLs). **Commodity** Application PHI Fluopyram **Experiment** Recommende Currently Method/ Residues Established d MRL (days) **Processing** (ppm) **MRL Total** (ppm) **Factor Application Rate** LAFT **HAF** (ppm) T (g ai/ha) Foliar spray/ 493-0 0.073 shelled pea Garden peas < 0.01 Not required None 511 and bean) Dry bean Foliar spray/ 494-13-14 < 0.01 0.068 Not required 0.4 (Dry **0.7** (CSG 6C: chickpeas, Dried shelled seed 514 dry lentils); pea and bean, Dry pea seed Foliar spray/ 494-14 Not required 0.03 0.350 0.09 (Dry except 509 beans) soybean) Soybean seed Foliar spray/ 485-0.160 No 12-14 < 0.01 0.1 (Dry **0.2** (Dry 519 concentratio soybeans) soybeans) n was observed in food commoditie **Tomatoes** Foliar spray/ 493-0 0.021 0.342 Dried None 0.5 (CSG 8-09A: 511 tomatoes (4.3x); no Tomatoes); concentratio **1.5** (Dried n was tomatoes) observed in other food commoditie Foliar spray/ 494-0 0.035 Not required None 4 (CSG 8-Bell peppers 0.359 512 09B: Peppers/ Foliar spray/ 490-0 0.117 1.233 None Eggplants) Nonbell Not required peppers 503 Foliar spray/ 499-0 0.439 1 (CSG 9A: Muskmelon 0.072 Not required Cucurbit 526 (Watermelo n) vegetables, Melon)² Cucumber Foliar spray/ 485-0 0.051 0.144 Not required None **0.3** (CSG 9B: 508 Cucurbit vegetables, Foliar spray/ 497-0 Summer 0.069 0.174 Not required None Squash/ squash 510 Cucumber)

Commodity	Application Method/ Total	PHI (days)	Fluopy Residu (ppm)		Experiment al Processing	Currently Established MRL	Recommende d MRL (ppm)
	Application Rate (g ai/ha)		LAFT	HAF T	Factor	(ppm)	
Apple	Foliar spray /491-517 (concentrated)	7	0.046	0.242	No concentratio n was	0.3 (apples)	0.8 (CG 11-09: Pome Fruits)
	Foliar spray /495- 511 (dilute)	7	0.063	0.255	observed in food commoditie s		
Pear	Foliar spray /494- 504 (concentrated)	6-7	0.122	0.497	Not required	None	
	Foliar spray /493- 503 (dilute)	6-7	0.126	0.406			
Cherry	Foliar spray /501-516 (concentrated)	0	0.066	0.640	Not required	1.5 (sweet cherries, tart cherries)	2 (CSG 12-09A: Cherries)
	Foliar spray /498- 512 (dilute)	0	0.155	1.179			
Peach	Foliar spray /489-511 (concentrated)	0	0.153	0.451	Dried peach (3.4x)	None	1 (CSG 12- 09B: Peaches): 2 (dried
	Foliar spray /494- 512 (dilute)	0	0.189	0.549			nectarines, dried peaches)
Plum	Foliar spray /481-499 (concentrated)	0	0.023	0.258	Prunes (1.2x)	None	0.5 (CSG 12-09C: Plums)
	Foliar spray /495- 509 (dilute)	0	0.024	0.284			
Raspberry/ blackberry	Foliar spray/ 499- 516	0	0.427	2.392	Not required	None	5 (CSG 13- 07A: Caneberry)

Commodity	Application Method/ Total	PHI (days)	Fluopy Residu (ppm)		Experiment al Processing	Currently Established MRL	Recommende d MRL (ppm)
	Application Rate (g ai/ha)		LAFT	HAF T	Factor	(ppm)	
Highbush blueberry	Foliar spray/ 491- 505	0	0.583	4.329	Not required	None	7 (CSG 13-07B: Bushberry)
Grape	Foliar spray/ 492- 513	6-7	0.099	0.948	Raisin (2.9x)	2 (Grapes)	2 (CSG 13- 07F: Small fruit, vine climbing, except fuzzy kiwifruit) ³ ; 3 (Raisins)
Strawberry	Direct broadcast/ 491-519	0	0.196	1.012	Not required	1.5 (Strawberrie s)	2 (CSG 13- 07G: Low growing berry) ⁴
Almond nutmeat	Foliar spray /481- 499 (concentrated)	14	<0.01	0.019	Not required	0.05 (CG 14-11: Tree Nuts)	None
	Foliar spray /495- 509 (dilute)	14	<0.01	0.015			
Pecan nutmeat	Foliar spray /481- 499 (concentrated)	12-14	<0.01	0.018	Not required		
	Foliar spray /495- 509 (dilute)	12-14	<0.01	0.031			
Field corn grain	Foliar spray/ 492- 520	11-14	<0.01	0.018	Corn bran (2.6x)	1.5 (CG 15: Cereals),	None
Kernels with cobs, no husks	Foliar spray/ 495- 527	0	<0.01	<0.01	Not required	except rice	None
Wheat grain	Foliar spray/ 492- 514	12-15	0.038	0.720	Wheat bran (2.7x), wheat germ (2.4x)		2 (Wheat bran, wheat germ)

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)	Fluopy Residu (ppm) LAFT		Experiment al Processing Factor	Currently Established MRL (ppm)	Recommende d MRL (ppm)
Sorghum grain	Foliar spray/ 495- 518	12-14	0.230	0.705	Not required		None
Basil, fresh leaves	Foliar spray/ 498- 520	0	18.78	30.00	Not required	None	70 (CSG 19A: Herbs/Fresh)
Basil, dried leaves	Foliar spray/ 498- 520	0	90.61	180.8	Not required	None	400 (CSG 19A: Herbs/Dried)
Dill seed, dried	Foliar spray/ 493- 513	14	9.162	29.59	Not required	None	70 (Dill seed)
Canola seed	Foliar spray/ 492- 508	12-14	0.096	0.425	No concentratio n was observed in food commoditie s	1.8 (Rapeseeds (canola))	1.8 (CSG 20A: Rapeseeds, Revised)
Sunflower seed	Foliar spray/ 486- 504	12-14	0.012	0.382	No concentratio n was observed in food commoditie s	None	0.7 (CSG 20B: Sunflowers, Revised)
Globe artichoke	Foliar spray/ 496- 507	0	1.02	1.37	Not required	None	4 (Globe artichokes)
Hops, dried cones	Foliar spray/ 494- 514	7	5.80	25.37	Not required	None	60 (Hops (dried))
Peanut nutmeat	Seed treatment (250 g ai/ha) + foliar application (250 g ai/ha)	6-10	0.012	0.128	No concentratio n was observed in food commoditie s	0.02	0.2 (Peanuts)

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

1 Except fresh chive leaves, which will be covered with a separate MRL of 50 ppm.

2 Except watermelon, which is covered with the existing MRL of 1 ppm.

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

Luna Privilege is a broad spectrum systemic fungicide currently registered (Reg No. 30509) for use on apples, watermelon, wine grapes, dry beans, chickpea, lentil, peanut, potato, cherry, strawberry and almond by ground and aerial (potato only) applications. The proposed applications rates and method of application are the same as those currently registered rates except for potato where the aerial application rate is increased. With revised aerial buffer zones for potatoes, use expansion to new crops and increased aerial application rates are not expected to pose additional environmental concerns.

Value Assessment

Excluding the registrant's request to register Luna Privilege for suppression of nematodes in crop subgroup 1C, other proposed label amendments have been previously evaluated under the original global joint review. All proposed claims for use against fungal diseases were either accepted or conditionally accepted in previous application. Therefore, the value assessment of the current application consisted of confirmatory value information for certain uses in sunflower, stone fruits and bulb vegetables. Scientific rationales and efficacy data from seven field trials demonstrated that Luna Privilege suppressed sclerotinia head rot in sunflower and controlled powdery mildew in stone fruits and purple blotch on bulb vegetables. The submitted value information was sufficient to support the label amendments for Luna Privilege.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Luna Privilege, and has found the information sufficient to add crops, add a disease claim, add in-furrow and drench application on some crops and to change rotational crop statement of the product label.

References

³ Except gooseberries, which are also in CSG 13-07B, and will be covered with the MRL of 7 ppm proposed on CSG 13-07B.

⁴ 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.

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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 green onions, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1 1661161 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 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 1661180 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 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 1661190 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,IIIA 6.3.1 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,IIIA 6.3.1 2008, AE C656948 500 SC - Magnitude of the residue in/on succ	1654389	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
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 1661159 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 1661174 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,IIIA 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,IIIA 6.3.1 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 1661200 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	1661292	round cabbage head and the processed fractions (washings; cooking water; head, cooked; head, washed) after spraying of AE C656948 & HWG 1608 (400 SC) in
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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
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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
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