



## Evaluation Report for Category B, Subcategory 3.5, 3.11, 3.12 Application

**Application Number:** 2014-1826

**Application:**

New or Changes to Product Labels-New Pests

New or Changes to Product Labels-New Site or Host

New or Changes to Product Labels-Rotational Crops\Plantback Intrvl

**Product:** Luna Tranquility Fungicide

**Registration Number:** 30510

**Active ingredients (a.i.):** Fluopyram, pyrimethanil

**PMRA Document Number :** 2576307

### Purpose of Application

The purpose of this application was to amend the currently registered label of Luna Tranquility Fungicide to add new crops, to add new pest claims and to revise the rotational cropping restrictions.

### Chemistry Assessment

No chemistry review was required for this application.

### Health Assessments

No toxicological review was required for this application.

The use of Luna Tranquility Fungicide on pome fruits, small berries, table grapes, bulb vegetables and field tomatoes is not expected to result in potential occupational or bystander exposure over the registered use of pyrimethanil. The occupational exposure and risk from the addition of the uses on pome fruits, small berries, table grapes, bulb vegetables and field tomatoes was assessed for fluopyram. 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 Tranquility on various crops. Fluopyram was applied to potatoes, dry bulb onions, green onions, tomatoes, raspberries, blackberries and highbush blueberries at label rates, and harvested according to label directions. Previously reviewed residue data from field trials conducted in/on potatoes, pome fruits, strawberries and grapes were reassessed in the framework of this petition. In addition, processing studies in treated tomatoes were reviewed, and processing data in treated potatoes, apples, grapes and strawberries were reassessed to determine the potential for concentration of residues of fluopyram into processed commodities.

No new residue data for pyrimethanil were submitted to support the registration of Luna Tranquility containing this active ingredient. Pyrimethanil is currently registered for use on pome fruits, grapes, strawberries, potatoes, tomatoes, bulb vegetables, highbush and lowbush blueberries, raspberries and gooseberries with higher rates and similar restrictions as proposed. No increase in dietary exposure to pyrimethanil is expected. The resulting residues of pyrimethanil will be covered under the established maximum residue limits (MRLs) of 14 ppm in/on Crop Group 11 (Pome Fruits), 0.1 ppm in/on Crop Subgroup 3-07A (Dry Bulb Onions), 2 ppm in/on Crop Subgroup 3-07B (Green Onions), 5 ppm in/on grapes and gooseberries, 0.05 ppm in/on potatoes, 15 ppm in/on Crop Subgroup 13-07A, 8 ppm in/on Crop Subgroup 13-07B, 3 ppm in/on Crop Subgroup 13-07G, and 0.5 ppm in/on tomatoes. Residues will not pose an unacceptable health risk to any segment of the population, including infants, children, adults and seniors.

### Maximum Residue Limits

The recommendation for 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).

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	HAF T			
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)	<b>0.1</b> (CSG 1C: Tuberous & Corm Vegetables)
Dry bulb onions	Foliar spray/ 482-501	0	0.016	0.186	Not required	None	<b>0.4</b> (CSG 3-07A: Bulb Onion Subgroup)
Green onions	Foliar spray/ 488-521	0	1.745	6.182	Not required	None	<b>15</b> (CSG 3-07B: Green Onion Subgroup) <sup>1</sup>

**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	HAF T			
Chives, whole plant w/o roots	Foliar spray/ 503-517	0	6.051	19.80	Not required	None	<b>50</b> (Fresh chive leaves)
Tomatoes	Foliar spray/ 493-511	0	0.021	0.342	Dried tomatoes (4.3x); no concentration was observed in other food commodities	None	<b>0.5</b> (CSG 8-09A: Tomatoes); <b>1.5</b> (Dried tomatoes)
Apple	Foliar spray /491-517 (concentrated)	7	0.046	0.242	No concentration was observed in food commodities	0.3 (apples)	<b>0.8</b> (CG 11-09: Pome Fruits)
	Foliar spray /495-511 (dilute)	7	0.063	0.255			
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			
Raspberry/blackberry	Foliar spray/ 499-516	0	0.427	2.392	Not required	None	<b>5</b> (CSG 13-07A: Caneberry)
Highbush blueberry	Foliar spray/ 491-505	0	0.583	4.329	Not required	None	<b>7</b> (CSG 13-07B: Bushberry)

**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			
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) <sup>2</sup> ; 3 (Raisins)
Strawberry	Direct broadcast/ 491-519	0	0.196	1.012	Not required	1.5 (Strawberries)	2 (CSG 13-07G: Low growing berry) <sup>3</sup>

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

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

<sup>2</sup> Except gooseberries, which are also in CSG 13-07B, and will be covered with the MRL of 7 ppm proposed on CSG 13-07B.

<sup>3</sup> 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.

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 Tranquility Fungicide is a broad spectrum fungicide with two technical actives, i.e., Fluopyram Technical Fungicide and Pyrimethanil Technical Fungicide. It is currently registered for use on apples and wine grapes by ground application equipment, and potatoes (aerial and ground equipment) for the control of fungal diseases. The application rates and the use pattern (ground and aerial applications) are the same as those currently registered. Use expansion of Luna Tranquility Fungicide to include bulb vegetables, pome fruit, small berries, strawberry and other low-growing berries, grapes and field tomatoes is, therefore, not expected to pose additional environmental concerns.

### Value Assessment

Based on the value information submitted with the original application and on efficacy data and rationales, the following uses and claims were supported:

- Control of botrytis leaf blight (*Botrytis cinerea* and *B. squamosa*) and purple blotch (*Alternaria porri*) and suppression of Stemphylium leaf blight (*Stemphylium vesicarium*) on bulb vegetables;
- Control of powdery mildew (*Uncinula necator*) and botrytis bunch rot / gray mold (*Botrytis cinerea*) on grapes;
- Control of powdery mildew (*Podosphaera leucotricha*) and leaf scab (*Venturia inaequalis*) on pome fruit;
- Control of powdery mildew (*Sphaerotheca* spp.) and botrytis gray mold (*Botrytis cinerea*) on small berries, Crop Sub-Groups 13A, 13B and 13G;
- Control of early blight (*Alternaria solani*) and Septoria leaf spot (*Septoria lycopersici*) on tomato.

The value of registering these claims is to provide an additional product for rotational and resistance management purposes for the diseases and crops proposed. Several of the new uses are listed as priorities for other active ingredients in the Canadian Grower Priority Database. The use of pyrimethanil for the control of powdery mildew on strawberries is listed as an intermediate priority.

## Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Luna Tranquility Fungicide, and has found the information sufficient to add new crops, to add new pest claims and to revise the rotational cropping restrictions to the product label.

## References

PMRA Document Number	Reference
1670080	2008, Fluopyram + pyrimethanil 500 SC fungicide(125 g a.i./L fluopyram + 375 g a.i./L pyrimethanil ) For control of listed diseases in grapes and small berries, bulb vegetables, tomatoes, and pome fruit, 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
2427390	2014, Luna tranquility fungicide for control of Stemphylium leaf blight on bulb vegetables caused by Stemphylium vesicarium, DACO: 1.1,10.2.1,10.2.2,10.2.3.1, 10.2.3.2, 10.2.3.3, 10.2.3.4,10.4,10.5.1,10.5.2,10.5.3.
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,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 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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