

Evaluation Report for Category B, Subcategory 3.1, 3.4, 3.6, 3.11, 3.12 Application

Application Number:	2016-3367			
Application:	Changes to Product Labels-New Pests, New Site, Application			
	Method, Rate and Pre-Harvest Interval			
Product:	Luna Sensation			
Registration Number:	32107			
Active ingredients (a.i.):	Fluopyram and Trifloxystrobin			
PMRA Document Number : 2813114				

Purpose of Application

The purpose of this application was to amend the product label of Luna Sensation to include the use on root vegetables (except sugar beet), cucurbit vegetables, stone fruits and hops for the control of several diseases, to amend the pre-harvest interval (PHI) for leafy petioles, and to include additional diseases for leafy vegetables and *Brassica* leafy vegetables.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A toxicological assessment was not required for this application.

An updated health risk assessment for trifloxystrobin and for fluopyram was conducted for chemical handlers, re-entry workers and bystanders. With revised precautions, no health risks of concern were identified for the use of Luna Sensation. No health risks of concern are expected when workers follow the label directions and wear the personal protective equipment identified on the label.

No new residue data for fluopyram were submitted to support the petitioned changes to the registered label of Luna Sensation. Previously reviewed residue data for fluopyram from field and processing trials were reassessed in the framework of this petition. Based on this assessment, residues in/on crops treated according to the approved use directions for Luna Sensation will be covered under the MRLs currently established for fluopyram (http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php).

Previously reviewed residue data for trifloxystrobin from field and processing trials with a water dispersible granule (WG) formulation of trifloxystrobin were reassessed in the framework of this petition. Additionally, new residue data from field trials with soluble concentrate (SC) and WG formulations of trifloxystrobin were submitted, given that the residue data on file for



trifloxystrobin were from trials conducted with WG formulations and that Luna Sensation is a SC formulation. The residue data from these bridging trials confirmed that residues of trifloxystrobin did not differ significantly following treatment with the SC and WG formulations. Based on this assessment, residues in/on crops treated according to the approved use directions for Luna Sensation will be covered under the MRLs currently established for trifloxystrobin (<u>http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php</u>), and under the following MRLs being proposed for promulgation for trifloxystrobin to support the new higher application rate on radishes and to support new use on hops.

Maximum Residue Limits - Trifloxystrobin

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The recommendation for maximum residue limits (MRLs) for trifloxystrobin was based upon the previously submitted field trial data, and the guidance provided in the <u>OECD MRL Calculator</u>. MRLs to cover residues of trifloxystrobin and the acid metabolite CGA-321113 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. 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) LAF HAF		Experimental Processing Factor	Currently Established MRL	Recommended MRL
			T	Т	ractor	(ppm)	(ppm)
Hops (dried)	Foliar/855	13-14	4.710	11.06 0	Not applicable	None	40 [hops (dried)]
Radish roots	Foliar/553-590	6-8	0.062	0.149	Not applicable	0.1 [CSG 1B, except sugar beet]	0.4 [radish roots]
Radish tops	Foliar/553-590	6-8	0.30	15.02	Not applicable	10 [radish tops]	30 [radish tops]
Peach	Foliar/570	1	<0.075	1.82	Not applicable	2.0 ppm ¹ [apricots, nectarines, peaches, plumcots, plums,	2.0 ppm ² [Japanese apricots, capulins, black cherries, nanking
Sweet cherry	Foliar/570	1	0.280	0.718	Not applicable		
Tart cherry	Foliar/570	1	0.460	0.555	Not applicable		

TABLE 1. Summary of Field Trial and Processing Data Used to Support Maximum Residue Limits (MRLs)							
Commodity	Application	PHI	Residues (ppm)		Experimental	Currently	Recommended
						prune	cherries,
						plums,	jujubes,
						sweet	American
						cherries,	plums, beach
						tart	plums,
	Foliar/570	1	<0.04	0.333		cherries]	Canada
							plums, cherry
					1.4x		plums,
Plum					[dried prune]		Chickasaw
							plums,
							damson
							plums,
							Japanese
							plums,
							klamath
							plums and
							sloes]

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

¹ Includes all stone fruit commodities in CG 12 (Stone Fruits).

² Proposed to include all stone fruit commodities in CG 12-09 (Stone Fruits).

The dietary burden to livestock is not expected to increase with the current petition.

The MRLs as proposed in Table 1 are recommended to cover residues of trifloxystrobin. No new MRLs are required for fluopyram for this petition. Residues of each active in these crop commodities at the proposed and established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

No new data were required in support of this use expansion. The use of the product following this use expansion is not expected to increase environmental risk when label directions are followed. Environmental statements on the product label, including buffer zones, are sufficient to address environmental concerns.

Value Assessment

Efficacy data from 35 trials conducted in multiple locations world-wide were provided in support of the use claims. Overall, Luna Sensation demonstrated an acceptable level of disease control against powdery mildew on root vegetables, leafy green and petiole vegetables, Brassica leafy vegetables, cucurbit vegetables, stone fruit and hops; against alternaria blight on root vegetables and Brassica leafy vegetables; against *Sclerotinia* disease on root vegetables; and against *Monilinia* diseases, cherry leaf spot and scab on stone fruit. The causative fungal pathogens for several diseases were modified and updated based on the disease information and the efficacy

data provided.

The registration of these new uses will provide Canadian growers with a new end-use product to manage these important diseases on root vegetables, leafy green and petiole vegetables, Brassica leafy vegetables, cucurbit vegetables, stone fruit and hops, and contribute to the resistance management. Based on the efficacy data provided, the use claims are supported from a value perspective.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the amendments for Luna Sensation.

References

PMRA	
Document	
Number	Reference
1913109	2009, Agricultural Handler Exposure Task Force (AHETF), Agricultural Handler
	Exposure Scenario Monograph: Open Cab Groundboom Application of Liquid
	Sprays. Report Number AHE1004. December 23, 2009.
2572745	2015, Agricultural Handler Exposure Task Force (AHETF), Agricultural Handler
	Exposure Scenario Monograph: Open Pour Mixing and Loading of Liquid
	Formulations. Report Number AHE1003-1. March 31, 2015.
2572743	2014, Agricultural Handler Exposure Task Force (AHETF), Agricultural Handler
	Exposure Scenario Monograph: Open Cab Airblast Application of Liquid Sprays.
	Report Number AHE1006. October 20, 2014.
2115788	2008, Agricultural Reentry Task Force (ARTF). Data Submitted by the ARTF to
	Support Revision of Agricultural Transfer Coefficients. Submission #2006-0257.
1193863	1999, CGA-279202 AND CGA-245704 - Magnitude of the residues in or on hops.,
	DACO: 7.4.1
1994776	2006, Trifloxystrobin: Magnitude of the residue on radish, DACO: 7.4.1
2739831	2009, Flint 50 WG and Gem 500 SC - Magnitude of the residue in/on grapes,
	DACO: 7.4.1,7.4.2,7.4.6,IIIA 8.3.1
2739832	2009, Gem 500 SC and Flint 50 WG - Magnitude of the residue in/on grasses grown
	for seed, DACO: 7.4.1,7.4.2,7.4.6,IIIA 8.3.1
2739833	2009, Gem 500 SC and Flint 50 WG - Magnitude of the residue in/on tomatoes,
	DACO: 7.4.1,7.4.2,7.4.6,IIIA 8.3.1
2739834	2009, Gem 500 SC and Flint 50 WG - Magnitude of the residue in/on peaches,
	DACO: 7.4.1,7.4.2,7.4.6,IIIA 8.3.1
1242324	2000, CGA-279202 and CGA-245704 - Magnitude of the Residues In or On Crop
	Group 12: Stone Fruit, DACO: 7.4.1,7.4.2

2656510	2016, Field trial reports: Value assessment of Luna Sensation fungicide for control of listed diseases in certain fruit and vegetable crops, 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
2656511	2016, Value assessment of Luna Sensation fungicide for control of listed diseases in certain fruit and vegetable crops, 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
2690715	2016, Trifloxystrobin Field Trials – hops and peach, DACO: 10.2.3.3
: 1911-8082	

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