Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2019-0782
Application: Changes to End-Use Product Labels – New Site or Host
Product: ORONDIS Gold Fungicide
Registration Number: 33508
Active ingredients (a.i.): Metalaxyl-M and S-Isomer, Oxathiaprolin
PMRA Document Number: 3168496

Purpose of Application

The purpose of this application was to amend the label of the end-use product, ORONDIS Gold Fungicide, to add crop subgroup (CSG) 13-07A (caneberries), CSG 13-07B (bushberries), listed low growing berries (bearberry, bilberry, lowbush blueberry, cloudberry, lingonberry, muntries, partridgeberry, strawberry, and cultivars, varieties and/or hybrids of these) and crop group (CG) 14-11 (tree nuts) for claims of control of phytopthora diseases.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A toxicology assessment was not required for this application.

The use of ORONDIS Gold Fungicide on Crop Subgroups 13-07A and 13-07B, listed tree nuts and listed low growing berries is not expected to result in risks of concern for chemical handlers, post-application workers, and bystanders provided that the product is used according to the label directions.

Residue data from pecan field trials using metalaxyl-M conducted in the United States were submitted to support the domestic use of ORONDIS Gold Fungicide on Crop Group 14-11 (Tree Nuts). Metalaxyl-M was applied to pecans at exaggerated rates, and harvested at longer preharvest intervals (PHIs) than proposed. Previously reviewed residue data for metalaxyl and metalayl-M from field trials conducted in/on caneberries, strawberries, blueberries and almonds were reassessed in the framework of this petition.

Residue data from field trials using oxathiapiprolin conducted in Canada and the United States were submitted to support the domestic use of ORONDIS Gold Fungicide on Crop Subgroup 13-07B (Bushberries, except lowbush blueberries), Crop Subgroup 13-07G (Low Growing Berries, except lingonberries and cranberries), and Crop Group 14-11 (Tree Nuts). Oxathiapiprolin was applied to highbush blueberries at exaggerated rates, and harvested according

to label directions. Oxathiapiprolin was applied to strawberries at the proposed rate, and harvested at shorter PHIs. Oxathiapiprolin was applied to almonds and pecans at the proposed rate, and harvested according to label directions. Previously reviewed residue data for oxathiapiprolin from field trials conducted in/on caneberries were reassessed in the framework of this petition.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for metalaxyl and oxathiapiprolin was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. MRLs to cover residues of metalaxyl-M and oxathiapiprolin in/on crops 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)		Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT		
Metalaxyl-M						
Raspberries	Soil-directed + foliar/ 2264-2443	0	0.296	0.686	0.5	1.5 Caneberries (Crop Subgroup 13-07A)
Blackberries	Soil-directed + foliar/ 2186-2253	0	0.387	0.396	Not established.	
Strawberries	Soil drench + drip irrigation/ 1122	27	0.39	0.39	10	10 Bearberries, bilberries, lowbush blueberries, cloudberries, muntries, partridgeberries
	Pre- or post-transplant + foliar/ 1122-1683	28	0.42	0.83		
	Drip irrigation/ 1683	0	0.09	0.99		
	Foliar or drench broadcast/ 1683	0-3	0.85	7.4		

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues (ppm)		Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT		
Almonds	Soil-directed broadcast/ 13452	28-29	<0.05	0.20	0.5	0.5 Tree Nuts (Crop Group 14-11, except almond nuts, black walnuts, and English walnuts)
Pecans	Soil-directed/ 6668-6749	56-70	<0.05	0.13	Not established.	
Oxathiapiprolin						
Highbush Blueberries	Soil drench/ 552-577	1	<0.01	0.27	Not established.	0.5 Bushberries (Crop Subgroup 13-07B, except lowbush blueberries)
Strawberries	Soil-directed + foliar/ 393-398	0	0.051	0.207	Not established.	0.4 Low Growing Berries (Crop Subgroup 13-07G, except lingonberries and cranberries)
Almonds	Soil-directed/ 268-283	27-31	<0.01	<0.01	Not established.	0.01 Tree Nuts (Crop Group 14-11)
Pecans	Soil-directed/ 279-280	26-30	<0.01	<0.01	Not established.	

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

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of metalaxyl-M and oxathiapiprolin. Residues in these crop 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

The proposed use patterns for ORONDIS Gold Fungicide are within those evaluated under previous risk assessments of metalaxyl-M and oxathiapiprolin. No increased environmental risks are expected from the use expansion of ORONDIS Gold Fungicide that cannot be mitigated through labelling.

Value Assessment

The results of nine efficacy trials and rationales were submitted to support the addition of claims against phytophthora diseases to the registration of ORONDIS Gold Fungicide. Based on the value information, it can be expected that ORONDIS Gold Fungicide will manage these phytopthora diseases on caneberries (CSG 13-07A), bushberries (CSG 13-07B), certain low growing berries, and certain tree nuts. Additionally, ORONDIS Gold Fungicide will provide two modes of action to manage these diseases, which may contribute to reducing the risk of pathogen resistance development. Therefore, the addition of these claims is supported.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found the information sufficient to support the addition of various crops on the label of ORONDIS Gold Fungicide.

References

PMRA Document Number	References
2965216	2017, Oxathiapiprolin (A21008A) - Magnitude of the Residues in Blueberry, USA, 2016 - Final Report, DACO: 7.4.1, 7.4.2
2965217	2018, Magnitude of Residues of Oxathiapiprolin OD (A20941A) and Mefenoxam SL (A13947A) in Tree Nuts - Pecans and Almonds, USA, 2016 - Final Report, DACO: 7.4.1, 7.4.2
2965218	2018, Oxathiapiprolin: Magnitude of the Residue on Strawberry, DACO: 7.4.1, 7.4.2
2965219	2018, ORONDIS Gold Value Summary - FINAL, DACO: 10.1
2965221	1997, Evaluate Phytotoxicity Potential of Ridomil Gold On Deciduous Fruit And Nut Replants, DACO: 10.2.3.3
2965222	1998, Evaluate Ridomil Gold For Control of Phytotoxicity And Root Rot Control In Almonds And Stone Fruits - Drench, DACO: 10.2.3.3
2965223	2016, Table x. Efficacy of soil treatments with registered and new fungicides for management of Phytophthora crown rot of Nonpareil almond on Hansen and Nemaguard rootstocka, DACO: 10.2.3.3
2965224	2019, Reduced risk document for soil uses on citrus and potato, DACO: 10.2.3.3
2965225	2015, Evaluate OXTP+MFX for Phytophthora control in citrus, DACO: 10.2.3.3
2965226	2013, Evaluation of mandipropamid (Revus) for crop safety and control of Phytophthora in citrus nurseries, DACO: 10.2.3.3
2965227	2014, Evaluation of new fungicides for management of Phytophthora root rot of citrus, DACO: 10.2.3.3
2965228	2016, Phytophthora Management- CRB project 5400-148 - JEA Report 7/2016 - Progress and findings, DACO: 10.2.3.3
2965229	2016, Evaluation of products to control Phytophthora crown rot in annual strawberry, 2015-2016, DACO: 10.2.3.3
2965232	2016, Evaluate OXTP for Phytophthora control in strawberries, DACO: 10.2.3.3