

## Evaluation Report for Category B, Subcategory 3.4, 3.11 Application

**Application Number:** 2016-2965  
**Application:** Changes to Product Labels-New Pests and Application Method  
**Product:** Orondis Fungicide  
**Registration Number:** 32103  
**Active ingredients (a.i.):** Oxathiapiprolin  
**PMRA Document Number:** 2781588

### Purpose of Application

The purpose of this application was to amend the label of Orondis Fungicide (100 g/L oxathiapiprolin) to add aerial application for potatoes, and in-furrow application for suppression of pink rot on potatoes.

### Chemistry Assessment

A chemistry assessment was not required for this application.

### Health Assessments

A toxicological assessment was not required for this application.

The addition of soil application method on potato will not result in an increase in occupational exposure. The aerial application method on potato may result in potential increase in occupational exposure. There are no dermal exposure concerns as no dermal toxicity endpoint was identified for oxathiapiprolin. An updated quantitative inhalation exposure risk assessment for aerial application on potato was conducted for mixers, loaders and applicators. No health risks of concern are expected for these workers or for postapplication workers from dry residues provided that workers follow the approved label directions and wear the personal protective equipment identified on the label.

Residue data from field trials conducted in Canada and the United States were submitted to support in-furrow application of Orondis Fungicide on potatoes at planting. Oxathiapiprolin was applied to potatoes at exaggerated rates, and harvested according to label directions. In addition, a processing study in treated potatoes was reassessed to determine the potential for concentration of residues of oxathiapiprolin into processed commodities.

### Maximum Residue Limit(s)

The recommendation for maximum residue limits (MRLs) for oxathiapiprolin was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of oxathiapiprolin 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 Limit (MRL)**

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Oxathiapiprolin Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT			
Potato tubers	In-furrow spray at planting + soil directed spray at-hilling/ 270-293	50-124	<0.01	0.0368	≤0.1x [Washed tubers, steam-peeled tubers, abrasion-peeled tubers, dried flakes, potato chips, peeled French fries, unpeeled French fries, boiled unpeeled potatoes, boiled peeled potatoes, microwave unpeeled (baked) potatoes].	0.01 [Tuberous and Corm Vegetables (Crop Subgroup 1C)]	0.04 [Tuberous and Corm Vegetables (Crop Subgroup 1C)]
Mustard greens	Foliar/ 138-144	0	1.460	4.291	There are no processed commodities associated with mustard greens.	None	10 [Brassica leafy greens (Crop Subgroup 4-13B)]

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

Following the review of all available data, the MRLs as proposed in Table 1 are recommended to cover residues of oxathiapiprolin. Residues in potato and CSG 4-13B 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 application rate for aerial application on potatoes is the same as the currently registered application rate for ground application. The environmental fate and behaviour and the environmental toxicity of oxathiapiprolin are summarized in the Proposed Registration Decision PRD2015-22, *Oxathiapiprolin*, and no outstanding environmental data were identified. The label for Orondis Fungicide was assessed and the label conforms to the recommendations included in the Proposed Registration Decision PRD2015-22, *Oxathiapiprolin*; however, buffer zones related label statements are required when Orondis Fungicide is being applied by air.

### **Value Assessment**

The applicant provided efficacy data from two trials conducted in Florida demonstrating simulated aerial applications for the control of late blight (*Phytophthora infestans*) on potatoes and three trials from Florida, Ontario and Manitoba to support the claim of suppression of pink rot (*Phytophthora erythroseptica*) on potatoes. The efficacy of ground and aerial applications was comparable and disease management of pink rot was effective under high disease pressure. Further, aerial applications permit the covering of larger crop areas while avoiding crop trampling, as well as treatment of saturated fields which are inaccessible by ground application equipment.

### **Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the information provided for Orondis Fungicide, and has found the information sufficient to support the addition of aerial application for potatoes, and in-furrow application for suppression of pink rot on potatoes.

## References

### PMRA

#### Document

Number	Reference
2648560	2016, Rationale for Using Available Residue Data to Amend the Labels to Include In-furrow Applications to Potatoes, DACO: 7.1
2648561	2016, Oxathiapiprolin SC (A21008A) Magnitude of the Residues in or on Potato Canada 2014, DACO: 7.4.1,7.4.2,7.4.5
2648562	2016, Oxathiapiprolin SC (A21008A) and Oxathiapiprolin OD (A20941A) - Magnitude of the Residues in or on Potato Raw Agricultural Commodities Resulting from Soil and Foliar Applications - USA, 2014, DACO: 7.4.1,7.4.2,7.4.5

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