



Evaluation Report for Category B, Subcategory 2.3, 2.4, 2.6, 3.11, 3.4 Application

Application Number: 2016-3014
Application: New end-use product: New combination of TGIAs, new formulation, new pests and application methods
Product: A21723E
Registration Number: 32806
Active ingredients (a.i.): Oxathiapiprolin
Metalaxyl-M and S-isomer
PMRA Document Number: 2781591

Purpose of Application

The purpose of this application was to register the fungicide, A21723E, with a combination of active ingredients, metalaxyl-M and S-isomer and oxathiapiprolin, for soil application on potatoes, ginseng and field cucumber.

Chemistry Assessment

A21723E is formulated as an emulsifiable concentrate containing metalaxyl-M and S-isomer at a nominal concentration of 210 g/L and oxathiapiprolin at 70 g/L. This end-use product has a density of 1.084 g/mL and pH of 4.4. The chemistry requirements for this product have been fulfilled.

Health Assessments

A21723E is of low acute toxicity via the oral, dermal and inhalation routes of exposure in rats. It is moderately irritating to the eye and minimally irritating to the skin of the rabbit. It is a skin sensitizer in the mouse via the local lymph Node assay.

The use pattern of A21723E on potato, ginseng and cucumber is covered by the registered soil use pattern for oxathiapiprolin and metalaxyl-M and S-isomer. No health risks of concern are expected when workers follow approved label directions and precautions including personal protective equipment stated on the label.

No residue data for oxathiapiprolin and metalaxyl-M and S-isomer were submitted to support registration of the end-use product A21723E, except for oxathiapiprolin in/on potatoes.

Residue data for oxathiapiprolin from field trials conducted in Canada and the United States were submitted to support in-furrow application of oxathiapiprolin in/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. Previously reviewed residue data from field trials conducted with oxathiapiprolin applied as foliar applications in/on ginseng were reassessed in the framework of this petition. In addition, the approved use directions for A21723E were compared to the labels of the precedent end-use products .

Based on this assessment, residues of oxathiapiprolin in/on treated commodities will be covered under the maximum residue limits (MRLs) currently established for cucurbit vegetables (Crop Group 9) at 0.2 ppm and for ginseng at 0.15 ppm, and residues of metalaxyl-M and S-isomer in/on treated commodities will be covered under the MRLs currently established for metalaxyl in/on cucumbers at 1 ppm, in/on ginseng at 0.5 ppm and in/on potato at 0.5 ppm. (<http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php>). Residues of oxathiapiprolin in/on potatoes will be covered under the MRL of 0.04 ppm (Table 1) proposed to replace the currently established MRL of 0.01 ppm for Crop Subgroup 1C (Tuberous and Corm Vegetables).

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)]

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

Following the review of all available data, an MRL as proposed in Table 1 is recommended to cover residues of oxathiapiprolin. Residues in potato commodities at the proposed MRL, and residues in ginseng and cucumbers at the established 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 A21723E is lower than the current labeled uses rates. 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. Moreover, the active ingredient, metalaxyl-M and S-isomer, has undergone re-evaluation (see Re-evaluation Decision RVD2008-03, *Metalaxyl and Metalaxyl-M*). The label for A21723E was assessed against the current, relevant labels for environmental statements. The label conforms to the recommendations included in the regulatory decisions, Re-evaluation Decision RVD 2008-03, *Metalaxyl and Metalaxyl-M* and the Proposed Registration Decision PRD2015-22, *Oxathiapiprolin*. Buffer zones and related label statements were assessed. A buffer zone from freshwater habitats <1 m in depth is required for A21723E when being used in ginseng.

Value Assessment

A combination of efficacy data and scientific rationales were provided in support of the application to register A21723E. The applicant referenced two products, each containing one of the active ingredients, in order to contrast the registered use patterns of oxathiapiprolin and metalaxyl-M and S-isomer with the uses of A21723E. The submitted efficacy trials, conducted in Canada, the United States, Mexico and Spain, demonstrated control of each pest when the active ingredients were used separately and conjointly. Based on the value information provided, all claims were supported.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of A21723E, for soil application on potatoes, ginseng and field cucumber.

References

PMRA

Document

Number	Reference
2649379	2016, Metalaxyl-M (Mefenoxam in USA)/Oxathiapiprolin A21723E - Document MIII, Section 1 Product Chemistry Volume , DACO: 3.1.1,3.1.2,3.1.3,3.1.4 CBI
2649380	2016, Metalaxyl-M (Mefenoxam in USA)/Oxathiapiprolin A21723E-Document J Product Chemistry Volume , DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.3.2 CBI
2649381	2015, Metalaxyl-M (Mefenoxam in USA)/Oxathiapiprolin Analytical Method SF-832/1 – Determination of Metalaxyl-M (including its S-isomer) and Oxathiapiprolin in A21723E by [CBI Removed], DACO: 3.4.1 CBI
2649382	2016, Metalaxyl-M (Mefenoxam in USA)/Oxathiapiprolin A21723E-Physico-Chemical Studies of the Formulation Product Chemistry Volume, DACO: 3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9 CBI
2649385	2016, Oxathiapiprolin /Metalaxyl-M DC (A21723E) Acute Oral Toxicity Up-And-Down Procedure in Rats, DACO: 4.6.1
2649386	2016, Oxathiapiprolin/Metalaxyl-M DC (A21723E) Acute Dermal Toxicity in Rats, DACO: 4.6.2
2649387	2016, Oxathiapiprolin/Metalaxyl-M DC (A21723E) Acute Inhalation Toxicity in Rats, DACO: 4.6.3
2649388	2016, Oxathiapiprolin/Metalaxyl-M DC (A21723E) Primary Eye Irritation in Rabbits, DACO: 4.6.4
2649391	2016, Oxathiapiprolin/Metalaxyl-M DC (A21723E) In Vitro Test for Eye Corrosives and Severe Irritants in Isolated Chicken Eyes, DACO: 4.6.4
2649396	2016, Oxathiapiprolin/Metalaxyl-M DC (A21723E) Primary Skin Irritation in Rabbits, DACO: 4.6.5
2649397	2016, Oxathiapiprolin/Metalaxyl-M DC (A21723E) Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6
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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