Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 3.11, 3.12 Application

Application Number: 2017-1737
Application: Changes to Product Label – New Pests and New Site or Host
Product: Acapela Fungicide
Registration Number: 30470
Active ingredient (a.i.): Picoxystrobin
PMRA Document Number (English PDF): 2957648

Purpose of Application

The purpose of this application was to amend the label of the end-use product, Acapela Fungicide, to add claims for control or suppression of a wide range of fungal diseases on various food and feed crops.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A toxicology assessment was not required for this application.

The occupational exposures and risks from the addition of the uses on alfalfa, sugar beet, potato, peanuts, sunflower, bulb vegetables, almond and grass grown for seed to the Acapela Fungicide label were assessed. No 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 from field trials conducted in Canada and the United States were submitted to support the domestic use of Acapela Fungicide on alfalfa, sugar beet, potato, peanuts, sunflower, bulb vegetables, almond and grass grown for seed. Picoxystrobin was applied to crops at exaggerated rates, and harvested according to label directions.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for picoxystrobin was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. MRLs to cover residues of picoxystrobin 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 (MRLs)						
Commodity	**Application**	**PHI**	**Residues (ppm)**	**Experimental**	**Currently**	**Recommended**

Canada

	Method/ Total Application Rate (g a.i./ha)	(days)	LAFT	HAFT	Processing Factor	Established MRL (ppm)	MRL (ppm)
Almond nuts	998-1008	7	<0.01	0.018	-	-	0.03
Dry bulb onion	988-1012	0	0.014	0.50	-	-	CSG 3-07A: 0.8
Green onion	983-1015	0	2.4	8.0	-	-	CSG 3-07B: 15
Peanuts	988-1014	7-8	<0.01	0.05		-	0.06
Potatoes	983-1023	3	<0.01	0.037	Chips: <0.15 Flakes: <0.15	-	CSG 1C: 0.04
Sugar beet roots	982-1029	3	0.013	0.43	Refined sugar: 0.1 Molasses: 0.08	-	0.6
Sunflower seeds	993-1019	6-9	0.015	1.5	-	-	CSG 20B: 3

LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial; CSG = Crop Subgroup

Following the review of all available data, MRLs as proposed in Table 1are recommended to cover residues of picoxystrobin. 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 new uses are within the currently registered use pattern of Acapela Fungicide, and therefore, no additional risk is expected from the use of Acapela Fungicide. The amended label includes the required environmental precautions and hazards statements, including buffer zone information, which adequately mitigates risks to the environment.

Value Assessment

The applicant submitted efficacy data to support each of the claims along with other types of value information such as considerations of benefits and rationales. A total of 51 efficacy field trials conducted between 2002 and 2015 in North America and Europe were reviewed. The potential for phytotoxicity was assessed in the majority of these efficacy trials with no symptoms of adverse effects reported in any of the tested crops.

Evidence from the submitted data was determined to be sufficient to support the value of all of the new uses. Registration of these new uses and claims on the Acapela Fungicide label will provide growers with additional product options to manage destructive fungal diseases on a wide range of crops. For certain claims, Acapela Fungicide represents either a first Canadian registration or one of only few available alternatives.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to amend the label of Acapela Fungicide to

add claims for control or suppression of a wide range of fungal diseases on various food and feed crops.

References

PMRA Document Number	References
1913109	2009, Agricultural Handler Exposure Scenario Monograph: Open Cab Groundboom Application of Liquid Sprays, DACO: 5.3, 5.4
2004944	2010, Agricultural Handler Exposure Scenario Monograph: Open Cab Airblast Application of Liquid Sprays, DACO: 5.3, 5.4
2172938	2012, Agricultural Handler Exposure Scenario Monograph: Closed Cockpit Aerial Application of Liquid Sprays, DACO: 5.3, 5.4
2572745	2015, Agricultural Handler Exposure Scenario Monograph: Open Pour Mixing and Loading of Liquid Formulations, DACO: 5.3, 5.4
2748637	2010, Magnitude and Decline of Picoxystrobin and Metabolite Residues in Grasses Grown for Seed Following Foliar Application of Picoxystrobin 250 g/l SC – U.S. and Canada, DACO: 7.4, 7.4.1, 7.4.2
2748638	2011, Magnitude of Picoxystrobin and Metabolite Residues in Processed Fractions of Sugar Beets Following Foliar Application of Picoxystrobin (DPX-YT669) 250 g/l SC at 5x Maximum Label Rate - U.S. And Canada, DACO: 7.4, 7.4.1, 7.4.2
2748639	2011, Magnitude of Picoxystrobin and Metabolite Residues in Processed Fractions of Potatoes Following Foliar Application of Picoxystrobin (DPX-YT669) 250 g/l SC at 5x Maximum Label Rate - U.S., DACO: 7.4, 7.4.1, 7.4.2
2748640	2011, Magnitude and Decline of Picoxystrobin and Metabolite Residues in Bulb Vegetables (Green Onion, Dry Bulb Onion) Following Foliar Application of Picoxystrobin (DPX-YTt669) 250 g/l SC at Maximum Label Rate - U.S. and Canada, DACO: 7.4, 7.4.1, 7.4.2
2748641	2011, Magnitude and Decline of Picoxystrobin and Metabolite Residues in Root and Tuber Vegetables (Potatoes, Carrots, Radishes, Sugarbeets, Turnips) Following Foliar or Soil Application of Picoxystrobin (DPX-YT669) 250 g/l SC at Maximum Label Rate - U.S. and Canada, DACO: 7.4, 7.4.1, 7.4.2
2748642	2011, Magnitude and Decline of Picoxystrobin and Metabolite Residues in Root and Tuber Vegetables (Potatoes, Carrots, Radishes, Sugarbeets, Turnips) Following Foliar or Soil Application of Picoxystrobin (DPX-YT669) 250 g/l SC at Maximum Label Rate - U.S. and Canada, DACO: 7.4, 7.4.1, 7.4.2
2748643	2011, Magnitude of Picoxystrobin and Metabolite Residues in Sunflower Following Foliar Application of Picoxystrobin (DPX-YT669) 250 g ai/l SC at Maximum Label Rate - U.S. and Canada, DACO: 7.4, 7.4.1, 7.4.2
2748644	2011, Magnitude of Picoxystrobin and Metabolite Residues in Tree Nuts (Almonds, Pecans) Following Foliar Application of Picoxystrobin (DPX-YT669) 250 g/l SC at Maximum Label Rate - U.S., DACO: 7.4, 7.4.1, 7.4.2
2748645	2011, Magnitude of Picoxystrobin and Metabolite Residues in Peanuts Following Foliar Application of Picoxystrobin (DPX-YT669) at Maximum Label

	Rate 250 g/l SC - U.S., DACO: 7.4, 7.4.1, 7.4.2
2748646	2016, Magnitude of Picoxystrobin and Metabolite Residues in Alfalfa Following Foliar Application of Picoxystrobin (DPX-YT669) 250 g/l SC at Maximum Label Rate - U.S. and Canada, DACO: 7.4, 7.4.1, 7.4.2
2748647	2016, Magnitude and Decline of Picoxystrobin and Metabolite Residues in Root and Tuber Vegetables (Sugarbeets) Following Foliar Application of Picoxystrobin (DPX-YT669) 250 g/l SC at Maximum Label Rate - U.S. and Canada, DACO: 7.4, 7.4.1, 7.4.2
2748648	2016, Magnitude of Picoxystrobin and Metabolite Residues in Bulb Vegetables (Green Onion, Dry Bulb Onion) Following Foliar Application of Picoxystrobin (DPX-YT669) 250 g/l SC at Maximum Label Rate - U.S. and Canada, DACO: 7.4, 7.4.1, 7.4.2
2748649	2016, Magnitude and Decline of Picoxystrobin and Metabolite Residues in Sunflower Following Foliar Application of Picoxystrobin (DPX-YT669) 250 g ai/L SC at Maximum Label Rate - Canada, DACO: 7.4, 7.4.1, 7.4.2
2748629	2017, Efficacy Biological Assessment Dossier for Control of Various Diseases in Sunflowers, Potatoes, Onions, Tree Nuts, Alfalfa, Sugarbeets, and Grass Grown for Seed with Acapela 250SC, DACO: 10.1, 10.2, 10.2.1, 10.2.3, 10.2.3.1, 10.2.3.3(D), 10.3.2, 10.3.2(B), 10.3.3, 10.4

ISSN: 1911-8082