

Evaluation Report for Category B, Subcategory 3.1, 3.5, 3.8, 3.12 Application

Application Number: 2016-5735
Application: B.3.1: Change Application Rate Increase or Decrease
B.3.5: Change Rotational Crops/Plantback Interval
B.3.8: Change Re-entry Interval
B.3.12: Change Site or Host
Product: Mettle 125 ME Fungicide
Registration Number: 30673
Active ingredients (a.i.): Tetraconazole
PMRA Document Number: 2967434

Purpose of Application

The purpose of this application was to amend the registration of Mettle 125ME by adding new uses on fruiting vegetables (Crop Group 8-09) and cucurbit vegetables (Crop Group 9).

Chemistry Assessment

Chemistry assessment was not required for this application.

Health Assessments

Residue data from field trials conducted in Canada and the United States were submitted to support the use of Mettle 125 ME Fungicide on Fruiting Vegetables (Crop Group 8-09) and Cucurbit Vegetables (Crop Group 9). Tetraconazole was applied to the crops at the proposed or exaggerated rates, and harvested according to label directions. In addition, processing studies in treated wheat, canola, tomato and field corn were reviewed to determine the potential for concentration of residues of tetraconazole into processed commodities.

Maximum Residue Limits

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

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT			
Wheat	Foliar/220-235	30-51	0.01	0.039	Total bran: 3.7, Whole meal flour: 2.0, Germ: 10.6	-	Wheat: 0.05 Wheat bran: 0.15 Wheat flour: 0.08 Wheat germ: 0.5
Barley	Foliar/217-236	28-51	<0.01	0.248	-	-	0.3
Dry pea	Foliar/219-228	13-18	<0.01	0.048	-	-	Crop Subgroup 6C: 0.09
Dry bean	Foliar/223-229	13-15	<0.01	0.070	-	-	
Rapeseed (canola)	Foliar/224-236	20-22	<0.012	0.870	Refined oil: 0.1	-	Crop Subgroup 20A: 0.9
Field corn	Foliar/95-105	29-95	<0.01	<0.01	-	-	Field corn: 0.01 Popcorn: 0.01
Cucumber	Foliar/217-223	0	<0.01	0.080	-	-	Cucurbit Vegetables (CG 9): 0.15
Cantaloupe	Foliar/216-220		0.014	0.077			
Summer squash	Foliar/217-231		<0.01	0.047			
Bell pepper	Foliar/144-149	0	0.014	0.059	-	-	Fruiting Vegetables (CG 8-09): 0.3
Non-bell pepper	Foliar/147-148		0.040	0.110	-	-	
Tomato	Foliar/144-153		0.016	0.097	Paste:0.3 Puree: 0.2 Juice: 0.1	-	

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

Based on the dietary burden and residue data, MRLs in livestock commodities in the following table to cover residues of tetraconazole are also proposed.

Table 2 Proposed MRLs in Livestock Commodities

Commodity	Proposed MRLs (ppm)
Milk	0.06
Cream (milk fat)	0.5
Meat byproducts of cattle, goats, horses and sheep (except liver)	0.08
Liver of cattle, goats, horses and sheep	2.0
Fat of cattle, goats, horses and sheep	0.3
Eggs	0.01
Meat and meat byproducts of poultry	0.02
Fat of poultry	0.03

Following the review of all available data, MRLs as proposed in Tables 1 and 2 are recommended to cover residues of tetraconazole. Residues in these crop/livestock commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

The use pattern of Mettle 125 ME Fungicide represents an expansion of use for tetraconazole with the addition of application to cucurbit vegetables and fruiting vegetables.

The risk assessment for tetraconazole was updated for mixer/loader/applicators as well as for workers entering treated sites for the new crops. No health risks of concern are expected provided workers follow directions and wear personal protective equipment as stated on the label.

Environmental Assessment

Given that this use expansion includes use on fruiting and cucurbit vegetables, a higher maximum seasonal application rate and a shorter reapplication interval of seven days (as opposed to the original 14 days), a revised environmental risk assessment was conducted.

Precautionary statements for terrestrial plants, beneficial arthropods, birds and aquatic organisms are present on the label of Mettle 125 ME Fungicide to protect these non-target organisms. In addition, risks are mitigated through the use of buffer zones to protect non-target habitats.

Value Assessment

Rationale was provided in support of the use claims on the Mettle 125ME label. Efficacy data for another tetraconazole containing product was used to support the claims for Mettle 125ME Fungicide. The efficacy data indicated acceptable value for Mettle 125ME.

The label expansion for Mettle 125ME will provide Canadian growers with a new product to manage listed diseases on cucurbit vegetables and fruiting vegetables. Claims are supported as proposed or with modifications from a value perspective.

Conclusion

The PMRA has reviewed the information provided in support of the amendment. Based on the results of this review, adding fruiting vegetables (Crop Group 8-09) and cucurbit vegetables (Crop Group 9) to the Mettle 125ME label is acceptable.

References

2765510	2017, Deficiency Response for Mettle 125 ME Fungicide, containing tetraconazole, EP Submission Number: 2016-5735, DACO: 10.2.3.3
1905206	2005, Tetraconazole residues and storage stability (-20C, in the dark) in eggs and biological tissues after oral administration to hens. DACO: 7.5.1
2686912	2014, Set up and validation of the analytical method for determination of Tetraconazole residue in wheat (middlings, germ, whole meal flour and whole grain bread), soybean (seed, forage and hay) and canola (meal and refined oil)., DACO: 7.2,7.2.2
2686915	2009, Set up and validation of multiresidue method QuEChERS (modified for some matrices) for the determination of Tetraconazole in plant material and in foodstuffs of animal origin, DACO: 171 - 4a,171 - 4c,171 - 4m,171-4a-4b,171-4c-4d,7.2.1,7.2.2,7.2.3A,860.1300,860.1340,860.1360,IIA 4.2.6,IIIA 5.3.1,b,d
2686917	2010, Magnitude of the Residue of Tetraconazole on Field Corn, DACO: 7.2.1,7.4.1,7.4.2,7.4.5
2686923	2010, Storage stability of tetraconazole in oilseed rape seed, plant and refined oil commodities stored in the dark below -20C, DACO: 7.3
2686932	2016, Magnitude of Tetraconazole and Metabolite Residues in Raw Agricultural Commodities Following Application of DOMARK(R) 230 ME to Field Corn in Canada, DACO: 7.2.1,7.4.1
2686934	2013, Tetraconazole and Triazole Metabolites Residues on Fruiting Vegetables (tomato, bell peppers, and non-bell peppers) in U.S.A. in 2012. Supporting Crop Group 8: Fruiting vegetables, DACO: 7.2.1,7.4.1,7.4.2,7.4.5
2686935	2013, Tetraconazole and Triazole metabolites Residues on Cucurbit Vegetables (cucumber, cantaloupe and summer squash) in U.S.A. in 2012. Supporting Crop Group 9: Cucurbit vegetables, DACO: 7.2.1,7.4.1,7.4.2,7.4.5
2686937	2016, Magnitude and Decline of Tetraconazole and Metabolite Residues in Raw Agricultural Commodities Following Application of DOMARK(R) 230 ME to Barley in North America, DACO: 7.2.1,7.4.1,7.4.2
2686938	2016, Magnitude and Decline of Tetraconazole and Metabolite Residues in Raw Agricultural Commodities Following Application of DOMARK(R) 230 ME to Dry Bean in North America, DACO: 7.2.1,7.4.1,7.4.2
2686940	2016, Magnitude and Decline of Tetraconazole and Metabolite Residues in Raw Agricultural Commodities Following Application of DOMARK(R) 230 ME to Dry Pea in North America, DACO: 7.2.1,7.4.1,7.4.2

2686941	2016, Magnitude and Decline of Tetraconazole and Metabolite Residues in Raw and Processed Commodities Following Application of DOMARK(R) 230 ME to Canola in North America, DACO: 7.2.1,7.4.1,7.4.2,7.4.5
2686944	2016, Magnitude and Decline of Tetraconazole and Metabolite Residues in Raw and Processed Commodities Following Application of DOMARK(R) 230 ME to Wheat in North America, DACO: 7.2.1,7.4.1,7.4.2,7.4.5
2817864	2013, Tetraconazole residues on fruiting vegetables (tomato and bell peppers) in U.S.A. in 2011, DACO: 7.4

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2019

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.