

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2016-3365
Application: Changes to product label; new site
Product: Folicur 250 EW Fungicide
Registration Number: 29820
Active ingredients (a.i.): Tebuconazole
PMRA Document Number : 2794211

Purpose of Application

The purpose of this application was to add the use on rye, triticale and canaryseed to the label of Folicur 250 EW Fungicide. Folicur 250 EW Fungicide is also registered to control or suppress diseases on wheat, barley, oats and soybean.

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 new crops, rye, triticale and canaryseed, to the label of Folicur 250 EW Fungicide for the control and/or suppression of fungal diseases represents an expansion of use for the active ingredient tebuconazole. As such, the existing mixer/loader/applicator and postapplication re-entry worker risk assessments were updated for this application. No risk to human health is expected from handling Folicur 250 EW Fungicide provided workers follow label directions and wear personal protective equipment as stated on the label.

No new residue data were submitted for tebuconazole to support the addition of rye, triticale and canaryseed to the label of Folicur 250 EW Fungicide. Previously reviewed residue data from field trials conducted with tebuconazole in/on wheat, barley and oats were reassessed in the framework of this petition. In addition, a processing study in treated wheat was also re-assessed to determine the potential for concentration of residues of tebuconazole into processed commodities.

Maximum Residue Limit(s)

The recommendation for MRLs on tebuconazole is based upon previously reviewed field trial data and the guidance provided in the [OECD MRL Calculator](#). As per the residue definition for enforcement purposes in plant matrices, MRLs to cover residues of tebuconazole in/on canaryseed, rye and triticale are proposed as shown in Table A.1. Residues in processed commodities not listed are covered under the proposed MRLs for the raw agricultural commodities (RACs).

TABLE A.1. Summary of Field Trial and Processing Data Used to Support Maximum Residue Limit(s) (MRLs) for Tebuconazole							
Commodity	Appl. Method/ Total Appl. Rate (g a.i./ha)	PHI (days)	Residues ¹ (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAF T			
Barley grain	Foliar application/ 122 – 129	29 – 31	0.068	0.247	(Based on wheat grain) Bran: 1 Patented flour: 0.13 Low grade flour: 0.25	0.3 for imported barley	0.15 for canaryseed, rye and triticale
	Foliar application/ 100 – 187.5	30 – 39	≤ 0.01	0.11			
Wheat grain	Foliar application/ 125-126	33 – 48	≤ 0.01	0.08		0.15 for wheat and oats	
Oat grain	Foliar application/ 62.5 – 94	35 – 82	≤ 0.01	0.13			

¹ Residues expressed as tebuconazole (; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial; the LOQ of 0.01 ppm was used for values <LOQ.

Following the review of available data, MRLs as proposed in Table A.1 are recommended to cover residues of tebuconazole in/on canaryseed, rye and triticale. Residues in these crop commodities at the proposed MRLs will not pose an unacceptable health risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

No new data were required in support of this use expansion. The use of the product following this use expansion is not expected to increase environmental risk. Environmental statements on the product label are sufficient to address environmental concerns.

Value Assessment

Scientific rationales were provided to support the value assessment of these claims and to support registration of an aerial use-pattern. Use history information was also provided on the safe use of a precedent product in France on rye and triticale. No crop safety concerns were reported. The use of Folicur 250 EW Fungicide is compatible with current pest management practices for these cereal crops. Based on the information provided, the use on, rye, triticale and canaryseed are supported from a value perspective.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the use of Folicur 250 EW

Fungicide on oats, rye, triticale and canaryseed.

References

PMRA

Document

Number

Reference

277444	2002, Folicur 432 F (Tebuconazole) Post-emergence Fungicide Spray. Data in Support of Registration of FOLICUR 432 F (Tebuconazole) Fungicide for Suppression of Fusarium Head Blight (Scab) and Control of Leaf Diseases in Wheat. DACO: 10.2
738425	2004, Prothioconazole 480 SC Fungicide for Control of Diseases in Pulse Crops, Cereal Crops, Canola and Rapeseed, Volume 2 - Barley, DACO: 10.2
738511	2004, Prothioconazole 480 SC Fungicide for Control of Diseases in Pulse Crops, Cereal Crops, Canola and Rapeseed, Volume 1 - Wheat, DACO: 10.2
1521840	2007, Folicur 432F foliar fungicide - Control of foliar disease in oats, DACO: 10.2
1521846	2007, Folicur 432 F foliar fungicide for control of leaf diseases in barley, DACO: 10.2
2424615	2014, Prosaro 250EC and Prosaro 421SC Fungicides for Disease Control on Tame Oats, DACO: 10.2
2656447	2016, Value assessment of Folicur 250 EW fungicide for control or suppression of listed diseases of rye, triticale, canaryseed, and oats, DACO: 10.1, 10.2.3.1, 10.2.3.3, 10.3.1, 10.3.2
2656448	2016, Value assessment of Folicur 250 EW fungicide for control or suppression of listed diseases of rye, triticale, canaryseed, and oats, DACO: 10.1, 10.2.3.1, 10.2.3.3, 10.3.1, 10.3.2
2656449	2016, Value assessment of Folicur 250 EW fungicide for control or suppression of listed diseases of rye, triticale, canaryseed, and oats, DACO: 10.1, 10.2.3.1, 10.2.3.3, 10.3.1, 10.3.2

ISSN: 1911-8082

**8 Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services
Canada 2017**

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.