Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2016-3364
Application: Changes to product label; new site
Product: Prosaro 250 EC Fungicide
Registration Number: 29821
Active ingredients (a.i.): Prothioconazole and Tebuconazole
PMRA Document Number : 2794214

Purpose of Application

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

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 Prosaro 250 EC Fungicide for the control and/or suppression of fungal diseases represents an expansion of use for the active ingredients tebuconazole (rye, triticale and canaryseed) and prothioconazole (canaryseed). 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 Prosaro 250 EC Fungicide provided workers follow label directions and wear personal protective equipment as stated on the label.

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

Maximum Residue Limit(s)

The recommendations for MRLs on prothioconazole and tebuconazole are based upon previously reviewed field trial data and the guidance provided in the OECD MRL Calculator. As per the residue definitions for each active ingredient for enforcement purposes in plant matrices, MRLs to cover residues of prothioconazole and the metabolite prothioconazole-

desthio in/on canaryseed are proposed as shown in Table A.1, while MRLs to cover residues of tebuconazole in/on canaryseed, rye and triticale are proposed as shown in Table A.2. 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 Prothioconazole

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	HAFT			
Barley grain	Foliar application/ 321 – 348	30 – 71	≤ 0.02	0.151	(Based on wheat grain) Bran: 2.4 Flour: <0.4 Germ: 2	0.35 for buckwheat, field corn, pearl millet, proso millet, oats, popcorn grain, rye, teosinte, triticale and wheat.	0.35 for canaryseed
Wheat grain	Foliar application/ 315 – 350	10; 30 – 57	≤ 0.02	0.045			
Field corn grain	Foliar application/ 784-821	11 – 14	≤ 0.02	0.062	No concentration observed in field corn edible processed fractions.		
Popcorn grain	Foliar application/ 795 – 812	14	≤ 0.02	0.02	Not required		
Sweet corn K+CWHR[2]	Foliar application/ 794 – 827)	0 and 7	≤ 0.02	0.02	Not required	0.04	

[1] Residues expressed as total prothioconazole (i.e., sum of prothioconazole and prothioconazole-desthio); LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial; the LOQ of 0.02 ppm was used for values <LOQ.
[2] K+CWHR = kernels plus cob with husks removed.

TABLE A.2. 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	HAFT			

TABLE A.2. Summary of Field Trial and Processing Data Used to Support Maximum Residue Limit(s) (MRLs) for Tebuconazole

Commodity	Appl. Method/	PHI	Residues[1] (ppm)		Experimental	Currently	Recommended
Barley grain	Foliar application/ 122 – 129 (US data; import)	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 (the residue definition includes only the parent molecule for both US and Canada); 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 Tables A.1 and A.2 are recommended to cover residues of prothioconazole in canaryseed, and residues of tebuconazole in 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

The applicant provided benefit information, a scientific rationale and the results of efficacy trials to add the uses on rye, triticale, and canaryseed to the label of Prosaro 250 EC Fungicide. The information provided showed that the use of Prosaro 250 EC was efficacious at the use rates and controlled or suppressed the listed diseases on rye, triticale and canaryseed. The claim for aerial application was also supported for the label expansion based on the previously registered uses. No crop safety concerns were reported. The applicant also provided information that the use of Prosaro 250 EC Fungicide contributes to risk reduction with the use of appropriate rates and that it is compatible with current pest management practices for these cereal crops. Based on these

considerations, the claims were supported as proposed.

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 Prosaro 250 EC Fungicide on 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 250 EC and Prosaro 421SC Fungicides for Disease Control on Tame Oats, DACO: 10.2
2656436	2016, Value assessment of Prosaro 250 EC Fungicide - Label expansion to include rye, triticale and canaryseed, DACO: 10.1,10.2.3.1,10.2.3.3,10.3.1,10.3.2
2656437	2016, Value assessment of Prosaro 250 EC Fungicide - Label expansion to include rye, triticale and canaryseed, DACO: 10.1,10.2.3.1,10.2.3.3,10.3.1,10.3.2
2656439	2016, Value assessment of Prosaro 250 EC Fungicide - Label expansion to include rye, triticale and canaryseed, DACO: 10.1,10.2.3.1,10.2.3.3,10.3.1,10.3.2

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