

## Evaluation Report for Category B, Subcategory 2.3, 2.4, 3.11, 3.12 Application

**Application Number:** 2016-3363  
**Application:** New end use product chemistry; change in identity and proportion of formulants, new pests and sites  
**Product:** Prosaro XTR Fungicide  
**Registration Number:** 32824  
**Active ingredients (a.i.):** Prothioconazole and Tebuconazole  
**PMRA Document Number :** 2794198

### Purpose of Application

The purpose of this application was to register a new end use product, Prosaro XTR Fungicide, for use on rye, triticale, wheat, barley, oats and canaryseed.

### Chemistry Assessment

Prosaro XTR Fungicide is formulated as an emulsifiable concentrate containing tebuconazole and prothioconazole each at a nominal concentration of 125 g/L. This end-use product has a density of 0.98 – 1.02 g/mL and pH of 3.8. The required chemistry data for Prosaro XTR Fungicide have been provided, reviewed and found to be acceptable.

### Health Assessments

Prosaro XTR Fungicide is of low acute toxicity via the oral dermal and inhalation routes of exposure. It is severely irritating to the eye and mildly irritating to the skin of the rabbit. It is a skin sensitizer in the mouse via the Local Lymph Node Assay.

The use of Prosaro XTR Fungicide on established cereals is considered to fall within the existing use pattern for prothioconazole, with the exception of canaryseed, and within the existing use pattern for tebuconazole on cereals, except for the new uses on rye, triticale and canaryseed. The existing risk assessments for prothioconazole and tebuconazole were updated for these new crops to support the corresponding use expansions for each active ingredient. Potential mixer/loader/applicator and postapplication worker exposure is not expected to result in health risks of concern when approved label directions and precautions are followed.

For prothioconazole and tebuconazole, no new residue data were submitted to support the registration of the new end-use product Prosaro XTR 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.

For the safener mefenpyr-diethyl, new residue data from field trials conducted in Canada and the United States on wheat, barley and oats were submitted to support the domestic registration of Prosaro XTR Fungicide on wheat, barley, oats, rye, triticale and canaryseed. Mefenpyr-diethyl was applied to the cereal crops with application rates ranging from 3.2- to 3.5-fold the recommended rate, and harvested according to label directions. In addition, a new processing study in wheat treated at an exaggerated rate corresponding to 17-fold the recommended rate of mefenpyr-diethyl was reviewed. However, processing of the raw agricultural commodities (RAC) was not performed nor required given that residues in/on raw agricultural commodities samples were all below the limit of quantitation (LOQ) of the method.

### Maximum Residue Limit(s)

For prothioconazole and tebuconazole, the recommendations for MRLs are based upon previously reviewed field trial data, while for the safener mefenpyr-diethyl, they are based upon the newly submitted field trial studies conducted on wheat, barley and oats, as well as the guidance provided in the [OECD MRL Calculator](#).

As per the residue definitions 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; 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.

<b>TABLE A.1. Summary of Field Trial and Processing Data Used to Support Maximum Residue Limit(s) (MRLs) for Prothioconazole</b>							
Commodity	Appl. Method/ Total Appl. Rate (g a.i./ha)	PHI (days)	Residues <sup>1</sup> (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAF T			
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 concentratio n observed in field corn edible processed fractions.		

**TABLE A.1. Summary of Field Trial and Processing Data Used to Support Maximum Residue Limit(s) (MRLs) for Prothioconazole**

Commodity	Appl. Method/	PHI	Residues <sup>1</sup> (ppm)		Experimental	Currently	Recommended
Popcorn grain	Foliar application/ 795 – 812	14	≤ 0.02	0.02	Not required		
Sweet corn K+CWHR <sup>2</sup>	Foliar application/ 794 – 827	0 and 7	≤0.02	0.02	Not required	0.04	

<sup>1</sup> Residues expressed as total prothioconazole (i.e., the 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.

<sup>2</sup> 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 <sup>1</sup> (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT			
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			

<sup>1</sup> 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 all available data, MRLs as proposed in Tables A.1, and A.2 are recommended to cover residues of prothioconazole and tebuconazole. Residues in these cereal 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. The information provided showed that the use of Prosaro XTR Fungicide was efficacious and controlled or suppressed the diseases on wheat, barley, oats, rye, triticale and canaryseed. The claim for aerial application is also supported based on the registered use pattern for a precedent product. No crop safety concerns were reported. The applicant also provided information that the use of Prosaro XTR 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 registration of Prosaro XTR Fungicide, for use on rye, triticale, wheat, barley, oats and canaryseed.

## References

<b>PMRA Document Number</b>	<b>Reference</b>
2656401	2015, Physical, chemical and technical properties of prothioconazole + tebuconazole [CBI removed] (125+125 [CBI removed] g/L), DACO: 3.1
2656402	2015, Safety-relevant data of prothioconazole + tebuconazole [CBI removed] (125+125 [CBI removed] g/L), DACO: 3.1
2656403	2007, Generic manufacturing description of formulation type EC (Emulsifiable concentrate), DACO: 3.2 CBI
2656404	2014, Determination of prothioconazole, tebuconazole and [CBI removed] in formulations ; Assay - HPLC, external standard, DACO: 3.4.1
2656405	2014, Validation of HPLC-method AM023814MF1 - Determination of prothioconazole, tebuconazole [CBI removed] in formulations - prothioconazole + tebuconazole [CBI removed] (125+125 [CBI removed] g/L), DACO: 3.4.1
2656406	2016, Storage stability and corrosion characteristics of prothioconazole + tebuconazole [CBI removed] (125+125 [CBI removed] g/L) - Packaging material: COEX/EVOH - Final report (12 months), DACO: 3.5.10,3.5.14
2656407	2015, Storage stability at elevated temperature and corrosion characteristics of prothioconazole + tebuconazole [CBI removed] (125+125 [CBI removed] g/L) - Packaging material: COEX/EVOH - Final report (14 days), DACO: 3.5.10

2656418	2016, Value assessment of Prosaro ReadyMix fungicide for control or suppression of listed diseases of wheat, barley, oats, rye, triticale, and canaryseed, DACO: 10.1, 10.2.3.1, 10.2.3.4, 10.3.1, 10.3.2
2656420	2016, Value assessment of Prosaro ReadyMix fungicide for control or suppression of listed diseases of wheat, barley, oats, rye, triticale, and canaryseed, DACO: 10.1, 10.2.3.1, 10.2.3.4, 10.3.1, 10.3.2
2656422	2016, Value assessment of Prosaro ReadyMix fungicide for control or suppression of listed diseases of wheat, barley, oats, rye, triticale, and canaryseed, DACO: 10.1, 10.2.3.1, 10.2.3.4, 10.3.1, 10.3.2
2656414	2016, Mefenpyr-diethyl: Magnitude of residues in/on oats following treatment with mefenpyr-diethyl EC 230 and PTZ+ TBZ+MPR EC 281.2 (125+125+31.2) G, DACO: 7.4.1,7.4.5
2656415	2016, Mefenpyr-diethyl: Magnitude of residues in/on wheat following treatment with mefenpyr-diethyl EC 230 and PTZ+TBZ+MPR EC 281.2 (125+125+31.2) G, DACO: 7.4.1,7.4.5
2656416	2016, Mefenpyr-diethyl: Magnitude of residues in/on wheat processed fractions following treatment with mefenpyr-diethyl, DACO: 7.4.1,7.4.5
2656417	2016, Mefenpyr-diethyl: Magnitude of residues in/on barley following treatment with mefenpyr-diethyl EC 230 and PTZ+TBZ+MPR EC 281.2 (125+125+31.2) G, DACO: 7.4.1,7.4.5
2699821	2016, White Paper: Effect of Herbicide Safeners on the Metabolism and Residues of Herbicides, DACO: 6.3,7.4.1
2720331	1996, Storage Stability of HOE 107892 and Its Metabolite HOE 094270 in Barley (Grain), DACO: 3.5.10 ( <i>should be DACO: 7.3</i> )

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