

## Evaluation Report for Category B, Subcategory 2.6 Application

**Application Number:** 2020-0212  
**Application:** New End-Use Product Chemistry-New Combination of Technical Grade Active Ingredients  
**Product:** Prosaro Pro  
**Registration Number:** 34093  
**Active ingredients (a.i.):** fluopyram, prothioconazole, tebuconazole  
**PMRA Document Number:** 3213089

### Purpose of Application

The purpose of this application was to register a new end-use product, Prosaro Pro, containing a new combination of active ingredients, prothioconazole, tebuconazole and fluopyram, for use on wheat, triticale, barley and oats to suppress ergot and fusarium head blight and to control various foliar diseases. An amendment to the maximum residue limits (MRLs) for fluopyram on Crop Group 15 (Cereal Grains) was also requested.

### Chemistry Assessment

Prosaro Pro is formulated as a suspension containing prothioconazole at a concentration of 200 g/L, fluopyram at a concentration of 100 g/L and tebuconazole at a concentration of 100 g/L. This end-use product has a density of 1.130-1.170 g/mL and pH of 5.0-7.5. The required chemistry data for Prosaro Pro have been provided, reviewed and found to be acceptable.

### Health Assessments

Prosaro Pro is of low acute oral, dermal, and inhalation toxicity. It is minimally irritating to the eyes and the skin. It is not a dermal sensitizer.

The occupational exposure and health risks from the use of Prosaro Pro, containing prothioconazole, tebuconazole and fluopyram, were assessed for use on wheat (spring and winter), barley, oats and triticale. For prothioconazole and tebuconazole, the uses fit within the registered use pattern. For fluopyram, the new uses represent an expansion for certain cereal crops; as such, the occupational risk assessment was updated. No risks of concern are expected from the use of Prosaro Pro, provided that workers follow the label directions and wear the personal protective equipment identified on the label.

No new residue data for prothioconazole or tebuconazole were submitted or are required to support the registration of Prosaro Pro as the use pattern is similar to that registered. Previously reviewed residue data were re-assessed in the framework of this application.

Based on this assessment, residues are not expected to be greater than that for the previously registered uses and will be covered by the established MRLs for each active ingredient. Consequently, dietary exposure to residues of prothioconazole and tebuconazole is not expected to increase with the registration of Prosaro Pro and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Residue data from field trials conducted in Canada and the United States with fluopyram were submitted to support the use of Prosaro Pro for use on barley, oats, wheat and triticale. Fluopyram was applied to barley, sorghum and wheat at exaggerated rates, and harvested according to label directions. In addition, a processing study in treated wheat was also re-assessed to determine the potential for concentration of residues of fluopyram into processed commodities.

### Maximum Residue Limits

The recommendation for MRLs for fluopyram was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of fluopyram 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)	Fluopyram Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT			
Wheat grain	Foliar/ 240-320	28-51	<0.01	0.137	Bran: 2.7x Flour: 0.12x Germ: 2.4x	1.5 (Crop Group 15, except rice and corn)	0.5 (Crop Group 15, except rice and corn)
Barley grain	Foliar/ 230-260	28-43	<0.011	0.232			
Sorghum grain	Foliar/ 200-210	28-55	0.054	0.302	n/a		

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

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of fluopyram. Residues in these crop commodities at the proposed MRLs will not pose risks of concern to any segment of the population, including infants, children, adults and seniors.

### **Environmental Assessment**

A scientific review of the available information demonstrates that the environmental risks associated with the uses of Prosaro Pro are acceptable when used according to the label directions.

### **Value Assessment**

Rationales and efficacy data from 56 trials conducted in Canada, the USA and some European countries were submitted in support of the use claims on the Prosaro Pro label. Efficacy of Prosaro Pro on the target diseases was tested in forms of the Prosaro Pro formulation or tank-mixing the relevant active ingredients, prothioconazole, tebuconazole and/or fluopyram, at the comparable application rates as formulated in Prosaro Pro. Prosaro Pro treatments have demonstrated an acceptable level of disease control or suppression under adequate disease pressure, for uses against listed diseases on wheat and barley. A similar level of disease control can also be expected for uses against listed diseases on triticale and oats as stated in the rationales.

The supporting evidence confirmed the value of Prosaro Pro for suppression of fusarium head blight and ergot, and control of other foliar diseases on listed crops. The registration of Prosaro Pro will provide Canadian growers with a new product to manage these important diseases on wheat, triticale, barley and oats.

### **Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found it sufficient to register Prosaro Pro, and to propose amendments to the MRLs of fluopyram on Crop Group 15 as described above.

### **Additional Information Being Requested**

The preliminary results of the one-year storage stability study at ambient temperature show that the levels of the active ingredients are within the established certified limits. However, the final report has not been provided. This GLP-compliant study is required as post-market information.

## References

### PMRA

#### Document

Number	Reference
3074034	2019, Description of the formulation process of USF0115, DACO: 3.2.2 CBI
3074035	2019, Discussion on the formation of impurities for USF0115, DACO: 3.2.3 CBI
3074036	2019, Justification for expanded limits - FLU+PTZ+TBZ SC 400 (100+200+100 g/L), DACO: 3.3.1 CBI
3074037	2019, Safety-relevant data of fluopyram + prothioconazole + tebuconazole SC 400 (100+200+100 g/L), DACO: 3.5.11,3.5.12,3.5.14,3.5.8
3080765	2019, Determination of fluopyram, prothioconazole and tebuconazole in formulations – HPLC-UV, external standard, DACO: 3.4.1 CBI
3080766	2019, Validation of analytical method AM035019MF1 - Determination of fluopyram, prothioconazole and tebuconazole in the formulation fluopyram + prothioconazole + tebuconazole SC 400(100+200+100 g/L), DACO: 3.4.1 CBI
3080767	2020, Physical, chemical and technical properties of fluopyram + prothioconazole + tebuconazole SC 400 (100+200+100 g/L), DACO: 3.5.1, 3.5.2, 3.5.3, 3.5.4, 3.5.6, 3.5.7, 3.5.9 CBI
3080768	2020, Waiver and summary report for USF0115, DACO: 3.5.13,3.5.15 CBI
3080769	2020, Storage stability at elevated temperature and corrosion characteristics of fluopyram + prothioconazole + tebuconazole SC 400 (100+200+100 g/L) - Packaging material: HDPE – Final report (8 weeks), DACO: 3.5.10,3.5.14,3.5.5 CBI
3207895	2021, Quantity of raw materials used in USF0115 product, DACO: 3.2.2 CBI
3074038	2019, FLU+PTZ+TBZ SC 400: Acute oral toxicity - Up-and-down procedure in rats, DACO: 4.6.1
3074039	2019, FLU+PTZ+TBZ SC 400: Acute inhalation toxicity in rats, DACO: 4.6.3
3074040	2019, FLU+PTZ+TBZ SC 400: Primary eye irritation in rabbits, DACO: 4.6.4
3074041	2019, FLU+PTZ+TBZ SC 400: Primary skin irritation in rabbits, DACO: 4.6.5
3074042	2019, FLU+PTZ+TBZ SC 400: Local lymph node assay (LLNA) in mice, DACO: 4.6.6
3080782	2018, An analytical method for the determination of residues of fluopyram (AE C656948) and AE F148815 in crop matrices using LC/MS/MS, DACO: 7.2.1
3080783	2020, Magnitude of fluopyram residues in barley after two foliar applications of fluopyram 500SC (500 g/L) in North America, DACO: 7.4.1,7.4.2
3080784	2019, Magnitude of the residue of fluopyram and prothioconazole in/on sorghum after spray application of fluopyram SC 500 (500 g/L) and prothioconazole SC 480 (480 g/L) in North America, DACO: 7.4.1,7.4.2
3080786	2019, Magnitude of the residue of fluopyram in/on wheat after spray application of fluopyram SC 500 (500 g/L) in North America, DACO: 7.4.1,7.4.2
3080756	2020, Value Assessment of USF 0115 Fungicide for Control or Suppression of Foliar and Head Diseases in Small-grain Cereals, DACO: 10.1, 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.3, 10.2.3.3(D), 10.2.4, 10.3.1, 10.3.2, 10.3.2(B), 10.4, 10.5.1, 10.5.2, 10.5.3

3080759 2020, Compilation of Field Trial Reports: Value Assessment of USF 0115  
Fungicide for Control or Suppression of Foliar and Head Diseases in Small-grain  
Cereals, DACO: 10.2.3.3,10.2.3.3(D),10.3.2(B)

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