

Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2020-0368
Application: New End-Use Product Chemistry-New Combination of Technical Grade Active Ingredients
Product: Delaro Complete
Registration Number: 34095
Active ingredients (a.i.): fluopyram, prothioconazole, trifloxystrobin
PMRA Document Number : 3213107

Purpose of Application

The purpose of this submission is to register a new end-use product, Delaro Complete, containing a new combination of active ingredients, prothioconazole, trifloxystrobin and fluopyram, for use on soybean, corn, teosinte, wheat, barley, oats and triticale to control listed diseases. An amendment to the maximum residue limits (MRLs) for fluopyram on Crop Group 15 (Cereal Grains) was also requested.

Chemistry Assessment

Delaro Complete is formulated as a suspension containing prothioconazole at a concentration of 176.2 g/L, fluopyram at a concentration of 128.3 g/L and trifloxystrobin at a concentration of 154 g/L. This end-use product has a density of 1.160-1.200 g/mL and pH of 7.2. The chemistry requirements for this product have been fulfilled.

Health Assessments

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

The occupational exposure and health risks from the use of Delaro Complete, containing prothioconazole, trifloxystrobin and fluopyram were assessed for use on soybeans, corn (sweet corn, field corn, popcorn & corn grown for seed) and various cereal grains (wheat, barley, oats and triticale). For prothioconazole and trifloxystrobin, 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 Delaro Complete, provided that workers follow the label directions and wear the personal protective equipment identified on the label.

No new residue data for prothioconazole were submitted or are required to support the registration of Delaro Complete 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 of prothioconazole are not expected to be greater than that for the currently registered uses and will be covered by the established MRLs. Consequently,

dietary exposure to residues of prothioconazole is not expected to increase with the registration of Delaro Complete 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 on corn (field, sweet and popcorn) conducted with trifloxystrobin were reviewed to support the reduction in preharvest interval from 30 days to 14 days. Other than this difference, the trifloxystrobin use pattern is similar to that registered. Based on the corn residue data supporting a 14-day PHI, the currently established MRLs are sufficient to cover the expected trifloxystrobin residues resulting from the use of Delaro Complete, as shown in the table below.

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)	Trifloxystrobin Residues ¹ (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)
			LAFT	HAFT		
Field corn grain	Foliar/ 553-578	11-17	<0.02	<0.03	Meal: <1x Grits: <1x	0.05
Sweet corn (K+CWHR)	Foliar/ 549-574	5-7	<0.02	<0.02	Flour: 1x Starch: <1x	0.04
Popcorn grain	Foliar/ 557-572	12-14	<0.02	<0.02	Refined oil: 1.3x	0.05

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

¹Combined residues of trifloxystrobin and CGA-321113.

Following the review of all available data, no revisions to MRLs are proposed to cover residues of trifloxystrobin. Consequently, dietary exposure to residues of trifloxystrobin is will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Residue data from cereal grain field trials conducted in Canada and the United States with fluopyram were submitted to support the use of Delaro Complete . Fluopyram was applied to barley, sorghum, and wheat at exaggerated rates, and harvested according to label directions. Previously reviewed residue data from field trials conducted in/on soybean and corn (field corn and sweet corn) were also re-assessed in the framework of this application. In addition, processing studies in treated wheat, soybean and corn were re-assessed to determine the potential for concentration of residues of fluopyram into processed commodities.

The recommendation for maximum residue limits (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 2 are covered under the proposed MRLs for the raw agricultural commodities (RACs).

TABLE 2. 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) ¹	Recommended MRL (ppm)
			LAF T	HAF T			
Field corn grain	Foliar/ 492-520	11-14	<0.01	0.018	Starch: 0.15x Refined oil: 0.6x	1.5 (Crop Group 15, except rice)	0.02 Field corn, popcorn grain
Sweet corn (K+CWH R)	Foliar/ 495-527	0	<0.01	<0.01	Grits: 0.5x Flour: 0.9x Meal: 0.8x Bran: 2.6x		0.01 Sweet corn K+CWHR
Wheat grain	Foliar/ 240-320	28-51	<0.01	0.137	Bran: 2.7x Flour: 0.12x Germ: 2.4x		0.5 (Crop Group 15, except rice and corn)
Barley grain	Foliar/ 230-260	28-43	0.013	0.291			
Sorghum grain	Foliar/ 200-210	28-55	0.054	0.302	n/a		

LAF T = Lowest Average Field Trial; HAF T = Highest Average Field Trial

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

Environmental Assessment

A scientific review of the available information has demonstrated that the environmental risks associated with the use of Delaro Complete are acceptable when used according to the label directions.

Value Assessment

Rationales and efficacy data from field trials conducted in Canada and the USA were submitted in support of the use claims. Overall, Delaro Complete at the tested rates demonstrated its

effectiveness against the listed diseases under adequate disease pressure. The value of Delaro Complete on the use claims was confirmed from both rationales and efficacy data.

The registration of Delaro Complete will provide Canadian growers with a new product to manage these important diseases on soybean, corn and various cereal grains.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found it sufficient to register Delaro Complete, 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
3040370	2019, Starting materials for USF0411 - FLU+PTZ+TFS SC 458.5 (128.3+176.2+154 g/L), DACO: 3.2.1 CBI
3040371	2019, Formulation process for USF0411 - FLU+PTZ+TFS SC 458.5 (128.3+176.2+154 g/L),bDACO: 3.2.2 CBI
3040372	2019, Discussion on the formation of impurities in USF0411, DACO: 3.2.3 CBI
3040373	2019, Justification of certified limits for USF0411 - FLU+PTZ+TFS SC 458.5 (128.3+176.2+154 g/L), DACO: 3.3.1 CBI
3040374	2019, Determination of fluopyram, prothioconazole and trifloxystrobin in formulations - HPLC-UV, external standard, DACO: 3.4.1 CBI
3040375	2019, Validation of analytical method AM034119MF1 - Determination of fluopyram, prothioconazole and trifloxystrobin in the formulation fluopyram + prothioconazole + trifloxystrobin SC 458.5 (128.3 + 176.2 + 154 g/L), DACO: 3.4.1 CBI
3040376	2019, Physical, chemical and technical properties of fluopyram + prothioconazole + trifloxystrobin SC 458.5 (128.3+176.2+154 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
3040377	2019, Storage stability at elevated temperature and corrosion characteristics of fluopyram + prothioconazole + trifloxystrobin SC 458.5 (128.3+176.2+154 g/L) - Packaging material: HDPE - Final report (6 weeks), DACO: 3.5.10,3.5.14,3.5.5 CBI
3040378	2019, Safety-relevant data of fluopyram + prothioconazole + trifloxystrobin SC 458.5 (128.3+176.2+154 g/L), DACO: 3.5.11,3.5.12,3.5.8 CBI
3207900	2021, Quantity of raw materials used in USF0411 product, DACO: 3.2.2 CBI

- 3040379 2019, Delaro 411: Acute Oral Toxicity – Up-And-Down procedure in rats, DACO: 4.6.1
- 3040381 2019, Delaro 411: Acute Inhalation Toxicity in rats, DACO: 4.6.3
- 3040382 2019, Delaro 411: Primary eye irritation in rabbits, DACO: 4.6.4
- 3040383 2019, Delaro 411: Primary skin irritation in rabbits, DACO: 4.6.5
3040384. 2019, Delaro 411: 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
- 2478843 2008, Trifloxystrobin 500 SC - Magnitude of the residue in/on field corn, popcorn, and sweet corn, DACO: 7.4.1,7.4.2
- 3088305 2020, Compilation of Trial Reports: Value Assessment of USF0411 Foliar Fungicide for Control of Foliar Diseases of Corn, Soybeans, and Small-grain Cereals, DACO: 10.2.3.3, 10.2.3.3(D),10.3.2(B)
- 3095337 2020, Value Assessment of USF0411 Foliar Fungicide for Control of Foliar Diseases of Corn, Soybeans, and 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

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