

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.6, 3.12 Application

Application Number: 2017-1638
Application: New End-use Product Chemistry – Guarantee, Identity and Proportion of Formulants, New combination of TGAIs; New Product Labels - New Site or Host
Product: Insure Cereal FX4
Registration Number: 33210
Active ingredients (a.i.): Fluxapyroxad, Metalaxyl, Pyraclostrobin, Triconazole
PMRA Document Number : 2843900

Purpose of Application

The purpose of this application was to register the end-use product Insure Cereal FX4, a seed treatment to provide broad-spectrum protection against certain seed- and soil-borne diseases in cereals.

Chemistry Assessment

Insure Cereal FX4 is formulated as a suspension containing four active ingredients: pyraclostrobin at a concentration of 16.7 g/L, triconazole at 16.7 g/L, metalaxyl at 10.0 g/L and fluxapyroxad at 8.35 g/L. This product has a density of 1.067 g/cm³ and pH of 6.35. The required chemistry data for Insure Cereal FX4 have been provided, reviewed and found to be acceptable.

Health Assessments

Insure Cereal FX4 is of low toxicity to rats via the oral, dermal, and inhalation routes. It is not irritating to the eye or skin of rabbits. It is not a dermal sensitizer in guinea pigs.

The use of Insure Cereal FX4 on barley, wheat (all types), oats, canary seed, triticale and rye as a seed treatment to control various seed-borne diseases is not expected to result in potential occupational or bystander exposure over the registered use of pyraclostrobin, triconazole and metalaxyl (with the exception of canary seed); however, there may be potential for increased exposure to fluxapyroxad. There are adequate risk assessments on file for all uses, and no health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label and follow all the label precautions.

Previously reviewed residue data from field trials conducted in/on wheat, barley, rye, and oats were reassessed in the framework of this petition. In addition, processing studies in treated wheat and barley were also reassessed to determine the potential for concentration of residues of metalaxyl, pyraclostrobin, fluxapyroxad, or triconazole into processed commodities.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for metalaxyl, pyraclostrobin, fluxapyroxad, and triticonazole was based upon previously reviewed wheat and barley field trial data (translated to annual canarygrass seeds), and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of metalaxyl (including metabolites convertible to the 2,6-dimethylaniline moiety), pyraclostrobin (including the metabolite BF 500-3), fluxapyroxad, and triticonazole in/on annual canarygrass seeds 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 Limits (MRLs).							
Commodity	Application Method/ Total Application Rate (g a.i./ha ¹)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAF T	HAF T			
Metalaxyl							
Wheat grain	Soil treatment at planting / 1120	209-259	<0.05	0.13 ²	Wheat flour: 1.6X	None	0.05 (annual canarygrass seeds)
Pyraclostrobin							
Wheat grain	Foliar application / 448	38-70	<0.04	0.05	Wheat flour: 0.7X	None	0.04 (annual canarygrass seeds)
Barley grain			<0.04	0.19 ³			
Fluxapyroxad							
Wheat grain	Foliar application / 200	20-27	0.09	0.19	Barley flour: 0.2X	None	0.01 (annual canarygrass seeds)
Barley grain			<0.01	1.2 ⁴			
Triticonazole							
Wheat grain	Seed treatment / 10 g a.i./100 kg seed	NA	<0.01	<0.01	Not expected to concentrate	None	0.01 (annual canarygrass seeds)
Barley grain			<0.01	<0.01			

LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial; NA = not applicable

¹ Unless otherwise specified.

² Based on the degree of exaggeration (933-fold) of a soil application, it was determined that residues resulting from seed treatment at 1.2 g a.i./ha of metalaxyl would not be quantifiable.

³ Based on the degree of exaggeration (224-fold) of a foliar application, it was determined that residues resulting from a seed treatment at 2 g a.i./ha pyraclostrobin would not be quantifiable.

⁴ Based on the degree of exaggeration (200-fold) of a foliar application, it was determined that residues resulting from a seed treatment at 1 g a.i./ha of fluxapyroxad would not be quantifiable.

Following the review of all available data, MRLs as proposed in Table 1 are recommended to

cover residues of metalaxyl, pyraclostrobin, fluxapyroxad, and triticonazole. Residues in annual canarygrass seeds at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use of the new combination of the registered fungicide active ingredients in Insure Cereal FX4 does not represent an increased environmental risk due to use rates which are below registered rates. Existing mitigation measures in the form of label statements are applicable. Therefore, Insure Cereal FX4 is acceptable from an environmental risk perspective.

Value Assessment

Scientific rationales and efficacy data from 21 greenhouse and field trials on barley, wheat and oat conducted in the USA, and AB, MB and SK were provided in support of the claims of control of seed rot, post-emergence damping-off, seedling blight and root rot caused by *Rhizoctonia solani*, and control of postemergence damping-off caused by *Fusarium* spp. on barley, canary seed, wheat (all types), oat, rye and triticale. Insure Cereal FX4 demonstrated an acceptable level of disease control on tested crops. Efficacy of Insure Cereal FX4 was comparable to that achieved by the commercial standard applied in the same trials.

Since all four fungicide active ingredients are currently registered and their activities on certain pathogens have been recognized previously, scientific rationales were sufficient to support certain claims. The registration of Insure Cereal FX4 will provide Canadian growers with another product with a wider disease spectrum for managing multiple seed- and soil-borne fungal diseases in barley, canary seed, oat, rye, triticale and wheat.

The registration of Insure Cereal FX4 is 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 registration of Insure Cereal FX4.

References

PMRA Document Number	Reference
2746655	2017, Insure(R) Cereal FX4 for Seed Treatment Use in Barley, Canary seed, Oat, Rye, Triticale and Wheat (all types), DACO: 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3, 10.2.3.1, 10.2.3.2(D), 10.2.3.3(D), 10.2.3.4, 10.3, 10.3.1, 10.3.2(B), 10.4, 10.5, 10.5.1, 10.5.2, 10.5.3, 10.5.4
2746656	2017, Trial Abstracts, DACO: 10.2.3.3(D),10.3.2(B)
2746657	2015, SOP FUSASP, DACO: 10.2.3.3(D)
2746658	2015, SOP RHISP, DACO: 10.2.3.3(D)
2746659	2006, SOP Application of test compounds to seed, DACO: 10.2.3.3(D)

PMRA Document Number	Reference
2746662	2017, DACO 3.1.1- 3.1.4, DACO: 3.1.1,3.1.2,3.1.3,3.1.4 CBI
2746663	2017, Stamina F4 cereals fungicide seed treatment (BAS 772 00 F) Group A - product identity, composition and analysis, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.4.1,3.4.2 CBI
2746664	2017, Amended final report - GLP validation of analytical method AFR0127/01 and certification of BAS 772 00 F, lot FD-151211-0008; BAS 772 UD F, lot FD-151217-0015, DACO: 3.4.1
2746665	2017, BAS 772 00 F: Determination of physical properties and oxidation reduction, DACO: 3.5.1,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9
2746666	2017, BAS 772 00 F: Storage stability and corrosion characteristics in commercial type containers (accelerated storage, 8 weeks at 40 C), DACO: 3.5.10,3.5.14
2746667	2017, Determination of Physico-chemical Properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008), DACO: 3.5.11,3.5.12 CB
2746668	2017, DACO 3.5.4_3.5.5_3.5.13_3.5.15, DACO: 3.5.13,3.5.15,3.5.4,3.5.5
2746669	2017, DACO 3.7- Insure Cereal FX4- Other data, DACO: 3.7 CBI
2746670	2017, DACO 3.7- Insure Cereal FX4- Labelling of preservatives, DACO: 3.7 CBI
2793496	2017, DACO 3.7- Insure Cereal FX4- Labelling of preservatives F6V1 F7V1, DACO: 3.7 CBI
2848403	2018, BAS 772 00 F: Storage stability and corrosion characteristics in commercial type container, DACO: 3.5.10
2746671	2016, BAS 772 00 F - Acute oral toxicity: Acute toxic class model in rats, DACO: 4.6.1
2746672	2016, BAS 772 00 F - Acute dermal toxicity in rats, DACO: 4.6.2
2746673	2016, BAS 772 00 F: Acute inhalation toxicity in rats, DACO: 4.6.3
2746674	2016, BAS 772 UD F: Primary eye irritation in rabbits, DACO: 4.6.4
2746675	2016, BAS 772 UD F: Primary skin irritation in rabbits, DACO: 4.6.5
2746676	2016, BAS 772 UD F: Dermal sensitization test in guinea pigs - Buehler method, DACO: 4.6.6

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