

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.6, 3.12 Application

Application Number: 2012-2454
Application: Product chemistry: guarantee, identity and proportion of formulants
Product labels: new site or host, pre-harvest
Product: Quilt Xcel Fungicide
Registration Number: 31074
Active ingredients (a.i.): azoxystrobin (AZY) and propiconazole (PON)
PMRA Document Number: 2328738

Purpose of Application

The purpose of this application was to register a new pre-mix product, Quilt Xcel Fungicide, for the control of various leaf diseases on cereals (barley, rye, triticale, wheat and oats). Quilt Xcel Fungicide contains the active ingredients azoxystrobin and propiconazole. Currently, these active ingredients are registered to control the same diseases on cereals in the following products, Quadris Flowable Fungicide (PMRA Reg. No. 26153, azoxystrobin), Tilt 250E Fungicide (PMRA Reg. No. 19346, propiconazole) and Quilt Fungicide (PMRA Reg. No. 28328, azoxystrobin + propiconazole). Quilt Xcel Fungicide contains the same quantity of propiconazole, but doubled amount of azoxystrobin comparing to Quilt Fungicide. The proposed use pattern is currently registered and the use rates are within the range of currently registered rates for both active ingredients.

Chemistry Assessment

Quilt Xcel Fungicide is formulated as a suspension containing azoxystrobin and propiconazole at nominal concentrations of 143 g/L and 124 g/L respectively. This end-use product has a density of 1.06 g/mL and pH of 5. The chemistry requirements for Quilt Xcel Fungicide have been completed.

Health Assessments

Quilt Xcel Fungicide is of slight acute oral toxicity ($LD_{50} = 1030$ mg/kg bw) and low acute dermal ($LD_{50} > 5000$ mg/kg bw) and acute inhalation toxicity ($LC_{50} > 2.56$ mg/L) in rats. It is severely irritating to the eye and mildly irritating to the skin of rabbits and is not a dermal sensitizer in guinea pigs.

Residue data for azoxystrobin and propiconazole in cereal grains were not submitted to support the registration of Quilt Xcel Fungicide. However, the use pattern is currently registered and the use rates are within the range of currently registered rates for both active ingredients.

Previously submitted processing studies for propiconazole in corn and wheat were reviewed in the context of the current submission. Given that there was a slight or no concentration of propiconazole residues in/on the processed commodities of wheat and corn used for human consumption, separate MRLs for the processed commodities of corn and wheat are not required, and will be covered under the maximum residue limits (MRLs) established for propiconazole in/on field corn and wheat.

Based on residue data and the dietary burdens, no revisions to the MRLs for azoxystrobin in livestock commodities are required. With respect to propiconazole in livestock commodities, it is proposed that the currently established MRL of 0.01 ppm for milk be replaced with 0.03 ppm, and the following MRLs be added: meat byproducts of goats, horses and sheep at 2 ppm; meat byproducts of hogs at 0.1 ppm; and fat of cattle, goats, hogs, horses, poultry and sheep and meat of goats, hogs, horses and sheep at 0.05 ppm.

The use of Quilt Xcel Fungicide on barley, rye, triticale, wheat and oats should not result in worker or bystander exposure that is greater than registered uses of propiconazole and azoxystrobin, since the application rate falls within the registered use pattern for this active ingredient on other crops.

Environmental Assessment

No environmental concerns were identified as the proposed application rate of Quilt Xcel Fungicide for use to control various diseases on cereals falls within that of the precedent product Quilt Fungicide.

Value Assessment

The cereal crops barley, rye, triticale, wheat and oats are subject to many common foliar pathogens which cause various leaf diseases such as leaf spot, scald and rust. No efficacy data were provided; however, the registrant submitted a scientific rationale to support the proposed use claims. The active ingredients azoxystrobin and propiconazole are currently registered to control the same diseases on cereals in several other fungicides and both active ingredients have activity against the same pathogens. The proposed use rate is within the range of currently registered rates for both active ingredients. The proposed formulation has enhanced the action of azoxystrobin. It will provide Canadian growers an additional product to manage various foliar diseases in cereals.

Conclusion

The PMRA has completed an assessment of the available information and is able to support the registration of Quilt Xcel Fungicide.

References

PMRA Document Number	Reference
2206066	2012, Starting Material and Certification of Limits, DACO: 3.2.1,3.3.1 CBI
2206067	2012, Manufacturing Process, DACO: 3.2.2 CBI
2206069	2012, Comparison, DACO: 3.3.2 CBI
2206070	2008, A15909B – Validation of Method SF-304/1, DACO: 3.4.1 CBI
2206071	2012, Chemical and Physical properties, DACO: 3.5.1,3.5.10,3.5.11,3.5.12, 3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9 CBI
2206073	2008, Azoxystrobin/Propiconazole SC (A15909B) - Acute Oral Toxicity Up-and-Down Procedure in Rats, DACO: 4.6.1
2206074	2008, Azoxystrobin/Propiconazole SC (A15909B) Acute Dermal Toxicity in Rats, DACO: 4.6.2
2206075	2008, Azoxystrobin/Propiconazole SC (A15909B) - Acute Inhalation Toxicity in Rats, DACO: 4.6.3
2206076	2008, Azoxystrobin/Propiconazole SC (A15909B) - Primary Eye Irritation in Rabbits, DACO: 4.6.4
2206077	2008, Azoxystrobin/Propiconazole SC (A15909B) - Primary Skin Irritation in Rabbits, DACO: 4.6.5
2206079	2008, Azoxystrobin/Propiconazole SC (A15909B) - Dermal Sensitization Test - Buehler Method, DACO: 4.6.6
1524586	1992, Determination of the Total Residues of Propiconazole in Corn Forage and Grain (Including Samples for Processing) Following Application of TILT 3.6E Formulation to Field Corn, DACO: 7.4.5
1524587	1997, Propiconazole: Magnitude of the Residue in or on Wheat, Including Processed Fractions, Following an Application of TILT, DACO: 7.4.5
1524588	1998, Propiconazole: Magnitude of the Residue in or on Wheat, Including Processed Fractions, Following an Application of TILT, DACO: 7.4.5
1524589	1997, Propiconazole: Magnitude of the Residue in or on Wheat, Including Processed Fractions and Rotational Lentils and Peas, Following Post Foliar Applications of TILT, DACO: 7.4.5
2206093	2012, Quilt Xcel Fungicide Efficacy rationale. DACO: 10.1, 10.2.3.1, 10.2.3.2, 10.3.1, 10.3.2

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