



Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2012-4258
Application: B.3.12 (Product label – new site or host)
Product: QUILT Fungicide
Registration Number: 28328
Active ingredients (a.i.): Azoxystrobin and Propiconazole
PMRA Document Number : 2350077

Purpose of Application

The purpose of this application was to add canola with a pre-harvest interval (PHI) of 30 days and to add aerial application for canola to the QUILT Fungicide label and to establish a Maximum Residue Limit (MRL) for propiconazole in/on canola.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A toxicology assessment was not required for this application.

The addition of the control of virulent blackleg on canola to the QUILT Fungicide label should not result in risks of concern from exposure to azoxystrobin or propiconazole when workers follow the label directions and wear the personal protective equipment identified on the label.

Residue data from field trials conducted in/on canola were assessed in the framework of this petition to support the addition of canola to the QUILT Fungicide label. A canola processing study was submitted.

Maximum Residue Limit

Based on the maximum residues observed in canola seeds treated according to one-fold supported rate, a maximum residue limit (MRL) of 0.02 ppm to cover residues of propiconazole *per se* in rapeseeds (canola) will be established as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRL for the raw agricultural commodity (RAC).

The currently established MRL for azoxystrobin in/on rapeseeds (canola) was not revised under the current submission as residues of azoxystrobin in/on rapeseeds (canola), following treatment at one-fold supported rate, will be covered by the MRL of 1 ppm.

TABLE 1. Summary of Field Trial and Processing Data Used to Establish Maximum Residue Limits (MRL).							
Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL	Recommended MRL
			Min	Max			
Propiconazole							
Rapeseeds (canola)	Foliar/ 125.3– 138.1-ULV	29-30	<0.01	0.013	None	None	0.02
	Foliar/ 117.7– 130.5-HV		<0.01	<0.01			
	Foliar/ 117.7– 138.1- ULV + HV		<0.01	0.013			
Azoxystrobin							
Rapeseeds (canola)	Foliar/ 74.9–75.6 g a.i./ha	29-30	0.0	0.01	None	1	None
Z-isomer							
Rapeseeds (canola)	Foliar/ 74.9–75.6 g a.i./ha	29-30	0.01	0.01	None	1	None

ULV: Ultra-low volume spray; HV: High volume spray

Following the review of all available data, a MRL of 0.02 ppm is recommended to cover residues of propiconazole in/on rapeseeds (canola). The currently established MRL of 1 ppm for azoxystrobin in/on rapeseeds (canola) was not revised under the current application. Residues of propiconazole and azoxystrobin in rapeseeds (canola) at the recommended or established MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

No environmental concerns were identified as the application rate of QUILT Fungicide (azoxystrobin and propiconazole) for the control of various diseases on canola fits within the registered use pattern for azoxystrobin and propiconazole use on canola (i.e. Quadris Flowable Fungicide – Registration Number 26153 and Tilt 250E Fungicide – Registration Number 19346,

respectively).

Value Assessment

The value of this new use was supported by a rationale stating that claims for control of virulent blackleg are already registered on the labels of products that contain the individual components of the pre-mixed product QUILT Fungicide; i.e. Tilt (propiconazole) and Quadris (azoxystrobin). Based on the similarity of use patterns for these single-active products and the new use of QUILT Fungicide along with the benefits of having multiple modes of action against a disease in a single application, the value of the use of QUILT Fungicide on canola was deemed to have been adequately demonstrated.

Conclusion

The PMRA has completed an assessment of the available information and is able to support the addition of canola with a pre-harvest interval (PHI) of 30 days and to specify aerial application for canola on the QUILT Fungicide label and to establish a Maximum Residue Limit of 0.02 ppm for propiconazole in/on canola.

References

A. List of Studies/Information Submitted by Registrant

PMRA No.	References
2234028	2012, Use Description and Scenario (Mixer/Loader/Applicator and Post-application) for Quilt Fungicide. DACO: 5.2
1278522	2006, LIVESTOCK, POULTRY, EGG AND MILK RESIDUE DATA (FROM FEEDING OF TREATED CROPS), DACO: 7.5
2234038	2005, Residue Analytical Method for the Determination of Residues of Propiconazole (CGA64250) in Crop Samples Final Determination by LC-LC-MS/MS, DACO: 7.2.2
2234045	2012, 7.4.1 - Residue trial study - Add canola to Quilt, DACO: 7.4.1,7.4.2,7.4.5
2346368	2008, Validation of Residue Analytical Method REM 130.11 for the Determination of Residues in Crop Samples, DACO: 7.2.1
2349389	US EPA DER of canola crop field trials with propiconazole: (2012) SYN545192 EC (A15457B), Difenoconazole EC (A7402T), Propiconazole EC (A6097AC) and Propiconazole/Azoxystrobin SU (A13705V) – Residue Levels on Canola Seed and Processed Fractions (Meal and Refined Oil) in Canada during 2011. Final Report. Project Number: CER 05903/11, 12SYN312.REP, TK0171471. Unpublished study prepared by Syngenta Crop Protection, and Syngenta Canada Inc. MRID 48604486 811 p.
2349392	US EPA DER of Canola processing study: (2012) SYN545192 EC (A15457B), Difenoconazole EC (A7402T), Propiconazole EC (A6097AC) and Propiconazole/Azoxystrobin SU (A13705V) – Residue Levels on Canola Seed and Processed Fractions (Meal and Refined Oil) in Canada during 2011. Final Report. Project Number: CER 05903/11, 12SYN312.REP, TK0171471. Unpublished study prepared by Syngenta Crop Protection, and Syngenta Canada

2234052 Inc. MRID 48604486 811 p.
2012. Summary Efficacy - Add canola to Quilt. 3 pp. DACO 10.1, 10.2.3.1,
10.2.3.2, 10.3.1, 10.3.2

B. Additional Information Considered

i) Published Information Considered

1.0 Human and Animal Health Assessment

1249254 1983. Residue levels of CGA 64250 Equivalent (Detected as 2m, 4-dichloronezoic acid methyl ester converted to CGA 64250) in milk and tissues. ABR-83091. 11 pgs.

1139712 1983. Residues of CGA 64250 and metabolites in eggs and tissues of laying hens receiving CGA 64250 in their diet. ABR-83092. 12 pgs.

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