Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2013-4084
Application: New or Changes to Product Labels-New Site or Host
Product: Fortenza
Registration Number: 30899
Active ingredients (a.i.): Cyantraniliprole
PMRA Document Number : 2368517

Purpose of Application

The purpose of this application was to amend the Fortenza label to include seed treatment uses in/on corn (field and pop), rapeseeds (canola), and mustard seed (oilseed and condiment type). This application was a workshare with the US Environmental Protection Agency.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

The amendment to the label did not impact the acute toxicity of this end-use product.

No new residue data for cyantraniliprole in canola, rapeseed, oilseed mustard, and condiment mustard were submitted to support the use expansion of this active. Previously reviewed residue data from field trials conducted in/on canola were reassessed in the framework of this petition. Residue data from field trials conducted in Canada and the United States were submitted to support the domestic use of Fortenza on field and popcorn. In addition, a processing study in treated corn was reviewed to determine the potential for concentration of residues of cyantraniliprole into processed commodities.

Maximum Residue Limit(s)

The recommendation for maximum residue limits (MRLs) for cyantraniliprole was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. MRLs to cover residues of cyantraniliprole 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/	PHI (days)	Residues (ppm)	Experimental Processing	Currently Established	Recommended MRL

Canada

	Total Application Rate		Min	Max	Factor	MRL (ppm)	(ppm)
Field corn	Seed treatment/0.5 mg ai/seed	na	<0.01	<0.01	na	None	0.01
Popcorn grain	Seed treatment/0.5 mg ai/seed	na	<0.01	<0.01	na	None	0.01

Following the review of all available data, MRLs as proposed in Table 1are recommended to cover residues of cyantraniliprole. Residues in these crops at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

A human health risk assessment was completed for Fortenza for use as a commercial seed treatment. Fortenza is to treat corn, Crop Sub Group 20A (oilseeds) and condiment mustard seeds. Dermal exposure was not calculated as systemic toxicity was not identified at short- to intermediate-term exposure durations for cyantraniliprole. Only inhalation exposure was calculated and not considered to be of concern if label amendments are adhered to.

Environmental Assessment

Cyantraniliprole is currently registered on a number of crops for foliar, soil and seed treatments, at higher rates. The seed treatment expansion is not expected to result in increased risk to birds and mammals. Current residue data indicate low levels of cyantraniliprole in pollen and/or nectar from other seed treatment crops, and a negligible oral risk. However, corn pollen residues are needed in order to confirm negligible risk from oral exposure for pollinators. Best Management Practice for dust reduction will also be implemented on the label.

Value Assessment

Submitted value information included 5 efficacy trials (2 greenhouse trials and 3 field trials) on cutworm in corn, 3 field trials on wireworm in corn, 1 field trial on northern masked chafer (*Cyclocephala borealis*) in corn, 3 field trials on cutworms in canola, and 3 field trials on flea beetles in canola. A rationale was submitted to extrapolate data on canola to oilseed mustard and condiment mustard and to extrapolate from data submitted on northern masked chafer to a claim of control of European chafer based on similarity of pest biology and behavior.

Information was only submitted on black cutworm in corn and black cutworm and army cutworm in canola. Despite the variable behavior and biology of cutworms (e.g. climbing cutworms vs army cutworm), it is expected that Fortenza, because it is systemic, would provide similar control of all cutworms. The submitted value information supported a claim for cutworms at an application rate of 83 to 167 ml product (50 to 100 g a.i.) per 100 kg seed and a claim for wireworms and European chafer at an application rate of 167 ml product (100 g a.i.) per 100 kg seed for corn. The submitted value information also supported a claim for cutworm at

an application rate of 500 ml product (300 g a.i.) per 100 kg seed and a claim for flea beetles at an application rate of 1333 ml product (800 g a.i.) per 100 kg seed for canola, rapeseed, and mustard (oilseed and condiment).

Tank mixes with other insecticide seed treatments (Cruiser 5 FS for corn and Helix Xtra for canola and condiment mustard) were supported from a value perspective based on the applicant rationale that they will increase the pest spectrum compared to each insecticide seed treatment alone. Tank mixes with fungicide seed treatments (Apron XL LS, Maxim XL, Dynasty 100FS, and/or Vibrance 500 FS) were supported for corn and a tank mix with Vibrance 500FS was supported for canola, rapeseed, and mustard (oilseed and condiment). These tank mixtures with registered fungicides will allow broadening the pest spectrum and should provide economical returns to the growers.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Fortenza, and has found the information sufficient to include seed treatment uses in/on corn (field and pop), rapeseeds (canola), and mustard seed (oilseed and condiment type) on the label.

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