Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 3.3 Application

Application Number: 2012-1042
Application: New or Changes to Product Labels-Application Number or Frequency
Product: Folicur 250 EW Fungicide
Registration Number: 29820
Active ingredients (a.i.): Tebuconazole
PMRA Document Number : 2391319

Purpose of Application

The purpose of this application was to add the option for sequential applications on this product's label. Folicur 250 EW Fungicide would be applied sequentially with Prosaro 250 EC Fungicide, Prosaro 421 SC Foliar Fungicide or USF 2010 Fungicide which also contain tebuconazole as the active ingredient. This application was therefore representing an increase of the maximum seasonal application rate for tebuconazole on wheat and barley. Folicur 250 EW Fungicide is currently a product used for control of various leaf diseases on wheat and barley (USC 13 - Terrestrial Feed Crop and USC 14 - Terrestrial Food Crop).

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

The occupational exposure and risk from the increase in seasonal amount of tebuconazole to wheat and barley to the Folicur 250 EW label was assessed. No health risks of concern are expected from the new use, provided that workers follow the label directions and wear the personal protective equipment identified on the label.

Residue data from field trials conducted in Canada were submitted to support the maximum approved seasonal rate of 226 g a.i./ha for tebuconazole on barley and wheat. Tebuconazole was applied to wheat and barley at label rates, and harvested according to label directions. In addition, previously reviewed processing studies in treated wheat were reassessed in the context of the current application.

Maximum Residue Limit(s)

Residues of tebuconazole in/on barley and wheat will be covered under the maximum residue limits (MRLs) established for tebuconazole in/on each of barley and wheat at 0.15 ppm. Residues in processed commodities not listed in Table 1 are covered under the MRL established for the raw agricultural commodity (RAC).

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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)**	**Residues (ppm)**		**Experimental Processing Factor**	**Currently Established MRL (ppm)**	**Recommended MRL (ppm)**
			Min	**Max**			
Barley	Broadcast foliar/ 223.5-233.6	33-43	<0.02	0.0360	No concentration of residues in wheat bran or flour (≤1)	0.15	None
Wheat	Broadcast foliar/ 223.3-227.8	34-43	<0.02	0.0880		0.15	None

No significant increase to the dietary burden of livestock is expected from the use of Folicur 250 EW Fungicide when applied according to the approved label directions.

Following the review of all available data, residues of tebuconazole in/on barley and wheat will be covered under the MRLs established for tebuconazole in/on each of barley and wheat at 0.15 ppm. Exposure to residues of tebuconazole in food and drinking water following the use of Folicur 250 EW Fungicide will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The proposed request for sequential application of a second tebuconazole containing product represents an increase in the maximum seasonal application rate for tebuconazole from 126 g a.i./ha to 226 g a.i./ha for use on wheat and barley. No new environmental data was submitted nor required for the evaluation of the proposed increase in application rate. New drinking water modeling was conducted for the proposed increase in application rate in order to report new estimated drinking water concentrations for use in the human dietary risk assessment. A risk to non-target terrestrial and non-target aquatic organisms was identified during the risk assessment. As such, environmental risk mitigation statements are required on the product label to mitigate the risk to non-target organisms from the use of Folicur 250 EW Fungicide. The environmental assessment directorate concludes that the proposed sequential application for Folicur 250 EW Fungicide and the associated increase in seasonal application rate of tebuconazole does not pose an unacceptable risk to non-target organisms provided that the mitigation measures on the product label are followed.

Value Assessment

This was an application to amend the labels of five tebuconazole-containing products to allow sequential use of these products to manage certain foliar diseases on wheat and barley. Management of foliar diseases prevents yield losses, especially when fungicide treatments are applied at two critical times, i.e. vegetative and flowering stages on wheat and barley. Tebuconazole is an effective fungicide against certain foliar diseases, such as powdery mildew and many leaf spotting pathogens. There is a value to growers in having access to multiple applications of tebuconazole-containing products.

Tebuconazole belongs to the Group 3 fungicide (within the chemical group DeMethylation Inhibitors, DMI) which has a medium risk of resistance development. However, several foliar pathogens on wheat and barley are currently listed as either at medium or high risk, and the combined risk factor for some diseases can be very high when considering the agronomic risk associated with wheat and barley production. Therefore, the Fungicide Resistance Action Committee - Sterol Biosynthesis Inhibitors (FRAC-SBI) working group has recommended restricting all DMI fungicide applications on cereal crops to a single application per season when used alone in order to maintain the effectiveness of these valuable actives. Tebuconazole is one of a few triazole fungicides where resistance has been confirmed in some countries.

An increase in the maximum number of seasonal tebuconazole applications will provide Canadian growers more access to the tebuconazole-containing products to manage different foliar diseases in wheat and barley. Equally important, long-term product sustainability must be also considered. Information from FRAC indicates a relatively stable sensitivity of cereal foliar pathogens to both tebuconazole and prothioconazole based on the long-term monitoring data collected from Europe where DMI fungicides have been intensively used for decades. In addition, the different resistance factors observed for tebuconazole and prothioconazole also demonstrate an incomplete cross-resistance pattern between different DMIs. Tebuconazole and prothioconazole are generally cross-resistant; however, the target-site mutations are different for individual DMI because of the structural differences of these active ingredients. The alternation of different DMIs within one season can be supported based on the expert's opinion from the FRAC SBI working group, although the mixtures of compounds that belong to the same cross-resistance fungicide group are still regarded as one single compound. Based on the value evidence submitted, in certain situations, sequential applications of tebuconazole and prothioconazole containing products can be allowed. Product-specific guidance is provided on all product labels for best resistance management practices.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product Folicur 250 EW Fungicide and has found the information sufficient to add the option for sequential applications with Prosaro 250 EC Fungicide, Prosaro 421 SC Foliar Fungicide or USF 2010 Fungicide for use on wheat and barley to the product label.

References

PMRA Doc No.	Reference
2166527	2011, Scientific rationale justifying the use of sequential applications of tebuconazole on wheat and barley. DACO: 10, 10.1, 10.2, 10.2.3, 10.2.3.3(D), 10.3, 10.3.1, 10.3.2.
2400615	2012, Bayer CropScience Position Paper: Sequential Applications of Tebuconazole-Containing Products in Wheat and Barley. DACO: 10.5
2400616	CBI reference document: Bayer CropScience Position Paper: Sequential Applications of Tebuconazole-Containing Products in Wheat and Barley. DACO:

10.5 CBI
2282071 2013, FRAC expert opinion - Resistance Risk of DMI fungicides used in Cereals. DACO: 10.2.1, 10.5.3.
2166532 2010, Tebuconazole - Magnitude of residues in/on wheat following multiple applications in one growing season, DACO: 7.4.1,7.4.2,7.4.6
2166533 2010, Tebuconazole - Magnitude of residues in/on barley following multiple applications in one growing season, DACO: 7.4.1,7.4.2,7.4.6

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