

Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2015-3727
Application: New product; new combination of TGAI's
Product: Rancona V RTU FS Fungicide
Registration Number: 32668
Active ingredients (a.i.): Ipconazole, carbathiin, metalaxyl
PMRA Document Number: 2737891

Purpose of Application

The purpose of this application was to register the end-use product, Rancona V RTU FS Fungicide (guarantee: 133.33 g carbathiin/L, 13.33 g metalaxyl/L and 5.0 g ipconazole/L), for use on cereal grains.

Chemistry Assessment

Rancona V RTU FS Fungicide is formulated as a suspension containing containing ipconazole at a nominal concentration of 5.0 g/L, carbathiin at a nominal concentration of 133.3 g/L, and metalaxyl at a nominal concentration of 13.33 g/L. This end-use product has a density of 1.040-1.080 g/mL and pH of 7.5-9.5. The chemistry requirements for this product have been fulfilled.

Health Assessments

In rats, Rancona V RTU FS Fungicide is of low acute toxicity by the oral, dermal, and inhalation routes of exposure. The formulation is minimally irritating to the rabbit eye and is slightly irritating to the rabbit skin. It is not a skin sensitizer in mice based on the local lymph node assay.

The registration of the seed treatment product Rancona V RTU FS Fungicide for commercial and on-farm use on cereal grains (spring and winter wheat, barley, oats, rye and triticale) fits within the existing use pattern for ipconazole and metalaxyl, but not for carbathiin. As such, occupational exposure and risk assessments were conducted and all new uses were supported. No health risks of concern are expected from the use of Rancona V RTU FS Fungicide provided that the recommended label amendments are made, and that workers follow all label directions, including wearing the appropriate personal protective equipment and using the engineering controls.

Previously reviewed residue data from field trials conducted in/on wheat, barley and corn were reassessed in the framework of this petition.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for carbathiin was based upon the previously reviewed field trial data, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of carbathiin, including metabolites determined as benzenamine and expressed as parent compound 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 Limits (MRLs)

Commodity	Application Method/ Total Application Rate (g a.i./100 kg seed)	DAP (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT			
Wheat	Seed treatment / 164	103 – 150	<LOQ	<LOQ	No quantifiable residues were observed at exaggerated rates.	None	0.2 ppm for Crop Group 15 (Cereal grains)
Barley	Seed treatment / 82 – 164	94 – 150	<LOQ	<LOQ			
Field corn	Seed treatment / 92 – 185	83 – 98	<LOQ	<LOQ			
Sweet corn	Seed treatment / 92 – 185	78 – 177	<LOQ	<LOQ			

DAP = days after planting; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial; LOQ = limit of quantitation

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of carbathiin. Residues in these crop commodities 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 rates for the actives carbathiin and metalaxyl on the end-use product label are within the registered rates for the same crops on currently registered products. As such, no increased environmental exposure or risk is anticipated.

The rates for ipconazole on legumes are higher than the currently registered rates for cereals, corn and canola, so a risk assessment was conducted. The increase in rate for ipconazole as a seed treatment poses negligible risk to birds, mammals, freshwater fish and amphibians. Mitigating label statements recommending burial of treated seed and cleanup of spilled treated seed are required.

Value Assessment

A total of 18 efficacy trials conducted in Canada and the US were submitted to support four claims. The submitted value data was sufficient to support the claims at the rate. The remaining claims were supported based on data reviewed under concurrent application and extrapolated from currently registered products.

Seed treatments protect cereal crops when they are young and more sensitive to soil pathogens at a relatively low application rate. These products are an important component of an IPM program.

Conclusion

Following review of the application, the PMRA approved the registration of Rancona V RTU FS Fungicide for use on cereal grains.

References

PMRA

Document

Number	Reference
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