

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

Application Number: 2015-3725
Application: New product; changes to product chemistry and new site
Product: Rancona V 100 Pro FS Fungicide
Registration Number: 32667
Active ingredients (a.i.): Ipconazole, Carbathiin
PMRA Document Number: 2737895

Purpose of Application

The purpose of this application was to register the end-use product, Rancona V 100 Pro FS Fungicide (guarantee: 400 g carbathiin/L and 25 g ipconazole/L), for use on cereal grains and legume vegetables.

Chemistry Assessment

Rancona V 100 Pro FS Fungicide is formulated as a suspension containing ipconazole at a nominal concentration of 25.0 g/L and carbathiin at a nominal concentration of 400.0 g/L. This end-use product has a density of 1.106-1.146 g/mL and pH of 7.5-9.5. The chemistry requirements for this product have been fulfilled.

Health Assessments

In rats, Rancona V100 Pro FS Fungicide is of low acute toxicity by the dermal and inhalation routes of exposure. It is slightly acutely toxic by the oral route. The formulation is minimally irritation to the rabbit eye but is moderately irritating to the rabbit skin. It is not a skin sensitizer in mice.

The registration of the seed treatment product Rancona V 100 Pro FS Fungicide for commercial and on-farm use on cereal grains (spring and winter wheat, barley, oats, rye and triticale) and legume vegetables (soybeans, dried shelled and succulent/edible podded peas and beans, lentils and chickpeas) does not fit within the existing use patterns for ipconazole and carbathiin. As such, occupational exposure and risk assessments were conducted and all uses were supported. No health risks of concern are expected from the use of Rancona V 100 Pro 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.

Residue data from field trials conducted in the United States including Canadian representative growing regions were submitted to support the domestic use of Rancona V 100 Pro FS Fungicide on soybeans, beans (dried shelled and succulent/edible podded) and peas (dried shelled and succulent/edible podded). Iaconazole was applied to soybean seed at exaggerated rates, and commodities grown from the treated seed were harvested according to label directions. Previously reviewed residue data from field trials conducted in/on soybeans for ipconazole, and peas, lentils, succulent beans, dry beans, soybeans and cereals for carbathiin were reassessed in the framework of this petition.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for ipconazole was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of ipconazole 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/ 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			
Soybean (succulent seed with pod)	Seed treatment / 12.5	92 – 155	<LOQ	<LOQ	No quantifiable residues were observed at exaggerated rates.	None	0.01 for Crop Subgroup 6A (Edible-podded legume vegetables)
Soybean (succulent seed without pod)	Seed treatment / 12.5	92 – 155	<LOQ	<LOQ		None	0.01 for Crop Subgroup 6B (Succulent shelled pea and bean)

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

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 2. Residues in processed commodities not listed in Table 2 are covered under the proposed MRLs for the raw agricultural commodities (RACs).

Table 2 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)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT			
Peas	Seed treatment / 49	Harvested at maturity	<LOQ	<LOQ	No quantifiable residues were observed at exaggerated rates.	None	0.03 ppm for Crop Group 6 (Legume vegetables [succulent or dried])
Lentils	Seed treatment / 55		<LOQ	<LOQ			
Succulent beans	Seed treatment / 100 – 200		<LOQ	<LOQ			
Dry beans	Seed treatment / 100 – 200		<LOQ	<LOQ			
Soybeans	Seed treatment / 52 – 185		<LOQ	<LOQ			
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			

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 Tables 1 and 2 are recommended to cover residues of ipconazole and 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 active carbathiin 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

Thirty-one field trials conducted in Canada and the US and scientific rationales were submitted to support the claims.

Cereals

Efficacy trials were submitted to support claims for control or suppression of seed and seedling diseases caused by *Rhizoctonia solani*, *Fusarium* spp., crown and foot rot caused by *F. culmorum*, and true loose smut of barley. The results of the trials support the claims. Claims currently registered on the precedent product labels that were not supported by data were extrapolated to the Rancona V 100 Pro FS Fungicide label since the rate of active ingredients delivered to the seed is equivalent between the products.

Legumes

Efficacy trials were submitted to support claims for control or suppression of seed and seedling diseases caused by *Rhizoctonia solani*, *Fusarium* spp., and sudden death syndrome. The use claims were supported as proposed. Claims reviewed and supported under a concurrent application to add legume use claims to a precedent product label were extrapolated to Rancona V 100 Pro FS Fungicide.

Seed treatments protect cereal and legume 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. The registration of Rancona V 100 Pro FS Fungicide also provides a new mode of action for the management of sudden death syndrome on soybean.

Conclusion

Following review of the application, the PMRA approved the registration of Rancona V 100 Pro FS Fungicide for use on cereal grains and legume vegetables.

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PMRA

Document

Number	Reference
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