

## Evaluation Report for Category B, Subcategory B.3.12 Application

**Application Number:** 2015-5695  
**Application:** Changes to Product Labels – New Site or Host  
**Product:** Rancona V RS Fungicide  
**Registration Number:** 30217  
**Active ingredients (a.i.):** Ipconazole and Carbathiin  
**PMRA Document Number:** 2675783

### Purpose of Application

The purpose of this application was to amend the label of the registered seed treatment product Rancona V RS Fungicide to add the new crop mustard seed to the oilseed crops listed on the label.

### Chemistry Assessment

A chemistry assessment was not required for this application.

### Health Assessments

For ipconazole, the addition of mustard seeds to the label of Rancona V RS Fungicide constitutes an expansion of use. However, no increase in exposure over the registered uses is expected for commercial and on-farm treaters, workers, and planters of treated seeds. The risk assessments on file are adequate to cover the exposure from the new use.

For carbathiin, the addition of mustard seeds to the label of Rancona V RS Fungicide fits within the use pattern of this active ingredient for commercial treatment and planting of treated seeds, but on-farm treatment constitutes an expansion of use. As such, an updated risk assessment was conducted and acceptable margins of exposure were obtained.

No health risks of concern are expected from the addition of mustard seeds to the label of Rancona V RS Fungicide provided that workers wear the appropriate personal protective equipment and follow all label use directions and restrictions.

No residue data for ipconazole or carbathiin were submitted to support the addition of the new crop mustard seed to the label of the registered seed treatment product Rancona V RS Fungicide. Ipconazole and carbathiin are registered in Canada for seed treatment on canola, and the application rates and use restrictions for the treatment of mustard seeds are identical to those registered for canola.

## Maximum Residue Limits

Based on the carbathiin residues observed in canola seeds treated according to label directions, maximum residue limits (MRLs) of 0.03 ppm in/on mustard seeds (condiment and oilseed types) to cover residues of carboxin, including metabolites determined as benzenamine and expressed as parent compound, will be established as shown in Table 1. Residues of carbathiin in processed commodities not listed in Table 1 are covered under established MRLs for the raw agricultural commodities (RACs).

<b>TABLE 1. Summary of Field Trial Data Used to Support the Maximum Residue Limits (MRLs) for Carbathiin.</b>						
Commodity	Application Method/ Total Application Rate	PHI (days)	Residues (ppm)		Currently Established MRL (ppm)	Recommended MRL (ppm)
			Min	Max		
Canola	Seed treatment/ 70 g a.i./100 kg seed	NA	0.008	0.029	0.03 {Rapeseeds (canola)}	<b>0.03</b> { <b>Mustard seeds (condiment and oilseed types)</b> }

Based on the ipconazole residues observed in canola seeds (<5 ppb) treated according to the label directions, an MRL of 0.01 ppm in/on mustard seeds (condiment type) to cover residues of ipconazole will be established as shown in Table 2. Residues of ipconazole in processed commodities not listed in Table 2 are covered under established MRLs for the RACs.

<b>TABLE 2. Summary of Field Trial Data Used to Support the Maximum Residue Limit (MRL) for Ipconazole.</b>						
Commodity	Application Method/ Total Application Rate	PHI (days)	Residues (ppm)		Currently Established MRL (ppm)	Recommended MRL (ppm)
			Min	Max		
Canola	Seed treatment (Radiotracer)/ 10 g a.i./100 kg seed	NA	<0.005	<0.005	0.01 <sup>1</sup> {Rapeseeds (canola) and Mustard seeds (oilseed type)}	<b>0.01</b> { <b>Mustard seeds (condiment type)</b> }

<sup>1</sup>Limit of quantitation (LOQ) of the enforcement method

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of carboxin, including metabolites determined as benzenamine and expressed as parent compound, and the MRL as proposed in Table 2 is recommended to cover residues of ipconazole. 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 use of Rancona V RS Fungicide on mustard seed was reviewed from an environmental perspective and was not considered to increase risk to the environment. Mitigation measures to reduce risk to the environment are listed on the product label.

## **Value Assessment**

Close similarities in biology, including disease susceptibility, between mustard seed and the crops currently registered on the Rancona V RS Fungicide label were sufficient to justify the addition of this crop. Minor changes were also made to the formatting of the current application instructions table and the species designation of one of the disease-causing pathogens. These amendments are intended as label improvements that do not impact the registered use pattern and, therefore, require no additional value information to be supported.

The addition of the new crop will provide mustard seed growers with an additional end-use product option for the management of widespread fungal diseases that can have major negative impacts on their crop's stand establishment and reduce yield potential.

## **Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the addition of the new crop mustard seed to the registered label of Rancona V RS Fungicide.

## References

<b>PMRA Document Number</b>	<b>Reference</b>
2576099	2015, Label Amendment to add Mustard Seed as an Additional Crop to Rancona V RS Fungicide label, DACO: 10.2.1, 10.2.2, 10.2.3, 10.2.4, 10.3, 10.4, 10.5
2581323	2015, Use Description and Exposure Scenarios for Mustard Seed Treated with Carbathiin and Ipconazole in Canada, DACO: 5.2

ISSN: 1911-8082

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