

Evaluation Report for Category B, Subcategory 2.6 Application

Application Number:	2011-4947
Application:	New end-use product chemistry – new combination of technical grade active ingredients
Product:	Rancona Pinnacle Fungicide
Registration Number:	30769
Active ingredients (a.i.):	Ipconazole and metalaxyl
PMRA Document Number:	2198861

Purpose of Application

The purpose of this application is to register a new end-use product, Rancona Pinnacle Fungicide, with a new combination of active ingredients (4.61 g/L ipconazole and 6.15 g/L metalaxyl) for seed treatment of wheat (spring and winter), barley, oats, rye and triticale. The target pests include various types of seed rots, pre- and post-emergence damping-off, seedling blights, smuts, bunts, leaf stripe and root rots.

Metalaxyl was re-evaluated and published as Proposed Re-evaluation Decision PRVD2007-10, *Metalaxyl and metalaxyl-M* and Re-evaluation Decision RVD2008-03, *Metalaxyl and metalaxyl-M*.

Chemistry Assessment

Rancona Pinnacle Fungicide is formulated as a solution containing ipconazole at a nominal concentration of 4.61 g/L and metalaxyl at a nominal concentration of 6.15 g/L. This end-use product has a density of 1.063 g/mL and a pH of 6.29. The chemistry requirements for Rancona Pinnacle Fungicide are complete.

Health Assessments

Rancona Pinnacle Fungicide is of low acute toxicity by the oral, dermal and inhalation routes in rats. It is non-irritating to the eye and minimally irritating to the skin of rabbits, and is not a skin sensitizer in guinea pigs.

No new residue data were submitted to support the registration of the new end-use product Rancona Pinnacle Fungicide, a co-formulation containing the two registered active ingredients ipconazole and metalaxyl. The application rates of each active ingredient in Rancona Pinnacle Fungicide are within the currently registered label rates. All other aspects of the use pattern remain the same. The disposition, translocation and magnitude of ipconazole and metalaxyl residues are not expected to be affected when they are co-formulated together. Therefore, the dietary risk is not expected to increase and the use of Rancona Pinnacle Fungicide will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

The use of Rancona Pinnacle Fungicide as a seed treatment on barley, oat, rye, triticale and wheat (spring and winter) is not expected to result in exposures above the registered uses of ipconazole. The exposure from commercial seed treatment with Rancona Pinnacle Fungicide is also not expected to exceed that from the registered uses of metalaxyl. A risk assessment was performed for workers that may be exposed to metalaxyl from on-farm treating and planting, which did not identify risks of concern. No unacceptable risk is expected when workers follow the label directions and wear the personal protective equipment identified on the label.

Environmental Assessment

The use rates and use pattern in this application are exactly the same as those already registered for ipconazole on cereals, and the use rates are lower than those already registered for metalaxyl on cereals. Therefore, the risk to the environment has already been assessed. There are no further requirements and this registration is supported from an environmental perspective.

Value Assessment

A total of 21 trials (11 field, seven greenhouse, and three lab trials) conducted in Canada and the USA between 2006 and 2010 were submitted and reviewed to support the claims. Data submitted on *Pythium* diseases demonstrated control of seed rot/pre-emergence damping-off and seedling blight caused by *P. ultimum*; efficacy was comparable to the registered commercial standard. Trials were conducted on wheat, barley and triticale. The pathogen is expected to affect all cereals in the same manner; therefore, the claims can be extrapolated to oats and rye. Metalaxyl efficacy against *Pythium* spp. has been previously demonstrated on many crops. The claims were supported at the rate for *Pythium* spp.

Bridging data on *Fusarium* spp., common bunt, and true loose smut demonstrated equivalent efficacy between Rancona Pinnacle Fungicide and Rancona Apex (Registration number 29176); therefore, all pests registered on the Rancona Apex label can be extrapolated to Rancona Pinnacle Fungicide.

The efficacy of ipconazole as a seed treatment has been previously demonstrated against *Fusarium* spp., *Cochliobolus sativus*, *Aspergillus* spp., *Penicillium* spp., smuts and bunts. The addition of metalaxyl provides further protection against *Pythium* spp. and eliminates the need to purchase another product for tank mixing.

Conclusion

The PMRA has completed an assessment of available information for Rancona Pinnacle Fungicide and has found the information sufficient to support the full registration of Rancona Pinnacle Fungicide.

References

PMRA

Document

Number	Reference
1398186	2007, Dermal and Inhalation Exposure to Handlers of a Liquid Seed Treatment Fungicide During On-Farm Treatment of Cereal Grain, DACO: 5.4
2115066	2011, Efficacy and Seed Safety of RANCONA Pinnacle Seed Treatment Applied to Wheat, Barley, Oats, Rye and Triticale, DACO: 10.1, 10.2.2, 10.2.3.1, 10.2.3.3, 10.3.1, 10.3.2
2115075	2011, Product Identity and Composition, Description of Materials, Method Used to Produce the Product, Description of the Formulation Process and Discussion of the Formation of Impurities for Rancona Pinnacle Fungicide, DACO 3.2.1, 3.2.2, CBI
2115077	2011, Certified Limits of Rancona Pinnacle Fungicide, DACO: 3.3.1 CBI
2115078	2008, Validation of an Analytical Method for the Determination of Ipconazole and Metalaxyl in Ipconazole/Metalaxyl 4.6/6.2 MD, DACO 3.4.1
2115081	2008, 3.5.1, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.9, 3.5.11 The Physical and Chemical Properties of Ipconazole/Metalaxyl 4.6/6.2 MD (UBI 4339-01), DACO 3.5.1, 3.5.11, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.9
2115082	2009, 3.5.10, 3.5.14 The Storage Stability and Corrosion Characteristics of Ipconazole/Metalaxyl 4.6/6.2 MD in 275 Gallon IBC Over 1 Year DACO: 3.5.10, 3.5.14
2115083	2009, 3.5.10, 3.5.14 The Storage Stability and Corrosion Characteristics of Ipconazole/Metalaxyl 4.6/6.2 MD in 2.5 Gallon Jugs Over 1 DACO: 3.5.10, 3.5.14
2115085	2008, 3.5.11 Flammability of Crusoe Pinnacle MD, DACO: 3.5.11
2115086	2008, 3.5.12 Explodability of Crusoe Pinnacle MD, DACO: 3.5.12
2115091	2008, 3.5.8 Oxidizing or Reducing Action of Crusoe Pinnacle MD, DACO: 3.5.8

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