

Evaluation Report for Category B, Subcategory 3.1, 3.12, 3.13 Application

Application Number: 2015-3729
Application: Changes to the product label; new site, rates and precautions.
Product: Rancona 3.8 FS Fungicide
Registration Number: 29175
Active ingredients (a.i.): Ipconazole
PMRA Document Number: 2737887

Purpose of Application

The purpose of this application was to amend the registration of the seed treatment, Rancona 3.8 FS Fungicide (registration number 29175, containing ipconazole). The amendments are to add the use on legume crops (soybeans, dried shelled and succulent/edible podded peas and beans, lentils and chickpeas), changes to the use rates, and label precautions.

Chemistry Assessment

Rancona 3.8 FS Fungicide is formulated as a suspension containing ipconazole at a nominal concentration of 450 g/L. This end-use product has a density of 1.090-1.130 g/ml and pH of 7.0-8.5. The chemistry requirements for this product have been fulfilled.

Health Assessments

No toxicological data were submitted or are required for this application.

The amendments to the registered seed treatment product Rancona 3.8 FS Fungicide by addition of the commercial and on-farm use on legume vegetable seeds (soybeans, dried shelled and succulent/edible podded peas and beans, lentils and chickpeas) does not fit within the existing use pattern for ipconazole. As such, occupational exposure and risk assessments were conducted and the new uses were supported. No health risks of concern are expected from the use of Rancona 3.8 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 3.8 FS Fungicide on soybeans, beans (dried shelled and succulent/edible podded) and peas (dried shelled and succulent/edible podded). Ipconazole 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 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

Following the review of all available data, MRLs as proposed in Table 1 are 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 rates for ipconazole on legumes are higher than the currently registered rates for cereals, corn and canola. 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 42 efficacy trials conducted in Canada and the US between 2009 and 2014 were submitted to support the claims. The value information was sufficient to support claims for control or suppression of seed and seedling diseases caused by *Rhizoctonia solani*, *Fusarium* spp., *Aspergillus* spp., *Penicillium* spp. on the proposed legume crops. The claims of control of seed rot caused by *Phomopsis longicolla* was also supported on soybean, as well as control of ascochyta blight on lentil (*Ascochyta lentis*) and chickpea (*A. rabiei*). A tank mix with seed treatment products containing metalaxyl for *Pythium* control was also supported.

Treatment of legume seed with Rancona 3.8 FS Fungicide will provide protection against a broad spectrum of seed and seedling disease pathogens. 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 as they may reduce the need for foliar applications during the growing season.

Conclusion

Following review of the application, the PMRA approved the label amendments for Rancona 3.8 FS Fungicide, including the addition of legume crops.

References

PMRA

Document

Number	Reference
2557588	2014, The Storage Stability and Corrosion Characteristics of [CBI Removed] in 2.5 Gallon HDPE Jugs Over 1 Year, DACO: 3.5.10,3.5.14
2557589	2014, The Storage Stability and Corrosion Characteristics of [CBI Removed] in 250 Gallon IBC Containers Over 1 Year, DACO: 3.5.10,3.5.14
2557590	2014, The Storage Stability and Corrosion Characteristics of [CBI Removed] in Stainless Steel Drums Over 1 Year, DACO: 3.5.10,3.5.14
2557713	2015, Table Detailing the changes on Proposed SPSF F5-V1 (2015-08-13) Rancona 3.8 FS Fungicide, Reg. No. 29175, DACO: 3.7
2557487	2015, Summary of Occupational Risk Assessments for the Seed Treatment Use of Rancona V RTU FS Fungicide and Rancona V 100 Pro FS Fungicide on Cereal Grains (wheat, barley, oats, rye and triticale) in Canada, DACO: 5.1
2557489	2009, Rancona 20/50 ME (UBI 6932) In Vitro Dermal Absorption Study Using Human Skin, DACO: 5.14
2557493	2015, Use Description and Exposure Scenarios for Crop Group 6: Legume Vegetable Seed Treated with Ipconazole in Canada, DACO: 5.2
2557497	2015, Mixer/Loader/Applicator Passive Dosimetry Study in Support of On-Farm Seed Treatment of Crop Group 6: Legume Vegetable Seed Treated with Ipconazole in Canada in Canada, DACO: 5.4
2645251	2016, A laboratory study to determine the level of free dust obtained from canola and legume seed following an application of Helix Xxtra to support Canadian registration submission, DACO: 5.15
2652860	2016, Summary of Occupational Risk Assessments for the Seed Treatment Use of Ipconazole on Crop Group 6: Legume Vegetable Seed in Canada, DACO: 5.1
2652862	2016, Mixer/Loader/Applicator Passive Dosimetry Study in Support of Commercial Seed Treatment of Crop Group 6: Legume Vegetable Seed Treated with Ipconazole in Canada, DACO: 5.4
2652863	2016, Seed Planter Agricultural re-entry / Non-Dietary Exposure in Support of the Planting of Crop Group 6: Legume Vegetable Seed Treated with Ipconazole, DACO: 5.6
2652864	2016, A laboratory study to determine the level of free dust obtained from maize and legume seed following an application of Gaucho 600 FS, Rancona 3.8 FS Fungicide and Rancona V 100 Pro Fungicide to support a Canadian registration submission, DACO: 5.15
2557685	2015, Efficacy and Seed Safety of Rancona 3.8 FS Seed Treatment Applied to Crop Group 6 Legume Vegetables (Soybeans, Dried Shelled & Succulent / Edible-Podded Beans and Peas, DACO: 10.1,10.2.1,10.2.2,10.2.3,10.2.4,10.3,10.4,10.5
2557515	2010, Ipconazole - Metabolism in Soybeans, DACO: 6.3
2557519	2015, Ipconazole Residue Data on Crop Group 6: Legume Vegetable (Dried Shelled and Succulent/Edible-podded) Seed - A Summary Report, DACO: 7.1
2557528	2009, Ipconazole (Seed Treatment) on Soybeans: Magnitude of the Residue Study, DACO: 7.4.1

2557529 2009, Ipconazole (Seed Treatment) on Soybeans: Magnitude of the Residue Study, DACO: 7.4.1

Task Force Data

1349637 2000, Occupational Risk Exposure Assessment for HELIX 289FS., DACO: 5.4

1398186 2007, Dermal and Inhalation Exposure to Handlers of a Liquid Seed Treatment Fungicide During On-Farm Treatment of Cereal Grain, DACO: 5.4

1571553 2007, Determination of Operator Exposure to Imidacloprid During Loading/Sowing of Gaucho Treated Maize Seeds Under Realistic Field Conditions in Germany and Italy, DACO: 5.4

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