



## Evaluation Report for Category B, Subcategory 3.12 Application

**Application Number:** 2010-2979  
**Application:** B.3.12 (Product labels – new site or host)  
**Product:** Rancona 3.8 FS Fungicide  
**Registration Number:** 29175  
**Active ingredients (a.i.):** Ipconazole (IPZ)  
**PMRA Document Number English PDF:** 1983394

### Background

Rancona 3.8 FS Fungicide Suspension is currently registered for the protection of seed, seedling and soil-borne diseases cause by *Aspergillus* spp., *Cladosporium* spp., *Fusarium* spp., *Penicillium* spp., *Rhizoctonia solani*, and *Rhizopus* spp. on field corn, sweet corn and popcorn.

### Purpose of Application

The purpose of this application was to add the seed treatment of canola (including canola quality *Brassica juncea*) and rapeseed crops to the existing label for Rancona 3.8 FS Fungicide (Registration number 29175) for the control of seed and seedling diseases.

### Chemistry Assessment

A chemistry assessment was not required for this application.

### Health Assessments

A toxicology assessment was not required for this application.

The addition of canola (including canola quality *Brassica juncea*) and rapeseed to the label of Rancona 3.8 FS Fungicide, for both commercial and on-farm applications, should not result in unacceptable risk when workers follow all use directions and precautions and wear personal protective equipment as presented on the label.

Previously reviewed data from radiotracer study in canola showed that the ipconazole residues in canola seeds were <5 ppb.

## Maximum Residue Limit(s)

Based on the ipconazole residues observed in canola seeds (<5 ppb) treated according to the label directions, maximum residue limits (MRLs) to cover ipconazole residues of 0.01 ppm in/on mustard seeds (oilseed types) and rapeseed (canola) commodities will be established as shown in Table 1. Residues of ipconazole in processed commodities not listed in Table 1 are covered under established MRLs for the raw agricultural commodities (RACs).

**TABLE 1. Summary of Field Trial Data (Radiotracer Study) Used to Establish Maximum Residue Limit(s) (MRLs)**

Commodity	Application Method/ Total Application Rate (g a.i./100 kg seed)	PHI (days)	Residues (ppb)		Experimental Processing Factor	Currently Established MRL	Recommend ed MRL (ppm)
			Min	Max			
Canola	Seed treatment/10	n/a	n/a	<5	n/a	None	0.01 (limit of quantitation of the enforcement method) for mustard seeds (oilseed type) and rapeseed (canola)

Following the review of data on file, an MRL of 0.01 ppm is recommended to cover residues of ipconazole in/on mustard seeds (oilseed type) and rapeseed (canola). Residues of ipconazole in the mustard seed and rapeseed (canola) commodities at the recommended MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

## Environmental Assessment

A refined risk assessment for birds and mammals was conducted during the original registration of ipconazole and related end-use products, which included appropriate mitigation label statements. The addition of a seed treatment on canola and rapeseed to the registered label does not require a new environmental risk assessment, as the application rate for these crops is lower than the highest registered rate. At this point, no further environmental data were required.

## Value Assessment

A total of 13 trials were submitted to support the claims for control of seed and seedling diseases caused by *Rhizoctonia* spp. (nine) and *Fusarium* spp. (four) on several different varieties of canola. All trials were conducted in greenhouses in Texas and Alberta in 2009.

Greenhouse trials on soil-borne *Rhizoctonia solani* demonstrated good efficacy against seed rot and damping-off on canola seedlings under extremely high disease pressure. Significant increases in plant height and biomass indicate that ipconazole will control seedling blight at the accepted rate. Root rot ratings indicate that ipconazole significantly reduced symptoms on roots. A comparison of average ratings to the inoculated control suggest the claim of suppression of root rot. A lower rate tested in the trials did not significantly increase emergence or stand counts in one trial; however, a considerable increase was observed, so this rate is also accepted to provide protection against seedling diseases incited by *R. solani*. Additional information is required to confirm this. *R. solani* was the only *Rhizoctonia* species tested in the trials; this is also the only *Rhizoctonia* species currently registered on the Rancona 3.8 FS Fungicide label. In addition, only soil inoculation was employed in the trials, so efficacy against seed-borne *Rhizoctonia solani* was not investigated. Therefore, the claim of control of seed rot, damping-off and seedling blight and suppression of root rot on canola (including canola-quality *Brassica juncea*) and rapeseed caused by soil-borne *Rhizoctonia solani* is accepted for conditional registration at 11.1 - 22.2 ml/100 kg seed (5 - 10 g a.i./100 kg seed). Additional field trials must be conducted at the accepted rates in canola and the rate currently registered for corn (5.6 ml/100 kg seed).

Although the results indicate that ipconazole is effective against the *Fusarium*, disease pressure was somewhat low in the greenhouse trials for this pest. The submitted trials are not a reliable indication of efficacy against *F. avenaceum*. In addition, only the proposed rate was tested in trials, which is four times higher than the rate currently registered for corn. More information is required to determine efficacy against this pest at lower rates. Claims of control of seed and seedling diseases (except root rot) caused by soil-borne *Fusarium* spp. are accepted for conditional registration for corn on the current Rancona 3.8 FS Fungicide label. Although the canola trials are not reliable due to low disease pressure, evidence provided for corn claims for the same *Fusarium* pests affecting canola was deemed acceptable for a conditional registration. Based on the provided evidence and conditional registration for the same pathogens on corn, the claim of control of seed rot, pre- and post-emergence damping-off and seedling blight and suppression of root rot on canola (including canola-quality *Brassica juncea*) and rapeseed caused by soil-borne *Fusarium* spp. is accepted for conditional registration at the rates of 11.1 – 22.2 ml/100 kg seed (5 – 10 g a.i./100 kg seed). Additional field trials are required to confirm that the 10 g a.i./100 kg seed rate is necessary to control seed and seedling diseases on canola caused by *Fusarium* spp. and *Rhizoctonia solani*.

No data were submitted to support the claim of control of blackleg (*Phoma lingam*) on canola. The claim was subsequently withdrawn by the applicant.

It was noted that only greenhouse trials were included in the data package for canola and rapeseed; however, trials on corn in application number 2007-2308 tested *R. solani* and several *Fusarium* species (*F. graminearum*, *F. avenaceum*) in field trials. Based on the acceptability of corn data for field uses, the claims for canola and rapeseed can be extrapolated.

## **Conclusion**

The PMRA has completed the review of all available information and is able to accept for full registration the addition of the seed treatment of canola (including canola quality *Brassica juncea*) and rapeseed for the control of seed and seedling diseases to the label of Rancona 3.8 FS Fungicide, although some of rates are accepted for conditional registration.

## **References**

- 1926989      2010, Efficacy and Seed Safety of RANCONA 3.8 FS on Canola and Rapeseed, DACO: 10.1,10.2.1,10.2.2,10.2.3,10.2.3.1,10.2.3.3,10.3.1,10.3.2

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