

Evaluation Report for Category B, Subcategory 3.11, 3.12 Application

Application Number: 2013-3988
Application: B.3.11 – Add new pests
B.3.12 - Add host
Product: Inspire Fungicide
Registration Number: 30004
Active ingredients (a.i.): Difenconazole
PMRA Document Number : 2541461

Purpose of Application

The purpose of this application was to expand the registration of Inspire Fungicide for the control of sclerotinia stem rot, alternaria black spot and blackleg in rapeseeds (Crop Subgroup 20A). Inspire Fungicide is a broad-spectrum fungicide that contains the active ingredient difenoconazole, and currently registered in Canada for the control or suppression of various fungal diseases on certain crops.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A toxicology assessment was not required for this application.

Inspire Fungicide for use on canola to control sclerotinia stem rot, alternaria black spot and virulent blackleg fits within the currently registered rate range of difenoconazole. The potential exposure for mixers, loaders, applicators and postapplication re-entry workers is not expected to exceed the current exposure to registered products provided workers follow label directions and wear the personal protective equipment as stated on the label.

Residue data from field trials conducted in Canada were submitted to support the domestic use of Inspire Fungicide on crops in Crop Subgroup 20A (Rapeseed). Difenconazole was applied to glyphosate-tolerant canola at label rates, and harvested according to label directions. In addition, a processing study in treated canola was reviewed to determine the potential for concentration of residues of difenoconazole into processed commodities.

Maximum Residue Limit(s)

The recommendation for maximum residue limits (MRLs) for difenoconazole was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of difenoconazole 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./ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			Min	Max			
Canola seed	Foliar broadcast/ 115.7-137.09	29-35	<0.01	0.081	No concentration of residues in refined oil (<1x).	0.05 [mustard seeds]; 0.03 ppm [rapeseeds (canola)]	0.1 [borage seeds, cuphea seeds, echium seeds, flaxseeds, gold of pleasure seeds, hare's ear mustard seeds, milkweed seeds, mustard seeds (condiment and oilseed types) ^a , oil radish seeds, poppy seeds, rapeseeds (canola) ^b , sesame seeds, sweet rocket seeds]

^a The MRL replaces the previously established 0.05 ppm MRL for mustard seeds.

^b The MRL replaces the previously established 0.03 ppm MRL.

No significant increase to the dietary burden of livestock is anticipated from the use of Inspire Fungicide on crops in Crop Subgroup 20A (Rapeseed).

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of difenoconazole. 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

As the ground and aerial application rate on canola is substantially less than the registered seasonal rate, the risk to aquatic and terrestrial habitats resulting from off-target spray drift would be less. Less restrictive spray buffer zones were determined for the application of Inspire Fungicide on canola based on a lower application rate.

Value Assessment

Seven field trials were reviewed to support the proposed claims for control of virulent blackleg and sclerotinia stem rot on canola. Overall, Inspire controlled both diseases when applied according to the use pattern. Inspire at 312 and 468 mL/ha reduced blackleg severity by 17 – 51% (average 36%) and 17 – 46% (average 37%) in three trials, respectively. The efficacy of Inspire was comparable to that achieved by commercial standards Quadris Flowable and Tilt 250E in the same trials, which are registered at the level of control. Since virulent blackleg is extremely difficult to manage, the levels of disease management achieved for Inspire were considered to be acceptable as control for this disease. Yield benefit from Inspire treatment was also observed in one blackleg trial.

Similar to blackleg trials, Inspire at 500 mL/ha demonstrated control of sclerotinia stem rot that is comparable to the included commercial standard Amistar 250EC (equivalent to Quadris Flowable) in two of the three trials. Inspire significantly reduced sclerotinia stem rot incidence by average 66% (41 and 91% in two trials) compared to the untreated controls. A scientific rationale was provided by the applicant to justify the use of efficacy data from France to support the claim of sclerotinia stem rot in Canada. The rationale was considered acceptable. The use of Inspire to control virulent blackleg and sclerotinia stem rot in canola (Crop Subgroup 20A) is supported according to the use pattern with a modification of use rate for sclerotinia stem rot.

The value of registering Inspire for virulent blackleg and sclerotinia stem rot is to provide Canadian growers with an additional product in the marketplace.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Inspire Fungicide, and has found the information sufficient to add the control of sclerotinia stem rot, alternaria black spot and blackleg in canola (Crop Subgroup 20A) to the product label.

References

PMRA Doc #	Reference
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2234045	2012, SYN545192 EC (A15457B), Difenoconazole EC (A7402T), Propiconazole EC (A6097AC) and Propiconazole/Azoxystrobin SU (A13705V)- Residue Levels on Canola Seed and Processed Fractions (Meal and Refined Oil) in Canada During 2011. Final Report., DACO: 7.4.1,7.4.2,7.4.5

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