

Evaluation Report for Category B, Subcategory 3.1, 3.10, 3.11, 3.12, 3.13, 3.6 Application

Application Number: 2014-0882
Application: New or Changes to Product Labels – Application Rate Increase or Decrease; Tank Mixes; New Pests; New Site or Host; Precautions; Pre-Harvest/Slaughter/With-Holding
Product: Inspire Super Fungicide
Registration Number: 30827
Active ingredients (a.i.): Difenoconazole, Cyprodinil
PMRA Document Number : 2448015

Purpose of Application

The purpose of this application was to add various disease control claims to grape, Amur river grape, gooseberry, blueberry (highbush and lowbush), currant, elderberry, huckleberry, and highbush cranberry; increasing the pre-harvest interval; increasing the application rate for difenoconazole; and several additional minor label amendments.

Chemistry Assessment

Inspire Super Fungicide is formulated as an emulsifiable concentrate containing difenoconazole at a nominal concentration of 86 g/L and cyprodinil at 249 g/L. This end-use product has a density of 1.03 g/mL and pH of 5 - 7. The chemistry requirements for Inspire Super Fungicide are complete.

Health Assessments

For cyprodinil, the addition of the use on grape, Amur river grape, gooseberry, blueberry (highbush and lowbush), currant, elderberry, huckleberry, and highbush cranberry to the Inspire Super Fungicide label is not expected to result in potential occupational or bystander exposure over the registered use. For difenoconazole, the occupational exposure and risk from the addition of the use on these crops to the Inspire Super Fungicide label was assessed. An updated health risk assessment for difenoconazole was conducted for re-entry workers. No risks of concern are expected when workers follow the label directions and wear the personal protective equipment identified on the label.

Relevant to the current application, cyprodinil is already registered on crop group (CG) 11-09 (Pome Fruits), crop subgroup (CSG) 13-07B (Bushberries), and CSG 13-07F (Small Fruit Vine Climbing, Except Fuzzy Kiwifruit).

For CG 11-09 and CSG 13-07F, no new residue data were submitted to support the amendments to the label of the end-use product Inspire Super Fungicide, but previously reviewed residue data

from field trials conducted on apples and grapes with cyprodinil were reassessed in the framework of this application. Processing studies in treated apples and grapes were also reassessed.

For CG 13-07B, new cyprodinil residue data from blueberry field trials conducted in Canada and in the United States were submitted. An oil-in-water emulsion (EW) formulation of cyprodinil was applied to highbush and lowbush blueberries at the label rate, and fruits were harvested according to label directions. In addition, previously reviewed residue data from field trials conducted on blueberries with cyprodinil were reassessed in the framework of the current petition. As no processed commodities are listed in DIR98-02 for CSG 13-07B, processing data were not required.

No increase in the dietary exposure to cyprodinil is expected from the amendments to the registration of Inspire Super Fungicide and the resulting residues of cyprodinil are covered under the following established maximum residue limits (MRLs) or in the process of promulgation:

- 1.7 ppm in/on commodities of CG 11-09 (Pome Fruits);
- 4.0 ppm in/on commodities of CSG 13-07B (Bushberries, including highbush blueberries and gooseberries);
- 6.0 ppm in/on commodities of CSG 13-07G (Low Growing Berries, including lowbush blueberries and lingonberries);
- 2.0 ppm in/on commodities of CSG 13-07F (Small Fruit Vine Climbing, Except Fuzzy Kiwifruit); and
- 3.0 ppm in/on raisins.

Residues of cyprodinil will not pose an unacceptable health risk to any segment of the population, including infants, children, adults, and seniors.

Relevant to the current application, **difenoconazole** is already registered on CG 11-09 (Pome Fruits) and grapes, but not any other commodities of CSG 13-07F (Small Fruit Vine Climbing, Except Fuzzy Kiwifruit), nor on any commodities of CSG 13-07B (Bushberries).

For CG 11-09 and CSG 13-07F, no new residue data were submitted to support the amendments to the label of the end-use product Inspire Super Fungicide, but previously reviewed residue data from field trials conducted on apples and grapes with difenoconazole were reassessed in the framework of this application. Processing studies in treated apples and grapes were also reassessed.

For CG 13-07B, new difenoconazole residue data from blueberry field trials conducted in Canada and in the United States were submitted. Two formulations of difenoconazole (emulsifiable concentrate (EC) and oil-in-water emulsion (EW)) were applied side-by-side to highbush and lowbush blueberries at the label rate, and fruits were harvested according to label directions. No previously reviewed residue data were on file for difenoconazole on CG 13-07B, and as stated above, given that no processed commodities are listed in DIR98-02 for CSG 13-07B, processing data were not required.

Maximum Residue Limit(s)

For **difenoconazole**, the recommendation for MRLs 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 summarizes the residue data used to calculate the proposed MRLs.

TABLE 1. Summary of Field Trial and Processing Data Used to Support Difenoconazole (DFZ) MRLs								
Commodity (Sub. No.)	Application Method/ Total Appl. Rate (g a.i./ha)	PHI (days)	DFZ Residues (ppm)		Exp. Processing Factor	Currently Established MRL (ppm)	MRL under Promulgation (ppm)	Recommended MRL (ppm)
			Min	Max				
Apples	Broadcast foliar/ 384 - 385	14	0.02	0.59	Apple juice: <0.4X	1.0 (CG 11-09) ¹	5.0 (CG 11-09) ¹	None
Pears	Broadcast foliar/ 385	14	0.01	0.30				
Grapes	Broadcast Foliar/ 520	7	0.08 0	1.8	Juice: 0.24X Raisins: 3.5X	4.0 (grapes) 6.0 (raisins)	4.0 (CSG 13-07F) ²	None
Highbush blueberries	Broadcast foliar/ 484 - 544	1	0.18	1.7	n/a ³	None	None	4.0 (CSG 13-07B, except gooseberries ²)
Lowbush blueberries	Broadcast foliar/ 500 - 515	1	0.99	1.9	n/a ³	None	2.5 (CG 13-07G) ⁴	

¹ The currently established MRL of 1.0 ppm for CG 11-09 is based on broadcast foliar applications and a PHI of 14 days (data presented herein). The MRL of 5.0 ppm in the process of being promulgated is based on postharvest use (data not presented).

² Gooseberries are included in CSG 13-07F and will remain covered under the MRL of 4.0 ppm for that crop subgroup given that the MRL proposed for CSG 13-07B as a result of the current application is equivalent.

³ As per DIR98-02 (Section 8, Appendix A, Table 1), there are no processed commodities listed for blueberries.

⁴ As a result of the current application, the MRL for lowbush blueberries and lingonberries,

currently established at 2.5 ppm under CSG 13-07G, will be replaced by the proposed MRL of 4.0 ppm for CSG 13-07B.

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

The other amendments to the registration of the end-use product Inspire Super Fungicide are also acceptable from a dietary exposure perspective.

Environmental Assessment

The amendment of Inspire Super Fungicide will not result in increased environmental exposure relative to the existing registered products Inspire Fungicide (Reg. No. 30004) and Vanguard 75WG (Reg. No. 25509). Potential risks to the environment have been mitigated through precautionary statements and required buffer zones on the product label.

Value Assessment

A total of 20 trials conducted in Canada, the US and the EU were reviewed to support the claims. Scientific rationales were also reviewed to support the extrapolation of certain claims from trials conducted on other crops or from registered claims on another product label.

All of the amendments were supported; however, some claims were not supported on all of the crops in the respective crop groups due to host specificity of the tested pathogens. The use patterns for three claims were amended based on the tested use pattern or current registrations for the same use.

Several of the diseases were identified as intermediate or high priorities on the Canadian Grower Priority Database. The value of cyprodinil in combination with difenoconazole in this pre-mix product was demonstrated for two diseases; grey mould and monilinia blight/mummyberry. Inspire Super Fungicide applications may target multiple diseases since these two diseases can infect crops throughout the growing season. The product may also facilitate resistance management with respect to management of monilinia blight/mummyberry or as a rotational product for the other diseases. Additional guidance was added to the label regarding the maximum number of seasonal applications of Group 9 fungicides recommended for control of *Botrytis cinerea*.

Conclusion

The PMRA has completed an assessment of the information provided and is able to support the amendments to Inspire Super Fungicide.

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