

Evaluation Report for Category B, Subcategory B.2.1, B.2.3, B.2.4, B.2.6, B.3.6, B.3.11, B.3.12 Application

Application Number: 2012-0168
Application: New combination of technical grade active ingredients.
Product: Inspire Super Fungicide
Registration Number: 30827
Active ingredients (a.i.): Cyprodinil and Difenoconazole
PMRA Document Number: 2214346

Background

The purpose of this application was to register the fungicide end-use product, Inspire Super Fungicide, for control of scab, brooks fruit spot, cedar-apple rust, quince rust, flyspeck and sooty blotch as well as for suppression of powdery mildew on pome fruit.

Inspire Super Fungicide is a liquid pre-mix formulation containing Difenoconazole Technical (Registration number 25631) and Cyprodinil Technical (Registration number 25508).

The active ingredient difenoconazole is registered for foliar use on pome fruits in Inspire Fungicide (Registration number 30004). The active ingredient cyprodinil is registered for use on apples in Vanguard 75WG (Registration number 25509).

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 6.4. The chemistry requirements for Inspire Super Fungicide are complete.

Health Assessments

Inspire Super Fungicide is of low toxicity to rats via the oral ($LD_{50} = 5000$ mg/kg bw), dermal ($LD_{50} > 5000$ mg/kg bw) and inhalation routes ($LC_{50} > 2.53$ mg/L). It is minimally irritating to the eye and slightly irritating to the skin of rabbits. It is not a dermal sensitizer in guinea pigs.

A health risk assessment was conducted for chemical handlers, postapplication workers and bystanders for the new end-use product, Inspire Super Fungicide. No risks of concern are expected when the label directions are followed and when workers wear the personal protective equipment identified on the approved label.

A new analytical method for the determination of cyprodinil residues in plant commodities and

residue data from field trials for difenoconazole and cyprodinil in apples were submitted to support the registration of Inspire Super Fungicide. Previously reviewed residue data from field trials conducted on apples and pears with either difenoconazole or cyprodinil were reassessed in the framework of this petition. Difenoconazole and cyprodinil are currently registered for use on pome fruits (Crop Group 11-09) with the same use pattern as the one on the Inspire Super Fungicide label. Consequently, no increase in dietary exposure is anticipated. Residues of difenoconazole at the established MRL of 1.0 ppm and residues of cyprodinil at the proposed MRL of 1.7 ppm (in the process of promulgation) in/on pome fruits (Crop Group 11-09) will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The formulated mixture Inspires Super Fungicide and its use rate will not result in increased environmental exposure relative to the existing registered products, Inspire Fungicide and Vanguard 75WG. Inspires Super Fungicide is not expected to pose a risk to the environment, and environmental concerns are mitigated through adequate statements on the product label.

Value Assessment

A total of 12 trials on apple and pear were provided in support of the scab claim. The label rates of difenoconazole and cyprodinil, whether tested in Inspire Super Fungicide, Inspire Fungicide (250 g/L difenoconazole), Vanguard 75WG (75% cyprodinil) or in a corresponding tank-mix, consistently controlled apple and pear scab under moderate to high disease pressure. In three apple trials, Inspire Super Fungicide suppressed powdery mildew incidence and severity on leaves by an average of 48% and 61%, respectively. In the data package, levels of protection from Inspire Super Fungicide applications were comparable to that achieved with the commercial standards. Based on similarities in crop biology among pome fruit, efficacy results may be extrapolated from apple and pear to the crop group. No trials were provided for the remaining claims, as the rate for control of brooks fruit spot, cedar-apple rust, quince rust, flyspeck and sooty blotch contains the same amount of difenoconazole as the registered rate for Inspire Fungicide. The claims were supported.

For apple scab management, recommendations from the Fungicide Resistance Action Committee (FRAC) limit the maximum number of applications per season to four. The use directions for Inspire Super Fungicide allowed five to seven applications in a season, which exceeds the FRAC recommendation. Therefore, the label use directions were amended to restrict the maximum number of applications per season when scab is present in the orchard.

Conclusion

Following review of the available information, the registration of Inspire Super Fungicide for control of scab, brooks fruit spot, cedar-apple rust, quince rust, flyspeck and sooty blotch as well as for suppression of powdery mildew on pome fruit was approved.

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