Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2007-6352
Application: B.3.12 Changes to Product Labels - New Site or Host
Product: Dynasty 100FS Fungicide
Registration Number: 28394
Active ingredients (a.i.): Azoxystrobin
PMRA Document Number: 1559578

Purpose of Application

Syngenta Crop Protection Canada has submitted an application to add canola to the Dynasty 100FS Fungicide label and to include Helix Xtra, containing the insecticide, thiamethoxam and the fungicides, metalaxyl-m, fludioxonil and difenoconazole, as a tank-mix partner for the seed treatment of canola.

Chemistry Assessment

A chemistry assessment was not required as the current application did not involve a change in the product chemistry.

Health Assessments

A toxicology assessment was not required for this application as the products is currently registered.

A risk assessment was conducted for handlers treating canola seeds at commercial facilities and for farmers and custom applicators planting treated seeds. All exposure estimates have margins of exposure (MOEs) that exceed the target and are considered acceptable when workers follow label directions and wear the personal protective equipment identified on the label.

Residue data for seed treatment of canola were not submitted to support the use expansion of the Dynasty 100FS Fungicide label. Previously reviewed residue data from field trials conducted for seed treated corn and soybeans were reassessed in the framework of this petition. In addition, field trial data for foliar treatment of corn, soybeans, and canola were reassessed. A processing study in treated canola was also reassessed to determine the potential for concentration of residues of azoxystrobin into processed commodities.

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As a result of this review, residues are not expected in mature canola and its processed fractions from the proposed treatment of canola seed. Furthermore, an increase in dietary exposure is not anticipated to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The rate of Dynasty 100FS Fungicide used as a seed treatment to control fungal diseases in canola is greater than the registered use rate as a seed treatment in corn on a per-hectare basis but will still release very little azoxystrobin compared to the foliar uses in the many registered crops and turf. The use in canola is also a large increase in the maximum possible dietary exposure for birds and small mammals. A conservative, screening-level risk assessment found some cause for concern if small and medium mammals are allowed free access to treated seed over the long term and if the diet over the long term is composed primarily of treated seed. This is highly unlikely to occur in planted fields, so the risk to wildlife can be mitigated by cleaning up spills of treated seed. Canola seed is not generally considered to be an attractive food source for wildlife, which further reduces the environmental risk for this use. Precautionary statements regarding the possible hazard to mammals and the need to clean up spilled seeds are being added to the label.

Value Assessment

Four efficacy trials were reviewed; two field trials and two growth room trials conducted in Manitoba and Ontario in 2006. The two field trials were inconclusive as disease pressure was extremely high, but some control was observed in plots treated with Dynasty 100FS Fungicide that was comparable to the commercial standard tested. Results from the two growth room trials indicated acceptable control with Dynasty 100FS Fungicide treated seed under moderate to high disease pressure that exceeded the performance of the commercial standard tested. The tank-mix with Helix Xtra Seed Treatment, which contains the insecticide thiamethoxam and the fungicides metalaxyl-m, fludioxonil and difenconazole, provided better levels of disease control compared to the inoculated check, both in natural and controlled environment conditions. The submitted efficacy data supports the claims of control of seed decay, pre- and post-emergence damping-off, and seedling blight on canola. *Rhizoctonia solani* was the only pathogen tested, so the claims are supported for this pathogen only.

The four trials from Ontario and Manitoba demonstrated that a tank mix of Dynasty 100FS Fungicide and Helix XTra Seed Treatment at the registered application rates did not have any adverse effects on canola plant emergence, fresh weight and yield and no phytotoxic effects of the tank mix were observed. Other insecticides containing the active ingredient thiamethoxam are registered for tank mixing with the fungicide active azoxystrobin on corn, dry beans and potatoes for control of a range of insect pests including flea beetles. Considering the results from the submitted trials and the currently registered use patterns of the actives in the tank mix, it is expected that a tank mix with Dynasty 100FS Fungicide will not negatively affect the efficacy of Helix Xtra Seed Treatment to control flea beetles on canola. Since Helix Xtra and Dynasty 100FS Fungicide are each individually registered for use on canola for control of the listed pests and diseases, the claim to add the tank mix to the Dynasty 100FS Fungicide label can be supported.

Conclusion

The PMRA has completed an assessment of this application and has found the information to be sufficient to amend the registration to add canola to the Dynasty 100FS Fungicide label and to include Helix Xtra as a tank-mix partner for the seed treatment of canola.

References

PMRA# 1467350. Efficacy Summary Tables. Syngenta Crop Protection Canada Inc., DACO 10.2.3.1.

PMRA# 1467351. Dynasty 100FS Fungicide Efficacy Summary. Syngenta Crop Protection Canada Inc., DACO 10.1, 10.2.2, 10.2.3.1, 10.3.1, 10.3.2.

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