



Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2013-3372
Application: Product label - new site or host
Product: Phostrol Fungicide
Registration Number: 30449
Active ingredients (a.i.): mono- & dibasic sodium, potassium and ammonium phosphites
PMRA Document Number: 2344279

Purpose of Application

The purpose of this application was to add the claims of control of flyspeck (*Schizothyrium pomi*) and sooty blotch (*Gloeodes pomigena*) on the Pome Fruit crop group and to extrapolate the claim of suppression of downy mildew (*Peronospora parasitica*) on Head and Stem Brassica crops (Crop Group 5A) to the entire Brassica Leafy Vegetables crop group (Crop Group 5) to the Phostrol Fungicide label.

Chemistry and Environmental Assessment

Chemistry and environmental assessments were not required for this application.

Health Assessments

Phostrol Fungicide is of low acute oral toxicity in rats ($LD_{50} > 5000$ mg/kg bw), low acute dermal toxicity in rats ($LD_{50} > 5000$ mg/kg bw), and low acute inhalation toxicity in rats ($LC_{50} > 2.06$ mg/L). Phostrol Fungicide is mildly irritating to the skin, minimally irritating to the eyes, and is not a dermal sensitizer.

The label statements for Phostrol Fungicide, coupled with the end-use product's low toxicity, is considered adequate to address any potential risk due to exposure of the mixer, loader, applicator, and bystanders.

Dietary risk to humans is considered negligible based on the intended use, long history of use, and low toxicity of the end-use product. The available literature suggests that there is no toxicological concern from ingestion of the end-use product residues.

It is anticipated that the use of Phostrol Fungicide in Canada on food crops will not pose a risk to any segment of the population, including infants, children, adults and seniors, when the foods are subjected to the normal process of washing, peeling and cooking for human consumption.

Although this end-use product will be used for agricultural crops outdoors, it is not to be applied near or directly to water. No risk due to exposure from drinking water is anticipated.

Maximum Residue Limit

Based on the available information, requirement of a maximum residue limit for the uses on brassica and pome fruit crops is not necessary for mono- and dibasic sodium, potassium, and ammonium phosphites.

Incident Reports

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on Health Canada's website. Incidents from Canada and the United States were searched and reviewed for active mono- and dibasic sodium, potassium, and ammonium phosphite. As of August 30, 2013, there have been no human and domestic animal incident reports for products containing mono- and dibasic sodium, potassium, and ammonium phosphite in Canada or the United States.

Value Assessment

One trial conducted in New York in 2006 was submitted to support the claims of control of flyspeck and sooty blotch. Flyspeck incidence was reduced by 99% and by 95% on apple fruit in the Phostrol Fungicide treatment. The level of control was statistically comparable to or significantly better than the commercial standards on Ginger Gold apples. Significantly greater control was observed on Golden Delicious apples compared to both standards. All treatments resulted in significantly less disease incidence compared to the control treatment.

Phostrol Fungicide and three commercial standards all completely controlled sooty blotch incidence on Ginger Gold fruit (100% control). Phostrol Fungicide also completely controlled disease incidence on Golden Delicious fruit (100% control). The results were statistically comparable to or significantly better than the commercial standards. All treatments resulted in significantly less disease incidence compared to the control treatment.

Very high levels of control of both flyspeck and sooty blotch incidence and severity were observed on two different cultivars of apples as a result of treatment with Phostrol Fungicide applied three or six times at the proposed rate at 9 – 21 day intervals. The submitted value information was sufficient to support the proposed claims on apple. The data were extrapolated to other crops in the Pome Fruit crop group based on known or assumed susceptibility to the pathogens established through the relationships between the crops.

A scientific rationale was submitted to support extrapolation of the current registration on Brassica Head and Stem Vegetables to the entire Brassica Leafy Vegetables crop group. The applicant did not propose changing the use pattern registered on other Brassica crops, including rates, application intervals, spray volume and number of seasonal applications. The extrapolation was supported based on similarities between the crops and their production practices and the progression of downy mildew on the crops.

Phostrol Fungicide is an effective non-conventional fungicide active against the proposed

diseases and is easily integrated into a pest management program. Short re-entry and pre-harvest intervals make it a desirable product for U-pick operations and late season disease control. This registration will satisfy disease priorities identified by growers for Pome Fruit and Brassica Leafy Vegetables on the Canadian Grower Priority Database.

Conclusion

The PMRA has completed an assessment of the available information and is able to support the addition of the proposed claims on the Pome Fruit crop group and to extrapolate the proposed claim on Head and Stem Brassica crops (Crop Group 5A) to the entire Brassica Leafy Vegetables crop group (Crop Group 5) on the label of Phostrol Fungicide.

References

- 1875158 2010, Use Description and Scenario (Mixer/Loader/Applicator and Post-application) for Phostrol Fungicide. DACO: 5.2
- 2340746 2013, Use Description and Scenario (Mixer/Loader/Applicator and Post-application) for Phostrol Fungicide. DACO: 5.2
- 2318328 2013, Value Summary for Phostrol Fungicide Label Expansion for Control of Fly Speck and Sooty Blotch in Apples and Downy Mildew in Brassica Vegetables, DACO: 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3, 10.2.3.1, 10.2.3.2, 10.2.3.3, 10.3, 10.3.1, 10.3.2(B), 10.3.3,10.4,10.5,10.5.1,10.5.2,10.5.3,10.5.4

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