

Evaluation Report for Category B, Subcategory 3.11 & 3.12 Application

Application Number: 2007-0264
Application: B.3.11 - New Pests
B.3.12 - New Host
Product: Pristine WG Fungicide
Registration Number: 27985
Active ingredients (a.i.): Boscalid and Pyraclostrobin
PMRA Document Number: 1783726

Background

Pristine WG Fungicide contains Boscalid (25.2%) and Pyraclostrobin (12.8%) as the active ingredients and has had a conditional registration since March 08, 2005. There are no outstanding data requirements for the Pristine WG Fungicide. However, full registration of this product is contingent upon the fulfilment of outstanding data gaps for Boscalid Technical Fungicide (Reg. No. 27494) and Pyraclostrobin Technical Fungicide (Reg. No. 27321). Pristine WG Fungicide is a broad spectrum fungicide for use in the berry group, bulb vegetables group, carrots, stone fruits group and strawberries. For specific details of uses, application rates and methods, precautions, restrictions, and personal protective equipment requirements, refer to the product label.

Purpose of Application

The purpose of this application is to add grapes and associated pests to the Pristine WG Fungicide label. The following pests on grapes are proposed for control or suppression at the rates indicated: for control of powdery mildew (*Uncinula necator*), bunch rot complex (*Cladosporium* spp., *Aspergillus* spp.), and for suppression of Botrytis grey mould (*Botrytis cinerea*) at 0.420-0.735 kg/ha, for control of foliar and fruit downy mildew (*Plasmopara viticola*) at 0.675-0.735 kg/ha, and for control of black rot (*Guignardia bidwellii*) on fruit only at 0.735 kg/ha.

Chemistry Assessment

A chemistry assessment was not required as there was no change to the product chemistry.

Health Assessments

A toxicological assessment was not required as there was no change to the product chemistry..

A risk assessment was conducted for workers mixing/loading and applying Pristine WG Fungicide to grapes and for workers entering treated vineyards. Margins of exposure (MOE) are above the targets for both pyraclostrobin and boscalid exposure to workers mixing/loading and applying Pristine WG Fungicide to grapes. A restricted entry interval (REI) of 21 days is required for hand harvesting, training, thinning, hand pruning and tying in order to reach the target MOE for pyraclostrobin and boscalid.

Based on the risk assessment, an REI of greater than 35 days would be required for girdling and cane turning in grapes. This REI is not considered to be agronomically feasible. Since girdling and cane turning are only conducted in table grapes, Pristine WG Fungicide is accepted for use on wine and juice grapes but not on table grapes.

The food residue chemistry data for pyraclostrobin and boscalid were re-assessed in the context of the current application for the addition of grapes to the Pristine WG Fungicide label. Residues of pyraclostrobin and the metabolite BF 500-3 in or on treated grape and commodities processed from grapes treated according to the use directions on the Pristine WG Fungicide label are not expected to exceed the maximum residue limits (MRLs) of 2.0 ppm and 7.0 ppm previously established for imported grapes and raisins, respectively (EMRL2008-02). Similarly, residues of boscalid in or on treated grapes and commodities processed from grapes treated according to the use directions on the Pristine WG Fungicide label are not expected to exceed the MRLs of 3.5 ppm and 8.5 ppm previously established for domestic grapes and raisins, respectively (EMRL2008-02). Accordingly, exposure to residues of pyraclostrobin and boscalid should not increase for any population subgroup.

Environmental Assessment

No environmental studies were required to support the registration of Pristine WG Fungicide on grapes. The rate and method of application for use on grapes is within the registered rates and method of application of this product. Thus, no increased risk to the environment is expected from the use of Pristine WG Fungicide on grapes at the accepted rates. Previously, the Pristine WG Fungicide label did not contain buffer zones for airblast application, even though use on crop groups amenable to this application method (e.g. stone fruits and berries) was registered. To adequately mitigate the risk to terrestrial and aquatic habitats from the use of Pristine WG Fungicide, the terrestrial and aquatic buffer zones for all field sprayer and airblast application uses were updated to current standards.

Value Assessment

An application for the claim for control of grape diseases was submitted previously (2004-4219) along with other crops including stone fruits, bulb vegetables, and strawberries. The application rates for grapes ranged from 0.42 kg - 1.6 kg product/ha with the higher rates being applied for the control of Botrytis grey mould and fruit downy mildew. All claims were accepted, however, the application was not supported due to the REI concerns. The applicant has submitted this application to modify the claim for Botrytis grey mould from control to suppression and to reduce the application rate for fruit downy mildew in order to satisfy REI requirements.

Insufficient data was submitted to support the fruit downy mildew claim and the applicant chose to withdraw this claim. The claims for control of powdery mildew, bunch rot complex, foliar downy mildew, black rot (on fruit only) and suppression of Botrytis grey mould are accepted.

Conclusion

The PMRA has completed an evaluation of the subject application and has found the information sufficient to amend the registration of Pristine WG Fungicide to include grapes with an REI of 21 days for specific re-entry activities. Based on the risk assessment, Pristine WG Fungicide can not be used on table grapes. As well, pest claim for control of fruit downy mildew (*Plasmopara viticola*) is not supported. Appropriate label statements will be required to mitigate health and environmental concerns.

References

A. List of Studies/Information Submitted by Registrant

Health Assessment

PMRA No.	Reference
742196	2003, 14C-BAS 500 F - Study of the Dermal Absorption in Rats, DACO: 5.8
1010637	2001, 14C-BAS 510 F - Study of the Dermal Absorption in Rats, DACO: 5.8
1082761	1999, BAS 500 00 F Dislodgeable Foliar Residue Study in Grapes, DACO: 5.9
1010639	2001, BAS 510 UCF Dislodgeable Foliar Residue Study in Grapes, DACO: 5.9

Value Assessment

PMRA No.	Reference
961600	2004, Pristine WG Fungicide (Boscalid:Pyraclostrobin) - Petition for Application in Bulb Vegetables, Carrots, Grapes, Stonefruit, Strawberries and Berry Crops, DACO: 10.1,10.2,10.3,10.4,10.5
961604	2004, Trial Abstracts Grapes, DACO: 10.2.3.3

B. Additional Information Considered

I) Published Information

Health Canada, Pest Management Regulatory Agency. 2008. EMRL2008-02: Transitioning the Legal Establishment of Maximum Residue Limits (MRLs) for Pesticides From the Food and Drugs Act to the Pest Control Products Act: Establishment of MRLs

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