

## Evaluation Report for Category B, Subcategory 3.11 & 3.12 Application

**Application Number:** 2007-0258  
**Application:** 3.11 - New Pests  
3.12 - New Host  
**Product:** Pristine WG Fungicide  
**Registration Number:** 27985  
**Active ingredients (a.i.):** Boscalid and Pyraclostrobin  
**PMRA Document Number :** 1783724

### 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 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

BASF Canada has submitted an application to amend the Pristine WG Fungicide label to include pome fruits and its associated pests. Pristine WG Fungicide is to be applied at 1-1.2 kg product/ha to control apple scab, pear scab & powdery mildew, and at 0.6-0.8 kg/ha to control flyspeck, sooty blotch and brooks blotch. Currently, Pristine WG Fungicide is registered (conditionally) for control of certain diseases on berry group, bulb vegetables group, carrots, stone fruits group and strawberries.

### 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 pome fruits and entering treated orchards. Exposure to workers mixing/loading and applying Pristine WG Fungicides to pome fruits does not pose health concerns when Pristine WG Fungicide is used according to the directions on the label. A restricted entry interval of 12 days is required for hand thinning in pome fruits and 5 days for hand harvesting. Exposure to adults and children at pick-your-own facilities is not of concern.

The food residue chemistry data for pyraclostrobin and boscalid were re-assessed in the context of the current application for the addition of pome fruits to the Pristine WG Fungicide label. Residues of pyraclostrobin and the metabolite BF 500-3 in or on treated pome fruits and commodities processed from apples treated according to the use directions on the Pristine label are not expected to exceed the maximum residue limit (MRL) of 1.5 ppm previously established for imported pome fruits (EMRL2009-01). Similarly, residues of boscalid in or on treated pome fruits and in or on commodities processed from apples treated according to the use directions on the Pristine label are not expected to exceed the MRL of 3.0 ppm proposed for imported pome fruits. Therefore, 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 pome fruit. The rate and method of application for use on pome fruit 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 pome fruit at the accepted rate. 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**

Twelve field trials were conducted from 2001-2004. Of these 12 trials, 2 were conducted in Canada (ON), and 10 were conducted in the US (NY, WN, BA, OR, MA, NC and VA). All trials were conducted in apple orchards and rationales were provided to bridge some diseases to pears. Results of review demonstrated that different formulations of Pristine WG applied at the accepted rate provided control of apple scab, pear scab, powdery mildew, flyspeck mildew, sooty blotch and brooks spot. Based on the submitted data, the label claims for Pristine WG is supported. Since scab, powdery, sooty blotch, flyspeck and brooks spot can also occur on other crops belonging to the pome fruit Crop Grouping (apple, crabapple, pear, oriental pear and quince), all claims supported in this application can be extended to the entire pome fruit Crop Group.

## 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 the pome fruit Crop Group. 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
1082759	2000, BAS 500 DIF (BAS 500 02F) Dislodgeable Foliar Residue Study in Peaches, DACO: 5.9
1010641	2001, BAS 510 UCF Dislodgeable Foliar Residue Study in Peaches, DACO: 5.9

#### Value Assessment

PMRA No.	Reference
1366076	2007, Pristine WG Fungicide (BAS 516F boscalid:pyraclostrobin) Pomefruit, DACO: 10.1,10.2,10.2.1,10.2.2,10.2.3,10.2.3.1,10.2.3.3(D),10.3,10.3.1,10.3.2
1366079	2006, PART 10 Excel summary tables, DACO: 10.2.3.4(C),10.3.2(B)

### B. Additional Information Considered

#### i) Published Information

Health Canada, Pest Management Regulatory Agency. 2009. EMRL2009-01: Pyraclostrobin

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