

Evaluation Report for Category B, Subcategory 3.6, 3.8 Application

Application Number: 2011-6061
Application: Changes to Product Labels - Pre-Harvest Interval and Re-entry Interval
Product: Vanguard 75WG Fungicide Agricultural
Registration Number: 25509
Active ingredients (a.i.): Cyprodinil
PMRA Document Number: 2175061

Purpose of Application

The purpose of the application was to amend the pre-harvest interval (PHI) on pome fruit from 72 days to 0 days and the restricted entry interval (REI) from 72 hours to 12 hours for apple orchards on the Vanguard 75WG Fungicide Agricultural label.

Chemistry, Environmental and Value Assessment

Chemistry assessment was not required for this application as there were no changes to the product chemistry. The requested amendments would not change the environmental and value assessments, thus these were not required.

Health Assessments

A health risk assessment was conducted for chemical handlers and postapplication workers for the amended use of Vanguard 75WG Fungicide Agricultural on apples. No risks of concern are expected when workers follow the label directions and wear the personal protective equipment identified on the label.

Residue data for cyprodinil in apples and pears were submitted to support the amendment of the preharvest interval for apples on the Vanguard 75 WG Fungicide Agricultural label. In addition, an apple processing study was reassessed to determine the potential for concentration of cyprodinil into processed commodities.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for cyprodinil was based upon the residues observed in crop commodities treated according to exaggerated rates from submitted field trials, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of cyprodinil in/on crops and processed commodities are proposed in Table 1. Residues in processed commodities not listed in Table 1 are covered under the recommended MRLs for the raw agricultural commodities (RACs).

Table 1. Summary of Field Trial and Processing Data Used to Establish Maximum

Residue Limits (MRLs)

Commodity	Application Method/ Total Application Rate (kg a.i./ha)	PHI (days)	Residues* (ppm)		Experimental Processing Factor	Currently Established MRL	Recommended MRL
			Min	Max			
Apple	Foliar broadcast spray application/ 1.4	0	0.17	1.4	Not applicable	0.1 (Pome fruit)	1.7 ^a All crops in Crop Group 11-09 (Pome Fruits)
Pear	Foliar broadcast spray application/ 1.4	0	0.11	0.73	Not applicable		

^aIt is recommended that the established MRL of 0.1 ppm for cyprodinil in/on pome fruit be replaced with 1.7 ppm to accommodate a reduction in the preharvest interval, and be extended to all commodities in the revised Crop Group 11-09 (Pome Fruits Group).

Based on the dietary burden and residue data, an MRL of 0.02 ppm in each of the fat, meat and meat byproducts of cattle, goats, hogs, horses and sheep, and milk to cover the combined residues of cyprodinil and the metabolite CGA-304075 are also proposed.

Conclusion

The PMRA has conducted a review of the available information and has determined that the PHI and REI can be amended on the Vanguard 75WG Fungicide Agricultural label. New MRLs were proposed to cover residues of cyprodinil. Residues of cyprodinil in these crop/livestock commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

References

PMRA No.	Reference
1672205	2006, Method Development for Analysis of CGA-304075 (metabolite of Cyprodinil) and Related Metabolites from a Lactating Goat, DACO: 7.2.1,7.2.2
1672206	2006, Cyprodinil Validation of Analytical Method GRM010.01A for the Determination of Residues of Cyprodinil and its Metabolite CGA304075 in Ruminant Livestock Commodities, DACO: 7.2.1,7.2.2
1672207	2006, Independent Laboratory Validation Analytical Method for the Determination of Residues of Cyprodinil and its Metabolite, CGA-304075 in Dairy Livestock Commodities, DACO: 7.2.1,7.2.2
1672209	2006, Cyprodinil Stability of CGA304075 in Animal Tissues and Milk under Freezer Storage Conditions, Final Report, DACO: 7.3
1672246	2006, Cyprodinil: Cyprodinil magnitude of the Residue including CGA304075, in Meat and Milk Resulting from the Feeding of Three Levels to Dairy Cattle, Final Report, DACO: 7.5.1
2140856	2010, Cyprodinil - Magnitude of the Residues in or on Apple and Pear as Representative Commodities of Fruit, Pome, Group II, DACO: 7.3,7.4.1,7.4.2,7.4.5
2115788	2008, Agricultural Reentry Task Force (ARTF). Data Submitted by the ARTF to Support Revision of Agricultural Transfer Coefficients.

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