

Evaluation Report for Category B, Subcategory 3.11, 3.12 Application

Application Number: 2014-2031
Application: New or changes to product labels – new pests, new site or host
Product: Gavel 75DF
Registration Number: 26842
Active ingredients (a.i.): Mancozeb and Zoxamide
PMRA Document Number : 2551576

Purpose of Application

The purpose of this submission was to add the claims of control of downy mildew and neck rot in bulb onions to the Gavel 75DF label.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

No new food residue chemistry data for mancozeb were submitted to support the foliar ground use of Gavel 75 DF on bulb onions. Several registered products containing mancozeb are currently registered for foliar use on bulb onions at a maximum rate of 2.6 kg a.i./ha/application with a 10-day preharvest interval (PHI), or at a maximum seasonal total rate of 4.8 kg a.i./ha with a 7-day PHI. The use pattern of Gavel 75DF on bulb onions of a maximum rate of 12 kg a.i./ha with a 7-day PHI does not fall within the currently registered use patterns of mancozeb on this crop. As such, the 7-day PHI with Gavel 75 DF for use on bulb onions was revised to 10 days. Based on this assessment, and contingent upon the required revision of the PHI from 7 to 10 days, the dietary exposure to mancozeb is not expected to increase and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Residue data for zoxamide from field trials conducted in Canada and the United States were submitted to support the domestic use of Gavel 75 DF on bulb onions. Zoxamide was applied to bulb onions and harvested according to label directions.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for zoxamide was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of zoxamide including the metabolites RH-1452 and RH-1455 in/on commodities of Crop Subgroup 3-07A are proposed as shown in Table 1.

Commodity	Application Method/ Total Application Rate (kg a.i./ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAF T	HAF T			
Bulb Onion – dry bulb	Foliar, ground/1.48-1.51	6-7	<0.063	<0.475	Not applicable	None	0.7 (for all Commodities in CSG3-07A)

LAF T = Lowest Average Field Trial; HAF T = Highest Average Field Trial

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of zoxamide. Residues in these crop commodities at the proposed MRLs will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

The exposure from the use of Gavel 75DF for the control of Downy mildew (*Peronospora destructor*) and neck rot (*Botrytis allii*) on bulb onions is not expected to increase over the current registered use of zoxamide and mancozeb. No health risks of concern were identified or are expected when workers follow the label directions and wear the personal protective equipment stated on the label.

Environmental Assessment

An environmental assessment was not required for this application.

Value Assessment

Value information was submitted in the form of efficacy trials. A total of four efficacy trials (three on downy mildew and one on neck rot) were reviewed to support the claims. Based on the value information, a claim of suppression of downy mildew (*Peronospora destructor*) and control of neck rot (*Botrytis allii*) in onions (dry bulb) is supported.

The Canadian growers have identified downy mildew and neck rot as priority diseases that require effective fungicide management. The expansion of the Gavel 75DF label to include a claim of suppression of downy mildew and control of neck rot in bulb onions will provide an alternative product with different modes of action to be used in rotation with other products.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Gavel 75DF, and has found the information sufficient to add the claim of suppression of downy mildew and control of neck rot in bulb onions to the label.

References

PMRA Document Number	Reference
2432278	2012, ONI 1201 : Gavel 75 DF for control of Downy Mildew compared to Industry Standard (Revus), DACO: 10.2.3.3
2432280	2013, CLV-13-12- Downey Mildew Control in Onion, DACO: 10.2.3.3
2432281	2014, Efficacy Summaries, DACO: 10.2.3.1
2479475	2014, Additional Value Information Summary, DACO: 10.2.3.1
2479476	2009, ONION DOWNY MILDEW/EFFICACY, DACO: 10.2.3.3(B)
2479477	2010, Foliar Disease Control in Onions with Gavel, DACO: 10.2.3.3(B)
2542666	2014, Onion Botrytis Trial, DACO: 10.2.3.3
2432277	2013, Magnitude of the Residue of Zoxamide and its Metabolites in or on Dry Bulb Onion Raw Agricultural Commodities Following Eight Foliar Applications of Gavel 75DF Fungicide – 2011; 397 pgs., DACO: 7.4.1, 7.4.2

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