

## Evaluation Report for Category B, Subcategory 3.1, 3.11, 3.12 Application

**Application Number:** 2016-4117  
**Application:** Changes to Product Labels – Application Rate Increase or Decrease, New Pests and New Site or Host  
**Product:** Exempla  
**Registration Number:** 32015  
**Active ingredients (a.i.):** Azoxystrobin and Difenoconazole  
**PMRA Document Number:** 2843176

### Purpose of Application

The purpose of this application was to add potatoes, dried shelled pea and bean, except soybean (CSG 6C) and soybeans to the Exempla label and to align the MRL for difenoconazole in/on crops belonging to Crop Subgroup 6C with the US Tolerance.

### Chemistry Assessment

A chemistry assessment was not required for this application.

### Health Assessments

The occupational exposure and risk from the addition of the use on potatoes, soybeans and pulse crops (CSG 6C) to the Exempla label was assessed. No health risks of concern are expected from the new use, provided that workers follow the label directions and wear the personal protective equipment identified on the label.

Residue data for difenoconazole in dry beans and peas were submitted to support the maximum residue limits on Dried shelled pea and bean (except soybean), Crop subgroup 6C. In addition, previously reviewed residue data from field trials with azoxystrobin and difenoconazole conducted in/on potatoes, dry beans and peas, and soybeans were reassessed in the framework of this petition. In addition, a processing study in treated soybeans was also reassessed to determine the potential for concentration of residues of difenoconazole into processed commodities.

### Maximum Residue Limits

The established maximum residue limits (MRLs) for azoxystrobin in/on potatoes and dry soybeans, beans, and peas are sufficient to cover the use expansion.

The recommendation for an MRL for difenoconazole was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. MRLs to cover residues of difenoconazole in/on crops and processed commodities are proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRLs for the raw agricultural commodities (RACs).

**TABLE 1 Summary of Field Trial and Processing Data Used to Support Maximum Residue Limit(s) (MRLs)**

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT			
Dry beans	514-522	13-15	<0.01	0.09	Not applicable	0.03 (CSG 6C)	0.2 (CSG 6C)
Dry peas		13-18	<0.01	0.03			

LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial

Following the review of all available data, an MRL as proposed in Table 1 is recommended to cover residues of difenoconazole. Residues in these crop commodities at the proposed MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

A toxicological assessment was not required for this application.

### Environmental Assessment

The uses for azoxystrobin and difenoconazole on potatoes, pulse crops (crop subgroup 6C), and soybeans fall within the use patterns already registered for other agricultural crops.

Therefore, the environmental risk associated with the use expansion is not expected to exceed the risk associated with the current registered uses of Exempla. Amendments to the environmental label statements, including buffer zones, have been provided.

### Value Assessment

Based on efficacy data provided, scientific rationales and extrapolations from precedent registrations, the addition of new crops and associated disease claims to the Exempla label are supported. Exempla will provide the growers with an additional end use product to control important diseases in soybeans, potatoes and pulse crops. This product also provides users with a resistance management tool, as both active ingredients provide control of most new claims.

### Conclusion

The Pest Management Regulatory Agency has completed an assessment of the available information and is able to support the amendments to the Exempla product label and to align the MRL for difenoconazole in/on crops belonging to Crop Subgroup 6C with the US Tolerance.

## References

PMRA Document Number	References
1913109	2009, AHETF, Agricultural Handler Exposure Scenario Monograph: Open Cab Groundboom Application of Liquid Sprays. Report Number AHE1004.
2172938	2012, AHETF, Agricultural Handler Exposure Scenario Monograph: Closed Cockpit Aerial Application of Liquid Sprays. Report Number AHE1007.
2572745	2015, AHETF, Agricultural Handler Exposure Scenario Monograph: Open Pour Mixing and Loading of Liquid Formulations. Report Number AHE1003-1.
2115788	2008, Agricultural Reentry Task Force (ARTF), Data Submitted by the ARTF to Support Revision of Agricultural Transfer Coefficients.
2664694	2013, Difenconazole (A7402T) - Magnitude of the Residues in or on Dry Beans and Dry Peas as Representative Commodities of Crop Group 6C (Except Soybeans) Following Foliar Application USA 2011, DACO: 7.4.1,7.4.5
2664693	2008, Difenconazole - Magnitude of the Residues in or on Leaf Lettuce, DACO: 7.4.1
2664696	2016, Value Summary, DACO: 10.1,10.2.2,10.2.3.1,10.3.1,10.3.2
2858407	2016, Efficacy Deficiency Response, DACO: 10.2

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