

## Evaluation Report for Category B, Subcategory 3.11, 3.12 & 3.6 Application

**Application Number:** 2014-0876  
**Application:** New or Changes to Product Labels-New Pests, New Site or Host  
Pre- Harvest/Slaughter|With-Holding  
**Product:** Caramba Fungicide  
**Registration Number:** 29767  
**Active ingredients (a.i.):** metconazole  
**PMRA Document Number :** 209150

### Purpose of Application

The purpose of this application was to amend the Caramba Fungicide label to include claims for suppression of corn ear rot caused by *Fusarium* spp. and *Gibberella* spp on corn (field, pop, sweet and seed) with a single application between silking and silk browning at a rate of 1.0 L product/ha (90 g a.i./ha).

### Chemistry Assessment

A chemistry review was not required for this application.

### Health Assessments

A toxicology review was not required for this application.

The occupational exposure and risk from the addition of the use on field, pop, sweet, and seed corn to the Caramba Fungicide label was assessed. No health risks of concern are expected from the amendment, provided that workers follow the label directions and wear the personal protective equipment identified on the label.

Residue data from field trials conducted in the United States including growing regions representative of Canada were submitted to support the domestic use of Caramba Fungicide on field corn, sweet corn, popcorn and corn grown for seed production. Metconazole was applied to field and sweet corn at exaggerated rates including an adjuvant in the spray mixtures. Sweet corn kernels plus cob with husks removed (K+CWHR) samples were harvested according to label directions, and field corn grain samples were harvested at longer preharvest intervals (PHIs) of 20-22 days compared to the 7-day PHI on the proposed label. In addition, a processing study in treated field corn was reviewed to determine the potential for concentration of residues of metconazole into processed commodities.

**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)
			Min	Max			
Field corn grain	Foliar applications/440	20-22	<0.01	0.02	Residues concentrate 1.1x in refined oil; residues do not concentrate in grits, flour or starch	None	0.04 (field corn and popcorn)
Sweet corn kernels plus cob with husks removed	Foliar applications/440	6-7	<0.01	<0.011	Not applicable	None	0.04

\*Recommended with PMRL2014-34; an update to the MRLs is not required to cover anticipated residues as a result of the domestic use of metconazole on corn.

Based on this assessment, the dietary exposure to metconazole is not expected to increase and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

### Environmental Assessment

The use of metconazole on corn, including ground and aerial application methods at the maximum use rate, falls within those already registered for other agricultural crops. Therefore, an increase in environmental exposure is not expected, and this application falls within the current environmental risk assessment. It has been determined that amendments to the precautionary label statements appearing on the proposed label are required in order to be reflective of current standards.

### Value Assessment

Five trials on wheat and three trials on corn testing the efficacy of Caramba Fungicide against the main fungal species that causes fusarium and gibberella ear rots were provided. The evidence from the wheat trials could be extrapolated to support this claim on corn given the shared causal pathogen and the similarities in disease development between the two crops. Disease reduction was assessed directly by evaluations of symptoms or indirectly by measurements of mycotoxin levels in harvested grain. Caramba Fungicide showed levels of disease and mycotoxin reduction

that were consistent with expectations from a suppression claim. Based on the demonstrated efficacy and the need for additional tools to manage gibberella and fusarium ear rots, the proposed claim for suppression is supported at the proposed rate of 1.0 L/ha with minor modification to the labelled pathogen designation.

## **Conclusion**

The PMRA has conducted a review of the available information in support of this application and has determined that the label amendment can be supported.

## **References**

<b>PMRA #</b>	<b>Reference</b>
2400601	2014, Part 10: Value Caramba on corn Value assessment, DACO: 10.1,10.2,10.2.2,10.2.3.2(D),10.3.2(B)
2400603	2014, Part 10: Value Caramba on corn Value assessment: Excel spreadsheets, DACO: 10.2.3.2(D),10.3.2(B)
2400608	2014, DACO 5.2
2115788	Agricultural Reentry Task Force (ARTF). 2008. Data Submitted by the ARTF to Support Revision of Agricultural Transfer Coefficients. Submission #2006-0257.
2400613	2006, Magnitude of the Residue of Metconazole and its Metabolites in or on Field Corn and Sweet Corn Raw Agricultural Commodities and Field Corn Processed Commodities Following Applications of BAS 555 01F; DACO 7.4
2400612	2011, Magnitude of Residues of Metconazole (BAS 555 F) in Sweet Corn Stover Following Applications of BAS 555 01 F; DACO 7.4
2400611	2007, Method Validation of BASF Analytical Method D0604 entitled “The Determination of Residues of BAS 555 F and Its Metabolites in Corn and Cotton Matrices using LC/MS/MS”; DACO 7.2

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