

## Evaluation Report for Category B, Subcategory 3.10, 3.11, 3.12 & 3.13 Application

**Application Number:** 2008-5940  
**Application:** New to Product Labels -Tank Mixes, New Pests, New Site or Host, and Precautions  
**Product:** Headline EC Fungicide  
**Registration Number:** 27322  
**Active ingredients (a.i.):** Pyraclostrobin (PYA)  
**PMRA Document Number:** 1905829

### Purpose of Application

BASF has submitted an application to add new crops (rapeseed, canola, canola quality *Brassica juncea*, mustard (oilseed and condiment) and sunflowers) to Headline EC Fungicide (Registration Number 27322). There was also a request to remove the regional restriction of Headline EC Fungicide for use on flax, to add new tank mixes for use in canola, and to amend some precautionary statements on the label.

### Chemistry Assessment

A chemistry assessment was not required for this application.

### Health Assessments

The addition of flax, sunflowers, rapeseed, canola, canola quality *Brassica juncea* and mustard (oilseed and condiment) on the label of Headline EC Fungicide for national use fits within the current registered use pattern of the product. Therefore, it should not result in an increase in potential occupational or bystander exposure over the registered uses of pyraclostrobin. No unacceptable risk is expected when workers follow label directions and wear personal protective equipment as recommended on the label.

Residue data for pyraclostrobin in sunflowers were submitted to support the use expansion of this active on the Headline EC Fungicide label. In addition, previously submitted residue data for pyraclostrobin in sunflowers and canola were reassessed to support the use expansion.

## Maximum Residue Limits

Based on the maximum residues observed in crops treated according to label directions or at exaggerated rates, maximum residue limits (MRLs) to cover residues of pyraclostrobin will be established as shown in Table 1. Residues of pyraclostrobin in processed commodities not listed in Table 1 are covered under the 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/ Application Rate (g a.i./ha)	Total PHI (days)	Combined Residues (ppm)		Experimental Processing Factor	Currently Established MRL	Recommended MRL (ppm)
			Min	Max			
Sunflower seed	Broadcast foliar/ 450 g a.i./ha	20-21	<0.04	0.25	No concentration observed into sunflower oil	0.3* {for sunflower seed}	0.45 {for Crop Subgroup 20B and for mustard seed (condiment type)}
Canola seed	Broadcast foliar/ 220-226 g a.i./ha	20-22	<0.04	0.11	1.4x in refined canola oil	0.45 {for Crop Subgroup 20A; PMRL2010-24}	
	Broadcast foliar/ 438-462 g a.i./ha	20-22	<0.04	0.27			

\* Currently established MRL of 0.3 ppm is being proposed to be replaced by 0.45 ppm.

Residues of pyraclostrobin and the metabolite BF 500-3 in these crop commodities at the established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

## Environmental Assessment

No additional environmental data were required to support the requested amendments to the Headline EC Fungicide label. Environmental exposure resulting from the amendments to the uses of Headline EC Fungicide is expected to be similar to that for existing registered uses. Environmental risks to aquatic organisms, non-target terrestrial plants and small wild mammals resulting from the use of Headline EC Fungicide have been mitigated through adequate statements and buffer zones on the product label.

## Value Assessment

A total of 22 trials were submitted to support the various claims. All claims except for sunflower rust (*Puccinia helianthi*) in sunflowers were acceptable. The registrant proposed a claim for control of sunflower rust but efficacy data only demonstrated suppression of the disease. Claims for control of blackleg (*Leptosphaeria maculans*) and black spot (*Alternaria brassicae* and *A.*

*raphani*) in rapeseed, canola, canola quality *Brassica juncea*, mustard (oilseed and condiment) were supported. The tank mix claim with Lance WDG Fungicide to control sclerotinia stem rot (*Sclerotinia sclerotiorum*) was supported.

Thirty-three trials examining tank mixes of Headline EC Fungicide with Poast Ultra Herbicide and Odyssey WDG Herbicide were submitted for review. The data provided showed that there was no loss of herbicide efficacy when Poast Ultra Herbicide or Odyssey Herbicide was tank mixed with Headline EC Fungicide. Crop tolerance for several crops was also acceptable when Headline was tank-mixed with Poast Ultra or Odyssey. Physical compatibility (miscibility) was acceptable in all trials.

In addition, the removal of the regionalized restriction on the flax crop for control of pasmo (*Septoria linicola*) and expand it nationwide was also supported.

### **Conclusion**

The PMRA has conducted a review of the available information for this application and has determined that the amendments to the Headline EC Fungicide Label are acceptable.

## References

### List of Studies/Information Submitted by Registrant

<b>PMRA #</b>	<b>Reference</b>
1335117	2005, The Magnitude of BAS 510 F and BAS 500 F Residues in Sunflowers, DACO: 7.4.1
1689632	2008, Summary of residue submitted and reviewed by PMRA, DACO: 7.1
1751598	2009, BASF response to PMRA letter dated May 5, 2009, DACO: 7.4.1,7.4.2
1689625	2006, PART 10, 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
1689628	2008, PART 10- summary tables Canola, DACO: 10.2.3.3(D),10.3.2(B)
1689629	2008, PART 10- summary tables-Sunflowers, DACO: 10.2.3.3(D),10.3.2(B)
1689630	2008, PART 10- summary tables- tank mixtures, DACO: 10.2.3.3(D),10.3.2(B)

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