

Evaluation Report for Category B, Subcategory B.3.11, B.3.12 Application

Application Number:2006-4555Application:B.3.11 Addition of Pests, B.3.12 Addition of Site or HostProduct:Headline EC FungicideRegistration Number:27322Active ingredients (a.i.):Pyraclostrobin (PYA)PMRA Document Number:1455353

Background

Headline EC Fungicide has been registered since March 3, 2003. For specific details of uses, application rates and methods, precautions, restrictions, and personal protective equipment requirements, refer to the product label.

Purpose of Application

The purpose of this submission is to register Headline EC Fungicide to treat crown rust on oats.

Chemistry Assessment

A chemistry assessment was not required as there was no change to product chemistry.

Health Assessments

A toxicology assessment was not required as there was no change to product chemistry. The use of Headline EC Fungicide on oats fits within the existing use pattern for pyraclostrobin. Exposure to handlers mixing/loading and applying the product to oats and workers entering treated oat fields is not expected to increase over the currently registered use pattern.

Residue data for pyraclostrobin in oats were submitted to support the use expansion on the Headline EC Fungicide label. Previously reviewed wheat processing study (cereal representative crop) was reassessed in the framework of this petition to determine the potential for concentration of residues of pyraclostrobin into oat processed commodities.

Maximum Residue Limit

Based on the maximum residues observed in oat grain treated according to label directions, a maximum residue limit (MRL) to cover residues of pyraclostrobin in/on oats will be established



as shown in Table 1. Residues of pyraclostrobin in processed commodities not listed in Table 1 are covered under established MRLs for the raw agricultural commodity(ies) (RACs).

TABLE 1. Summary of Field Trial and Processing Data Used to Establish Maximum Residue Limit(s) (MRLs)						
Commodity	Application	PHI (days)	Residues (ppm)		Currently	Recommended
	Method/ Total Application Rate		Min	Max	Established MRL	MRL
Oats	Foliar Broadcast	7	< 0.10	0.75	None	1.2 ppm
	200 g a.i./ha per season					

Environmental Assessment

An environmental assessment was not required as the application rate, number of applications, frequency of application, and application methods fell within that registered for wheat, barley and rye. There are no environmental concerns with the use of the subject product that are not mitigated by the existing label statements.

Value Assessment

Three efficacy trials conducted in Manitoba (2 trials) and in Brazil (1 trial) were reviewed. Results of these trials showed that under moderate disease pressure, when applied at the proposed rates of 0.3-0.4 L/ha, Headline provided a high level of crown rust control. No trial was conducted under high disease pressure, so the efficacy of the rates have not been confirmed for severe infections. No phytotoxicity was reported in any of the submitted trials. The proposed label claims are supported as submitted.

Conclusion

The Agency has completed an assessment of available information for Headline EC Fungicide and has found the information sufficient to allow the use on oats to treat crown rust. Following the review of all available data, an MRL of 1.2 ppm for oats is recommended to cover residues of pyraclostrobin. Total residues of pyraclostrobin on oats and on all the other registered uses at the established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

References

PMRA #	Reference
1279940	2006. Headline EF Fungicide (pyraclostrobin): petition for application in oats (<i>Avena sativa</i>) for the control of crown rust (<i>Puccinia coronata</i> f.sp. <i>avenae</i>). BASF Canada. Data requirement - Part 10: value, 2006, pp. 41.
1279941	Summary Tables Headline EC Fungicide on Oats for Crown Rust (<i>Puccinia coronata</i>) control.
1279934	2006, PMRA FORM- PROPOSED NEW USES, N.A, MRID: N.A, DACO: 0.1.6023
1279935	2006, COVER LETTER, N.A, MRID: N.A, DACO: 0.8
1279937	2006, DACO 1.1, N.A, MRID: N.A, DACO: 1.1
1279939	2006, RESIDUE, 137717, DACO: 7.4.1

B. Additional Information Considered

I) Published Information

Pest Management Regulatory Agency. 2003. Regulatory Note REG2003-06, Pyraclostrobin, Headline EC, Cabrio EG. Ottawa. pp. 106.

II) Unpublished Information

Studies submitted under Sub. No. 2005-3432:

PMRA #	Reference
1087933	Effects of BAS 500 00 F on seedling emergence and growth of selected non-target terrestrial plants (Tier 1). ABC Laboratory Inc. Laboratory Study No. 46887. Study report date: 18-October-2001. BASF Registration Document No. 2001/5002405. 51 pages. DACO 9.8.4.
1087934	Effects of BAS 500 00 F on vegetative vigor of selected non-target terrestrial plants (Tier 1). ABC Laboratory Inc. Laboratory Study No. 46888. Study report date: 18-October-2001. BASF Registration Document No. 2001/5002406. 49 pages. DACO 9.8.4.

1359262	Acute toxicity of Reg No. 340266 (metabolite of BAS 500F) to <i>Daphnia magna</i> Straus in a 48 hour static test. BASF Aktiengesellschaft BASF Agricultural Center Limburgerhof. BASF Study Code 172480. Study report date: 21-December-2006. BASF Registration Document No. 2006/1038907. 20 pages. DACO 9.3.2.
1359263	Effect of BF 500-3 (Reg. No. 340266, metabolite of BAS 500F) on the growth of the green alga <i>Pseudokirchneriella subcapitata</i> . BASF Aktiengesellschaft BASF Agricultural Center Limburgerhof. BASF Study Code 172483. Study report date: 22-December-2006. BASF Registration Document No. 2006/1038445. 31 pages. DACO 9.8.2.
1370731	Reg. No. 340266 (metabolite BF 500-3 of BAS 500F): acute toxicity study on the rainbow trout (<i>Oncorhynchus mykiss</i>) in a static system over 96 hours. Experimental Toxicology and Ecology BASF Aktiengesellschaft. Laboratory Project No. 12F0681/065050. 06-February-2007. BASF Registration Document No. 2007/1010836. 41 pages. DACO 9.5.2.1.

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