

## Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.1 and 3.12 Application

**Application Number:** 2014-6068  
**Application:** New end-use product chemistry: Guarantee, identity and proportion of formulants  
New end-use product labels: Application rate increase or decrease, and new site or host  
**Product:** Headline AMP  
**Registration Number:** 32189  
**Active ingredients (a.i.):** Pyraclostrobin and Metconazol  
**PMRA Document Number :** 2519148

### Purpose of Application

The purpose of this application was to register a new end-use product, Headline AMP (guarantee: 146 g/L pyraclostrobin and 55 g/L metconazole), as a broad spectrum fungicide for use in cereals and corn.

### Chemistry Assessment

Headline AMP is formulated as a liquid suspension containing pyraclostrobin at a nominal concentration of 146 g/L and metconazole at a nominal concentration of 55 g/L. This end-use product has a density of 1.05-1.07 kg/L and pH of 6.0-7.5. The chemistry requirements for this product have been fulfilled.

### Health Assessments

Headline AMP is of moderate acute oral toxicity and low acute dermal and inhalation toxicity in rats. It is minimally irritating to the eyes and mildly irritating to the skin of rabbits. It is not a dermal sensitizer in guinea pigs.

No new residue data for pyraclostrobin and metconazole in cereals (barley, oats, rye, wheat and triticale) and corn (field corn, popcorn, sweet corn & seed production corn) were submitted to support the registration of Headline AMP. Previously reviewed residue data from field trials conducted in/on cereals and corn were reassessed in the framework of this petition. In addition, processing studies in treated cereals and corn were also reassessed to determine the potential for concentration of residues of pyraclostrobin and metconazole into processed commodities.

Following the review of all available data, no revisions and no new maximum residue limits (MRLs) are being proposed for promulgation. The MRLs currently

established for residues of pyraclostrobin and metconazole in/on cereals and corn commodities, as well as livestock commodities, are considered adequate to cover the expected residue levels generated by the use of Headline AMP. No health concerns have been identified for any segment of the population including infants, children, adults and seniors.

Headline AMP for use on corn (field corn, popcorn, sweet corn & seed production corn) and cereal crops (barley, oats, rye, wheat and triticale) to control various diseases fits into the registered use pattern for pyraclostrobin but does not fit within the registered use pattern for metconazole. A postapplication quantitative risk assessment was conducted and restricted entry intervals are required for hand harvesting/detasseling on corn and for handset irrigation on all crops. No health risks of concern are expected when workers follow label direction and wear the personal protective equipment identified on the label.

### **Environmental Assessment**

No environmental risk assessment has been conducted as the application rates of Headline AMP are not higher than the currently registered uses of its active ingredients, pyraclostrobin and metconazole. Applying Headline AMP according to the label directions is not expected to increase environmental risks.

### **Value Assessment**

Currently, Headline EC Fungicide (Registration Number 27322; guarantee 250 g/L pyraclostrobin), Caramba Fungicide (Registration Number 29767; guarantee 90 g/L metconazole), and Twinline Fungicide (Registration Number 30337; guarantee 130 g/L pyraclostrobin and 80 g/L metconazole) are registered for use on the same cereal crops against the same cereal leaf diseases as for Headline AMP. In addition, Headline EC Fungicide is registered for use on the same corn types against two of the same corn leaf diseases as for Headline AMP. Efficacy data and rationales were provided to support three new leaf diseases on corn. Sufficient value information, including data from efficacy trials and rationales, was submitted to support the use of Headline AMP to control the listed leaf diseases on cereals and corn at the labelled use rates.

This new premix will offer an alternative product to be used in integrated pest management to control leaf diseases in cereals and corn. It should be noted that when compared to solo applications of Headline EC Fungicide and Caramba Fungicide, the lower application rate of Headline AMP to control cereal leaf diseases will result in a significant reduction in metconazole. The impact of this on resistance management is unknown.

### **Conclusion**

The PMRA has completed a review of all available information in support of Headline AMP and found it sufficient to grant full registration.

### **References**

<b>PMRA Document Number</b>	<b>Reference</b>
2486674	2014, Value summary, DACO: 10.1,10.3.1,10.3.2
2502684	2015, Part 10 Value response to PMRA questions, DACO: 10.2.3.3(D)
2486681	2014, Headline AMP - Product identification, DACO 3.1.1 to DACO 3.1.4, DACO: 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4
2486682	2008, BAS 556 F SC Fungicide: Group A - Product identity, composition, and analysis, DACO: 3.1, 3.1.4, 3.2, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4 CBI
2486683	2008, BAS 556 02 F: Determination of physical/chemical properties, DACO: 3.5, 3.5.1, 3.5.11, 3.5.12, 3.5.2, 3.5.3, 3.5.4, 3.5.6, 3.5.7, 3.5.9
2486684	2014, DACO 3.5 - Chemical and physical properties: Headline AMP a new fungicide product for use on corn containing pyraclostrobin and metaconazole, DACO: 3.5.13, 3.5.15
2486685	2008, BAS 556 02 F: Accelerated storage stability, DACO: 3.5.10, 3.5.14, 3.5.5
2486686	2008, BAS 556 02 F: Determination of oxidation/reduction, DACO: 3.5.8
2526912	2008, BAS 556 UU F: GLP validation of BASF method AFR0039/02 and GLP certification of BAS 556 UU F, lot # 1606-90, DACO: 3.4.1
2538074	2015, BASF response to PMRA questions, DACO: 3.2.2, 3.7 CBI
2486687	2014, Toxicology Summary - Headline AMP, DACO: 4.1
2486688	2008, BAS 556 02 F - Acute oral toxicity study in rats, DACO: 4.6.1
2486689	2008, BAS 556 02 F - Acute dermal toxicity study in rats, DACO: 4.6.2
2486690	2008, BAS 556 02 F - Acute inhalation toxicity study in Wistar rats - 4-hour liquid aerosol exposure, DACO: 4.6.3
2486691	2008, BAS 556 02 F - Acute eye irritation in rabbits, DACO: 4.6.4
2486692	2008, BAS 556 02 F - Acute dermal irritation/corrosion in rabbits, DACO: 4.6.5
2486693	2008, BAS 556 02 F Buehler test in guinea pigs, DACO: 4.6.6

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