



## Evaluation Report for Category B, Subcategory 2.6 Application

**Application Number:** 2010-4343  
**Application:** B.2.6 (Product Chemistry – new combination of TGAIs)  
**Product:** Twinline Fungicide  
**Registration Number:** 30337  
**Active ingredients (a.i.):** Metconazole (GHA), Pyraclostrobin (PYA)  
**PMRA Document Number English PDF:** 2020745

### Purpose of Application

The purpose of this application was to register a new end-use product with a new combination of two active ingredients, metconazole (Registration Number 29766) and pyraclostrobin (Registration Number 27321). These two active ingredients are both currently registered for control of foliar diseases on cereals and other agricultural crops (USC 13/14).

### Chemistry Assessment

Twinline Fungicide is formulated as an emulsifiable concentrate containing pyraclostrobin at a nominal concentration of 130 g/L and metconazole at a nominal concentration of 80 g/L. This end-use product has a density of 1.08 g/mL and pH of 5.6. The chemistry requirements for Twinline Fungicide are complete.

### Health Assessments

Twinline Fungicide was of high acute toxicity in rats via the oral route ( $LD_{50} > 50$  mg/kg bw  $< 300$  mg/kg bw), low acute toxicity by the dermal route ( $LD_{50} > 5000$  mg/kg bw) and slight toxicity by the inhalation route ( $LC_{50} = 0.88$  mg/L). This product is severely irritating to the eyes and mildly irritating to the skin of rabbits. It is not a dermal sensitizer in guinea pigs.

The use of Twinline Fungicide is considered acceptable when workers follow label directions and precautions, including listed personal protective equipment, restricted entry interval and amount handled per day restrictions.

No new residue data for pyraclostrobin or metconazole were submitted or required to support the use of these actives in a new end-use product, since these active ingredients are currently registered in Canada for use on wheat, barley, rye and oats at equivalent or higher rates. The requested use for these active ingredients in/on triticale, a small grain cross between wheat and rye, is supported by the residue trial data on file for pyraclostrobin and metconazole in/on these crops.

### **Maximum Residue Limits**

Based on this assessment, Maximum Residue Limits (MRLs) of combined residues of pyraclostrin and the BF 300 metabolite in/on treated cereal commodities will be covered by the MRLs established for combined residues of pyraclostrin and the BF 300 metabolite in/on barley (0.4 ppm), oats (1.2 ppm), rye (0.04 ppm) and wheat (0.2 ppm). Based on the maximum MRL established for each of wheat and rye, a MRL of 0.2 ppm to cover combined residues of pyraclostrin and the BF 300 metabolite will be established on triticale.

Based on this assessment, MRLs of residues of metconazole in/on treated cereal commodities will be covered by the MRLs of metconazole in/on barley (2.5 ppm), rye (0.25 ppm), oats (1 ppm) and wheat (0.15 ppm) currently under promulgation. Based on the maximum MRL recommended for promulgation for each of wheat and rye, a MRL of 0.25 ppm to cover residues of metconazole will be established on triticale.

Following the review of all available data, MRLs of 0.25 ppm for metconazole and 0.04 ppm for combined residues of pyraclostrobin and the BF 300 metabolite in/on triticale are recommended to cover residues of metconazole and pyraclostrobin in/on this crop. Residues of metconazole and pyraclostrobin in this commodity at the established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

### **Environmental Assessment**

The proposed application rates and use pattern of Twinline Fungicide are within the range of those currently registered for both of the active ingredients: metconazole and pyraclostrobin. Therefore, an increased risk to the environment is not expected as a result of the labelled use of this new combination end-use product. Due to the change in application rates, a re-calculation of spray buffer zones was conducted. For the protection of terrestrial habitats, spray buffer zones of 1 m and 10 m are necessary for ground and aerial application, respectively. For the protection of aquatic habitats, spray buffer zones up to 5 m are required for ground application and up to 250 m are required for aerial application. Precautionary environmental label statements on the Twinline Fungicide label are also required as a mitigation measure.

### **Value Assessment**

A total of 109 field trials were submitted to support the use claims. All trials were conducted in Canada and the United States between 2007 and 2009.

#### **Tan spot (*Pyrenophora tritici-repentis*)**

Nine trials conducted in Canada and the United States between 2007 and 2009 were submitted for review. Average levels of control expressed in the trials suggest that Twinline Fungicide is suppressing disease severity (DS), although the higher tested rates controlled tan spot in some trials. The average levels of control for the Twinline Fungicide treatments were numerically higher and statistically comparable to the commercial standards registered for same use, including Headline and Caramba. The claim of control of tan spot on wheat is supported.

**Septoria leaf blotch (*Septoria tritici*, *Stagonospora nodorum*)**

Thirteen trials conducted in Canada and the United States between 2007 and 2009 were submitted for review. Both of the proposed rates of Twinline Fungicide controlled DS on wheat infected by *Septoria tritici*. Application using ULV sprays shows equivalent efficacy when applied aerially. Only one trial was submitted on *Stagonospora nodorum*. The trial demonstrated high efficacy on leaves under moderate disease pressure; disease pressure was too low on glumes to determine efficacy. Usually, a minimum of three trials are required to support a disease claim; however, both pyraclostrobin and metconazole are registered to control this pest. It should be noted that the rates delivered as Twinline Fungicide are lower than registered on either label; however, the submitted trial demonstrates efficacy at the proposed rates. Based on the known efficacy of the active ingredients and the information provided, the claim for control of leaf blotch caused by *Septoria tritici* and *Stagonospora nodorum* is supported.

**Leaf rust (*Puccinia recondita*)**

Twenty-six trials conducted in Canada and the United States between 2007 and 2009 were submitted to support this claim. Seven trials were not reviewed as disease pressure was too low to determine efficacy. Twinline Fungicide controlled leaf rust on wheat in many of the reviewed trials. Average levels of control imply high levels of suppression; however, the average levels of control in the Twinline Fungicide treatments were statistically comparable to the commercial standards registered for same use. Application using ULV sprays shows equivalent efficacy when applied aerially. Significant yield increases also indicate an economic benefit as a result of applying Twinline Fungicide to wheat crops. The efficacy and yield data submitted by the applicant support the proposed claim on wheat. Extrapolation of the use claim to triticale and rye is supported.

**Stripe rust (*Puccinia striiformis*)**

Nineteen trials conducted on wheat in the United States between 2007 and 2009 were submitted for review. Four trials were not considered in the efficacy review as disease pressure was too low; however, yield data was considered. The submitted efficacy and yield data demonstrate control of stripe rust on wheat with Twinline Fungicide when applied as proposed. A single trial was also submitted on barley; Twinline Fungicide applied at rates of 77 g and 107 g a.i./ha controlled stripe rust. The claim of control of stripe rust is supported on both crops.

**Powdery mildew (*Erysiphe graminis* f. sp. *tritici*)**

Nine trials conducted in the United States in 2007 and 2008 were submitted for review. Three trials were not considered as disease pressure was too low. Twinline Fungicide provided control of powdery mildew up to 84.4% at both rates. Yield increases were observed in the majority of trials in Twinline Fungicide treatments with significant increases noted in two trials. The efficacy results and the observed yield benefit suggest that Twinline Fungicide will control powdery mildew on wheat, so the claim is supported as proposed. Extrapolation of the use claim to triticale and rye is supported.

**Fusarium head blight – FHB (*Fusarium graminearum*)**

Two trials conducted in Germany in 2010 were submitted for review. Twinline Fungicide suppressed disease incidence (DI) and DS on wheat in both trials. The results were comparable to metconazole, which is registered for suppression of FHB on barley, oats, rye and wheat. The claim of suppression of FHB on wheat is supported as proposed. Extrapolation of the use claim to barley, rye and triticale is also supported.

**Net blotch (*Pyrenophora teres*)**

Fourteen trials conducted in Canada and the United States between 2007 and 2008 were submitted for review. Four trials were not reviewed and another four were considered as supplementary data in assessing aerial application and LER due to low disease pressure. Data demonstrates that Twinline Fungicide will control net blotch on barley at the proposed rates. Yield data shows an economic benefit from applying Twinline Fungicide to control net blotch, as yield increases were observed even under low disease pressure. The claim of control of net blotch on barley is supported as proposed.

**Spot blotch (*Cochliobolus sativus*)**

Six trials conducted in Canada in 2008 and 2009 were submitted for review. Only one trial could be reviewed for efficacy as disease pressure was low in the remaining five trials. The levels of control expressed by Twinline Fungicide at the proposed rates indicate that this product is only partially suppressing spot blotch. Pyraclostrobin and metconazole applied alone at higher rates also demonstrated partial suppression. Pyraclostrobin is registered to control spot blotch on barley at the tested rate. The other registered standards partially suppressed or suppressed spot blotch in the trials. Treatment with Twinline Fungicide using ULV sprays demonstrated comparable efficacy to ground sprays. Based on the above, it is assumed that Twinline Fungicide treatments should suppress spot blotch; however, more data are required to confirm efficacy. The claim of suppression of spot blotch on barley is supported with the condition that the registrant submits two additional trials conducted under moderate to high disease pressure. The claim of control will be supported if demonstrated by the submitted data. Extrapolation of this claim to wheat and triticale is also supported.

**Scald (*Rhynchosporium secalis*)**

Seven trials conducted in Canada and the United States in 2008 and 2009 were submitted for review. One trial could not be reviewed due to low disease pressure. Data demonstrates that Twinline Fungicide will control scald on barley at the proposed rates, although the average level of control expressed at the high rate suggests suppression. Yield data shows an economic benefit from applying Twinline Fungicide to control scald, as yield increases were observed even under low disease pressure. Based on efficacy and yield data, the claim of control of scald on barley is supported as proposed.

**Crown rust (*Puccinia coronata*)**

Four trials conducted in Canada in 2009 were submitted for review. One trial was not reviewed due to low disease pressure. Efficacy and yield data indicate that Twinline Fungicide controls crown rust on oats at the rates proposed. Treatment with pyraclostrobin and metconazole demonstrates that both active ingredients have activity against this pest. The claim of control of crown rust on oats is supported as proposed.

### **Aerial application**

Aerial application was tested in five trials (three on wheat, two on barley) using side-by-side treatments of Twinline Fungicide (105 g a.i./ha) with ultra-low volume sprays at 50 L water/ha and ground application spray volumes of 100 L water/ha. Equivalent efficacy was demonstrated between the two treatments in all trials, which show that the crops receive adequate coverage at the lower spray volumes associated with aerial application to control or suppress the proposed diseases. In addition, aerial application is currently registered on the Headline and Caramba labels. Since wheat, barley, rye and oats are of similar architecture and cropping systems, this application method should be appropriate for these crops as well. Aerial application is supported for all of the proposed crops.

### **Lowest Effective Rate (LER)**

Rates lower than proposed (45 - 60 g a.i./ha) were included in six trials on wheat, barley and oats to demonstrate that the selected low rate of 79.8 g a.i./ha is the lowest effective rate. Three trials did not provide adequate information. One trial each on wheat (tan spot), barley (spot blotch) and oats (crown rust) demonstrated that rates below 79.8 g a.i./ha did not provide appropriate or consistent levels of control. The proposed low rate of 79.8 g a.i./ha is supported as the lowest effective rate.

### **Two applications**

Two applications are intended to target both foliar diseases and Fusarium head blight. For cereals, it is recommended by the Fungicide Resistance Action Committee (FRAC) that rotation to a fungicide with a different mode of action occur after no more than two sequential applications of a group 11 fungicide. This recommendation includes mixtures containing group 11 fungicides. Since the use pattern falls within the recommendations from FRAC, a maximum of two applications per season at the rates and timings proposed are supported.

### **Value**

Both of the active ingredients in Twinline Fungicide are currently registered on cereal crops to control or suppress diseases. The value of combining the active ingredients includes the following: broadens the disease spectrum, eliminates the labour involved in tank mixing, pest resistance management and reduction in the amount of active ingredients applied to crops to control foliar diseases.

### **Conclusion**

The PMRA has completed an assessment of the available data and is able to support the full registration of Twinline Fungicide.

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