

## Evaluation Report for Category B, Subcategory 2.6, 3.1, 3.12 Application

**Application Number:** 2011-3599  
**Application:** B.2.6 (Product chemistry – new combination of TGAIs)  
B.3.1 (Product labels – application rate increase)  
B.3.12 (Product labels – new site or host)  
**Product:** Insure Cereal  
**Registration Number:** 30685  
**Active ingredients (a.i.):** Metalaxyl, Pyraclostrobin, Triticonazole  
**PMRA Document Number:** 2143200

### Purpose of Application

The purpose of this application was to register a new end-use product, Insure Cereal. It is intended for use as a seed treatment for control or suppression of various smuts and bunts as well as seedling diseases caused by *Cochliobolus sativus*, *Fusarium* spp. and *Pythium* spp. on cereal grains.

### Chemistry Assessment

Insure Cereal is formulated as a suspension containing pyraclostrobin at 17 g/L, triticonazole at 17 g/L and metalaxyl at 10 g/L. The end-use product has a density between 1.06-1.08 g/cm<sup>3</sup> and a pH between 6.0-8.0. The chemistry requirements for Insure Cereal are complete.

### Health Assessments

Insure Cereal is of low oral (LD<sub>50</sub> >2000 mg/kg bw), dermal (LD<sub>50</sub> > 5000 mg/kg bw) and inhalation (LC<sub>50</sub> > 5.8 mg/L) toxicity in the rat. It is not irritating (MAS (24-72 hours) = 0.0/110) to the eye or the skin (MAS (24-72 hours) = 0.0/8) of the rabbit. It is a dermal sensitizer in the mouse in the Local Lymph Node Assay.

The use of Insure Cereal on wheat, barley, rye, triticale and oat seed does not fit within the registered use of pyraclostrobin, triticonazole and metalaxyl. A health risk assessment was conducted for commercial seed treatment workers and on-farm workers. No risks of concern are expected when workers follow the label directions and wear the personal protective equipment on the label.

No new residue data for metalaxyl, pyraclostrobin or triticonazole were submitted to support the use of these actives as a new coformulated end-use product, Insure Cereal, for use as a seed treatment on barley, oats, rye, triticale and wheat (all types). Metalaxyl and pyraclostrobin are currently registered in Canada for use as a seed treatment or for foliar application on these cereals, at equivalent or higher rates. Triticonazole is registered in Canada for use as a seed treatment barley, oats and wheat at equivalent rates. The use on rye and triticale is supported by the triticonazole data on file for barley, oats and wheat.

### **Maximum Residue Limits**

Residues of metalaxyl in/on treated barley, oats, rye, triticale and wheat will be covered by the existing MRLs established for these commodities. Residues of pyraclostrobin will be covered by the existing MRLs established in/on barley, oats, rye and wheat, and by MRLs under promulgation in/on triticale. Based on the residue data and the existing MRLs on wheat, barley and oats, a MRL of 0.01 ppm will be established on rye and triticale to cover residues of triticonazole.

Following the review of data on file, a MRL of 0.01 ppm is recommended to cover residues of triticonazole in/on rye and triticale. The use of the coformulation of metalaxyl, pyraclostrobin and triticonazole as a seed treatment on barley, oats, rye, triticale and wheat (all types) can be supported from a food residue exposure point of view. Residues of metalaxyl, pyraclostrobin and triticonazole in these commodities at the established MRLs will not pose an unacceptable health risk to any segment of the population, including infants, children, adults and seniors.

### **Environmental Assessment**

The active ingredients, pyraclostrobin, triticonazole and metalaxyl, are fully registered as seed treatment fungicides at rates higher or equal to those proposed for Insure Cereal. The registration of Insure Cereal is considered acceptable and is not anticipated to represent an increase in risk to non-target organisms. Label amendments were required for consistency with current environmental risk mitigation requirements.

### **Value Assessment**

To support their claims, the applicant presented evidence in the form of field and greenhouse trials conducted on wheat (32 trials), barley (31 trials) and oats (17 trials) in Alberta, Manitoba and Saskatchewan. In total, 20 field and 60 greenhouse trials were submitted for evaluation. Insure Cereal at 13.2 g a.i./100 kg seed consistently controlled or suppressed seedling diseases caused by *Fusarium* spp., *Cochliobolus sativus* and *Pythium* spp. on wheat, barley and oats. Support of certain smut and bunt diseases was extrapolated from a related pyraclostrobin-containing product registered at the same pyraclostrobin rate. Extrapolation to rye and triticale was accepted based on similarities in pest and crop biology. All claims were supported without modifications to the use pattern.

The individual active ingredients triticonazole and pyraclostrobin have shown to effectively control seed and seedling diseases caused by *Fusarium* spp. and *C. sativus*. Combining these single-site fungicides in a pre-mix strengthens resistance management against the two pathogens. Insure Cereal provides a new mode of action to seed treatments registered for use on cereal crops.

## Conclusion

The PMRA has completed an assessment of the available information and is able to support the registration of Insure Cereal for use as a seed treatment for control or suppression of various smuts and bunts as well as seedling diseases caused by *Cochliobolus sativus*, *Fusarium* spp. and *Pythium* spp. on cereal grains.

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