

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

**Application Number:** 2011-4204  
**Application:** Changes to Product Label, New Pest and Site  
**Product:** Raxil 312 FS (Seed Treatment Fungicide)  
**Registration Number:** 25762  
**Active ingredients (a.i.):** Tebuconazole  
**PMRA Document Number:** 2132069

### Background

Raxil 312 FS is registered for the control of common bunt on wheat seed and the control of loose smut on wheat seed, barley seed and oat seed at an application rate of 6.4 to 9.6 mL per 100 Kg of seed (2 to 3 g a.i. tebuconazole per 100 Kg seed). Tebuconazole is also registered as a foliar fungicide on a variety of food crops for use site categories 13 and 14.

### Purpose of Application

The purpose of this application was to expand the registration of Raxil 312 FS (registration number 25762), a seed treatment fungicide, to include the control of soil-borne and seed-borne head smut (*Sphacelotheca reiliana*) on corn (sweet corn, field corn, field corn grown for seed, and popcorn).

### Chemistry Assessment

A chemistry assessment was not required for this application.

### Health Assessments

A toxicological assessment was not required for this application.

The use of tebuconazole in Raxil 312 FS as a seed treatment fungicide on corn is not expected to result in risks of concern to commercial chemical handlers and post-application workers provided the product is applied according to the label directions.

Previously reviewed residue trial data for tebuconazole in/on field corn and sweet corn were assessed in support of this petition. Based on the maximum residues observed in field and sweet corn commodities treated using application methods, rates and pre-harvest intervals (PHIs) representing worst case scenarios for residues, the currently recommended maximum residue limits (MRLs) of 0.05 ppm for field corn, 0.05 ppm for popcorn grain and 0.5 ppm for sweet corn kernels plus cob with husks removed are adequate to cover anticipated residues as a result of the approved domestic seed treatment in these commodities. Residues in processed field corn commodities are covered under the recommended MRL for the raw agricultural commodity (RAC). Anticipated residues in meat, milk and eggs from the domestic use of tebuconazole will

be covered under the currently established MRLs for these commodities. Residues of tebuconazole in these crop commodities as a result of the domestic use will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

### **Environmental Assessment**

The active ingredient, tebuconazole, is fully registered as seed treatment fungicide at rates that are equal to the use on corn. The use expansion of Raxil 312 FS as a seed treatment fungicide for use on corn is not anticipated to represent an increase in risk to birds or other non-target organisms. Label amendments are required for consistency with current environmental risk mitigation requirements.

### **Value Assessment**

Four field trials conducted in the USA (TX, NE, CA and KS) in 2005 and 2010 and one field trial conducted in New Zealand in 2006, were submitted to demonstrate the efficacy of Raxil 312 FS for control of head smut on corn and sweet corn. The US trials demonstrated that Raxil 2.6 FS (which has the same formulation as Raxil 312 FS) applied at the rates of 7.5 and 15 g a.i./100 kg seed reduced head smut on field corn. Raxil 2.6 F at 7.5 g a.i./100 kg seed significantly reduced the smut infection by 60% under a moderate level of disease pressure (14% head smut infection), and Raxil 2.6 F at 15 g a.i./100 kg seed reduced head smut by 46 - 100% (average 71%) under moderate to high disease pressure (19 - 57% infection). There was no Canadian commercial standard available in the trials. Raxil 312 FS applied at a rate of 2.5 g a.i./100 kg seed partially suppressed the smut infection in the New Zealand trial.

The following elements were considered in assessing the value information for this application: 1) 80 - 100% disease control was achieved at the proposed high rate (15 g a.i./100 kg seed) under moderate disease pressure in two out of the three US trials; 2) the level of head smut control was relatively low in other trials under severe disease pressure; 3) the rate lower than the proposed provided insufficient control in the New Zealand trial, while rate higher than the proposed rate provided limited increase in the efficacy as demonstrated in two US trials; 4) although head smut is currently a minor disease on corn in Canada and resistant hybrids are available to the growers, an effective management option is needed for disease outbreaks; and 5) there are only pre-mix products of carbathiin and thiram registered for this disease in Canada, therefore, registering Raxil 312 FS for use on corn would provide Canadian growers an alternative product with new mode of action for the control of head smut. The registration of Raxil 312 FS for control of soilborne and seed-borne head smut (*Sphacelotheca reiliana*) in corn is supported.

### **Conclusion**

An evaluation of available scientific information supported the registration of Raxil 312 FS as a seed treatment fungicide to include the control of soil-borne and seed-borne head smut (*Sphacelotheca reiliana*) on corn (sweet corn, field corn, field corn grown for seed, and popcorn).

### **References**

## PMRA

### Document Reference

#### Number

2100788	2011, Occupational exposure and risk assessment for tebuconazole resulting from use of Raxil 312 FS seed treatment formulation on corn in Canada. DACO 5.2, 5.3.
1885209	2010, Observational study to determine dermal and inhalation exposure to workers in commercial seed treatment facilities: Mixing/treating with a liquid pesticide product and equipment clean-out. DACO 5.4, 5.6.
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1965958	2010, Assessment of Bayer laboratory dust-off studies conducted in support of multiple Bayer seed treatment formulation risk assessments. DACO 5.14.
2100777	2011, Raxil 312 FS Seed Treatment Fungicide (tebuconazole) for Control of Soil-borne and Seed-borne Head Smut ( <i>Sphacelotheca reiliana</i> ) on Corn. DACO: 10, 10.1, 10.2, 10.2.2, 10.2.3, 10.2.3.1, 10.2.3.3(B), 10.3, 10.3.1, 10.3.2(A), 10.5.1, 10.5.3.
2119735	2006, Fungicide control of head smut ( <i>Sporisorium reilianum</i> ) of sweetcorn ( <i>Zea mays</i> ). New Zealand Journal of Crop and Horticultural Science, 2006, Vol. 34: 23-26. DACO: 10.2.3.

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