



## Evaluation Report for Category B, Subcategory 3.11 Application

**Application Number:** 2007-3163  
**Application:** B.3.1 (New or Changes to Product Labels-Application Rate Increase)  
B.3.11 (New or Changes to Product Labels-New Pests)  
**Product:** CRUISER 5FS SEED TREATMENT  
**Registration Number:** 27045  
**Active ingredients (a.i.):** Thiamethoxam (THE)  
**PMRA Document Number:** 1574771

### Purpose of Application

The purpose of this application is to add a new pest, corn rootworm (including Western and Northern) to the Cruiser 5 FS Seed Treatment (Reg. No. 27045, 47.6% Thiamethoxam) label for corn.

### Chemistry Assessment

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

### Health Assessments

#### Toxicology:

Cruiser 5FS is of low toxicity to rats via the oral ( $LD_{50}$  between 2000 and 6000 mg/kg) and dermal ( $LD_{50} > 2000$  mg/kg) routes, and of slight toxicity via the inhalation route ( $LC_{50}$  0.5-2.0 mg/L). It is minimally irritating to the eye and skin of rabbits. It is not a dermal sensitizer in guinea pigs.

#### Food Residue Exposure Assessment:

No new data were provided to support the increased rate of thiamethoxam as a seed treatment on corn on the CRUISER 5FS label. Residue data on file support the increase in rate of thiamethoxam as a seed treatment on corn on the CRUISER 5FS label for field corn, sweet corn and popcorn. Residues of thiamethoxam on progeny corn harvested from treated seed are expected to be covered by the established maximum residue limit (MRL) on corn of 0.02 ppm. No increase in dietary exposure is anticipated with the increased rate of corn seed treatment with thiamethoxam on the CRUISER 5FS label.

#### Occupational Exposure:

A surrogate commercial seed treatment exposure study done on canola seed treated thiamethoxam was considered to be an acceptable surrogate study for exposure to workers treating corn seed to control corn rootworm.

Even though estimated margins of exposure (MOEs) for workers treating corn seed at the proposed application rate of 500 g ai/100 kg seed are above the target MOEs, the submitted dust off study indicates that the surrogate study in canola is likely to underestimate exposure to workers treating corn. As such, data is required for workers treating corn seed.

To estimate exposure to workers planting corn seed treated with Cruiser 5FS Seed Treatment intended to control corn rootworm, a surrogate study which was previously submitted to PMRA was used.

To achieve the combined target MOE of 300, mitigation measures are required for workers planting corn seed treated with 500 g thiamethoxam/100 kg corn seed. Loaders and planters must wear cotton coveralls over long sleeved shirts and long pants and chemical resistant gloves plus a respirator during loading and planting of treated corn seed, and the amount of seed that may be planted in a day must not exceed 1000 kg.

#### **Environmental Assessment**

An increase in the rate of Cruiser 5FS seed treatment on corn from 100 g a.i./100 kg seed to 500 g a.i./100 kg seed was found to have potential risk to medium sized birds (e.g. blue jay) and small and medium sized mammals (e.g. mice and rats) for a very short period of time right after planting. To limit these risks, a statement requiring that all seed be buried or disposed of is required on the label. This increase in rate was found to have negligible risk to bees through loss of the treatment coating during planting.

#### **Value Assessment**

Eight trials were submitted to support a control claim for corn rootworm on corn, 5 of which were conducted in Canada at Ridgetown, Ontario, and 3 of which were conducted in the USA (Missouri, South Dakota, and Iowa). These studies tested a range of Cruiser 5 FS application rates, including 125, 150, 500, and 1000 mg ai per 100 kg seed. These studies support an application rate of 500 g ai /100kg seed (not less than 1.25 mg ai per kernel). A clear rate effect was demonstrated for Cruiser 5FS: the 500 g ai/100 kg seed application rate almost always resulted less root damage than lower application rates (e.g., 125 or 250 g ai/100 kg seed). Little to no benefit was seen from increasing the application rate to 1000 g ai/100 kg seed.

The tank mix of Cruiser 5FS and Maxim XL or Maxim 480 FS + Apron XL LS is currently registered on corn, though at rates no higher than the equivalent of 166 mL Cruiser 5FS / 100 kg seed. Therefore, it is reasonable to assume that a higher rate of Cruiser 5FS mixed with Maxim XL or Maxim 480 FS + Apron XL LS will not result in a decrease in the insecticide efficacy.

An application rate of 500 g ai /100 kg seed (not less than 1.25 mg ai per kernel) for control of corn rootworm in corn (field, seed, popcorn, and sweet corn), with a tank mix of Maxim XL or Maxim 480 FS + Apron XL LS is conditionally supported from a value and efficacy perspective.

## Conclusion

The PMRA has completed the assessment of available data and has found the information adequate to conditionally support the addition of corn rootworm (including Western and Northern) to the Cruiser 5 FS Seed Treatment label for corn pending the submission of the following additional scientific information. The applicant must submit the following information by September 30, 2010.

- Small scale field or greenhouse trials demonstrating that the tank-mix of Cruiser 5FS Seed Treatment and Maxim XL does not negatively affect efficacy when applied at the approved rate for corn rootworm.
- Data to estimate exposure to workers treating corn

## References

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