

Evaluation Report for Category B, Subcategory 4.1 Application

Application Number: 2008-0649
Application: Conversion to full registration without consultation.
Product: Helix Liquid Seed Treatment
Registration Number: 26637
Active ingredients (a.i.): Thiamethoxam
PMRA Document Number : 1877690

Background

Helix Liquid Seed Treatment (Registration Number 26637) was first granted temporary registration in 2000 as part of a Workshare review with the USA Environmental Protection Agency. Helix Liquid Seed Treatment contains the technical grade active ingredient Thiamethoxam Technical Insecticide (Registration Number 26665) which was granted temporary registration in 2000. Helix Liquid Seed Treatment and Thiamethoxam Technical Insecticide were converted from temporary to conditional registration in accordance with Subsection 73(4) of the *Pest Control Products Regulations* in order to fulfill the requirements of the new *Pest Control Products Act (PCPA)* in 2007. A detailed review of the seed treatment use can be found in Regulatory Note REG2001-03, *Thiamethoxam – Helix, Helix XTra*.

At the time of initial registration of Helix Liquid Seed Treatment in 2000, the condition of registration was the requirement for the registration status of Thiamethoxam Technical Insecticide to convert to full registration. Therefore, at the time of this application the only condition of registration is the status of the conditionally registered Thiamethoxam Technical Insecticide.

Purpose of Application

The current application is to convert Helix Liquid Seed Treatment from conditional registration to full registration. A similar application has been made for Thiamethoxam Technical Insecticide (application number 2008-0617).

Chemistry Assessment

The product chemistry data for Helix Liquid Seed Treatment were submitted under the original application and assessed to be complete. No additional data were submitted in support of the conversion from conditional to full registration.

Health Assessments

A toxicology assessment was not required as there was no change to the product formulation.

Previously reviewed occupational data, registrant-submitted data, and updated toxicology information have been assessed. The application for conversion from conditional to full registration of Helix Liquid Seed Treatment is acceptable based on the occupational risk assessment for commercial seed treatment facilities worker and post-application handler/planter of treated seed. Use of this agricultural end-use product is acceptable when wearing the personal protective equipment and following the precautions and directions on the label.

As no residue data was submitted with this application, previously reviewed data as well as ERC2007-01 and REG2001-03 were referenced to support the application for full registration of Helix Liquid Seed Treatment. Helix Liquid Seed Treatment will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

During the environmental review of the application for conversion of the technical thiamethoxam and its associated end-use products, new data were reviewed which confirmed that thiamethoxam and its transformation product clothianidin are persistent in the environment. Clothianidin, an insecticide in its own right, is also expected to leach to groundwater. At the proposed application rate and use pattern, there are concerns with the use of Helix Liquid Seed Treatment in regards to toxicity to bees and other non-target arthropods for both thiamethoxam and clothianidin. Due to these concerns, a new study has been requested to establish potential exposure to bees and non-target arthropods.

Value Assessment

Twelve trials conducted in Manitoba and Saskatchewan in 2001 were reviewed to support an extended period of flea beetle control on canola when a higher rate of thiamethoxam was used. The trials demonstrated that both Helix XTra Seed Treatment and Helix Liquid Seed Treatment provide adequate control of flea beetle damage in the early period of plant growth and in areas where levels of flea beetle infestation are low or moderate. Compared with Helix Liquid Seed Treatment, Helix XTra Seed Treatment provided an extended period of protection, particularly in areas with heavy and prolonged flea beetle attack. Based on the evidence originally submitted and the additional efficacy data, the current use claims for Helix Liquid Seed Treatment to control flea beetle on canola and Oriental mustard were supported from an efficacy and value perspective.

Conclusion

The PMRA has completed an assessment of available information for Helix Liquid Seed Treatment. Based on the requirement for additional environmental data requested for the seed treatment products, Helix Liquid Seed Treatment is to continue with conditional registration.

References

List of Studies/Information Submitted by Registrant

- 1571553 Determination of Operator Exposure to Imidacloprid During Loading/Sowing of Gaucho Treated Maize Seeds Under Realistic Field Conditions in Germany and Italy. SGS Institut Fresenius GmbH, Tanunusstein, Germany, Study Number IF-05/00328969. Unpublished.
- 1349637 2000. Commercial Seed Treatment Plant Worker Exposure Study with HELIX 289FS Seed Treatment on Canola. Novartis Crop Protection Canada Inc.
- 1406544 2007, Thiamethoxam (A9765C) - Dust-Off Measurements of Corn Treated with CRUISER 5FS Seed Treatment Insecticide, CER 03290/07, DACO: 5.14,5.2

PMRA Document Number	Reference
1080391	2001, Efficacy Summary / Rationale to support HELIX XTra, DACO: 10.2.3.1
1080393	1001, Efficacy Trials to Support HELIX XTra rationale., DACO: 10.2.3.3
1610615	2008, Thiamethoxam 25 WG Formulation (A9584C): Herbicide Profiling Test to Evaluate the Phytotoxicity to Terrestrial (non-target) Higher Plants, A51197, DACO: 9.8.4
1529809	1998, Assessment of the Side Effects of ACTARA 25WG on the Honey Bee (<i>Apis mellifera</i> L.) After Application on Broad Beans, 982553, DACO: 9.2.4.3,9.2.9
1529851	2007, CGA-355190 - Acute Toxicity to <i>Chironomus riparius</i> Under Static Conditions, T007450-06, DACO: 9.3.4
1529852	2003, Effects of CGA 353042 (Metabolite of CGA 293343) on the Development of Sediment Dwelling Larvae of <i>Chironomus riparius</i> in a Water-Sediment System, 848311, DACO: 9.3.4
1529853	2007, NOA404617 - Acute Toxicity to <i>Chironomus riparius</i> Under Static Conditions, T007454-06, DACO: 9.3.4
1529854	2000, Toxicity Test of NOA-407475 (Metabolite of CGA 293343) on Sediment Dwelling <i>Chironomus riparius</i> (syn. <i>Chironomus thummi</i>) Under Static Conditions, 982580, DACO: 9.3.4
1610615	2008, Thiamethoxam 25 WG Formulation (A9584C): Herbicide Profiling Test to Evaluate the Phytotoxicity to Terrestrial (non-target) Higher Plants, A51197, DACO: 9.8.4

Additional Information Considered

i) Published Information

U.S. EPA, 2003. EFED Risk Assessment for the Seed Treatment of Clothianidin 600FS on Corn and Canola. United States Environmental Protection Agency. DP Barcode 278110.

<http://epa.gov/pesticides/foia/reviews/044309/index.htm>

U.S. EPA, 2004. EFED Registration Chapter for Clothianidin for use on Tobacco, Turf, Applies, Pears and Ornamentals. United States Environmental Protection Agency. DP Barcode 296177 and D287186.

<http://epa.gov/pesticides/foia/reviews/044309/index.htm>

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