

Evaluation Report for Category B, Subcategory 4.1 Application

Application Number: 2008-4386
Application: Conversion to full registration without consultation
Product: Prosper FL Flowable Insecticide and Fungicide Seed Treatment
Registration Number: 27564
Active ingredients (a.i.): Clothianidin, Metalaxyl, Thiram, Carboxin
PMRA Document Number: 1966667

Background

The insecticide active ingredient, clothianidin, and the associated end-use product, Titan ST Insecticide (formerly known as Poncho 600 Seed Treatment Insecticide), were granted temporary registration under Section 17 of the Pest Control Products Regulations in 2004. Regulatory Note REG2004-06, *Clothianidin, Poncho 600 Seed Treatment Insecticide* provides a summary of data previously reviewed, the rationale for the regulatory decision, and the additional studies required as a condition of registration. Prosper FL Flowable Insecticide and Fungicide Seed Treatment is a related end-use product that is registered as a seed treatment for control of flea beetles, seed rot, damping off, seedling blight, early season root rot and seed borne blackleg on canola and rapeseed.

Purpose of Application

The purpose of this application was to convert the end-use product, Prosper FL Flowable Insecticide and Fungicide Seed Treatment, to full registration. Full registration of this product was contingent on pre-requisite applications for conversion to full registration of Clothianidin Technical Insecticide (Application Number 2007-6020) and Titan ST Insecticide (Application Number 2007-6051).

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

In light of the new toxicology data submitted to support conversions to full registration of Clothianidin Technical Insecticide and Titan ST Insecticide, dietary reference doses, toxicological endpoints selected for occupational exposure risk assessment, and factors applied in the risk assessment were reconsidered. These updated values were used to assess the uses of Prosper FL Flowable Insecticide and Fungicide Seed Treatment during the review of the current application.

Commercial seed treatment workers, who mix, load or treat seeds using Prosper FL Flowable Insecticide and Fungicide Seed Treatment as well as workers handling or planting fields with treated seeds, can come in direct contact with Poncho Prosper FL Flowable Insecticide and Fungicide Seed Treatment residues on the skin and by inhalation. Therefore, the label specifies that workers in a commercial seed treatment facility or handling and planting treated seed wear personal protective equipment. Taking into consideration these label statements and the expectation of the exposure period for seed treatment workers and other handlers and planters of treated seed, the risks to these individuals are acceptable when following the listed precautions and directions on the registered label. Bystanders are not expected to be present during seed treatment or sowing. Therefore, health risks to bystanders are not expected.

For any future use expansion request, the registrant must submit an appropriate worker exposure study with closed mix/load transfer, treating system (including mixing, loading, calibrating, treating, clean-up and repair) and current personal protective equipment requirements in order to verify that mitigation measures to protect workers in seed treatment facilities are appropriate.

Environmental Assessment

In the pre-requisite application for conversion to full registration of Titan ST Insecticide, the submitted hive study with honey bees was not acceptable because clothianidin residues were detected in the control hives. Therefore, a new hive study that examines chronic exposure and reports the relevant effects endpoints to honey bees foraging on clothianidin-treated canola is required. A hive study with treated canola seed will serve as surrogate data for all crop seed treatments.

Incident Reports

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the Pesticides and Pest Management portion of Health Canada's website <http://www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/incident/index-eng.php>. Incidents from Canada and the United States were searched and reviewed for products containing the active ingredient clothianidin as of July 15, 2010.

There have been two human health-related incident reports submitted to the PMRA for an end-use product containing clothianidin, and none reported in the United States. The two incidents were classified as minor. In the first incident, a commercial applicator reported experiencing fever and chills after a small amount of an end-use product came into contact with an open wound. This applicator was told to consult a doctor since the symptoms may have been related to an infection unrelated to the product. The second incident involved a commercial applicator experiencing redness, itchy and irritated skin on areas of both arms after opening bags of treated seeds and pouring the seeds into hoppers. These symptoms had resolved by the next day without the need for medical attention. The PMRA concluded that the information from the incident reports did not impact the risk assessment.

The USEPA Ecological Incident Information System (EIIS) contained one incident relating bee mortality to clothianidin exposure which occurred in Germany. It was concluded that it was highly probable that dust-off from the planting of corn seeds treated with Poncho caused massive bee mortality in adjacent fields. In Canada, two voluntary incident reports have been submitted to the PMRA suggesting possible honey bee mortality from exposure to clothianidin. Both of these incidents are currently under review. The PMRA will consider these three incidents and any other reported incidents on honey bees in conjunction with new data requested when this product is reconsidered for full registration.

Detailed information for the human health- and environment-related incidents can be found on the PMRA [Public Registry](#).

Value Assessment

A value assessment was not required for this application.

Conclusion

The PMRA determined that there was insufficient information to support full registration of Clothianidin Technical Insecticide and Titan ST Insecticide in the pre-requisite applications. Although the risks and value have been found acceptable when all risk reduction measures are followed, the registrant must submit a new honey bee hive study as a condition of registration. Therefore, the conversion to full registration of Prosper FL Flowable Insecticide and Fungicide Seed Treatment was not supported.

References

List of studies/information submitted by registrant

PMRA Document Number: 1464602

Reference: 2007, Clothianidin stewardship program report for 2004, 2005 And 2006, Data Numbering Code: 5.14

PMRA Document Number: 1464606

Reference: 2005, An investigation of the potential long-term impact of clothianidin seed treated canola on honey bees, *Apis mellifera* L., Data Numbering Code: 9.2.4.3

PMRA Document Number: 1464608

Reference: 2006, Spring 2006 assessment of overwintered colonies studied in an investigation of the potential long-term impact of clothianidin seed treated canola on honey bees, *Apis mellifera* L., Data Numbering Code: 9.2.4.3

PMRA Document Number: 1565990

Reference: 2003, Foreign review of dermal penetration study in monkey, Data Numbering Code: 5.8

Additional information considered

PMRA Document Number: 1734574

Reference: PMRA, 2009, Human incident report no. 2009-0792 for Poncho 600 FS or Prosper FL, Data Numbering Code: 4.8, 5.14

PMRA Document Number: 1874470

Reference: PMRA, 2010, Human incident report no. 2010-1001 for Prosper FL, Data Numbering Code: 4.8, 5.14

PMRA Document Number: 1932503

Reference: PMRA, 2010, Environmental incident report no. 2010-3100 for thiamethoxam and clothianidin, Data Numbering Code: 9.9

PMRA Document Number: 1938308

Reference: 2008, Environmental incident no. I019743-001 for clothianidin in the United States, Data Numbering Code: 9.9, 12.5.9

PMRA Document Number: 1938727

Reference: PMRA, 2010, Environmental incident report no. 2010-3391 for clothianidin, Data Numbering Code: 9.9

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