

Evaluation Report for Category B, Subcategory 4.2 Application

Application Number: 2013-5131
Application: Renewal without consultation
Product: Actara 25WG Insecticide
Registration Number: 28408
Active ingredients (a.i.): Thiamethoxam
PMRA Document Number : 2481889

Background

Actara 25WG Insecticide (Registration Number 28407) was first registered for foliar use in Canada in 2006. During the original review, Actara 25WG Insecticide was conditionally registered based on data requirements for the technical, Thiamethoxam Technical (Registration Number 26665), as well as the requirement to provide additional data to assess environmental exposure of Actara 25WG Insecticide to terrestrial plants and bees under field conditions.

During subsequent applications (2008-0617 and 2008-0620) for conversion from conditional to full registration, data/information was submitted which satisfied the original conditions of registration. While the evaluation of the pollinator data did not indicate any risks of concern, additional confirmatory environmental data were required for the end-use product. As such, the current environmental data required for Actara 25WG Insecticide include: A new hive study and data on the residues of thiamethoxam and its major metabolite clothianidin in pollen and nectar of terrestrial plants.

During the course of the pollinator study reviews for thiamethoxam, a new harmonized pollinator risk assessment framework was under development. This new framework is a more scientifically robust framework that is designed to address impacts on pollinators (adult, larvae and hive health) from multiple exposure pathways. The new framework includes a tiered approach to pollinator risk assessment (Tier I (laboratory studies), Tier II (semi-field and residue studies), and Tier III (field studies)), and is now being used by both the PMRA and US EPA for all new chemicals. The new guidance for the harmonized pollinator risk assessment was posted on the Health Canada Website in June 2014.

In order to conduct pollinator assessments according to the new framework, the PMRA and US EPA announced the re-evaluation of clothianidin and thiamethoxam in June 2012 (REV2012-02, *Re-evaluation of Neonicotinoid Insecticides*) and requested additional studies. A status update was provided in REV2013-15, *Re-evaluation Update for Neonicotinoid Insecticides*.

Purpose of Application

The purpose of this application was to extend Actara 25WG Insecticide's registration validity period in order to allow time for the registrant to generate the necessary data to address the

remaining conditions of registration.

Chemistry, Health and Value Assessments

Chemistry, health and value assessments were not required for this application.

Environmental Assessment

A number of residue and toxicity studies have been submitted, while others are ongoing, and will be submitted to the PMRA upon completion. The registrant continues to work cooperatively with the PMRA, the US EPA and the California Department of Pesticide Regulation to develop study protocols that will best address the remaining data requirements.

To date, none of the submitted studies that have been reviewed have indicated any areas of risk concern that would trigger additional regulatory action beyond a requirement to submit additional studies.

To facilitate the PMRA conducting a more comprehensive environmental review, the PMRA supports the extension of registration of Actara 25WG Insecticide.

Conclusion

The PMRA granted an extension to the conditional registration of Actara 25WG Insecticide to December 31, 2016, as well, the due date for all outstanding data requirements is now September 1, 2016. These timelines are aligned with those of all the other thiamethoxam containing end-use products.

References

None

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