

Evaluation Report for Category B, Subcategory 4.2 Application

Application Number: 2013-5132
Application: Renewal without consultation
Product: Actara 240SC Insecticide
Registration Number: 28407
Active ingredients (a.i.): Thiamethoxam
PMRA Document Number : 2481912

Background

Actara 240SC Insecticide (Registration Number 28408) was first registered for in-furrow use in Canada in 2006. During the original review, Actara 240SC Insecticide was conditionally registered based on data requirements for the technical, Thiamethoxam Technical (Registration Number 26665).

During subsequent applications (2008-0617 and 2008-0622) for conversion from conditional to full registration, data/information was submitted which satisfied the original conditions of registration. However, additional confirmatory environmental data were required for the end-use product. As such, the current environmental data required for Actara 240SC Insecticide include: A new hive study as well as 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 240SC Insecticide's registration validity period in order to allow time for the registrant to generate 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 comprehensive environmental review, the PMRA supports the extension of registration of Actara 240SC Insecticide.

Conclusion

The PMRA granted an extension to the conditional registration of Actara 240SC 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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