

Section 12 Notice **Additional Information Required to Fulfill the Terms and Conditions for Conditional Registration**

Product Name: Clutch 50 WDG Insecticide

Registration Number: 29382

Application Number: 2012-1069

PMRA # : 2282100

During the conditional registration period which has been granted to **December 31, 2015**, the following information is to be generated and must be provided to the Pest Management Regulatory Agency by **September 1, 2015** and should indicate the DACO numbers specified. A partial response to the outlined Terms and Conditions will not be accepted.

PART 8 ENVIRONMENTAL CHEMISTRY AND FATE

DACO: 8.3.2.3
Title: Other Terrestrial field dissipation study

Details: Laboratory studies indicate that Clothianidin may be classified as having a medium to high mobility in soil. However, no adequate terrestrial field dissipation studies were submitted to validate these observations. Note that the available lysimeter studies have been conducted with seed treatment formulations and, therefore, a Lysimeter study conducted in coarse textured soil with a WDG formulation is required.

DACO: 8.5
Title: Fate of Clothianidin in plants, including concentrations in nectar and pollen.

Details: A potential risk to bees has been identified and this data is required to refine the risk assessment and determine the potential risk. The available environmental fate data for clothianidin indicates that the chemical is persistent and systemic and has the potential to accumulate in soils from year to year with repeated uses. New studies are required to generate the data necessary to characterize the potential exposure of pollinators to translocated Clothianidin in nectar and pollen resulting from spray applications. The applicant is required to discuss the protocol with the PMRA before starting of the study which determines the concentration of nectar and pollen in plants (plant fate study).

DACO:**9.2.4.3****Title:****Hive study (field)****Details:**

The EAD has identified a potential chronic risk to bees. In order to refine this risk, fate and toxicity data are required.

During the original review of the seed treatment use of Clothianidin (REG2004-06_revision), the EAD had identified data gaps linked with the potential of toxic exposure of non-target pollinators to residues of Clothianidin from the pollen and nectar of treated seeds. This triggered a requirement for field testing (DACO 9.2.4.3) to evaluate the possible chronic exposure to honey bee larvae and queen. The study submitted to fulfill this data requirement was deemed unacceptable.

This data is also required for the assessment of the spray applications uses proposed for Clothianidin, as it is expected that such uses will also lead to the translocation of Clothianidin residues into pollen and nectar.

To date, no valid Hive studies have been submitted to the PMRA. This represents a critical data gap in the risk assessment of Clothianidin.

A new study is required to address the toxicity of Clothianidin to bees. This study must be designed to characterise the fate of Chlothianidin under field conditions, as well as chronic toxicity of Clothianidin to bees. The applicant is required to discuss the protocol with the PMRA before starting of the study.