

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

***Product Name: PONCHO 600 SEED TREATMENT INSECTICIDE***

***Registration Number: 27449***

***Application Number: 2006-7235***

***PMRA #: 1443616***

During the conditional registration period which has been granted to December 31, 2008, the following information is to be generated and must be provided to the Pest Management Regulatory Agency by **June 1, 2008**, and must indicate the DACO numbers specified. A partial response to the outlined Terms and Conditions will not be accepted.

### **PART 5                                      EXPOSURE (OCCUPATIONAL AND/OR BYSTANDER)**

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**The applicant is in the process of addressing the Exposure data requirements through a Product Stewardship Program. The results of this program will determine if the applicant will need to submit a chemical specific exposure study.**

**DACO                                      5.4/5.5 (OECD IIIA 7.3.3)/(OECD IIIA 5.8, IIIA 7.3.3)**  
**Title:                                      Mixer/Loader/Applicator - Passive Dosimetry or Biological Monitoring**

**Required DATA:                      Passive Dosimetry: studies that estimate the amount of a chemical depositing on the surface of the skin or clothing and the amount of the chemical available for inhalation. Refer to the *OECD Guidance Document for the Conduct of Studies of Occupational Exposure to Agricultural Pesticides* or the US/EPA's *OPPTS Test Guideline Series 875 - Occupational and Residential Exposure Test Guidelines: Group A - Applicator Exposure Monitoring Test Guidelines* (formerly Subdivision U).**

**Biological Monitoring: Since biological monitoring uses urine or other biological matrices to measure exposure, the toxicokinetics of the compound must be well-understood prior to conducting biological monitoring studies.**

**NOTE: This requirement may be waived based on the results of the Product Stewardship Programme.**

**DACO:** 5.14  
**Title:** Other - Product Stewardship Programme

**NOTE:** Risk levels for seed treatment workers are anticipated to improve with additional measures to reduce exposure potential (eg. additional Personal Protective Equipment; closed mix/load systems; product stewardship programme).

**Required DATA:** The comprehensive report, including the program outline, presentation material and result of plant audits.

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**PART 7 FOOD, FEED AND TOBACCO RESIDUE STUDIES**

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**DACO:** 7.4.4 (OECD Annex IIIA, Point 8.6)  
**Title:** Field Crop Rotation Study

**Required DATA:** Submission of two rotational crop field trials showing residues of clothianidin and the TZNG metabolite in mature soybeans are each less than LOQ (0.01 ppm) using the LC-MS/MS enforcement method. The petitioner should also include information pertaining to the weather conditions (temperature and rainfall) over the course of the study and the soil types at the field trial sites.

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**PART 8 ENVIRONMENTAL CHEMISTRY AND FATE**

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**DACO:** 8.3.4  
**Title:** Special studies of environmental fate (A prospective groundwater monitoring study (PGW) with a study protocol submitted prior to the conduct of the study).

**Required DATA:** None at this time

**NOTE:** As an interim measure, the following study is required in lieu of the PGW study to refine estimates of the amount of clothiandin likely to leach to groundwater. If these refinements are insufficient to reduce concern about clothiandin leaching to the groundwater, then a PGW study may be required.

**DACO:** 8.5  
**Title:** Seed leaching study

**Required DATA:** A greenhouse study to assess the leaching of clothiandin out of the seed coating, leaching in the seed column and uptake by a corn seedling is required. Soil (at different depths) and plant (both shoot and root) samples should be analyzed at different intervals until plant maturity, to determine the fate and movement of clothiandin and its

transformation products. As this study will evaluate the leaching potential of clothianidin, enough moisture should be added to provide the downward water movement equivalent to a wet field season.

**PART 9 ENVIRONMENTAL TOXICOLOGY**

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**DACO:** 9.2.4.3  
**Title:** Hive study

**Required DATA:** The full study on the chronic toxicity of clothianidin to hives of honey bees under field conditions are required. Note that the PMRA previously reviewed and commented on the protocol.

**DACO:** 9.6.5  
**Title:** Field studies

**Required DATA:** The full study on the toxicity of clothianidin, when used for treatment of corn seed, to wild birds under field use conditions is required.