

**Section 12 Notice** Additional Information Required to Fulfill the Terms

and Conditions for Conditional Registration

Product Name: WOCOSEN 100SL

Registration Number: 24514 Application Number: 2006-7612 PMRA #: 1437591

During the conditional registration period which has been granted to *December 31*, 2009, the following information is to be generated and must be provided to the Pest Management Regulatory Agency by *December 31*, 2008 and should indicate the reference numbers specified. A partial response to the outlined Terms and Conditions will not be accepted.

PART 4 TOXICOLOGY

DACO: 4.5.12

Title: Acute Neurotoxicity Study (rat)

**Required DATA:** The acute neurotoxicity study requested by the US EPA should also

be submitted to the PMRA.

PART 5 EXPOSURE (OCCUPATIONAL AND/OR BYSTANDER)

**DACO:** 5.4 and 5.6

Title: Mixer/Loader/Applicator, Post-Application - Passive Dosimetry

**Required DATA:** Exposure estimates for spray and coat treatment operators (chemical

operators), cleanup crew and maintenance/repair workers (millwrights) must be refined. The PMRA recommends the registrant generate

product-specific and site-specific (i.e. joinery facilities) passive dosimetry

data for these workers.

Refer to the OECD Guidance Document for the Conduct of Studies of Occupational Exposure to Agricultural Pesticides or the EPA's OPPTS Test Guideline Series 875 - Occupational and Residential Exposure Test Guidelines: Group A - Applicator Exposure Monitoring Test Guidelines (formerly Subdivision U) for details on conducting these types of studies. Prior to study generation, the applicant must submit protocols to the PMRA for comment.



**DACO:** 5.8

Title: Dermal Absorption

Required DATA: If available, Janssen should submit the following dermal

absorption studies:

Hassler, S. 2000. The in vitro percutaneous absorption of [Phenyl-U-14] CGA 64250 formulated as TILT 250 EC (A-6097 K) through rat and human epidermis. Novartis Crop Protection AG, Basel, Switzerland. Study Report No. 044AM02, 04.01.2000 GLP, not published. Novartis File N\* CGA64250/4276.

Hassler, S. 2000. Dermal absorption of [Phenyl-U-14C] CGA 64250 formulated as Tilt 250 EC (A-6097 K) in the rat. Novartis Crop Protection AG, Basel, Switzerland. Study Report No. 044AM01, 09.02.2000 GLP, not published. Novartis File N\* CGA64250/4292.