

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

Product Name: SYLVANEX FLAKES

Registration Number: 27560

Application Number: 2006-7973

PMRA #: 1443936

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 **September 1, 2008**, and must indicate the DACO numbers specified. A partial response to the outlined Terms and Conditions will not be accepted.

PART M2 PRODUCT CHARACTERIZATION AND ANALYSIS

DACO: M2.11
Title: Storage Stability Testing

Required DATA: Additional storage stability data are required to ensure product performance. Such data must include lots which are analyzed intermittently over a suitable period of time determined by the applicant. Storage stability testing must be conducted on batches stored under expected operational conditions (e.g., 25°C). Other storage temperatures must also be considered. In order to minimize variability, a homogenization step must be included in the protocol for determining potency of the active microorganism in Sylvanex preparations.

PART M4 HUMAN HEALTH AND SAFETY TESTING

DACO: M4.4
Title: Acute Dermal Toxicity/Pathology

Required DATA: A replacement study is required, with the end-use product (Sylvanex Flakes) as the test material, applied at a dose of 2g/kg body weight, as specified in the U.S. EPA Microbial Pesticide Test Guidelines OPPTS 885.3100 *Acute Dermal Toxicity/Pathology*.

DACO:**M10.2.3.4****Title:****Operational Trials****Required DATA:**

1. Research permit 49-RP-02 was granted in 2002 to test Sylvanex on red pine and white pine. The report from this research permit is required. The final report must include all raw data and details of trial protocol. If research permit 49-RP-02 was not conducted, the applicant will have to generate the data.
2. An operational trial must be conducted on black spruce. Other commercially important wood species may be tested as well. This trial must be conducted according to the previously submitted 2001 Alberta trial protocol.