

Section 12 Notice

Additional Information Required to Fulfill a Condition of Registration

Product Name: Disparvirus Nuclear Polyhedrosis Virus for Gypsy Moth Larvae
Registration Number: 24869
Application Number: 2010-6341
PMRA #: 2970756
Date of Issuance: March 26, 2019

The information specified below is required to be submitted to the PMRA in accordance with section 12 of the *Pest Control Products Act (PCPA)* within three months of the next production run following January 1, 2019.

PART 0 INDEX

DACO: 0
Title: Index

Required Data: Please submit an electronic index of the data package submitted in response to this letter. Please refer to *Regulatory Directive 2006-05, Requirements for Submitting Data Index, Documents and Forms*, for additional information.

PART 3 CHEMISTRY REQUIREMENTS FOR THE REGISTRATION OF MANUFACTURING CONCENTRATES AND END-USE PRODUCTS FORMULATED FROM REGISTERED TECHNICAL GRADE OF ACTIVE INGREDIENTS OR INTEGRATED SYSTEM PRODUCTS

DACO: 0.1.6003
Title: Control Product Specification Form

Required Data: The registrant is required to submit a new Statement of Product Specification Form (SPSF) for Disparvirus[®] Nucleopolyhedrovirus For Gypsy Moth Larvae indicating the New Brunswick address of the manufacturing site for Sylvar Technologies Inc.

PART M2

PRODUCT CHARACTERIZATION AND ANALYSIS

DACO: M2.9.2
Title: Potency Estimation and Product Guarantee

Required Data: **Submission of confirmation data of potency of the end-use product by a physical count (PIBs per unit of weight) must be submitted within three months of the start of the next production.**

DACO: M2.10.2
Title: Analysis for Microbial Contaminants

Required Data: **Submission of batch analysis data on all production runs, confirming the absence of human pathogens and that the level of microbial contamination is at an acceptable level, is required.**