



Conditional Registration on the subject product which is contingent on the conditional registration on the associated technical grade active ingredient. Evaluation Report for Category B, Subcategory B.2.1. (new guarantee), B.2.3. (new formulants), B.2.4-S-N-EP (new proportion of formulants) Application

Application Number: 2004-4220
Application: Category B, Subcategory B.2.1. (new guarantee), B.2.3. (new formulants), B.2.4-S-N-EP (new proportion of formulants) Application
Product: Spinosad 0.5% SC Naturalyte Insect Control Product
Registration Number: 28602
Active ingredients (a.i.): spinosad at 0.5%
PMRA Document Number: 1412622

Purpose Of Application

The purpose of this application is to register a new spinosad insecticide with the following amendments: i) a new guarantee, ii) new formulation and iii) new proportion of formulants. Spinosad 0.5% SC Naturalyte Insect Control Product is intended for the control of various insect pests as a post-emergence application on turfgrass, outdoor ornamentals, fruits and vegetables. The requested use pattern is similar to that of Success 480 SC Naturalyte Insect Control Product (Registration No. 26835; 480 g/L spinosad), Conserve 120 SC Naturalyte Insect Control Product (Registration No. 27278) and Conserve 120 SC Domestic Naturalyte Insect Control Product (Registration No. 27285) and Entrust 80 W Naturalyte Insect Control Product (Registration No. 27825; 80% spinosad).

Chemistry Assessment

Spinosad 0.5% SC Naturalyte Insect Control Product is a solution containing the active ingredient spinosad at a nominal concentration of 0.5%. This product has a density of 1.06 - 1.1 g/mL and pH of 6.0 - 9.0. The chemistry requirements for this product have been completed.

Health Assessment

A waiver has been provided in place of the acute toxicity studies required to support this application. At this time, the rationale is adequate to waive the acute toxicity data requirements for the proposed product. In the absence of acute toxicity data for the proposed product, the acute toxicity profile of technical grade Spinosad will be used for labelling purposes. Technical spinosad is considered to be of low acute toxicity by the oral ($LD_{50} > 2.0$ g/kg bw), dermal ($LD_{50} > 2.0$ g/kg bw) and inhalation ($LC_{50} > 5.2$ mg/L) routes. It is non-irritating to the skin and minimally irritating to the eyes of rabbits. It is not a dermal sensitizer in guinea pigs.

The registration of Spinosad 0.5 % SC Naturalyte Insect Control Product is acceptable from a residential exposure perspective. Exposure to residential handlers and bystanders resulting from the proposed use is not expected to exceed that for the currently registered use pattern for spinosad.

Residues of spinosad (spinosyn A and spinosyn D) on treated crops resulting from the use of Spinosad 0.5% SC Naturalyte Insect Control Product are expected to be covered by the maximum residue limits (MRLs) (established or in the process of promulgation) for spinosad as the use patterns for all crops/crop groups on the product label, including the rates and PHIs, are essentially identical to a similarly registered use product. As such, exposure of all population subgroups to residues of spinosad through food and water will not increase.

Environmental Assessment

No environmental studies were required to support registration of Spinosad 0.5% SC since it belongs to the same chemical class as, and has the same use pattern as Entrust 80W Naturalyte Insect Control Product (PCP No. 27825). In addition, Success 0.5%SC does not contain any formulants of concern. Therefore, no additional impact to the environment is expected from use of Spinosad 0.5% SC

Value Assessment

Several different formulations of spinosad [Conserve 480 SC (Reg. No. 26834, 480 g/L spinosad), Success 480 SC (Reg. No. 26835, 480 g/L spinosad) Conserve 120 SC (Commercial Reg. No. 27278, Domestic Reg. No. 27285, 120 g/L spinosad), and Entrust 80 W (Reg. No. 27825, 80% spinosad)] were previously registered for sale and use in Canada, and are considered to have comparable efficacy when applied at equivalent application rates of the active ingredient spinosad. The use patterns and application rates for Spinosad 0.5% SC are equivalent to those for Success 480 SC (which has the broadest use pattern of the spinosad-based products registered in Canada), and therefore efficacy is expected to be comparable. Spinosad 0.5% SC contains a very low concentration of active ingredient, with proportionately larger amounts of various other formulants, but has been marketed in the United States for several years (EPA Reg. No. 62719-314, first registered in 1999) with no reports of phytotoxicity.

Conclusions

The agency has completed an assessment of available information for Spinosad 0.5% SC Naturalyte Insect Control Product and has found it sufficient to allow for conditional registration, with full registration being contingent upon fulfilling the following requirements: Conversion of the registration of Spinosad Technical Insecticide (Registration No. 26833) from conditional to full registration.

Reference List

A. List of Studies/Information Submitted by Registrant

Chemistry Assessment

- PMRA No. 954507 Product Identification., Dow AgroSciences Canada Inc, DACO: 3.1
- PMRA No. 954508 Group A: Product Identity, Composition, and analysis for Spinosad 0.5% SC, a Suspension Concentrate Formulation Containing 0.5% Spinosad Insecticide. 118 pages., Dow AgroSciences LLC, NAFST822., DACO: 3.2,3.3.1,3.4.1
- PMRA No. 1109709 2005, Storage Stability and Package Corrosion Characteristics of GF-1418: Accelerated and One-Year Study, Dow AgroSciences LLC, FOR-05-002, MRID: N/A, DACO: 3.5.10
- PMRA No. 1347374 2006, Storage Stability and Package Corrosion Characteristics of NAF-371: One-Year Study, Dow AgroSciences LLC, FOR-05-021, MRID: N/A, DACO: 3.5.10

Environment Assessment

None.

Health Assessment

None.

Value Assessment

None.

B. Additional Information Considered

i) Published Information

Chemistry Assessment

None.

Environment Assessment

None.

Health Assessment

- PMRA# 649920. PMRA Regulatory Note REG2001-10, August 17, 2001. Spinosad Success™ 480SC Naturalyte Insect Control Product Conserve™ 480SC Naturalyte Insect Control Product.

Value Assessment

None.

ii) Unpublished Information Considered

Chemistry Assessment

None.

Environment Assessment

None.

Health Assessment

None.

Value Assessment

None.

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services
Canada 2007

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.