

Category B Evaluation Report

Application Number: 2006-5101
Application: Application category B, subcategory: 1.3 (new source by the current registrant and specifications or manufacturing process)
Product: Thiophanate-Methyl Technical Fungicide
Registration Number: 22710
Active ingredients (a.i.): Thiophanate-Methyl Technical at 98.3%
PMRA Document Number: 1448767

Background

The original source of thiophanate-methyl technical grade active ingredient, “Thiophanate-Methyl” (Reg. No. 22710) was first registered in 1973.

Purpose of Application

The purpose of this submission is for the amendment of the guarantee for Thiophanate-Methyl Technical from minimal to nominal. The guarantee is expressed minimally and reads 95% on the current label. The Registrant is requesting that the guarantee be changed to 98.3%, which would be expressed nominally. Thiophanate-Methyl Technical Fungicide is not an item of commerce, but is the active ingredient used in the end-use products: Senator 70WP (PCP #25343), Senator 70WP1 (PCP #12279), Senator 70WP WSB1 (PCP #27297), Senator PSPT (PCP #26236), Senator MUP (PCP #27539) and Senator PSPT1 (PCP #14599).

For specific details of uses, application rates and methods, precautions, restrictions, and personal protective equipment requirements, refer to the product label.

Chemistry Assessment

Common Name: Thiophanate-methyl
IUPAC Chemical Name: Dimethyl 4-4' - (o-phenylene)bis(3-thioallophanate)
CAS Chemical Name: Dimethyl [1,2-phenylenebis(iminocarbonothioyl)]bis[carbamate]

Thiophanate-methyl Technical Fungicide has the following properties:

Property	Result
Colour and physical state	white to light tan powder
Nominal concentration	98.3%
Odour	Faint sulphur
Density	1.4 - 1.6 g/cm ³
Vapour pressure	6.6 x 10 ⁻⁸ mmHg
pH	5.0-8.0
Solubility in water	practically insoluble
n-Octanol/water partition coefficient	12.8

The chemistry requirements for Thiophanate-Methyl Technical Fungicide are complete.

Health Assessment

No toxicological data were required since results from the chemistry review confirmed the identity of the active ingredient and supported a 98.3% nominal concentration on the label. As there was no change in the site of manufacture or the manufacturing processes for this active ingredient, the toxicology profile of Thiophanate-Methyl Technical Fungicide is not expected to change.

The request to amend the guarantee of Thiophanate-methyl Technical Fungicide (Reg. No. 22710) is not expected to alter the residues in food and feed crops treated with end-use products containing Thiophanate-methyl Technical Fungicide (Reg. No. 22710). Therefore, no increase in dietary exposure to thiophanate-methyl is anticipated.

Environmental Assessment

An environmental assessment was not required since the use pattern, including host crops, application rates and timings remained unchanged and the chemical properties of Thiophanate-Methyl Technical Fungicide were confirmed during the chemistry assessment.

Value Assessment

A value assessment is not required for technical grade active ingredient products.

Conclusions

The PMRA has completed an evaluation of the subject application and has determined that Thiophanate-Methyl Technical Fungicide is eligible for registration, with a nominal guarantee of 98.3% a.i.

References

Studies/Information Provided by Applicant/Registrant

- 1291282 2006, Product Chemistry DACO 2.1 to 2.10 for Thiophanate-methyl, E20060001-R, MRID: N/A, DACO: 2.1,2.10,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9
- 1291287 2006, Submission of Samples of Analytical Standards and Residues of Concern of Thiophanate-methyl, E20060008-R, MRID: n/a, DACO: 2.15

ISSN: 1911-8082

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