

Evaluation Report for Category B, Subcategory 2.3, 2.4, 2.5, 3.1, 3.10 Application

Application Number: 2014-0639
Application: New End-Use Product – Identity and proportion of formulants, formulant type, application rate increase or decrease, tank mixes
Product: Thiophanate-Methyl 500 SC Fungicide
Registration Number: 31784
Active ingredients (a.i.): Thiophanate-methyl
PMRA Document Number: 2634327

Purpose of Application

The purpose of this application was to register a new commercial end-use product, Thiophanate-Methyl 500 SC Fungicide (guarantee 500 g/L thiophanate-methyl), for use on a variety of crops, ornamentals (greenhouse and outdoor), turf and trees to control various fungal diseases.

Chemistry Assessment

Thiophanate-Methyl 500 SC Fungicide is formulated as a suspension concentrate containing thiophanate methyl at a nominal concentration of 500g/L. This end-use product has a density of 1.197 g/cm³ and pH of 5.8 – 6.2. The chemistry requirements for this product have been fulfilled.

Health Assessments

Thiophanate-Methyl 500 SC Fungicide was of moderate acute toxicity via the oral route, slight acute toxicity via the inhalation route and low acute toxicity via the dermal route in the rat. It was minimally irritating to the eye and skin of rabbits. It is not a dermal sensitizer in guinea pigs.

New residue data from field trials conducted in the United States, and including growing regions representative of Canada, with three different formulations of thiophanate-methyl were submitted to support the domestic registration of the new end-use product Thiophanate-Methyl 500 SC Fungicide on various crops in Canada. Thiophanate-methyl, formulated as a wettable powder, flowable liquid (equivalent to a soluble concentrate) or water dispersible granules, was applied to cherries, cucumbers and watermelons at rates similar to or higher than the Canadian use pattern, and harvested according to label directions (preharvest intervals (PHI) ≤ 7 days). Residue levels of thiophanate-methyl and the metabolite carbendazim present in/on treated samples from trials conducted with each formulation were quantitated and compared in order to assess the formulation equivalency. These data were found to be adequate to support the registration of Thiophanate-Methyl 500 SC Fungicide.

Based on the review of all available data, residue levels of thiophanate-methyl and carbendazim (metabolite MBC) found in/on food commodities treated with the proposed new formulated product Thiophanate-Methyl 500 SC Fungicide are not expected to increase over the levels observed with currently registered products and will be covered by the established MRLs for thiophanate-methyl and carbendazim. Hence, the dietary exposure to thiophanate-methyl and carbendazim is not expected to pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

The use of the new end-use product Thiophanate-Methyl 500 SC Fungicide on listed crops and sites is not expected to result in potential occupational and non-occupational exposure over the registered use of thiophanate-methyl. No risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

Environmental Assessment

No additional risk to the environment is expected from the use of this product compared to other registered uses of thiophanate-methyl. Environmental concerns have been mitigated through adequate statements on the product label.

Value Assessment

No efficacy trials were submitted for this application. The registrant provided two rationales to waive the value data requirements for the use of Thiophanate-Methyl 500 SC Fungicide and additional tank mix uses. The active ingredient thiophanate methyl in 500 SC formulation is currently registered and used in many countries around the world. For the value assessment, it was recognized that thiophanate methyl is an old fungicide active ingredient widely used as a systemic fungicide with both curative and preventative activities. End-use products containing thiophanate methyl are formulated into various formulations, and the SC formulation has the advantage of ease and speed of mixing compared to the WP formulation. The same use patterns and rates of active ingredient that were accepted for Thiophanate-Methyl 500 SC Fungicide are comparable to what is registered in other thiophanate methyl products in Canada. Although efficacy assessments have not been conducted in each country where pesticides are registered; however, many jurisdictions require the registrant to provide the evidence of product performance against the target pests. Therefore, the world-wide acceptance of SC formulation of thiophanate methyl would also provide support to register Thiophanate-Methyl 500 SC in Canada. Registering the SC formulation will ensure a stable supply of thiophanate methyl products to Canadian growers in the event the wettable powder is no longer produced or available.

Based on the rationales provided and other available information, the efficacy of thiophanate methyl formulated as Thiophanate-Methyl 500 SC Fungicide is unlikely to be affected by the formulation change, compared with the currently registered thiophanate methyl products in Canada. All use claims are supported as proposed.

Conclusion

The PMRA has completed a review of all available information for Thiophanate-Methyl 500 SC

Fungicide and found it sufficient to support a full registration.

References

PMRA Document Number	Reference
2394969	2014, Rationale to Waive Requirement of Efficacy and Crop Tolerance Data for the Thiophanate-Methyl 500 SC Fungicide, DACO: 10.1
2407115	2014, Rationale to Waive Requirement of Efficacy Data for the Thiophanate-Methyl 500 SC Fungicide tankmixed with Captan or Thiram, DACO: 10.1
2394955	2013, Thiophanate Methyl 4.1 SC Fungicide: Product Identity, Composition, and Analysis. DACO: 3.1, 3.2, 3.3.1, 3.4, CBI
2394956	2012, Certificate of Analysis, including Development and Validation of an Analytical Method for the Determination of the Content of Thiophanate-Methyl in the Formulation Thiophanate-Methyl 500 SC. DACO: 3.4.1, 3.4.2, CBI
2394957	1994, Physical and Chemical Properties Report for Cercobin FL - BAS 325 10F. DACO: 3.5.1, 3.5.10, 3.5.11, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.9, CBI
2394958	2004, Topsin 50% SC: Determination of Accelerated Storage Stability and Physicochemical Characteristics. DACO: 3.5.1, 3.5.10, 3.5.12, 3.5.14, 3.5.2, 3.5.3, 3.5.7, 3.5.8, CBI
2394959	1997, Shelf Life in Original Container of BAS 325 10F Physical Properties Report [24-month-storage]. DACO: 3.5.1, 3.5.10, 3.5.12, 3.5.14, 3.5.2, 3.5.3, 3.5.7, 3.5.8, CBI
2470382	2014, Nippon Soda's Response to PMRA Clarification Request Regarding the Thiophanate Methyl 500 SC Registration Application. DACO:1.1.1, 3.2, 3.3.1, CBI
2394960	2013, Thiophanate-Methyl 500 SC Fungicide: Acute Oral Toxicity Up and Down Procedure in Rats, DACO: 4.6.1
2394961	1988, Report on the Study of Acute Dermal Toxicity on the Rat Based on OECD and EPA (FIFRA) of BAS 325 10 F, DACO: 4.6.2
2394962	1989, Report on the Study of Acute Inhalation Toxicity L50 of BAS 325 10 F, as a Liquid Aerosol in Rats, 4-hour Exposure, Based on OECD, DACO: 4.6.3
2394963	1988, Report on the Acute Irritation to the Eye of the White Rabbit Based on OECD of BAS 325 10 F, DACO: 4.6.4
2394964	1988, Report on the Acute Dermal Irritation/Corrosively to the Intact Dorsal Skin of the White Rabbit Based on OECD of BAS 325 10 F, DACO: 4.6.5
2394966	2012, Skin Sensitization Study of Thiophanate-methyl 500SC In Guinea Pigs (Maximization Test), DACO: 4.6.6
2394968	2013, Use Description/Scenario (Application and Post Application) for Thiophanate-Methyl 500 SC Fungicide, DACO: 5.2
2502109	2014, Clarification Response for Proposed Use Pattern of Thiophanate-Methyl 500 SC Fungicide, DACO: 5.2
1530432	2003, Stability of Thiophanate Methyl in Soybean Seed during Frozen Storage Pending Analysis, DACO: 7.3
1530435	2003, Stability of Thiophanate Methyl in Wheat Grain during Frozen Storage Pending Analysis, DACO: 7.3

1530436	2005, Stability of Thiophanate Methyl in Sugar Beets during Frozen Storage Pending Analysis, DACO: 7.3
1530437	2003, Stability of Thiophanate Methyl in Snap Beans during Frozen Storage Pending Analysis, DACO: 7.3
1530438	2002, Stability of Thiophanate Methyl in Cucumbers during Frozen Storage Pending Analysis, DACO: 7.3
2394967	2014, Rationale to Waive Requirement of Residue Data for the Thiophanate-methyl 500 SC Fungicide, DACO: 7.1, 7.2.1, 7.3, 7.4.1, 7.4.2. 7.4.5
2394968	2013, Use Description/Scenario (Application and Post Application) for Thiophanate-Methyl 500 SC Fungicide, DACO: 5.2
2432575	2002, Comparison of Thiophanate-Methyl Residues from Crop Field Trials Conducted with Various Formulations , DACO: 7.4.1
2437647	2002, Thiophanate-Methyl and Its Metabolites: Magnitude of the Residue in Cucumber, DACO: 7.4.1
2437648	2002, Thiophanate-Methyl and Its Metabolites: Magnitude of the Residue in Watermelon, DACO: 7.4.1
2437652	2002, Thiophanate-Methyl and Its Metabolites: Magnitude of the Residue in Cherry, DACO: 7.4.1
2502109	2014, Clarification Response for Proposed Use Pattern of Thiophanate-Methyl 500 SC Fungicide, DACO: 5.2

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