



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2022-4969
Application: Application Subject to Protection of Proprietary Interests in Pesticide Data (PIIP) Policy – Equivalency/Data Compensation Assessment
Product: Thames
Registration Number: 35287
Active ingredient (a.i.): Thiophanate-methyl
PMRA Document Number: 3550151

Purpose of Application

The purpose of this application was to register the end-use product, Thames, based on a registered precedent product.

Chemistry Assessment

Thames is formulated as a wettable powder containing thiophanate-methyl at a concentration of 70%. This end-use product has a density of 0.358 g/mL and pH of 6.65. The required chemistry data for Thames have been provided, reviewed and found to be acceptable.

Health Assessments

Thames is considered toxicologically comparable to the registered precedent product; therefore, no toxicology data were required. Thames is considered to be of low acute toxicity via the oral and dermal routes. Thames is considered to be of slight acute toxicity via the inhalation route and moderately irritating to the eyes and skin. Thames is considered to be a dermal sensitizer.

The use pattern of Thames is comparable to the registered use pattern of the precedent product. Therefore, potential exposure for mixers, loaders, applicators, bystanders and postapplication workers is not expected to exceed the current exposure to the registered products of *thiophanate-methyl*. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

No new residue data for thiophanate-methyl were submitted or were required to support the registration of Thames. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the Thames label, including the target crops, method (crop dependent), rates and timing of application, preharvest intervals, spray volumes and re-application intervals are comparable to those on the label of the registered precedent end-use product.

Based on this assessment, residues are not expected to be greater than those from the currently registered uses and will be covered by the established maximum residue limits (MRLs). Consequently, dietary exposure to residues of thiophanate-methyl is not expected to increase with the registration of Thames and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use pattern for Thames is within the registered use pattern of thiophanate-methyl. Therefore, unacceptable risks to the environment are not anticipated when Thames is used in accordance with the label directions.

Value Assessment

The formulation of Thames was compared to that of the registered precedent product. Based on this comparison, it was concluded that these products are expected to perform similarly, both in terms of efficacy and crop tolerance. Therefore, acceptable value was demonstrated to support the extrapolation of the use pattern from the registered precedent product label to the Thames label, with some minor modifications. The registration of this product will provide growers with an additional option for managing certain diseases on label-listed crops.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the registration of Thames.

References

PMRA

Document

Number	Reference
3391928	2022, Applicants Name & Address; Formulating Plants Name & Address; Product Data, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.2.3,3.3.1,3.5.13,3.5.15,3.5.5
3391929	2022, Manufacturing Process, DACO: 3.2.1,3.2.2,3.2.3 CBI
3391930	2022, Determination of Physico-chemical Properties of Thiophanate-methyl 70% WP, DACO: 3.5.11,3.5.12,3.5.13,3.5.6,3.5.8
3391931	2022, Accelerated Storage Stability and Corrosion Characteristics to Packing Material of Thiophanate-methyl 70% WP, DACO: 3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.7

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