



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2020-1805
Application: Submissions subject to Protection of Proprietary Interests in Pesticide Data (PIIP) policy-Equivalency/Data Compensation Assessment
Product: Theme 480 SC Insecticide
Registration Number: 34379
Active ingredient (a.i.): Thiacloprid
PMRA Document Number : 3264833

Purpose of Application

The purpose of this submission was to register a new insecticide end-use product for use on pome fruit, based on a precedent.

Chemistry Assessment

Theme 480 SC Insecticide is formulated as suspension containing thiacloprid at a concentration of 480 g/L. This end-use product has a density of 1.1568 – 1.1713 g/mL and pH of 6.94. The required chemistry data for Theme 480 SC Insecticide have been provided, reviewed and found to be acceptable.

Health Assessments

Theme 480 SC Insecticide was considered to be toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Theme 480 SC Insecticide is considered to be of high acute toxicity via the oral route, low acute toxicity via the dermal route, and of slight acute toxicity via the inhalation route of exposure. It is expected to be non-irritating to the eyes and skin, although it is considered to be a potential dermal sensitizer.

The use pattern of Theme 480 SC Insecticide is identical 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 product. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

No new residue data for thiacloprid were submitted or are required to support the registration of Theme 480 SC. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the Theme 480 SC label, including the target crops, method (ground), rates, timing of application, and preharvest intervals are identical to the precedent end-use product.

Based on this assessment, residues are not expected to be greater than those for the currently registered uses and will be covered by the established maximum residue limits. Consequently, dietary exposure to residues of thiacloprid is not expected to increase with the registration of Theme 480 SC, and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The application rate and use pattern for Theme 480 SC Insecticide is within the currently registered use pattern of thiacloprid. Risk to the environment is acceptable when Theme 480 SC Insecticide is used according to the label directions.

Value Assessment

A formulation comparison of Theme 480 SC Insecticide to a precedent product was conducted to support claims for control various pests in pome fruits. The claims on the precedent product label were extrapolated to the Theme 480 SC Insecticide label based on the similarity in formulation. Registration of Theme 480 SC Insecticide will provide growers with an additional product to control pests in pome fruits.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found it sufficient to support the registration of Theme 480 SC Insecticide.

References

PMRA

Document

Number	Reference
3119907	2019, Determination of Flash Point of Thiacloprid 48% SC, DACO: 3.5.11 CBI
3119908	2019, Determination of Explosive Properties of Thiacloprid 48% SC, DACO: 3.5.12 CBI
3119909	2019, Oxidizing Properties of Thiacloprid 48% SC, DACO: 3.5.8 CBI
3119910	2019, Determination of Viscosity of Thiacloprid 48% SC, DACO: 3.5.9 CBI
3119911	2019, Determination of Density and Relative Density of Thiacloprid 48% SC, DACO: 3.5.6 CBI
3119912	2019, Accelerated Storage Stability Test by Heating at Elevated Temperature of Thiacloprid 48% SC, DACO: 3.4.1,3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.5,3.5.7,3.7 CBI
3119924	2020, Manufacturing Description - Thiacloprid 480 SC, DACO: 3.2.1,3.2.2,3.2.3
3253209	2021, Particle Size, DACO: 3.2.2

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