



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2024-1433
Application: Submission subject to the Protection of Proprietary Interests in Pesticide Data (PIIP) policy - Equivalency/Data Compensation Assessment
Applicant: Jiangsu Agrochem Laboratory Co., Ltd.
Product: JSAL Prothio 480 SC
Registration Number: 35768
Active ingredient (a.i.): Prothioconazole
PMRA Document Number : 3735522

Purpose of Application

The purpose of this application was to register the end-use product, JSAL Prothio 480 SC, based on a registered precedent product.

Chemistry Assessment

JSAL Prothio 480 SC is formulated as a suspension containing prothioconazole at a concentration of 480 g/L. This end-use product has a density of 1.17 g/mL and a pH of 5.18. The required chemistry data for JSAL Prothio 480 SC have been provided, reviewed and found to be acceptable.

Health Assessments

JSAL Prothio 480 SC is considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. JSAL Prothio 480 SC is considered to be of low acute toxicity by the oral and dermal routes of exposure, and slightly acutely toxic by the inhalation route. It is considered to be non-irritating to the eyes and slightly irritating to the skin, and is not considered to be a potential skin sensitizer.

The use pattern of JSAL Prothio 480 SC is comparable to the registered use pattern of the precedent product.

Therefore, potential exposure for mixers, loaders, applicators, bystanders and post-application workers is not expected to exceed the current exposure to the registered products of prothioconazole. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

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

The use directions on the JSAL Prothio 480 SC label, including the target

crops, methods (ground and aerial), rates and timing of application, preharvest intervals, and crop rotation restrictions are comparable to those on the label of the precedent 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 prothioconazole is not expected to increase with the registration of JSAL Prothio 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 uses on the JSAL Prothio 480 SC label are within the currently registered uses for prothioconazole. No additional risk is expected when JSAL Prothio 480 SC is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

The formulation of JSAL Prothio 480 SC was compared to a precedent product with equivalent label claims. Based on this comparison, it was concluded that these two products are expected to perform similarly, both in terms of efficacy and crop tolerance. Therefore, the evidence of value for use claims included in the registration of that precedent product is acceptable for extrapolation to support comparable claims on the JSAL Prothio 480 SC label.

The registration of JSAL Prothio 480 SC will provide Canadian growers with an additional end-use product option to manage various diseases on labelled 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 JSAL Prothio 480 SC.

References

PMRA

Document

Number	Reference
3574932	2020, Manufacturing process, DACO: 3.2.2 CBI
3574933	2024, Discussion of the formation of impurities, DACO: 3.2.3
3574935	2018, Physical and chemical report 1 and method validation, DACO: 3.4.1, 3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8
3574936	2020, Physical and chemical report 2, DACO: 3.5.11,3.5.9
3574937	2024, Formulation type, DACO: 3.5.4
3574938	2024, Container material and description, DACO: 3.5.5
3574939	2024, Explodability, DACO: 3.5.12

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