



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2020-2195
Application: Submission subject to the *Protection of Proprietary Interests in Pesticide Data* (PPIP) policy-Equivalency/Data Compensation Assessment
Product: Pavise 480
Registration Number: 35065
Active ingredient (a.i.): Prothioconazole
PMRA Document Number : 3263441

Purpose of Application

The purpose of this application was to register Pavise 480, a new end-use product for use in terrestrial food and feed crops, and industrial oil seeds and fibre crops to control and suppress various fungal diseases, based on a registered precedent product.

Chemistry Assessment

Pavise 480 is formulated as a suspension containing prothioconazole at a concentration of 480 g/L. This end-use product has a density of 1.201–1.216 g/mL at 20 °C and pH of 6.75 (1% solution). The required chemistry data for Pavise 480 have been provided, reviewed and found to be acceptable.

Health Assessments

Pavise 480 was considered toxicologically equivalent to the precedent product; therefore no toxicology data were required. Pavise 480 is considered of low toxicity by the oral and dermal routes. It is considered slightly acutely toxic by the inhalation route. It is considered no irritating to the eyes and slightly irritating to the skin and is not considered to be a potential skin sensitizer.

The requested use pattern of the new end-use product Pavise 480 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 are required to support the registration of Pavise 480. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the Pavise 480 label, including the target crops, method (ground, aerial, and drip/drench), rates and timing of application, preharvest intervals, feeding restrictions, and crop rotation restrictions are comparable to the precedent end-use product. Based on this assessment, residues resulting from the use of the

new end-use product on the proposed crops are not expected to be greater than that for 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 the new end-use product Pavise 480 and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The registration of Pavise 480 will not pose any additional risk to the environment when used according to the label.

Value Assessment

The formulation of Pavise 480 was compared to that of the precedent product. Based on this comparison, it was concluded that Pavise 480 would be expected to perform similarly to the precedent product in terms of both efficacy and crop tolerance. Therefore, all uses and claims included in the registration of the precedent product are acceptable for Pavise 480.

The registration of Pavise 480 will provide growers with an alternative end-use product for management of the labelled diseases.

Conclusion

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

References

PMRA Document Number	Reference
3127370	2020, Manufacturing Process of Prothioconazole 480 g/L SC, DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI
3127391	2020, Study on the Method Validation of Prothioconazole 480 g/L Suspension Concentrate, DACO: 3.4.1,3.4.2
3127392	2020, Study on the Physico-Chemical Properties of Prothioconazole 480 g/L Suspension Concentrate, DACO: 3.5.1,3.5.13,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9,3.7
3127393	2020, Study on the Accelerated Storage and Packaging Stability of Prothioconazole 480 g/L Suspension Concentrate, DACO: 3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.7
3127394	2020, Study on the Auto-Ignition Temperature of Prothioconazole 480 g/L Suspension Concentrate, DACO: 3.5.11
3127395	2020, Study on the Explosive Properties of Prothioconazole 480 g/L Suspension Concentrate, DACO: 3.5.12

3127396 2020, Study on the Oxidizing Properties of Prothioconazole 480 g/L
Suspension Concentrate, DACO: 3.5.8
3228691 2021, Manufacturing Process of Prothioconazole 480 g/L SC - Revised,
DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI

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