

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number:	2022-6103
Application:	Application Subject to the Protection of Proprietary Interests in
	Pesticide Data (PPIP) Policy-Equivalency/Data Compensation
	Assessment
Product:	Spade II Fungicide
Registration Number:	35276
Active ingredient (a.i.):	Pyraclostrobin
PMRA Document Number	: 3603419

Purpose of Application

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

Chemistry Assessment

Spade II Fungicide is formulated as an emulsifiable concentrate containing pyraclostrobin at a concentration of 250 g/L. This end-use product has a density of 1.05 g/mL and pH of 6.07. The required chemistry data for Spade II Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

Spade II Fungicide was considered toxicologically equivalent to the precedent product; therefore , no toxicology data were required. Spade II Fungicide is considered to be of high acute toxicity via the oral route, and of low acute toxicity via the dermal and inhalation routes. It is moderately irritating to the eyes and skin, and is not considered a potential skin sensitizer.

The use pattern of Spade II Fungicide 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 this active ingredient. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

No new residue data for pyraclostrobin were submitted or were required to support the registration of Spade II Fungicide. Previously reviewed residue data were re-assessed in the framework of this application.



The use directions on the Spade II Fungicide label, including the target crops, methods (ground and/or aerial), rates and timing of application, geographic restrictions, preharvest intervals, feeding restrictions, and crop rotation 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 pyraclostrobin is not expected to increase with the registration of Spade II Fungicide 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 Spade II Fungicide is within the registered use pattern of the precedent product, therefore, no additional risk is expected from the use of Spade II Fungicide.

The label includes all the required environmental precautions, directions for use and spray buffer zones information which adequately mitigate risks to the environment.

Risk from use of Spade II Fungicide is acceptable from an environmental perspective when used according to label directions.

Value Assessment

The formulation of Spade II Fungicide was compared to that of a registered precedent product. It was concluded that these products are expected to perform similarly, both in terms of efficacy and crop tolerance. All uses and claims included in the registration of the precedent product are acceptable for Spade II Fungicide. Certain tank mix directions were amended due to the registration status of recommended partner products.

The availability of Spade II Fungicide will provide Canadian growers with an additional product to manage common and economically important 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 Spade II Fungicide.

References

PMRA	
Document	
Number	Reference
3409381	2022, Composition of Pyraclostrobin 250 EC, DACO: 3.2.1 CBI
3409382	2022, NewAgco Pyraclostrobin 250 EC Fungicide, DACO:
	3.1.1,3.1.2,3.1.3,3.1.4,3.2.3,3.3.1,3.5.5 CBI
3409383	2022, Description of Manufacturing Pyraclostrobin 250g/L EC, DACO:
	3.2.1,3.2.2 CBI
3409384	2017, Physchem Report, DACO:
	3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9 CBI
3461693	2017, Validation of Analytical Methodology for the Assay of Active Ingredient
	in Pyraclostrobin 250 EC, DACO: 3.4.1,3.5.10 CBI
3602499	2024, Chemical and Physical Characterisation of Pyraclostrobin 250g/L EC:
	Oxidation/Reduction, DACO: 3.5.8 CBI

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