



Evaluation Report for Category L, Subcategory 1.1 Application

Application Number: 2022-5072
Application: Application Subject to the Protection of Proprietary Interests in Pesticide Data (PPIP) Policy - Equivalency/Data Compensation Assessment
Product: Miraculous Prothioconazole Technical
Registration Number: 35192
Active ingredient (a.i.): Prothioconazole
PMRA Document Number: 3584445

Purpose of Application

The purpose of this application was to register a new source of prothioconazole, Miraculous Prothioconazole Technical, based on a registered precedent product.

Chemistry Assessment

Common Name: Prothioconazole
IUPAC* Chemical Name: (RS)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-thione
CAS† Chemical Name: 2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-3H-1,2,4-triazole-3-thione

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Miraculous Prothioconazole Technical has the following properties:

Property	Result
Colour and physical state	White solid
Nominal concentration	98.38%
Odour	Characteristic odour
Density	1.4027 g/mL at 20°C
Vapour pressure	5.92×10^{-5} mPa at 25°C
pH	5.62
Solubility in water	13.8 mg/L (pH 7.56)

Property	Result
n-Octanol/water partition coefficient	Log K _{ow} = 4.06 (pH 4.01)

The required chemistry data for Miraculous Prothioconazole Technical have been provided, reviewed, and found to be acceptable.

Health, Environmental and Value Assessments

Health, environmental and value assessments were not required for this application.

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 Miraculous Prothioconazole Technical.

References

PMRA

Document

Number	Reference
3400920	2021, Manufacturing process of Miraculous Prothioconazole technical, DACO: 2.11.1,2.11.3 CBI
3400921	2021, Discussion of formation of impurities, DACO: 2.11.4
3400922	2021, Method validation, DACO: 2.13.1
3400923	2021, 5 batch data of Miraculous Prothioconazole technical, DACO: 2.13.3 CBI
3400924	2021, Color, physical state and odour of Miraculous Prothioconazole technical, DACO: 2.14.1,2.14.2,2.14.3
3400925	2020, Dissociation constant, DACO: 2.14.10
3400926	2021, Partition coefficient, DACO: 2.14.11
3400927	2021, UV-VIS absorption spectra, DACO: 2.14.12
3400928	2021, Stability, DACO: 2.14.13
3400929	2021, Accelerated storage stability, DACO: 2.14.14
3400930	2021, pH of Miraculous Prothioconazole technical, DACO: 2.14.15,830.7000
3400931	2021, Melting point, DACO: 2.14.4
3400932	2021, Density, DACO: 2.14.6
3400933	2021, Solubility in water and solvent, DACO: 2.14.7,2.14.8
3400934	2021, Vapour pressure, DACO: 2.14.9
3441994	2022, Analysis of [CBI REMOVED] in Miraculous Prothioconazole technical, DACO: 2.13.4
3441995	2023, Analysis of [CBI REMOVED] in Miraculous Prothioconazole technical, DACO: 2.13.4
3496489	2021, New Dissociation constant report, DACO: 2.14.10
3550070	2024, Impurity [CBI REMOVED] test of Prothioconazole technical, DACO: 2.13.4

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