

Evaluation Report for Category L, Subcategory 1.1 Application

Application Number: 2021-0744
Application: Submissions subject to Protection of Proprietary Interests in Pesticide Data policy-Equivalency/Data Compensation Assessment
Product: Nufarm Prothioconazole Technical Fungicide
Registration Number: 34486
Active ingredient (a.i.): Prothioconazole
PMRA Document Number : 3315919

Purpose of Application

The purpose of this application was to register a new source of technical-grade prothioconazole based on a registered precedent.

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

Nufarm Prothioconazole Technical Fungicide has the following properties:

Property	Result								
Colour and physical state	White powder								
Nominal concentration	98.0%								
Odour	Odourless								
Density	1.1546 g/cm ³								
Vapour pressure	7.4×10 ⁻⁷ mPa (20°C) 1.8×10 ⁻⁶ mPa (25°C) 4.66 x 10 ⁻⁴ mPa (23.0°C)								
pH	6.06								
Solubility in water	<table border="0"> <tr> <td style="text-align: center;"><u>pH</u></td> <td style="text-align: center;"><u>Solubility (mg/L)</u></td> </tr> <tr> <td style="text-align: center;">4</td> <td style="text-align: center;">22.0</td> </tr> <tr> <td style="text-align: center;">7</td> <td style="text-align: center;">22.5</td> </tr> <tr> <td style="text-align: center;">9</td> <td style="text-align: center;">1240.0</td> </tr> </table>	<u>pH</u>	<u>Solubility (mg/L)</u>	4	22.0	7	22.5	9	1240.0
<u>pH</u>	<u>Solubility (mg/L)</u>								
4	22.0								
7	22.5								
9	1240.0								

Property	Result	
n-Octanol/water partition coefficient	<u>pH</u>	<u>log K_{ow}</u>
	4	3.4
	7	2.0
	9	0.2

The required chemistry data for Nufarm Prothioconazole Technical Fungicide 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 it sufficient to support the registration of Nufarm Prothioconazole Technical Fungicide.

Additional Information Being Requested

Since this technical product is manufactured only at pilot scale before registration, five-batch data representing commercial-scale production are required as post-market information after registration.

References

PMRA

Document

Number	Reference
3203384	2016, Manufacturing Process of Prothioconazole Technical, DACO: 2.11.1,2.11.2, 2.11.3,2.11.4,2.2 CBI
3203385	2017, Five-Batch Analysis of Prothioconazole TGAI, NUL3207 - Active Ingredient content, DACO: 2.13,2.13.2,2.13.3 CBI
3203386	2016, Validation of Analytical Methodology for the Assay of Active Ingredient in Prothioconazole TGAI, DACO: 2.13,2.13.1 CBI
3203387	2017, Five-Batch Analysis of Prothioconazole TGAI, NUL3207 – [CBI Removed] and Water content, DACO: 2.13,2.13.2,2.13.3 CBI
3203388	2017, Validation of Analytical Methodology for the Assay of [CBI Removed] in Prothioconazole TGAI, DACO: 2.13,2.13.1 CBI
3203389	2018, Five-Batch Analysis of Prothioconazole TGAI, NUL3207 - Impurity I to III, DACO: 2.13,2.13.2,2.13.3 CBI
3203390	2018, Validation of Analytical Methodology for the Assay of Impurities in Prothioconazole TGAI, DACO: 2.13,2.13.1 CBI

- 3203391 2018, Five Batch Analysis of Prothioconazole TGAI, NUL3207 – [CBI Removed],
DACO: 2.13,2.13.2,2.13.3,2.13.4 CBI
- 3203392 2018, Validation of Analytical Methodology for the Assay of Impurities in Prothioconazole TGAI – [CBI Removed], DACO: 2.13,2.13.1,2.13.4 CBI
- 3203393 2017, Physical and Chemical Characterization of Prothioconazole PAI - Melting Point and Vapor Pressure, DACO: 2.14.4,2.14.9
- 3203394 2018, Physical and Chemical Characterization of Prothioconazole TGAI, DACO: 2.14.1, 2.14.10, 2.14.11, 2.14.13, 2.14.14, 2.14.15, 2.14.2, 2.14.3, 2.14.6, 2.14.7, 2.14.8, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 830.7000
- 3213337 2021, PTZ_Supp. Chem_Report PTZ-RK-220321, DACO: 2.1, 2.12.1, 2.14.12, 2.3, 2.3.1
- 3274046 2021, Determination of [CBI Removed] in Prothioconazole, DACO: 2.13.4 CBI

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