

Evaluation Report for Category B, Subcategory 1.3, 4.6 Application

Application Number: 2022-6618
Application: Changes to Technical Grade Active Ingredient Product Chemistry – Specifications, Fulfill Conditions of Registration
Product: ADAMA Prothioconazole Technical
Registration Number: 34061
Active ingredient (a.i.): Prothioconazole
PMRA Document Number: 3559141

Purpose of Application

The purpose of this application was to amend the manufacturing process and provide commercial-scale batch data to fulfill conditions of registration for ADAMA Prothioconazole Technical.

Chemistry Assessment

Common Name: Prothioconazole
English 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

ADAMA Prothioconazole Technical has the following properties:

Property	Result
Colour and physical state	White dust
Nominal concentration	98.8%
Odour	No odour
Density	1.45 g/mL at 20°C
Vapour pressure	7.4×10^{-7} Pa at 20°C
pH	5 - 6 (1% in water)
Solubility in water	10.2 mg/L (pH 4), 21.2 mg/L (pH 7), 864 mg/L (pH 8.9)

Property	Result
n-Octanol/water partition coefficient	log K _{ow} = 3.94 (pH 4), 3.04 (pH 7), 2.65 (pH 9)

The required chemistry data for ADAMA 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 amend the manufacturing process and fulfill conditions of registration for ADAMA Prothioconazole Technical.

References

PMRA Document Number	Reference
3420510	2022, DACO 2.11 Manufacturing Process- [PRIVACY INFO REMOVED]- Updated w [PRIVACY INFO REMOVED], DACO: 2.11.1,2.11.2,2.11.3 CBI
3427265	2021, Determination of active ingredient and impurities present in five representative batches of Prothioconazole Technical, DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI

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