

Evaluation Report for Category L, Subcategory 1.1 Application

Application Number: 2019-7111
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data Policy-Equivalency/Data Compensation Assessment
Product: ADAMA Prothioconazole Technical
Registration Number: #####
Active ingredient (a.i.): Prothioconazole
PMRA Document Number : 3173136

Purpose of Application

The purpose of this application was to register a new source of prothioconazole, ADAMA Prothioconazole Technical, by a new registrant.

Chemistry Assessment

Common Name: Prothioconazole
IUPAC* Chemical Name: *rac*-2-[(2*R*)-2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-3*H*-1,2,4-triazole-3-thione
CAS† Chemical Name: 2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-3*H*-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 solid (powder)
Nominal concentration	99.4%
Odour	No odour
Relative density	1.45
Vapour pressure	7.4×10^{-7} Pa at 20°C 1.4×10^{-6} Pa at 25°C 2.5×10^{-5} Pa at 50°C
pH	5–6 (1% in water)

Property	Result
Solubility in water at 20 °C	10.2 mg/L at pH 4 21.2 mg/L at pH 7 864 mg/L at pH 8.9
n-Octanol/water partition coefficient at 20 °C	Log K _{ow} 3.94 at pH 4 Log K _{ow} 3.04 at pH 7 Log K _{ow} 2.65 at 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 it sufficient to support the registration of ADAMA Prothioconazole Technical.

Additional Information Being Requested

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

References

PMRA Document Number	References
3071738	2019, Manufacturing Process of Prothioconazole, DACO: 2.11.1,2.11.2,2.11.3 CBI
3071739	2017, Quantification 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
3071740	2017, Quantification of Active Ingredient and Impurities Present in five Representative Batches of MCW-344 technical, DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
3071741	2019, Physical State, Colour and Odour of Prothioconazole Technical, DACO: 2.14.1,2.14.2,2.14.3 CBI
3071742	2019, Prothioconazole-Dissociation Constants in Water, DACO: 2.14.10

3071743 2019, Partition coefficient of Prothioconazole at pH 4,7 and 9, DACO: 2.14.11

3071744 2019, UV Vis Spectrum, Infrared Spectrum and Mass Spectrum of Prothioconazole, DACO: 2.14.12

3071746 2019, Determination of the pH Value of an Aqueous Solution of Prothioconazole, DACO: 2.14.15,830.7000

3071747 2019, Melting Point of Prothioconazole, DACO: 2.14.4 CBI

3071748 2019, Boiling Point of Prothioconazole, DACO: 2.14.5 CBI

3071749 2019, Relative Density of Prothioconazole Technical Substance, DACO: 2.14.6 CBI

3071750 2019, Water Solubility of Prothioconazole, DACO: 2.14.7 CBI

3071751 2019, Solubility of Prothioconazole in Organic Solvents, DACO: 2.14.8 CBI

3071752 2019, Vapour Pressure of Prothioconazole, DACO: 2.14.9 CBI

3071753 2019, Prothioconazol Tecnico Manufacturing Process and Formation of Impurities, DACO: 2.11.1,2.11.2,2.11.3,2.11.4,2.4,2.5,2.6,2.7,2.8,2.9 CBI

3123192 2020, 2019-7111 DACO 2.11 Manufacturing Process-[PRIVACY INFO REMOVED], DACO: 2.11 CBI

3123193 2020, 2019-7111 DACO 2.11 Manufacturing Process-[PRIVACY INFO REMOVED], DACO: 2.11 CBI

3123195 2020, 2019-7111 CBI from [PRIVACY INFO REMOVED] for MP of [CBI REMOVED], DACO: 2.16 CBI

3147036 2019, Solubility of Prothioconazole in Organic Solvents , DACO: 2.14.8 CBI

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