

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number:	2016-5161
Application:	New TGAI/Product Chemistry - New site/Same registrant
Product:	Preventol A12 II
Registration Number:	31821
Active ingredient (a.i.):	Propiconazole
PMRA Document Number	: 2741056

Purpose of Application

The purpose of this application was to add a new manufacturing site for Preventol A12 II.

Chemistry Assessment

Common Name:	Propiconazole
IUPAC* Chemical Name:	(2RS,4RS;2RS,4SR)-1-[2-(2,4-dichlorophenyl)-4-propyl-1,3-
	dioxolan-2-ylmethyl]-1H-1,2,4-triazole
CAS [†] Chemical Name:	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-
	1,2,4-triazole

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Property	Result
Colour and physical state	Yellow liquid
Nominal concentration	98.5%
Odour	Odourless
Density at 20 °C	1.2876 g/mL
Vapour pressure	7.4×10^{-5} Pa (at 25°C)
pH	5.1
Solubility in water	177 mg/L (at 20°C, pH 6.5)
n-Octanol/water partition coefficient	Log $K_{ow} = 3.3 \text{ (pH 7.3)}$

Preventol A 12 II has the following properties:

The required chemistry data for Preventol A12 II 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 submitted, and has found the information sufficient to support the addition of a new manufacturing site for Preventol A12 II.

References

PMRA Document	Reference
Number	
2676125	2016, Applicant's Name and Office Address, Formulating Plant and address, Trade Name and Odour for New Source of Preventol A12 II (Reg. No. 31821), DACO: 2.1,2.14.3,2.2,2.3,2.3.1
2676126	2016, Applicant's Name and Office Address, Formulating Plant and address, Trade Name and Odour for New Source of Preventol A12 II (Reg. No. 31821), DACO: 2.1,2.14.3,2.2,2.3,2.3.1 CBI
2676127	2012, Preliminary Analysis and Enforcement Analytical Methods for Propiconazole TGAI: Selected Studies to Fulfill the Requirements of OPPTS Guideline 830.1700 and 830.1800 and Regulation (EC) No. 1107/2009, DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
2676128	2012, Preliminary Analysis and Enforcement Analytical Methods for Propiconazole TGAI: Selected Studies to Fulfill the Requirements of OPPTS Guideline 830.1700 and 830.1800 and Regulation (EC) No. 1107/2009 - Confidential Attachment, DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
2676129	2016, Determination of Polychlorinated Dibenzo-p-dioxins (PCDDs) and Polychlorinated Dibenzofurans (PCDFs) by GC/HRMS in 5 batches of Propiconazole, DACO: 2.13.4 CBI
2676130	2016, Physico-Chemical Properties of Propiconazole, DACO: 2.14.1,2.14.10,2.14.12,2.14.13,2.14.15,2.14.2,2.14.5,2.14.6,2.16,830.7000
2676131	2016, Partition Coefficient of Propiconazole, DACO: 2.14.11
2676133	2016, Determination of the Water Solubility of Propiconazole, DACO: 2.14.7
2676134	2016, Solubility of Propiconazole in organic solvents, DACO: 2.14.8
2676135	2016, Vapour Pressure, DACO: 2.14.9
2676136	2015, Manufacture Process and Synthesis Pathway, DACO: 2.11.1,2.11.2,2.11.3 CBI
2676137	2015, Formation of Impurities, DACO: 2.11.4 CBI
2737388	2017, Confirmation of the Incorrectly Reported Internal Diameters of Columns, DACO: 2.13.1
2737390	2017, Manufacture Process and Synthesis Pathway Product: Propiconazole Technical Grade Material, DACO: 2.11.3 CBI
2737391	2017, Formation of Impurities, DACO: 2.11.4 CBI
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