

Evaluation Report for Category B, Subcategory B.1.2 Application

Application Number: 2014-0896

Application: New Source of Technical Grade Active Ingredient by a New Registrant

Product: Preventol A12 II

Registration Number: 31821

Active ingredients (a.i.): Propiconazole

PMRA Document Number: 2526135

Background

The source of propiconazole used to determine chemical equivalence was Registration Number 22434.

Purpose of Application

The purpose of this application was to register a new source of the active ingredient, propiconazole, by a different Registrant.

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

Preventol A12 II has the following properties:

Property	Result
Colour and physical state	Yellowish
Nominal guarantee	98.5%
Odour	Odourless
Density	1.2876
Vapour pressure	5.6×10 -2 mPa at 25°C
рН	6.55
Dissociation Constant	pKa = 1.70 (for the protonated active ingredient)
Solubility in water	196.71 mg/L (20°C)



Property	Result
n-Octanol/water partition	$Log K_{ow} = 3.76$
coefficient	

Health and Environmental Assessments

As the new source of propiconazole is chemically equivalent to the registered source, the health and environmental risk profiles are expected to be similar to that of the product used to determine chemical equivalence. No additional assessments were required.

Value Assessment

A value assessment is not required for technical grade active ingredient products.

Conclusion

The PMRA has completed an evaluation of the subject application and has determined that it can support the registration of Preventol A12 II.

References

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	2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.2, 2.14.3, 2.14.5, 2.14.6, 2.14.7, 2.14.8
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	12. DACO: 2.13.4
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ISSN: 1911-8082

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