Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2011-2328
Application: New/Changes TGAI Prod Chemistry-New Source (site) same registrant
Product: Propiconazole Technical
Registration Number: 22434
Active ingredients (a.i.): Propiconazole (PON)
PMRA Document Number English PDF: 2108918

Purpose of Application

The purpose of this application was to add a new source for Propiconazole Technical (Registration No. 22434).

Chemistry Assessment

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

Propiconazole Technical has the following properties:

Property	Result
Colour and physical state	clear yellow liquid
Nominal concentration	95%
Odour	very slight mild odour
Density	1.30 g/mL
Vapour pressure	Temp°C — Pa 20 — 1.3×10^{-4} 30 — 4.8×10^{-4} 40 — 1.5×10^{-3}
pH	N/A
Solubility in water	110 mg/L
n-Octanol/water partition coefficient	log K_{ow} = 3.7 (pH 6.6)

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The chemistry requirements for Propiconazole Technical have been completed.

Health, Environmental and Value Assessments

Health, environmental and value assessments were not required for this application.

Conclusion

The PMRA has reviewed the information provided for this application and can support the addition of a new source for Propiconazole Technical (Registration No. 22434).

References

Studies/Information Provided by Applicant/Registrant

PMRA No.	Reference
1427427	Propiconazole Technical. Chromatogram of a typical production batch using method AK-88/5; NMR spectra and mass spectra of impurities, DACO: 2.11.1,2.13.2,2.13.3 CBI
2061487	2011, 2.1-1 - Applicant's Name and Address, DACO: 2.1,2.2 CBI
2061488	2011, 2.11.1-1 - Manufacturing Summary - Description of Production Process, DACO: 2.11.1,2.11.3 CBI
2061489	2011, 2.11.2-1 - Description of Materials Used to Produce the Product, DACO: 2.11.2 CBI
2061490	2011, 2.11.4-1 - Discussion of Formation of Impurities, DACO: 2.11.4 CBI
2061491	2011, 2.12.1-1 - Propiconazole Technical (PCP 22434) Certification of Limits, DACO: 2.12.1 CBI
2061492	2010, 2.13.1-1 - Methodology/Validation - Analytical Method, DACO: 2.13.1 CBI
2061494	1995, 2.13.1-2 - Methodology/Validation - CGA 64250 By-Products, DACO: 2.13.1 CBI
2061495	2011, 2.13.2-1 - Propiconazole Confirmation of Identity, DACO: 2.13.2 CBI
2061497	2010, 2.13.3-1 - Analysis of five representative production batches reproduced at Monthey with Propiconazole crude from Seven Continents, DACO: 2.13.3 CBI

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