

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2022-1394

Application: Changes to Technical Grade Active Ingredient (Product

Chemistry) – New Source (site) same registrant

Product: Tebuconazole Technical

Registration Number: 34371

Active ingredient (a.i.): Tebuconazole PMRA Document Number: 3492798

Purpose of Application

The purpose of this application was to register two new sources of the technical grade active ingredient Tebuconazole Technical.

Chemistry Assessment

Common Name: tebuconazole

IUPAC* Chemical Name: (RS)-1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4-triazol-1-

ylmethyl)pentan-3-ol

CAS† Chemical Name: α -[2-(4-chlorophenyl)ethyl]- α -(1,1-dimethylethyl)-1*H*-1,2,4-

triazole-1-ethanol

Tebuconazole Technical has the following properties:

Property	Result
Colour and physical state	White solid
Nominal concentration	97.9 %
Odour	Odourless
Density	1.21 – 1.24 g/mL at 20°C
Vapour pressure	0.042 mPa at 20 °C
рН	7.5
Solubility in water	0.0466 g/L (pH 6-7)
n-Octanol/water partition coefficient	$\log K_{\rm ow} = 3.6$



^{*} International Union of Pure and Applied Chemistry

[†] Chemical Abstracts Service

The required chemistry data for Tebuconazole 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 support the registration of the two new sources of tebuconazole for Tebuconazole Technical.

References

PMRA	
Document	
Number	Reference
3338618	2016, The Manufacturing Process of Tebuconazole Technical, DACO:
	2.11.1, 2.11.2,2.11.3,2.11.4,2.12.1 CBI
3338619	2016, Formation of Impurities in the Technical Grade Active Ingredient
	Tebuconazole, DACO: 2.11.4 CBI
3338620	2016, 5-Batch Analysis of Tebuconazole TGAI in Accordance with
	International Regulatory Requirements (EU, US, Brazil and Mexico), DACO:
	2.11.4,2.13.1,2.13.2,2.13.3,2.13.4 CBI
3338621	2020, Product and Identity Composition, DACO: 2.11.1,2.11.2,2.11.3,2.11.4,
	2.12.1 CBI
3338622	2016, Determination of Active Content and Impurity Profile of
	Tebuconazole, DACO: 2.11.4,2.13,2.13.1,2.13.2,2.13.3,2.13.4 CBI
3400400	2022, 2.13.4 Five Batches Report for Solvents in Tebuconazole Technical,
	DACO: 2.13.4 CBI

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