

## Evaluation Report for Category B, Subcategory 1.1 Application

**Application Number:** 2021-5393  
**Application:** Changes to Technical Grade Active Ingredient (Product Chemistry) – New Source (Site), Same Registrant  
**Product:** Difenoconazole Technical Fungicide  
**Registration Number:** 25631  
**Active ingredient (a.i.):** Difenoconazole  
**PMRA Document Number:** 3509586

### Purpose of Application

The purpose of this application was to register a new manufacturing site for Difenoconazole Technical Fungicide.

### Chemistry Assessment

Common Name: Difenoconazole  
IUPAC\* Chemical Name: 1-({2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl)methyl)-1H-1,2,4-triazole  
CAS† Chemical Name: 1-[[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole

\* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Difenoconazole Technical Fungicide has the following properties:

Property	Result
Colour and physical state	White powder
Nominal concentration	95%
Odour	Slightly sweet
Density	1.37 - 1.40 g/cm <sup>3</sup> at 20°C
Vapour pressure	6.6 × 10 <sup>-8</sup> Pa (at 20°C)
pH	6.9
Solubility in water	3.3 g/L
n-Octanol/water partition coefficient	log Kow = 4.2

The required chemistry data for Difenoconazole Technical Fungicide 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 a new manufacturing site for Difenoconazole Technical Fungicide.

**Additional Information Being Requested**

Good Laboratory Practice (GLP)-compliant five-batch data for the impurity of concern, representing commercial-scale production at the approved manufacturing site will be required as post-market information after registration.

## References

<b>PMRA Document Number</b>	<b>Reference</b>
3275441	2021, Difeniconazole Technical (CGA169374) - Manufacturing Process Description and Supporting Data, DACO: 2.1,2.11,2.11.1,2.11.2,2.11.3, 2.11.4,2.12,2.12.1,2.13,2.13.1,2.13.2,2.13.3,2.13.4,2.2,2.3,2.4,2.5,2.6,2.7, 2.8,2.9 CBI
3346658	2022, Confidential Business Information Difeniconazole Technical Reg. No. 25631, DACO: 2.13.1,2.13.4 CBI
3492887	2023, Confidential Business Information Difeniconazole Technical Reg. No. 25631, DACO: 2.13.1 CBI

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