

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2010-4467
Application: New/Changes to the technical grade active ingredient – new source (site) same registrant
Product: Fenbuconazole Technical Fungicide
Registration Number: 27293
Active ingredients (a.i.): Fenbuconazole
PMRA Document Number English PDF: 2044278

Purpose of Application

The purpose of this application was to add a new manufacturing site of the technical grade active ingredient febuconazole to the currently registered product, Fenbuconazole Technical Fungicide, Registration Number 27293.

Chemistry Assessment

Common Name: Fenbuconazole
Chemical Name: α -[2-(4-chlorophenyl)ethyl]- α -phenyl-1H-1,2,4-triazole-1-propanenitrile

Fenbuconazole Technical Fungicide has the following properties:

Property	Result
Colour and physical state	Off-white to white powder
Nominal concentration	98.4% as determined by GC
Odour	Faint sulfur-like
Relative Density	1.27 – 1.28
Vapour pressure	0.37×10^{-7} mm Hg (at 25°C)
Solubility in water	3.8 ppm
n-Octanol/water partition coefficient	Log K_{ow} = 3.22 ± 0.08

The chemistry requirements for Fenbuconazole Technical Fungicide have been completed.

Health, Environmental and Value Assessments

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

Conclusion

The PMRA has conducted a review of the available information for this application and has concluded that the addition of a new manufacturing site for the production of Fenbuconazole Technical Fungicide is acceptable.

References

- 1957800 2010, Applicant and Manufacturer Name & Address, product & common names, DACO: 2.1, 2.2, 2.3, 2.4 CBI
- 1957801 2010, Group A-Product Identity, Description of Materials Used to Produce the Product, Description of the Production Process, Discussion of the Formation of Impurities, Preliminary Analysis, Certified Limits and Enforcement Analytical Method for Fenbuconazole DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.13.1, 2.13.2, 2.13.3, 2.13.4 CBI
- 1957803 2010, Manufacturing Information, DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4 CBI
- 1957804 2010, Analysis of Product Samples for Active Ingredient and Impurities in Technical Grade Fenbuconazole, DACO: 2.12.1, 2.13.2, 2.13.3 CBI
- 1957805 2010, Analysis and Certification of Product Ingredients in Fenbuconazole, DACO: 2.13.1 CBI
- 2040412 2011, Clarification response, Description of Starting Materials, DACO: 2.11.2 CBI

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