

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2010-1258
Application: New/Changes to the technical grade active ingredient – new source (site) same registrant
Product: Myclobutanil Technical Fungicide
Registration Number: 27916
Active ingredients (a.i.): Myclobutanil
PMRA Document Number English PDF: 2002271

Purpose of Application

The purpose of this application was to add a new manufacturing site of the technical grade active ingredient myclobutanil to the currently registered product, Myclobutanil Technical Fungicide, Registration Number 27916.

Chemistry Assessment

Common Name: Myclobutanil
Chemical Name: (RS)-2-(4-chlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)hexanenitrile
 OR
 α-butyl-α-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile

Myclobutanil Technical Fungicide has the following properties:

Property	Result
Colour and physical state	Pale yellow solid
Nominal concentration	95.5%
Density	1.22 g/cm ³
Vapour pressure	0.213 mPa
Solubility in water	142 mg/L
n-Octanol/water partition coefficient	logP = 2.94, pH 7-8

The chemistry requirements for Myclobutanil 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 Myclobutanil Technical Fungicide is acceptable.

References

- 1348089 2001, Manufacturing Technology Package, DACO: 2.11.1, 2.11.2, 2.11.3 ,2.11.4 CBI
- 1348091 2003, Analytical Method and Validation for the Determination of the Assay and Impurities in Myclobutanil Technical (RH-3866), DACO: 2.13.1,2.13.2,2.13.3 CBI
- 1884179 2010, Applicant & Manufacturer- Myclobutanil Tech-Alternate source, DACO: 2.1, 2.2, 2.3, 2.4 CBI
- 1884182 2001, Manufacturing Technology Package for Myclobutanil, DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4 CBI
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- 1988189 2010, Group A-Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Production Process, Discussion of Formation of Impurities, Certified Limits, and Enforcement Analytical Method for Myclobutanil Technical, DACO: 2.1, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.13.1, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 CBI

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