

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2009-2485
Application: B.1.1 - New / Changes TGAI or ISP Prod Chemistry-New Source (site) same registrant
Product: Bifenazate Technical
Registration Number: 27923
Active ingredients (a.i.): Bifenazate [BFZ]
PMRA Document Number: 1838083

Purpose of Application

The purpose of this application is to register a new manufacturing site.

Chemistry Assessment

Bifenazate Technical is guaranteed to contain Bifenazate, Isopropyl 2-(4-methoxybiphenyl-3-yl) hydrazinecarboxylate, at 98.5% nominal as determined by HPLC.

Bifenazate Technical has the following properties:

Property	Description
Colour	Beige
Physical state	Solid
Odour	Slight odour characteristic of aromatic compounds
Melting point/range	120-124°C
Density	1.31 g/cm ³ at 24.2°C
Water solubility at 20°C	0.376 mg/ 100 mL
Vapour pressure at 25°C	< 1 × 10 ⁻⁷ torr (0.013 mPa)
Dissociation constant (pK _a)	pK _a = 12.94 ± 0.06 at 23 °C
Octanol/water partition coefficient (K _{ow})	log K _{ow} = 3.4 ± 2.85%

The chemistry requirements for Bifenazate Technical are complete.

Health Assessments

Health assessments were not required for this application.

Environmental Assessment

Environmental assessments were not required for this application.

Value Assessment

Value assessments were not required for this application.

Conclusion

Following the assessment of all available data, the application for the new manufacturing site is acceptable for registration.

References

PMRA #	Title
1698012	“CBI INFORMATION REMOVED”Chemistry Requirements for the Registration of a Technical Grade of Active
1698024	1995, “CBI INFORMATION REMOVED”. Determination of the Color of D2341 Technical Experimental Miticide.,
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1698026	1995, “CBI INFORMATION REMOVED”, Determination of the Odor of D2341 Technical Experimental Miticide.,
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1698028	1995, “CBI INFORMATION REMOVED”, Determination of the Density of D2341 Technical Experimental Miticide,
1698029	1993, “CBI INFORMATION REMOVED”, Solubility of Experimental Miticide D2341 in Water, DACO: 2.14.7 CBI
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1698032	1997, “CBI INFORMATION REMOVED”, Final Report. Determination of the Dissociation Constant of D2341 Using a Spectrophotometric method,
1698033	1993, “CBI INFORMATION REMOVED”; Determination of the N-Octanol/Water Partition Coefficient (Pow) of D2341 Experimental Miticide.,
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1698036	1996, “CBI INFORMATION REMOVED”; The Stability of D2341 Experimental Miticide in the Presence of Metals and Metal Ions,

- 1698037 1996, "CBI INFORMATION REMOVED"; Accelerated Storage Test for D2341 Experimental Miticide,
- 1779795 Impurities of Toxicological Concern
- 1779796 2009, Sample(s) of Analytical Standard and Residue of Concern,
- 1779797 2009, Description of Materials, Methods Used to Produce the Technical Material, Description of the Production Process and Discussion of the Formation of Impurities in Technical Bifenazate
- 1825814 2009, Bifenazate standard chromatogram supplement to that submitted originally with 2009-2485,
- 1825815 2003, Analytical Method Determination of Trace Organic Impurities in Bifenazate Technical Material Using High Performance Liquid Chromatography,

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