



Evaluation Report for Category B, Subcategory 1.3 Application

Application Number: 2015-6483
Application: Changes to the Technical Grade Active Ingredient Product Chemistry - Specifications
Product: Bifenazate Technical
Registration Number: 27923
Active ingredients (a.i.): Bifenazate
PMRA Document Number: 2630806

Background

Bifenazate Technical (Registration Number 27923) was first registered for use in Canada in 2005 to formulate end-use products.

Purpose of Application

The purpose of this application was to update the manufacturing process at one of the manufacturing sites of Bifenazate Technical.

Chemistry Assessment

Common Name:	Bifenazate	
IUPAC* Chemical Name:	propan-2-yl yl)hydrazinecarboxylate	2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate
CAS† Chemical Name:	1-methylethyl yl)hydrazinecarboxylate	2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Bifenazate Technical has the following properties:

Property	Result
Colour and physical state	Beige solid
Nominal concentration	98.2%
Odour	Slight odour characteristic of aromatic compounds
Density	1.31 g/mL
Vapour pressure	<0.013 mPa (at 25°C)

Property	Result
Solubility in water	0.376 mg/ 100 mL (20°C)
n-Octanol/water partition coefficient	Log K _{ow} = 3.4

The required chemistry data for Bifenazate Technical have been provided, reviewed, and found to be acceptable.

Health Assessment

The change in manufacturing process is not expected to significantly impact the health risk profile of Bifenazate Technical.

Environmental and Value Assessments

Environmental and value assessments were not required for this application.

Conclusion

The PMRA has completed a review of all available information for Bifenazate Technical and found it sufficient to support the changes to the manufacturing process.

References

PMRA Document Number	Reference
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 as Manufactured [CBI removed], Ltd, DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4 CBI
2586288	2015, Manufacturing Summary, Description of Starting Materials, Detailed Production Process Description & Discussion of the Formation of Impurities for Bifenazate, DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4 CBI
2586289	2015, Bifenazate Technical Manufacturing Process Optimization, DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.13.2 CBI
2586290	2015, Preliminary Analysis of Bifenazate Technical - Non Confidential Section, DACO: 2.13
2586291	2015, Preliminary Analysis of Bifenazate Technical - Confidential Section, DACO: 2.13 CBI
2626762	2016, Daco 2.11.3 - Response to Process Inquiry for Bifenazate Technical, DACO: 2.11.3 CBI
2629756	2016, 27923 Bifenazate Tech SPSF F4V2 - Amended, DACO: 2.12 CBI

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