

Evaluation Report for Category B, Subcategory 1.1, 1.3 Application

Application Number: 2020-2004
Application: Changes to Technical Grade Active Ingredient (Product Chemistry)
 – New Source (site) same registrant; specifications
Product: PYRIDABEN TECHNICAL MITICIDE/INSECTICIDE
Registration Number: 25133
Active ingredient (a.i.): Pyridaben
PMRA Document Number : 3268318

Purpose of Application

The purpose of this application was to add a new source of technical pyridaben to the registered product PYRIDABEN TECHNICAL MITICIDE/INSECTICIDE.

Chemistry Assessment

Common Name: Pyridaben
IUPAC* Chemical Name: 2-*tert*-butyl-5-[(4-*tert*-butylbenzyl)thio]-4-chloropyridazin-3(2*H*)-one
CAS† Chemical Name: 4-chloro-2-(1,1-dimethylethyl)-5-[[[4-(1,1-dimethylethyl)phenyl]methyl]thio]-3(2*H*)-pyridazinone

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

PYRIDABEN TECHNICAL MITICIDE/INSECTICIDE has the following properties:

Property	Result
Colour and physical state	White crystalline solid
Nominal concentration	99.4 %
Odour	Odourless
Density	1.204 g/cm ³
Vapour pressure	10.9 mPa
pH	6.3 (1%)
Solubility in water	0.012 mg/L

Property	Result
n-Octanol/water partition coefficient	log K _{ow} = 6.37

The required chemistry data for PYRIDABEN TECHNICAL MITICIDE/INSECTICIDE have been provided, reviewed, and found to be acceptable.

Health Assessments

The toxicological profile of PYRIDABEN TECHNICAL MITICIDE/INSECTICIDE is not expected to be significantly altered by the addition of a new manufacturing site.

Dietary and occupational exposure risk assessments were not required for this application.

Environmental and Value Assessments

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 it sufficient to register the new source for PYRIDABEN TECHNICAL MITICIDE/INSECTICIDE.

Additional Information Being Requested

Since this new source is manufactured only at pilot scale before registration, five-batch data representing commercial-scale production at the new manufacturing site will be required as post-market information after registration.

References

PMRA Document Number	Reference
3123579	2020, Manufacturing Process of Pyridaben in [CBI removed] Manufacturing Plant, 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 CBI
3123580	2020, Pyridaben: Batch Analysis, DACO: 2.12.1,2.13.2,2.13.3 CBI
3237264	2021, [CBI Removed], DACO: 2.11.3,2.13.3,2.13.4 CBI
3261999	2021, [CBI removed] analysis as residue solvent of five batch [CBI Removed], DACO: 2.13.4 CBI

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