

Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2015-4561
Application: New technical grade active ingredient product chemistry – New source (site) for a new registrant
Product: Sharda Acetamiprid Technical
Registration Number: 32734
Active ingredients (a.i.): Acetamiprid
PMRA Document Number (English PDF): 2680739

Purpose of Application

The purpose of this application was to register a new source of acetamiprid, Sharda Acetamiprid Technical, by a new registrant. This application is being reviewed under Phase 1 of the Protection of Proprietary Interest in Pesticides (PIIP) and is based on a registered precedent product.

Chemistry Assessment

Common Name: Acetamiprid
IUPAC* Chemical Name: (*E*)-*N*¹-[(6-chloro-3-pyridyl)methyl]-*N*²-cyano-*N*¹-methylacetamidine
CAS† Chemical Name: (1*E*)-*N*-[(6-chloro-3-pyridinyl)methyl]-*N*'-cyano-*N*-methylethanimidamide

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Sharda Acetamiprid Technical has the following properties:

Property	Result
Colour and physical state	Off-white solid
Nominal concentration	99.5%
Odour	Characteristic odour
Density	1.2573 – 1.2633 g/mL
Vapour pressure	< 1.5 × 10 ⁻⁵ Pa (at 20°C)
pH	6.23
Solubility in water	3.2 g/L (20°C, pH 6.5)

Property	Result
n-Octanol/water partition coefficient	Log K _{ow} = 0.77

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

Health, Environmental and Value Assessments

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

Conclusion

The PMRA has completed a review of the available information provided in support of Sharda Acetamiprid Technical and found it sufficient to support full registration.

References

PMRA Document Number	Reference
2562132	2015, Applicant's Name and Office Address, Formulating Plant and address, Product Identity and Stability for Sharda Acetamiprid Technical, DACO: 2.1, 2.14.13, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 CBI
2562133	2015, Applicant's Name and Office Address, Formulating Plant and address, Product Identity and Stability for Sharda Acetamiprid Technical, DACO: 2.1, 2.14.13, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 CBI
2562134	2015, Acetamiprid Manufacturing process and Synthesis Pathway, DACO: 2.11.1, 2.11.2, 2.11.3 CBI
2562141	2015, Justification of Impurities, DACO: 2.11.4 CBI
2562142	2015, Composition With Limit of Each Impurity to Acetamiprid, DACO: 2.12, 2.12.1 CBI
2562143	2013, Preliminary Analysis of Acetamiprid TGAI, DACO: 2.13, 2.13.1, 2.13.2, 2.13.3 CBI
2562144	2013, Preliminary Analysis of Acetamiprid TGAI, DACO: 2.13.1, 2.13.2 CBI
2562145	2013, Preliminary Analysis of Acetamiprid TGAI, DACO: 2.13, 2.13.1, 2.13.2 CBI
2562146	2015, Declaration of Samples of Acetamiprid Technical, DACO: 2.13.3 CBI
2562147	2015, Acetamiprid Discussion of Impurities of Concern, DACO: 2.13.4 CBI
2562148	2008, Acetamiprid Technical: Determination of the Colour, Odour and Physical State, DACO: 2.14.1, 2.14.2, 2.14.3
2562149	2008, Acetamiprid Technical: Determination of the Dissociation Constant in Water, DACO: 2.14.10
2562150	2014, Chemical and Physical Characterization of Acetamiprid TGAI: Melting Point, Partition Coefficient, Solubility and Vapor Pressure, DACO: 2.14.11, 2.14.4, 2.14.7, 2.14.8, 2.14.9
2562151	2008, Acetamiprid Technical: UV/VIS, IR, MS and NMR Spectra, DACO: 2.14.12 CBI
2562152	2010, Acetamiprid Technical: Two Years Storage Stability and Corrosion Characteristics, DACO: 2.14.14, 2.16
2562153	2008, Acetamiprid: Determination of Accelerated Storage Stability and Corrosive Characteristics, DACO: 2.14.13
2562154	2008, Acetamiprid Technical: Determination of the Oxidizing Properties, DACO: 2.14.13
2562155	2008, Acetamiprid Technical: Determination of the pH Value and Acidity or Alkalinity, DACO: 2.14.15, 830.7000
2562156	2009, Acetamiprid Technical: Boiling Point, DACO: 2.14.5
2562157	2008, Acetamiprid Technical: Determination of the Relative Density, DACO: 2.14.6
2562158	2015, Applicant DER, DACO: 2.16 CBI
2619373	2016, Sharda Acetamiprid Technical Deficiency Response, DACO: 2.11.3, 2.13.4 CBI
2619374	2016, Study Plan (Analysis of CBI removed), DACO: 2.13.4 CBI

2664630	2016, Analysis and Method Validation for 5 Batches of Acetamiprid Technical Material to Determine the Content of Specified Impurities, in Compliance with Good Laboratory Practice Part 1 of 2, DACO: 2.13.4 CBI
2664632	2016, Recovery Precision, DACO: 2.13.4 CBI
2678090	2016, Batch Information, DACO: 2.13.4 CBI

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