

Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2013-6686
Application: New Source of Technical Grade Active Ingredient by a New Registrant
Product: Veto-Pharma Amitraz Technical (Insecticide)
Registration Number: 31777
Active ingredients (a.i.): Amitraz
PMRA Document Number : 2513750

Purpose of Application

The purpose of this application was to register a new source of the active ingredients, amitraz, by a different Registrant.

Chemistry Assessment

Common Name: amitraz
CAS Chemical Name: *N'*-(2,4-dimethylphenyl)-*N*-[[[(2,4-dimethylphenyl)imino]methyl]-*N*-methylmethanimidamide
IUPAC Chemical Name: *N'*-(2,4-dimethylphenyl)-*N*-{[(2,4-dimethylphenyl)imino]methyl}-*N*-methylmethanimidamide

Veto-Pharma Amitraz Technical (insecticide) has the following properties:

Property	Result
Colour and physical state	Off-white or straw-coloured crystalline solid
Nominal concentration	99%
Odour	Slight amine odour
Density	1.13 g/mL at 20°C
Vapour pressure	0.34 mPa at 25°C
pH	Not available due to low solubility in water
Solubility in water	1 ppm at 20°C
n-Octanol/water partition coefficient (K_{ow})	$\log K_{ow} = 5.5$ at 25°C (pH 5.5)

The chemistry requirements for Veto-Pharma Amitraz Technical (insecticide)

have been fulfilled.

Health and Environmental Assessment

As the new source of amitraz is chemically equivalent to the registered source, the health and environmental risk profiles are expected to be similar to that of the product used to determine chemical equivalence. No additional assessments were required.

Value Assessment

A value assessment is not required for technical grade active ingredient products.

Conclusion

The PMRA has completed an evaluation of the subject application and has determined that it can support the registration of Veto-Pharma Amitraz Technical (Insecticide).

References

PMRA Document Number	Reference
2367269	2013, Product Chemistry for Amitraz - Group A, DACO: 2.11.1,2.11.2,2.11.3,2.11.4,2.12.1,2.13.1,2.13.2,2.13.3,2.4,2.5,2.6,2.7,2.8,2.9 CBI
2367271	2013, Chemical Physical Properties, DACO: 2.14.1,2.14.13,2.14.2,2.14.3,2.14.4,2.14.6,2.14.8,2.14.9,2.15 CBI
2479518	2014, Product Chemistry for AMITRAZ Group A Amendment to Report submitted on September 19, 2013, DACO: 2.13.1 CBI
2479519	2012, Analytical Validation Report, DACO: 2.13.1 CBI
2479520	2014, Preliminary Analysis - Physio Chemical tests on Five Batches of Technical Amitraz, DACO: 2.13.3 CBI
2479521	2014, Preliminary Analysis of Five Batches of Technical Amitraz, DACO: 2.13.3 CBI

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