Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2010-1348
Application: New Source of Technical Grade Active Ingredient by a New Registrant
Product: MANA Imidacloprid Technical
Registration Number: 30374
Active ingredients (a.i.): Imidacloprid
PMRA Document Number English PDF: 2134073

Background

The source of imidacloprid used to determine chemical equivalence was Registration Number 24486.

Purpose of Application

The purpose of this application was to register two new sources of the active ingredient, imidacloprid, by a different Registrant.

Chemistry Assessment

Common Name: Imidacloprid
Chemical Name: (E)-1-(6-chloro-3-pyridylmethyl)-*N*-nitroimidazolidin-2-ylidazolidinimine

MANA Imidacloprid Technical has the following properties:

Property	Result
Colour and physical state	White solid (powder)
Nominal concentration	98.3%
Odour	Practically odourless
Density	1.51 g/mL
Vapour pressure	4×10^{-7} mPa at 20°C and 9×10^{-7} mPa at 25°C
pH	5.8-7.2
Solubility in water	0.61 g/L
n-Octanol/water partition coefficient	Log K_{ow} = 0.57 at 21°C

Canada

The chemistry requirements for MANA Imidacloprid Technical have been completed.

Health and Environmental Assessments

As the new sources of imidacloprid are 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 MANA Imidacloprid Technical.

References

PMRA Document Number	Reference
1888479	Chemistry Part 2, DACOs 2.1-2.3.1, DACO: 2.1,2.2,2.3,2.3.1
1888481	Additional Information on the Discussion of the Formation of Impurities, Supplement to MRID Number 47344704, DACO: 2.11.4 CBI
1888482	Technical Imidacloprid: Determination of Purity and Impurity Profiles of Five Technical Batches Including Analysis for [CBI removed], DACO: 2.13.1,2.13.2,2.13.3 CBI
1888483	Technical Imidacloprid: Determination of Purity and Impurity Profiles of Five Technical Batches Including Analysis for [CBI removed], DACO: 2.13.1,2.13.2,2.13.3 CBI
1888484	Physical and Chemical Characteristics: Color, Physical State, Odor, Stability to normal and Eleveated Temperatures-Metals and Metal Ions, pH and Densityin, DACO: 2.14.1,2.14.13,2.14.2,2.14.3,2.14.6
1888485	Discussion of pH and Density Results, DACO: 2.14.6
1888486	Imidacloprid Techmical - Physical and Chemical Properties-Summary, DACO: 2.14.10,2.14.11,2.14.12,2.14.4,2.14.7,2.14.8,2.14.9
1888487	Imidacloprid Technical Product Chemistry Data, DACO: 2.11.1,2.11.2,2.11.3,2.11.4,2.12.1,2.4,2.5,2.6,2.7,2.8,2.9 CBI

1947143 MANA Imidacloprid TGAI-letter of intent-16august2010-deficiency response, DACO: 0.8,2.11.4 CBI

1947144 Absence of the [CBI removed] Compound Explanation, DACO: 2.13.4 CBI

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