



Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2010-3435
Application: New Source of Technical Grade Active Ingredient by a New Registrant
Product: Nufarm Lambda-Cyhalothrin Technical
Registration Number: 31604
Active ingredients (a.i.): lambda-cyhalothrin
PMRA Document Number : 2475548

Background

The source of lambda-cyhalothrin used to determine chemical equivalence was Registration Number 24567.

Purpose of Application

The purpose of this application was to register a new source of the active ingredient, lambda-cyhalothrin, by a different Registrant.

Chemistry Assessment

Common Name: Lambda-cyhalothrin
Chemical Name: (*R*)- α -cyano-3-phenoxybenzyl (1*S*)-*cis*-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (*S*)- α -cyano-3-phenoxybenzyl (1*R*)-*cis*-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate
OR
(*R*)-cyano(3-phenoxyphenyl)methyl (1*S*,3*S*)-*rel*-3-[(1*Z*)-2-chloro-3,3,3-trifluoro-1-propen-1-yl]-2,2-dimethylcyclopropanecarboxylate

Nufarm Lambda-cyhalothrin Technical has the following properties:

Property	Result
Colour and physical state	White solid
Odour	No discernible odour
Melting point/range	45.5-51.5°C
Boiling point/range	Decomposes at approximately 213°C
Specific gravity at 25°C	1.25
Solubility in water	0.002 mg/L

Property	Result
Octanol/water partition coefficient (K _{ow})	Log K _{ow} > 6.2

The chemistry requirements for Nufarm Lambda-cyhalothrin Technical have been completed.

Health and Environmental Assessments

As the new source of lambda-cyhalothrin 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 Nufarm Lambda-Cyhalothrin Technical.

References

Studies/Information Provided by Applicant

PMRA No	Title
1939803	2010, NUP 07315 Chem 1 Report - 30Jul10, DACO: 2.1,2.2,2.3,2.3.1 CBI
1939804	2008, NUP 07315 PIC - 30Jul10, DACO: 2.11,2.11.1,2.11.2,2.11.3,2.11.4,2.4,2.5,2.6,2.7,2.8,2.9 CBI
1939805	2008, NUP 07315 method validation - 30Jul10, DACO: 2.13.1,2.13.2 CBI
1939807	2008, NUP 07315 5 batch - 30Jul10, DACO: 2.13.3,2.13.4 CBI
1939809	2008, NUP 07315 Appearance - 30Jul10, DACO: 2.14.1,2.14.2,2.14.3 CBI
1939810	2007, NUP 07315 Melting point - 30Jul10, DACO: 2.14.4 CBI
1939811	2007, NUP 07315 Boiling point - 30Jul10, DACO: 2.14.5 CBI
1939813	2008, NUP 07315 density - 30Jul10, DACO: 2.14.6 CBI
1939814	2008, NUP 07315 water solubility - 30Jul10, DACO: 2.14.7 CBI
1939815	2008, NUP 07315 solvent solubility - 30Jul10, DACO: 2.14.8 CBI
1939816	2008, NUP 07315 vapour pressure - 30Jul10, DACO: 2.14.9 CBI
1939817	2007, NUP 07315 dissociation constant - 30Jul10, DACO: 2.14.10 CBI
1939818	2007, NUP 07315 partition coefficient - 30Jul10, DACO: 2.14.11 CBI
1939819	2008, NUP 07315 spectra - 30Jul10, DACO: 2.14.12 CBI
1939820	2008, NUP 07315 stability - 30Jul10, DACO: 2.14.13 CBI

1939821 2009, NUP 07315 storage stability - 30Jul10, DACO: 2.14.14 CBI
2047947 2008, Mass Spectrometric Investigation into Impurities Detected in Lambda-
cyhalothrin using GC-MS, DACO: 2.11.4 CBI

ISSN: 1911-8082

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