Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2018-5557
Application: Changes to Product Chemistry-New Source(site); same registrant
Product: Technical Flonicamid Insecticide
Registration Number: 29795
Active ingredients (a.i.): Flonicamid
PMRA Document Number : 3171489

Purpose of Application

The purpose of this application was to add an alternate manufacturing site for Technical Flonicamid Insecticide.

Chemistry Assessment

Common Name: Flonicamid
IUPAC* Chemical Name: *N*-(cyanomethyl)-4-(trifluoromethyl)pyridine-3-carboxamide
CAS† Chemical Name: *N*-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide

* International Union of Pure and Applied Chemistry
† Chemical Abstracts Service

Technical Flonicamid Insecticide has the following properties:

Property	Result
Colour and physical state	Light beige
Nominal concentration	98.4%
Odour	Odourless
Density	1.5 g/cm^3 at 20°C
Vapour pressure	9.43 x 10^{-4} mPa at 20.0°C
pH	4.5
Solubility in water	5.3 mg/mL at 20°C
n-Octanol/water partition coefficient	Log K_{ow} = 0.30

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

Canada

Health, Environmental and Value Assessments

Health, 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 the information sufficient to amend the registration of Technical Flonicamid Insecticide.

Additional Information Being Requested

Since this technical product is manufactured only at pilot scale before registration, five-batch data representing commercial-scale production will be required as post-market information after registration.

References

PMRA Document Number	Reference
1581848	2002, Description of Manufacturing Process/Technical Flonicamid Insecticide
1581849	2002, Description of Materials Used to Produce the Products/Technical Flonicamid Insecticide (IKI-220), DACO: 2.11.2,2.11.3 CBI
1581852	2002, Discussion of impurities/Technical Flonicamid Insecticide (IKI-220), DACO: 2.11.4 CBI
1581854	2001, IKI-220 - Method Validation [Determination of AI and Related Impurities in IKI-220, TGAI [CBI Removed]], DACO: 2.13.1 CBI
1581873	2003, Product Chemistry Review of ISK Biosciences Technical Flonicamid Insecticide and End-Use Product Flonicamid 50WG, DACO: 2.11.1,2.11.2,2.11.3, 2.11.4, 2.12.1,2.13.1,2.13.2,2.13.3,2.14.1,2.14.10, 2.14.11,2.14.13,2.14.14, 2.14.2, 2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9 CBI
2929525	2017, Content Analysis of IKI-220 TGAI, DACO: 2.13.3 CBI
2929526	2017, Batch Manufacturing Dates, DACO: 2.13.3 CBI
3082851	2017, Validation of Analytical Method for IKI-220 TGAI, DACO: 2.13.1 CBI
3082852	2019, Content analysis of IKI-220 Technical, DACO: 2.13.4 CBI
3105362	2020, [CBI Removed] Clarification Transmittal Letter, DACO: 2.13.3.