



Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2017-3477
Application: Changes to TGAI Product Chemistry- New Source/ Same Registrant
Product: Fluopyram Technical Fungicide
Registration Number: 30508
Active ingredient (a.i.): Fluopyram
PMRA Document Number: 2878467

Purpose of Application

The purpose of this application was to register a new manufacturing site for Fluopyram Technical Fungicide.

Chemistry Assessment

Common Name: Fluopyram
IUPAC* Chemical Name: *N*-{2-[3-chloro-5-(trifluoromethyl)-2-pyridyl]ethyl}- α,α,α -trifluoro-*o*-toluamide
CAS† Chemical Name: *N*-[2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]ethyl]-2-(trifluoromethyl)benzamide

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Fluopyram Technical Fungicide has the following properties:

Property	Result
Colour and physical state	White solid
Nominal concentration	98.4%
Odour	No noticeable odour
Density	1.53 g/cm ³
Vapour pressure	3.1 × 10 ⁻⁶ Pa at 25°C
pH	6.6 (1% solution)
Solubility in water	16 mg/L (20°C, pH 7)

Property	Result
n-Octanol/water partition coefficient	Log K _{ow} = 3.3 at 20°C

The required chemistry data for Fluopyram Technical Fungicide 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 Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of the new source of Fluopyram Technical Fungicide.

References

PMRA Document Number	Reference
2782856	2017, Manufacturing Summary, DACO: 2.11.1,2.11.2,2.11.3 CBI
2782858	2017, Manufacturing Summary, DACO: 2.11.1,2.11.2,2.11.3 CBI
2782859	2017, Discussion of Formation of Impurities, DACO: 2.11.4 CBI
2782861	2014, Methodology/Validation, DACO: 2.13.1 CBI
2782862	2013, Methodology/Validation, DACO: 2.13.1 CBI
2782863	2017, Methodology/Validation, DACO: 2.13.1 CBI
2782864	2017, Methodology/Validation, DACO: 2.13.1 CBI
2782865	2017, Batch Data, DACO: 2.13.3 CBI
2782866	2008, Tier 2 summary of the physical and chemical properties of the active substance - Fluopyram (AE C656948), DACO: 12.7.2,Document J,Document M
2782868	2017, Fluopyram - Product chemistry evaluation (based on OECD dossier numbering) - Identity, physical and chemical properties, analytical methods, confidential information, DACO: 12.7.2,2.1,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9,Document J,Document M
2782869	2017, Fluopyram - Product chemistry evaluation (based on OECD dossier numbering) - Identity, physical and chemical properties, analytical methods, confidential information, DACO: 12.7.2,2.1,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9,Document J,Document M
2870024	2018, Detailed Production Process Description, DACO: 2.11.3 CBI
2874714	2018, Manufacturing Summary, DACO: 2.11.1,2.11.2,2.11.3 CBI

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