

Evaluation Report for Category B, Subcategory 1.3 Application

Application Number: 2022-1319
Application: Changes to TGAI Product Chemistry - Specifications
Product: Fluopyram Technical Fungicide
Registration Number: 30508
Active ingredient (a.i.): Fluopyram
PMRA Document Number: 3482381

Purpose of Application

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

Chemistry Assessment

Common Name: fluopyram
 IUPAC* Chemical Name: *N*-[2-[3-chloro-5-(trifluoromethyl)-2-pyridyl]ethyl]-2-(trifluoromethyl)benzamide
 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 powder
Nominal concentration	98.8%
Odour	No noticeable odour
Density	1.53 g/cm ³ at 20°C
Vapour pressure	1.2 × 10 ⁻⁶ Pa at 20°C
pH	6.6 (1% solution)
Solubility in water	16 mg/L (pH 7)
n-Octanol/water partition coefficient	log K _{ow} = 3.3 at 20°C (pH 6.5)

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 are not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the new manufacturing process for Fluopyram Technical Fungicide.

References

PMRA

Document

Number	Reference
3336186	2022, Fluopyram (AE C656948) - Description of manufacturing process of the technical grade active substance for USA and Canada, DACO: 2.11.1,2.11.2,2.11.3 CBI
3336187	2022, Fluopyram (AE C656948) - Technical grade active substance – Discussion on the formation of impurities for USA and Canada, DACO: 2.11.4 CBI
3336189	2013, Fluopyram (AE C656948) - Determination of [CBI removed] in fluopyram (AE C656948) technical grade active substance - IC - External standard, DACO: 2.13.1 CBI
3336190	2020, Validation of IC-method AM022513MP3 Fluopyram (AE C656948) determination of [CBI removed] in fluopyram - IC - external Standard, DACO: 2.13.1,2.13.2 CBI
3336191	2021, Validation of method AM028717MP1 - Fluopyram (AE C656948) – Determination of [CBI Removed], DACO: 2.13.1,2.13.2 CBI
3336192	2014, Fluopyram (AE C656948) - Determination of impurities in technical grade active substance - HPLC - external standard, DACO: 2.13.1 CBI
3336193	2019, Validation of AM003906MP7 - Fluopyram (AE C656948) - Determination of impurities in technical grade active substance - HPLC - external standard, DACO: 2.13.1,2.13.2 CBI
3336194	2022, Material accountability of technical fluopyram (AE C656948) - 5 batch analysis, DACO: 2.13.2,2.13.3 CBI
3400718	2022, [CBI removed] content in the material accountability study 15-920-2878 of technical fluopyram (AE C656948), DACO: 2.13.4 CBI
3400719	2022, [CBI Removed] content in the material accountability study 15-920-2878 of technical fluopyram (AE C656948), DACO: 2.13.4 CBI

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