

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2018-6515
Application: B.1.1: New Source Same Registrants
Product: Fluopyram Technical Fungicide
Registration Number: 30508
Active ingredients (a.i.): Fluopyram
PMRA Document Number : 3052342

Purpose of Application

The purpose of this application was to register two additional manufacturing sites 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	98.7 %
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)
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 Assessment

Health, environmental and value assessments were not required for this application.

Conclusion

The PMRA has reviewed the information provided in support of these two additional manufacturing sites. Based on the results of this review, the two additional manufacturing sites are acceptable.

References

- 2943562 2018, Fluopyram - Description of the manufacturing process of the technical grade active substance for Canada, DACO: 2.11.1,2.11.2,2.11.3 CBI
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- 2943564 2018, Fluopyram (AE C656948) - Technical grade active substance - Discussion on the formation of impurities, DACO: 2.11.4 CBI
- 2943565 2018, Fluopyram (AE C656948) - Technical grade active substance - Discussion on the formation of impurities, DACO: 2.11.4 CBI
- 2943569 2017, Material accountability of technical fluopyram (AE C656948) - 5 batch analysis - 1. Amendment, DACO: 2.13.3 CBI
- 2943570 2017, Material accountability of technical fluopyram (AE C656948) - 5 batch analysis - 1. Amendment, DACO: 2.13.3 CBI

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