

Evaluation Report for Category B, Subcategory 1.3 Application

Application Number: 2019-3225
Application: B.1.3: Changes to Chemistry-Specifications
Product: Fluopicolide Technical
Registration Number: 30049
Active ingredients (a.i.): Fluopicolide
PMRA Document Number: 3106128

Purpose of Application

The purpose of this application was to make minor change to the manufacturing process of Fluopicolide Technical.

Chemistry Assessment

Common Name: Fluopicolide
IUPAC* Chemical Name: 2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]benzamide
CAS† Chemical Name: 2,6-dichloro-N-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]methyl]benzamide

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Fluopicolide Technical has the following properties:

Property	Result
Colour and physical state	Beige solid
Nominal concentration	98.8 %
Odour	Odourless
Relative Density	1.65
Vapour pressure	8.03×10^{-4} mPa (at 25°C)
pH	6.5 at 22 °C
Solubility in water	3.02 mg/L (20°C)

Property	Result
n-Octanol/water partition coefficient	log Kow = 2.9

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

Health Assessments

The Fluopicolide Technical produced with the new manufacturing process is considered toxicologically equivalent to the precedent product. Consequently, no toxicological data were reviewed or are required.

Environmental and Value Assessments

Environmental and value assessments were not required for this application.

Conclusion

The PMRA has reviewed the information provided in support of the change in manufacturing process. Based on the results of this review, the new manufacturing process is acceptable.

References

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- 3010055 2018, Material Accountability of Technical Fluopicolide (AE C638206), DACO: 2.13.3
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- 3010062 2019, Material Accountability of Technical Fluopicolide (AE C638206), DACO: 2.13.3
- 3010063 2019, Fluopicolide Technical (AE C683206): Discussion of Four 5-Batch Analysis Studies, DACO: 2.11.2,2.11.3,2.13.3 CBI
- 3010064 2019, Fluopicolide Technical (AE C683206): Discussion of Four 5-Batch Analysis Studies, DACO: 2.11.2,2.11.3,2.13.3 CBI
- 3075718 2020, Fluopicolide (AE C638206; BCS-AM59797) Description of the Manufacturing Process of the Technical Grade Active Substance (Specification No. 102000035244) For Canada, DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4 CBI
- 3075720 2020, Fluopicolide (AE C638206; BCS-AM59797) Description of the Manufacturing Process of the Technical Grade Active Substance (Specification No. 102000016444) For Canada, DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI

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