Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2016-7478
Application: New TGAI, new registrant
Product: Zhongshan Florasulam Technical 98%
Registration Number: #####
Active ingredient (a.i.): Florasulam
PMRA Document Number: 2805448

Purpose of Application

The purpose of this application was to register a new source of florasulam, Zhongshan Florasulam Technical 98%.

Chemistry Assessment

Common Name: Florasulam
IUPAC* Chemical Name: 2',6',8-trifluoro-5-methoxy[1,2,4]triazolo[1,5-*c*]pyrimidine-2-sulfonanilide
CAS† Chemical Name: *N*-(2,6-difluorophenyl)-8-fluoro-5-methoxy[1,2,4]triazolo[1,5-*c*]pyrimidine-2-sulfonamide

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

Zhongshan Florasulam Technical 98% has the following properties:

Property	Result
Colour and physical state	White solid
Nominal concentration	98.43%
Odour	No characteristic odour
Density at 20°C	1.524 g/mL
Vapour pressure at 25°C	6.4×10^{-5} Pa
pH	4.32 (1% aqueous dilution)

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Property	Result	
Solubility in water at 25°C	pH	solubility (g/L)
	4	0.030
	7	3.5
	9	121
n-Octanol/water partition coefficient	pH	Log K_{ow}
	4	1.03
	7	-1.22
	9	-2.43

The required chemistry data for Zhongshan Florasulam Technical 98% 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 Zhongshan Florasulam Technical 98%.

References

PMRA Document Number	Reference
2703433	2016, Chemistry requirements for TGAI, DACO: 2.1,2.2,2.3,2.3.1,2.4,2.5,2.6, 2.7,2.8,2.9
2703434	2016, Manufacturing methods for TGAI, DACO: 2.11 CBI
2703435	2015, Five Batches Data, DACO: 2.12.1,2.13.1,2.13.2,2.13.3,2.13.4 CBI
2703436	2015, Chemical and Physical Properties, DACO: 2.14 CBI
2771282	2017, Manufacturing methods, DACO: 2.11 CBI
2771284	2017, Impurities concern, DACO: 2.13.4 CBI
2771285	2016, Stabilities test, DACO: 2.14.13 CBI
2771286	2015, pH value, DACO: 2.14.15,830.7000 CBI
2796390	2017, enforcement analytical method of [CBI Removed], DACO: 2.13.4 CBI
2796391	2017, Storage stability, DACO: 2.14.14 CBI

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