

Evaluation Report for Category L, Subcategory 1.1 Application

Application Number: 2017-5796
Application: Submissions subject to PPIP policy
Product: Sharda Florasulam Technical
Registration Number: 33243
Active ingredient (a.i.): Florasulam
PMRA Document Number : 2895169

Purpose of Application

The purpose of this application was to register a new source of florasulam, Sharda Florasulam Technical, by a new registrant.

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

Sharda Florasulam Technical has the following properties:

Property	Result								
Colour and physical state	White solid								
Nominal concentration	99.01%								
Odour	Characteristic								
Density	1.5887 g/mL								
Vapour pressure	7.21×10^{-6} Pa at 20 °C								
pH	4.9 (1% w/v aqueous dilution) at 20 °C								
Solubility in water	<table border="0"> <tr> <td><u>pH</u></td> <td><u>Solubility (g/L, 20 °C)</u></td> </tr> <tr> <td>4</td> <td>0.051</td> </tr> <tr> <td>7</td> <td>3.47</td> </tr> <tr> <td>10</td> <td>12.96</td> </tr> </table>	<u>pH</u>	<u>Solubility (g/L, 20 °C)</u>	4	0.051	7	3.47	10	12.96
<u>pH</u>	<u>Solubility (g/L, 20 °C)</u>								
4	0.051								
7	3.47								
10	12.96								

Property	Result	
n-Octanol/water partition coefficient	pH	$\log K_{ow}$
	4	0.64
	7	-1.61
	10	-3.60

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

Health Assessments

The new source of Florasulam Technical is toxicologically equivalent to a registered source. Subsequently no toxicological data were submitted or are required.

Exposure assessments were not required for this application.

Environmental Assessment

The new source of active ingredient is not expected to increase the environmental exposure relative to the registered precedent product. Environmental concerns have been mitigated through adequate statements on the product label.

Value Assessment

A value assessment was 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 Sharda Florasulam Technical.

References

PMRA Document Number	References
2807739	2017, Florasulam Manufacture Process, DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI
2807740	2017, Answers to questions about starting materials used to manufacture Sharda Florasulam Technical, DACO: 2.11.2,2.11.3 CBI
2807741	2017, Starting material used to manufacture Sharda florasulum technical, DACO: 2.11.2,2.11.3 CBI
2807763	2014, Analysis and Method Validation for 5 batches of Florasulam Technical Material to determine the content of the active ingredient and specified impurities, in compliance with Good Laboratory Practice, DACO: 2.13.1,2.13.2,2.13.3,2.13.4

- 2807764 2014, Analysis and Method Validation for 5 batches of Florasulam Technical Material to determine the content of the active ingredient and specified impurities, in compliance with Good Laboratory Practice, DACO: 2.13.1,2.13.2,2.13.3,2.13.4
- 2807765 2014, Analysis and Method Validation for 5 batches of Florasulam Technical Material to determine the content of the active ingredient and specified impurities, in compliance with Good Laboratory Practice, DACO: 2.13.1,2.13.2,2.13.3,2.13.4
- 2807766 2014, Analysis and Method Validation for 5 batches of Florasulam Technical Material to determine the content of the active ingredient and specified impurities, in compliance with Good Laboratory Practice, DACO: 2.13.1,2.13.2,2.13.3,2.13.4
- 2807767 2015, Analysis and Method Validation for 5 batches of Florasulam Technical Material to determine the content of the active ingredient and specified impurities, in compliance with Good Laboratory Practice, DACO: 2.13.1,2.13.2,2.13.3,2.13.4
- 2807768 2015, Analysis and method validation for 5 batches of Florasulam Technical, DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
- 2807769 2017, Determination Of [CBI Removed] In 5 Samples of Technical Florasulam, DACO: 2.13.4 CBI
- 2807770 2016, Declaration of Sample origin for 5 batch analysis, DACO: 2.13.3 CBI
- 2807771 2016, Florasulam Technical Determination of Physio-chemical Properties, DACO: 2.14.1,2.14.10,2.14.11,2.14.12,2.14.15,2.14.2,2.14.3,2.14.4,2.14.6, 2.14.7,2.14.8,2.14.9
- 2807772 2016, Florasulam Technical Determination of the Accelerated Storage Stability and Corrosion Characteristics, DACO: 2.14.13,2.14.14
- 2807773 2016, Florasulam Technical Determination of the Oxidizing Properties and Explosive Properties, DACO: 2.16
- 2844959 2018, TGAI batches source confirmation, DACO: 2.13.3 CBI

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