

Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2015-5989
Application: New Technical Grade Active Ingredient - New Source /
 New Registrant
Product: Sharda Fluroxypyr-meptyl Technical
Registration Number: #####
Active ingredient (a.i.): Fluroxypyr (present as 1-methylheptyl ester)
PMRA Document Number: 2738088

Purpose of Application

The purpose of this application was to register Sharda Fluroxypyr-meptyl Technical, a new source of the active ingredient fluroxypyr, present as 1-methylheptyl ester, by a new registrant.

Chemistry Assessment

Common Name: Fluroxypyr-meptyl
CAS[†] Chemical Name: 1-methylheptyl 2-[(4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy]acetate
IUPAC* Chemical Name: *rac*-(2*R*)-octan-2-yl [(4-amino-3,5-dichloro-6-fluoropyridin-2-yl)oxy]acetate

[†] Chemical Abstracts Service

* International Union of Pure and Applied Chemistry

Sharda Fluroxypyr-meptyl Technical has the following properties:

Property	Result
Colour and physical state	White solid
Nominal concentration	68.9%
Odour	Musty
Density	1.261 g/mL
Vapour pressure	$< 4.4 \times 10^{-4}$ Pa
pH	6.10
Solubility in water	0.09 mg/L
n-Octanol/water partition coefficient (K_{ow})	Log K_{ow} = 5.04 (published value)

The chemistry requirements for Sharda Fluroxypyr-meptyl Technical have been fulfilled.

Health Assessments

Sharda Fluroxypyr-meptyl Technical is considered toxicologically equivalent to the currently registered precedent product. New toxicological data were neither submitted nor required.

Occupational and dietary exposure assessments were not required for this application.

Environmental Assessment

The technical grade active ingredient has been shown to contain contaminants which have been identified in the federal government's *Toxic Substances Management Policy* (TSMP, 1995) as Track 1 substances. When compared to other registered sources, the use of the proposed new source is not expected to result in an increase in the release of Track 1 contaminants. PMRA's strategy to manage Track 1 contaminants in pest control products is captured in DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*.

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 Fluroxypyr-meptyl Technical.

References

PMRA Document Reference

Number

2580752	2015, Manufacturing process of Fluroxypyr-meptyl , DACO: 2.11.1, 2.11.2, 2.11.3 CBI
2580762	2015, Justification of Impurity, DACO: 2.11.4 CBI
2580764	2013, Purity Profile of five Batches of Fluroxypyr-meptyl Technical, DACO: 2.13,2.13.1,2.13.2,2.13.3,2.14.12 CBI
2580766	2012, Purity Profile of five Batches of Fluroxypyr-meptyl Technical-Pre-screening Phase, DACO: 2.13,2.13.1,2.13.2 CBI
2629128	2016, Dioxins and Furans Analysis, DACO: 2.13.4 CBI
2580772	2009, Fluroxypyr-meptyl Physical/Chemical Tests, DACO: 2.14.1, 2.14.10, 2.14.11, 2.14.13, 2.14.14, 2.14.15, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 830.7000

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