

Evaluation Report for Category B, Subcategory 2.1 Application

Application Number: 2006-3604
Application: Category B, subcategory 1.1
 (new source by same registrant)
Product: Triflurex Technical
Registration Number: 18602
Active ingredient (a.i.) contained in product: Trifluralin at 96.6%
PMRA Document Number: 1432704

Background

The original source of Triflurex Technical was registered in 1985.

Purpose of Application

The purpose of this application is to add a new site of manufacture for Triflurex Technical.

Chemistry Assessment

Common Name: Trifluralin
IUPAC Chemical Name: α,α,α -trifluoro-2,6-dinitro-*N,N*-dipropyl-*p*-toluidine
CAS Chemical Name: 2,6-dinitro-*N,N*-dipropyl-4-(trifluoromethyl)benzenamine

Triflurex Technical has the following properties:

Property	Result	
Colour and physical state	Yellow-orange solid	
Nominal concentration	96.6%	
Odour	Not provided	
Density	1.36 g/cm ³	
Vapour pressure	6.1 mPa	
pH	5.0-9.0	
Solubility in water	pH	
	Solubility (mg/L)	
	5	0.184 0.343 (technical)
	7	0.221 0.395 (technical)
9	0.189 0.383 (technical)	
n-Octanol/water partition coefficient	Log K _{OW} = 4.83	

The chemistry requirements for Triflurex Technical are complete.

Health and Environmental Assessment

The health and environmental risk profile of the new source of Triflurex Technical is expected to be similar to that of the original registered source.

Value Assessment

A value assessment is not required for technical grade active ingredient products.

Conclusion

The PMRA has completed an evaluation of the subject application and has determined that the new manufacturing site for Triflurex Technical is eligible for registration.

References

- 1257842 Chemistry Part 2 TGAI, NS, DACO: 2.1,2.11.1,2.11.2,2.11.3
1257843 2006, Quali-quantitative Composition, NS, DACO: 2.11.1
1257845 2006, Trifluralin Technical Discussion of Formation of Impurities, 90009481,
DACO: 2.11.4
1257846 2001, Triflurex Technical - Five Lots Analysis and Method Validation, 01-09/2,
MRID: NS, DACO: 2.13.1,2.13.2,2.13.3
1257847 2001, Triflurex Technical - Five Lots Analysis and Method Validation
(Confidential Attachment), 01-09/2, DACO: 2.13.1,2.13.2,2.13.3
1380909 2007, Milenia Declaration (Detailed Production Process Description), NS,
DACO: 2.11.3

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