

**Register New Source of Technical Active Ingredient FUNGINEX (Triforine)
by the Current Registrant and Amend the Specifications
Evaluation Report for Category B, Subcategory B.1.1 and B.1.3 Application**

Application Number: 2006-6161
Application: Register New Source of Technical Active Ingredient FUNGINEX (Triforine) by the Current Registrant and Amend the Specifications
Product: Technical Active Ingredient FUNGINEX (Triforine)
Registration Number: 20333
Active ingredients (a.i.): Triforine
PMRA Document Number: 1494484

Background

The original source of triforine technical grade active ingredient, “Technical FUNGINEX (Triforine)” (Registration No. 20333), was first registered in 1987.

Purpose of Application

The purpose of this application is to replace the registered German site with the new Indian site and to amend the specifications.

Chemistry Assessment

Common Name: Triforine
Chemical Name: N,N’-{piperazine-1,4-diy]bis[(trichloromethyl)methylene]} diformamide

Technical Active Ingredient FUNGINEX (triforine) has the following properties:

Property	Result
Colour and physical state	white to light brown crystal
Nominal concentration	99.15%
Odour	N/A
Density @ 20°C	1.55 g/cm ³
Vapour pressure @ 25°C	8 x 10 ¹ mPa
pH	5.57-8.33

Property	Result
Solubility in water @ 20°C	9 mg/L
n-Octanol/water partition coefficient	$\log K_{ow} = 2.2$

The chemistry requirements for Technical Active Ingredient FUNGINEX (triforine) have been completed.

Health Assessments

The active ingredients produced at the registered and new sites of manufacture of Technical Active Ingredient FUNGINEX (Triforine) are chemically equivalent. Therefore, the health risk profile of Technical Active Ingredient FUNGINEX (Triforine) is expected to be similar to that of the original registered source and no toxicological data were required.

The food residue risk profile of Technical Active Ingredient FUNGINEX (99.15% triforine) is expected to be similar to that of the original registered source.

Conclusion

The PMRA has completed an evaluation of the subject application and has determined that Technical Active Ingredient FUNGINEX (Triforine) is eligible for registration.

References

A. List of Studies/Information Submitted by Registrant

Chemistry Assessment

- 1301011 2006, Product Chemistry DACO 2.1 to 2.9 for Triforine, E20060006-R, MRID: N/A, DACO: 2.1,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9
- 1301012 2006, Product Chemistry DACO 2.1 to 2.9 for Triforine, E20060006-R, MRID: n/a, DACO: 2.1,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9
- 1301013 1999, Production Process Information for Technical Triforine, P-306C.01, MRID: n/a, DACO: 2.11.1,2.11.2,2.11.3
- 1301014 1998, Triforine (AC 902194) Technical Material: Description of the Materials Used to Produce the Product and of the Production Process Conform EPA Product Properties Test Guidelines OPPTS 830.1600 and OPPTS 830-1620, CFS 1998-045, MRID: n/a, DACO: 2.11.1,
- 1301015 1997, Analysis of Technical Grade Triforine (AC 902194) for the Evaluation of Chemical Equivalence, CFS 1996-171, MRID: n/a, DACO: 2.11.2
- 1301018 2006, Five (5) Batches Analyses of SC-581211 (Triforine), Koei P05005, MRID: n/a, DACO: 2.11.4,2.12.1,2.13.1,2.13.2,2.13.3
- 1301024 1994, Composition of Triforine (CL 182,362) Technical Grade Material for Registration Purposes, APBR 384, MRID: n/a, DACO: 2.12.1,2.13.2,2.13.3
- 1301025 1995, Composition of Triforine (CL 182,362) Technical Grade Material for Registration Purposes (Report Amendment), APBR 384.01, MRID: n/a, DACO: 2.12.1,2.13.2,2.13.3

- 1301026 1996, Response to Questions Posed by the Canadian Pest Management Regulatory Agency Regarding the Triforine (AC 902194) Product Chemistry Data Submitted in December 1994, APBR 627, MRID: n/a, DACO: 2.12.1,2.13.2,2.13.3
- 1388457 1996, Method of Analysis CFS-DPA M7/3/N. High Performance Liquid Chromatographic Method to Assay for Minor Components in the Technical Grade of Triforine (CL 902224), CFS-DPA M7/3/N, MRID: n/a, DACO: 2.13.1
- 1388458 1996, Response to Questions Posed by the Canadian Pest Management Regulatory Agency Regarding the Triforine (AC 902194) Product Chemistry Data Submitted in December 1994, APBR 627, MRID: n/a, DACO: 2.13.1

Health Assessment

None.

B. Additional Information Considered

i) Published Information

Chemistry Assessment

None.

Health Assessment

None.

ii) Unpublished Information Considered

Chemistry Assessment

- 1389660 2000. Chemistry Evaluation of Triforine. PMRA review report with submission number 2000-1527.

Health Assessment

None.

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