

Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2004-1719
Application: New source by different registrant
Product: Cambrex TRA
Registration Number: 28481
Active ingredients (a.i.): trichloro-s-triazinetrione 90%
PMRA Document Number: 1414585

Background

The original source of trichloro-s-triazinetrione technical grade active ingredient, “Clearon CDB-90 Chlorinating Granules” (Reg. No. 12883) was first registered in 1973.

Purpose of Application

The purpose of this application is to register a new technical source of trichloro-s-triazinetrione.

Chemistry Assessment

Common Name: Trichloroisocyanuric acid
IUPAC Chemical Name: 1,3,5-trichloro-1,3,5-triazine-2,4,6(1H,3H,5H)-trione
CAS Chemical Name: 1,3,5-trichloro-1,3,5-triazinetrione

Cambrex TRA has the following properties:

Property	Result
Colour and physical state	white solid granular
Nominal concentration	90% (available chlorine present as sodium trichloro-s-triazinetrione)
Odour	chlorine
Specific gravity	0.95
Vapour pressure	<0.00005 mm Hg
pH	2.6-3.2 for 1% solution
Solubility in water	1.2 g/100 mL at 25°C
n-Octanol/water partition coefficient	not determined.

The chemistry requirements for Cambrex TRA are complete.

Health and Environmental Assessment

The health and environmental risk profile of Cambrex TRA is expected to be similar to that of the original registered source of Clearon CDB-90 Chlorinating Granules. However, due to product specific registration (data protection) considerations (see Trade Memorandum T-1-249, “Product-Specific Registration and Proprietary Rights to Data”), the applicant was required to generate the following studies as a condition of registration:

Study description and organism/type		DACO
Human Toxicology		
Acute neurotoxicity	rat	(DACO 4.5.12)
Short-Term Neurotoxicity	rat	(DACO 4.5.13)

Value assessment

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

Conclusions

The PMRA has completed its evaluation of the subject application and has determined that Cambrex TRA is eligible for full registration.

References

References List

7.1.1 Studies/Information Provided by Applicant/Registrant

- 1140680 2004, Chemistry Requirements for the registration of a TGAI, Manufacturing Methods for the TGAI TGAI, Changzhou, DACO: 2.1,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9
- 1140681 2004, Chemistry Requirements for the registration of a TGAI, Manufacturing Methods for the TGAI TGAI, Changzhou, DACO: 2.11.1,2.11.2,2.11.3,2.11.4
- 1140731 2004, Chemistry Requirements for the registration of a TGAI: Establishing Certified Limits., Changzhou, DACO: 2.12.1
- 1140732 2004, Preliminary Analysis; Methodology/Validation; Confirmation of Identity; Batch Data, Changzhou, DACO: 2.13.1,2.13.2,2.13.3
- 1140737 2004, Chemical and Physical Properties; Storage Stability Data, Changzhou, DACO: 2.14.1,2.14.13,2.14.14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8, 2.14.9

