

Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2004-1723
Application: New source by different registrant
Product: Cambrex RF-TRA
Registration Number: 28482
Active ingredients (a.i.): trichloro-s-triazinetrione 90%
PMRA Document Number: 1414597

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

Cambrex RF-TRA has the following properties:

Property	Result
Colour and physical state	white solid granular
Nominal concentration	90.0% (available chlorine present as sodium trichloro-s-triazinetrione)
Odour	chlorine
Specific Gravity	0.95 at 25°C
Vapour pressure	< 0.00005 mm Hg
pH	2.6-3.2 for 1% solution
Solubility in water	1.2 g/100mL
n-Octanol/water partition coefficient	not determined.

The chemistry requirements for Cambrex RF-TRA have been completed.

Health and Environmental Assessment

The health and environmental risk profile of Cambrex RF-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 RF-TRA is eligible for full registration.

References

7.1.1 Studies/Information Provided by Applicant/Registrant

- 1168918 Chemistry Requirements for the registration of a TAGI, DACO: 2.1,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9
- 1168919 Cambrex RF-TRA Manufacturing Summary, Description of Starting Materials, Detailed Product Process Description and Description of Formation Impurities, DACO: 2.11.1,2.11.2,2.11.3,2.11.4
- 1168920 Cambrex RF-TRA Establishing Certified Limits, DACO: 2.12.1
- 1168921 Cambrex RF-TRA Preliminary Analysis, Confirmation of Identity and Batch data, DACO: 2.13.1,2.13.2,2.13.3
- 1168922 Cambrex TF-TRA Chemical and Physical Properties, DACO: 2.14
- 1168923 Dissociation Constant, Octanol/Water Partition Coefficient and UV/Visible Absorption Spectra Waiver Request, DACO: 2.14.10,2.14.11,2.14.12

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