

Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2004-1717
Application: New source by different registrant
Product: Cambrex SDD
Registration Number: 28506
Active ingredients (a.i.): Sodium dichloro-s-triazinetriene
PMRA Document Number: 1414573

Background

The original source of sodium dichloro-s-triazinetriene technical grade active ingredient, “CDB Clearon Chlorinating Granules” (Reg. No.12149) was first registered in 1973.

Purpose of Application

The purpose of this application is to register a new technical source of sodium dichloro-s-triazinetriene.

Chemistry Assessment

Common Name: Sodium dichloroisocyanurate
IUPAC Chemical Name: 1,3-dichloro-1,3,5-triazine-2,4,6(1H,3H,5H)-trione, sodium salt dihydrate
CAS Chemical Name: 1,3-dichloro-1,3,5-triazinetriene, sodium salt dihydrate

Cambrex SDD has the following properties:

Property	Result
Colour and physical state	white, solid, granular
Nominal concentration	56.0% (available chlorine present as sodium dichloro-s-triazinetriene dihydrate)
Odour	chlorine-like
Density	0.80 - 0.95 kg/L at 25°C
Vapour pressure	<0.00005 mm Hg
pH	6.47-6.74
Solubility in water	26g/100g at 25°C
n-Octanol/water partition coefficient	not determined

The chemistry requirements for Cambrex SDD are complete.

Health and Environmental Assessment

The health and environmental risk profile of Cambrex SDD is expected to be similar to that of the original registered source of CDB Clearon 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 SDD is eligible for full registration.

References

References List

7.1.1 Studies/Information Provided by Applicant/Registrant

- 1161391 Cambrex SDD Chemistry Requirements, DACO: 2.3,2.4,2.5,2.6,2.7,2.8,2.9
- 1161392 Cambrex SDD Chemical and Physical Properties, DACO:
2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9
- 1161394 Cambrex SDD Chemistry Requirements, DACO:
2.1,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9
- 1161395 Cambrex SDD Manufacturing Summary, DACO: 2.11.1
- 1161396 Cambrex SDD Description of Starting Material Chlorine (gas), caustic soda, isocyanuric acid, DACO: 2.11.2
- 1161397 Cambrex SDD Detailed production process description - Process Flow chart, DACO: 2.11.3
- 1161398 Cambrex SDD Establishing Certified Limits, DACO: 2.12.1
- 1161399 Cambrex SDD Preliminary Analysis Methodology/Validation, DACO: 2.13.1
- 1161400 CONFIRMATION OF IDENTITY, DACO: 2.13.2
- 1161401 Summary of Batch Data and Certificate of Analysis, DACO: 2.13.3
- 1161402 Cambrex SDD Chemical and Physical Properties and Storage, Stability Data, DACO: 2.14
- 1161403 Cambrex SDD, Dissociation Constant, Octanol/Water Partition Coefficient, UV/Visible Absorption Spectra - Waiver Request, DACO:
2.14.10,2.14.11,2.14.12

ISSN: 1911-8082

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