

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2008-5714
Application: B.1.1 - New / Changes TGAI Prod Chemistry-New Source (site)
same registrant
Product: Cambrex BCDMH Tabs
Registration Number: 29179
Active ingredients (a.i.): 1-bromo-3-chloro-5,5-dimethylhydantoin
PMRA Document Number: 1814272

Purpose of Application

The purpose of this application is to add a second manufacturing site for Cambrex BCDMH Tabs, a technical grade active ingredient containing 1-bromo-3-chloro-5,5-dimethylhydantoin for use as swimming pool algicide/swimming pool bactericide.

Chemistry Assessment

Common Name: BCDMH, bromochlorodimethylhydantoin
Chemical Name: 1-bromo-3-chloro-5,5-dimethylimidazolidine-2,4-dione

Cambrex BCDMH Tabs has the following properties:

Property	Result
Colour and physical state	White solid (powder)
Nominal concentration	96.7% as determined by HPLC
Odour	Chlorine-Like
Density	0.52 g/cm ³ (at 20°C)
Vapour pressure	Not applicable
pH	Not applicable
Solubility in water	Highly Soluble
n-Octanol/water partition coefficient	Not available, technical quickly hydrolyzes in water.

The chemistry requirements for Cambrex BCDMH Tabs have been completed.

Health, Environmental and Value Assessments

Health, environmental and value assessments were not required for this application.

Conclusion

The PMRA has conducted a review of the available information and has concluded that the addition of a new manufacturing site for Cambrex BCDMH Tabs can be supported.

References

PMRA No.	Title
1147179	Manufacturing Summary, DACO: 2.11.1 CBI
1147180	2004, Dantoin BCDMH Technical (1- Bromo-3-chloro-5,5- dimethylhydantoin): Product Identity and Composition, Description of Beginning Materials, Manufacturing Process, Discussion of Potential Impurity Formation, DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI
1147181	2001, Test Method - Active Bromine and Active Chlorine by Autotitrator, DACO: 2.13.1 CBI
1147182	BCDMH - Preliminary Analysis, DACO: 2.13.2,2.13.3 CBI
1147183	Colour, Physical State, Odour, Melting Point, Boiling Point, Density or Specific Gravity, Water Solubility, Solvent Solubility, Vapour Pressure, Dissociation Constant, Octanol/Water Partition Coefficient, DACO: 2.14.1,2.14.10,2.14.11,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,8.2.1 CBI
1147184	2003, Product Chemistry for Technical BCDMH: UV/Visible Absorption, DACO: 2.14.12,8.2.1 CBI
1147185	2004, BCDMH - One Year Storage Stability and Corrosion Characteristics, DACO: 2.14.13,2.14.14,8.2.1 CBI
1157809	Applicants Name and Office Address, Manufacturing Plants Name and Address, Product Trade Name, Other Names, Common Name, Chemical Name, Chemical Abstracts Registry Number, Structural Formula, Molecular Formula, Molecular Weight., DACO: 2.1,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9 CBI

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