

Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2007-2933

Application: Registration of a new source of TGAI by a new registrant

Product: Cambrex BCDMH Tabs

Registration Number: 29179

Active ingredients (a.i.): 1-bromo-3-chloro-5,5-dimethylhydantoin

PMRA Document Number: 1725025

Background

The original source of 1-bromo-3-chloro-5,5-dimethylhydantoin technical grade active ingredient, "Dihalo Technical" (Reg. No. 19358) was first registered in 1986.

Purpose of Application

The purpose of this application is to register a new technical source of BCDMH by a different registrant.

Chemistry Assessment

Common Name: bromochlorodimethylhydantoin, BCDMH

IUPAC Chemical Name: 1-bromo-3-chloro-5,5-dimethylimidazolidine-2,4-dione CAS Chemical Name: 1-bromo-3-chloro-5,5-dimethyl-2,4-imidazolidinedione

Cambrex BCDMH Tabs has the following properties:

Property	Result
Colour and physical state	white powder
Nominal concentration	98.5%
Odour	faint halogen
Density	1 g/cm ³
Vapour pressure	not determined
рН	no data provided
Solubility in water	2 g/l (25°C)
n-Octanol/water partition	Not feasible since the product very quickly hydrolyses in water to
coefficient	dimethylhydantoin and OCl ⁻ and OBr ⁻

The chemistry requirements for Cambrex BCDMH Tabs have been completed.



Health and Environmental Assessment

N/A

Value assessment

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

Conclusions

The PMRA has completed an evaluation of the subject application and has determined that Cambrex BCDMH Tabs is eligible for full registration.

References

Atoloi dileeb	
PMRA	Reference
Documen	
t Number	
1402557	2007, Cambrian Chemicals Inc, Chemisty Requirement for a TGAI, DACO:
	2.0,2.1,2.10,2.11,2.11.2,2.11.3,2.11.4,2.12,2.12.1,2.12.2,2.13,2.14,2.14.1,2.14.10,2.1
	4.11,2.14.12,2.14.13,2.14.14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,2
	.15 CBI
1402558	2007, Chemisty equation, DACO: 2.11.3 CBI

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