



Evaluation Report for Category B, Subcategory 2.1 Application

Application Number: 2003-2924
Application: New source by different registrant
Product: BCDMH
Registration Number: 28416
Active ingredients (a.i.): 1-bromo-3-chloro-5,5-dimethylhydantoin 94%
PMRA Document Number: 1414628

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 1-bromo-3-chloro-5,5-dimethylhydantoin.

Chemistry Assessment

Common Name: 1-bromo-3-chloro-5,5-dimethylhydantoin (BCDMH)
 Chemical Name: 1-bromo-3-chloro-5,5-dimethylhydantoin (BCDMH)

Physical and Chemical Properties of Sani-Marc BCDMH:

Property	Result
Colour	White
Physical state	Solid
Nominal concentration	Available bromine present as 1-bromo-3-chloro-5,5-dimethylhydantoin.....61% Available chlorine present as 1-bromo-3-chloro-5,5-dimethylhydantoin27%
Odour	Slight halogen odour
Density	0.96 g/mL
Vapour pressure	Not applicable
pH	4.5 (0.1% dispersion)
Solubility in water	0.2 g/100 mL
n-Octanol/water partition coefficient	Not determined

The chemistry requirements for Sani-Marc BCDMH are found to be complete.

Health and Environmental Assessment

The health and environmental risk profile of BCDMH is expected to be similar to that of the original registered source of Dihalo Technical. 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 is required to generate the following studies as a condition of registration:

Table 1: Toxicology data requested to supplement the BCD database

DACO	Study^a	Point Value
4.2.6	Acute inhalation	9
4.3.1	Short-term oral (90-day) (rodent)	50
4.3.4	Short-term dermal (90-day)	50
4.3.6	Short-term inhalation (90-day)	200
4.4.4	Combined chronic/Oncogenicity (rodent)	825
4.5.1	Multigeneration Reproduction (rodent)	270
4.5.2	Developmental (rodent)	140
4.5.3	Developmental (non-rodent)	140
4.5.12	Acute neurotoxicity	50
4.5.11	Short-term neurotoxicity	120
4.5.9	Metabolism/Toxicokinetics	225
Total point value		2079

^aNote: All studies to be performed with 1-bromo-3-chloro-5,5-dimethylhydantoin

Table 2: Environmental data requested to supplement the BCD database

DACO	Study^a	Point Value
9.5.2.4	Acute toxicity to one of Coho, Chinook or Atlantic salmon	5
9.8.2	Toxicity to green algae, <i>Selenastrum capricornutum</i> , recently names <i>Pseudokirchneriella subcapitata</i> .	28
9.8.2	Toxicity to blue-green algae, <i>Anabaena flos-aquae</i>	28
9.8.2	Toxicity to the fresh water diatom, <i>Navicula pelliculosa</i>	28
9.8.3	Toxicity to the marine diatom, <i>Skeletonema costatum</i>	28
9.8.5	Toxicity to the vascular aquatic plant, Lemna gibba or Lemna minor	28
Total point value		145

^aNote: All studies to be performed with 1-bromo-3-chloro-5,5-dimethylhydantoin

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 BCDMH is eligible for conditional registration, with registration being contingent upon fulfilling the following requirements:

- submission of studies as required under product specific registration.

References

7.1.1

PMRA 1134744. Product Chemistry of Sani-Marc BCDMH, Doc ID 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.13.1, 2.13.2, 2.13.3, 2.13.4, 2.14, 2.16, Volume No. 2 of 2, submitted 2003-11-14.

PMRA 1134627. Product Chemistry of Sani-Marc BCDMH, Doc ID 2.11.4, 2.13.2, 2.13.3, 2.13.4 and 2.4 submitted 2004-10-25.

PMRA 1134752. Product Chemistry of Sani-Marc BCDMH, Certificate of Analysis, Doc. ID 2.13.2 submitted 2004-11-14.

PMRA 1134753. Product Chemistry of Sani-Marc BCDMH, Quality control, Doc. ID 2.13.2 submitted 2003-11-14.

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