



Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2005-1297
Application: New source by different registrant
Product: Sani-Marc Bromine
Registration Number: 28624
Active ingredients (a.i.): 1-bromo-3-chloro-5,5-dimethylhydantoin 94%
PMRA Document Number: 1424975

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

Sani-Marc Bromine has the following properties:

Property	Result
Colour and physical state	White solid
Nominal concentration	66% available bromine and 29% available chlorine
Odour	Faint bromine and chlorine
Density	1.72 g/mL
Vapour pressure	N/A
pH	4.5 for a 0.1% solution
Solubility in water	Sparingly soluble in cold water
n-Octanol/water partition coefficient	0.35

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

Health and Environmental Assessment

The health and environmental risk profile of Sani-Marc Bromine 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

^a Note: 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

^a Note: 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 Sani-Marc Bromine 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 Studies/Information Provided by Applicant/Registrant

- 1074208 Chemistry Information, DACO: 2.1,2.11,2.12,2.13,2.14,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9
- 1074211 Inspection Data and Way, DACO: 2.13.1
- 1074212 2005, SANI-MARC BROMINE: "Recherche 1" and Certificate of Analysis, DACO: 2.13.2
- 1161147 2005, Sub. 2005-1297 DACO 2.13.1, rewritten - method descriptions received by e-mail Nov. 9, 2005 , DACO: 2.13.1
- 1161148 2005, DACO 2.13.1, rewritten - calculations received by e-mail Nov. 9, 2005, DACO: 2.13.1
- 1240285 2006, Revision May 1st, 2006. Chemistry Information., DACO: 2.11,2.13.1,2.13.3
- 1304462 2006, Sani-Marc Bromine, sub # 2005-1297 - Response to Clarification Request [of 2006-07-31], DACO: 2.13.1,2.13.3

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services
Canada 2007

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.