

Evaluation Report for Category B, Subcategory B.1.1 Application

Application Number: 2006-7179
Application: Category B, subcategory 1.1 (new source by the same registrant)
Product: Technical Fenbutatin Oxide
Registration Number: 18594
Active ingredients (a.i.): Fenbutatin Oxide
PMRA Document Number: 1710405

Background

The original source of fenbutatin oxide active ingredient, “Technical Fenbutatin Oxide” (Reg. No.18594) was first registered in 1984.

Purpose of Application

The purpose of this application is to register a new technical source of fenbutatin oxide by the same registrant. This new source of technical grade active ingredient, “Technical Fenbutatin Oxide” (Reg. No. 18594) is intended for use in the manufacture of Vendex 50WP Miticide (PCP # 16162) and Vendex 50W Wettable Powder Miticide (PCP # 16309).

Chemistry Assessment

Common Name: Fenbutatin oxide

Technical Fenbutatin Oxide has the following properties:

Property	Result
Colour	Colourless
Physical state	Solid (Crystals)
Melting point/range	140 - 145°C
Boiling point/range	Decomposes at 230 - 310°C
Density at 25°C	0.224 g/cm ³
Water solubility at 20°C	0.0127 mg/L

Property	Result
Octanol/water partition coefficient	log K _{ow} = 5.2

Health and Environmental Assessment

The health and environmental risk profile of Technical Fenbutatin Oxide is expected to be similar to that of the original registered source of Technical Fenbutatin Oxide.

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 the new source of Technical Fenbutatin Oxide is eligible for registration.

References List

PMRA 1317417	2006, CAT B1.1 Fenbutatin Oxide - New Source Chemtura DACO 2.1 - 2.9, n/a, MRID: n/a, DACO: 2.1,2.2,2.3,2.4,2.5, 2.6, 2.7, 2.8,2.9
PMRA 1338894	Manufacturing Summary, DACO: 2.11.1
PMRA 1338895	2006, Description of Starting Materials, Methods of Manufacture and Discussion of the Formation of Impurities for Fenbutatin Oxide Technical, DACO: 2.11.2
PMRA 1338898	2004, Validation of an Analytical Method for the Determination of Fenbutatin Oxide in Technical Material using HPLC with Internal Standardization, GRL-12119, DACO: 2.13.1
PMRA 1338899	2004, Validation of an Analytical Method for the Determination of Organic Impurities in Technical Fenbutatin Oxide using HPLC., GRL-12120, DACO: 2.13.1
PMRA 1338902	2006, Validation of an Analytical Method for the Determination of FT-04 in Technical Fenbutatin Oxide., GRL-12224, DACO: 2.13
PMRA 1338903	2006, Preliminary Analysis of Fenbutatin Oxide, GRL-12222, DACO: 2.13.3
PMRA 1403658	2007, Final Report Amendment - Description of Starting Materials, Methods of Manufacture and Discussion of the Formation of Impurities for Fenbutatin Oxide Technical., DACO: 2.11.4

PMRA 1403659	2004, Preliminary Analysis of Fenbutatin Oxide, GRL-12221, DACO: 2.13.3
PMRA 1403660	2004, Determination of BHTO impurity in Fenbutatin Oxide - Lot numbers 1880, 1881, 1887, 1896, 1898 and 1899 by TLC, GRL- 12492, DACO: 2.13.3
PMRA 1427867	1987, Vendex (Fenbutatin Oxide). Product Identity and Composition., Y4332.A (ES), DACO: 2.16

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services
Canada 2009

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.

