



Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2006-7847
Application: Application category B, subcategories 1.1 (Changes to technical grade active ingredient product chemistry - new source(site) same applicant) and 3.13 (Changes to product labels-precautions)
Product: Fenbuconazole Technical Fungicide
Registration Number: 27293
Active ingredients (a.i.): Fenbuconazole (98.9% a.i.)
PMRA Document Number: 1555213

Background

The original source of fenbuconazole technical grade active ingredient, "Fenbuconazole Technical Fungicide" (Reg. No. 27293) was first registered in 2003.

Purpose of Application

The purpose of this application is to change the site of manufacture by the same registrant and to amend the first aid precautions.

For specific details of uses, application rates and methods, precautions, restrictions and personal protective equipment requirements, refer to the product label.

Chemistry Assessment

Common Name: Fenbuconazole
Chemical Name: α - [2-(4-chlorophenyl)ethyl]- α - phenyl-1*H*-1,2,4-triazole-1-propanenitrile

Fenbuconazole Technical Fungicide has the following properties:

Property	Result
Colour and physical state	Off-white solid
Nominal concentration	98.9% as determined by GC
Odour	Faint sulfur-like odour
Density	1.27 g/ml
Vapour pressure	0.37×10^{-7} mm Hg (at 25°C)
pH	not applicable
Solubility in water	3.8 ppm
n-Octanol/water partition coefficient	$\text{Log } K_{ow} = 3.22 \pm 0.08$

The chemistry requirements for Fenbuconazole Technical Fungicide have been completed.

Health Assessments

A toxicology review for Fenbuconazole Technical Fungicide was not required as the active ingredient produced at the registered and new sites of manufacture are chemically equivalent. Therefore, the health risk profile of Fenbuconazole Technical Fungicide is expected to be similar to that of the original registered product. The First Aid statement changes bring the label to current standards according to the Regulatory Directive *First Aid Labelling Statements* (DIR2007-01).

Dietary and crop residue assessments were not required since the use pattern, including host crops, application rates and timings remain unchanged, and since an assessment was conducted on the technical grade active ingredient (Ap*plication No. 1999-0529).

Environmental Assessment

An environmental assessment was not required since the use pattern, including host crops, application rates and timings remained unchanged and the chemical properties of Fenbuconazole Technical Fungicide were confirmed during the chemistry assessment.

Value Assessment

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

Conclusion

The PMRA has completed an evaluation of the subject application and has determined that Fenbuconazole is eligible for registration.

References

PMRA #	Description	PMRA CBI Verified
1322796	1991, Product Chemistry Series 61 RH-7592 Technical Product Identity and Composition, APR/SH-91-046, DACO: 2.10,2.11,2.11.1,2.11.2,2.11.3,2.11.4,2.4,2.5,2.6,2.7,2.8,2.9	P

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services
Canada 2008

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.