



Regulatory Decision Document

RDD2001-04

Difenoconazole Fungicide

The manufacturing concentrate Dividend MG and fungicide seed treatments Dividend 36FS and Dividend 360FS (Pest Control Products Act registration numbers 25776, 25775 and 25633), which contain difenoconazole as the active ingredient, are eligible for full registration pursuant to Section 13 of the Pest Control Products (PCP) Regulations.

This decision document outlines this stage of the Pest Management Regulatory Agency's (PMRA) regulatory decision-making process concerning the use of difenoconazole products for the control of certain seed-borne, soil-borne and foliar diseases of spring and winter wheat.

(publié aussi en français)

September 7, 2001

This document is published by the Submission Coordination and Documentation Division, Pest Management Regulatory Agency. For further information, please contact:

**Publications Coordinator
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9**

**Internet: pmra_publications@hc-sc.gc.ca
www.hc-sc.gc.ca/pmra-arla/
Information Service:
1-800-267-6315 or (613) 736-3799
Facsimile: (613) 736-3798**



ISBN: 0-662-31040-3

Catalogue number: H113-6/2001-4E-IN

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2001

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.

1.0 Introduction

This decision document outlines this stage of the PMRA's regulatory decision-making process concerning the use of difenoconazole products for the control of certain seed-borne, soil-borne and foliar diseases of spring and winter wheat.

2.0 Background

Difenoconazole is a systemic fungicide for use as a seed treatment on wheat. The end-use products include Dividend 360FS for application in commercial seed treatment plants and Dividend 36FS for on-farm seed treatment to control or suppress bunts, smuts, seed rots and seedling blights and certain root diseases.

The PMRA carried out an assessment of available information in accordance with Section 9 of the PCP Regulations. The assessment found that there was sufficient information, pursuant to Section 18*b*, to allow a determination of the safety, merit and value of difenoconazole, Dividend MG, Dividend 36FS and Dividend 360FS, manufactured by Syngenta Crop Protection. The PMRA concluded that the use of Dividend MG, Dividend 36FS and Dividend 360FS in accordance with the labels accompanying the products has merit and value consistent with Section 18*c* of the PCP Regulations and does not entail an unacceptable risk of harm pursuant to Section 18*d*.

The products were proposed for registration in the Proposed Regulatory Decision Document PRDD99-01, *Difenoconazole*, <http://www.hc-sc.gc.ca/pmra-arla/english/pdf/prdd/prdd9901-e.pdf> published on April 14, 1999. Comments received by the PMRA concerning PRDD99-01 <http://www.hc-sc.gc.ca/pmra-arla/english/pdf/prdd/prdd9901-e.pdf> are presented in Appendix I.

3.0 Regulatory decision

Based on the considerations outlined above, Difenoconazole Technical, Dividend MG, Dividend 36FS and Dividend 360FS for use on wheat are eligible for full registration, pursuant to Section 13 of the PCP Regulations.

Appendix I Comments and responses

Comments were received by the PMRA concerning PRDD99-01, *Difenoconazole*, published on April 14, 1999. The comments were from government and related to the environmental assessment for difenoconazole, Dividend MG, Dividend 36FS and Dividend 360FS. The PMRA has consolidated and summarized the comments received and provides responses to the comments below.

Comments on PRDD99-01 Sections 6.1 and 6.2

- 1.1 No mention is made of potential effects to nontarget plants.
- 1.2 Given the stated persistence of the product in soil, effects on earthworms and other soil organisms should be mentioned.
- 1.3 There is no mention of the standard reproduction studies conducted with bobwhite quail and mallard duck. Reviews of reproduction studies conducted with two other conazole fungicides showed reproductive toxicity to bobwhite quail.

Responses

- 1.1 Nontarget plant data are not required for seed treatment products, as the probability of exposure of nontarget terrestrial and aquatic plants to toxic levels of a pesticide applied as a seed treatment is very low. These data, however, would be required if the company applied for an expansion of the product label to include a use that involved broadcast (spray) application.
- 1.2 Canadian field studies indicated that difenoconazole is only moderately persistent in soil (DT₅₀ of 35–63 days). Data on toxicity to non-mammalian and non-avian terrestrial fauna, i.e., earthworms and beneficial insects, are not required for seed treatment products, as the probability of exposure to toxic levels of pesticide applied as a seed treatment is very low. These data would be required if the company applied for an expansion of the product label to include a use that involved broadcast (spray) application.
- 1.3 At the time of the original review of difenoconazole, avian reproduction studies were not required for seed treatment products, but were conditionally required, i.e., triggered by other factors such as acute effects, persistence, bioconcentration potential, mammalian reproductive effects, potential for exposure or frequency of application. Based on the review of difenoconazole alone, the need for avian reproductive studies was not triggered.

As a result of the comment on other “conazole” fungicides, avian reproduction studies on difenoconazole were requested from Syngenta. The PMRA has reviewed the submitted data and determined that difenoconazole will not pose an unacceptable risk to the bobwhite quail and mallard duck on a reproductive effects basis, when used as fungicide seed treatments Dividend 36FS and Dividend 360FS. Avian reproduction studies are now a standard data requirement for applications for registration of pesticides for seed treatment use.