



Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2010-1275
Application: New product label: new site or host
Product: PENPRO 118FS
Registration Number: 30361
Active ingredient (a.i.): Penflufen, Prothioconazole
PMRA Document Number: 2130846

Background

PENPRO 118FS is a new commercial-class seed treatment product containing the active ingredients penflufen and prothioconazole for protection against certain seed-borne diseases of potato seed pieces.

For a detailed scientific evaluation related to the new active ingredient penflufen, please refer to Proposed Regulatory Decision PRD2012-02, *Penflufen*.

The active ingredient prothioconazole was recently approved for control of certain seed- and soil-borne diseases of cereals, chickpea, corn, dry beans, dry peas (including field peas), lentil and soybean (Proposed Regulatory Decision PRD2011-07, *Prothioconazole*).

Purpose of Application

The purpose of this application was to assess the new use of the active ingredient prothioconazole on potato based on the precedent products JAU 6476 100 FS Seed Treatment Fungicide (Registration Number 30101) and K1386 Seed Treatment Fungicide (Registration Number 30102).

Chemistry Assessment

Please refer to Proposed Regulatory Decision PRD2012-02, *Penflufen*.

Health Assessment

A risk assessment was conducted for workers treating potato seed pieces with prothioconazole and for workers planting treated potato seed pieces. Margins of exposure (MOEs) for all scenarios were above the target MOEs for prothioconazole and are not of concern when workers follow all label precautions.

Based on the residue data, a maximum residue limit (MRL) of 0.02 ppm to cover residues of prothioconazole including the prothioconazole-desthio metabolite in/on potato will be established as shown in Table 1. Residues of prothioconazole and prothioconazole-desthio in potato processed commodities are covered under the MRL for the raw agricultural commodity. Residues of prothioconazole, including prothioconazole-desthio, at the established MRL will not pose an unacceptable health risk to any segment of the population, including infants, children, adults and seniors.

Table 1 **Summary of field trial and processing data used to establish MRLs**

Commodity	Application Method/ Total Application Rate	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL	Recommended MRL (ppm)
			Min	Max			
Potato	Seed treatment/ 0.37 g a.i./100 kg seed	NA	<0.01	<0.01	Not required	None	0.02*

* sum of the LOQ (0.01 ppm) of each analyte

Environmental Assessment

The treatment rate of prothioconazole on potato seed pieces is lower than the registered treatment rates of prothioconazole on the precedent product labels for other seed types. As a result, no increase in environmental exposure is expected. Therefore, additional environmental data were not required to support the prothioconazole use expansion to potato seed pieces.

Value Assessment

Please refer to Proposed Regulatory Decision PRD2012-02, *Penflufen*.

Conclusion

The PMRA conducted an evaluation of the subject application and determined that use expansion of prothioconazole to potato seed pieces has value and will not pose unacceptable health or environmental risk. An MRL of 0.02 ppm is recommended for residues of prothioconazole, including prothioconazole-desthio, in/on potato.

References

- 1372835 2006, ADMIRE 240F - Determination of dermal and inhalation exposure of workers during on-farm seed piece treatment of potatoes, DACO: 5.4
- 1525896 2001, Determination of Exposure to pencycuron during loading and application of Monceren® -Droogontsmetter (Monceren DS 12.5) in potato fields, DACO: 5.4, 5.6
- 1885329 2010, Determination of the total radioactive residue (TRR) of [triazole-UL-14C] prothioconazole in potato following seed treatment, DACO: 7.4.1, 7.4.2, 7.4.6

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2012

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.