Australian Government
Australian Pesticides and Veterinary Medicines Authority

ADVICE SUMMARY

APPLICATION FOR VARIATION OF A REGISTERED CHEMICAL PRODUCT

Product name: EVERGOL PRIME SEED TREATMENT AND IN-FURROW FUNGICIDE

Applicant: BAYER CROPSCIENCE PTY LTD

Product number: 64744

Application number: 62330

Purpose of Application and Description of Use: Variation of registration and label approval to amend the product name and extend the claims for use to include oats and in-furrow application.

Active Constituent(s): PENFLUFEN

Regulatory Decision:

To grant the application subject to the following conditions:

Standard Conditions of Label Approval

1. Label must contain a Date of Manufacture and Batch Number

For full conditions, refer to the Conditions of Product Label Approval on the APVMA website.

ADVICE

Australian Government Department of Health and Ageing, Office of Chemical Safety

The ARfD (Acute Reference Dose) for penflufen was previously established at 0.5 mg/kg bw/d in 2012 based on a NOAEL (No Observed Adverse Effect Level) of 50 mg/kg bw/d in an acute neurotoxicity study for decreased motor and locomotor activity in female rats and incorporating a 100 fold safety factor.

Penflufen is listed in Schedule 5 of the SUSMP (Standard for the Uniform Scheduling of Medicines and Poisons) without cut-offs and exceptions. EverGol Prime Seed Treatment and In-Furrow Fungicide contains penflufen at 240g/L and is therefore classified as a Schedule 5 poison.

No new data was submitted to support the current application. Based on the findings of the toxicological studies previously evaluated, the product has low acute oral, acute dermal and acute inhalational toxicity. It is not a skin irritant or eye irritant, and does not cause skin sensitisation.

The acute toxicology data of the product, along with previously evaluated information on the toxicology profile of the active constituent were relied on by the OCS to establish a hazard profile for the proposed product.

The risk assessment concluded that exposure to the product during mixing, loading and application were determined to be at acceptable levels without the use of personal protective equipment (PPE). Consequently no changes to the existing First Aid Instructions or Safety Directions are required.

After consideration of the hazards associated with the registered product, along with the exposure and risks expected with the extension of use of the registered product, it was considered that the proposed extension of use of EverGol Prime Seed Treatment and In-Furrow Fungicide will not be an undue health hazard to humans according to the criteria stipulated in Section 14 of the Ag/Vet Code Act of 1994**.**

Data relied on to provide the advice

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
68803	I	U. Gillissen	Acute toxicity in the rat after dermal administration.	22 September 2009	Toxicology	Acute dermal studies, product	Bayer Cropscience Pty Ltd	49879
68807	I	C. Gmelin	Acute eye irritation on rabbits.	24 September 2009	Toxicology	Acute eye irritation studies, product	Bayer Cropscience Pty Ltd	49879

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
67894	I	Folkerts, A.	BYF 14182 - Activity ID TXELP010 - Acute inhalation toxicity in rats	7 December 2007	Toxicology	Acute inhalation studies, active	Bayer Cropscience Pty Ltd	50258
68802	I	U. Gillissen	Acute toxicity in the rat after oral administration.	22 September 2009	Toxicology	Acute oral studies, product	Bayer Cropscience Pty Ltd	49879
68806	I	C. Gmelin	Acute skin irritation/corrosion on rabbits.	24 September 2009	Toxicology	Acute skin irritation studies, product	Bayer Cropscience Pty Ltd	49879
68820	I	M. Repetto	Evaluation of potential skin sensitization in the local lymph node assay in the mouse.	16 October 2009	Toxicology	Acute skin sensitisation studies, product	Bayer Cropscience Pty Ltd	49879
68821	I	Odin-Feurtet, M.	Comparative in vitro dermal absorption study using human and rat skin.	16 October 2009	Toxicology	Other information	Bayer Cropscience Pty Ltd	49879
68813	I	Odin-Feurtet, M.	In vivo dermal absorption study in the male rat.	9 October 2009	Toxicology	Other information	Bayer Cropscience Pty Ltd	49879

APVMA Residues and Trade Section

The Residues and Trade Section of the APVMA evaluated the available metabolism, residue trials, analytical methodology, fate in storage, processing data and residues in trade issues, including that submitted by Bayer CropScience Pty Ltd to support their application, to assess whether this product is an undue hazard to the safety of consumers exposed to its residues, and further to determine whether there is any undue prejudice to Australia's trade of treated commodities.

The National Estimated daily Intake for chronic dietary exposure to penflufen is equivalent to <1% of the ADI (Acceptable Daily Intake) and is acceptable.

The highest acute dietary intake (as estimated by the National Estimated Short Term Intake (NESTI) calculation) associated with the proposed use of penflufen on wheat, barley and oats was estimated at < 1 % of the ARfD (Acute Reference Dose for both children (2-6 years) and the general population (2+ years). It is concluded that the acute dietary exposure is acceptable.

The proposed use has been assessed according to the safety criteria as defined by section 14(3)(e)(i) & (ii) of the Schedule to the Code Act. Subject to implementation of all required label amendments, the APVMA is satisfied that, with respect to residues, that the use of the product in accordance with the required label instructions would not be harmful or an undue hazard to the safety of people exposed to residues in food as per section 14(3)(e)(i) & (ii) and has had regard to the residues aspects of section 14(5) of the Schedule to the Agvet Code Act.

The proposed use has also been assessed according to the trade criteria as defined by section 14(3)(e)(iv) of the Schedule to the Agvet Code Act. Residues of penflufen are not expected to arise in major trade commodities as a result of the proposed use. It was therefore concluded that the proposed new use in oats, and the proposed in-furrow application (with or without seed treatment) will not increase the trade risk when compared with the registered uses on wheat and barley. The Residues and Trade Sections recommended that APVMA should be satisfied that, with respect to residues, the proposed use meets the trade criteria as defined by s14(3)(e)(iv).

Data relied on to provide the advice

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
68874	I	J. N. Brungardt, K. A. Dallstream	Penflufen ? Magnitude of the Residue in Dairy Cows	26 October 2010	Residues	Animal commodity residues crop transfer	Bayer Cropscience Pty Ltd	49879
68673	I	L. Radunz	Determination of residues of BYF 14182 (penflufen) in the forage, grain and straw of wheat and oats following a seed treatment application of BYF 14182 240FS at rates of 20, 30 or 45 g a.i./100 kg of seed.	29 July 2010	Residues	Crop residues human consumption	Bayer Cropscience Pty Ltd	49879
68674	I	L. Radunz	Determination of residues of BYF 14182 (penflufen) in the forage, grain and straw of wheat following a seed treatment application of BYF 14182 240FS at rates of 20 or 30 g a.i./100 kg of seed.	22 July 2010	Residues	Crop residues human consumption	Bayer Cropscience Pty Ltd	49879

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
68675	I	L. Radunz	Determination of residues of BYF 14182 (penflufen) in the forage, grain and straw of barley and oats following a seed treatment application of BYF 14182 240FS at rates of 20 or 30 g a.i./100 kg of seed.	28 July 2010	Residues	Crop residues human consumption	Bayer Cropscience Pty Ltd	49879
68672	I	L. Radunz	Determination of residues of BYF 14182 (penflufen) in the forage, grain and straw of wheat and barley following a seed treatment application of BYF 14182 240FS at rates of 20, 30 or 45 g a.i./100 kg of seed.	27July 2010	Residues	Crop residues human consumption	Bayer Cropscience Pty Ltd	49879
68764	I	Justus, K.	Storage stability of BYF 14182 residues in plant matrices	3 June 2006	Residues	Fate - storage, processing and cooking	Bayer Cropscience Pty Ltd	49879
68873	I	C. Cavaillé, I. Meilland-Berthier	Storage stability of residues of BYF 14182 and its metabolites (BCS-AA10006, BCS-AA10790, BCS-AA10791 and BCS-CM41431) in plants during deep freeze storage for up to 24 months.	17 June 2011	Residues	Fate - storage, processing and cooking	Bayer Cropscience Pty Ltd	49879
68819	I	C.Cavaillé and H. Péronnet	Storage stability of residues of BYF 14182 and its metabolites (BCS-AA10006, BCS-AA10790, BCS-AA10791 and BCS-CM41431) in plants during deep freeze storage for up to 24 months.	9 July 2010	Residues	Fate - storage, processing and cooking	Bayer Cropscience Pty Ltd	49879
68865	I	Murphy, I.	BYF 14182 240 FS red - Magnitude of residues in/on wheat (5X)	11 March 2010	Residues	Fate - storage, processing and cooking	Bayer Cropscience Pty Ltd	49879
68818	I	Cavaille, C.	Phase report: 9 months storage stability of study 08-16 - Storage stability of residues of BYF 14182 and its metabolites (BCS-AA10006, BCS-AA10790, BCS-AA10791 and BCS-CM41431) in plants during deep freeze storage for up to 24 months	20 October 2009	Residues	Fate - storage, processing and cooking	Bayer Cropscience Pty Ltd	49879

State/External Efficacy Reviewer

The results of 21 Australian trials on the efficacy and crop safety of 240 g/L penflufen were presented. Sixteen of these trials were in barley, four were in wheat and one in oats. Most trials compared in-furrow application with seed treatment while some also included a split application of seed treatment plus in-furrow application.

The trials were randomised complete block/split plot design with 3, 4 or 6 replicates plus untreated controls. The trials tested crop emergence and establishment, crop growth and vigour, efficacy against *Rhizoctonia* and Loose and Covered smut disease and crop safety (phytotoxicity). Yield and grain quality was also assessed.

Trial results show that treatment with penflufen did not adversely affect crop emergence, crop establishment, growth, biomass, yield, or grain quality. Treatment did not always significantly reduce the incidence and severity of disease but in many trials disease was assumed to be controlled as crop establishment, growth, yield etc. was not affected when disease was present at least at medium levels. Results also showed penflufen was safe to use in-furrow on barley, wheat and oats at rates up to 120 mL/ha.

The data demonstrated that Evergol Seed Treatment and In-Furrow Fungicide will control/suppress diseases at the proposed label rates in wheat, barley and oat crops when applied in-furrow and in combination with the product when used as a seed treatment. The data also demonstrated that the product is safe to use in these crops at proposed label rates.

No data were submitted for the extension of existing seed treatment uses in wheat and barley to oats. However, as the same/similar smut diseases and the same rhizoctonia diseases affect oat crops, which are also cereals and as both formulations have been shown to be safe to use in oats, the extension to include oats is supported.

Based on the information provided the APVMA is satisfied that the product should be as safe and efficacious as claimed.

Data relied on to provide the advice

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
87486	S	Stone, N.	EverGol Prime applied as a seed treatment and in-furrow on liquid fertilizer for control of Rhizoctonia root rot in barley. Elmore / VICTORIA / 2012	27 January 2014	Efficacy and safety	Efficacy	Applicant	
87464	S	Anderson, C.	Penred 240 FS applied as a seed treatment and In-Furrow with liquid fertilizer for control of Rhizoctonia (Rhizoctonia solani) root rot (inoculated) in wheat. Strathalbyn, South Australia, 2011.	27 August 2012	Efficacy and safety	Efficacy	Applicant	
87465	S	Bogacki, P.; McKay, A.; Desbiolles, J.	Efficacy of EverGol Prime applied on seed and in-furrow to reduce yield loss caused by Rhizoctonia bare	21 October 2013	Efficacy and safety	Efficacy	Applicant	

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
			patch. Lameroo, South Australia, 2013					
87466	S	Bogacki, P.; McKay, A.; Desbiolles, J.	Efficacy of EverGol Prime applied on seed and in-furrow to reduce yield loss caused by Rhizoctonia bare patch. Wynarka, South Australia, 2013.	21 January 2014	Efficacy and safety	Efficacy	Applicant	
87467	S	Clarke, M.	EverGol Prime applied as a seed treatment and In-Furrow in liquid fertilizer for control of Rhizoctonia root rot (inoculated) in barley. Beverley, Western Australia, 2011.	17 October 2012	Efficacy and safety	Efficacy	Applicant	
87468	S	Clarke, M.	Penred applied as a seed treatment and In-Furrow on liquid fertilizer for control of Rhizoctonia root rot (inoculated) in barley. Beverley/ Western Australia/ 2012.	17 January 2014	Efficacy and safety	Efficacy	Applicant	
87469	S	Clarke, M.	EverGol Prime applied as a seed treatment and In-Furrow on liquid fertiliser for control of Rhizoctonia root rot, R. solani (non inoculated) in barley. Harrismith / Western Australia / 2013	27 January 2014	Efficacy and safety	Efficacy	Applicant	
87470	S	Clarke, M.	Penred applied as a seed treatment and In-Furrow on liquid fertilizer for control of Rhizoctonia root rot (inoculated) in barley. Talbot/ Western Australia/ 2012.	27 January 2014	Efficacy and safety	Efficacy	Applicant	
87471	S	Horbury, R.	Demonstration of EverGol vs., Dividend on Seed and in furrow.	5 February 2014	Efficacy and safety	Efficacy	Applicant	
87472	S	Horbury, R.	Demonstration of EverGol Prime on seed and infurrow for rhizoctonia with a comparison of commercial standards for covered smut control in barley.	5 February 2014	Efficacy and safety	Efficacy	Applicant	
87474	S	Horbury, R.	Demonstration of EverGol on Seed and In-Furrow for rhizoctonia control in wheat with a comparison to standards for covered and loose smut control.	5 February 2014	Efficacy and safety	Efficacy	Applicant	
87477	S	Huberli, D.	Evergol Prime applied as a seed treatment or in-furrow for control of rhizoctonia root rot in wheat. Salmon Gums, Western Australia, 2011	5 May 2012	Efficacy and safety	Efficacy	Applicant	
87478	S	Huberli, D.	EverGol Prime applied as a seed treatment or In-Furrow for control of Rhizoctonia root rot in barley. Lake Grace, Western Australia, 2012.	16 January 2014	Efficacy and safety	Efficacy	Applicant	
87479	S	Mackay, A.; Desbiolles, J	Evergol prime applied as a seed treatment or in-furrow for control of rhizoctonia root rot in barley. Minipa, South Australia, 2011	9 May 2012	Efficacy and safety	Efficacy	Applicant	
87480	S	Mackay, A.; Desbiolles, J	Evergol prime applied as a seed treatment or in-furrow	9 May 2012	Efficacy and	Efficacy	Applicant	

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
			for control of rhizoctonia root rot in barley. Yulami, South Australia, 2011		safety			
87482	S	McKay, A.; Bogacki, P.; Desbiolles, J.	Efficacy of EverGol Prime applied on the seed and in-furrow to reduce yield loss caused by Rhizoctonia bare patch. Karoonda, South Australia, 2012.	21 October 2013	Efficacy and safety	Efficacy	Applicant	
87483	S	McKay, A.; Bogacki, P.; Desbiolles, J.	Efficacy of EverGol prime applied on the seed and in-furrow to reduce yield loss caused by rhizoctonia barepatch. Port Julia, South Australia, 2012	21 October 2013	Efficacy and safety	Efficacy	Applicant	
87484	S	Porter, R.	Evaluation of Penred 240 FS applied via seed treatment and liquid fertilizer for control of Rhizoctonia root rot (Rhizoctonia solani) in wheat cv. Wyalkatchem. Lameroo, South Australia, 2011.	21 October 2013	Efficacy and safety	Efficacy	Applicant	
87485	S	Robertson, G.	Crop safety of Baytan T and EverGol Prime applied as seed treatments to cereals. Tullamarine / VIC / 2013	17 January 2014	Efficacy and safety	Efficacy	Applicant	
87487	S	Tidd, J.	Penred applied as a seed treatment and In-Furrow on liquid fertilizer for control of Rhizoctonia root rot in barley.	10 April 2012	Efficacy and safety	Efficacy	Applicant	
87463	S	Haigh, N.	Determination of the physical compatibility of EVERGOL PRIME (Spec. 102000025750; UVP 80210922) with a variety of fertilisers and fungicides for in-furrow applications.	16 January 2014	Efficacy and safety	Other information	Applicant	

** S = Data submitted with the application*

I = Data inherited (that is, referenced) from another application