



ADVICE SUMMARY

APPLICATION FOR VARIATION OF A REGISTERED CHEMICAL PRODUCT

Product name: NUFARM FILAN FUNGICIDE
Applicant: NUFARM AUSTRALIA LIMITED
Product number: 59032
Application number: 42941

Purpose of Application and Description of Use: Variation of label approval to extend use into potatoes, capsicum, eggplant, peppers and tomatoes and for the control of powdery mildew in grapevines, and to allow a rate range to control *Botrytis cinerea* in grapevines.

Active Constituent(s): BOSCALID

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 (Ag only)

For full conditions, refer to http://www.apvma.gov.au/advice_summaries/adv_summaries.shtml.

ADVICE

Australian Government Department Of Health And Ageing, Office Of Chemical Safety

No new toxicological studies were presented as part of the submission and the existing toxicological database was used in performing the current OH&S risk assessment by the Office of Chemical Safety (OCS).

OCS supported all the extensions of use proposed by the applicant with no changes required to the existing toxicological standards established for boscalid including the Acceptable Daily Intake (ADI of 0.06 mg/kg bw/day), Acute Reference Dose (ARfD of 3 mg/kg bw), First Aid Instructions or its exemption (SUSDP - Appendix B) status from the requirements of poisons scheduling. OCS did however make amendments to the existing Safety Directions for uses in new the crops of Potatoes, Capsicum, Eggplant, Peppers and Tomatoes that the applicant has incorporated into the product label.

The APVMA accepts the advice of OCS on this application.

Australian Government Department Of Environment And Heritage

In addition to one new study that was provided as part of the submission DEWHA in performing the risk assessment relied upon studies previously submitted for registration of the product Filan Fungicide (56362) for which this product Nufarm Filan Fungicide is a repack.

DEWHA advised that the new uses proposed would not pose unacceptable risks to the environment and supported all proposed extensions of use.

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.
16527	S	Palmer, Kendell, Krueger and Holmes	BAS 510F: A 96-hour toxicity test with the freshwater diatom (<i>Navicula pelliculosa</i>)	February 23, 2001	Environment Toxicology	Aquatic Organisms Acute	BASF Australia Ltd	

APVMA Chemistry And Residues Program, Residues Team

The applicant provided a number of new studies for assessment of new uses into potatoes, tomatoes, capsicums, eggplants and peppers.

Potatoes

The applicant provided details of 4 Australian trials plus 16 trials conducted in the US. Detectable residues were not found in potatoes from either Australian trials (n = 4) at the proposed rate (0 – 35 days after last application DALA) or US trials (n = 16) in which a much higher application rate was employed (6.8×, 29 – 30 DALA). However, in 4 European rotational cropping trials, residues were present at low levels up to 0.06 mg/kg in potatoes that were planted as rotational crops. In other rotational crop studies, the maximum residue in root and tuber vegetables was 0.32 mg/kg in radish roots. On the basis of the data provided an MRL of 0.5 mg/kg is established for boscalid on potatoes to cover residues resulting from both direct application and those arising from uptake in rotational situations.

Tomatoes, capsicum, eggplant and peppers

The applicant provided details of 6 Australian trials on tomatoes and capsicums. At the proposed 14 day WHP for tomatoes residues were 0.01, 0.02 and 0.08 mg/kg after the last application at 75 g ai/ha (1× proposed rate). At the proposed 14 day WHP for capsicums residues were 0.02, 0.03 and 0.04 mg/kg after the last application at 75 g ai/ha (1× proposed rate). The tomato and capsicum data was considered acceptable for extrapolation to the minor crops of eggplant and peppers. An MRL of 1 mg/kg was recommended for *Fruiting vegetables, other than cucurbits*.

The highest tomato residue of 0.08 mg/kg in the Australian trials would give a maximum predicted residue of 0.17 mg/kg in wet tomato pomace or 0.87 mg/kg on a dry weight basis. An MRL of 1 mg/kg for *Tomato pomace, dry* as a livestock feed was recommended for inclusion in Table 4 of the *MRL Standard*.

Rotational crops

A number of rotational crop studies were also submitted including investigations of aged residue availability in soils and an additional animal transfer study.

The maximum residue found in a crop for human consumption was 0.32 mg/kg in radish roots (after treatment of the primary crop with 5 applications of boscalid, each application at 415 g ai/ha and a plantback interval of 14 days - a clear decline in residues in radish roots was not observed for samples grown after plantback intervals of 30 and 45 days). In most of the rotational residue studies that were submitted, the plant back interval following treatment of soil with boscalid was approximately 14 days. One study investigated the magnitude of boscalid residues in rotational crops grown on soil containing aged or fresh boscalid residues. Residues of boscalid in wheat, radish and spinach grown in the aged soil were on average 53% of the residues found in the same crops grown in freshly treated soil under the same conditions.

A study was conducted to determine boscalid residues in rotational ryegrass after application of boscalid to primary crops of winter squash and pumpkin at separate sites in New Zealand. Two applications of boscalid were made, each at 100 g ai/ha (proposed rate for Filan 2 × 75 g ai/ha). The ryegrass was sown

following harvest of the primary crop. At the winter squash site residues (FW basis) of boscalid in annual ryegrass foliage declined from 0.02 mg/kg (n=3) at 97 days after the last treatment (58 days after plantback), to <0.01 (n=2) and 0.01 mg/kg at 125 days after treatment (DAT), and to <0.01 mg/kg (n=3) at 163 DAT. At the pumpkin site residues of boscalid in perennial ryegrass foliage declined from <0.01 and 0.01 mg/kg (n=2) at 163 (58 days after plantback) DAT to <0.01 mg/kg (n = 3) at 191 DAT.

Data on boscalid residues in soil and plant samples were also obtained from 4 sites where boscalid had been applied to commercial crops of leafy lettuce and green beans at annual application rates that ranged from 750 g ai/ha to 2 kg ai/ha. One site was subjected to a total application of 3 kg ai/ha over a 13 month period. The lettuce and green beans were rotated to bok choy, clover and ryegrass, ryegrass, and oats under-sown with ryegrass. While boscalid residues were detected in all the soil samples, no boscalid residues were detected above the LOD (0.005 mg/kg) in any of the succeeding crops 182 to 203 days after the last treatment was applied (3 to 5 months after plantback).

It was recommended that an MRL of 0.5 mg/kg be established for *All Other Foods* to cover the likelihood of residues appearing in various commodities in rotational crop situations.

Animal transfer studies were provided with feeding levels of 1.8, 5.9 and 20 ppm; (Tilting 2001) and 35.8 and 116.3 ppm (Malinsky & Pyradun, 2009). The feeding levels used in the Malinsky & Pyradun study (35.8 and 116.3 ppm) are significantly higher than the anticipated livestock dietary burden and the transfer of boscalid residues to animal tissues was much lower in these studies containing higher feeding levels. A number of factors were identified that may have contributed to the reduced transfer in these studies, and it is considered that transfer is dose dependent. Depuration data was also available from both studies following dosing at the highest feeding levels of 20 ppm and 116 ppm boscalid in the feed confirming that boscalid is rapidly depurated from tissues and the half life of parent boscalid in fat is ≤ 2.6 days.

A significant number of overseas trials were provided for commodities from rotational crops which may be used as livestock feeds. This included 2 trials on wheat (planted after treatment to strawberries), 6 trials on peas and beans, 49 trials on cereals and soybeans and 26 trials on grasses, alfalfa and clover. The maximum residue in a commodity from a rotational crop which may be used as a livestock feed was 9.5 mg/kg (dry weight) in bean forage (after treatment of soil with 3 applications of boscalid at a total rate of 2 kg ai/ha and a 14 day plantback interval). It was recommended to establish a Table 4 entry of 15 mg/kg for boscalid in *Primary feed commodities* based on a proposed restriction in the annual application rate of boscalid.

The maximum predicted livestock dietary exposure to boscalid will be as a result of the consumption of grape pomace as 20% of the diet with primary feed commodities derived from rotational crops making up the remaining 80%. The maximum predicted boscalid intake for cattle based on residues in rotational crops after application of boscalid at higher rates than required for the product will be 9.7 ppm (i.e. considering use rates approved by permit), an increase from the maximum feeding level of 2.1 ppm from the registered use on grapes. Based on the animal transfer study of Tilting (2001), where dairy cattle were fed

boscalid at 20 ppm in the diet for 28 days. The highest residues were present in the cream, kidney, fat and liver at 0.381, 0.318, 0.292 and 0.182 mg/kg, respectively. The highest residue detected in whole milk was 0.096 mg/kg on day 18 of the treatment.

The following changes were recommended to the current animal commodity MRLs based on a maximum feeding level of 9.7 ppm:

MM 0095 Meat [mammalian] [in the fat]	from 0.1 to 0.3 mg/kg
MO 0105 Edible offal (Mammalian)	from 0.05 to 0.3 mg/kg
ML 0106 Milks	from *0.02 to 0.1 mg/kg
Milk fats	new MRL at 0.7 mg/kg

Trade:

Application of the product as proposed is expected to result in significantly lower residues in rotational crops than those used to estimate the animal commodity MRLs.

Studies provided suggest quantifiable residues should not be found in animal commodities derived from livestock which have been fed rotational crops when no more than 2 applications of Filan have been made to the primary crop at the proposed rate. A restraint limiting the total number of application to two per year is recommended for the use of Nufarm Filan Fungicide to ensure trade risk considerations remain appropriate:

The existing product label for use on grapevines contained a 7 day export slaughter interval for livestock that have been fed treated produce. On the basis of evaluation of new data, the potential livestock burden and the short half lives of boscalid in tissues it is considered that the ESI is no longer required.

Half lives in other tissues and in milk could not be reliably estimated as residues were less than LOQ at sampling after dose withdrawal (except for one sample of milk from the 116 ppm group 2 days after withdrawal). The data confirms that boscalid residues depurate rapidly from animal tissues. The assessment concluded that the risk to trade associated with the proposed use of Nufarm Filan Fungicide on potatoes, tomatoes, peppers and eggplant was low and acceptable.

Chronic and acute dietary exposures are acceptable and within the currently established public health standards (ADI & ARfD). The APVMA Residues Section have advised the proposed extension of use of *Nufarm Filan Fungicide* to potatoes, tomatoes, peppers and eggplant be supported.

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.
16519	S	Grote, C. and Platz, K.	Accumulation behaviour of BAS 510 F under field conditions over a 7-year-period (1998 - 2004) after application onto vegetables.	31 May 2005.	Residues	Crop Residues Human Consumption	Prev Sub, Not Protected	
16518	S	Kellner, O., Grote, C. and Platz, K.	Accumulation behaviour of BAS 510 F under field conditions over a 5-year-period (1998 - 2003) after application onto grapes in a vineyard.	07 September 2004	Residues	Crop Residues Human Consumption	Prev Sub, Not Protected	
16512	S	Wofford, J. T, Abdel-Baky, S.	The magnitude of BAS 510 F residues in potato	21/03/2001	Residues	Crop Residues Human Consumption	Applicant	
16516	S	Versoi, P.L, Abdel-Baky, S.	The magnitude of BAS 510 F residues in bell and chili peppers	2000	Residues	Crop Residues Human Consumption	Applicant	
16526	S	Jordan	Field rotation study for BAS 510 on grasses, alfalfa and clover as livestock feed crops	February 27, 2002	Residues	Crop Residues Human Consumption	BASF Australia Ltd	
16515	S	Haughey, D.W., Abdel-baky, S.	The magnitude of BAS 510 F residues in tomato.	2001	Residues	Crop Residues Human Consumption	Applicant	
16524	S	Leonard	Sugar Beet, Garden Beet and Turnip Field Rotational Crop Study for BAS 510 02F Residues	March 27, 2003	Residues	Crop Residues Human Consumption	BASF Australia Ltd	
16514	S	Peracto Pty Ltd, Burn, R.	Determination of boscalid residues in tomatoes and capsicums.	2007	Residues	Crop Residues Human Consumption	Applicant	
16522	S	Versoi and Abdel-Baky	Magnitude of the Residues of BAS 510F In Peas and Beans Planted as Rotational Crops and of BAS 500F in Peas and Beans When Applied as a Foliar Spray	February 7, 2002	Residues	Crop Residues Human Consumption	BASF Australia Ltd	
16525	S	Beck, Lehmann, Grote and Mackenroth	Study on the residue behaviour of boscalid (BAS 510F) on succeeding crops after application of BAS 510 01F on bare soil and cultivation of potatoes under field conditions in Denmark, France, Germany and Great Britain, 2002	2002	Residues	Crop Residues Human Consumption	BASF Australia Ltd	
16513	S	Peracto Pty Ltd, Burn, R.	Determination of levels of boscalid residues in potatoes.	2006/2007	Residues	Crop Residues Human Consumption	Applicant	
16528	S	Haughey D.W., Abdel-Baky, S	The magnitude of BAS 510 F residues in tomato processed fractions	2001	Residues	Crop Residues Human Consumption	Applicant	
16520	S	Staudenmaier, H.	Plateau concentrations of BAS 510 F (Boscalid) in soil after long-term use.	30 September	Residues	Crop Residues Human Consumption	Prev Sub, Not Protected	

				ber 2005.				
16523	S	Jordan	Cereal Grain and Soybean Field Rotational Crop Study for BAS 510F Amendment	2007	Residues	Crop Residues Human Consumption	BASF Australia Ltd	
16521	S	Haughey and Abdel-Baky	Limited Rotation Crop Study for the Use of BAS 510F	March 9, 2001	Residues	Crop Residues Human Consumption	BASF Australia Ltd	
42162	S	J.A. Geelan	Residues of boscalid in rotational crops following the application of Colliss to commercial pumpkin and winter squash crops in Hawke's Bay. Interim Report.	2009	Residues	Other Information	BASF Australia Limited	
42160	S	D.S. Malinsky and R. Pryadun	A meat and milk magnitude of the residue study with BAS510F in lactating dairy cows [Study code 229114].	2009	Residues	Other Information	BASF Australia Limited	
42161	S	H. Penning, T. Richter, and C. Schriever	Accumulation behaviour of BAS 510F in soil under field conditions over several years after application onto vegetables.	2009	Residues	Other Information	BASF Australia Limited	
42159	S	Phillip Frost	Soil and plant testing for Boscalid persistence following application to beans, pyrethrum and lettuce in Tasmania	2009	Residues	Other Information	Applicant	
42163	S	I. Beck	Study on soil degradation and long-term sorption in soil [Study code 280072].	2008	Residues	Other Information	BASF Australia Limited	
42164	S	Z. Schweda	Study on the residue behaviour of BAS510F in the rotational crops: wheat, spinach, and radish after growing on soil with different aged Boscalid.	2009	Residues	Other Information	BASF Australia Limited	

External Efficacy Reviewer

The applicant supplied data from 22 studies in support of the proposed new label claims.

This included replicated field trials conducted into the efficacy of Nufarm Filan Fungicide (at the rate of 150g/ha) for control of Early blight in potatoes, tomatoes and capsicums. Data from aerial application spray trials on potato were also submitted. The trials submitted were conducted in Australia and verified the results obtained from trials conducted in the USA where boscalid is registered as a fungicide in combination with other fungicides for the control of fungal diseases in potato.

Trials conducted on grapes when used at a lower than label rate of 100 to 120 g per 100L, provided adequate control of *Botrytis* (grey mould in grapevines) in those situations where there is low disease pressure or when used in combination with another fungicide (pyraclostobin).

Data from trials conducted on tomatoes and capsicums (peppers – sweet) were accepted for extrapolation to those minor crops eggplant and peppers (chilli).

All trials conducted were performed under commercial growing conditions in both field and greenhouse situations. Sites were chosen with the expectation of diseases developing with adequate disease pressure in control plants. Assessments were made using disease severity and disease incidence rankings as well as yield parameters. No phytotoxic effects were observed in any of the target crops.

The trial designs and experimental conditions were all considered appropriate with replicated trials and adequate control plots included in the trials reported. Appropriate statistical analyses using analysis of variance (ANOVA) were conducted and appropriate interpretations of results were provided.

The reviewer advised that the data provided supports registration of the proposed new uses.

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.
16535	S	Horsfield, A	Comparing the efficacy of potato fungicides applied at two water volumes+/- Du Wett, on the control of target spot in processing potatoes in South Australia	2007	Efficacy and Safety	Efficacy	Applicant	
16536	S	MacLeod, S.	Control of Alternaria (target spot) in potatoes with BAS 516 00F and BAS 510 01F in Australia.	2001	Efficacy and Safety	Efficacy	Applicant	
16540	S	Lewis, K.	Control of Alternaria target spot in tomatoes with BAS 510 01F and BAS 516 GBF in Australia.	2000	Efficacy and Safety	Efficacy	Applicant	
16551	S	Paton, S	Botrytis control in grapevines.	2006	Efficacy and Safety	Efficacy	Applicant	
16550	S	Wicks, T., Bartlett, L., Walter, A., & Hall, B.	Evaluation of Filan fungicide for the control of Botrytis bunch rot on grapevines	2006	Efficacy and Safety	Efficacy	Applicant	
16537	S	Blackney, R.	Evaluation of the yield effects of Filan 500 WG and Aero (550 + 50)WG in potatoes cv. Pike.	2007	Efficacy and Safety	Efficacy	Applicant	
16548	S	Dr Trevor Wicks, Lee Bart	The efficacy of BAS 510 01F for the control of Botrytis bunch rot on grapevines	May 2003	Efficacy and Safety	Efficacy	Applicant	
16539	S	Frost, P., & Pung, H.	Comparison of BAS 518 01F and BAS 510 01F with Amistar 500 WG for control of Early	2006	Efficacy and Safety	Efficacy	Applicant	

			Blight (<i>Alternaria solani</i>) by aerial application in potatoes cv Russet Burbank					
16546	S	Wicks, T., Bartlett, L., Walter, A., & Hall, B.	Evaluation of tank mixes of Cabrio (Pyraclostrobin) plus Filan (Boscalid) against powdery mildew on grapevines cv. Chardonnay	2005	Efficacy and Safety	Efficacy	Applicant	
16529	S	Davies, K., & Wicks, T.	The evaluation of BAS 510 01F for the control of target spot (<i>Alternaria solani</i>) on potatoes.	June 2002.	Efficacy and Safety	Efficacy	Applicant	
16544	S	Wicks, T. & Bartlett, L.	The evaluation of Cabrio EC & WG formulations for the control of Powdery Mildew on Grapevines.	2004	Efficacy and Safety	Efficacy	Applicant	
16530	S	Lewis, K	Comparison of BAS 518 01F and Filan 500 WG with Amistar 500 WG for the control of Target Spot (<i>Alternaria solani</i>) in potatoes cv. Sebago : Pezzalato.	2005	Efficacy and Safety	Efficacy	Applicant	
16531	S	Lewis, K	Comparison of BAS 518 01f and Filan 500 WG with Amistar 500 WG and Score 250 EC for the control of Target Spot (<i>Alternaria solani</i>) in potatoes cv. Sebago:Poggioli	2005	Efficacy and Safety	Efficacy	Applicant	
16549	S	Wicks, T., Bartlett, L., Walter, A., & Hall, B.	Evaluation of tank mixes of Filan (Boscalid) plus Cabrio (Pyraclostrobin) for the control of Botrytis bunch rot in grapevines cv. Pinot Noir	2005	Efficacy and Safety	Efficacy	Applicant	
16532	S	Paton, S	Filan:Target Spot Control in Potatoes	2006	Efficacy and Safety	Efficacy	Applicant	
16545	S	Sumner, M.W.	Comparison of Cabrio 250 EC plus Filan 500 WG tankmixes with Cabrio, Flint 500 WG, Prosper 500 EC, Filan and Scala 400 SC when applied as dilute applications on a two spray schedule commencing at early flowering for the control of powdery mildew (<i>Uncinula necator</i>) in grapevines cv. Chardonnay	2005	Efficacy and Safety	Efficacy	Applicant	
16533	S	Paton, S	PowerYield-Program comparison for early blight control	2007	Efficacy and Safety	Efficacy	Applicant	
16547	S	Horsfield, A	Evaluation of several fungicides for the control of powdery mildew in grapevines	2006	Efficacy and Safety	Efficacy	Applicant	
16543	S	Sumner, M.W.	Comparison of Cabrio 250 EC, Filan 500 WG and BAS 560 SC with Flint 500 WG when applied as dilute sprays for the control of powdery mildew (<i>Uncinula necator</i>) in grapevines cv. Chardonnay.	2004	Efficacy and Safety	Efficacy	Applicant	
16541	S	Lewis, K.	Comparison of BAS 518 01F 600 WG and Filan	2006	Efficacy and Safety	Efficacy	Applicant	

			500 WG with Amistar 500 WG for the control of Target spot (<i>Alternaria solani</i>) in tomato (cv. Guardian)					
16534	S	Horsfield, A	Evaluation of the Nufarm PowerYield fungicide program for the control of target spot in processing potatoes in South Australia.	2007	Efficacy and Safety	Efficacy	Applicant	
16538	S	Holding, R.	BAS 518&BAS510/early blight (Target spot) Late blight / Potatoes/Aerial Application.	2006	Efficacy and Safety	Efficacy	Applicant	

* *S = Data submitted with the application*

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