



ADVICE SUMMARY

APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

Product name: SOLO 800WG FUNGICIDE AND MITICIDE
Applicant: CROP CARE AUSTRALASIA PTY LTD
Product number: 70314
Application number: 63112

Purpose of Application and Description of Use: Registration of a 800 g/kg sulphur (S), water dispersible granule product for the control of certain fungal diseases and mites in grapevines and other crops.

Active Constituent(s): SULPHUR

Regulatory Decision:

To grant the application subject to the following conditions:

Standard Conditions of Registration/Approval

1. Containers must meet AgVet Code Regulation 18
2. Label must contain a Date of Manufacture and Batch Number

For full conditions, refer to Standard Conditions for Applications on the APVMA website.

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External Efficacy Reviewer

The proposed product Solo 800WG Fungicide and Miticide (Solo) contains the same active constituent at the same concentration, has the same formulation type and the same claims for use and label instructions as the reference product Kumulus DF Wettable Sulphur Fungicide Spray (Kumulus).

The results from seven overseas field trials (six in Italy and one in US), five Australian (SA) field trials (included in a published report) and other information presented on the comparative performance and claims for a range of sulphur formulations demonstrate that Solo is equivalent, in terms of efficacy and crop safety, to Kumulus.

In the six Italian trials Solo was tested against a commercial standard (80% micronized sulphur) and an 80% wettable powder formulation for the control of moderate to high infection levels (50-88%) of powdery mildew in grapevines and tomatoes. Significant reductions in powdery mildew infection levels (62-91%) compared with the untreated control (UTC) and no adverse crop effects were demonstrated across all six trials using sulphur at the label mid-rate of 400 g/100 L with no significant differences in the results for all three products.

In the US trial a program of sprays using Solo at 2x the proposed label rate was tested against a conventional synthetic fungicide spray program on five apple cultivars for the control of severe (80%) apple scab infection. The results showed 96-99% control of apple scab lesions on fruit at harvest across all 5 apple cultivars with the Solo program and no phytotoxicity reported with any Solo or standard fungicide program treatment. There were no significant differences in the results between treatment programs.

The series of five field trials conducted across the wine growing districts of SA in the 1998/99 season compared the performances of several commercial standards - 80% sulphur, wettable powder, 80% sulphur, micronised dry flowable, and 80% sulphur, flowable liquid, applied at 1x and 2x the label rate for the control of powdery mildew in grapes. The results demonstrated that when the three sulphur formulations were applied to achieve complete and even coverage and applied at equivalent rates there were no differences in their control of grape powdery mildew (all provided a significant reduction in incidence and severity). At 2x the recommended rate it was demonstrated that phytotoxicity was more likely to occur with wettable powder formulations than with micronised sulphur formulations.

The trials support the applicant's claim that the efficacy and crop safety of Solo could be expected to be the same, when applied at an equivalent rate, for the same claims as any other registered sulphur formulation.

The trials were conducted by suitably qualified personnel, were carried out using standard scientific methodology and rigour, were fully randomised with 3-5 replicates & treated & untreated controls, used suitable statistical analysis (ANOVA with means separated using LSD techniques) and were conducted under conditions comparable to standard commercial practice in Australia (for overseas trials they were carried out for the most part on varieties that are grown in Australia, against the same diseases that occur in Australia, with comparable cultural practices and under similar growing conditions).

The product formulations used in the trials are consistent with that proposed for registration as Solo or with those of the other currently registered products. The label claims and instructions for Solo are consistent with those of the registered reference product Kumulus, with other currently approved Australian and overseas labels, with the results from the eleven field trials and with the other data and scientific arguments presented by the applicant. They are therefore considered appropriate.

It is recommended that, in relation to efficacy and crop safety, the proposal to register Solo as similar to Kumulus be accepted.

The APVMA accepts the advice of its advisor in this regard and is satisfied on the efficacy and crop safety criteria providing the proposed product is used as directed on the label.

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.
93807	S	-	Superior Sulfur Protection, Micronized Wettable Sulfur Formulation	2002	Efficacy and safety	Efficacy	Applicant	
93808	S	Patrizia M.	Efficacy of Sulphur 80% WP and Sulphur 80% WG on powdery mildew in grapevine, Southern and Northern Europe 2007.	8 Nov 2007	Efficacy and safety	Efficacy	Applicant	
93809	S	Annon.1991.	U.S EPA R.E.D. FACTS Sulfur.	May 1991	Efficacy and safety	Efficacy	Public	
93810	S	B. Emmett	Strategic Use of Sulphur in Integrated Pest and Disease Management (IPM) Programs for Grapevines.	Dec 2003	Efficacy and safety	Efficacy	Public	
93811	S	Daniele S; Renzo B.	Efficacy of Sulphur 80% WP and Sulphur 80% WG on powdery mildew in grapevine, Southern and Northern Europe 2007.	9 Nov 2007	Efficacy and safety	Efficacy	Applicant	
93812	S	Daniele S; Renzo B.	Efficacy of Sulphur 80% WP and Sulphur 80% WG on powdery mildew in grapevine, Southern and Northern Europe 2007.	12 Nov 2007	Efficacy and safety	Efficacy	Applicant	

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
93813	S	Daniele S; Renzo B.	Efficacy of Sulphur 80% WP and Sulphur 80% WG against powdery mildew on tomato.	12 Nov 2007	Efficacy and safety	Efficacy	Applicant	
93814	S	Daniele S; Renzo B.	Efficacy of Sulphur 80% WP and Sulphur 80% WG against powdery mildew on tomato.	14 Nov 2007	Efficacy and safety	Efficacy	Applicant	
93815	S	Daniele S; Renzo B.	Efficacy of Sulphur 80% WP and Sulphur 80% WG against powdery mildew on tomato.	14 Nov 2007	Efficacy and safety	Efficacy	Applicant	
93816	S	J. W. Travis, N. O. Halbrecht, J. Rytter.	Evaluation of organic alternatives for control of apple scab, 2005.	Aug 2005	Efficacy and safety	Efficacy	Applicant	

* S = Data submitted with the application

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