



## ADVICE SUMMARY

### APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

**Product name:** ALLITRON SYSTEMIC FUNGICIDE  
**Applicant:** ZELAM PTY LTD  
**Product number:** 63023  
**Application number:** 44533

**Purpose of Application and Description of Use:** Registration of a 375g/L triadimenol suspension concentrate product for the control of White Rot in onions and Powdery Mildew in Grapevines

**Active Constituent(s):** TRIADIMENOL

#### **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. Agricultural products must meet Active Constituents Quality Assurance Requirements
3. Label must contain a Date of Manufacture and Batch Number

For full conditions, refer to [http://www.apvma.gov.au/advice\\_summaries/adv\\_summaries.shtml](http://www.apvma.gov.au/advice_summaries/adv_summaries.shtml).

## **ADVICE**

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

Triadimenol has an ADI of 0.06 mg/kg bw/d, based on a NOEL of 6.25 mg/kg bw/d in a 2-year rat study and using a 100-fold safety factor. No ARfD has been established. Triadimenol is listed in Schedule 5 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

The toxicology data in the OCSEH internal database together with publicly available data were used to estimate the toxicological profile of, and establish Safety Directions for, the product. The estimate of toxicology was relied on by the OCSEH in considering whether the proposed use of the product would not be an undue health hazard to humans. Based on the estimate, Allitron Systemic Fungicide is likely to have low acute oral, dermal and inhalational toxicity. It is likely to be a slight skin and eye irritant, and a potential skin sensitiser.

The Pesticide Handler Exposure Database (PHED) Surrogate Exposure Guide was used to determine the potential risks associated with acute exposure and repeat-dose exposure for Allitron Systemic Fungicide.

The proposed use of Allitron Systemic 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.

### **Australian Government Department Of Environment And Heritage**

DEWHA has conducted the environmental risk assessment based on data derived from the Pesticide Properties Database and the USEPA's 'Reregistration Eligibility Decision (RED) for Triadimefon and Tolerance Reassessment for Triadimenol' as well as the European Food Standards Authority (EFSA) 'Conclusion Regarding Peer Review of the Pesticide Risk Assessment of the active substance Triadimenol'.

Triadimenol is moderately water soluble and is stable against aqueous hydrolysis. It is unlikely to bioaccumulate given the low BCF of 21 in fish and the moderate water solubility. The chemical may be persistent in soil with a half-life of up to 178 days in the laboratory. However, rain may effectively promote the dissipation of the chemical in soil due to the moderate water solubility and medium mobility in soil. Although there is potential for leaching, the calculated predicted concentration in groundwater is very low (0.1 mg ac/L). Triadimenol was found to be, at worst, moderately toxic to aquatic organisms and slightly toxic to other terrestrial organisms. These characteristics along with the use pattern (three applications per annum for onions) and taking into consideration the use patterns for existing triadimenol products, do not increase concerns of environmental accumulation or long term impacts based on the conducted risk assessment to both terrestrial and aquatic organisms.

#### ***Environmental Risk Assessment***

Triadimenol is, at worst, moderately toxic to some aquatic organisms such as the rainbow trout, daphnia and green algae, however, aquatic risk modelling for 10% spray drift scenario indicated acceptable risk quotient values from multiple seasonal applications with no requirement for downwind spray drift buffers. Likewise, run-off modelling indicated an acceptable risk to aquatic organisms. Acceptable risk quotient values with respect to aquatic organisms were also obtained for the major metabolite, 1,2,4-triazole. Triadimenol is slightly toxic to birds although after standard risk modelling there was a marginal chronic risk to the bobwhite quail. The risk is, however, mitigated since it is highly unlikely that 100% of the bird's diet will be from treated food sources. Therefore it is unlikely that triadimenol will pose an unacceptable risk to birds. Similarly, there was a marginal chronic risk to the rat but the risk is also mitigated since it is highly unlikely 100% of the rat's diet will be from treated food sources, especially in an onion field. Honeybees, earthworms, predatory mites and wasps, and soil microorganisms are also unlikely to be harmed by triadimenol and 1,2,4-triazole at the proposed rates and use pattern. Limited data were available with respect to the effects of triadimenol on non-target plants. It appears unlikely that triadimenol will pose an unacceptable risk to non-target plants as studies using a different formulated product, albeit at a third of the proposed product's rate, indicated no damage to the non-target plants, and a much higher rate (four times) is used on turf in currently registered products.

Given the use pattern of the product as a fungicide for the treatment of white rot in onions, risk of exposure to triadimenol, and its major soil metabolite 1,2,4-triazole, would be expected to be acceptable for both terrestrial organisms and aquatic life.

Consequently, DEWHA can recommend to the APVMA that the use of the product in the proposed manner would not be likely to have an unintended effect that is harmful to animals, plants or things, or to the environment under Section 14 Subsection 1 of the AgVet Code.

### **APVMA Pesticides Residues Section**

Two GLP residue studies undertaken on onions in Tasmania. The trials involved treating onions with 3 applications of Tribute™ SC fungicide (triadimenol 375 g/L) at 375 g ai/ha and 750 g ai/ha. Residue samples were taken at 0, 3, 7, 14, 28, and 57 days after the last application and controls were sampled at 0, 28 and 57 days. Treatments were applied at 8- 9 weeks after planting, 21- 24 days after the first application and the final application at 25 days after the second application.

At the proposed rate of 3 applications of 375 g ai/ha following a 28 day WHP residues were; <LOQ (2) (0.02 mg/kg). At the application rate of 750 g ai/ha (2x) following a 28 day WHP residues were; 0.042 and 0.044 mg/kg in onions. Residues in rank order treated with 3 applications at 375 g ai/ha following a 28 day WHP were; <0.02, <0.02, 0.021 (0.042÷2) and 0.022 (0.044÷2) mg/kg. Residues are at or near to the limit of quantification after a 28 day WHP. An onion MRL of 0.05 mg/kg and a 28 day WHP is recommended based on the data provided.

The proposed use on grapevines is considered acceptable as similar triadimenol (250 g/L) products to Allitron Systemic Fungicide (375 g/L) are registered for use on grapevines for dilute spraying at 2.5 g ai/100L.

The Pesticides Residues section *is satisfied* that the use of triadimenol in accordance with the required instructions would not unduly prejudice trade and commerce between Australia and places outside Australia as per Section 14(3)(e)(iv) of the Agricultural and Veterinary Chemicals Codes.

#### 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.
24664	S	Dale Griffin	Determination of residues of triadimenol in bulb onions following applications of the product (Triadimenol 375g/L)	02/03/07	Residues	Crop Residues Human Consumption	Applicant	
24663	S	Dale Griffin	Determination of residues of triadimenol in bulb onions following applications of the product (Triadimenol 375g/L)	02/03/07	Residues	Crop Residues Human Consumption	Applicant	

#### State/External Efficacy Reviewer

Field studies were undertaken in Tasmania (2 studies) and New Zealand (6 studies) evaluating a 375g/L formulation of triadimenol for the control of the fungus disease white rot on onions. All the trials were adequately designed with randomised and replicated treatments and the inclusion of untreated plots.

The results show that triadimenol is safe to use on onions and that it controls white rot. The label also states a suitable seed treatment is recommended but this was used in only one New Zealand trial.

One field trial was used to evaluate triadimenol for the control of powdery mildew in grapes. The trial was adequately designed with replicated treatments and unsprayed plots, which showed that low levels of disease developed in the vines. The trial demonstrated that the 7mL/100L rate controlled powdery mildew.

#### 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.
24665	S	Dale Griffin	Evaluating the Efficacy of Tribute SC (Triadimenol 375g/L) for the control of white rot disease in bulb onions	24/05/07	Efficacy and Safety	Efficacy	Applicant	

24667	S	PG Lobb	Allitron (triadimenol) - Grapes powdery mildew control	1 March 2000	Efficacy and Safety	Efficacy	Applicant	
24666	S	PG Lobb	Trial results for 5 field trials in NZ evaluating the efficacy of Triadimenol for white rot control in onions	MARC H 06	Efficacy and Safety	Efficacy	Applicant	
24668	S	RA Fullerton, A Stewart, EA Slade	Use of demethylation inhibiting fungicides (DMI's) for the control of onion white rot ( <i>Sclerotium cepivorum</i> Berk.) in New Zealand	1995	Efficacy and Safety	Efficacy	Public	

\* *S* = Data submitted with the application

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