Australian Government
Australian Pesticides and Veterinary Medicines Authority

ADVICE SUMMARY

APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

Product name: ROTAM TOLEDO 430SC FUNGICIDE

Applicant: ROTAM AGROCHEMICAL CO., LTD.

Product number: 69174

Application number: 60132

Purpose of Application and Description of Use: Registration of a 430 g/L tebuconazole, suspension concentrate product for control of various diseases of bananas, peanuts, grapes, cereal crops, vegetables and other crops.

Active Constituent(s): TEBUCONAZOLE

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 Standard Conditions for Applications on the APVMA website.

Non-Standard Conditions of Registration/Approval

Nil.

ADVICE

External Efficacy Reviewer

Supporting efficacy and crop safety data for the registration of Toledo was provided from two field bioequivalence trials conducted in Tasmania and Queensland. The trials were conducted in lettuce for the control of lettuce drop (*Sclerotinia minor*) and bananas for the control of leaf speckle (*Mycosphaerella musae*). Rotam Toledo 430 SC Fungicide is a 430 g/L suspension concentrate formulation of the active ingredient tebuconazole, trials compared the proposed Toledo formulation with a registered and suitable reference product.

All of the trials were conducted using randomised complete block trial design with adequate plot sizes and replication. Detailed assessments for crop safety where appropriate; weed control assessments were undertaken. Statistical analysis was undertaken using an analysis of variance (ANOVA). Assessments were adequate for both trials. The trials were undertaken by suitably qualified researchers.

In the lettuce trial the total number of wilting or wilted plants due to *S. minor* infection were counted and compared between treatments. The severity of leaf speckle in bananas was assessed using the following disease rating scale (0-7): 0 = no disease symptoms; 1 = 1-3% of leaf with disease symptoms (streaks and/or 10 lesions); 2 = 4-6% of leaf with disease symptoms; 3 = 7-12% of leaf with disease symptoms; 4 = 13-25% of leaf with disease symptoms; 5 = 26-50% of leaf with disease symptoms; 6 = 51-75% of leaf with disease symptoms; and 7 = 76-100% of leaf with disease symptoms.

In the lettuce trial, six applications of tebuconazole were applied over 40 days. Assessment of efficacy was by cumulative number of infected plants and the percentage of plants infected from the total number of plants, by lettuce drop (*Sclerotinia minor*), at various times, the final assessment being 19 days after the 6th application DAA-6), when the plants were ready for harvest. At the final assessment, the untreated control had developed significant disease (mean 33% plants infected) and both Toledo and the reference product demonstrated equivalent levels of control. The levels of disease in the treated plots at the proposed label rate, were significantly lower than the untreated control, but were not significantly different to each other.

No phytotoxicity symptoms were seen through visual assessment at the time of each application.

The trial in Cavendish bananas was conducted in Bundaberg, Queensland, also using a randomised complete block design. Five foliar applications of tebuconazole were applied between crop growth stages 7-8 leaves and 7-12 leaves comparing Toledo and the reference product at 3 rates each, including the recommended label rate of the reference product. Efficacy was assessed as the youngest leaf spotted (YLS) and the disease severity index (DSI) prior to treatment application and then at 21DAA2, 21DAA3, 23DAA4 and 19DAA5. Mean leaf speckle YLS and DSI increased from 7 and 2.7 respectively, prior to treatment, to 7.1 and 10.26, respectively, in the untreated control over the course of the trial. Although treatment effect on mean leaf speckle YLS following

treatment with tebuconazole was not significant, the mean DSI in the Toledo and reference product treated plots at the proposed label rate were significantly lower than the untreated control, but were not significantly different to each other.

No crop injury or visual symptoms of phytotoxicity to bananas were observed during the length of the trial when treated with Toledo or the reference product. Both trials used label rates (lettuce - 350 mL/ha, bananas - 230 mL/ha), half and double label rates to test efficacy and crop safety for bioequivalence of Toledo to the reference product.

Data presented from the two trials demonstrate that Toledo, applied as a 430 g/L SC (suspension concentrate) formulation of the active tebuconazole, will perform at least as well as reference product when applied according to the proposed label directions. Data presented also demonstrate and support that Toledo will be as safe as the reference product to apply to the same proposed crops and situations.

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.
89846	S	Cross, A., Bennett, K., Themsen, C.	Comparison of Toledo 430 SC and Folicur 430 SC for the control of leaf speckle (Mycosphaerella musae) in bananas cv. Cavendish.	July 2014	Efficacy and safety	Efficacy	Applicant	
89845	S	Pung, H., Cross, S.	Comparison of Toledo 430 SC and Folicur 430 SC for the control of lettuce drop (Sclerotinia minor) in red multi leaf lettuces cv. Telex.	July 2014	Efficacy and safety	Efficacy	Applicant	

** S = Data submitted with the application*

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