Australian Government
Australian Pesticides and Veterinary Medicines Authority

# ADVICE SUMMARY

## APPLICATION FOR VARIATION OF A REGISTERED CHEMICAL PRODUCT

**Product name:** DUPONT TALENDO FUNGICIDE

**Applicant:** DU PONT (AUSTRALIA) PTY LTD

**Product number:** 64165

**Application number:** 61214

**Purpose of Application and Description of Use:** Variation of registration and the label approval to extend registration to include use in capicums and tomatoes for control of powdery mildew.

**Active Constituent(s):** PROQUINAZID

**Regulatory Decision:**

To grant the application subject to the following conditions:

**Standard Conditions of Label Approval**

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

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

Based on the findings of the toxicological studies previously evaluated, the product has low acute oral and acute dermal toxicity. It is a severe skin and eye irritant, but not a skin sensitiser. While the product has low acute inhalational toxicity it is considered irritating to the respiratory tract mucous membranes.

Proquinazid is listed in Schedule 6 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). DuPont Talendo Fungicide contains proquinazid at 200 g/L and is therefore classified as a Schedule 6 poison. Based on the toxicology profile of the product, this classification is considered appropriate.

An exposure assessment was conducted, and in conjunction with the hazard profile, used to determine whether the proposed extension of use of the product would be an undue health hazard to humans.

After consideration of the hazards associated with the proposed extension of product use to include tomatoes and capsicums, it was considered that the proposed extension of use of DuPont Talendo 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 the Environment

No new environmental fate and effects data were provided. The Department of the Environment has used the existing information on environmental fate and effects of proquinazid in its data holdings to assess the risk associated with the increase in environmental exposure as the result of the higher use rate.

The risk to aquatic systems from spray drift with single and multiple applications was assessed using contemporary models and current APVMA policy, and found to be acceptable as long as the proposed downwind no-spray zone of 5 m for the protection of the aquatic environment is maintained for the ground application to capsicums and tomatoes.

The risk resulting from the run-off following the proposed application rate in environmental water bodies was assessed using the Department's screening run-off model. The chemical characteristics such as solubility, mobility and degradability were taken into account. The concentrations of proquinazid from use of DuPont Talendo Fungicide in environmental water bodies as a result of run-off showed an acceptable risk to aquatic systems.

Risk for the exposure of the product to terrestrial organisms, including birds, honey bees, earthworms, soil micro-organisms, other beneficial organisms and plants was assessed based on the available endpoints and the proposed application rate of the product. The environmental risk assessment has concluded that the acute and chronic risk from the proposed use of the product will be acceptable to terrestrial organisms.

Consequently, the Department of the Environment recommended that the APVMA be satisfied that the variation of 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.

**APVMA Residues and Trade Section**

The proposed use pattern for the use of DuPont Talendo Fungicide (200 g/ L proquinazid) on capsicums and tomatoes, is for a maximum of three applications of 500 mL/ha (100 g ai/ha) with a minimum retreatment interval of 7 days and a withholding period of “Not required when used as directed”.

In support of the proposed uses, the Applicant has provided an Australian study in which 8 residues trials were carried out on capsicums and tomatoes (4 each) at various locations in Australia.

Considering the available information, the proposed use of proquinazid on tomatoes and capsicums is supported from a residues perspective. An MRL at 0.3 mg/kg for VO 0448 Tomato, is considered appropriate for the use of proquinazid on tomatoes and an MRL at 0.2 mg/kg for VO 0445 Peppers, Sweet [Capsicums], is considered appropriate for the use of proquinazid on capsicums.

The APVMA Residues and Trade Section recommended that: 1) the APVMA be satisfied 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 that the residues aspects of section 14(5) of the Agvet Codes have been met, and 2) use of the product in accordance with the required instructions is unlikely to unduly prejudice trade and commerce between Australia and places outside Australia as per section 14(3)(e)(iv) of the AgVets Codes as capsicums and tomatoes are not considered to be major export commodities. The use of proquinazid is likely to result in detectable residues in capsicums and tomatoes, and the Applicant should be responsible for informing growers/producers/stakeholders of any potential risks to industry.

## 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. |
|---|---|---|---|---|---|---|---|---|
| 81427 | S | Haller, B., Westcott, A. | Dertermination of residues of proquinazid in fruiting vegetables following three applications of talendo applied at seven-day interval. [DUP12404] | 7 August 2013 | Residues | Crop residues human consumption | Applicant | |

**State/External Efficacy Reviewer**

The results of 5 trials are presented to support extension of the registration to include control of powdery mildedw in capsicums and tomatoes. Three trials, conducted in Victoria and Queensland, tested efficacy against Powdery mildew and crop safety in tomatoes (varieties Red Ruby and Pinnacle). Two trials, conducted in Korea, tested efficacy against Powdery mildew and crop safety in Bell peppers (capsicums).

All trials were field trials and all were randomised complete block with 4 or 5 replicates and untreated controls. Rates tested ranged from 125 to 750mL/ha (25 to 150gai/ha). The trials assessed the incidence and severity of disease and crop safety. The trials on capsicums also looked at percentage control.

The trial results presented showed that treatment with Talendo significantly reduced powdery mildew disease in tomatoes and in Bell peppers (capsicums). No phytotoxicity was observed in any of the trials.

Based on the data 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. |
|---|---|---|---|---|---|---|---|---|
| 81421 | S | Monsour, C. | Comparison of fungicides for the control of powdery mildew (Leveillula taurica) in tomatoes cv. Pinnacle Bowen,Queensland, 2009. [AUE-09-609] | 10 November 2009 | Efficacy and safety | Efficacy | Applicant | |
| 81422 | S | Monsour, C. | Comparison of fungicides for the control of powdery mildew (Leveillula taurica) in tomatoes cv. Pinnacle Bowen, Queensland, 2011. [AUE-11-616] | 27 October 2011 | Efficacy and safety | Efficacy | Applicant | |
| 81423 | S | Porch, J.R., Martin, K.H. | Proquinazid (DPX-KQ926) 20EC: Effects on vegetative vigor of six terrestrial plants following foliar exposure under greenhouse conditions.[DuPont-14329] | 21 April 2004 | Efficacy and safety | Efficacy | Applicant | |
| 81420 | S | Montagna, M. | Evaluation of an experimental fungicide for the control of powdery mildew in tomatoes ONE FIELD TRIAL, MURCHISON, VICTORIA, AUSTRALIA, 2009. [AUE-09-602] | 12 June 2009 | Efficacy and safety | Efficacy | Applicant | |
| 81425 | S | Balluff, M. | Proquinazid (DPX-KQ926) 20EC: A Greenhouse Study to Investigate The Effects on Vegetative Vigor of Several Terrestrial Plants Following Foliar Exposure. [DuPont-12084] | 16 September 2003 | Efficacy and safety | Phytotoxicity and crop safety | Applicant | |

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| 81426 | S | Park, U | KQ926 : Determine the break rate of KQ926 EW for control of powdery mildew on chili by PPI. [SGU-09-702] | 9 November 2009 | Efficacy and safety | Phytotoxicity and crop safety | Applicant | |
| 81424 | S | Park, U | KQ926 : Determine the break rate of KQ926 EW for control of powdery mildew on chili by SBC. [SGU-09-701] | 9 November 2009 | Efficacy and safety | Phytotoxicity and crop safety | Applicant | |

** S = Data submitted with the application*

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

**Other Details about the APVMA's Decision to Grant the Application**

Other information was made available to the APVMA to allow the APVMA to be satisfied on the associated risks.