

## Evaluation Report for Category B, Subcategory 2.1, 2.6, 3.11, 3.12 Application

**Application Number:** 2011-1385  
**Application:** B.2.1 (Product chemistry - guarantee)  
B.2.6 (Product chemistry - new combination of TGAIs)  
B.3.11 (Product labels - new pests)  
B.3.12 (Product labels - new site or host)  
**Product:** Quadris Top  
**Registration Number:** 30518  
**Active ingredients (a.i.):** Azoxystrobin (AZY), Difenconazole (DFZ)  
**PMRA Document Number :** 2077133

### Purpose of Application

The purpose of this application was to register a new broad spectrum fungicide, Quadris Top (guarantees: 200 g AZY + 125 g DFZ/L), for control of broad-spectrum diseases in tuberous and corm vegetables subgroup, carrots, sugar beets, bulb vegetables, brassica leafy vegetables, dried shelled pea and bean subgroup, fruiting vegetables, and cucurbits vegetables. Quadris Top is a liquid pre-mix formulation containing the currently registered active ingredients Azoxystrobin Technical (Registration number 26152) and Difenconazole Technical (Registration number 25631).

### Chemistry Assessment

Quadris Top is a suspension containing the active ingredients azoxystrobin and difenoconazole at nominal concentrations of 200 g/L and 125 g/L, respectively. It also contains 1,2-benzisothiazoline-3-one at a nominal concentration of 0.031 % as a preservative. This product has a density of 1.113 g/mL and pH of 6.7. The chemistry requirements for Quadris Top have been completed.

### Health Assessments

Quadris Top is of low acute toxicity by the oral ( $LD_{50} > 2000$  mg/kg), dermal ( $LD_{50} > 2000$  mg/kg) and inhalation ( $LC_{50} > 2.06$  mg/L) routes in rats. It is non-irritating to the eye and to the skin of rabbits. Based on the skin sensitization study using the method of the Buehler, Quadris Top is not a sensitizer in guinea pigs.

The use of Quadris Top on tuberous and corm vegetables, carrots, sugar beets, bulb vegetables, brassica leafy vegetables, dried shelled peas and beans, fruiting vegetables and cucurbit vegetables did not fit within the registered use pattern for azoxystrobin and difenoconazole. A quantitative risk assessment was conducted for all uses and no unacceptable risks were identified.

New residue data for difenoconazole and azoxystrobin on carrot, dry peas and dry beans were submitted to support the registration of Quadris Top fungicide. In addition, bridging data to compare the magnitude of difenoconazole residues in tomatoes and mustard greens resulting from SC and EC formulations were submitted. Previously reviewed residue data for both azoxystrobin and difenoconazole from field trials conducted in/on Crop Subgroup 1C [Tuberous and Corm Vegetable SubGroup (plus Sugarbeet and Carrot)], Crop Group 3-07 [Bulb Vegetables (Allium spp.) Group], Crop Group 5 [Brassica (Cole) Leafy Vegetables Group], Crop Subgroup 6C [Dried Shelled Pea and Bean (except soybean) Group], Crop Subgroup 8-09 [Fruiting Vegetables Group], and Crop Group 9 (Cucurbit Vegetables Group), and the processing data for related processed commodities were assessed in the context of the current submission.

**Maximum Residue Limit(s)**

Based on the residues observed in crops treated according to label directions, maximum residue limits (MRL) will be established for difenoconazole on carrot and crops in Crop Subgroup 6C (Dried shelled pea and Bean, except soybean). The MRLs currently established for azoxystrobin and difenoconazole for all other crops are adequate to cover the uses of Quadris Top fungicide.

**TABLE 1. Summary of Field Trial and Processing Data Used to Establish Maximum Residue Limit(s) (MRLs)**

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Difenoconazole (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL
			Min	Max			
Carrot	Broadcast foliar application/ Azoxystrobin: 600 Difenoconazole: 375	7	<0.01	0.203	n/a	n/a	0.5
Dry pea	Broadcast foliar application/ Azoxystrobin: 250 Difenoconazole: 156	30	<0.01	0.013	n/a	n/a	0.03 (for all crops in Crop Subgroup 6C)
Dry bean			<0.01	0.026	n/a	n/a	

Following the review of all available data, MRLs of 0.5 ppm for carrot and 0.03 ppm for crops in Crop Subgroup 6C are recommended to cover residues of difenoconazole in these crops. Residues of difenoconazole and azoxystrobin in all commodities on the Quadris Top label at the proposed and established MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

## **Environmental Assessment**

The new formulation Quadris Top fungicide and its use pattern will not result in an increase in environmental exposure relative to the existing registered products containing azoxystrobin and difenoconazole; therefore minimal risk is expected. Environmental concerns have been mitigated through adequate statements on the product label.

## **Value Assessment**

A total of 83 trials were submitted to support 32 disease claims on eight crops or crop groups. Eleven trials were reviewed as supplementary data because Quadris Top or its components were applied in rotation with another fungicide or because two diseases were evaluated as one assessment. A total of 16 trials were not reviewed because of the use of Quadris Top or its components in rotation with another fungicide or because disease pressure was too low to determine efficacy with confidence.

For each crop group, the use pattern was established on a primary pest. The use pattern established for the primary pest is also proposed for secondary pests. Due to alternation recommendations from the Fungicide Resistance Action Committee (FRAC) for QoI fungicides, secondary pests with no alternatives can only receive a single application of Quadris Top. The label will recommend a single application of Quadris Top to target these pests and will designate suppression as the level of control to be expected as a result of application.

Of the 32 disease claims, 20 were supported; seven of which were amended to change the rate, number of applications or level of control. Six disease claims were conditionally supported with amendments to four claims. Four disease claims were withdrawn by the applicant. Two claims could not be supported based on the submitted evidence. Aerial application was conditionally supported on potatoes pending the outcome of another application requesting aerial application on the Inspire label. The claim of aerial application to dried shelled peas was withdrawn by the applicant.

### **Value:**

Quadris Top combines two fungicides with different modes of action. This strategy helps reduce the risk of resistance development, which is of particular interest with QoI fungicides such as azoxystrobin. As a pre-mix fungicide, Quadris Top is also a good option for use as a rotational product with currently registered products to manage pest resistance as well. The registration addresses some minor diseases on multiple crop groups that previously had no registered products. The combination of active ingredients and the registration of minor diseases will broaden the spectrum of control for many crops.

## **Conclusion**

The PMRA has completed an assessment of the available information and is able to support the registration of Quadris Top for control of broad-spectrum diseases in tuberous and corm vegetables subgroup, carrots, sugar beets, bulb vegetables, brassica leafy vegetables, dried shelled pea and bean subgroup, fruiting vegetables, and cucurbits vegetables.

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