



## Evaluation Report for Category B, Subcategory 2.6 Application

**Application Number:** 2012-2314  
**Application:** New EP Product Chemistry-New combination of TGIAs  
**Product:** Stadium Fungicide  
**Registration Number:** 31050  
**Active ingredients (a.i.):** Azoxystrobin, Difenoconazole, Fludioxonil  
**PMRA Document Number:** 2258349

### Purpose of Application

The purpose of this application was to register a new end-use product, Stadium Fungicide, containing azoxystrobin, difenoconazole and fludioxonil. Stadium Fungicide is used as a post-harvest spray for control of fusarium dry rot (*Fusarium* spp.) and suppression of silver scurf (*Helminthosporium solani*) on potato as well as for control of rot (*Fusarium* spp.) and rhizopus rot (*Rhizopus stolonifer*) on sweet potato.

### Chemistry Assessment

Stadium Fungicide is formulated as a suspension containing fludioxonil, azoxystrobin and difenoconazole at nominal concentrations of 143 g/L, 143 g/L and 112 g/L respectively. This end-use product has a density of 1.146 g/mL and pH of 8.8. The chemistry requirements for Stadium Fungicide are complete.

### Health Assessments

Stadium Fungicide is of moderate acute toxicity to rats via the oral route ( $LD_{50} = 550$  mg/kg bw, 95% C.I. 238.5-1010 mg/kg bw), and of low acute toxicity via the dermal ( $LD_{50} > 5000$  mg/kg bw) and inhalation routes ( $LC_{50} > 2.55$  mg/L). It is non-irritating to the eye and skin of rabbits. It is not a skin sensitizer in guinea pigs.

Stadium Fungicide for post-harvest use on potatoes and sweet potatoes to control storage diseases fits within the registered use pattern for azoxystrobin, difenoconazole and fludioxonil. The potential exposure for mixers, loaders, applicators and workers handling treated potatoes is not expected to exceed the current exposure to registered products. No risks of concern are expected when all label directions and precautions are followed.

No new residue chemistry data were submitted to support the registration of the new end-use product, Stadium Fungicide, a coformulation containing three registered active ingredients azoxystrobin, difenoconazole and fludioxonil for post-harvest use on potatoes and sweet potatoes. Previously reviewed residue data from field trials conducted on potatoes (post-harvest) were reassessed in the framework of this petition. In addition, processing studies in treated potatoes were also reassessed to determine the potential for concentration of residues azoxystrobin, difenoconazole or fludioxonil into processed commodities.

**Maximum Residue Limit(s)**

Based on the residues observed in potato commodities treated according to label directions, maximum residue limits (MRLs) to cover residues of azoxystrobin, difenoconazole and fludioxonil in/on tuberous and corm vegetables (Crop Subgroup 1C) will be established as shown in Table 1. Residues of azoxystrobin, difenoconazole and fludioxonil in processed commodities not listed in Table 1 are covered under established MRLs for the raw agricultural commodity(ies) (RACs).

**TABLE 1. Summary of Field Trial Used to Establish Maximum Residue Limit(s) (MRLs) for Azoxystrobin, Difenoconazole and Fludioxonil.**

Commodity	Application Method/ Total Application Rate (g a.i./100 kg potatoes)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL	Recommended MRL
		Min	Max			
<b>Azoxystrobin</b>						
Potatoes	Post-harvest spray 0.44-0.50	<1.00	<4.16	<1 (flakes and chips)	0.03	8.0 <sup>a</sup>
<b>Difenoconazole</b>						
Potatoes	Post-harvest spray 0.34-0.38	0.60	2.39	<1 (flakes and chips)	0.01	4.0 <sup>b</sup>
<b>Fludioxonil</b>						
Potatoes	Post-harvest spray 0.44-0.50	0.53	3.35	<1 (flakes and chips)	0.02	6.0 <sup>c</sup>

<sup>a</sup> The MRL is proposed to replace the currently established 0.03 ppm for potatoes and add MRLs for the remaining commodities in the crop subgroup.

<sup>b</sup> The MRL is proposed to replace the currently established 0.01 ppm for potatoes and add MRLs for the remaining commodities in the crop subgroup.

<sup>c</sup> The MRL is proposed to replace the currently established 0.02 ppm for potatoes and of 3.5 ppm on Tuberous and corm vegetables except potato (Crop Subgroup 1D), except true yam tubers for which an MRL of 8.0 ppm is currently established.

Following the review of all available data, it was determined that MRLs of 8.0 ppm and 4.0 ppm for residues of azoxystrobin and difenoconazole, respectively, in/on tuberous and corm vegetables (Crop Subgroup 1C) and an MRL of 6.0 ppm for residues of fludioxonil in/on tuberous and corm vegetables (Crop Subgroup 1C, except true yam), are considered adequate to cover residues of azoxystrobin, difenoconazole and fludioxonil in/on those commodities as a result of this new use. Residues of azoxystrobin, difenoconazole and fludioxonil in tuberous and corm vegetables (Crop Subgroup 1C) at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

## **Environmental Assessment**

An environmental assessment was not required for this application.

## **Value Assessment**

Stadium Fungicide is proposed for the same potato uses as those registered in the three-way tank-mix of Quadris Flowable Fungicide (250 g azoxystrobin/L), Inspire Fungicide (250 g difenoconazole/L) and Scholar 230SC Fungicide (230 g fludioxonil/L). The applicant adequately showed that fungicide active ingredient rates from one post-harvest spray of Stadium Fungicide on potato are comparable to that applied with the registered tank-mix. The two potato claims are supported as proposed.

The claim of control of fusarium rots on sweet potato is supported as proposed based on the similarities in development, behaviour, monitoring and cultural management of post-harvest *Fusarium* diseases in potato and sweet potato production.

The claim of control of rhizopus rot on sweet potato is supported as proposed based on the registered uses of Scholar 230SC (230 g fludioxonil/L). Fludioxonil is delivered using the same method of application and at a higher rate with Stadium Fungicide; it is therefore expected to similarly control rhizopus rot on sweet potato. Stadium Fungicide is applied preventatively and the proposed rate is required to control fusarium rots at the same time.

## **Conclusion**

The PMRA has conducted a review of the available information and can support the registration of the new end-use product, Stadium Fungicide, as a post-harvest spray for control of fusarium dry rot (*Fusarium* spp.) and suppression of silver scurf (*Helminthosporium solani*) on potato as well as for control of rot (*Fusarium* spp.) and rhizopus rot (*Rhizopus stolonifer*) on sweet potato.

## References

PMRA #	Reference
2202808	2012, Stadium Identification, DACO: 3.1.1,3.1.3,3.1.4 CBI
2202809	2012, Stadium Identification, DACO: 3.1.2 CBI
2202810	2012, Starting materials and certification of limits, DACO: 3.2.1,3.3.1 CBI
2202813	2012, Formulation process, DACO: 3.2.2 CBI
2202814	2011, Analytical Method SF-520/1, DACO: 3.4.1 CBI
2202816	2011, Validation of Analytical method, DACO: 3.4.1 CBI
2202818	2012, Chemical and Physical Properties, DACO: 3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3. 5.8,3.5.9 CBI
2202860	2012, Rationale, DACO: 10.1,10.2.1,10.2.2,10.2.3.1,10.3.1,10.3.2
2044028	2011, Azoxystrobin + Fludioxonil + Difenoconazole: Magnitude of the Residue on Potato following post-harvest treatment, DACO: 7.4.1,7.4.2 (from submission 2011-1721, need to be linked)
2202820	2012, Azoxystrobin/Difenoconazole/Fludioxonil SC (A19432A) Acute Oral Toxicity Up-and-Down Procedure in Rats, DACO: 4.6.1
2202821	2012, Azoxystrobin/Difenoconazole/Fludioxonil SC (A19432A) Acute Dermal Toxicity in Rats, DACO: 4.6.2
2202822	2012, Azoxystrobin/Difenoconazole/Fludioxonil SC (A19432A) Acute Inhalation Toxicity in Rats, DACO: 4.6.3
2202823	2012, Azoxystrobin/Difenoconazole/Fludioxonil SC (A19432A) Primary Eye Irritation in Rabbits, DACO: 4.6.4
2202825	2012, Azoxystrobin/Difenoconazole/Fludioxonil SC (A19432A) Primary Skin Irritation in Rabbits, DACO: 4.6.5
2202826	2012, Azoxystrobin/Difenoconazole/Fludioxonil SC (A19432A) Dermal Sensitization Test - Buehler Method, DACO: 4.6.6

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