

Evaluation Report for Category B, Subcategory 3.11, 3.12, 3.2 Application

Application Number:	2014-5632		
Application:	Changes to Product Label; New Pests, Site and Application Timing		
Product:	Delaro 325 SC Fungicide		
Registration Number:	31533		
Active ingredients (a.i.):	Prothioconazole and trifloxystrobin		
PMRA Document Number : 2603717			

Purpose of Application

The purpose of this application was expand the label of Delaro 325 SC Fungicide (registration number 31533) for control of certain diseases on all types of corn and to revise the application timing for use on pulse crops.

This application was reviewed concurrently with similar applications for Stratego PRO Fungicide (registration number 31436, application number 2014-5631) and USF0728 325 SC Fungicide (registration number 31435; application number 2014-5628). All three products have the same guarantee.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

The additions and amendments to the label of Delaro 325 SC Fungicide fit within the exposures from the registered use patterns of trifloxystrobin and prothioconazole. The exposures of mixers, loaders, applicators, post-application re-entry workers, and bystanders are not expected to exceed the current exposures to registered products. No risks of concern are expected when following label instructions and precautions, including wearing the personal protective equipment identified on the label.

No new residue data were submitted to support the amendments. Residue data on file for prothioconazole and trifloxystrobin were reassessed in the framework of these submissions. The current MRL of 0.35 ppm for the combined residues of prothioconazole and prothioconazole-desthio is already established in/on crop group 15 (Cereal grains; except sweet corn kernels plus cob with husks removed, rice, and sorghum). Total residues of prothioconazole will not pose an unacceptable health risk to any segment of the population, including infants, children, adults and seniors.

The current MRL of 0.05 ppm for the combined residues of trifloxystrobin



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and metabolite CGA-321113 in/on barley, field corn, oats and wheat will be extended to the entire Crop Group 15 (Cereal grains, except sweet corn, sorghum, and rice). Total residues of trifloxystrobin will not pose an unacceptable health risk to any segment of the population, including infants, children, adults and seniors.

Maximum Residue Limit

The recommendation for maximum residue limits (MRLs) for trifloxystrobin were based upon previously reviewed residue data. MRLs to cover residues of trifloxystrobin and metabolite CGA-321113 in/on Crop group 15, Cereal Grains (except sweet corn, rice, and sorghum) are proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRL for the raw agricultural commodities (RACs).

TABLE 1. Summary of Field Trial and Processing Data Used to Support the Maximum Residue Limit (MRL).							
	Application Method/Total	PHI (days)	Residues** (ppm)		Experimental	Currently Establishe	Recommended
Commodity	Application Rate (g ai/ha)		LAFT ¹	HAFT ²	Processing Factor	d MRL (ppm)	MRL (ppm)
Wheat	Foliar/247- 263	31-62	< 0.04	0.05	1.05 (wheat bran)	0.05	0.05* (CG 15: cereal grains, except sweet corn, rice, and sorghum)
Barley	Foliar/121- 136	39-62	< 0.04	< 0.04	NA	0.05	
Oats	Foliar/120- 132	38-57	< 0.04	< 0.04	NA	0.05	
Popcorn	Foliar/494	29-30	< 0.04	< 0.04	NA	0.05	
Field Corn	Foliar/494	28-34	<0.04	0.05	1.7 (corn oil refined)	0.05 (field corn); 0.1 (corn oil refined)	

1. LAFT = lowest average field trial residues; 2. HAFT = highest average field trial residues

* The MRL is proposed to extend the currently established 0.05 ppm MRL for barley, field corn, oats, popcorn grain, and wheat, to the entire crop group.

** Residues of trifloxystrobin and metabolite CGA-321113.

Environmental Assessment

The host crop and pest combinations does not represent an increase in application rate, number of applications permitted per crop season, or the minimum application interval. As such, the PMRA has determined that the addition of the new host crop and pest combinations does not represent an increase in risk to non-target aquatic or terrestrial organisms. When used according to label directions, Delaro 325 SC Fungicide poses a negligible risk to non-target aquatic and terrestrial organisms.

Value Assessment

Scientific rationales and results from 25 efficacy trials conducted mostly in Canada between 2013 and 2014 and some trials in South Africa and in Brazil were reviewed to support the use claims. The efficacy trials, demonstrated an acceptable level of disease control for leaf rust, tan spot and septoria leaf blotch on wheat, net blotch and scald on barley, and common rust, southern corn rust, northern corn leaf blight, eye spot and grey leaf spot on corn. In most cases, the efficacy was comparable to that achieved by commercial standards applied in the same field trials.

The availability of Delaro 325 SC Fungicide will provide Canadian growers with an additional option to manage these important crop diseases.

Conclusion

Following review of the application the label expansions of Delaro 325 SC Fungicide for control of certain diseases on all types of corn and to revise application timing for use on pulse crops were approved.

References

PMRA

Document							
Number	Reference						
2478846	2014, Stratego PRO, USF0728 324 SC, and Delaro 325 SC Fungicides - Rationale justifying a chang e in the application timing of these fungicides for sclerotina white mould control in pulse crops, DACO: 10.1						
2478847	2014, Stratego PRO and USF0728 325 SC Fungicides - Use expansion to include						
	small-grain cereals, corn, millet, and teosinte, DACO:						
	10.1,10.2.2,10.2.3.1,10.2.3.3(D),10.3.1,10.3.2(B)						
2478843	2008, Trifloxystrobin 500 SC - Magnitude of the residue in/on field corn, popcorn,						
	and sweet corn, DACO: 7.4						
2306685	2013, Assessment of worker exposure and risk resulting from application of						
	USF0728 325 SC to field crops, DACO: 5.2,5.3						
2478845	2014, Assessment of worker exposure and risk resulting from the application of						
	Stratego PRO Fungicide to cereals, soybeans, and corn, DACO: 5.2,5.3						
	Stratego I KO Fungicide to cereais, soybealls, and colli, DACO. 5.2,5.5						

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