

Evaluation Report for Category B, Subcategories 3.1, 3.11, 3.12 Application

Application Number: 2022-0565

Application: Changes to Product Labels-Application Rate Increase or Decrease,

New Pests, New Site or Host

Product: DELARO COMPLETE

Registration Number: 34095

Active ingredients (a.i.): Fluopyram, Prothioconazole, Trifloxystrobin

PMRA Document Number: 3458587

Purpose of Application

The purpose of this application was to amend the label of the registered end-use product, DELARO COMPLETE, to add uses on certain dried shelled bean and pea commodities, i.e., field peas, lentils, chickpeas and dry beans, for control of listed fungal diseases.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A toxicology assessment was not required for this application.

The occupational exposure and risk from the addition of the uses on dried shelled beans and peas to control various listed fungal diseases to the DELARO COMPLETE label were assessed. No health risks of concern are expected from the new uses, provided that workers follow the label directions and wear the personal protective equipment identified on the label.

No new residue data for prothioconazole, trifloxystrobin and fluopyram were submitted to support the current application and none were required given that each active ingredient in DELARO COMPLETE is currently registered for use on the requested dried shelled bean and pea commodities. Previously reviewed residue trial data were re-assessed in the context of the current application. The request to add dried shelled bean and pea commodities to the DELARO COMPLETE label is not expected to impact dietary exposure and as such, there are no health risks of concern identified for any segment of the population.

The recommendation for proposed maximum residue limits (MRLs) for fluopyram, prothioconazole and trifloxystrobin was based upon the previously reviewed field trial data, and the guidance provided in the <u>OECD MRL Calculator</u>. MRLs to cover residues of fluopyram, prothioconazole and the metabolite prothioconazole-desthio and trifloxystrobin and the metabolite CGA-321113 in/on the indicated crops are proposed as shown in Table 1.



TABLE 1. Summary of Field Trial and Processing Data Used to Support Maximum Residue Limits (MRLs)							
Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues (ppm) HAFT	Experimental Processing	Currently Established MRL (ppm)	Proposed MRL (ppm)	
				Factor			
Fluopyram re	esidues						
Bean, dried shelled			0.068		0.7 - (Crop subgroup 6C except soybean, dry crowder peas and dry field beans)	0.7 in/on dry field beans and dry crowder peas	
Pea, dried shelled	493-514	13-14	0.35				
Sum of proth	ioconazole and proth	ioconazo	ole-desthio re	esidues			
Bean, dried shelled	598-650	7-8	0.243		0.9	0.9 in/on dry field beans and dry crowder peas	
Pea, dried shelled	595–615		0.661		- (Crop subgroup 6C except soybean, dry crowder peas and dry field beans)		
Sum of triflox	xystrobin and CGA 3	21113 re	sidues				
Bean, dried shelled	258-272	28-32	<0.023		soybean, fie and		
Pea, dried shelled	261-266	29-31	<0.032			0.06 in/on dry field beans and dry crowder peas	

ppm = parts per million; PHI = preharvest interval; HAFT = Highest Average Field Trial

Following the review of all available data, the MRLs proposed in Table 1 are recommended to cover residues of fluopyram, prothioconazole and trifloxystrobin. Dietary risks from exposure to residues of fluopyram, prothioconazole and trifloxystrobin in these crop commodities at the

proposed MRLs were shown to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors. Thus, the foods that contain residues as listed in Table 1 are considered safe to eat.

Environmental Assessment

The uses of DELARO COMPLETE on field peas, lentils, chickpeas and dry beans are within the currently registered uses of prothioconazole, trifloxystrobin and fluopyram, Therefore, no additional risk is expected when DELARO COMPLETE is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

To support claims against white mould, grey mould, chocolate spot in fava bean, ascochyta blight, mycosphaerella blight, anthracnose in lentils, anthracnose in dry bean, Asian soybean rust and powdery mildew, the applicant submitted a scientific rationale comparing the amount of active ingredients delivered by DELARO COMPLETE at the approved rate to that of three precedent products. The comparison shows that comparable amounts of active ingredients are delivered by DELARO COMPLETE uses as those delivered by the registered claims for the precedent products and, as such, are expected to control the listed diseases.

Cultivation of pulses in Canada is economically important and a valuable source of crop diversification. Registration of the listed uses of DELARO COMPLETE will provide additional options for the management of major diseases in pulse crops and thus benefit Canadian pulse growers.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to amend the label of DELARO COMPLETE, to add uses on field peas, lentils, chickpeas and dry beans, for control of listed fungal diseases.

References

DMD A

PMRA	
Document	
Number	Reference
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	10.3.2, 10.4, 10.5.1, 10.5.2, 10.5.3
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2306663	2013, USF 0728 325 SC foliar fungicide - Control or suppression of listed diseases in field pea, lentil, chickpea, soybean and winter wheat, DACO: 10.1, 10.2.3.1, 10.2.3.3, 10.3.1, 10.3.2
2379468	2013, Propulse Fungicide - Control of anthracnose (Colletotrichum

2379470	lindemuthianum) in dry bean and Asian soybean rust (<i>Phakopsora pachyrhizi</i>) in listed pulse crops -, DACO: 10.1, 10.2, 10.2.2,10.2.3, 10.2.3.1, 10.2.3.3(D) 2013, Propulse Fungicide - Control of anthracnose (<i>Colletotrichum lindemuthianum</i>) in dry bean and Asian soybean rust (<i>Phakopsora pachyrhizi</i>) in listed pulse crops -, DACO: 10.1, 10.2,10.2.2, 10.2.3, 10.2.3.1, 10.2.3.3(D)
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2647534	2016, Value assessment of USF0728 325 SC fungicide - Petition to include the following label claims: white mould control on dry beans and faba bean and chocolate spot control on faba bean, DACO: 10.3.2(B)
2826886	2017, Value Assessment of USF0728 325 SC Fungicide - Label expansion to include sequential applications in lentil, DACO: 10.2.2, 10.2.3.3(D), 10.5
2826887	2017, Value Assessment of USF0728 325 SC Fungicide - Label expansion to include sequential applications in lentil, DACO: 10.2.2, 10.2.3.3(D), 10.5 CBI
3084940	2020, Compilation of Field Trial Reports: Value Assessment of USF0411 Foliar Fungicide for Control of Foliar Diseases of Corn, Soybeans, and Small-grain Cereals, DACO: 10.2.3.3, 10.2.3.3(D), 10.3.2(B)
3095337	2020, Value Assessment of USF0411 Foliar Fungicide for Control of Foliar Diseases of Corn, Soybeans, and Small-grain Cereals, DACO: 10.1, 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.3, 10.2.3.3(D), 10.2.4, 10.3.1, 10.3.2, 10.3.2(B), 10.4, 10.5.1, 10.5.2, 10.5.3
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3318428	2022, Value Assessment of DELARO COMPLETE for Control of Foliar, Stem and Pod Diseases in Pulse Crops, DACO: 10.1, 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.3, 10.2.3.3(D), 10.2.4, 10.3.1, 10.3.2, 10.3.2(B), 10.4, 10.5.1, 10.5.2, 10.5.3
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