Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2021-3228
Application: Changes to Product Labels – New Site or Host
Product: USF0728 325 SC Fungicide
Registration Number: 31435
Active ingredients (a.i.): Prothioconazole and trifloxystrobin
PMRA Document Number :3384131

Purpose of Application

The purpose of this application was to expand the registration of USF0728 325 SC Fungicide to include the control or suppression of early blight (*Alternaria solani*), brown spot (*Alternaria alternata*), black dot (*Colletotrichum coccodes*) and white mold (*Sclerotinia sclerotiorum*) on potato.

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 use of USF0728 325 SC Fungicide on potatoes was assessed. No risks of concern to mixers/loaders, applicators, postapplication workers and bystanders are expected from use of the product, provided that workers follow the label directions and wear the personal protective equipment identified on the label.

Residue data from field trials conducted with prothioconazole in Canada and the United States were submitted to support the use of USF0728 325 SC Fungicide on potatoes. Prothioconazole was applied to potatoes at the labelled rate, and harvested according to label directions. Previously reviewed residue data from field trials conducted with trifloxystrobin in/on potatoes were also reassessed in the framework of this application. In addition, a processing study conducted with prothioconazole in treated potatoes was reviewed to determine the potential for concentration of residues of prothioconazole into processed commodities. Processing studies conducted with trifloxystrobin in treated potatoes were also reassessed to determine the potential for concentration of residues of trifloxystrobin into processed commodities.

Maximum Residue Limit

Based on the residues observed in potatoes treated according to the current label directions, harvested at the appropriate PHI, and the guidance provided in the OECD MRL Calculator, it was determined that residues of prothioconazole in potatoes would be

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covered under the MRL currently established for this commodity. Residues in processed commodities are covered under the maximum residue limit (MRL) for the raw agricultural commodity (RAC).

TABLE 1. Summary of Field Trial and Processing Data Used to Support Maximum Residue Limit (MRL) for Prothioconazole

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT			
Potato tuber	Foliar/ 296-311	13-14	<0.02	<0.02	--	0.02	None
Potato chips	Foliar/ 1500	12-14	<0.02	<0.02	1X	--	--
Potato Flakes	Foliar/ 1500	12-14	<0.02	<0.02	1X	--	--

LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial

Based on the residues observed in potatoes treated at exaggerated rates, harvested at a shorter PHI than proposed, and the guidance provided in the OECD MRL Calculator, it was determined that residues of trifloxystrobin in potatoes would be covered under the 0.04 ppm MRL currently established for this commodity. Residues in processed commodities are covered under the MRL for the raw agricultural commodity (RAC).

Following the review of all available data, it was determined that the current established MRL of 0.02 ppm for residues of prothioconazole in/on potatoes is considered adequate to cover residues of prothioconazole in/on this commodity as a result of this use. Residues of prothioconazole in potatoes at the established MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Following the review of all available data, it was determined that the current established MRL of 0.04 ppm for residues of trifloxystrobin in/on potatoes is considered adequate to cover residues of trifloxystrobin in/on this commodity as a result of this use. Residues of trifloxystrobin in potatoes at the established MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use pattern on potatoes is within the registered use pattern of USF0728 325 SC Fungicide; therefore, no additional risk is expected from the use of USF0728 325 SC Fungicide.

The label includes all the required environmental precautions, directions for use and spray buffer zone information which adequately mitigate risks to the environment.

Risk from use of USF0728 325 SC Fungicide is acceptable from the environmental perspective when used according to label directions.

Value Assessment

Rationales and efficacy data from eight trials conducted in Canada and the USA were reviewed to support the label expansion of USF0728 325 SC Fungicide. Under adequate disease pressure in fields, USF0728 325 SC Fungicide demonstrated an acceptable level of disease control or suppression against listed diseases on potato. The other supporting evidence also confirmed the value of USF0728 325 SC Fungicide for control of early blight and brown leaf spot, or for suppression of white mold and black dot on potato.

The label expansion will provide Canadian growers with a product to manage important diseases on potato. In addition, it will address minor use needs for Canadian potato growers since all of the supported potato diseases have been identified as minor use priorities through the National Minor Use Priority Setting process in 2020.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to amend the label of USF0728 325 SC Fungicide to include use on potato.

References

PMRA Document Number	Reference
3250536	Magnitude of the residues of fluopyram and prothioconazole in/on potato after foliar spray and overhead chemigation application of fluopyram + prothioconazole SC 400 (200 + 200 g/L), 2021, DACO 7.4.1, 7.4.2
3250537	Magnitude of the residues of fluopyram and prothioconazole in/on potato processed commodities after overhead chemigation application of fluopyram + prothioconazole SC 400 (200 + 200 g/L), 2021, DACO 7.4.5
3250527	2021, Value Assessment of PROPULSE and DELARO Fungicides on Various Diseases in Potatoes, DACO: 10.2.1,10.2.2,10.2.3.1,10.2.3.3(D),10.3.2(B),10.5.1,10.5.2,10.5.3,10.5.4
3250529	2021, Value Assessment of PROPULSE and DELARO Fungicides on Various Diseases in Potatoes, DACO: 10.2.3.3(D)