Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2022-1222
Application: Changes to Product Labels –New Site or Host
Product: Salibro Nematicide
Registration Number: 34182
Active ingredient (a.i.): Fluazaindolizine
PMRA Document Number: 3504182

Purpose of Application

The purpose of this application was to amend the label of Salibro Nematicide to add new crops: bearing and non-bearing small fruit vine climbing (Crop subgroup 13-07F, except fuzzy kiwifruit), tree nuts (Crop group 14-11), non-bearing stone fruit (Crop group 12-09), and low growing berries (Crop subgroup 13-07G). An assessment was also conducted on head cabbages to fulfill the requirement for the OECD super crop subgroup of leafy vegetables and brassicas.

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 use on non-bearing stone fruit, bearing and non-bearing tree nuts, bearing and non-bearing small fruit vine climbing and low growing berries to the Salibro Nematicide label was assessed. No 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.

Residue data from field trials conducted in Canada and the United States were submitted to support the uses of Salibro Nematicide on non-bearing stone fruit, bearing and non-bearing small fruit vine climbing, low growing berries, and tree nuts. Fluazaindolizine was applied to grapes, strawberries, almonds, and pecans at the label rates and harvested according to label directions. Processing studies in treated grapes were reviewed to determine the potential for concentration of residues of fluazaindolizine into processed commodities. In addition, field accumulation studies conducted on head cabbages were submitted to fulfill the second subgroup of the leafy vegetables and brassicas category of the OECD super crop group for Tier III (extended field) studies.

Canada

The supported maximum residue limits (MRLs) for fluazaindolizine was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. MRLs to cover residues of fluazaindolizine in/on crops and processed commodities are supported as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the MRLs for the raw agricultural commodities (RACs).

Table 1 Summary of Field Trial and Processing Data Used to Support Maximum Residue Limits (MRLs)

Commodity	Application Method/ Total Application Rate (kg a.i./ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	MRL (ppm)
			LAFT	HAFT			
Primary Crops							
Grapes	Soil application/ 2.24	36-42	<0.01	0.028	Juice: No concentration in processed fraction Raisins: >1.2x Wine: No concentration in processed fraction	Not established	0.04
Strawberries	Soil application/ 2.24	6-8	<0.01	0.075	No concentration in processed fractions	0.01	0.15
Almonds	Soil application/ 2.26	38-41	<0.01	0.021	Not applicable	Not established	0.04
Pecans	Soil application/ 2.26	28-34	<0.01	<0.01	Not applicable	Not established	0.04
Secondary Crops							
Head cabbages, leaf lettuce, spinach, broccoli, Swiss chard, head lettuce (Crop groups 4-13 & 5-13)	Soil application/2.24	7-30 (PBI)	<0.01	0.017	Not required	0.015	0.02

ppm = parts per million; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial; PHI= Preharvest interval; PBI= Plantback interval

Following the review of all available data, the MRLs in Table 1 are recommended to cover residues of fluazaindolizine. Dietary risks from exposure to residues of fluazaindolizine in these crop commodities at the supported 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

After a scientific review of the available information, the PMRA has concluded that the environmental risks associated with the use of Salibro Nematicide are acceptable when used according to the label directions.

Value Assessment

The registrant provided seven field efficacy trials conducted in the United States to support the claims to control root knot nematode on certain vine and tree crops and three field efficacy trials from the United States to support the claim to suppress dagger nematode on vine crops. One greenhouse trial report along with a rationale and crop tolerance reports were submitted to support the claim to suppress root knot nematode on certain low growing berries. Results of these trials demonstrate that Salibro Nematicide, when applied following the labelled use pattern, will manage nematode damage on labelled crops.

Root knot nematodes and dagger nematodes can cause significant reductions in plant health and crop yield. The addition of these claims to Salibro Nematicide label will provide growers with an additional product to combat these pests in Canada.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the addition of new crops on the label of Salibro Nematicide.

References

PMRA Document Number	Reference
3333335	2021, Study ID 190051 - MOR Strawberry, DACO: 7.1
3333340	2020, DuPont-48223 Rev 1 - MOR tree nuts, DACO: 7.1
3333342	2021, DuPont-46041 Grape Processing Study, DACO: 7.1
3333343	2017, DuPont-46040 Rev 1 - MOR grapes, DACO: 7.1
3333360	2021, DuPont-40345 RV2 Residues of DPX-8U80, DACO: 7.1, 7.4
3333366	2021, Cabbage MOR, DACO: 7.4.4
3353416	2021, Magnitude of DPX-Q8U80 Related Residues in Cabbage Planted as a Rotational Crop Following Soil Directed Applications of DPX Q8U80 500 SC - NAFTA 2018-2019-2020, DACO: 7.4.4
3333329	2022, DACO 10, Salibro Nem, add tier II crops, DACO: 10.2.3.
3333331	2019, Eval of Salibro 500 SC for nematode control in strawberry, DACO: 10.2.3.3
3391138	2022, Deficiency response for strawberries, Salibro 22-1222, DACO: 10.3.3