Health Canada Santé Canada

Evaluation Report for Category B, Subcategories 3.11, 3.12, 3.4, 3.9 Application

Application Number: 2023-1121
Application: Changes to Product Label-New Pests, New Site or Host, Application Method, Level of Control
Product: Zetigo PRM Fungicide
Registration Number: 34701
Active ingredients (a.i.): Florylpicoxamid and Pyraclostrobin
PMRA Document Number: 3588657

Purpose of Application

The purpose of this application was to add new crops (wheat, barley, chickpeas, field peas and faba beans), new pests, aerial applications (for wheat and barley), and an increased level of control of blackleg on canola to the registered label of Zetigo PRM Fungicide.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A toxicology assessment was not required for this application.

The amendments to the registered label of the end-use product Zetigo PRM Fungicide, which consist of adding chickpeas, field peas, faba beans and cereals (wheat and barley), adding aerial application to cereals (wheat and barley), and expanding the target diseases on existing crops, are not expected to result in potential occupational or bystander exposure over the registered uses of pyraclostrobin. The occupational exposure and risks from these changes to the use pattern of florylpicoxamid were assessed since they represent a use expansion. 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 either florylpicoxamid or pyraclostrobin were submitted or required to support the new uses of Zetigo PRM Fungicide on barley, wheat, chickpeas, faba beans and field peas. Previously reviewed residue data for each active ingredient from field trials conducted in/on barley, wheat, and dry beans and peas were reassessed in the framework of this application. In addition, processing studies in treated barley and wheat were also reassessed to determine the potential for concentration of residues of these active ingredients into processed commodities.

Canada

Florylpicoxamid
The currently established 0.01 ppm maximum residue limits (MRLs) for florylpicoxamid in/on dried shelled beans, except soybeans (crop subgroup 6-21E); dried shelled peas (crop subgroup 6-21F); and wheat (crop subgroup 15-21A) are sufficient to cover residues resulting from all these new uses of Zetigo PRM Fungicide, except from barley for which a new MRL is proposed.

Maximum Residue Limit
The recommendation for the proposed MRL for florylpicoxamid was based upon the reassessed field trial data, and the guidance provided in the OECD MRL Calculator. The MRL to cover residues of florylpicoxamid in/on barley and processed commodities is 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 commodity (RAC).

Table 1 Summary of Field Trial and Processing Data Used to Support the Maximum Residue Limit (MRL)

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Proposed MRL (ppm)
			LAFT	HAFT			
Barley grain	Foliar / 157-167	30-86	<0.01	0.024	No quantifiable residues observed at exaggerated rates	None	0.03 [Barley (crop subgroup 15-21B)]

ppm = parts per million; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial

Based on the dietary burden and residue data, the established MRLs of 0.02 ppm in eggs, milk, fat, meat and meat by-products of cattle, goats, hogs, horses, poultry and sheep are expected to cover residues of florylpicoxamid in/on livestock commodities as a result of this action.

Following the review of all available data, the MRL proposed in Table 1 is recommended to cover residues of florylpicoxamid in/on barley. Dietary risks from exposure to residues of florylpicoxamid in barley commodities at the proposed MRL 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.

Pyraclostrobin
Following the reassessment of the residue data on file, the currently established MRLs of 0.5 ppm for dry chickpeas and dry broad beans, 1.4 ppm for barley and 0.2 ppm for wheat are sufficient to cover residues resulting from these new uses of Zetigo PRM Fungicide. As no increases to the dietary burden are expected as a result of this action, no revisions to the MRLs established for livestock commodities are needed (Maximum residue limits search - Health Canada). As such, dietary risks from exposure to residues of pyraclostrobin are considered to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors.

Environmental Assessment

The use of Zetigo PRM Fungicide on chickpeas, field peas, faba beans, wheat (spring, durum, winter) and barley is within the currently registered use pattern for florylpicoxamid and pyraclostrobin. Therefore, the risk is acceptable when Zetigo PRM Fungicide is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

Ninety five trials submitted to support the value of new disease claims on wheat, barley, pulse crops, and canola on the Zetigo PRM Fungicide label were reviewed. The value information demonstrated commercially acceptable levels of efficacy against economically important fungal diseases on the subject crops when the product was applied according to the use directions. Zetigo PRM Fungicide combines two fungicides with distinct modes of action, which may contribute to disease resistance management. Registration of these disease claims will also provide growers with an additional co-formulated product option for use against labelled diseases.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the registration of Zetigo PRM Fungicide.

References

PMRA Document Number	Reference
3447203	2023, Efficacy and Safety Studies, GF-3840, GF-4017, DACO: 10.1,10.2.1,10.2.2,10.3.1,10.4,10.5,10.5.1,10.5.2,10.5.3,10.5.4,10.5.5
3447204	2023, Table Efficacy and Safety of GF-3840 and GF-4017_Nov2020, DACO: 10.2.3.1,10.3.1
3447205	2023, Table Efficacy and Safety of GF-3840 and Zetigo PRM_Feb2023, DACO: 10.2.3.1,10.3.1
3447206	2023, Table Efficacy and Safety of GF-3840 GF-4017_Canola, Lentil Suppl Nov2020, DACO: 10.2.3.1,10.3.1
3447207	2023, Agriculture Research Manager (ARM) Reports-canola -Appendix 3, DACO: 10.2.3.2,10.3.2
3447208	2023, Agriculture Research Manager (ARM) Reports-cereals -Appendix 1, DACO: 10.2.3.2,10.3.2
3447209	2023, Agriculture Research Manager (ARM) Reports-pulses -Appendix 2, DACO: 10.2.3.2,10.3.2
3259587	2021, 10.2.3.2, 10.3.2 Field Trials ARM Reports V2, DACO: 10.2.3.2,10.3.2
3113587	2020, Field Trials, ARM Reports, DACO: 10.2.3.2,10.3.2
3173582	2020, ARM reports suppl Canola & Lentils, DACO: 10.2.3.2,10.3.2
3173578	2020, Efficacy & Safety, GF-3840_GF-4017_Nov-2020-suppl, DACO: 10.1,10.2.1,10.2.2,10.4,10.5
3173579	2020, Efficacy & Safety of GF-3840_GF-4017 Canola & Lentils, supplement, DACO: 10.2.3.1,10.3.1
3113598	2020, Residues of XDE-659 in Barley and Process Fractions at Harvest Following Multiple Applications of GF-3840 - Northern Europe - 2018, DACO: 7.4.5
3113606	2019, Magnitude of Residues of XDE-659 in Barley Following Two Foliar Applications of GF-3840 in the USA and Canada - 2018, DACO: 7.4.1, 7.4.2