

Evaluation Report for Category B, Subcategory 3.12, 3.3 Application

Application Number: 2021-2476
Application: Changes to product label: new site, application number.
Product: ORONDIS GOLD Fungicide
Registration Number: 33508
Active ingredients (a.i.): Metalaxyl-M and S-isomer and oxathiapiprolin
PMRA Document Number (: 3389381

Purpose of Application

The purpose of this application was to add use of ORONDIS GOLD Fungicide on bulb vegetables and fruiting vegetables, to increase the number of applications per year to ginseng and to increase the spray volume when used on cucumber.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A toxicological assessment was not required for this application.

The addition of new crops (bulb vegetables and fruiting vegetables) and the increase in the number of applications per year to ginseng on the label of ORONDIS GOLD Fungicide represents an expansion of the use pattern for metalaxyl-M and S-isomer and oxathiapiprolin. However, an updated risk assessment for mixers, loaders and applicators was not required since the most recent risk assessment on file was conducted with input parameters applicable to the exposure scenarios. For cucumbers treated using handled application equipment, the increase in water volume is considered acceptable as the application solution will be more dilute, and thus will result in a reduction in exposure. No health risks of concern were identified provided that workers wear the appropriate personal protective equipment and follow all label directions.

An updated postapplication worker exposure quantitative risk assessment was conducted and no health risks of concern were identified provided that workers follow the restricted-entry interval of 12 hours and all label directions. Bystander exposure and risk are not of health concern since the potential for drift is expected to be minimal.

Residues Assessment:

Oxathiapiprolin

No new residue data for oxathiapiprolin in bulb vegetables, fruiting vegetables, or in ginseng were submitted or are required to support the use expansion of this active

ingredient on the ORONDIS GOLD Fungicide label. Previously reviewed residue data from field trials conducted in/on the crops noted above were reassessed for this application. In addition, a processing study in treated tomatoes was also reassessed to determine the potential for concentration of residues of oxathiapiprolin into processed commodities.

Based on this assessment, the use expansion will be covered by the established MRLs for oxathiapiprolin. Consequently, dietary exposure to residues of oxathiapiprolin is not expected to increase and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Metalaxyl-M and S-Isomer

No new residue data for metalaxyl in bulb vegetables, fruiting vegetables, or in ginseng were submitted or are required to support the use expansion of this active on the ORONDIS GOLD Fungicide label. Previously reviewed residue data from field trials conducted in/on the crops noted above were reassessed in the framework of this application. In addition, a processing study in treated tomatoes was also reassessed to determine the potential for concentration of residues of metalaxyl into processed commodities.

Maximum Residue Limits

The recommendation for proposed maximum residue limits (MRLs) for metalaxyl was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of metalaxyl including metabolites that can be converted to the 2,6-dimethylaniline in/on crops and processed commodities are proposed 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).

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAF T	HAF T			
Green onions	Soil + foliar application/ 2.24 + 0.67 = 2.91	7	0.73	3.84	Not applicable	10 (Green onion)	10 (Green onion, crop subgroup 3-07B)
Bulb onions	Soil + foliar application/ 2.24 + 1.12 = 3.36	7	0.06	1.74		3.0 (Bulb onion)	3.0 (Bulb onion, crop subgroup 3-07A)

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

Following the review of all available data, the MRLs in Table 1 are recommended to cover

residues of metalaxyl. Dietary risks from exposure to residues of metalaxyl 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 addition of new crops (bulb vegetables and fruiting vegetables), the increase in the number of applications per year to ginseng, and the increase of the minimum spray volume on cucumbers to the label of ORONDIS GOLD Fungicide does not pose an increase risk to the environment. The product label contains adequate directions for use and environmental precautions.

Value Assessment

Value information was submitted in the form of efficacy data and rationales. Data from four field studies demonstrated that ORONDIS GOLD Fungicide can be expected to control downy mildew on bulb vegetable crops when applied prior to disease onset at 1.0 L/ha up to three times per year. The combination of data from one field trial conducted on bell pepper and rationales based on precedent registrations demonstrated that ORONDIS GOLD Fungicide applied to soil at 2.0 L/ha, with the first of a maximum of three applications per year made at planting can be expected to control pythium damping-off in fruiting vegetable crops as well as phytophthora blight and crown rot on tomato, pepper (bell and non-bell) and eggplant.

ORONDIS GOLD Fungicide is already registered for application to cucumber to control pythium damping-off and phytophthora root and crown rot and to ginseng once per season to control pythium damping-off and phytophthora root rot. Rationales support application of ORONDIS GOLD Fungicide by drench up to three times per year in ginseng to control phytophthora root rot. An increase in water volume from 200 to 400 L/ha used to apply ORONDIS GOLD Fungicide to cucumber would not be expected to negatively impact efficacy.

The availability of ORONDIS GOLD Fungicide will provide growers of fruiting vegetable crops and bulb vegetable crops with an additional product to manage economically important diseases. The option to apply ORONDIS GOLD Fungicide to ginseng multiple times per year will help maintain control of phytophthora root rot, which if not adequately managed, can result in severe economic losses to growers.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to amend the registration of ORONDIS GOLD Fungicide to use on bulb vegetables and fruiting vegetables, to increase the number of applications per year to ginseng and to increase the spray volume when used on cucumber.

References

PMRA**Document****Number****Reference**

- 3236051 2021, Efficacy and Crop Response for Control of *Peronospora destructor* in Bulb Vegetables, Efficacy and Crop Response for *Phytophthora capsici* and *Pythium* spp. in Fruiting Vegetables, Rationale for Adjusted Water Volume for control of *Phytophthora capsici* and *Pythium* spp. in Cucumbers, and Rationale for Additional Applications in Ginseng for Control of *Phytophthora cactorum* with Orondis Gold Fungicide., DACO: 10.1
- 3236053 2020, Evaluate foliar application of Orondis Gold for control of downy mildew in onion, DACO: 10.2.3.3
- 3236054 2020, Evaluate foliar application of Orondis Gold for control of downy mildew in onion, DACO: 10.2.3.3
- 3236055 2015, Evaluate oxathiapiprolin for control of *P. capsici* in bell pepper (resistant variety), DACO: 10.2.3.3
- 3236056 2015, Biological activity of A21069A against onion downy mildew, DACO: 10.2.3.3
- 3236057 2019, Profiling & registration of EXF16939C / EXF16956C in onion in EAME 2019, DACO: 10.2.3.3

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