

Evaluation Report for Category B, Subcategories 2.3, 2.4 Application

Application Number: 2023-1113
Application: New End-use Product (Product Chemistry)-Proportion and Identity of Formulants
Product: Orondis Gold DC Fungicide
Registration Number: 35176
Active ingredients (a.i.): Metalaxyl-M and S-isomer, and Oxathiapiprolin
PMRA Document Number: 3581615

Purpose of Application

The purpose of this application was to register a new end-use product, Orondis Gold DC Fungicide.

Chemistry Assessment

Orondis Gold DC Fungicide is formulated as an emulsifiable concentrate containing metalaxyl-M and S-isomer at a concentration of 105 g/L and oxathiapiprolin at a concentration of 35 g/L. This end-use product has a density of 1.038 g/mL and a pH of 5.3. The required chemistry data for Orondis Gold DC Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

Orondis Gold DC Fungicide is of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is moderately irritating to the eyes and slightly irritating to the skin. It is not a skin sensitizer.

The use of Orondis Gold DC Fungicide on potatoes, ginseng, cucumbers, crop group 8-09 (fruiting vegetables), bulb vegetables, crop subgroup 13-07A (caneberries), crop subgroup 13-07B (bushberries, except lowbush blueberries), tree nuts and low growing berries is not expected to result in potential occupational or bystander exposure over the registered uses of oxathiapiprolin and metalaxyl-M and S-isomer. No risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

No new residue data for metalaxyl-M and S-isomer or oxathiapiprolin in potatoes, ginseng, cucumbers, Crop Group 8-09: Fruiting Vegetables, Crop Group 3-07: Bulb Vegetables (selected), Crop Subgroup 13-07A: Caneberries, Crop Subgroup 13-07B: Bushberries (except lowbush blueberry), Crop Group 14-11: Tree Nuts (selected), and Crop Subgroup 13-07G: Low growing berries (except lingonberry and cranberry) were submitted or were required to support the registration of Orondis Gold DC Fungicide. Previously reviewed residue data were re-assessed in the framework of this application.

Based on this assessment, residues are not expected to be greater than those from the currently registered uses and will be covered by the established maximum residue limits (MRLs). Consequently, dietary exposure to residues of metalaxyl-M and S-isomer and oxathiapiprolin is not expected to increase with the registration of Orondis Gold DC Fungicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

After a scientific review of the available information, it has been concluded that the environmental risks associated with the use of Orondis Gold DC Fungicide are acceptable when used according to the label directions.

Value Assessment

Efficacy data and scientific rationales were submitted to support the value of disease claims for potato, ginseng, cucumber, fruiting vegetables, bulb vegetables, caneberries, bushberries, tree nuts, and low growing berries on the Orondis Gold DC Fungicide label. The value information demonstrated that acceptable levels of efficacy can be expected against economically important fungal diseases on the subject crops when the product is applied according to the use directions. Orondis Gold DC Fungicide combines two fungicides with distinct modes of action, which is expected to contribute to disease resistance management. Registration of these disease claims will also provide growers with an additional 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 Orondis Gold DC Fungicide.

References

PMRA Document Number	Reference
3447069	2023, DACO 10 VALUE SUMMARY: Efficacy and Crop Response for Control of Pythium and Phytophthora in Potatoes, Ginseng, Cucumbers, Fruiting Vegetables; Downey Mildew in Bulb Vegetables; Phytophthora Root Rot in Caneberry, Bushberry and Tree nuts; Phytophthora Root and Crown Rot and Red Stele Root Rot in Strawberries with ORONDIS GOLD DC FUNGICIDE., DACO: 10.1
3447070	2023, Efficacy Summary for Orondis Gold DC NYR for Control of Pythium and Phytophthora in Potatoes, Ginseng, Cucumbers, Fruiting Vegetables; Downey Mildew in Bulb Vegetables; Phytophthora Root Rot in Caneberry, Bushberry and Tree nuts; Phytophthora Root and Crown Rot and Red Stele Root Rot in Strawberries, DACO: 10.2.3.1
3447071	2022, Evaluate crop tolerance of A22556 [C] and ProPhyt applied in ginseng, DACO: 10.2.3.3
3447072	2022, Evaluate A22556 [C] for the control of Downey mildew in onions, DACO: 10.2.3.3
3447073	2022, Evaluate new formulations of ORONDIS GOLD for the control of phytophthora in highbush blueberries, DACO: 10.2.3.3
3447074	2022, Evaluate OXTP+MFX for Phytophthora or Pythium control in potato, DACO: 10.2.3.3
3447075	2022, Evaluate OXTP+MFX for phytotoxicity in fruiting veg, DACO: 10.2.3.3
3447076	2022, Evaluate OXTP+MFX for phytotoxicity in cucurbits, DACO: 10.2.3.3
3447077	2022, Fungicide - Development Support - 2022 US, DACO: 10.2.3.3
3447078	2022, Evaluate OXTP+MFX for Phytophthora or Pythium control in potato, DACO: 10.2.3.3
3447079	2022, Evaluate OXTP+MFX for phytotoxicity in fruiting veg, DACO: 10.2.3.3
3447080	2022, A23980B - Manufacturing Process Description and Supporting Data, DACO: 3.1,3.2,3.4 CBI
3447081	2022, A22556C - Physical and Chemical Properties, DACO: 3.5 CBI
3447082	2022, Metalaxyl-M/Oxathiapiprolin DC (A22556C) Acute Oral Toxicity - Up-And-Down Procedure in Rats, DACO: 4.6.1
3447083	2022, Metalaxyl-M/Oxathiapiprolin DC (A22556C) - Acute Dermal Toxicity Waiver, DACO: 4.6.2
3447084	2022, Metalaxyl-M/Oxathiapiprolin (A22556C) - Acute Inhalation Toxicity in Rats, DACO: 4.6.3
3447085	2022, Metalaxyl-M/Oxathiapiprolin DC (A22556C) - Primary Eye Irritation in Rabbits, DACO: 4.6.4
3447086	2022, Metalaxyl-M/Oxathiapiprolin DC (A22556C) - In Vitro Eye Irritation Test in Isolated Chicken Eyes, DACO: 4.6.4

3447087	2022, Metalaxyl-M/Oxathiapiprolin DC (A22556C) - Primary Skin Irritation in Rabbits, DACO: 4.6.5
3447088	2022, Metalaxyl-M/Oxathiapiprolin DC (A22556C) - In Vitro Skin Irritation Test in the EPISKIN™ Model, DACO: 4.6.5
3447089	2022, Metalaxyl-M/Oxathiapiprolin DC (A22556C) - Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6

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