Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2024-2445
Application: New Manufacturing Concentrate (Product Chemistry) - New combination of Technical Grade Active Ingredients
Applicant: Bayer CropScience Inc.
Product: EverGol Rise MUP Seed Treatment Fungicide
Registration Number: 35642
Active ingredients (a.i.): Metalaxyl, Penflufen, Prothioconazole, Trifloxystrobin
PMRA Document Number : 3739492

Purpose of Application

The purpose of this application was to register a new manufacturing concentrate product, EverGol Rise MUP Seed Treatment Fungicide.

Chemistry Assessment

EverGol Rise MUP Seed Treatment Fungicide is formulated as a suspension (SU) containing metalaxyl at 50 g/L, penflufen at 50 g/L, prothioconazole at 50 g/L and trifloxystrobin at 50 g/L. This manufacturing concentrate has a density of 1.14 - 1.18 g/cm^3 and pH of 5.5 - 7.0. The required chemistry data for EverGol Rise Seed MUP Treatment Fungicide have been provided, reviewed and found to be acceptable.

Health Assessments

EverGol Rise MUP Seed Treatment Fungicide is of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is non-irritating to the eye and non-irritating to the skin, and is not a skin sensitizer.

Occupational and dietary exposure assessments were not required for this application.

Environmental and Value Assessments

Environmental and value assessments were not required for this application.

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 EverGol Rise MUP Seed Treatment Fungicide.

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References

PMRA Document Number	Reference
3586876	2024, Metalaxyl + Penflufen + Prothioconazole + Trifloxystrobin FS 200 (50+50+50+50 g/L): Acute Oral Toxicity - Up-And-Down Procedure in Rats, DACO: 4.6.1
3586877	2024, Waiver for an Acute Dermal Toxicity Study on the Mixture Formulation Metalaxyl + Penflufen + Prothioconazole + Trifloxystrobin FS 200, DACO: 4.6.2
3586878	2024, Metalaxyl + Penflufen + Prothioconazole + Trifloxystrobin FS 200 (50+50+50+50 g/L): Acute Inhalation Toxicity in Rats, DACO: 4.6.3
3586879	2024, Metalaxyl + Penflufen + Prothioconazole + Trifloxystrobin FS 200 (50+50+50+50 g/L): Primary Eye Irritation in Rabbits, DACO: 4.6.4
3586880	2024, Metalaxyl + Penflufen + Prothioconazole + Trifloxystrobin FS 200 (50+50+50+50 g/L): Primary Skin Irritation in Rabbits, DACO: 4.6.5
3586881	2024, Metalaxyl + Penflufen + Prothioconazole + Trifloxystrobin FS 200 (50+50+50+50 g/L): Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6
3586871	2024, Product Chemistry Data to Support the Registration of Trilex EverGol RTU Seed Treatment Product (Product Identity and Composition), DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1 CBI
3586872	2024, EverGol Rise: Quantities of raw materials (formulants) used in the formulating process, DACO: 3.2.2 CBI
3586873	2024, Validation of the analytical method [CBI Removed] for the determination of metalaxyl, penflufen, prothioconazole, and trifloxystrobin in MTL+PFL+PTZ+TFS FS 200, specification 102000060925, DACO: 3.4.1 CBI
3586874	2024, Validation of the analytical method [CBI Removed] for the determination of [CBI Removed] in MTL+PFL+PTZ+TFS FS 200, specification 102000060925, DACO: 3.4.1 CBI
3586875	2024, Determination of physical chemical properties and accelerated storage stability study on MTL+PFL+PTZ+TFS FS 200 (specification number 102000060925), DACO: 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI
3627704	2023, Determination of metalaxyl, penflufen, prothioconazole and trifloxystrobin in formulation - HPLC, DACO: 3.4.1 CBI
3627705	2023, Determination of [CBI Removed] in formulation - HPLC/MS/MS, DACO: 3.4.1 CBI