Health Canada Santé Canada

Evaluation Report for Category B, Subcategories 2.6 and 3.10 Application

Application Number: 2022-2925
Application: New End-use Product (Product Chemistry) – New Combination of Technical Grade Active Ingredients; New Product Label – Tank Mixes
Product: Raxil Rise
Registration Number: 35475
Active ingredients (a.i.): Metalaxyl, Penflufen, Prothioconazole and Tebuconazole
PMRA Document Number: 3699003

Purpose of Application

The purpose of this application was to register the end-use product, Raxil Rise, for use as a seed treatment fungicide for seed and seedling protection against certain seed-borne and soil-borne diseases on labeled crops.

Chemistry Assessment

Raxil Rise is formulated as a suspension containing metalaxyl at 6.2 g/L, penflufen at 15.4 g/L, prothioconazole at 15.4 g/L, and tebuconazole at 3.0 g/L. This end-use product has a density of 1.03–1.07 g/mL and pH of 6.8–7.8. The required chemistry data for Raxil Rise have been provided, reviewed and found to be acceptable.

Health Assessments

Raxil Rise is of low acute toxicity via the oral, dermal and inhalation routes of exposure. It is minimally irritating to the eye and skin, and is not a dermal sensitizer.

The use of Raxil Rise as a seed treatment on barley, oats, wheat, rye and triticale is not expected to result in potential occupational or bystander exposure over the registered uses of tebuconazole, prothioconazole, metalaxyl or penflufen. No health 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, penflufen, prothioconazole, or tebuconazole in barley, oats, rye, triticale, or wheat were submitted or were required to support the registration of Raxil Rise. Previously reviewed residue data from field trials conducted in/on barley, wheat, corn, and oats were reassessed in the framework of this application. In addition, processing studies in treated wheat were reassessed to determine the potential for concentration of residues of these four active ingredients into processed commodities.

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The established maximum residue limits (MRLs) for metalaxyl, penflufen, prothioconazole, and tebuconazole will cover the use of Raxil Rise, and the dietary exposure for the general population and all subpopulations, including infants, children, adults and seniors is acceptable.

Environmental Assessment

The use of Raxil Rise for seed and seedling protection against certain seed-borne and soil-borne diseases on cereal crops (barley, wheat, oats, rye and triticale) is within the currently registered use pattern for tebuconazole, prothioconazole, penflufen and metalaxyl. Therefore, the environmental risk is acceptable when Raxil Rise is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

A total of 11 trials conducted in Canada (Alberta, Manitoba, and Saskatchewan) and the United States (Missouri and Montana) between 2017 and 2021 were reviewed to support two claims. The results demonstrated acceptable efficacy against true loose smut on barley and seed and seedling diseases caused by *Rhizoctonia solani* on wheat, barley, oats, rye, and triticale. Support for the value of the remaining disease claims was extrapolated from precedent product labels.

Seed treatments provide early season control of seed- and soil-borne pathogens at relatively low application rates. When used in a disease management plan, seed treatments can reduce the need for foliar fungicide applications later in the growing season.

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 Raxil Rise.

References

PMRA Document Number	Reference
3367227	2022, Validation of the Analytical Method for the Determination of Metalaxyl, Tebuconazole, Prothioconazole, and Penflufen in MTL+PFL+PTZ+TBZ FS 40.03, Specification 102000058205, DACO: 3.4.1 CBI
3367229	2022, Accelerated Aging and Package Stability of Metalaxyl, Tebuconazole, Prothioconazole, and Penflufen in MTL+PFL+PTZ+TBZ FS 40.03, Specification 102000058205, DACO: 3.5.10,3.5.14,3.5.5 CBI
3367230	2022, Product Chemistry Study on MTL+PFL+PTZ+TBZ FS 40.03, Specification 102000058205, DACO: 3.5.1,3.5.11,3.5.12,3.5.13,3.5.15,3.5.2,3.5.3,3.5.6, 3.5.7,3.5.8,3.5.9 CBI
3367231	2022, Product Chemistry Data to Support the Registration of Raxil EverGol Fungicide Seed Treatment product (Product Identity and Composition), DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI
3367232	2022, Raxil EverGol: Quantities of raw materials (formulants) used in the formulating process, DACO: 3.2.2 CBI
3367233	2022, Metalaxyl + Penflufen + Prothioconazole + Tebuconazole FS 40.03 (6.19+3.04+15.4+15.4 g/L): Acute Oral Toxicity – Up-And-Down Procedure in Rats, DACO: 4.6.1
3367234	2022, Waiver for an Acute Dermal Toxicity Study on Metalaxyl + Penflufen + Prothioconazole + Tebuconazole FS 40.03 (6.19+3.04+15.4+15.4 g/L), DACO: 4.6.2
3367235	2022, Metalaxyl + Penflufen + Prothioconazole + Tebuconazole FS 40.03 (6.19+3.04+15.4+15.4 g/L): Acute Inhalation Toxicity in Rats, DACO: 4.6.3
3367236	2022, Metalaxyl + Penflufen + Prothioconazole + Tebuconazole FS 40.03 (6.19+3.04+15.4+15.4 g/L): Primary Eye Irritation in Rabbits, DACO: 4.6.4
3367237	2022, Metalaxyl + Penflufen + Prothioconazole + Tebuconazole FS 40.03 (6.19+3.04+15.4 +15.4 g/L): Primary skin irritation in rabbits, DACO: 4.6.5
3367238	2022, MTL+PFL+PTZ+TBZ FS 40.03: Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6
3367241	2022, Value Assessment of Raxil EverGol Seed Treatment Fungicide for Protection Against Certain Seed-Borne and Soil-Borne Diseases on Labeled Cereal Crops, DACO: 10.1,10.2,10.2.1,10.2.2,10.2.3,10.2.3.1,10.2.3.3(D),10.3, 10.3.1,10.3.2,10.3.3,10.4,10.5,10.5.2,10.5.3,10.5.4
3367242	2022, Trial Report Compilation Raxil EverGol, DACO: 10.2.3.3(D)
3678088	2025, Summary-clarification response, DACO: 10.2.3.1