

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2017-3102
Application: B.3.12: New Site or Host
Product: Raxil Pro
Registration Number: 30102
Active ingredients (a.i.): Tebuconazole, Prothioconazole, Metalaxyl
PMRA Document Number : 2870273

Purpose of Application

The purpose of this application was to add the seed treatment of rye and triticale to the Raxil Pro label.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

The use directions for Raxil Pro were compared to precedent end-use products containing prothioconazole and precedent end-use products containing prothioconazole and metalaxyl.

The application rates for prothioconazole on rye and triticale are within the currently registered rates. As such, exposure to residues of prothioconazole in/on treated rye and triticale should not increase as a result of the use application and will be covered under the maximum residue limit (MRL) currently established at 0.35 ppm for residues of prothioconazole in/on rye and triticale.

The application rates for metalaxyl on rye and triticale are lower compared to the rates currently registered. As such, exposure to residues of metalaxyl in/on treated rye and triticale should not increase as a result of this action and will be covered under the MRL currently established at 0.05 ppm for residues of metalaxyl in/on rye and triticale.

Tebuconazole is currently registered for foliar use on rye and triticale and MRLs for tebuconazole are established at 0.15 ppm in/on rye and triticale. Given that exposure to residues of tebuconazole in/on treated rye and triticale from the seed treatment use are expected to be less compared to the currently registered foliar use and that tebuconazole is currently registered for seed treatment use on wheat, barley, oats and corn, residues of tebuconazole in/on treated rye and triticale as a result of this seed treatment will be covered under the MRLs for tebuconazole in/on rye and triticale.

Based on this assessment, residues of prothioconazole, metalaxyl and tebuconazole in rye and triticale commodities will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

The risk assessments on file for the use pattern of prothioconazole and metalaxyl were used to assess the use of prothioconazole and metalaxyl as a seed treatment on rye and triticale. These risk assessments indicated no health risks of concern are expected from the use of these actives as a seed treatment on rye and triticale when workers follow the label directions and wear the personal protective equipment identified on the label.

The occupational exposure and risk from the addition of rye and triticale seed treatment to the Raxil Pro label is an expansion of use for tebuconazole. A risk assessment was performed for commercial treaters, on-farmer treaters and planters that may be exposed to tebuconazole and acceptable margins of exposure were calculated. Hence, the use on rye and triticale as a seed treatment should not result in health risks of concern for tebuconazole when workers follow the label directions and wear the personal protective equipment identified on the label.

Environmental Assessment

The use of Raxil Pro on rye and triticale do not result in changes in environmental concerns and the existing label statements are adequate for risk mitigation.

Value Assessment

Scientific rationales were submitted to extrapolate claims from currently registered crops on the Raxil Pro label from other precedent products. The submitted value information was sufficient to support these claims. Raxil Pro offers growers another fungicide choice for use in rye and triticale. Although rye and triticale are minor crops, the availability of Raxil Pro will benefit commercial seed plants and seed sellers that sell wheat, barley, oat and rye or triticale and growers who cultivate both wheat, barley, oat and rye or triticale.

Conclusion

The PMRA has reviewed information to support this application to add the seed treatment of rye and triticale to the Raxil Pro label. Based on the results of this review, the addition of the seed treatment of rye and triticale to the Raxil Pro label is acceptable for registration.

References

- 2776525 2017, Value assessment of Raxil Pro Fungicide - Label expansion to include seed and seedling diseases of rye & triticale, DACO: 10.1,10.2.3.3,10.3.2,10.4,10.5

1335563	2006, Gaucho 480 SC - Worker Exposure During On-farm and Commercial Seed Treatment of Cereals, DACO: 5.4,5.6(A)
2224496	2012, Laboratory dust-off study of millet, rye, triticale, and wheat seeds treated with JAU6476 100FS and EverGol Energy seed treatment formulations, DACO: 5.15

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