

Evaluation Report for Category B, Subcategory 2.6, 3.4, 3.12 Application

Application Number: 2007-8785
Application: New end-use product chemistry, new host of barley, and aerial application use for prothioconazole
Product: Prosaro 250 EC Fungicide
Registration Number: 29821
Active ingredients (a.i.): Prothioconazole & Tebuconazole
PMRA Document Number : 1930367

Purpose of Application

The purpose of this application was to register a new commercial end-use product, Prosaro 250 EC Fungicide, containing a new combination of active ingredients, tebuconazole (100 g a.i./ha) and prothioconazole (100 g a.i./ha). This product is proposed for use on Use Site Category 13 and 14 (Terrestrial Feed and Food Crops) to control or suppress various foliar diseases on wheat and barley.

Chemistry Assessment

Prosaro 250 EC Fungicide is a liquid emulsifiable concentrate containing the active ingredients tebuconazole and prothioconazole at a nominal concentration of 125 g/L each. This product has a density of 0.98 g/mL and pH of 7.8 for a 10 % solution in water. The chemistry requirements for this product have been completed.

Health Assessments

Prosaro 250 EC Fungicide is of low acute toxicity by the oral route ($LC_{50} > 2,000$ mg/kg bw/day), by the dermal route ($LC_{50} > 4,000$ mg/kg bw/day) and by the inhalation route ($LC_{50} \geq 5.153$ mg/L) in rats. It is a mild dermal irritant (MAS = 2/8) and is moderately irritating, persistent, to the eyes (MAS = 31.8/110) of rabbits. Prosaro 250 EC Fungicide is not a dermal sensitizer in guinea pigs.

No occupational exposure risks of concern were identified for the new end-use product Prosaro 250EC Fungicide, containing the active ingredients, tebuconazole and prothioconazole. No unacceptable risk is expected when workers follow the label directions and wear the personal protective equipment identified on the label.

No new residue data were submitted to support the registration of Prosaro 250 EC Fungicide, containing the registered active ingredients tebuconazole and prothioconazole. Data on file support the use of tebuconazole and prothioconazole on wheat and barley. The use of Prosaro 250 EC Fungicide will not result in residues of tebuconazole or prothioconazole exceeding the established or recommended MRLs in these commodities. Therefore, dietary exposure to these active ingredients is not expected to increase, and no unacceptable risk is anticipated to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The proposed rates for the use of Prosaro 250 EC Fungicide on wheat and barley were less than currently registered. The PMRA does not anticipate that the registration of this new end-use product will result in an unacceptable risk to non-target terrestrial or aquatic organisms.

Value Assessment

Twenty trials were submitted to support the disease claims. Efficacy data demonstrated suppression of Fusarium head blight on wheat and barley and control of the tested foliar diseases. No data were submitted to support the claims for control of stem and stripe rusts and powdery mildew on wheat and for control of scald, leaf, stem and stripe rusts, speckled leaf blotch and powdery mildew on barley. The claims on wheat and the claim for control of scald on barley are currently registered on one or both of the labels of the component products, so these claims are also supported. The claims for control of leaf, stem and stripe rusts, speckled leaf blotch and powdery mildew on barley were reviewed and supported under application number 2007-8779 for Folicur 432 F Foliar Fungicide and are, therefore, supported on the label of Prosaro 250 EC Fungicide. A claim for aerial application is supported based on the fact that both component products are currently registered for aerial uses, including application to wheat (Folicur 432 F Foliar Fungicide). The proposed product contains two Group 3 fungicides. Although Prosaro 250 EC Fungicide contains two active ingredients that both belong to the same fungicide class, there is value in using the product since only a single application is needed to control the listed diseases. Using either of the component products alone will require either 1-2 applications at different application timing depending on the disease being controlled/suppressed.

Conclusion

The PMRA has completed an assessment of available information for Prosaro 250 EC Fungicide and has found the information sufficient to support the registration.

References

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