

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.6, 3.4, 3.12 Application

Application Number: 2007-8770
Application: New end-use product with guarantee, Identity/Proportion of formulants, new combination of technical grade active ingredients, new site or host (barley for tebuconazole), and application method.
Product: Prosaro 421 SC Foliar Fungicide
Registration Number: 29819
Active ingredients (a.i.): Prothioconazole & Tebuconazole
PMRA Document Number : 1930378

Purpose of Application

The purpose of this application was to register a new commercial end-use product, Prosaro 421 SC Foliar Fungicide, containing a new combination of actives, tebuconazole (100 g a.i./ha) and prothioconazole (100 g a.i./ha). This product was proposed for use on Use Site Category 13 and 14 (Terrestrial Feed and Food Crops) for suppression of Fusarium Head Blight and control of leaf diseases in wheat and barley by ground or aerial application.

Chemistry Assessment

Prosaro 421 SC Foliar Fungicide is a liquid suspension concentrate containing the active ingredients tebuconazole at 210.5 g/L nominal, prothioconazole at 210.5 g/L nominal and the preservative 1,2-benzisothiazolin-3-one (at 0.048 %). This product has a density of 1.112 g/mL and pH of 7.8 for a 10 % solution in water. The chemistry requirements for Prosaro 421 SC Foliar Fungicide have been completed.

Health Assessments

Prosaro 421 SC Foliar Fungicide is of low acute toxicity by the oral route ($LD_{50} > 2000$ mg/kg bw/day), of low acute toxicity by the inhalation route ($LC_{50} > 2.18$ mg/L air) and of low acute toxicity by the dermal route ($LD_{50} > 5050$ mg/kg bw/day) in rats. Prosaro 421 SC Foliar Fungicide is minimally irritating to the eyes (MAS = 0/110) and not irritating to the skin (MAS = 0.0/8) of rabbits. It is not a dermal sensitizer in guinea pigs.

No occupational exposure risks of concern were identified for the new end-use product, Prosaro 421 SC Foliar 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 421 SC Foliar 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 421 SC Foliar 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 421 SC Foliar 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

Fifty-three trials were reviewed 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 scald, leaf and stem rusts, and powdery mildew and a single trial was submitted to support the claim of control of speckled leaf blotch on barley. The claim for control of scald on barley is currently registered on the Proline 480 SC label, so this claim is also supported. The claims for control of leaf and stem rusts, speckled 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 421 SC Foliar 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 421 SC Foliar Fungicide contains two active ingredients that both belong to the same fungicide class (Group 3), 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 421 SC Foliar Fungicide and has found the information sufficient to support the registration.

References

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