

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2009-0470
Application: B.3.12-Changes to Product Labels-New Site
Product: Scala SC Fungicide
Registration Number: 28011
Active ingredients (a.i.): Pyrimethanil (PYI)
PMRA Document Number English PDF: 2008987

Purpose of Application

The purpose of this application was to expand the region of use for the late season application on apples for Scala SC Fungicide from a local registration in Ontario and Québec to a national registration.

Chemistry Assessments

A chemistry assessment was not required for this application.

Health Assessments

A toxicological assessment was not required for this application.

The proposed expansion of region for the product Scala SC Fungicide, will not increase the occupational exposure of the active ingredient, pyrimethanil. 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 for pyrimethanil were submitted to support the expansion of region from a provincial registration in Ontario and Québec to a national registration for the late season application on apples of Scala SC Fungicide. Previously reviewed residue data from apple field trials with early and late season applications were used to support the use expansion. Based on the review of submitted data, changes in the existing Maximum Residue Limits are not required, and the changes in dietary exposure to pyrimethanil residues are not expected. Dietary exposure from the supported pyrimethanil uses do not pose an unacceptable risk to human health.

Environmental Assessment

The use of Scala SC Fungicide on apples is considered acceptable from an environmental perspective for all apple growing regions of Canada. Aquatic runoff and drift scenarios were conducted based on application rate, frequency of application, environmental degradation, and

relevant environmental endpoints. Buffer zones based on drift modelling were determined, and environmentally-related label statements have been updated to reflect the environmental risk assessment. No further environmental review is required based on the conditions of the currently registered use pattern of Scala SC Fungicide. Further environmental data and review may be required if the current use pattern is expanded or changed.

Value Assessment

No efficacy trials were submitted to support this application. However, a total of five trials conducted between 1999 and 2003 were submitted under other applications to evaluate the activity of Scala SC Fungicide on blue mould (*Penicillium expansum*) and gray mould (*Botrytis cinerea*) on apples in storage. Four trials were conducted in British Columbia and one trial was conducted in Ontario. Data demonstrated that use of Scala SC Fungicide provided control of gray mould and suppression of blue mould.

Both pathogens occur and cause apple storage diseases in apple-producing regions throughout Canada. The efficacy of the product is not expected to differ among various regions in Canada. The Pest Management Regulatory Agency supports the claim to expand the local registration for control/suppression of apple storage diseases (gray mould and blue mould) in Ontario and Quebec to a national registration on the Scala SC Fungicide label without further requirement of efficacy data.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support for the product Scala SC Fungicide, and has found the information sufficient to support the expansion of region for use on apples.

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