Evaluation Report for Category B, Subcategory B.4.1 Application

Application Number: 2007-1409
Application: B.4.1 (Conversion to full registration without consultation)
Product: Scala SC Fungicide
Registration Number: 28011
Active ingredients (a.i.): Pyrimethanil (PYI)
PMRA Document Number English PDF: 1590451

Purpose of Application

The purpose of the application is to convert the product registration from conditional to full. Scala SC Fungicide, containing the active ingredient Pyrimethanil, was granted conditional registration in 2005. Additional information related to the toxicological profile of an environmental metabolite and efficacy data were required for conversion to full registration.

Chemistry Assessment

A chemistry assessment was not required for this application. For the full assessment of the chemistry please refer to REG2006-04, Pyrimethanil.

Health Assessments

A health assessment was not required for this application. For the full health assessment please refer to REG2006-04, Pyrimethanil.

Environmental Assessment

The applicant submitted two sediment toxicity studies and a request for waiver from conducting a study to determine the log K_{ow} value for the major transformation product. Submitted information was reviewed and considered acceptable. No further information is required at this time.

An updated aquatic risk assessment was conducted for pyrimethanil and Scala SC Fungicide. At the screening level, potential risk to fish and amphibians through the use of pyrimethanil was indicated. Therefore, a refined assessment was conducted to characterize the risk to aquatic organisms from runoff and spray drift. Negligible risk to aquatic organisms is expected from runoff. Risk from spray drift was identified to freshwater fish and amphibians; to mitigate this risk, new aquatic buffer zone distances were determined.

Value Assessment

Three efficacy requirements were necessary for full registration to be considered, including additional data on gray mold on strawberry, bunch rot on grape and early blight on potato. Ten studies over 2 years from Ontario, Manitoba and Alberta were submitted. The data confirmed the registered rates and application directions for these uses. From an efficacy perspective the conditions for full registration have been met.

Conclusion

The registrant has adequately addressed the requirements for conversion to full registration. Therefore, the PMRA can support this application. However, due do to conditions on the active ingredient, Pyrimethanil Technical Fungicide, Scala SC Fungicide will remain conditional.

References

PMRA 1379041	1998, Pyrimethanil Substance Technical 99% w/w Code: AE B100309 00 1D99 00. Pyrimethanil: effects on sediment dwelling *Chironomus riparius* in a water sediment system, ENVIR/39AN
PMRA 1379042	2006, Pyrimethanil - toxicity to Midge (*Chironomus tetans*) During a 10-day Sediment Exposure, 13798.6180
PMRA 1580066	DACO: 9.9 Chironomid template.
PMRA 1379040	2005, Waiver Request for the Pow study Required by the PMRA-Canada for 2-Amino-4,6-Dimethylpyrimidine
PMRA 1379062	2007, Scala 400 SC Fungicide for control of Botrytis Gray Mould in Strawberries, Botrytis Bunch Rot in Grapes, and Early Blight in Potatoes. 94 pp.

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