

Evaluation Report for Category B, Subcategory B.4.1 Application

Application Number: 2007-1408
Application: B.4.1 (Conversion to full registration without consultation)
Product: Pyrimethanil Technical Fungicide
Registration Number: 28010
Active ingredients (a.i.): Pyrimethanil (PYI)
PMRA Document Number English PDF: 1570770

Purpose of Application

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

Chemistry Assessment

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

Health Assessments

As a condition of registration, additional data on the toxicological properties of the environmental metabolite 2-amino-4,6-dimethylpyrimidine were requested. 2-amino-4,6-dimethylpyrimidine was determined to be of moderate acute oral toxicity in rats and non-genotoxic in bacteria. However, the premature culling of moribund animals in the acute oral study shortly after dosing prevented a better estimation of the actual LD₅₀. As a result, there was some indication that 2-amino-4,6-dimethylpyrimidine may be more toxic after acute oral dosing in rats than the parent pyrimethanil, which was classified as being of low acute toxicity. Based on the uncertainty surrounding the acute oral study, the increased sensitivity of rats compared to mice in the short-term studies for pyrimethanil, and the uncertainty of the toxicological effects of 2-amino-4,6-dimethylpyrimidine after acute and short-term exposure, additional toxicology data are requested. There were no outstanding toxicology data requirements for the end-use product, Scala SC Fungicide.

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

A value assessment was not required for this application.

Conclusion

The registrant has not adequately addressed the requirements for conversion to full registration. Therefore, additional data on the toxicological properties of the environmental metabolite are required. The PMRA can support continued conditional registration for this application.

References

- PMRA 1379039 2006, Summary of toxicity data for pyrimethanil metabolite 2-amino-4,6-dimethylpyrimidine, DACO: 4.1
- PMRA 1444437 1998, AE F132593 (soil metabolite of pyrimethanil), code: AE F132593 00 ID99 0001, Bacterial Reverse Mutation Assay, TOX 98081, DACO: 4.8
- PMRA 1444438 1998, AE F132593 (soil photolysis metabolite of pyrimethanil), Code: AE F132593 00 1D99 0001, Rat acute oral toxicity, TOX 98080, DACO: 4.8
- PMRA 1457582 2007, Response to July 3, 2007 Request from PMRA Regarding DACO 4.1, DACO: 4.1
- PMRA 1464265 DACO: 4.8
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- 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 tentans*) 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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