Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.1 Application

Application Number: 2008-1319
Application: Register a New Commercial End Use Product for use on Turf
Product: The Andersons 0.72% Prophesy On DGPro Fungicide
Registration Number: 29951
Active ingredients (a.i.): Propiconazole (PON)
PMRA Document Number : 2268357

Purpose of Application

The Andersons Lawn Fertilizer Division, Inc. has submitted an application to register a new commercial End Use Product (EP) for use on Turf.

Chemistry Assessment

The Andersons 0.72% Prophesy on DGPro Fungicide is formulated as granules containing propiconazole at a nominal concentration of 0.72%. This end-use product has a density between 705 and 804 kg/m^3. The chemistry requirements for The Andersons 0.72% Prophesy on DGPro Fungicide are complete.

Health Assessments

The acute toxicology of the new end use product is based primarily on that of the technical active product. The acute toxicity of the new end use product is considered slight via the inhalation (LC_{50} = 1.264 mg/L) route, and low via the oral and dermal routes in rats. It is considered mildly irritating to the eye and the skin of rabbits and is considered a potential skin sensitizer.

The use of the new end use product The Andersons 0.72% Prophesy on DGPRO Fungicide on turf should not result in an increase in potential exposure to mixer/loaders and applicators over the registered uses of propiconazole. A post application health risk assessment was conducted which identified no unacceptable risk to workers and bystanders if label directions are followed. No unacceptable risk is expected when workers follow label directions and wear personal protective equipment identified on the label.

Environmental Assessment

The risk to the environment was assessed for propiconazole in its granular form as Andersons 0.72% Prophesy on DGPro Fungicide, since birds and mammals could be exposed via oral ingestion of contaminated granules. It was determined that a low risk exists to birds and mammals. To further reduce the availability of the granule for ingestion, the

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label will include a mitigative statement which will ensure watering of the product after application.

Value Assessment

Eight trials conducted in the US between 2003 and 2005 were submitted for review: two trials on grey snow mould, two on fusarium patch, two on brown patch and two on dollar spot. In some of these trials, both The Andersons 0.72% Prophesy On DGPro Fungicide and Banner MAXX Fungicide (Registration Number 27003) were tested. The applicant proposes to use these trials as bridging trials to demonstrate equivalence between The Andersons 0.72% Prophesy On DGPro Fungicide and Banner MAXX Fungicide and to extrapolate the results to the rest of the use claims registered on the Banner MAXX Fungicide label.

One trial was reviewed for grey snow mould. The Andersons 0.72% Prophesy On DGPro Fungicide provided control under moderate disease pressure. Results were statistically comparable to a tank-mix of Banner MAXX Fungicide and Daconil 2787; however, biological equivalence could not be determined between The Andersons 0.72% Prophesy On DGPro Fungicide and Banner MAXX Fungicide.

One trial on fusarium patch showed that The Andersons 0.72% Prophesy On DGPro Fungicide reduced disease better than Banner MAXX Fungicide applied at a rate higher than registered, but the disease assessment was not significantly different from the untreated control.

Both trials on brown patch demonstrated an initial lag in the efficacy effects of The Andersons 0.72% Prophesy On DGPro Fungicide compared to Banner MAXX Fungicide, after which efficacy was statistically comparable between the two products .

Levels of control expressed by The Andersons 0.72% Prophesy On DGPro Fungicide in the dollar spot trials were statistically comparable to Banner MAXX Fungicide at all assessments under low to moderate disease pressure, even when Banner MAXX Fungicide was applied at a rate higher than registered. No lag in efficacy was observed as in the brown patch trials.

Since The Andersons 0.72% Prophesy On DGPro Fungicide is a granular formulation, it cannot be tank mixed with a liquid fungicide. Products containing PCNB and chlorothalonil that are registered for turf in Canada are all liquid or wettable powder formulations; therefore, tank mixing The Andersons 0.72% Prophesy On DGPro Fungicide with these active ingredients is not possible.

Overall, the weight of evidence does not support biological equivalence between The Andersons 0.72% Prophesy On DGPro Fungicide and Banner MAXX Fungicide; therefore, the uses registered on the Banner MAXX Fungicide label are not supported for registration on the The Andersons 0.72% Prophesy On DGPro Fungicide label. It should be noted, however, that the efficacy data submitted supports the claim of control of dollar spot and conditionally supports claims for control of brown patch and grey mould. Confirmatory trials are required for the claims on brown patch and grey mould. Additional data is required to demonstrate product equivalence between The Anderson's 0.72% Prophesy on DGPro Fungicide and Banner MAXX Fungicide.

Conclusion

The PMRA has completed an evaluation of the subject application and has found the information sufficient to register The Andersons 0.72% Prophesy On DGPro Fungicide for control of dollar spot, brown patch and grey mold on turf.

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