

Evaluation Report for Category B, Subcategory 2.3 and 2.4 Application

Application Number: 2010-1555

Application: B.2.3: Amend Identity of Formulants

B.2.4: Amend proportion of Formulants

Product: Banner MAXX Fungicide

Registration Number: 27003

Active ingredients (a.i.): Propiconazole [PON] PMRA Document Number English PDF: 2076956

Purpose of Application

The purpose of this application was to amend the product, Banner MAXX Fungicide, to add two new formulation options with new formulants and proportions of the formulants. Banner MAXX Fungicide is fully registered for use on golf course turf and nursery crops.

Chemistry Assessment

Banner MAXX Fungicide is formulated as an emulsfiable concentrate containing propiconazole at a nominal concentration of 14.3%. This end-use product has a density of 1.128-1.226 g/cm³ and a pH between 4-7. The chemistry requirements for Banner Maxx Fungicide are complete.

Health Assessments

The change in identity and proportion of formulants does not increase exposure to propiconazole over the registered use pattern. No increase in risk is expected when workers mix, load and apply Banner MAXX Fungicide following label directions and wearing the required personal protective equipment.

In rats, Banner MAXX Fungicide is slightly acutely toxic by the oral route (LD50 = 1750 mg/kg), but of low acute toxicity by the dermal (LD50 > 5000 mg/kg), and inhalation routes (LC50 > 2.55 mg/L). It is minimally irritating to the eye and skin of rabbits. It is not a dermal sensitizer in guinea pigs.

Environmental Assessment

No new environmental data were submitted to support the registration of the amended product, Banner MAXX Fungicide to add two new formulations with new formulants and proportions of the formulants. Additional environmental data were not required to support this registration. The trace levels of the Batch 7 Challenge substance, 1,4-dioxane, contained within the proposed new formulations is not expected to be of environment concern.

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Value Assessment

One to three applications of Banner MAXX Fungicide and A6780L 3.1 formulation at the rates of 26 and 51 ml/100 m² consistently provided statistically similar levels of control in the four bridging trials conducted on mixed stands of creeping bentgrass and annual bluegrass under various disease pressures, i.e. 3-50% disease severity in the untreated control. Minor differences in the concentration of formulants are observed between the two A6780L formulations. Given that the overall formulation change is lower than 1%, it is not expected to affect product efficacy. Based on these factors, Banner MAXX Fungicide and the two A6780L formulations are considered equivalent in terms of efficacy.

Four bridging trials conducted in 2008 were provided to compare the efficacy of Banner MAXX Fungicide and A6780L 3.1 formulation. Three trials were carried out on golf course turf in Ontario under fairway conditions. The fourth trial was performed on a research turf plot in Pennsylvania.

One to three applications of Banner MAXX Fungicide and A6780L 3.1 formulation at the rates of 26 and 51 ml/100 m² consistently showed statistically similar levels of dollar spot control in the four bridging trials conducted on mixed stands of creeping bentgrass and annual bluegrass. Under moderate to high disease pressure, i.e. 15-50% disease severity in the untreated control, the Banner MAXX Fungicide and A6780L 3.1 formulation rates provided an average of 81% and 86% reduction of dollar spot, a major turf disease.

Banner MAXX Fungicide and A6780L 3.1 formulation are thus considered biologically equivalent; similar efficacy is expected against the other proposed diseases. Minor differences in the concentration of formulants are observed between the two A6780L formulations. The overall formulation difference is lower than 1%, which is not expected to affect product efficacy. Based on these factors, all disease claims on Banner MAXX Fungicide are supported for A6780L 3.1 and A6780L 4.1 formulations.

Conclusion

The PMRA has completed an assessment of available information for Banner MAXX Fungicide and has found the amendments to be acceptable.

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