

Evaluation Report for Category B, Subcategory 2.3 & 2.4 Application

Application Number: 2005-3845
Application: Category B, subcategory 2.3 (Identity of Formulants), 2.4 (Proportion of Formulants)
Product: Bumper 14.3 ME
Registration Number: 28797
Active ingredients (a.i.): Propiconazole at 154.5 g/L
PMRA Document Number: 1489896

Purpose of Application

The purpose of this application is to register Bumper 14.3 ME, an end-use product containing the active ingredient propiconazole, for the control of fungal diseases on turf (at a variety of application rates and timings) at a maximum single application rate of 206 mL product /100 m² (20.6 L/ha or 3.18 kg a.i./ha) and an annual cap of 473 mL product/100 m² (47.3 L/ha or 7.3 kg a.i./ha). The requested use pattern of this product is similar to that of Banner Maxx Fungicide (Reg # 27003).

Chemistry Assessment

Bumper 14.3 ME is a solution containing the active ingredient propiconazole at a nominal concentration of 154.5 g/L. This product has a density of 1.08 g/mL and pH of 6-8 (1% solution). The chemistry requirements for Bumper 14.3 ME are complete.

Health Assessments

Bumper 14.3 ME is of low acute toxicity by the dermal ($LD_{50} > 5000$ mg/kg) and by oral routes [female $LD_{50} = 3096$ mg/kg bw (95% confidence interval, 2574-3575 mg/kg bw), male $LD_{50} > 5000$ mg/kg bw] in rats. It is of low toxicity via inhalation with an LC_{50} greater than 2.03 mg/L in rats. Bumper 14.3 ME is mildly irritating to the skin of rabbits and minimally irritating to rabbit eyes. This product is a dermal sensitizer in guinea pigs.

The requested uses of Bumper 14.3 ME fungicide are within the established use pattern for propiconazole, therefore, new exposure and risk assessments for workers were not required. Based on the acute hazard labelling of the product, label amendments were required.

Environmental Assessment

An environmental assessment based on the use of the active ingredient was not required since the proposed use site category, seasonal rates and application are the same as a registered product. Product-specific aquatic toxicity studies are required for products that contain propiconazole due to significant differences between formulated product toxicity and the toxicity of the active ingredient alone. This product is approved for conditional registration pending submission of the required aquatic toxicity studies by December 01, 2007. A precautionary aquatic environmental hazard statement has been added to the label pending the results of these studies.

Value Assessment

Six trials in Quebec and Ontario, involving 3 diseases (dollar spot, gray and pink snow mold), were evaluated. Bumper 14.3 ME demonstrated acceptable control of dollar spot and gray and pink snow mold when applied according to the proposed label. It is expected that Bumper 14.3 ME will perform as well as Banner Maxx, for all turf diseases on the Bumper 14.3 ME label.

Conclusion

The PMRA has completed an assessment of available information for Bumper 14.3 ME and has found the information sufficient to allow for conditional registration, with full registration being contingent on the submission of the following additional scientific information:

Daphnia Acute Toxicity according to OPPTS 850.1010 with *Daphnia magna*
(acute immobilization test, 48 h, static)

Daphnia Reproduction Test according to OPPTS 850.1300 with *Daphnia magna*
(dose-response test, 21 d, semi-static)

Acute Toxicity to Fish - Cold Water according to OPPTS 850.1075 with rainbow trout
(dose-response test, 96 h, static)

Fish Early Life Stage Test - Cold Water Fish according to OPPTS 850.1400 with rainbow trout
(dose-response test, 100 d, flowthrough)

Acute Toxicity to Fish - Warm Water according to OPPTS 850.1075 with bluegill sunfish
(dose-response test, 96 h, static)

Fish Early Life Stage Test - Cold Water Fish according to OPPTS 850.1400 with bluegill sunfish
(dose-response test, circa 35 d, flowthrough)

Control Analysis - Propiconazole a.i. via HPLC with suitable detection, method development, implementation and validation.

References

1.0 Chemistry

- 1102932 Product Identification., DACO: 3.1
- 1102933 Description of Starting Materials., DACO: 3.2.1
- 1102934 Bumper 14.3% ME, Product Chemistry., DACO: 3.2.2, 3.2.3, 3.4.1, 3.4.2
- 1102935 Establishing Certified Limits., DACO: 3.3.1
- 1102936 Bumper 14.3% ME, Product Chemistry., DACO: 3.5.1, 3.5.11, 3.5.12, 3.5.13, 3.5.15, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.8, 3.5.9
- 1102937 Formulation Type., DACO: 3.5.4
- 1102943 Bumper 14.3% ME, Product Chemistry., 45607601, DACO: 3.5.5
- 1102944 2002, Physical and Chemical Characteristics of Propiconazole 14.3% EC: Storage Stability and Corrosion Characteristics., BUM 49, DACO: 3.5.10, 3.5.14

2.0 Toxicology

- 1102938 (2001) Acute Oral Toxicity in Rats - Defined LD₅₀. Laboratory Study Report No. 10542. Reference No. 010424-1R. Study report date: 8-August-2001. pp. 1-24. DACO 4.6.1.
- 1102939 (2001) Acute Dermal Toxicity in Rats - Limit Test. Laboratory Report No. 10543. Reference No. 010424-1R. Study report date: 19-June-2001. pp. 1-15. DACO 4.6.2.
- 1102940 (2001) Acute Inhalation Toxicity in Rats - Limit Test. Laboratory Report No. 10544. Reference No. 010424-1R. Study report date: 19-June-2001. pp. 1-15. DACO 4.6.3.
- 1102941 (2001) Primary Eye Irritation Study in Rabbits. Laboratory Report No. 10545. Reference No. 010424-1R. Study report date: 19-June-2001. pp. 1-15. DACO 4.6.4.
- 1102942 (2001) Primary Skin Irritation Study in Rabbits. Laboratory Report No. 10546. Reference No. 010424-1R. Study report date: 18-June-2001. pp. 1-15. DACO 4.6.5.
- 1102946 (2001) Dermal Sensitization Study in Guinea Pigs (Buehler Method). Laboratory Report No. 10541. Reference No. 010424-1R. Study report date: 18-June-2001. pp. 1-24. DACO 4.6.6.

3.0 Value

- 1102950 Efficacy Summary. DACO:10.2.3.1

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