

## Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.1, 3.11, 3.12 Application

**Application Number:** 2012-5360  
**Application:** B.2.1: Product Chemistry-Guarantee  
B.2.3: Product Chemistry-Identity of Formulants  
B.2.4: Product Chemistry-Proportion of Formulants  
B.3.1: Product Labels-Application Rate Increase or Decrease  
B.3.11: Product Labels-New Pests  
B.3.12: Product Labels-New Site or Host  
**Product:** Medallion Fungicide  
**Registration Number:** 31528  
**Active ingredients (a.i.):** Fludioxonil  
**PMRA Document Number :** 2294739

### Purpose of Application

The purpose of this application was to register a new end-use product, Medallion Fungicide, for use on golf course turf and outdoor ornamentals.

### Chemistry Assessment

Medallion Fungicide is formulated as a suspension containing fludioxonil at a nominal concentration of 125 g/L. This end-use product has a density of 1.07 g/mL and pH of 6.7. The chemistry requirements for Medallion Fungicide are complete.

### Health Assessments

Medallion Fungicide is of low acute oral ( $LD_{50} = 5000$  mg/kg bw), dermal ( $LD_{50} > 5000$  mg/kg bw) and inhalation ( $LC_{50} > 2.59$  mg/L) toxicity in rats. It is minimally irritating to the eyes and non-irritating to the skin of rabbits. It is not a dermal sensitizer in guinea pigs.

Medallion Fungicide for use on golf course turf and outdoor ornamentals does not fit within the registered use pattern for fludioxonil. However, the potential exposure for mixers, loaders, applicators and postapplication re-entry workers is not expected to result in risks of concern provided that all precautions, directions and instructions are followed.

As the purpose of this submission was to register the new end-use product Medallion Fungicide, containing the active ingredient fludioxonil, for use on non-food sites such as outdoor ornamentals and golf course turfgrass, no metabolism or residue data were required by the PMRA. However, the use expansion of fludioxonil triggered the update of drinking water Estimated Environmental Concentrations (EECs) since applications to turf are done later in the year and at a higher single application rate than was previously modelled. Consequently, an update to the dietary exposure assessment (DEA) was required to incorporate the newly

modelled EEC values.

In summary, aggregate (food + drinking water) dietary exposure to fludioxonil was considered acceptable and below the level of health concern. Hence, the consumption estimates coupled with the MRLs indicate that there is adequate protection to the consumer, including infants, children, adults and seniors, from dietary residues of fludioxonil following use in accordance with Good Agricultural Practice (GAP).

### **Environmental Assessment**

The use of Medallion Fungicide on turf constitutes a rate increase, thus a revised environmental risk assessment was required. Using current risk assessment methodology along with previously evaluated environmental fate and ecotoxicology information (ERC-2008-02, REG2006-08), it has been determined that in addition to the conclusions from the original review, a hazard statement indicating toxicity to birds and mammals was required.

In terms of mitigating newly identified risks, the end-use product label was reviewed and updated to reflect current standards. Spray buffer zones were adjusted to reflect the new use pattern. Required spray buffer zones for aquatic habitats are 3 m and 20 m in size for field sprayer and airblast application, respectively; and they are 1 m in size for terrestrial habitats for both types of application equipment.

### **Value Assessment**

Thirty-one small plot research trials were conducted across Canada and the US from 1996 to 2011 to assess the efficacy of fludioxonil applied as a drench or foliar application to turf and outdoor ornamentals.

**Turf:** A total of 15 efficacy trials conducted in Canada and the US between 2000 and 2008 were submitted for review. Good control of anthracnose was observed in three of four turf trials and the results were comparable to the commercial standard registered to control this pathogen. Efficacy was demonstrated against both the foliar phase of the disease and against basal rot at the proposed rate and spray interval.

Good efficacy was observed by fludioxonil against brown patch; significantly greater control was noted compared to the commercial standards in some cases. Equally satisfactory efficacy was also observed when fludioxonil was applied in tank mixes.

Average efficacy was in the control range (>80%) in three of the four trials, but only partially suppressed leaf spot in the fourth trial. The fludioxonil treatment was comparable to the commercial standards in all trials, including the trial where only partial suppression was expressed. Tank mixes provided similar levels of efficacy compared to the treatments applied alone. The addition of a plant growth regulator (PGR) had no significant negative effect on the efficacy of fludioxonil or on turf quality.

Fludioxonil suppressed or partially suppressed fusarium patch in the trials when applied curatively, significantly in two of the trials. The level of efficacy expressed was comparable or

better than the registered commercial standard. Equivalent efficacy was observed when fludioxonil was applied in tank mixes with the commercial standard and the PGR. Higher levels of efficacy are expected with preventative applications. The final ratings indicate that the treatment reduced damage to a tolerable level.

**Ornamentals:** A total of 16 trials (greenhouse and field) conducted in the US between 1997 and 2007 were submitted for review. Three trials were reviewed as supplemental information as disease assessments were conducted using ordinal rating scales ranking treatments qualitatively rather than quantitatively and no statistical information was presented.

In *Alternaria* trials, reduction of disease incidence was variable, but good control of defoliation and disease severity was observed. Both rates of fludioxonil resulted in significant control that would lead to a marketable plant. All assessments were made primarily on leaves, so the common disease name supported is alternaria leaf spot. As there is no information on other *Alternaria* species besides the two tested, so the claim was amended to include the two tested species, *A. alternata* and *A. zinnia*.

*Botrytis cinerea* trials demonstrated consistent control of disease severity at the high rate. The low rate resulted in variable efficacy, but numerically reduced incidence and severity under lower disease pressure. The efficacy data suggests that the low rate would only be appropriate under conditions of low disease pressure. Assessments were primarily made on leaves supporting the claim of control of grey mould and botrytis blight.

Both rates of fludioxonil provided low levels of control of fusarium wilt incidence and reduced severity to tolerable levels. No other diseases caused by *Fusarium* spp. were tested. Overall, results support a claim for suppression of fusarium wilt caused by *Fusarium oxysporum* at the accepted rates.

The low rate of fludioxonil completely controlled *Rhizoctonia* symptoms on whole plants or stem cankers with results comparable to the non-inoculated control. Reduction of incidence on leaves was also comparable to the non-inoculated control on zinnia and geranium at both accepted rates. Assessments were made on leaves and stems of plants inoculated with *R. solani*; therefore the claim was supported as control of aerial blight and stem canker caused by *R. solani* at the accepted rates.

Fludioxonil has demonstrated control of a broad spectrum of turf and ornamental diseases. This fungicide will provide a new mode of action for these target pests to golf course superintendents and ornamental growers as well as a new tool for integrated pest management and resistance management strategies.

## **Conclusion**

The PMRA has reviewed the information provided in support of Medallion Fungicide. Based on this review, Medallion Fungicide is acceptable for full registration.

## **References**

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