

Evaluation Report for Category B, Subcategory 2.3, 2.4, 3.12, C.3.1 & C.8.1 Application

Application Number: 2011-5942
Application: New/Changes EP Product Chemistry-Identity and Proportion of Formulants; New/Changes to Product Labels-New Site or Host, Application Rate Decrease; and Master Product Status
Product: Belmont 2.7 FS
Registration Number: 30246
Active ingredients (a.i.): Metalaxyl [MTA]
PMRA Document Number: 2258699

Background

Belmont 2.7 FS has been registered since November 25, 2011 as a commercial product for use as a Seed Treatment Fungicide for control of seedling blights and seed rots caused by *Pythium* spp on various crops. Currently, Belmont 2.7 FS is approved for use on for wheat, barley, oat and rye for seed destined for export at rate of 46 to 110 mL per 100 kg.

Purpose of Application

The purpose of this application was to add the currently registered use on cereals (for export) for domestic use at a lower rate (6.3 to 12.6 mL/100 kg seeds); add the use for seed treatment on triticale; add a new formulation; upgrade to Master product status; and change in container size range. Belmont 2.7 FS contains the active ingredient metalaxyl.

Chemistry Assessment

Belmont 2.7 FS is formulated as a suspension containing metalaxyl at a nominal concentration of 317 g/L. This end-use product has a density of 1.094 g/mL and pH of 7.75. The chemistry requirements for Belmont 2.7 FS are complete.

Health Assessments

Belmont 2.7 FS is chemically equivalent to a registered product. Subsequently, no toxicological data were submitted or are required.

No new residue data for metalaxyl were submitted to support the addition of a new formulation for Belmont 2.7 FS, and the addition of the domestic use with this end-use product for seed treatment on cereals, including triticale. Metalaxyl is currently registered in Canada as a seed treatment on cereals, and there are residue data on file for cereals at foliar application rates significantly higher than the proposed seed treatment rates. The use of Belmont 2.7 FS as a

domestic seed treatment on barley, oats, rye, triticale and wheat can be supported from a food residue exposure point of view. Residues of metalaxyl in/on treated barley, oats, rye, triticale and wheat will be covered by the existing MRLs established for these commodities. Residues of metalaxyl in these commodities at the established MRLs will not pose an unacceptable health risk to any segment of the population, including infants, children, adults and seniors.

An occupational risk assessment was performed for workers that may be exposed to metalaxyl from the domestic use of Belmont 2.7 FS on barley, oat, rye, wheat, and triticale seed. The new uses of Belmont 2.7 FS are not expected to result in unacceptable risk when workers follow the label directions and wear the personal protective equipment identified on the label.

Environmental Assessment

No new environmental data were submitted to support the label amendments for Belmont 2.7 FS, and none were required. The addition of a lower rate for domestic use on cereals and the addition of use on triticale are acceptable from an environmental perspective, as the product is already registered at equivalent rates for comparable crops.

Value Assessment

A total of 11 trials were submitted and reviewed to support the claims. Biological equivalency between the reduced rates of Belmont 2.7 FS and Dividend XL RTA was demonstrated in 7 efficacy trials submitted by the applicant. In 4 additional efficacy trials, the higher rate proposed (4.0 g metalaxyl/100 kg seeds) provided higher control of pre-emergence damping off/seed rot than the lower rate (2.0 g metalaxyl/100 kg seeds). The higher rate proposed is to be used when planting into cold and wet soils as per the registered label. A scientific rationale was also submitted and deemed acceptable to extrapolate the proposed claims to triticale.

Based on the efficacy trials and scientific rationale, the use of Belmont 2.7 FS to control seed rot and seedling blight caused by *Pythium* on cereals at the reduced rate range (6.3-12.6 mL/100 kg seeds, i.e. 2.0 to 4.0 g metalaxyl) on cereals including triticale, can be supported from an efficacy point of view.

Conclusion

The PMRA has conducted a review of the available information to amend the Belmont 2.7 FS label, formulation, Master product status and container size and has determined that these changes are acceptable.

References

- 2136802 2011, The Efficacy for Belmont 2.7 FS Fungicide Seed Treatment Applied to Barley, Oat, Rye, Triticale and Wheat, DACO: 10.1,10.2.2,10.2.3.1,10.2.3.3,10.3.1
- 1398186 2007, Dermal and Inhalation Exposure to Handlers of a Liquid Seed Treatment Fungicide During On-Farm Treatment of Cereal Grain, DACO: 5.4

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