

Evaluation Report for Category B, Subcategory 3.13 Application

Application Number: 2013-2112
Application: New or Changes to Product Labels-Precautions
Product: Taegro
Registration Number: 30720
Active ingredients (a.i.): *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24
PMRA Document Number: 2316811

Background

Taegro is a wettable powder formulation containing *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 as the active ingredient. Taegro is registered for use as commercial-class biological fungicide to suppress bottom rot on lettuce (greenhouse and field), late blight on tomato (greenhouse and field), *Fusarium* wilt on greenhouse cyclamen and *Fusarium* head blight on wheat.

Purpose of Application

The purpose of this application was to update the storage instructions based on updated shelf life/storage stability data.

Chemistry Assessment

The storage stability data on Taegro showed that *Bacillus subtilis* var. *liquefaciens* strain FZ24 was stable at 4°C, 23°C and at 35°C over a period of up to 36 months. This study, however, was based on the results of a single lot of product. To support storage stability claims, PMRA generally requires storage stability data on 3–5 representative batches of product. The requirement for testing on more than one batch of product is to ensure product performance despite batch to batch variability. In this instance, the requirement for 3–5 representative batches of product was waived since the microbial pest control agent (MPCA) is a documented thermo-stable species; the MPCA in the end-use product is manufactured as a resilient endospore; and the product is formulated as a wettable powder which, based on past PMRA experiences, offers the best stability for MPCAs.

Health, Environmental and Value Assessment

Health, environmental and value assessments were not required for this application.

Conclusion

The PMRA has reviewed the information provide in support of this application and can support a 36-month storage period at temperatures of 4–35°C.

References

2293300 DACO: M2.11 CBI.

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