

Evaluation Report for Category B, Subcategory 4.1 Application

Application Number: 2014-3225
Application: To convert to full registration, not requiring consultation
Product: Serifel
Registration Number: 30054
Active ingredients (a.i.): *Bacillus subtilis*, strain MBI 600
PMRA Document Number : 2476319

Purpose of Application

The purpose of this application was to provide value information to fulfill conditions of registration for Serifel (registration number 30054) and convert the product to full registration. In the original Category B submission, 2010-4096, it was determined that additional confirmatory data to support the claims of suppression of damping-off and root diseases caused by *Fusarium* spp., *Rhizoctonia solani* and *Pythium* spp. on greenhouse ornamentals was required.

Chemistry, Health and Environmental Assessments

The registration conditions for Serifel applied to claims of suppression and it was determined that assessments of chemistry, health and environment were not required.

Value Assessment

A scientific rationale was provided in support of the claims of suppression of damping-off and root diseases caused by *Fusarium* spp., *Rhizoctonia solani* and *Pythium* spp. on greenhouse ornamentals. The scientific rationale addressed the non-specificity of the diseases, thus allowing an extrapolation of the claims from greenhouse fruiting vegetables and cucurbits to greenhouse ornamentals. The scientific rationale was determined to be acceptable.

Conclusion

The PMRA has completed an assessment of the information provided and determined that the conditions of registration for Serifel have been fulfilled and the product was converted to full registration.

References

PMRA Document Number	Reference
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2448027 2014, Part 10 Value: Response to Section 12 Notice: Additional information required to fulfill the terms and conditions for conditional registration, DACO: 10.2.3.2

ISSN: 1911-8082

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