

Evaluation Report for Category B, Subcategory 2.2 Application

Application Number: 2020-1321
Application: Changes to EP Product Chemistry - Form of Technical Grade Active Ingredient
Product: SERENADE SOIL
Registration Number: 30647
Active ingredient (a.i.): *Bacillus subtilis* (strain QST 713)
PMRA Document Number : 3167364

Purpose of Application

The purpose of this application was to update the registration of the end-use product (EP) SERENADE SOIL to reflect the use of the newly registered technical grade active ingredient (TGAI) QST 713 Technical 1.

Product Characterization and Analysis

The description of the formulation process for the registered EP, SERENADE SOIL, was updated to reflect the use of a newly registered technical grade active ingredient (TGAI), QST 713 Technical 1.

Health Assessments

SERENADE SOIL produced using QST 713 Technical 1 is considered to be biologically equivalent to that produced using the existing registered TGAI. As the human health and safety database for the active ingredient, *Bacillus subtilis* strain QST 713, and SERENADE SOIL is considered complete, no additional information is required.

Maximum Residue Limit

Bacillus subtilis strain QST 713 is currently registered in Canada for food uses. The Pest Management Regulatory Agency (PMRA) has determined that specification of a maximum residue limit (MRL) under the *Pest Control Products Act* (PCPA) is not required for *B. subtilis* strain QST 713 (see ERC2007-06, *Evaluation Report - Bacillus subtilis strain QST 713, Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate, Serenade Garden Ready To Use*).

Environmental Assessment

SERENADE SOIL produced using QST 713 Technical 1 is considered to be biologically equivalent to that produced using the existing registered TGAI. As the environmental toxicology database for the active ingredient, *Bacillus subtilis* strain QST 713, and SERENADE SOIL is considered complete, no additional information is required.

Value Assessment

A value assessment was not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to update the registration of SERENADE SOIL.

References

PMRA Document Number	Reference
3110368	2020, Manufacturing process for Serenade ASO for Canada, DACO: M2.8 CBI
3110369	2015, Material accountability of Serenade ASO - (<i>B. subtilis</i> QST713 SC) - 5 batch analysis, DACO: M2.10.1,M2.10.2,M2.9.2 CBI
3110370	2015, Determination of the total spore number in different biological formulations based on bacterial spores, DACO: M2.10.1,M2.9.2 CBI

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