

## Evaluation Report for Category B, Subcategory 2.2 Application

**Application Number:** 2020-1318  
**Application:** Changes to EP Product Chemistry - Form of Technical Grade Active Ingredient  
**Product:** SERENADE ASO  
**Registration Number:** 28626  
**Active ingredient (a.i.):** *Bacillus subtilis* (strain QST 713)  
**PMRA Document Number :** 3167340

### Purpose of Application

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

### Health Assessments

SERENADE ASO 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 ASO 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 ASO 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 ASO 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 ASO.

## References

<b>PMRA Document Number</b>	<b>Reference</b>
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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