

## Evaluation Report for Category B, Subcategory 3.12 Application

**Application Number:** 2018-1939  
**Application:** Changes to Product Labels-New Site or Host  
**Product:** Serenade ASO  
**Registration Number:** 28626  
**Active ingredient (a.i.):** *Bacillus subtilis* strain QST 713  
**PMRA Document Number (English PDF):** 2953329

### Purpose of Application

The purpose of this application was to expand the label of Serenade ASO to add suppression of rhizoctonia root rot, pythium root rot, and fusarium root rot on corn crops (field, sweet, pop-, seed and silage corn) via soil application.

### Chemistry Assessment

A chemistry assessment was not required for this application.

### Health Assessments

Since no changes have been made to the formulation of Serenade ASO, and the human health and safety databases for this product is considered complete, no additional toxicological information was required. Previously submitted information indicates that the technical grade active ingredient, *Bacillus subtilis* strain QST 713, is of low toxicity when administered via the oral, pulmonary, intravenous, and dermal routes and is not pathogenic or infective via the oral, pulmonary and intravenous routes.

The changes relating to the addition of corn crops to the label of Serenade ASO, including site, rate, method, and timing of application, are consistent with existing registered uses of the product. The potential occupational exposure from the proposed changes is not expected to increase, and therefore, no additional exposure information was required. While the expansion of soil applications to include corn may increase the dietary share of consumers to food and feed crops which have been treated with this product, no pathogenicity, infectivity or oral toxicity were identified for the product. In addition, the label instructs users not to contaminate irrigation or drinking water supplies or aquatic habitats through equipment cleaning or waste disposal. Therefore, the anticipated dietary risks are acceptable when the product is applied according to the label instructions. Available information was sufficient to support the changes to the label of Serenade ASO.

### Maximum Residue Limit (MRL)

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that the consumption of the maximum amount of residues that are

expected to remain on food products when a pesticide is used according to label directions will not be a concern to human health. This maximum amount of residues expected is then legally specified as an MRL under the *Pest Control Products Act* (PCPA) for the purposes of adulteration provision of the *Food and Drugs Act* (FDA). Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

The specification of an MRL is not required for *Bacillus subtilis* strain QST 713, based on the low toxicity profile demonstrated in Tier I testing.

### **Environmental Assessment**

Since no changes have been made to the formulation of Serenade ASO and the environmental toxicological database for this product is considered complete, no additional environmental toxicological information was required. Previously submitted information indicates that the use of Serenade ASO for terrestrial food and feed crops does not pose an environmental risk of concern to non-target organisms.

### **Value Assessment**

A rationale was provided with this application to support the extrapolation of suppression of listed root rot diseases to corn for Serenade ASO. The listed diseases are currently on the registered label, and the rationale justified extrapolation of Serenade ASO use to corn based on similarities of the pests and the timing of application. Based on the value information provided, the claim of suppression of rhizoctonia root rot, pythium root rot, and fusarium root rot, when applied at the registered rate range of 2.7-14 L/ha, is supported from a value perspective.

### **Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found it sufficient to support the expansion of the label of Serenade ASO to add suppression of rhizoctonia root rot (*Rhizoctonia solani*), pythium root rot (*Pythium* spp.), and fusarium root rot (*Fusarium* spp.) on corn crops (field, sweet, pop-, seed and silage corn) via soil application.

### **References**

<b>PMRA Document Number</b>	<b>Reference</b>
2882584	2018, Value assessment of soil-applied Serenade ASO bio-fungicide on corn for suppression of root rots, DACO: 10.1, 10.2, 10.22, 10.3, 10.3.1, 10.3.2, 10.3.2.1, 10.3.2.2, 10.4, 10.4.2, 10.4.3, 10.4.4
2882585	2018, Value assessment of soil-applied Serenade ASO bio-fungicide on corn for suppression of root rots, DACO: 10.1, 10.2, 10.22, 10.3, 10.3.1, 10.3.2, 10.3.2.1, 10.3.2.2, 10.4, 10.4.2, 10.4.3, 10.4.4

2882586	2018, Value assessment of soil-applied Serenade ASO bio-fungicide on corn for suppression of root rots, DACO: 10.1, 10.2, 10.22, 10.3, 10.3.1, 10.3.2, 10.3.2.1, 10.3.2.2, 10.4, 10.4.2, 10.4.3, 10.4.4
2882587	2018, Field Trial Compilation: Value assessment of soil-applied Serenade ASO bio-fungicide on corn for suppression of root rots, DACO:10.2.2
2918022	2018, Addendum to: Value Assessment of soil-applied Serenade ASOTM Bio-fungicide on corn for suppression of root rots, DACO: M10.2,M10.2.2,M10.5

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