



Health Canada Santé  
Canada Canada

Your health and  
safety... our priority.

Votre santé et votre  
sécurité... notre priorité.

PRD2009-16

## Proposed Registration Decision

# ***Bacillus subtilis* strain QST 713**

*(publié aussi en français)*

**16 November 2009**

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications  
Pest Management Regulatory Agency  
Health Canada  
2720 Riverside Drive  
A.L. 6605C  
Ottawa, Ontario  
K1A 0K9

Internet: [pmra\\_publications@hc-sc.gc.ca](mailto:pmra_publications@hc-sc.gc.ca)  
[healthcanada.gc.ca/pmra](http://healthcanada.gc.ca/pmra)  
Facsimile: 613-736-3758  
Information Service:  
1-800-267-6315 or 613-736-3799  
[pmra\\_infoserv@hc-sc.gc.ca](mailto:pmra_infoserv@hc-sc.gc.ca)

**Canada** 

HC Pub: 091138

ISBN: 978-1-100-14122-0 (978-1-100-14123-7)  
Catalogue number: H113-9/2009-16E (H113-9/2009-16E-PDF)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2009

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

## Table of Contents

Overview.....	1
Proposed Registration Decision for <i>Bacillus subtilis</i> strain QST 713.....	1
What Does Health Canada Consider When Making a Registration Decision?.....	2
What is <i>Bacillus subtilis</i> strain QST 713?.....	2
Health Considerations .....	3
Environmental Considerations .....	5
Value Considerations.....	5
Measures to Minimize Risk.....	5
Next Steps.....	6
Other Information .....	6
Science Evaluation.....	7
1.0 The Active Ingredient, Its Properties and Uses .....	7
1.1 Identity of the Active Ingredient.....	7
1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product .....	8
1.3 Directions for Use.....	9
1.4 Mode of Action.....	9
2.0 Methods of Analysis .....	9
2.1 Methods for Identification of the Microorganism .....	9
2.2 Methods for Establishment of Purity of Seed Stock.....	10
2.3 Methods to Define the Content of the Microorganism in the Manufactured Material Used for the Production of Formulated Products .....	10
2.4 Methods to Determine and Quantify Residues (Viable or Non-viable) of the Active Microorganism and Relevant Metabolites.....	10
2.5 Methods for Determination of Relevant Impurities in the Manufactured Material.....	10
2.6 Methods to Show Absence of Any Human and Mammalian Pathogens .....	10
2.7 Methods to Determine Storage Stability, Shelf-life of the Microorganism.....	10
3.0 Impact on Human and Animal Health .....	11
4.0 Impact on the Environment.....	11
5.0 Value .....	11
5.1 Effectiveness Against Pests .....	11
5.1.1 Acceptable Efficacy Claims for Serenade MAX.....	11
6.0 Formulants and Microcontaminants of Health or Environmental Concern.....	11
7.0 Summary .....	11
7.1 Methods for Analysis of the Micro-organism as Manufactured.....	11
7.2 Human Health and Safety .....	12
7.3 Environmental Risk .....	12
7.4 Value .....	12
8.0 Proposed Regulatory Decision.....	12
List of Abbreviations .....	13
Appendix I Tables and Figures .....	15
Table 1 Supported and Unsupported Uses for Serenade MAX .....	15
References.....	17

# Overview

## Proposed Registration Decision for *Bacillus subtilis* strain QST 713

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the Pest Control Products Act and Regulations, is proposing full registration for the sale and use of *Bacillus subtilis* QST 713 Technical Powder and the following end-use products: Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate and Serenade Garden Ready To Use, containing the active ingredient *Bacillus subtilis* strain QST 713 to suppress various fungal diseases in asparagus, bushberries, caneberries, bulb vegetables, brassica (cole) crops, cucurbit vegetables, fruiting vegetables, grapes, legume vegetables, leafy vegetables, mint, pome fruits, rutabaga, turnip, radish, strawberries and ornamentals.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

*Bacillus subtilis* QST 713 Technical Powder (Registration Number 28548), Serenade MAX (Registration Number 28549), Serenade ASO (Registration Number 28626), Rhapsody ASO (Registration Number 28627), Serenade Garden Concentrate (Registration Number 28628) and Serenade Garden Ready To Use (Registration Number 28629) are currently conditionally registered in Canada. The detailed review of these products can be found in Evaluation Report ERC2007-06, *Bacillus subtilis* strain QST 713. The purpose of the current applications is to convert *Bacillus subtilis* QST 713 Technical Powder, Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate and Serenade Garden Ready To Use from conditional to full registration.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of *Bacillus subtilis* QST 713 Technical Powder and Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate and Serenade Garden Ready To Use.

## What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable<sup>1</sup> if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value<sup>2</sup> when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at [healthcanada.gc.ca/pmra](http://healthcanada.gc.ca/pmra).

Before making a final registration decision on *Bacillus subtilis* strain QST 713, the PMRA will consider all comments received from the public in response to this consultation document.<sup>3</sup> The PMRA will then publish a Registration Decision<sup>4</sup> on *Bacillus subtilis* strain QST 713, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

### What is *Bacillus subtilis* strain QST 713?

***Bacillus subtilis* strain QST 713 is a microbial pest control agent used to suppress a number of bacterial and fungal plant pathogens.**

The five end-use products, Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate and Serenade Garden Ready to Use, are preventative biofungicides that contain *Bacillus subtilis* strain QST 713 as the active ingredient. The five products

---

<sup>1</sup> "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

<sup>2</sup> "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

<sup>3</sup> "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

<sup>4</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

are intended for different target markets. Serenade MAX and Serenade ASO are for agricultural use, particularly for organic growers. Rhapsody ASO is a product that can be used for organic production of ornamentals. Serenade Garden Concentrate and Serenade Garden Ready to Use are for home and garden use on ornamentals, fruits and vegetables.

## Health Considerations

### Can Approved Uses of *Bacillus subtilis* strain QST 713 Affect Human Health?

***Bacillus subtilis* strain QST 713 is unlikely to affect your health when Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate or Serenade Garden Ready To Use are used according to label directions.**

People could be exposed to *Bacillus subtilis* strain QST 713 during handling of Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate or Serenade Garden Ready To Use. When assessing health risks, the PMRA considers several key factors as follows:

- the microorganism's biological properties (for example, production of toxic byproducts);
- reports of any adverse incidents;
- its potential to cause disease or toxicity as determined in toxicological studies; and
- the levels to which people may be exposed relative to exposures already encountered in nature to other strains of the microorganism.

Toxicology studies in laboratory animals describe potential health effects from large doses in order to determine the potential of this organism to cause disease or toxicity. No significant toxicity and no signs of causing disease were observed when *Bacillus subtilis* strain QST 713 was tested on laboratory animals.

### Residues in Water and Food

**Dietary risks from food and water are not of concern.**

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for the *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value determines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

*Bacillus subtilis* strains are common in nature, and the use of Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate and Serenade Garden Ready To Use is not expected to significantly increase the natural environmental background levels of this microorganism. Some strains of *Bacillus subtilis* have been isolated from food samples implicated in food poisoning. However, these strains demonstrated the ability to produce a highly heat-stable toxin that may be similar to a toxin produced by *Bacillus cereus*, a known food-borne pathogenic microorganism. *Bacillus subtilis* strain QST 713 is not reported to produce this toxin. Also, no such effects were reported for this microorganism in the United States where it has been registered since 2000. Furthermore, there was no significant toxicity and no signs of causing diseases were observed when *Bacillus subtilis* strain QST 713 was administered orally to rats. Therefore, the establishment of an MRL is not required for *Bacillus subtilis* strain QST 713. In addition, the likelihood of residues of *Bacillus subtilis* strain QST 713 contaminating drinking water supplies is negligible to non-existent. Consequently, dietary exposure and risk are minimal to non-existent.

### **Occupational Risks From Handling Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate or Serenade Garden Ready To Use**

Occupational risks are not of concern when Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate or Serenade Garden Ready To Use are used according to label directions, which include protective measures.

Growers handling Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate or Serenade Garden Ready To Use can come into direct contact with *Bacillus subtilis* strain QST 713 on the skin, in the eyes or by inhalation. For this reason, the product labels specify that growers exposed to these end-use products must wear water proof gloves, long-sleeved shirts, long pants and shoes plus socks. Commercial users must wear a NIOSH-approved respirator (with any N-95, P-95, R-95 or HE filter for biological products) and domestic users should avoid breathing spray mists. Eye goggles are not required as the eye irritation studies submitted indicated minimal eye irritation potential.

For the bystander, exposure is expected to be much less than that of handlers and mixer/loaders and is considered negligible. Therefore, health risks to bystanders are not of concern.

## **Environmental Considerations**

### **What Happens When *Bacillus subtilis* strain QST 713 Is Introduced Into the Environment?**

#### **Environmental risks are not of concern.**

Studies designed to examine the effects of *Bacillus subtilis* strain QST 713 on various non-target organisms were evaluated. No significant adverse effects were observed in birds, freshwater fish, terrestrial arthropods (including honeybees), aquatic invertebrates, marine animals or algae.

*Bacillus subtilis* is not generally considered to be a disease causing agent. Therefore, Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate and Serenade Garden Ready To Use are expected to present a negligible risk to non-target organisms.

## **Value Considerations**

### **What Is the Value of Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate, Serenade Garden Ready To Use?**

These end-use products contain the active ingredient *Bacillus subtilis* strain QST 713 and are biofungicides that suppress various bacterial and fungal diseases on a number of agricultural crops as well as ornamentals grown indoors, outdoors, in greenhouses, homes and gardens. These products can be used as resistance-management tools because the active ingredient, *Bacillus subtilis* strain QST 713, has a multiple-site mode of action. By rotating their use with other registered chemical fungicides in an integrated pest management program, growers can reduce the possibility of developing resistance among pathogen populations to chemical fungicides as well as potentially reducing the number of applications of chemical fungicides. Serenade MAX, Serenade ASO and Rhapsody ASO can be used in organic vegetable and ornamental production.

## **Measures to Minimize Risk**

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate and Serenade Garden Ready To Use to address the potential risks are as follows.



## Key Risk-Reduction Measures

### Human Health

- As with all microbial pest control products, there are concerns with skin irritation and with users developing allergic reactions through repeated high exposures to *Bacillus subtilis* strain QST 713. Therefore, anyone handling Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate and Serenade Garden Ready To Use must wear waterproof gloves, long-sleeved shirt, long pants and shoes plus socks. Commercial users must wear a NIOSH-approved respirator (with any N-95, P-95, R-95 or HE filter for biological products) and domestic users are directed to avoid breathing spray mists. Eye goggles are not required as the eye irritation studies submitted indicated minimal eye irritation potential.

### Environment

- As a general precaution, handlers are advised not to contaminate irrigation or drinking water or aquatic habitats by cleaning of equipment or by disposing of wastes.

### Next Steps

Before making a final registration decision on *Bacillus subtilis* QST 713 Technical Powder and the following end-use products containing the active ingredient *Bacillus subtilis* strain QST 713: Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate and Serenade Garden Ready To Use, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

### Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on *Bacillus subtilis* QST 713 Technical Powder and the following end-use products containing the active ingredient *Bacillus subtilis* strain QST 713: Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate and Serenade Garden Ready To Use (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

# Science Evaluation

## *Bacillus subtilis* strain QST 713

A detailed assessment of the chemistry database for *Bacillus subtilis* QST 713 Technical Powder are presented in Evaluation Report ERC2007-06, *Bacillus subtilis* strain QST 713. The outstanding data identified during the original review included: ribotyping data to distinguish *Bacillus subtilis* strain QST 713 from other strains of *Bacillus subtilis*; storage stability data to ensure product performance and safety; as well as two additional efficacy trials on tomato early blight under adequate disease pressures are required for Serenade MAX. Information to address the outstanding requirements was submitted to the PMRA and has been found to be adequate. Results of these data are outlined below.

### 1.0 The Active Ingredient, Its Properties and Uses

#### 1.1 Identity of the Active Ingredient

<b>Active microorganism</b>	<i>Bacillus subtilis</i> strain QST 713
<b>Function</b>	Suppresses many fungal and bacterial plant pathogens including powdery mildew, gray mould, downy mildew, early blight, late blight, Botrytis blight, neck rot, pod rot and leaf blight, white mould, pink rot, fire blight, scab
<b>Binomial name</b>	<i>Bacillus subtilis</i> strain QST 713
<b>Taxonomic designation</b>	
<b>Kingdom</b>	Eubacteria
<b>Phylum</b>	Firmicutes
<b>Class</b>	Bacilli
<b>Order</b>	Bacillales
<b>Family</b>	Bacillaceae
<b>Genus</b>	Bacillus
<b>Species</b>	<i>subtilis</i>
<b>Strain</b>	QST 713
<b>Patent status information</b>	A Canadian patent application was submitted in May of 1998. The patent is pending.
<b>Minimum purity of the active ingredient</b>	$7.3 \times 10^9$ colony forming units (CFU)/g

**Identity of relevant impurities of toxicological, environmental and/or significance.**

The technical grade active ingredient does not contain any impurities or micro contaminants known to be TSMP Track 1 substances. Secondary metabolites produced by *Bacillus subtilis* strain QST 713 were isolated and identified. A total of 6 iturins, 14 pliplastatins, 4 surfactins and 2 agrastatins were identified. These secondary metabolites work together to destroy germ tubes and mycelia of targeted plant pathogenic fungi. Literature searches failed to uncover any reports regarding in vivo mammalian toxicity associated with these metabolites. Furthermore, the results of human health and toxicity studies did not indicate any significant adverse effects.

**1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product**

**Technical Grade Active Ingredient–*Bacillus subtilis* QST 713 Technical Powder**

Property	Result
Colour	Light brown
Odour	Earth-like, sweet
Physical State	Powder
Guarantee	$7.3 \times 10^9$ CFU/g
Density	0.48 g/cm <sup>3</sup>
Storage Stability	One year at ambient temperatures
Flammability	Non-flammable
Explodability	Non-explosive

**End-Use Product–Serenade MAX**

Property	Result
Colour	Medium gray-brown
Odour	Sweet, earthy
Physical state	Powder
Formulation type	Wettable powder
Guarantee	14.6 % <i>Bacillus subtilis</i> strain QST 713 minimum of $7.3 \times 10^9$ CFU/g
Density	0.45 g/cm <sup>3</sup>

Property	Result
Storage stability	2 years at 20°C
Corrosion characteristics	Non-corrosive
Flammability	Non-flammable
Explodability	Non-explosive

### End-Use Products–Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate and Serenade Garden Ready To Use

Property	Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate	Serenade Garden Ready To Use
Colour	Medium brown	Light tan
Odour	Sweet, earthy	Earthy
Physical state	Liquid, aqueous suspension	Liquid, aqueous suspension
pH	5.36	5.0–5.5
Guarantee	1.34% <i>Bacillus subtilis</i> strain QST 713 minimum of $1 \times 10^9$ CFU/g	0.074% <i>Bacillus subtilis</i> strain QST 713 minimum of $1 \times 10^8$ CFU/g
Density	1.023 g/mL	1.0 g/mL
Boiling point	>100°C	>100°C
Storage stability	2 years at room temperature	2 years at room temperature
Corrosion characteristics	Non-corrosive	Non-corrosive
Flammability	Non-flammable	Non-flammable
Explodability	Non-explosive	Non-explosive

### 1.3 Directions for Use

Refer to ERC2007-06 for full details on the directions for use.

### 1.4 Mode of Action

Refer to ERC2007-06 for full details on the mode of action.

## 2.0 Methods of Analysis

### 2.1 Methods for Identification of the Microorganism

The genus *Bacillus* consists of a large, diverse group of bacteria that includes species such as *thuringiensis*, *licheniformis*, *pumilis*, *cereus* and *anthracis*. Some strains of *Bacillus anthracis* and *Bacillus cereus* are known to be pathogenic to humans and animals. Therefore, methods to

distinguish between species of *Bacillus* are important. *Bacillus subtilis* strain QST 713 can be distinguished from *Bacillus anthracis*, *Bacillus cereus*, and *Bacillus thuringiensis* by a number of morphological or physiological features (for example, size, motility, spore location, maximum growth temperature) and biochemical tests (API identification system by bioMerieux Vitek).

Information provided supported that Strain QST 713 can be distinguished from other *Bacillus subtilis* strains by a ribotyping classification method.

## **2.2 Methods for Establishment of Purity of Seed Stock**

Refer to ERC2007-06 for a detailed assessment.

## **2.3 Methods to Define the Content of the Microorganism in the Manufactured Material Used for the Production of Formulated Products**

Refer to ERC2007-06 for a detailed assessment.

## **2.4 Methods to Determine and Quantify Residues (Viable or Non-viable) of the Active Microorganism and Relevant Metabolites**

Refer to ERC2007-06 for a detailed assessment.

## **2.5 Methods for Determination of Relevant Impurities in the Manufactured Material**

Refer to ERC2007-06 for a detailed assessment.

## **2.6 Methods to Show Absence of Any Human and Mammalian Pathogens**

Refer to ERC2007-06 for a detailed assessment.

## **2.7 Methods to Determine Storage Stability, Shelf-life of the Microorganism**

The storage stability of *Bacillus subtilis* QST 713 Technical Powder was assessed by determining the titres initially and after three, six and twelve months of storage under warehouse conditions (18–32°C and 14–80% relative humidity). Assay results indicated that QST 713 Technical Powder was stable for up to one year when stored at warehouse conditions.

Storage stability data were submitted for one batch of Serenade MAX. The data indicate that Serenade MAX is stable for up to 24 months and maintains the label guarantee of a minimum of  $7.3 \times 10^9$  CFU/g when stored at 20°C.

Storage stability data were submitted for one batch of Serenade ASO. The data indicate that Serenade ASO is stable at room temperature for up to 24 months and maintains the label guarantee of a minimum of  $1 \times 10^9$  CFU/g. The storage stability data for Serenade ASO are acceptable for Rhapsody ASO and Serenade Garden Concentrate.

Storage stability data were submitted for one batch of Serenade Garden Ready To Use. The data indicate that Serenade Garden Ready To Use is stable for up to 24 months and maintains the label guarantee of a minimum of  $1 \times 10^8$  CFU/g when stored at room temperature.

### **3.0 Impact on Human and Animal Health**

No additional data were required to assess human and animal health. Refer to ERC2007-06 for full details on the human and animal health assessment.

### **4.0 Impact on the Environment**

No additional data were required to assess environmental exposure. Refer to ERC2007-06 for full details on the environmental assessment.

### **5.0 Value**

#### **5.1 Effectiveness Against Pests**

##### **5.1.1 Acceptable Efficacy Claims for Serenade MAX**

###### **Early blight (*Alternaria solani*) on tomatoes**

The claim that Serenade MAX suppresses tomato early blight was supported at 4.5 kg/ha but additional trials were required to demonstrate consistency. Following this request, three trials on tomatoes were submitted. At an equivalent rate of 2–2.5 kg of Serenade MAX/ha, 26–42% control of early blight on tomato was obtained. The claim that Serenade MAX suppresses early blight on tomatoes is supported at the proposed rate of 4.5 kg/ha. The claim was extended to include other fruiting vegetables which are susceptible to this disease. Acceptable claims are listed in Appendix I, Table 1.

### **6.0 Formulants and Microcontaminants of Health or Environmental Concern**

Refer to ERC2007-06 for a detailed assessment.

### **7.0 Summary**

#### **7.1 Methods for Analysis of the Micro-organism as Manufactured**

The product characterization data for *Bacillus subtilis* strain QST 713 (*Bacillus subtilis* QST 713 Technical Powder), Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate and Serenade Garden Ready To Use are adequate to assess their safety to human health and the environment. The technical material was adequately characterized and the specifications were supported by the analysis of a sufficient number of batches. A method to distinguish the strain of the active ingredient from other *Bacillus subtilis* strains was proposed and found to be acceptable.

Storage stability data were sufficient to support an expiration date of one year for *Bacillus subtilis* QST 713 Technical Powder when stored at ambient temperatures. Storage stability data were submitted on one batch each of Serenade MAX, Serenade ASO/Rhapsody ASO/Serenade Garden Concentrate, and Serenade Garden Ready To Use. These data support a storage period of up to two years at 20°C for Serenade MAX and up to two years at room temperature for Serenade ASO/Rhapsody ASO/Serenade Garden Concentrate and Serenade Garden Ready To Use.

## **7.2 Human Health and Safety**

No additional data were required to assess human and animal health. Refer to ERC2007-06 for full details on the human and animal health assessment.

## **7.3 Environmental Risk**

No additional data were required to assess environmental exposure. Refer to ERC2007-06 for full details on the environmental assessment.

## **7.4 Value**

Refer to ERC2007-06 for a detailed value assessment. Additional data required for Serenade Max have been addressed. The claims of suppression of early blight on fruiting vegetables are acceptable based on the submitted scientific data.

## **8.0 Proposed Regulatory Decision**

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of *Bacillus subtilis* QST 713 Technical Powder and the following end-use products: Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate and Serenade Garden Ready To Use, containing the active ingredient *Bacillus subtilis* strain QST 713 to suppress various fungal diseases in asparagus, bushberries, caneberries, bulb vegetables, brassica (cole) crops, cucurbit vegetables, fruiting vegetables, grapes, legume vegetables, leafy vegetables, mint, pome fruits, rutabaga, turnip, radish, strawberries and ornamentals.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

**List of Abbreviations**

°C	degree(s) Celsius
CFU	colony forming unit
cm	centimetre(s)
cm <sup>3</sup>	cubic centimetre(s)
g	gram(s)
ha	hectare(s)
kg	kilogram(s)
L	litre(s)
mL	millilitre(s)
MRL	maximum residue limit
N/A	not applicable
PMRA	Pest Management Regulatory Agency
TSMP	Toxic Substances Management Policy





## Appendix I Tables and Figures

**Table 1 Supported and Unsupported Uses for Serenade MAX**

**Serenade MAX**

Applicant-proposed Label Claims	Accepted Label Claims	Unsupported Label Claims and Comments
Suppression of early blight ( <i>Alternaria solani</i> ) on tomatoes	Suppression of early blight ( <i>Alternaria solani</i> ) on Fruiting Vegetables: eggplant, ground cherry, pepino, peppers (all varieties), tomatillo and tomatoes	N/A

For information on other supported and unsupported uses, refer to ERC2007-06.



---

## References

### A. List of Studies/Information Submitted by Registrant

#### 1.0 Chemistry

PMRA Document Number: 1641783

Reference: 2004, Comparison of *Bacillus subtilis* QST 713 to Additional *Bacillus subtilis* Strains by Ribotyping Using the Enzyme PvuII, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1643517

Reference: 2008, Physico-Chemical Properties of the Formulation Serenade MAX, Data Numbering Code: M2.11 Confidential Business Information

PMRA Document Number: 1643398

Reference: 2007, Data Numbering Code: M2.11

PMRA Document Number: 1643494

Reference: 2007, Serenade Garden Disease Control Ready To Use, Data Numbering Code: M2.11 Confidential Business Information

#### 4.0 Value

PMRA Document Number: 1728698

Reference: 2008, Efficacy of Aqueous and Dried formulations of a Biofungicide (*Bacillus subtilis*, QRD 141 Serenade Max or QRD 145 Serenade ASO) Against Foliar Diseases of Tomato and Cucumber Under Greenhouse and Field Conditions, Data Numbering Code: 10.2.3.3(D)

PMRA Document Number: 1728697

Reference: Hausbek, M.K. and B.D. Cortright, 2004, Control of diseases of fresh market tomatoes with foliar sprays, 2003, Data Numbering Code: 10.2.3.3(D)

PMRA Document Number: 1728696

Reference: Zitter, T.A. and J.L. Drennan, 2002, Comparing Fungicides for early blight and late blight control in tomato, 2001, F&N Tests 57:V124, Data Numbering Code: 10.2.3.3(D)

### B. Additional Information Considered

#### Published Information

ERC2007-06: *Bacillus subtilis* strain QST 713