



BIOPESTICIDE REGISTRATION ACTION DOCUMENT
***Bacillus subtilis* Strain QST 713**
(PC Code 006479)

U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
***Bacillus subtilis* Strain QST 713**
(PC Code 006479)

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I. EXECUTIVE SUMMARY

Bacillus subtilis strain QST 713 as an active ingredient is a biological control agent for use on several minor crops to treat a variety of plant diseases and fungal pathogens including gray mold, powdery mildew, early and late blight, fire blight, scab, sour rot, bacterial spot, and walnut blight. *Bacillus subtilis* is a ubiquitous bacteria commonly found in various ecological niches including soil, water and air which does not have a history of pathogenicity from contact in the environment. In addition, there are other strains of *B. subtilis* which are registered as microbial pesticides.

The Agency has received all data that were required as a condition of registration of *Bacillus subtilis* strain QST 713 products and that were previously discussed in the original Biopesticides Registration Action Document issued on June 20, 2000.

Sufficient data are available to determine that *Bacillus subtilis* strain QST 713 has low toxicity to mammals and is not expected to be pathogenic in humans. Standard personal protective equipment is required to mitigate any risk to pesticide handlers and applicators. No significant risk is expected from the terrestrial ground, aerial, chemigation applications or post-harvest treatment with the end-use products to birds, fish, ladybird beetles, green lacewings, honey bees, parasitic wasps, and aquatic invertebrates.

The acute oral toxicity, acute dermal toxicity, acute pulmonary, acute intravenous, primary eye irritation, primary dermal irritation, and delayed contact hypersensitivity test are acceptable. The acute pulmonary study showed no mortality and no adverse effects when performed using the technical product. There was also no mortality from the acute inhalation study using the end-use product although some clinical signs and weight loss were noted. However, the acute inhalation study did not measure the actual concentration of the product in the test. Considering that the particle size of the wettable powder poses a low risk of inhalation exposure and the nature of the inerts in the product, the Agency is using the acute inhalation study as confirmatory of the acute pulmonary study and waiving the requirement for a repeated acute inhalation study. In addition, any risk is mitigated by standard personal protective equipment and the reentry interval required for the end-use products.

II. OVERVIEW

A. Product Overview

- **Microbial Pesticide Name:** *Bacillus subtilis* strain QST 713
- **Trade Name(s):** QST 713 Technical, Serenade[®], Rhapsody[®], Rhapsody[®] ASO, Serenade[®] ASO, Serenade[®] MAX[™], Serenade Biofungicide Wettable Powder, Serenade[®] AS, Serenade[®] Garden Disease Control Concentrate, and Serenade[®] Garden Disease Control Ready To Use
- **OPP Chemical Code:** 006479
- **Basic Manufacturer:** AgraQuest, Inc., 1530 Drew Ave., Davis, CA 95616

B. Use Profile

1. **Type of Pesticide:** Biological control agent, Microbial Fungicide

2. **Mechanism of action:** The bacterium, *Bacillus subtilis*, is prevalent in soils and has been found in a variety of habitats worldwide. The QST 713 strain of *B. subtilis* is known to be antagonistic toward many fungal plant pathogens. This antagonism may be achieved in several ways including nutrient competition, site exclusion, colonization, and attachment of the bacteria to the fungal pathogen. In addition, AgraQuest reports that the QST 713 strain of *B. subtilis* has been shown to induce plants' natural systemic resistance or systemic acquired resistance (SAR) against bacterial pathogens. These bacteria can stop plant pathogen spores from germinating, disrupt germ tube growth, and inhibit attachment of the plant pathogen to the leaf.

3. **Use Sites:** Terrestrial Food: almond, apples, apricot, artichoke, asparagus, avocado, bananas, barley, beans, beechnut, beets, blackberry, blueberry, brassica crops, broccoli, brussels sprouts, bulb vegetables, bushberry, butternut, cabbage, caneberry, canola, cantaloupe, carrots, cassava, cashew, castor, cauliflower, celery, cereal grains, cherry, chestnut, chick peas, citrus, coffee, collards, corm crops, corn, coconut, crabapple, cranberry, cucumber, cucurbits, currant, dry beans, eggplant, elderberry, filberts, flax, garbanzo beans, garlic, ginger, ginseng, gooseberry, grapefruit, grapes, ground cherry, herbs/spices, hops, horseradish, huckleberry, kale, kiwi, kohlrabi, leafy vegetables, legumes, lemon, lentils, lettuce, lima beans, loganberry, mango, mayhaw, melons, millets, mint, muskmelon, mustard greens, nectarines, oat, oil seed crops, oil palm, okra, olive, onions, orange, papaya, parsley, peach, peanuts, pears, peas, pecan, peppers, pineapple, pistachio, plantains, plum, pome fruit, , popcorn, pummelo, potatoes, quince, radicchio, radish, rapeseed, raspberry, rice, root/tuber, rye, safflower, seed corn, sesame,

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shallots, shell beans, silage crops, snap beans, sorghum, soybeans, spinach, split peas, squash, stone fruits, strawberry, sugar beets, sunflower, sweet corn, sweet potato, tangelo, tangerine, tomatillo, tomatoes, tree nuts, triticale, tropical fruits, turnip, walnut, watercress, watermelon, wheat Terrestrial Non-Food: field roses, forestry seedling production, lawns, ornamental flowering plants, ornamental foliage plants, ornamental trees and shrubs, seed production crops (including: blue grass, rye grass, fescue, and orchard grass), sod, tobacco, and turf.

4. Target Pests for Active Ingredient: *Alternaria* Leaf Spot, Blight and Fruit Rot (*Alternaria* spp.); Angular Leaf Spot (*Pseudomonas syringae*, *Xanthomonas fragariae*); Anthracnose (*Colletotrichum* spp.); *Aphonomyces* spp.; Asian Soybean Rust (*Phakopsora pachyrhizi*); Bacterial Blast, Blight, and Streak (*Pseudomonas syringae*, *Pseudomonas viridiflava*, *Xanthomonas* Spp.); Bacterial Fruit blotch (*Acidovorax avenaesubsp*); Bacterial Crown Rot (*Erwinia chrysanthemi*); Bacterial Leaf Blight (*Xanthomonas campestris*); Bacterial Canker (*Clavibacter michiganensis*, *Pseudomonas* spp., *Xanthomonas campestris*); Bacterial Pustule (*Xanthomonas* spp.); Bacterial Soft Rot (*Erwinia* spp., *Pseudomonas* spp.); Bacterial Speck (*Pseudomonas syringae*); Bacterial spot (*Pseudomonas syringae*, *Xanthomonas* spp.); Bean Rust (*Uromyces appendiculatus*); Black Rot (*Xanthomonas campestris*); Black Rot (*Guignardia bidwelli*); Black Root Rot/Black Crown Rot (*Alternaria* spp.); Black Spot of Rose (*Diplocarpon rosea*); Blast (*Pyricularia oryzae*); Blight (*Monilinia laxa*); Blue Mold (*Penospora hyoscyami*); Botryosphaeria Blight (*Botryosphaeria dothidea*); Botrytis Blight, Botrytis Fruit Rot, Botrytis Neck Rot, and Botrytis Leaf Blight (*Botrytis* spp.); Brown patch (*Rhizoctonia solani*); Brown Rot; Brown Rot Blossom; Brown Spot (*Monilinia* spp., *Septoria glycines*); Cercospora Leaf Spot (*Cercospora brassiacola*, *Cercospora* spp.); Coffee Berry Disease (*Colletotrichum coffeanum*); Dollar Spot (*Lanzia* spp., *Moellerodiscus*, spp. formerly *Sclerotinia homeocarpa*); Downy mildew (*Bremia lactucae*, *Peronospora* spp., *Plasmopara viticola*, *Pseudoperonospora cubensis*); Early Blight (*Alternaria solani*); Early Leaf Spot (*Cercospora arachidicola*); *Erwinia* spp.; Eutypa (*Eutypa lata*); Fire Blight (*Erwinia amylovora*); *Fusarium* spp.; Fruit Brown Rot (*Monilinia fruiticola*); Gray mold (*Botrytis cinerea*, *Botrytis* Spp.); Greasy spot (*Mycosphaerella citri*); Gummy stem blight (*Didymella bryoniae*, *Phoma curcurbitacearum*); Late Blight (*Phytophthora infestans*); Late Leaf Spot (*Cercosporidium personatum*); Leaf Rust (*Pucciniastrum vaccinii*); Leaf Spots (*Alternaria* spp., *Cercospora* spp., *Entomosporium* spp., *Helminthosporium* spp., *Myrothecium* spp., *Septoria* spp.); Melanose (*Diaporthe citri*); Mummy berry (*Monilinia vaccinii-corymbosi*); Northern Corn Leaf Blight (*Exserohilum turcium*); Olive Knot (*Pseudomonas savastanoi*); Onion Downy Mildew (*Peronospora destructor*); Onion Purple Blotch (*Alternaria porri*); Pecan Scab (*Cladosporium caryigenum*); *Phytophthora* spp.; Pin Rot (*Alternaria/Xanthomonas* complex); Pink Rot (*Sclerotinia sclerotiorum*); Phomopsis (*Phomopsis viticola*, *Phomopsis vaccinii*); *Phytophthora* spp.; Pod and Stem Blight (*Diaporthe phaseolorum* var. *sojae*, *Phomopsis longicola*); Post Bloom Fruit Drop (*Colletotrichum acutatum*); Powdery mildew (*Erysiphe* spp., *Leveillula taurica*, *Oidiopsis taurica*, *Oidium* spp., *Podosphaera* spp., *Podosphaera leucotricha*,

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Sphaerotheca spp., *Uncinula necator*); *Psuedomonas* spp.; *Pythium* spp.; *Ramularia* (*Ramularia* spp.); *Rhizoctonia* spp.; Rust (*Puccinia menthae*, *Puccinia porri*, *Puccinia* spp., *Uromyces appendiculatus*, *Uromyces betae*); Rusty Spot (*Podospaera leucotricha*); Sclerotinia, head and leaf drop (*Sclerotinia* spp.); Scab (*Cladosporium carpophilum*, *Elsinoe fawcetti*, *Sphaceloma perseae*, *Venturia* spp.); Sheath Spot and Blight (*Rhizoctonia oryzae*); Shot Hole (*Bhumeriella gaapi*, *Cercospora* spp., *Wilsonomyces carpophilus*, *Xanthomonas pruni*); Sigatoka (*Mycosphaerella* spp.); Silver Scurf (*Helmithosporium solani*) Smut (*Ceratobasidium* spp., *Cerccospora* spp., *Cochliobolus* spp., *Entyloma* spp., *Dresclera* spp., *Tilletia barclayana*); Sooty mold; Sour Rot; Southern Blight (*Scerotium rolfsii*); Southern Corn Leaf Blight (*Bipolaris maydis*, *Helminthosporium maydi*, *Cochliobolus heterostrophus*); Stem rot (*Scerotium oryzae*, *Magnaporthe* spp.) Thanatephorus kernel; Walnut blight (*Xanthomanas campestris*); Web Blotch (*Phoma arachidicola*); White Mold (*Sclerotinia sclerotiorum*); White Rot (*Scerotium cepivorum*); *Xanthomonas* Leaf spot (*Xanthomanas campestris*); and *Xanthomonas* spp.

5. Formulation Types Registered:

Type: Technical and End-Use Products

Form: 0.074% Ready to Use Spray; 1.34% Aqueous Suspension; 10% and 14.6% Wettable Powder; 14.6% Technical Powder

6. Method and Rates of Application:

Types of Treatment: Ground spray; Aerial application; chemigation; post-harvest spray

Equipment: sprinkler or drip type irrigation systems; and others not specified

Rates of Application: 1 to 10 lbs per an acre (rate varies depending on crop), number of applications unspecified

C. Regulatory History

AgraQuest Inc. Serenade[®] Biofungicide Wettable Powder and QST 713 Technical products were first registered as conditional time-limited registrations on June 20, 2000, with specific data requirements that were to be completed before these registrations could be converted to unconditional registrations. The conditional registration data requirements included storage stability, manufacturing process data, freshwater fish toxicity/pathogenicity, freshwater aquatic invertebrates toxicity/pathogenicity, 30 day toxicity/pathogenicity in *Paleomonetes vulgaris* (shrimp), non-target insect- parasitic *Hymenoptera*, and honey bee dietary toxicity/ pathogenicity data. In the Federal Register of July 5, 2000 (Volume 65, Number 129), an exemption from the requirement of a tolerance was established for residues of the microbial pesticide *Bacillus subtilis* strain QST 713 when used in or on all food commodities.

The data requirements that were specified as original conditions of registration have been

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satisfied and a complete review of these data has been completed.

III. SCIENCE ASSESSMENT

A. Physical and Chemical Properties Assessment

Product Identity:

The Agency has classified *Bacillus subtilis* strain QST 713 as a microbial pesticide. Serenade® Biofungicide Wetable Powder and QST 713 Technical contain living *Bacillus subtilis* strain QST 713 as the active ingredient. *Bacillus subtilis* is a rod-shaped, gram positive, aerobic, motile (peritrichous flagella) bacterium that is ubiquitous in nature. *Bacillus subtilis* is commonly found in various ecological niches including soil, water and air. The bacterium commonly produces proteases and other enzymes which is why strains of the bacterium are commonly used for industrial production of enzymes and other chemicals. The bacterium also can produce an endospore which allows the organism to endure extreme environmental conditions (e.g. heat, drought).

The genus *Bacillus* is a large, diverse genus of bacteria that includes species such as *thuringiensis*, *licheniformis*, *pumilis*, *cereus* and *anthracis*. Two of these species, *B. cereus* and *B. anthracis*, are known to be pathogenic to humans and animals. Because of this, the ability to differentiate species is extremely important. Biochemical tests and other tools exist which allow for the proper identification of the organism in question, *B. subtilis*. Product chemistry data that support the registration of *Bacillus subtilis* strain QST 713 are summarized in Table 1.

Table 1. Physical and Chemical Properties for *Bacillus subtilis* QST 713 Technical

OPPTS GUIDELINE Number	STUDY	RESULT	MRID#
885.1100	Product Identity and Disclosure of Ingredients	ACCEPTABLE	446517-02, 446517-04, 446517-03, 450845-01
885.1200	Manufacturing Process	ACCEPTABLE	446519-04, 452090-01 452061-01
885.1300	Formation of Unintentional Ingredients	ACCEPTABLE	446519-04, 450845-01

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OPPTS GUIDELINE Number	STUDY	RESULT	MRID#
885.1400	Analysis of Samples	ACCEPTABLE	446519-02
885.1500	Certification of Limits	ACCEPTABLE	450845-01
830.6302 830.6303 830.6304 830.7000 885.7300	Product Chemistry	ACCEPTABLE	446519-01 446519-03
830.6317	Storage Stability	ACCEPTABLE	454552-01

B. Human Risk Assessment

1. Human Toxicity Assessment

The acute oral toxicity, acute dermal toxicity, acute pulmonary, acute intravenous, primary eye irritation, primary dermal irritation, and delayed contact hypersensitivity test are acceptable. The acute pulmonary study showed no mortality and no adverse effects when performed using the technical product. There was also no mortality from the acute inhalation study using the end-use product although some clinical signs and weight loss were noted. However, the acute inhalation study did not measure the actual concentration of the product in the test. Considering that the particle size of the wettable powder poses a low risk of inhalation exposure and the nature of the inerts in the product, the Agency is using the acute inhalation study as confirmatory of the acute pulmonary study and waiving the requirement for a repeated acute inhalation study. In addition, any risk is mitigated by standard personal protective equipment and the reentry interval required for the end-use product.

Table 2. Toxicity Data Requirements

OPPTS GUIDELINE NUMBER	STUDY	RESULT	MRID#
885.3050	Acute Oral Toxicity/ Pathogenicity	Acceptable , Toxicity Category IV	446519-06

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OPPTS GUIDELINE NUMBER	STUDY	RESULT	MRID#
885.3100	Acute Dermal Toxicity/ Pathogenicity	LD ₅₀ of <i>QST 713 Technical</i> in rats is >2g /kg body weight. Acceptable , Toxicity Category III	446519-07
885.3150	Acute Pulmonary Toxicity/ Pathogenicity	Acceptable. No mortality and no adverse effects. The test microbe was detectable (both pre- and post- heat treatments) in the lung through day 35, but at significantly reduced levels compared to day 0.	446519-09
870.1300	Acute Inhalation (End-Use Product WP)	Study considered confirmatory for the acute pulmonary study. Some clinical signs and weight loss were noted, but no mortality resulted from dosing. The actual concentration was not determined. Normally, particles the size of those measured for QST 713 wettable powder pose a low risk of inhalation exposure. Study results could be enhanced with analytical data indicating the actual concentration used in dosing. Potential risk is mitigated by protective clothing requirements of a dust/mist filtering respirator and the reentry interval.	446527-05

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OPPTS GUIDELINE NUMBER	STUDY	RESULT	MRID#
885.3200	Acute Intravenous Toxicity/Pathogenicity	Acceptable. No mortality and no adverse clinical signs in rats dosed with QST 713 Technical powder. The test microbe cleared from most organs by day 35; however, low levels were detected in the spleen and liver after 35 days.	446519-08
870.2400	Primary Eye Irritation	Acceptable, Toxicity Category III	446646-02
870.2500	Primary Dermal Irritation	Acceptable, Toxicity Category IV	446646-01
870.2600	Delayed Contact Hypersensitivity in Guinea Pigs (QST 713 Wettable Powder)	Acceptable - QST 713 WP product elicited a very mild delayed hypersensitivity response. Potential dermal sensitizer.	446647-05

2. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

A battery of tests determined that QST 713 Technical product is not pathogenic and has no significant toxicity. The acute oral toxicity/pathogenicity, acute pulmonary toxicity/pathogenicity, and acute intravenous toxicity/ pathogenicity studies demonstrated no significant toxicity and a lack of pathogenicity. The dermal toxicity and eye irritation studies resulted in a Toxicity Category III classification. The acute dermal irritation study resulted in a Toxicity Category IV classification. *Bacillus subtilis* is a ubiquitous organism in the environment and there have been no reports of the organism affecting the immune system. The submitted toxicity/pathogenicity studies in rodents with *Bacillus subtilis* strain QST 713 indicated that following several routes of exposure, the immune system is still intact and able to process and clear the active ingredient. As would be expected for any microbial pesticide, QST

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713 did elicit a very mild delayed hypersensitivity response and is considered a potential dermal sensitizer. Further, the *Bacillus subtilis* species is known to produce the enzyme subtilisin which has been reported to produce allergenic or hypersensitivity reactions to individuals repeatedly exposed to the enzyme in industrial settings. However, it is not known whether strain QST 713 produces this enzyme. The use of personal protective equipment required for applicators and other handlers mitigates the hypersensitivity risk by minimizing exposure. No hypersensitivity risk is expected for dietary exposure due to the low likelihood that any significant residues will occur on treated food.

3. Aggregate Exposures

In examining aggregate exposure, FFDCFA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

a. Dietary Exposure

Dietary exposure to the microbial pesticide is likely to occur. However the lack of acute oral toxicity/pathogenicity and the ubiquitous nature of the microbe support the establishment of an exemption from the requirement of a tolerance for *Bacillus subtilis* strain QST 713.

1) *Food*. Dietary exposure to the microbe is expected to be minimal. The risk posed to adults, infants and children is minimal because of the low acute oral toxicity/pathogenicity potential of the microbial pesticide. In addition, standard practices of washing, peeling, cooking or processing fruits and vegetables reduces residues of *Bacillus subtilis* strain QST 713 and further minimizes dietary exposure.

2) Drinking water exposure. Oral exposure, at very low levels, may occur from ingestion of drinking water. Drinking water is not being screened for *Bacillus subtilis* strain QST 713 as a potential indicator of microbial contamination. Both percolation through soil and municipal treatment of drinking water would reduce the possibility of exposure to the bacterial active ingredient through drinking water. If oral exposure should occur through drinking water, the Agency concludes that such exposure would present insignificant risk due to the lack of acute oral toxicity/pathogenicity and the ubiquitous nature of the microbe.

b. Other Non-Occupational Exposure

The use sites for these products includes residential garden sites, as well as agricultural sites. *Bacillus subtilis* presence is ubiquitous in the environment. Based on evaluations of the Tier I acute toxicity tests, the Agency believes that the potential aggregate non-occupational risk derived from dermal and inhalation exposure through the application of *Bacillus subtilis* strain QST 713 fall below the currently tested microbial safety levels.

4. Cumulative Effects

No mechanism of toxicity in mammals has been identified for *Bacillus subtilis* strain QST 713. Therefore, no cumulative effect with other related organisms is anticipated. Because the data available demonstrate a low toxicity/pathogenicity potential of the active ingredient, the likelihood of adverse dietary effects is expected to be minimal.

5. Determination of Safety for U.S. Population, Infants and Children

FFDCA section 408(b)(2)(C) as amended by the Food Quality Protection Act (FQPA) of 1996, provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) also provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children.

Based on the acute toxicity information discussed above, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to the United States population, including infants and children, to residues of *Bacillus subtilis* strain QST 713. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because the data available on *Bacillus subtilis* strain QST 713 demonstrate a low toxicity/pathogenicity potential. *Bacillus subtilis* is not a human pathogen and has not been implicated in human disease, but has been isolated as a rare contaminant from human infections. Thus, there are no threshold effects of concern and, as a result, the provision requiring an additional margin of safety does not apply. Further, the considerations of consumption patterns, special susceptibility, and cumulative effects do not apply to pesticides without a demonstrated significant adverse effect.

6. Other Considerations

a. Endocrine Disruptors

EPA is required under section 408(p) of the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there is no scientific basis for including,

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as part of the screening program, the androgen and thyroid hormone systems in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, *Bacillus subtilis* strain QST 713 may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

The Agency has no information to suggest that *Bacillus subtilis* strain QST 713 has an effect on the endocrine system. No specific tests have been conducted with *Bacillus subtilis* strain QST 713 to determine such effects. However, the submitted toxicity/pathogenicity studies in rodents indicated that following several routes of exposure, the immune system is still intact and able to process and clear the active ingredient. *Bacillus subtilis* strain QST 713 is a ubiquitous organism in the environment and there have been no reports of the organism affecting endocrine systems. Therefore, it is unlikely that this organism would have estrogenic or endocrine effects because it is practically non-toxic to mammals.

b. Analytical Method(s)

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation; therefore, the Agency has concluded that an analytical method is not required for enforcement purposes for *Bacillus subtilis* strain QST 713.

C. Environmental Assessment

1. Environmental Fate

Bacillus subtilis is common in soil and plant litter without documented toxicity or pathogenicity in the environment. When *B. subtilis* was used as a tracer in ground water studies it was noted that it moves faster than rhodamine WT dye in an alluvial gravel aquifer. *Bacillus subtilis* endospores are reported as having longevity in ground water (Pang, L; Close, M. and; Noonan, M; 1998).

2. Ecological Toxicity

Following ecological effects data requirements listed in 40 CFR Part 158 for microbial pesticides, studies were conducted on birds, fish, non-target insects, aquatic invertebrates, grass shrimp, and non-target plants using *B. subtilis* strain QST 713. As described below, QST 713 was determined to be practically non-toxic to bobwhite quail and the risk quotients for fish were far below the levels of concern. Exposure to aquatic sites and organisms (fish and aquatic invertebrates) are minimal to non-existent. There are no aquatic use sites. No phytotoxicity was reported at the specified label rates. *Bacillus subtilis* is a very well studied microorganism and no evidence of fish or aquatic invertebrate toxicity or pathogenicity was found in published literature.

No significant risk is expected from the terrestrial ground, aerial, and chemigation application of the end-use product of *B. subtilis* strain QST 713 to birds, fish, ladybird beetles, green lacewings, parasitic wasps, honey bees, and aquatic invertebrates.

TABLE 3. RESULTS OF NON-TARGET STUDIES

GRN	MRID #	Study	Status, Classification & Comments
885.4050	446519-10	Avian Oral LD ₅₀ (Quail)	The avian oral LD ₅₀ is greater than 5000 mg/kg body weight. QST 713 Technical containing <i>B. subtilis</i> strain QST 713 is considered practically non-toxic to bobwhite quail due to the high dose used and the effects observed. CLASSIFICATION: Acceptable.
154-17		Avian Injection test	Not required since <i>B. subtilis</i> is not related to any known bird pathogens and signs of pathogenicity were not demonstrated in the avian oral study.

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GRN	MRID #	Study	Status, Classification & Comments
885.4200	454552-02	Freshwater Fish Toxicity/ Pathogenicity	The 30-Day LC ₅₀ in rainbow trout was calculated as 1.4×10^7 cfu/ mL. <i>B. subtilis</i> QST 713 in water given concurrently in feed. The no mortality and no observed adverse effect level was 1.7×10^6 cfu/ mL. Since the observed adverse effects were > 10X the Maximum Hazard Dose of 10^6 cfu/mL, no hazard to freshwater fish populations is expected from terrestrial application of QST 713 at the current label use rates [maximum label application rate of 10 lb/acre]. CLASSIFICATION: Acceptable
885.4240	454552-03	21-Day Freshwater Aquatic Invertebrate Toxicity/ Pathogenicity	The 21-Day EC ₅₀ for neonate cladocerans (<i>Daphnia magna</i>) is calculated as 1.6×10^6 cfu/mL <i>Bacillus subtilis</i> QST 713 and the no observed adverse effect level is 7.9×10^5 cfu/mL. Since the EC ₅₀ is above the required maximum hazard test dose of 10^6 cfu /mL, no hazard to aquatic invertebrate populations is expected from terrestrial application of QST 713 at the current label use rates [maximum label application rate of 10 lb/acre]. CLASSIFICATION: Acceptable

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GRN	MRID #	Study	Status, Classification & Comments
885.4280	454552-04	Estuarine and Marine Animal Testing	<p>There was no reported mortality, abnormal physical appearance or behaviour observed in grass shrimp over the 30-day test period. The 30-day LC₅₀ for grass shrimp is > 3.7 x 10⁶ cfu/g QST 713 in feed; 100X the estimated environmental concentration (EEC) at the maximum label application rate of 10 lbs/acre. Since the LC₅₀ is above the required maximum hazard test dose of 10⁶ cfu/ mL, no hazard to estuarine animal populations is expected from terrestrial application of QST 713 at the current label use rates.</p> <p>CLASSIFICATION: Acceptable</p>
885.4300	None	Non-Target Plant Study	<p>This data requirement is waived because a review of scientific literature does not indicate that <i>Bacillus subtilis</i> is a common pathogen or phytotoxic agent.</p>

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GRN	MRID #	Study	Status, Classification & Comments
885.4340	446519-16	Non-Target Insect Study-Green Lacewing	The study is acceptable and fulfills the guideline requirement. The mortalities observed were not treatment related and the LC ₅₀ was greater than 60,000 ppm. However, due to decreased pupation, the no observed effect concentration (NOEC) was 600 ppm (1.2×10^7 CFU/g). CLASSIFICATION: Acceptable.
885.4340	446519-15	Non-Target Insect Study -Ladybird Beetle	The study is acceptable and fulfills the guideline requirement. The mortalities observed were not treatment related and the LC ₅₀ was greater than 60,000 ppm. The no observed effect concentration (NOEC) was 60,000 ppm (1.2×10^9 CFU/mL). CLASSIFICATION: Acceptable.
885.4340	454552-05	Non-Target Insect Study -Parasitic Hymenoptera	The calculated 10-day LC ₅₀ for parasitic Hymenoptera to <i>Bacillus subtilis</i> strain QST 713 was 24,739 ppm (1.3×10^9 CFU/mL). This is 351X the maximum hazard dose of 3.7×10^6 CFU/mL . As a result, no hazard to parasitic hymenoptera is expected from the current uses of <i>Bacillus subtilis</i> strain QST 713. CLASSIFICATION: Acceptable

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GRN	MRID #	Study	Status, Classification & Comments
885.4380	461729-02	Honey bee Dietary Toxicity/ Pathogenicity	There were no behavioral or morphological abnormalities seen in any of the treatments in the two studies conducted through total adult honey bee emergence (22 and 24 days). Since the LD ₅₀ > 100,000, which represents an application rate of 400X and >800X the EEC, no hazard to honey bees is expected from terrestrial application of QST 713 at the current label use rates. CLASSIFICATION: Acceptable

3. Non-target Wildlife Testing and Hazard Assessment

a. Avian

The avian oral LD₅₀ is greater than 5000 mg/kg body weight. QST 713 Technical containing *B. subtilis* strain QST 713 is considered practically non-toxic to bobwhite quail. The toxicity at the high dose administered was the cause for the 1 bird mortality and the 7 birds that exhibited signs of clinical toxicity (MRID 446519-10). The data requirement is satisfied for bobwhite quail. The mallard study (for guideline 885.4050) is waived based on the lack of avian pathogenicity in the literature and the limited toxicity observed in the quail study.

b. Freshwater Fish

A study was done to evaluate the toxic and pathogenic effects of QST 713 Technical on the rainbow Trout (*Oncorhynchus mykiss*) during a 30 day exposure period under static renewal condition (MRID 454552-02). No signs of pathogenicity were observed in any QST 713 Technical treatment group. *Bacillus subtilis* QST 713 was not recovered from gills, intestines, or muscle of necropsied fish indicating lack of pathogenicity. After 30 days of exposure, there was 100 percent mortality in the highest technical treatment group (3.68 X 10⁷ CFU/mL). The 30-Day LC₅₀ was determined to be 1.4 X 10⁷ CFU/mL. No mortalities or adverse effects were noted at 1.7 X 10⁶ CFU/mL. Mortality of *O. mykiss* exposed to the attenuated control at a concentration equal to the highest QST 713 Technical group was also 100 percent. Therefore, the observed mortalities were not due to pathogenicity, but to toxicity or fouling of the test solution with high concentrations of cellular material (present in the test system at >10X the maximum hazard test dose or 1,000X the application rate). Since the observed adverse effects are >10X above the maximum hazard test dose of 10⁶ CFU/mL for direct aquatic applications, no hazard to freshwater fish populations is expected from terrestrial uses of QST 713 at the

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proposed label use rates (maximum label application rate of 10 lb/acre). Aerial drift which is estimated to be no higher than 10% of the terrestrial application rate would result in an additional 10-fold reduction in exposure to freshwater fish populations.

Conclusion

A hazard assessment based on a study performed to evaluate the toxic and pathogenic effects of QST 713 Technical on the rainbow trout (*Oncorhynchus mykiss*) during a 30-day exposure period shows that no hazard to freshwater fish populations is expected from terrestrial application of the product at the current label use rates.

c. Freshwater Aquatic Invertebrate

The 21-Day EC50 for neonate cladocerans (*Daphnia magna*) is calculated as 1.6×10^6 CFU/mL *Bacillus subtilis* QST 713 and the no observed adverse effect level is 7.9×10^5 CFU/mL. Both lower dissolved oxygen and toxic effects not associated with pathogenicity contributed to mortality at the highest test dose (1,000 X EEC). Since the EC50 is above the maximum hazard test dose of 10^6 CFU/mL, no hazard to aquatic invertebrate populations is expected from terrestrial application of QST 713 at the proposed label use rates (maximum label application rate of 10 lb/acre). Aerial drift from terrestrial use applications which is estimated to be no higher than 10% of the application rate, would further reduce exposure to aquatic invertebrates. (MRID 454552-03).

d. Estuarine and Marine Animal Testing

Data to determine potential pathogenicity of *B. subtilis* QST 713 to grass shrimp (*Palaemonetes pugio*) has been submitted to the Agency and are summarized herein. *P. pugio* was used as the test species instead of *P. vulgaris* due to seasonal availability and upon agreement with the EPA as to the sympatry of these species. There was no reported mortality, or abnormal physical appearance (lesions or necroses) or behavior observed in grass shrimp over the 30-day test period. There was no noticeable difference in mean length or weight between treatments at test termination. The rates incorporated into feed were 3.7×10^6 cfu/g. The 30-day LC₅₀ was $> 3.7 \times 10^6$ cfu/g QST 713 in feed. This dosage represents 100X the Expected Environmental Concentration (EEC) at the maximum label application rate of 10 lbs/acre. Since the LC₅₀ is above the required maximum hazard test dose of 10^6 CFU/mL, no hazard to estuarine animal populations is expected from terrestrial application of QST 713 at the proposed label use rates. Aerial drift which is estimated to be no higher than 10% of the terrestrial use application rate would further reduce exposure to estuarine animals. (MRID 454552-04)

e. Non-Target Plants

This data requirement is waived because a review of scientific literature does not indicate that *Bacillus subtilis* is a common pathogen or phytotoxic agent. In addition, AgraQuest reported (5/12/99 facsimile) no phytotoxicity when Serenade[®] was applied as a foliar spray to the following crops in various countries: almonds, crookneck and acorn squash, watermelon, mushroom, nectarine, peanut, pistachio, potato, strawberry, and tomato. A minimal amount of foliar marginal necrosis and berry scarring was reported at an application rate of 17 lbs/acre of Serenade[®] on grapes. However, no phytotoxicity in grapes was observed at the current label rate of 8 lbs. The registrant is to inform the Agency of any incidents of damage to crops or non-target plants as a result of registered uses of Serenade[®] for further hazard evaluation.

f. Non-Target Insects

i. Green lacewing

After QST Technical treatment, the mortalities observed were not treatment related and the LC₅₀ was greater than 60,000 ppm. However, due to decreased pupation, the no observed effect concentration (NOEC) was 600 ppm (1.2×10^7 CFU/g). The LOEC was 6000 ppm or 24 times the EEC of 250 ppm. The data requirement is satisfied. The risk to green lacewing from the use of the end-use product Serenade[®] is not considered significant. (MRID 446519-16)

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ii. Ladybird beetle

The study is acceptable and fulfills the guideline requirement. The mortalities observed were not treatment related and the LC₅₀ was greater than 60,000 ppm. The no observed effect concentration (NOEC) was 60,000 ppm (1.2×10^9 CFU/mL). Data requirement is satisfied. The risk to ladybird beetles from the use of the end-use product Serenade® is not considered significant at registered field use rates. (MRID 446519-15)

iii. Parasitic Hymenoptera

Data to determine potential pathogenicity of *B. subtilis* QST 713 to parasitic Hymenoptera has been submitted to the Agency and are summarized herein. The calculated 10-day LC₅₀ for parasitic Hymenoptera (*N. vitripennis*) to *B. subtilis* strain QST 713 was 24,739 ppm [1.3×10^9 cfu/ mL], which is 351X the maximum hazard dose of 3.7×10^6 CFU/mL. The no observed effect concentration was 1730 ppm [9.1×10^7 CFU/mL], 25X the maximum hazard dose. No signs of disease process were seen at the maximum hazard level and there were no significant differences from the negative control group. As a result, no hazard to parasitic hymenoptera is expected from the proposed uses of *Bacillus subtilis* strain QST 713. (MRID 454552-05).

iv. Honey Bee

Data requested by EPA to determine potential pathogenicity of *B. subtilis* QST 713 to honey bees has been submitted to the Agency and are summarized herein. (MRID 461729-02) The dietary whole hive study consisted of a non-replicated range-finding assay and two replicated studies.

In the first study, no behavioral or morphological abnormalities were seen in any of the treatments and there were no statistically significant differences in survival to adult emergence among the dietary treatments [100,000 ppm test material -65%; 10,000 ppm test material -66.35%; 1000 ppm test material -81.25%; larval bee diet (LBD) stock solution control -95%, positive control (5 ppm dimethoate) -96.25%; and an untreated control (mapped only) -83.75%].

The second study was conducted to confirm that the low dosage of the positive control administered in the first study (5 ppm) was responsible for the high rate of survival of honey bees rather than a lack of ingestion of the control. There were no behavioral or morphological abnormalities seen in any of the treatments in the two studies conducted until total adult honey bee emergence (22 and 24 days). Honey bee survival to emergence in the 100,000 ppm group in the second study was 52.5%, significantly lower than that of the larval bee diet (LBD) control and

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the untreated control.

An analysis of the pooled mean data shows that honey bee survival in the 100,000 ppm test material treatments was 61.67% [LD₅₀: >100,000 ppm]. Estimated environmental concentrations (EECs) for the technical grade active ingredient with a single application (at the use rate of 10 lb/acre) via the Kenaga nomogram (based on the most appropriate substrates for a honey bee assessment - leaves and leafy crops and forage, alfalfa, clover) are 250 ppm and 115 ppm, respectively. Since the LD₅₀ is >100,000 ppm, which represents an application rate 400X and 800X the EEC, no hazard to honey bees is expected from terrestrial application of QST 713 at the current label use rates.

4. Endangered Species Considerations:

The non-target data reviewed by the Agency and information from open literature indicate that *Bacillus subtilis* is not harmful to terrestrial or aquatic plants and wildlife at the proposed label use rates. However, there is an unconfirmed report from New Zealand of *B. subtilis* toxicity to terrestrial amphipods, but the methods used to identify the implicated agent as *B. subtilis* were preliminary and were not confirmed. Nevertheless the Agency looked for related endangered species and noted that there are 3 aquatic amphipods currently listed as endangered in the US: the Hay's Spring Amphipod (likely to occur in the District of Columbia), the Illinois Cave Amphipod (likely to occur in Monroe County, Illinois), and the Peck's Cave Amphipod (likely to occur in Comal County, Texas). The Agency then examined the toxicity/pathogenicity data on a related estuarine animal, the grass shrimp, to ascertain any possible adverse effects. There was no reported mortality, abnormal physical appearance (lesions or necroses) or behavior observed in grass shrimp over the 30-day test period. Therefore, the endangered amphipod species are not expected to be affected by the uses of QST 713 strain of *B. subtilis* because of the lack of adverse effects on the grass shrimp, the most closely related animal tested. Also, direct exposure of the endangered amphipod species is unlikely by the registered terrestrial use of *B. subtilis* strain QST 713. As a result of these analyses, the Agency concludes that there is no "may effect" finding to endangered/threatened species from the proposed uses of *B. subtilis* strain QST 713 because this strain has not been identified as toxic or pathogenic to any species listed by the United States Fish and Wildlife Service (USFWS) and the National Oceanic & Atmospheric Administration (NOAA).

IV. RISK MANAGEMENT AND REGISTRATION DECISION

A. Determination of Eligibility

Section 3(c)(5) of FIFRA provides for the registration of new active ingredients if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (C) it will perform its intended function without unreasonable adverse effects on the environment; and (D) when used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment.

To satisfy criterion "A" above, *Bacillus subtilis* strain QST 713 has well known properties. The Agency has no knowledge that would contradict the claims made on the label of this product.

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Criterion "B" is satisfied by the current label and by the data presented in this document. It is believed that this new pesticidal active ingredient will not cause any unreasonable adverse effects, is a broad spectrum microbial fungicide, and provides protection as claimed, satisfying criterion "C." Criterion "D" is satisfied in that *Bacillus subtilis* strain QST 713 is not expected to cause unreasonable adverse effects when used according to label instructions.

Therefore, *Bacillus subtilis* strain QST 713 is eligible for registration. The uses are listed in the Section II, B. Use Profile. There are no ineligible uses for *Bacillus subtilis* strain QST 713.

B. Regulatory Position

1. Unconditional Registration

The data requirements are fulfilled and the Biopesticides and Pollution Prevention Division recommends unconditional registration of products that contain *Bacillus subtilis* strain QST 713 as the sole Active ingredient: Serenade[®] Biofungicide Wettable Powder, QST 713 Technical, Serenade[®], Serenade[®] AS, Rhapsody[®] AS, Serenade[®] MAX[™], Serenade[®] ASO, Serenade[®] Garden Disease Control Ready to Use, Serenade[®] Garden Disease Control Concentrate and Rhapsody[®] ASO.

2. Tolerances for Food Uses and /or exemptions

On July 5, 2000, (FR Volume 65, Number 129) EPA issued a notice establishing an exemption from the requirements of a tolerance for residues of *Bacillus subtilis* strain QST 713 in or on all food commodities.

3. CODEX Harmonization

There are no CODEX values for *Bacillus subtilis* strain QST 713.

4. Risk Mitigation

To mitigate any risk to pesticide handlers and applicators, standard personal protective equipment are required, including: long sleeved shirt and long pants; waterproof gloves; shoes plus socks; dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE filter; and a Restricted-entry Interval (REI) of 4 hours are required to mitigate occupational exposure and risk to pesticide handlers.

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5. Endangered Species Statement

The Agency concludes that there is no “may effect” finding to endangered/threatened species from the proposed uses of *B. subtilis* strain QST 713 because this strain has not been identified as toxic or pathogenic to any species listed by the Services (USFWS and NOAA). As a result there is no requirement for an endangered species labeling statement.

C. Labeling Rationale

1. Human Health Hazard [Worker Protection Standard (WPS)and non-WPS]

Bacillus subtilis strain QST 713 products with commercial use sites are subject to the Worker Protection Standard (WPS). Because of the low toxicity of *Bacillus subtilis* strain QST 713, the REI for uses within the scope of WPS is 4 hours. Precautionary statements and personal protective equipment as specified below are required based on the acute toxicity categories of this organism.

2. Environmental Hazard

Precautionary labeling is required as indicated below.

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V. ACTIONS REQUIRED BY REGISTRANTS

A. Precautionary Labeling

Bacillus subtilis strain QST 713 products that are within the scope of WPS must include the following statements under the heading “Precautionary Statements”:

Personal Protective Equipment/ (PPE) required for Applicators and other handlers must wear:

Long sleeved shirt and long pants. Waterproof gloves. Shoes plus socks. Dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with any N, P, R, or HE filter.”

WPS labels must state the following under the heading “User Safety Recommendations”

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. If gloves are worn, wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

B. Environmental Hazards Labeling

Provided the following statements are placed into the environmental hazards statement, the risk of *Bacillus subtilis* strain QST 713 is minimal to nonexistent to non-target organisms including endangered species.

1. End-Use Product Environmental Hazards Labeling

" Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate."

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2. Manufacturing-Use Product Environmental Hazards Labeling

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

3. Application Rate

It is the Agency's position that the labeling for the pesticide products containing *Bacillus subtilis* strain QST 713 as the active ingredient complies with the current pesticide labeling requirements. The Agency has not required a maximum number of applications per season of this active ingredient. However, the maximum application rate is 10 lbs/acre.

C. Labeling

Some of the essential label requirements are highlighted below.

Signal word for the currently registered products is "Caution," based on Toxicity Category III. The product labels shall contain the following information:

- Product Name
- Ingredient Statement
- Registration Number
- Precautionary Statements
- "Keep Out of Reach of Children"
- Signal Word (CAUTION)
- Personal Protective Equipment (PPE) Requirements
- Environmental Hazard Statement
- Storage and Disposal Statement
- Agricultural Use Requirements
- Directions for Use

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MRID: 44651701

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MRID: 44651702

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MRID: 44651903

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MRID: 44651912

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MRID: 44652004

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MRID: 44652005

Citation: Harrington, K. (1998) Toxicity/Pathogenicity Testing of QST 713 Following Acute Intratracheal Challenge in Rats: Lab Project Number: L08726SN6. Unpublished study prepared by IIT Research Institute. 137 p. {OPPTS 885.3150}

MRID: 44652006

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Citation: Hoxter, K.; Krueger, H.; Palmer, S. (1998) A Dietary Pathogenicity and Toxicity Study with the Honey Bee (*Apis mellifera*): (QST 713): Lab Project Number: 189-102C. Unpublished study prepared by Wildlife International Ltd. 22 p. {OPPTS 885.4380}

MRID: 44652011

Citation: Hoxter, K.; Krueger, H.; Palmer, S. (1998) A Dietary Pathogenicity and Toxicity Study with the Parasitic Hymenoptera (*Nasonia vitripennis*): (QST

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713): Lab Project Number: 489-105A. Unpublished study prepared by Wildlife International Ltd. 21 p. {OPPTS 885.4340}

MRID: 44652012

Citation: Hoxter, K.; Krueger, H.; Palmer, S. (1998) A Dietary Pathogenicity and Toxicity Study with the Ladybird Beetle (*Hippodamia convergens*): (QST 713): Lab Project Number: 489-103B. Unpublished study prepared by Wildlife International Ltd. 24 p. {OPPTS 885.4340}

MRID: 44652013

Citation: Hoxter, K.; Krueger, H.; Palmer, S. (1998) A Dietary Pathogenicity and Toxicity Study with the Green Lacewing Larvae (*Chrysoperia carnea*): (QST 713): Lab Project Number: 489-104. Unpublished study prepared by Wildlife International Ltd. 17 p. {OPPTS 885.4340}

MRID: 44664500

Citation: AgraQuest, Inc. (1998) Submission of Toxicity Data in Support of the Application for Registration of Serenade WP Biofungicide. Transmittal of 7 Studies.

MRID: 44664501

Citation: Mallory, V. (1998) Acute Oral Exposure Toxicity Study in Rats with QST 713 WP: Final Report: Lab Project Number: 0402XA54.001. Unpublished study prepared by Chrysalis. 26 p.

MRID: 44664503

Citation: Mallory, V. (1998) Primary Dermal Irritation in Rabbits with QST 713 WP: Final Report: Lab Project Number: 0420XA54.003. Unpublished study prepared by Chrysalis. 26 p.

MRID: 44664504

Citation: Mallory, V. (1998) Primary Eye Irritation in Rabbits with QST 713 WP: Final Report: Lab Project Number: 0421XA54.003. Unpublished study prepared by Chrysalis. 30 p.

MRID: 44664505

Citation: Mallory, V. (1998) Delayed Contact Hypersensitivity in Guinea Pigs with QST 713 WP: (Buehler Method): Final Report: Lab Project Number: 0424XA54.001. Unpublished study prepared by Chrysalis. 40 p.

MRID: 44664506

Citation: Mallory, V. (1998) Primary Eye Irritation in Rabbits with QST 713 TP: Final Report: Lab Project Number: 0421X54.004. Unpublished study prepared by Chrysalis. 28 p.

MRID: 44664507

Citation: Mallory, V. (1998) Primary Dermal Irritation in Rabbits with QST 713 TP: Final Report: Lab Project Number: 0420XA54.004. Unpublished study prepared by Chrysalis. 25 p.

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MRID: 44664600

Citation: AgraQuest, Inc. (1998) Submission of Toxicity Data in Support of the Application for Registration of QST 713 Technical. Transmittal of 2 Studies.

MRID: 44664601

Citation: Mallory, V. (1998) Primary Dermal Irritation in Rabbits with QST 713 TP: Final Report: Lab Project Number: 0420XA54.004. Unpublished study prepared by Chrysalis. 16 p.

MRID: 44664602

Citation: Mallory, V. (1998) Primary Eye Irritation in Rabbits with QST 713 TP: Final Report: Lab Project Number: 0421XA54.004. Unpublished study prepared by Chrysalis. 16 p.

MRID: 44884800

Citation: AgraQuest, Inc. (1999) Submission of Toxicity Data in Support of the Registration of Serenade WP BioFungicide, and QST 713 Technical Powder, and the Petition for Tolerance of Serenade. Transmittal of 1 Study.

MRID: 44884801

Citation: Drottar, K.; Krueger, H. (1999) *Bacillus subtilis*: A Five-Concentration Toxicity and Pathogenicity Test with the Rainbow Trout (*Oncorhynchus mykiss*): Final Report: Lab Project Number: 498A-101. Unpublished study prepared by Wildlife International Ltd. 38 p. {OPPTS 885.4200}

MRID: 44892300

Citation: AgraQuest (1999) Submission of Product Chemistry Data in Support of the Application for Registration of Serenade WP Biofungicide. Transmittal of 1 Study.

MRID: 44892301

Citation: Bellet, E. (1999) Manufacturing and Analytical Data for Serenade WP. Unpublished study prepared by Chemical Consultants International, Inc. 54 p. {OPPTS 885.1100, 885.1200, 885.1300, 885.1400, 885.1500, 885.1600}

MRID: 44894400

Citation: Agra Quest (1999) Submission of Product Chemistry Data in Support of the Application for Registration of Serenade WP Biofungicide. Transmittal of 1 Study.

MRID: 44894401

Citation: Bellet, E. (1999) Manufacturing and Analytical Data for Serenade WP. Unpublished study prepared by Chemical Consultants International, Inc. 57 p. {OPPTS 885.1200, 885.1300, 885.1400, 885.1500}

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MRID: 44907100

Citation: AgraQuest Inc. (1999) Submission of Product Chemistry Data in Support of the Petition for Tolerance of the QST 713 Technical Containing Product Serenade WP. Transmittal of 1 Study.

MRID: 44907101

Citation: Gingras, B. (1999) Storage Stability of Technical QST 713: Final Report: Lab Project Number: L08726 SN2. Unpublished study prepared by IIT Research Institute. 18 p.

MRID: 45084500

Citation: Agraquest, Inc. (2000) Submission of Product Chemistry Data in Support of the Application for Registration of QST 713 Technical and Serenade WP Biofungicide. Transmittal of 1 Study.

MRID: 45084501

Citation: Fox, J. (2000) Manufacturing Process and Discussion of Blending and Concentrating for Serenade WP Biofungicide. Unpublished study prepared by Agraquest, Inc. 19 p.

MRID: 45165400

Citation: AgraQuest, Inc. (2000) Submission of Product Chemistry Data in Support of the Application for Registration of Serenade Organic. Transmittal of 1 Study.

MRID: 45165401

Citation: Fox, J. (2000) Product Chemistry of Serenade Organic. Unpublished study prepared by AgraQuest, Inc. 40 p. {OPPTS 885.1100, 885.1200, 885.1300, 885.1400, 885.1500, 830.1800, 830.6302, 830.6303, 830.6304, 830.6313, 830.6315, 830.6317, 830.7300}

MRID: 45188100

Citation: AgraQuest, Inc. (2000) Submission of Product Chemistry Data in Support of the Registration of QST 713. Transmittal of 1 Study.

MRID: 45188101

Citation: Gingras, B. (1999) Storage Stability of QST 713 Strain of Dried *Bacillus Subtilis* with Residual Fermentation Media Identified as QST 713 WP: (Interim Report): Lab Project Number: L08726 SN9: L08726. Unpublished study prepared by IIT Research Institute. 22 p. {OPPTS 830.6317}

MRID: 45206100

Citation: AgraQuest, Inc. (2000) Submission of Product Chemistry Data in Support of the Registration of QST 713 Technical Powder. Transmittal of 1 Study.

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Biopesticide Registration Action Document

MRID: 45206101

Citation: Hilbig, L. (2000) Manufacturing Process Amendment for QST 713 Technical Powder. Unpublished study prepared by AgraQuest, Inc. 23 p. {OPPTS 885.1200, 885.1400}

MRID: 45209000

Citation: AgraQuest, Inc. (2000) Submission of Product Chemistry Data in Support of the Registration of Serenade Biofungicide Wettable Powder. Transmittal of 1 Study.

MRID: 45209001

Citation: Cunningham, L. (2000) Manufacturing Process Amendment for Serenade Biofungicide Wettable Powder. Unpublished study prepared by AgraQuest, Inc. 39 p. {OPPTS 885.1200, 885.1400}

MRID: 45234600

Citation: AgraQuest, Inc. (2000) Submission of Toxicity Data in Support of the Registration of Serenade Fungicide Wettable Powder. Transmittal of 1 Study.

MRID: 45234601

Citation: Mayer, D. (2000) Honey Bee Field Study of Serenade Biofungicide Wettable Powder in Alfalfa. Unpublished study prepared by Washington State University. 59 p. {OPPTS 850.3040}

MRID: 45327500

Citation: AgraQuest, Inc. (2001) Submission of Product Chemistry Data in Support of the Registration of Serenade. Transmittal of 1 Study.

MRID: 45327501

Citation: Hilbig, L.; Czocho, L. (2001) Response to US EPA Review of Serenade Organic Product Chemistry Original Report Reference: MRID No.45165401. Unpublished study prepared by AgraQuest, Inc. 10 p. {OPPTS 885.1100 and 885.1200}

MRID: 45385300

Citation: AgraQuest, Inc. (2001) Submission of Product Chemistry and Toxicity Data in Support of the Application for Registration of Serenade AS. Transmittal of 9 Studies.

MRID: 45385301

Citation: Van Koppenhagen, J.; Hilbig, L. (2001) Product Chemistry of Serenade AS: Lab Project Number: QC-012301. Unpublished study prepared by AgraQuest, Inc. 95 p. {OPPTS 885.1100, 885.1200, 885.1300, 885.1400, 885.1500, 830.1800, 830.6302, 830.6303, 830.6304, 830.6313, 830.6315, 830.6317, 830.6320, 830.7000, 830.7100, 830.7220, 830.7300}

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Biopesticide Registration Action Document

MRID: 45385302

Citation: O'Leary, A. (2001) Five Batch Analysis of Serenade AS: Lab Project Number: 012878-1. Unpublished study prepared by Ricerca, LLC. 11 p. {OPPTS 885.1400}

MRID: 45385303

Citation: Van Koppenhagen, J.; Hilbig, L. (2001) Serenade AS: Certification of Limits. Unpublished study prepared by AgraQuest, Inc. 15 p. {OPPTS 885.1500}

MRID: 45385304

Citation: Freeman, D. (2000) Acute Oral Toxicity Study in Albino Rats with Serenade AS: Lab Project Number: 012770-1. Unpublished study prepared by Ricerca, LLC. 21 p. {OPPTS 885.3050}

MRID: 45385305

Citation: Freeman, D. (2000) Acute Dermal Toxicity Study in Albino Rats with Serenade AS: Lab Project Number: 012773-1. Unpublished study prepared by Ricerca, LLC. 25 p. {OPPTS 885.3100}

MRID: 45385306

Citation: Wilson, C. (2001) An Acute Nose-Only Inhalation Toxicity Study in Rats with Serenade AS: Final Report: Lab Project Number: 3474.2. Unpublished study prepared by Springborn Laboratory, Inc. 46 p. {OPPTS 885.3150}

MRID: 45385307

Citation: Freeman, D. (2000) Acute Eye Irritation Study in Albino Rabbits with Serenade AS: Lab Project Number: 012772-1. Unpublished study prepared by Ricerca, LLC. 28 p. {OPPTS 870.2400}

MRID: 45385308

Citation: Freeman, D. (2000) Acute Dermal Irritation Study in Albino Rabbits with Serenade AS: Lab Project Number: 012771-1. Unpublished study prepared by Ricerca, LLC. 23 p. {OPPTS 870.2500}

MRID: 45385309

Citation: Freeman, D. (2000) Dermal Sensitization Study (Closed-Patch Repeated Insult) in Guinea Pigs with Serenade AS: Lab Project Number: 012774-1. Unpublished study prepared by Ricerca, LLC. 36 p. {OPPTS 870.2600}

MRID: 45455200

Citation: AgraQuest, Inc. (2001) Submission of Product Chemistry and Toxicity Data in Support of the Registration of Serenade Wettable Powder and Serenade. Transmittal of 5 Studies.

MRID: 45455201

Citation: Gingras, B. (2000) Storage Stability of QST 713 Strain of Dried *Bacillus subtilis* with Residual Fermentation Media Identified as QST 713 WP:

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Interim Report: Lab Project Number: L08726 SN9. Unpublished study prepared by IIT Research Institute. 24 p. {OPPTS 830.6317}

MRID: 45455202

Citation: Drottar, K.; Flaggs, R.; Krueger, H. (2001) QST 713 Technical: A Five-Concentration Toxicity and Pathogenecity Test with the Rainbow Trout (*Oncorhynchus mykiss*): Final Report: Lab Project Number: 489A-108. Unpublished study prepared by Wildlife International, Ltd. 39 p. {OPPTS 885.4200}

MRID: 45455203

Citation: Drottar, K.; Flaggs, R.; Krueger, H. (2001) QST 713 Technical: A 21-Day Life-Cycle Toxicity and Pathogenecity Test with the Cladoceran (*Daphnia magna*): Final Report: Lab Project Number: 489-107A. Unpublished study prepared by Wildlife International, Ltd. 39 p. {OPPTS 885.4240}

MRID: 45455204

Citation: Machado, M. (2001) QST 713 Technical Powder--Infectivity and Pathogenicity to Grass Shrimp (*Palaemonetes pugio*) During a 30-Day Static Renewal Test: Lab Project Number: 13759.6101. Unpublished study prepared by Springborn Laboratories, Inc. 64 p. {OPPTS 885.4280}

MRID: 45455205

Citation: Bryan, R.; Porch, J.; Krueger, H. (2001) *Bacillus Subtilis* Strain QST 713: A Dietary Pathogenicity and Toxicity Study with the Parasitic Hymenopteran (*Nasonia vitripennis*): Final Report: Lab Project Number: 489-107B. Unpublished study prepared by Wildlife International, Inc. 25 p. {OPPTS 885.4340}

MRID: 45489000

Citation: AgraQuest, Inc. (2001) Submission of Toxicity Data in Support of the Registration of Serenade and Serenade Biofungicide Wettable Powder. Transmittal of 1 Study.

MRID: 45489001

Citation: Mayer, D. (2001) Draft Protocol: Evaluation of the Potential Acute Toxicity to the Honey Bee of Serenade Biofungicide WP in a Semi-Field Study: Lab Project Number: 01-005. Unpublished study prepared by Washington State University. 13 p. {OPPTS 885.4380}

MRID: 45603400

Citation: AgraQuest, Inc. (2002) Submission of Efficacy Data in Support of the Registration of Serenade Biofungicide Wettable Powder and Serenade. Transmittal of 1 Study.

MRID: 45603401

Citation: Scherm, H. (2002) Efficacy of Serenade Biofungicide Against Mummy Berry Disease when Applied to Blueberry Flowers by Bees: Unpublished study prepared by University of Georgia. 8 p. {OPPTS 885.4380}

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Biopesticide Registration Action Document

MRID: 45662300

Citation: AgraQuest, Inc. (2002) Submission of Product Chemistry Data in Support of the Application for Registration of Serenade AS. Transmittal of 1 Study.

MRID: 45662301

Citation: Czochoz, L. (2002) Amendment to MRID No. 45385301, Manufacturing Process: Submission of Replacement Page 17. Unpublished study prepared by AgraQuest, Inc. 8 p. {OPPTS 885.1200}

MRID: 45830300

Citation: AgraQuest, Inc. (2002) Submission of Product Chemistry Data in Support of the Application for Registration of Rhapsody. Transmittal of 1 Study.

MRID: 45830301

Citation: Van Koppengagen, J.; Hilbig, L. (2001) Rhapsody: Certification of Limits. Unpublished study prepared by AgraQuest, Inc. 15 p. {OPPTS 885.1500}

MRID: 45883200

Citation: AgraQuest, Inc. (2003) Submission of Product Chemistry Data in Support of the Application for Registration of Serenade MAX. Transmittal of 1 Study.

MRID: 45883201

Citation: Linn, J.; Martinez, T. (2003) Serenade MAX: Certification of Limits. Unpublished study prepared by AgraQuest, Inc. 9 p. {OPPTS 885.1500}

MRID: 45929100

Citation: AgraQuest, Inc. (2003) Submission of Product Chemistry Data in Support of the Application for Registration of Serenade Max. Transmittal of 1 Study.

MRID: 45929101

Citation: Lin, J.; Martinez, T.; Czochoz, L. (2003) Product Chemistry of Serenade Max. Unpublished study prepared by AgraQuest, Inc. 35 p. {OPPTS 885.1100, 885.1200, 885.1300, 885.1400, 885.1500, 830.1800, 830.6302, 830.6303, 830.6304, 830.6313, 830.6325, 830.6317, 830.6320, 830.7300}

MRID: 46012200

Citation: AgraQuest, Inc. (2003) Submission of Product Chemistry Data in Support of the Application for Registration of Serenade ASO. Transmittal of 2 Studies.

MRID: 46012201

Citation: Lin, J.; Martinez, T.; Czochoz, L. (2003) Product Chemistry of Serenade ASO. Project Number: AC/F/007/1. Unpublished study prepared by AgraQuest Inc. 79 p.

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MRID: 46023300

Citation: AgraQuest, Inc. (2003) Submission of Product Chemistry Data in Support of the Amended Registration of Serenade. Transmittal of 1 Study.

MRID: 46023301

Citation: Lin, J.; Czochor, L. (2003) Serenade Manufacturing Process. Unpublished study prepared by Agraquest Inc. 8 p.

MRID: 46042300

Citation: AgraQuest, Inc. (2003) Submission of Product Chemistry Data in Support of the Application for Registration of Serenade Garden Ready-To-Use. Transmittal of 2 Studies.

MRID: 46042301

Citation: Lin, J.; Martinez, T; Czochor, L. (2003) Product Chemistry of Serenade Garden RTU. Unpublished study prepared by AgraQuest, Inc. 44 p.

MRID: 46042302

Citation: Lin, J.; Martinez, T. (2003) Serenade Garden Ready-To-Use: Certification of Limits. Unpublished study prepared by AgraQuest, Inc. 13 p.

MRID: 46103300

Citation: AgraQuest, Inc. (2003) Submission of Product Chemistry Data in Support of the Reregistration of *Bacillus subtilis* QST 713 WP. Transmittal of 1 Study.

MRID: 46103301

Citation: Gingras, B. (2001) Storage Stability of QST 713 Strain of Dried *Bacillus subtilis* With Residual Fermentation Media Identified as QST 713 WP. Project Number: L08726/SN9, L08726, 9. Unpublished study prepared by IIT Research Institute. 27 p.

MRID: 46107000

Citation: AgraQuest, Inc. (2003) Submission of Product Chemistry Data in Support of the Amended Registration of QST 713 Technical. Transmittal of 1 Study.

MRID: 46107001

Citation: Lin, J. (2003) Supplement to MRID No. 45084501 QST 713 Technical Certification of Limits. Unpublished study prepared by Agraquest, Inc. 9 p.

MRID: 46172900

Citation: AgraQuest, Inc. (2004) Submission of Toxicity Data in Support of the Registrations of Serenade Biofungicide Wettable Powder, QST 713 Technical, Serenade, Serenade AS, Rhapsody AS, and Serenade Garden Disease Control RTU. Transmittal of 2 Studies.

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MRID: 46172901

Citation: Jimenez, D. (2004) Discussion of the Results of Honeybee Studies Conducted with QST 713 Technical and Serenade Products. Unpublished study prepared by Agraquest Inc and California State Polytechnic College and Montana State University. 237 p.

MRID: 46172902

Citation: Jimenez, D.; Richards, K. (2004) Evaluation of the Dietary Effect(s) of QST 713 Technical Powder on Larval Honeybee Development (*Apis mellifera* L.). Project Number: CAR/158/03. Unpublished study prepared by California Agricultural Research Inc. 70 p.

MRID: 46243200

Citation: AgraQuest, Inc. (2004) Submission of Product Chemistry Data in Support of the Application for Registration of Rhapsody ASO. Transmittal of 1 Study.

MRID: 46243201

Citation: Lin, J.; Czochor, L. (2004) Rhapsody ASO Certification of Limits. Unpublished study prepared by AgraQuest Inc. 9 p.

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