BIOPESTICIDES REGISTRATION ACTION DOCUMENT

Chromobacterium subtsugae strain PRAA4-1^{T}

Pesticide Chemical (PC) Code: 016329

U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division

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TABLE OF CONTENTS

BIOPESTICIDES REGISTRATION ACTION DOCUMENT TEAM

Office of Pesticide Programs (OPP)
Biopesticides and Pollution Prevention Division
Microbial Pesticides Branch

Science Reviews

Joel V. Gagliardi, Ph.D.	Product Analysis, Human Health
John L. Kough, Ph.D.	Product Analysis, Human Health
Anna Gross	Environmental Effects
Zigfridas Vaituzis, Ph.D.	Environmental Effects
Shannon Borges	Environmental Effects

Regulations

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I. EXECUTIVE SUMMARY

Chromobacterium subtsugae strain PRAA4-1^T is a gram-negative, violet-pigmented bacterium that was isolated from soil under an eastern hemlock (*Tsuga canadensis*) in the Catoctin Mountain region of central Maryland. The United States Department of Agriculture found this isolate of *Chromobacterium subtsugae* to be orally toxic to Colorado potato beetle (*Leptinotarsa decemlineata*) larvae, small hive beetle (*Aethina tumida*) larvae, southern corn rootworm (*Diabrotica undecimpunctata*) larvae and adults, and southern green stink bug (*Nezara viridula*) adults. Additional testing has shown that *Chromobacterium subtsugae* strain PRAA4-1^T-treated diet resulted in reduced feeding in beet armyworm (*Spodoptera exigua*), cabbage looper (*Trichoplusia ni*), tobacco budworm (*Heliothis virescens*), diamondback moth (*Plutella xylostella*), and southern corn rootworm, suggesting this microbe's insecticidal activity is due to reduction in weight or inhibition of feeding. In light of the demonstrated insecticidal and miticidal capabilities of *Chromobacterium subtsugae* strain PRAA4-1^T, Marrone Bio Innovations proposed to register both a manufacturing-use pesticide product, MBI-203 TGAI, and an end-use pesticide product, MBI-203 EP Bioinsecticide (formerly MBI-203 EP), containing this bacterium. MBI-203 EP Bioinsecticide will be used to control label-specified insect and mite pests (e.g., European corn borer, citrus rust mite, and stink bugs) on agricultural and greenhouse crops, including vegetables, fruit, flowers, bedding plants, ornamentals, and turf.

Environmental Protection Agency (EPA) scientists reviewed product analysis, toxicology, and nontarget organism data and information (40 Code of Federal Regulations (CFR) §§ 158.2120, 158.2140, and 158.2150, respectively) submitted to support the registration of the two aforementioned *Chromobacterium subtsugae* strain PRAA4-1^T pesticide products. Overall, such data and information are adequate for risk assessment purposes, fulfill current data requirements, and allow for registration under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Product analysis data requirements for *Chromobacterium subtsugae* strain PRAA4-1^T, including product chemistry and composition, analysis of samples, and physical and chemical characteristics, were fulfilled by acceptable guideline studies.

Adequate mammalian toxicology data and information were submitted to support the *Chromobacterium subtsugae* strain PRAA4-1^T pesticide products. The acute injection toxicity/pathogenicity study showed that, at a single high dose, *Chromobacterium subtsugae* strain PRAA4-1^T is not toxic, infective, and/or pathogenic via the intravenous route of exposure. Acute pulmonary and oral toxicity/pathogenicity tests were waived after considering the results of the intravenous test and MBI-203 TGAI-specific toxicity tests (acute oral and inhalation). Moreover, no hypersensitivity incidents, occurring during research, development, or testing of *Chromobacterium subtsugae* strain PRAA4-1^T, were reported by the applicant. In light of the results of the intravenous study, the acceptable rationale provided to waive the acute pulmonary and oral toxicity/pathogenicity tests, and the absence of hypersensitivity incidents, testing at higher tiers (i.e., Tiers II and III) was not required.

EPA concluded that there is a reasonable certainty that no harm will result to the United States population, including infants and children, from aggregate exposure to residues of *Chromobacterium subtsugae* strain PRAA4-1^T. No dietary risks are expected from use of *Chromobacterium subtsugae* strain PRAA4-1^T as an active ingredient in pesticide products.

Significant dietary exposure—through food and drinking water—is not anticipated given the potential for this bacterium to degrade due to both predation by other biological organisms and exposure to environmental factors (e.g., sunlight and varying temperatures) in the phyllosphere, the filtering effect of many particulate soil types, and conditions (e.g., filtration and pH adjustments) water is subjected to in wastewater treatment systems and drinking water facilities. Should *Chromobacterium subtsugae* strain PRAA4-1^T be present on food or in drinking water, the acute oral toxicity and pathogenicity data/information demonstrated no toxicity, infectivity, and/or pathogenicity is likely to occur with any exposure level of this microbial pest control agent.

Despite the low toxicological profile of *Chromobacterium subtsugae* strain PRAA4-1^T, baseline personal protective equipment (PPE) is required for handlers that may be exposed to the active ingredient, due to their occupation, for prolonged periods or numerous times. Handlers working with *Chromobacterium subtsugae* strain PRAA4-1^T in agricultural settings are directed to wear a long-sleeved shirt, long pants, socks, shoes, waterproof gloves, and a dust/mist filtering respirator meeting National Institute for Occupational Safety and Health (NIOSH) standards of at least N-95, R-95, or P-95. EPA may require additional PPE, other than the standard described above, on a product-specific basis.

The data and data waiver rationale, submitted by the applicant to support the pesticide products containing *Chromobacterium subtsugae* strain PRAA4-1^T, are sufficient to fulfill the Tier I nontarget organism data requirements and for risk assessment purposes. Further testing of nontarget organisms at higher tier levels (i.e., Tiers II, III, and IV) is not required for the current uses and application methods. EPA performed an environmental risk assessment based on the data and data waiver rationale provided by the applicant and determined that the uses of *Chromobacterium subtsugae* strain PRAA4-1^T do not pose significant risk to nontarget organisms when used according to label directions. Based on study results, there are concerns of toxicity to terrestrial arthropods, aquatic invertebrates, and honey bees. Use sites and application methods, in combination with mitigating label language (see Table 7 in Appendix A), however, will limit exposure. EPA has made “no effect” determinations for direct effects, indirect effects, and effects to habitat (including designated critical habitat) to listed species for all foliar and soil-directed applications to crop plants treated within greenhouses. On the other hand, EPA concludes that all outdoor foliar applications made by chemigation and aerial spray equipment have the potential to cause direct effects, indirect effects, and effects to habitat (including designated critical habitat) to listed species.

On October 1, 2009, EPA announced a new policy to provide a more meaningful opportunity for the public to participate in major registration decisions before they occur. According to this policy, EPA intends to provide a public comment period prior to making a registration decision for, at minimum, the following types of applications: new active ingredients; first food uses; first outdoor uses; first residential uses; or any other registration actions for which EPA believes there may be significant public interest.

Consistent with the policy of making registration actions more transparent, the pesticide products containing *Chromobacterium subtsugae* strain PRAA4-1^T, a new active ingredient, and allowing for this active ingredient’s first outdoor and food uses were subject to a 30-day comment period. During this comment period, no comments were received on EPA’s preliminary decision to register the *Chromobacterium* subtsugae strain PRAA4-1^T pesticide products, MBI-203 TGAI

and MBI-203 EP Bioinsecticide. Therefore, EPA maintained that, based upon the risk assessment and information submitted in support of registration of such pesticide products, it was in the best interest of the public and the environment to issue the MBI-203 TGAI and MBI-203 EP Bioinsecticide registrations. The basis for this decision can be found in the risk assessment for *Chromobacterium subtsugae* strain PRAA4-1^T, which is characterized throughout this BRAD.

II. ACTIVE INGREDIENT OVERVIEW

Biological Name:	*Chromobacterium subtsugae* strain PRAA4-1^T
Culture Deposit:	Agricultural Research Service Culture Collection (also known as the Northern Regional Research Laboratory (NRRL) Collection) in Peoria, Illinois under Accession Number NRRL B-30655
OPP Chemical Code:	016329
Type of Pesticide:	Microbial Pesticide – Insecticide See Appendix B for specific information (e.g., use sites, application rates, methods of application, formulation types, and target pests) regarding the registered pesticide products containing this active ingredient.

III. REGULATORY BACKGROUND

A. Applications for Pesticide Product Registration

On December 22, 2009, Marrone Bio Innovations (address: 2121 Second Street, Suite B-107; Davis, California 95618) submitted applications to register a manufacturing-use pesticide product, MBI-203 TGAI (EPA File Symbol 84059-O), and an end-use pesticide product, MBI-203 EP (EPA File Symbol 84059-RN), under FIFRA section 3. On March 10, 2010, EPA announced receipt of these applications to register pesticide products containing a new active ingredient (75 Federal Register (FR) 11175) and opened a 30-day public comment period pursuant to the provisions of FIFRA section 3(c)(4). No comments were received following this publication.

B. Food Tolerance Exemption

Concurrent with its registration applications and under Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(d), Marrone Bio Innovations submitted a petition to establish an exemption from the requirement of a tolerance for *Chromobacterium subtsugae* strain PRAA4-1^T (Pesticide Petition (PP) 9F7674). In the Federal Register of March 10, 2010 (75 FR 11171), EPA announced that Marrone Bio Innovations proposed to establish an exemption from the requirement of a tolerance for residues of the insecticide, *Chromobacterium subtsugae* strain

PRAA4-1^T, in or on all food commodities and opened a 30-day comment period. No comments were received following this publication.

On September 7, 2011, EPA established an exemption from the requirement of a tolerance for residues of *Chromobacterium subtsugae* strain PRAA4-1^T in or on all food commodities when applied as an insecticide or miticide and used in accordance with good agricultural practices (40 CFR § 180.1305; 76 FR 55272).

IV. RISK ASSESSMENT

In the Federal Register of October 26, 2007, EPA issued a Final Rule on the data requirements to support registration of microbial pesticides and updated the definition for microbial pesticides (72 FR 61002). The rule became effective on December 26, 2007. The data and information evaluated for this BRAD were considered in light of these requirements.

The classifications that are found for each data submission are assigned by EPA science reviewers and are an indication of the usefulness of the information contained in the documents for risk assessment. A rating of "acceptable" indicates the study is scientifically sound and is useful for risk assessment. A "supplemental" rating indicates the data provide some information that can be useful for risk assessment. The studies may have certain aspects determined not to be scientifically acceptable ("supplemental: upgradeable"). If a study is rated as "supplemental: upgradeable," EPA always provides an indication of what is lacking or what can be provided to change the rating to "acceptable." If there is simply a "supplemental" rating, the reviewer will often state that the study is not required by 40 CFR Part 158. Both "acceptable" and "supplemental" studies may be used in the risk assessment process as appropriate. An "unacceptable" rating indicates that new data must be submitted.

For the acute toxicity data requirements, Toxicity Categories are assigned based on the hazard(s) identified from studies and/or other information submitted to EPA in support of a pesticide registration. The active ingredient or particular product is classified into Toxicity Category I, II, III, or IV, where Toxicity Category I indicates the highest toxicity and Toxicity Category IV indicates the lowest toxicity (see 40 CFR § 156.62).

A. Product Analysis Assessment (40 CFR § 158.2120)

All product analysis data requirements for *Chromobacterium subtsugae* strain PRAA4-1^T have been fulfilled. Refer to Tables 1, 2, 3, and 4 in Appendix A for a brief summary of the data requirements, including both generic and product-specific information.

B. Human Health Assessment (40 CFR § 158.2140)

1. Toxicity

All toxicology data requirements for *Chromobacterium subtsugae* strain PRAA4-1^T have been fulfilled. Acceptable Tier I mammalian toxicology data and information support registration of the *Chromobacterium subtsugae* strain PRAA4-1^T pesticide products. Furthermore, Tier II and Tier III studies were not required for *Chromobacterium subtsugae* strain PRAA4-1^T based on the lack of acute toxicity/pathogenicity in the Tier I studies.

For a comprehensive summary of the generic toxicology data requirements described in sections IV(B)(1)(a) and IV(B)(1)(b), as well as additional product-specific data submitted to support the individual registrations, refer to Tables 5 and 6 in Appendix A.

a. Acute Toxicity/Pathogenicity – Tier I

Acute Oral Toxicity/Pathogenicity (Office of Chemical Safety and Pollution Prevention (OCSPP) Guideline 885.3050; Master Record Identification Number (MRID No.) 479450-23): Upon consideration of results of other definitive toxicological data submitted by the applicant, EPA waived acute oral toxicity/pathogenicity testing for *Chromobacterium subtsugae* strain PRAA4-1^T. In an acute up and down oral toxicity study (MRID No. 479450-03), three female rats were gavaged once with 5,000 milligrams per kilogram (mg/kg) of the test material. All animals survived and gained weight, and there were no signs of gross toxicity, adverse effects, or abnormal behavior. The acute oral median lethal dose (LD_{50}) was greater than 5,000 mg/kg. In an acute intravenous study (MRID No. 479450-11), groups of rats received a single intravenous injection of inactive test material or active test material (2.62×10^8 colony-forming units per milliliter (cfu/mL)). Three males and three females from the active test material group were sacrificed and necropsied on days 0, 3, 7, 14, and 21 after treatment. Tissue and blood samples were collected at necropsy and cultured to provide qualitative and quantitative measurements of the test organism. There was no mortality during the study, and all rats appeared normal throughout. The test organism had cleared completely from blood, kidneys, mesenteric lymph nodes, lungs, brain, liver, spleen, and cecum contents by day 3. The test material was nontoxic and noninfective. EPA believes these data, when taken together, clearly indicate that *Chromobacterium subtsugae* strain PRAA4-1^T would not be toxic, infective, and/or pathogenic through the oral route of exposure and that further testing is not necessary.

Acute Pulmonary Toxicity/Pathogenicity (OCSPP Guideline 885.3150; MRID No. 479450-23): Upon consideration of results of other definitive toxicological data submitted by the applicant, EPA waived acute pulmonary toxicity/pathogenicity testing for *Chromobacterium subtsugae* strain PRAA4-1^T. In an acute inhalation study (MRID No. 479450-05), male and female rats were exposed to an aerosol concentration of 2.12 milligrams per liter (mg/L) of the test material for 4 hours in a nose-only inhalation chamber. No deaths occurred during exposure or during the 14-day observation period. Clinical signs included decreased activity and piloerection, which resolved by day 5. Necropsy was unremarkable. The acute inhalation median lethal concentration (LC_{50}) was greater than 2.12 mg/L. In an acute intravenous study (MRID No. 479450-11), groups of rats received a single intravenous injection of inactive test material or active test material (2.62×10^8 cfu/mL). Three males and three females from the active test material group were sacrificed and necropsied on days 0, 3, 7, 14, and 21 after treatment. Tissue and blood samples were collected at necropsy and cultured to provide qualitative and quantitative measurements of the test organism. There was no mortality during the study, and all rats appeared normal throughout. The test organism had cleared completely from blood, kidneys, mesenteric lymph nodes, lungs, brain, liver, spleen, and cecum contents by day 3. The test material was nontoxic and noninfective. EPA believes these data, when taken together, clearly indicate that *Chromobacterium subtsugae* strain PRAA4-1^T would not be toxic, infective, and/or pathogenic through the inhalation route of exposure and that further testing is not necessary.

Acute Injection Toxicity/Pathogenicity (Intravenous) – Rat (OCSPP Guideline 885.3200; MRID No. 479450-11): In an acute intravenous injection toxicity and pathogenicity study, groups of young adult Sprague-Dawley rats were injected at 3.1 x 10^6 colony-forming units (cfu)/animal. Animals were observed up to 21 days. Five males and five females were treated with inactive MOI 203 [MBI 203] TGAI, while five males and five females were not treated and served as controls. All animals survived, gained weight, and appeared normal during the study. No observable abnormalities were noted in any animal at necropsy. There were no significant variations among organ weights. MOI 203 [MBI 203] organism cleared from the blood, brain, lungs, spleen, liver, kidneys, mesenteric lymph nodes, and cecum contents of animals by day 3. MOI 203 [MBI 203] was not detected in the tissues/organs of animals treated with autoclaved test material or the untreated control group. MOI 203 [MBI 203] does not appear to be toxic, infective, and/or pathogenic to rats when dosed intravenously at 3.1 x 10^6 cfu per animal. This study was rated acceptable.

Hypersensitivity Incidents (OCSPP Guideline 885.3400; MRID No. 479450-23): No hypersensitivity incidents, including immediate-type or delayed-type reactions of humans and domestic animals that occurred during research, development, or testing of *Chromobacterium subtsugae* strain PRAA4-1^T, were reported by the applicant. Any future hypersensitivity incidents must be reported to EPA (refer to test note #3 of 40 CFR § 158.2140(d)).

Cell Culture (OCSPP Guideline 885.3500): This study is not required because *Chromobacterium subtsugae* strain PRAA4-1^T is not a virus (refer to test note #4 of 40 CFR § 158.2140(d)).

b. Acute Toxicology and Subchronic Toxicity/Pathogenicity – Tier II; Reproductive Fertility Effects, Carcinogenicity, Immunotoxicity, and Infectivity/Pathogenicity Analysis – Tier III

Tier II and Tier III studies were not required for *Chromobacterium subtsugae* strain PRAA4-1^T based on the lack of acute toxicity/pathogenicity in the Tier I studies.

c. Endocrine Disruptors

As required under FFDCA section 408(p), EPA has developed the Endocrine Disruptor Screening Program (EDSP) to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a quantitative relationship between the dose and the E, A, or T effect.

Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. This list of chemicals was selected based on the potential for human exposure through pathways such as

food and water, residential activity, and certain post-application agricultural scenarios. This list should not be construed as a list of known or likely endocrine disruptors.

Chromobacterium subtsugae strain PRAA4-1^T is not among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP. Under FFDCA section 408(p), EPA must screen all pesticide chemicals. Accordingly, EPA anticipates issuing future EDSP orders/data call-ins for all pesticide active ingredients.

For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, the test guidelines and the Tier 1 screening battery, please visit our website: *http://www.epa.gov/endo/*.

2. Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...." Additionally, section 408(b)(2)(D) of FFDCA requires that EPA consider "available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information, 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.

Based on the acute toxicity/pathogenicity data and information discussed previously and presented in Table 5 in Appendix A, the data required for a FFDCA risk assessment for *Chromobacterium subtsugae* strain PRAA4-1^T have been fulfilled.

a. Aggregate Exposure

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other nonoccupational 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).

Food Exposure and Risk Characterization: Any exposure to this naturally occurring soil bacterium is anticipated to be negligible. Although *Chromobacterium subtsugae* strain PRAA4-1^T may be applied directly to food, it is not expected to persist or accumulate in any reservoirs on plants or food commodities (the phyllosphere) because, as a soil microorganism, it is best adapted to more favorable conditions underground. Rather, after application, it likely will degrade due to predation by other biological organisms (e.g., protists) and exposure to particular environmental factors (e.g., sunlight and varying temperatures) (Lindow and Brandl 2003; U.S. EPA 1996). Should this microbial pesticide be present on food, the acute oral toxicity and pathogenicity data/information demonstrated no toxicity, infectivity, and/or pathogenicity is likely to occur with any exposure level of *Chromobacterium subtsugae* strain PRAA4-1^T (see section IV(B)(1)(a) and Table 5 in Appendix A).

Drinking Water Exposure and Risk Characterization: Exposure of humans to residues of *Chromobacterium subtsugae* strain PRAA4-1^T in consumed drinking water is unlikely. The proposed use patterns for *Chromobacterium subtsugae* strain PRAA4-1^T do not include direct application to aquatic environments, thereby limiting contact with surface water. Furthermore, ground water is not expected to have significant exposure to *Chromobacterium subtsugae* strain PRAA4-1^T since, like other microorganisms, this bacterium would likely be filtered out by the particulate nature of many soil types (Aislabie *et al*. 2001; DeFelice *et al*. 1993; Pang *et al*. 2008) and is not known to survive in water or deep soil. If *Chromobacterium subtsugae* strain PRAA4-1^T were to be transferred to surface or ground waters that are intended for eventual human consumption (e.g., through spray drift or runoff) and directed to wastewater treatment systems or drinking water facilities, it likely would not survive the conditions water is subjected to in such systems or facilities, including high temperatures, chlorination, pH adjustments, and/or filtration (Centers for Disease Control and Prevention 2009; U.S. EPA 2004). In the remote likelihood that this microbial pesticide is present in drinking water (e.g., in water not subject to treatment systems or facilities), the acute oral toxicity and pathogenicity data/information demonstrated no toxicity, infectivity, and/or pathogenicity is likely to occur with any exposure level of *Chromobacterium subtsugae* strain PRAA4-1^T (see section IV(B)(1)(a) and Table 5 in Appendix A).

Non-occupational, Residential Risk Characterization: Dermal and inhalation non-occupational exposure to *Chromobacterium subtsugae* strain PRAA4-1^T is not expected as all proposed pesticide applications will take place in distinct agricultural settings. Even if dermal and inhalation non-occupational exposures were to occur, such exposures would not exceed EPA's level of concern given testing that indicated that *Chromobacterium subtsugae* strain PRAA4-1^T is not toxic (acute inhalation and dermal toxicity), is only slightly irritating (primary dermal irritation), is not a sensitizer (dermal sensitization), and is not pathogenic or infective (acute injection toxicity/pathogenicity) (see section IV(B)(1)(a) and Table 5 in Appendix A).

b. Cumulative Effects from Substances with a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance exemption, EPA consider "available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that have a common mechanism of toxicity."

EPA has not found *Chromobacterium subtsugae* strain PRAA4-1^T to share a common mechanism of toxicity with any other substances, and *Chromobacterium subtsugae* strain PRAA4-1^T does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that *Chromobacterium subtsugae* strain PRAA4-1^T does not have a common mechanism of toxicity with other substances. Following from this, therefore, EPA concludes that there are no cumulative effects associated with *Chromobacterium subtsugae* strain PRAA4-1^T that need to be considered. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

c. Determination of Safety for the United States (U.S.) Population, Infants and Children

FFDCA section 408(b)(2)(C) 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) provides that EPA shall apply an additional tenfold (10X) 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 on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor. In applying this provision, EPA either retains the default value of 10X or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

Based on the acute toxicity and pathogenicity data/information summarized in section IV(B)(1)(a) and Table 5 in Appendix A, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to the residues of *Chromobacterium subtsugae* strain PRAA4-1^T. Such exposure includes all anticipated dietary exposures and all other exposures for which there is reliable information. EPA has arrived at this conclusion because, considered collectively, the data (e.g., lack of toxicity noted for oral, dermal, and inhalation routes of exposure) available on *Chromobacterium subtsugae* strain PRAA4-1^T do not demonstrate toxic, pathogenic, and/or infective potential to sensitive populations from exposure to this microbial pest control agent. Thus, there are no threshold effects of concern and, as a result, the provision requiring an additional margin of safety is not necessary.

3. Occupational Exposure and Risk Characterization

Handler exposure to *Chromobacterium subtsugae* strain PRAA4-1^T is not expected to pose any undue risk. Regardless, appropriate personal protective equipment and precautionary statements are required on pesticide product labels to mitigate any potential risks to pesticide handlers due to prolonged or numerous exposures. Handlers applying *Chromobacterium subtsugae* strain PRAA4-1^T end-use pesticide products in agricultural settings must wear a long-sleeved shirt, long pants, socks, shoes, waterproof gloves, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Additional PPE, other than the standard described above, may be required on a product-specific basis.

4. Human Health Risk Characterization

EPA considered human exposure to *Chromobacterium subtsugae* strain PRAA4-1^T in light of the standard for registration in FIFRA and the relevant safety factors in FFDCA. A determination has been made that no unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, will result when *Chromobacterium subtsugae* strain PRAA4-1^T pesticide products are used in accordance with EPA-approved labeling.

C. Environmental Assessment (40 CFR § 158.2150)

The data and data waiver rationale, submitted by the applicant to support the pesticide products containing *Chromobacterium subtsugae* strain PRAA4-1^T, fulfill the Tier I nontarget organism data requirements and are sufficient for risk assessment purposes. Further testing of nontarget organisms at higher tier levels (i.e., Tiers II, III, and IV) is not required for the current uses and application methods. EPA has performed an environmental risk assessment based on the data and data waiver rationale provided by the applicant and has determined that the use of *Chromobacterium subtsugae* strain PRAA4-1^T does not pose significant risk to nontarget organisms when used according to label directions. Based on study results, there are concerns of toxicity to terrestrial arthropods, aquatic invertebrates, and honey bees. Use sites and application methods, in combination with mitigating label language, however, will limit exposure.

For a comprehensive summary of the generic data requirements described in sections IV(C)(1), refer to Table 7 in Appendix A.

1. Ecological Exposure and Risk Characterization

a. Terrestrial Animals and Plants

The end-use product (EP) is a concentrated liquid that is labeled as a foliar spray with ground or aerial applications at 3-10 day intervals. Aerial applications would increase exposure to nontarget insects and honey bees and, due to potential toxicity concerns, were not recommended. Terrestrial animals and plants may be exposed to *Chromobacterium subtsugae* strain PRAA4-1^T through direct sprays and exposure on foliar surfaces.

Birds (OCSPP Guideline 885.4050) and Mammals (OCSPP Guideline 885.4150): A study (MRID No. 479450-13) was conducted to determine the acute toxicity and pathogenicity of MBI-203 TGAI (active ingredient, 100.00% *Chromobacterium subtsugae* strain PRAA4-1^T cells and

spent fermentation media) to northern bobwhite (*Colinus virginianus*). Fourteen-day-old chicks were dosed with the test material (4.0×10^{11} colony-forming units per kilogram (cfu/kg) body weight), attenuated test material, or sterile saline once a day for five days and observed for an additional 25 days. No signs of toxic or pathogenic effects were observed throughout the test or at necropsy. This study demonstrates that toxicity/pathogenicity to birds is not expected from labeled applications of *Chromobacterium subtsugae* strain PRAA4-1^{T}.

In an acute oral toxicity study (MRID No. 479450-03), three fasted young adult female Sprague-Dawley rats were given a single oral gavage dose of MOI 203 [MBI 203] TGAI at a concentration of 5,000 mg/kg body weight. The test material was allowed to thaw at room temperature prior to dosing. The animals were observed for 14 days. All animals survived, gained weight, and appeared active and healthy throughout the study. No gross abnormalities were found in any animal at necropsy. This study demonstrates that toxicity/pathogenicity to wild mammals is not expected from labeled applications of *Chromobacterium subtsugae* strain PRAA4-1^{T}.

Nontarget Insects (OCSPP Guideline 885.4340) and Honey Bees (OCSPP Guideline 885.4380): Nontarget insect studies were submitted for ladybird beetles, green lacewing larvae and parasitic wasps. Two studies were submitted for ladybird beetles, both of which indicated toxicity. An acute toxicity study (MRID No. 479450-16) was of insufficient duration but supplemental for the purposes of the risk assessment, and a feeding study (MRID No. 479450-17) fulfilled the testing guidelines but also indicated toxicity. A green lacewing study (MRID No. 479450-18) that fulfilled testing requirements was submitted; there were no observed effects from test concentrations of *Chromobacterium subtsugae* strain PRAA4-1^{T}, and the LC_{50} for MBI TGAI was greater than 70,000 parts per million (ppm) in a moth egg diet. A parasitic wasp study (MRID No. 481129-05) was also submitted and was supplemental for the purposes of the risk assessment. While there were no statistically significant differences in the control and test substance groups, the dose of *Chromobacterium subtsugae* strain PRAA4-1^{T} to which the wasps were exposed was not adequately characterized and the duration of the test was insufficient.

Three honey bee studies were submitted, all of which were sufficient for the purposes of the risk assessment. Results indicated toxicity to honey bees with the use of *Chromobacterium subtsugae* strain PRAA4-1^{T} (MRID Nos. 479450-19, 479450-20 and 479450-21).

In conclusion, according to studies conducted on nontarget insects and honey bees, there are toxicity concerns with the use of *Chromobacterium subtsugae* strain PRAA4-1^{T}. To address these concerns and to reduce exposure to nontarget insects and honey bees that may occur through outdoor ground and aerial applications, EPA is requiring particular aerial drift reduction information, as well as the following mitigation language, on the MBI-203 EP Bioinsecticide label:

Environmental Hazards Statements

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

This product is toxic to certain nontarget terrestrial arthropods. Minimize spray drift away from target area to reduce effects to nontarget insects.

Nontarget Plants (OCSPP Guideline 885.4300): The applicant submitted both data waiver rationale (MRID No. 479450-23) and a study (MRID No. 479450-15) to fulfill the nontarget plant testing requirement. While *Chromobacterium subtsugae* strain PRAA4-1^{T} occurs naturally in soils and is not related to any known plant pathogen, effects of mild phytotoxicity were observed in cucumbers at 5X and 10X the field application rate, and in chrysanthemum flowers at all application rates. Even though effects in cucumbers and chrysanthemum flowers were mild, the MBI-203 EP Bioinsecticide label will still require all users to test for phytotoxicity prior to pesticide application.

b. Aquatic Animals and Plants

Freshwater Fish (OCSPP Guideline 885.4200), Freshwater Invertebrates (OCSPP Guideline 885.4240), and Estuarine/Marine Fish and Invertebrates (OCSPP Guideline 885.4280): MBI-203 EP Bioinsecticide (94.50% *Chromobacterium subtsugae* strain PRAA4-1^{T}) is not labeled for aquatic uses, and the label includes language to prevent application to or contamination of water. Due to demonstrated toxicity to aquatic invertebrates, aquatic uses should not be added to the label without further testing. The applicant submitted studies to fulfill the freshwater fish and freshwater invertebrate testing requirements, as well as data waiver rationale for testing on estuarine/marine organisms. The freshwater fish study (MRID No. 479450-14) fulfills the testing requirements and did not show any adverse effects to fathead minnows (*Pimephales promelas*). Toxicity was shown in two supplemental studies (MRID Nos. 479450-12 and 481129-04) submitted by the applicant that tested the effects of *Chromobacterium subtsugae* strain PRAA4-1^{T} on *Daphnia magna.* The studies were sufficient for the purposes of this registration, but do not support aquatic uses. The data waiver rationale submitted for estuarine/marine organisms was acceptable for the labeled use patterns, as MBI-203 EP Bioinsecticide is not intended for direct application into the estuarine or marine environment or expected to enter such environment in significant concentrations.

Even though MBI-203 EP Bioinsecticide is not applied directly to aquatic environments, EPA is requiring that the maximum labeled application rate not exceed 12 quarts of product per acre and that specific aerial drift reduction text, as well the following mitigation language, be included on the label to reduce the potential for exposure to aquatic invertebrates:

Environmental Hazards Statements

This product is toxic to aquatic invertebrates. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas.

Buffer Zone for Aerial Applications (in the Directions for Use) (see U.S. EPA 2011c, 2011d)

Do not apply within 75 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds).

Information on Droplet Size (in the Directions for Use) (see U.S. EPA 2011c, 2011d)

Use only medium or coarser spray nozzles according to ASAE (S572) definition for standard nozzles.

c. Open Literature Information

Literature searches were performed to determine if other effects have been reported that were not contained within the information provided by the applicant. Both the Science Citation Index Expanded database (1970-present) and the Environmental Information Search service (1964-present) were searched using the terms "*Chromobacterium*" and "*Chromobacterium subtsugae.*" The Environmental Information Search service includes the Agricola; Biosis Previews; CAB Abstracts; Energy, Science, and Technology; General Science Abstracts; National Technical Information Service; and Waternet databases. None of the records found in any of the searches described here reported effects on any nontarget species. The only results relevant to the active ingredient were two documents published by the United States Department of Agriculture – Agricultural Research Service concerning the toxicity of *Chromobacterium subtsugae* to Colorado potato beetle and other insect pests (Martin *et al*. 2007a), as well as to southern green stink bug and corn rootworm (Martin *et al*. 2007b). Neither document provided additional information on environmental or nontarget effects useful for the purposes of this risk assessment.

2. Environmental Fate Data

As the information provided, for the current uses and application methods, is sufficient to both satisfy the Tier I nontarget organism data requirements and for nontarget organism risk assessment for *Chromobacterium subtsugae* strain PRAA4-1^{T}, further testing at higher tier levels (i.e., Tiers II, III, and IV) is not required.

3. Threatened and Endangered Species Assessment

EPA has determined that there is a potential for effects to nontarget organisms, including endangered and threatened species as a result of the proposed labeled applications (aerial sprays and chemigation) of *Chromobacterium subtsugae* strain PRAA4-1^{T}. There are toxicity concerns for certain terrestrial arthropods and honey bees, as well as for aquatic invertebrates. Further analysis is needed to characterize the specific effects and affected species. For this reason, aerial applications were not recommended. Terrestrial applications through sprinkler irrigation systems (chemigation) are expected to result in exposure to nontarget insects, though to a lesser extent than aerial applications. MBI-203 EP Bioinsecticide is also labeled for greenhouse use, which will not result in significant exposure to nontarget organisms. Aquatic applications are not permitted for this product, which will limit exposure to aquatic invertebrates and other aquatic organisms. Mitigation language (e.g., requirement for a buffer between aquatic and treatment areas and use of only medium to coarser spray nozzles for aerial applications), addressing concerns of *Chromobacterium subtsugae* strain PRAA4-1^{T}'s toxicity to honey bees, terrestrial arthropods, and aquatic invertebrates, has been added to the MBI-203 EP Bioinsecticide label.

The Biopesticides and Pollution Prevention Division (BPPD) makes "no effect" determinations for direct effects, indirect effects, and affects to habitat (including designated critical habitat) for listed species for the following labeled applications of *Chromobacterium subtsugae* strain PRAA4-1^{T} to the proposed crops:

- All foliar and soil directed liquid applications to the proposed crop plants treated within enclosed greenhouses

BPPD concludes that the following types of labeled applications of *Chromobacterium subtsugae* strain PRAA4-1^{T} to the proposed crops have the potential to cause direct effects, indirect effects, and effects to habitat (including designated critical habitat) to listed species. Further analyses are needed to characterize the effects that are likely to occur and the species potentially affected.

- All outdoor foliar applications made by chemigation and aerial spray equipment.

V. ENVIRONMENTAL JUSTICE

EPA seeks to achieve environmental justice—the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income—with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. Fair treatment means that no group of people, including racial, ethnic, or socioeconomic groups, should bear a disproportionate share of the negative environmental consequences resulting from industrial, municipal, and commercial operations or the execution of federal, state, local, and tribal environmental programs and policies. Meaningful involvement means that (1) potentially affected community residents have an appropriate opportunity to participate in decisions about a proposed activity that will affect their environment and/or health; (2) the public's contribution can influence the regulatory agency's decision; (3) the concerns of all participants involved will be considered in the decision-making process; and (4) the decision-makers seek out and facilitate the involvement of those potentially affected. EPA has this goal for all communities and persons across the United States.

To help address potential environmental justice issues, during the 30-day public participation comment period, EPA sought information on any groups or segments of the population who, as a result their location, cultural practices, or other factors, may have atypical, unusually high exposure to *Chromobacterium subtsugae* strain PRAA4-1^{T}, compared to the general population. No public comments were received on this particular matter.

For additional information regarding environmental justice issues, please visit EPA's web site at *http://www.epa.gov/compliance/environmentaljustice/index.html*.

VI. RISK MANAGEMENT DECISION

Section 3(c)(5) of FIFRA permits for the registration of a pesticide provided that all the following determinations are made:

(1) Its composition is such as to warrant the proposed claims for it;
(2) Its labeling and other material required to be submitted comply with the requirements of FIFRA;
(3) It will perform its intended function without unreasonable adverse effects on the environment; AND
(4) When used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment.

To satisfy criterion 1, the *Chromobacterium subtsugae* strain PRAA4-1^T pesticide products have well-known properties. EPA has no knowledge that would contradict the claims made on the MBI-203 TGAI and MBI-203 EP Bioinsecticide labels, and such products are not expected to cause unreasonable adverse effects on the environment when used according to the label instructions. Criterion 2 is satisfied by the current product labels, as well as the data and information presented in this document. It is believed that the *Chromobacterium subtsugae* strain PRAA4-1^T pesticide products will not cause any unreasonable adverse effects on the environment, and MBI-203 EP Bioinsecticide (end-use pesticide product), in particular, is likely to provide protection against insect and mite pests as claimed, satisfying criterion 3. Criterion 4 is satisfied in that the *Chromobacterium subtsugae* strain PRAA4-1^T pesticide products are not expected to cause unreasonable adverse effects when used according to label instructions. Therefore, MBI-203 TGAI and MBI-203 EP Bioinsecticide, containing *Chromobacterium subtsugae* strain PRAA4-1^T as a new active ingredient, are eligible for registration under FIFRA section 3(c)(5) for the labeled uses. If the applicant proposes uses that are more extensive in the future (e.g., aquatic uses), EPA will likely require that additional data, in conjunction with a registration amendment request, be submitted.

VII. ACTIONS REQUIRED BY THE REGISTRANT

A. Final Printed Labeling

Before releasing pesticide products containing *Chromobacterium subtsugae* strain PRAA4-1^T for shipment, the registrant is required to provide appropriate final printed labeling to EPA.

B. Terms of Registration

As terms of the MBI-203 EP Bioinsecticide registration, the registrant must submit the following data within one year of this product's registration:

(1) Analysis of Samples (OCSPP Guideline 885.1400): A five-batch analysis, addressing all quality control parameters (i.e., dry weight, standard plate count, viscosity, density, and pH).

(2) Storage Stability (OCSPP Guideline 830.6317) and Corrosion Characteristics (OCSPP Guideline 830.6320): The results of a two-year storage stability and corrosion characteristics study (ongoing).

C. Reporting of Adverse Effects and Hypersensitivity Incidents

Notwithstanding the information stated in the previous sections, it should be clearly understood that certain, specific data are required to be reported to EPA as a requirement for maintaining the federal registration for a pesticide product. A brief summary of these types of data are described below.

Reports of all incidents of adverse effects to the environment must be submitted to EPA under the provisions stated in FIFRA section 6(a)(2). Additionally, all incidents of hypersensitivity (including both suspected and confirmed incidents) must be reported to EPA under the provisions of 40 CFR § 158.2140(d).

VIII. GLOSSARY OF ACRONYMS AND ABBREVIATIONS

ASAE	American Society of Agricultural Engineers
BPPD	Biopesticides and Pollution Prevention Division
BRAD	Biopesticides Registration Action Document
CFR	Code of Federal Regulations
cfu	colony-forming unit(s)
cfu/kg	colony-forming units per kilogram
cfu/mL	colony-forming units per milliliter
cP	centipoise
EDSP	Endocrine Disruptor Screening Program
EP	end-use product
EPA	Environmental Protection Agency (the "Agency")
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
FR	Federal Register
g/mL	gram per milliliter
LC_{50}	median lethal concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air, or feed (e.g., mg/L, mg/kg, or ppm).
LD_{50}	median lethal dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, or inhalation). It is expressed as a weight of substance per unit weight of animal (e.g., mg/kg).
mg/kg	milligrams per kilogram
mg/L	milligrams per liter
MP	manufacturing-use product
MRID No.	Master Record Identification Number
NIOSH	National Institute for Occupational Safety and Health
NRRL	Northern Regional Research Laboratory
OCSPP	Office of Chemical Safety and Pollution Prevention
OPP	Office of Pesticide Programs
PC Code	Pesticide Chemical Code
PP	Pesticide Petition
PPE	personal protective equipment
ppm	parts per million
TGAI	technical grade of the active ingredient
U.S.	United States

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APPENDIX A. MICROBIAL PESTICIDES DATA REQUIREMENTS (40 CFR PART 158 – SUBPART V)

TABLE 1. Product Analysis Data Requirements for the Technical Grade of the Active Ingredient (TGAI)/Manufacturing-Use Product (MP), MBI-203 TGAI (40 CFR § 158.2120)				
OCSPP Guideline Number	**Data Requirement**	**Results**		**MRID No.**
		TGAI	**MP**	
885.1100	Product Identity	Not applicable	Submitted data fulfill the requirement for product identity. MBI-203 TGAI contains 100.00% by weight *Chromobacterium subtsugae* strain PRAA4-1^T cells and spent fermentation media (minimum of 1,500 Cabbage Looper Potency (or Killing) Units per milligram).	479450-01 481129-02 481307-01
885.1200	Manufacturing Process	Submitted data fulfill the requirement for manufacturing process.		479450-01 481129-03
Not applicable	Deposition of a Sample in a Nationally Recognized Culture Collection	*Chromobacterium subtsugae* strain PRAA4-1^T is on deposit with the Agricultural Research Service Culture Collection (also known as the Northern Regional Research Laboratory Collection) in Peoria, Illinois under Accession Number NRRL B-30655.	Not applicable	479450-01
885.1300	Discussion of Formation of Unintentional Ingredients	Submitted data fulfill the requirement for discussion of formation of unintentional ingredients.		479450-01
885.1400	Analysis of Samples	Submitted data fulfill the requirement for analysis of samples.		479450-01
885.1500	Certification of Limits	Not applicable	Limits listed on the confidential statement of formula are adequate/acceptable.	479450-01
Additional Studies				
830.1800	Enforcement Analytical Method	Not applicable	Submitted data fulfill the requirement for an enforcement analytical method.	479450-01

TABLE 2. Product Analysis Data Requirements for the End-Use Product (EP), MBI-203 EP Bioinsecticide (40 CFR § 158.2120)			
OCSPP Guideline Number	**Data Requirement**	**Results**	**MRID No.**
885.1100	Product Identity	Submitted data fulfill the requirement for product identity. MBI-203 EP Bioinsecticide contains 94.50% by weight *Chromobacterium subtsugae* strain PRAA4-1^T cells and spent fermentation media (minimum of 1,000 Cabbage Looper Potency (or Killing) Units per milligram).	479450-02 481129-06
885.1200	Manufacturing Process	Submitted data fulfill the requirement for manufacturing process.	479450-02 481129-06 481129-07
Not applicable	Deposition of a Sample in a Nationally Recognized Culture Collection	Not applicable	Not applicable
885.1300	Discussion of Formation of Unintentional Ingredients	Submitted data fulfill the requirement for discussion of formation of unintentional ingredients.	479450-02
885.1400	Analysis of Samples	Submitted date fulfill the requirement for analysis of samples for purposes of FIFRA section 3(c)(5) registration. **As a term of the MBI-203 EP Bioinsecticide registration, EPA is requiring a five-batch analysis, addressing all quality control parameters (i.e., dry weight, standard plate count, viscosity, density, and pH), be submitted within one year.**	479450-02
885.1500	Certification of Limits	Limits listed on the confidential statement of formula are adequate/acceptable.	479450-02
Additional Studies			
830.1800	Enforcement Analytical Method	Submitted data fulfill the requirement for an enforcement analytical method.	479450-02

TABLE 3. Physical and Chemical Characteristics for the Technical Grade of the Active Ingredient (TGAI)/Manufacturing-Use Product (MP), MBI-203 TGAI (40 CFR § 158.2120)				
OCSPP Guideline Number	**Data Requirement**	**Results**		**MRID No.**
		TGAI	**MP**	
830.6302	Color	Purple-blue	Not applicable	479450-01
830.6303	Physical State	Liquid	Not applicable	479450-01
830.6304	Odor	Grass-like	Not applicable	479450-01
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	Expected to be stable	Not applicable	479450-01
830.6317	Storage Stability	Stable for one year when stored per label directions.		479450-01 484406-01
830.6319	Miscibility	Not applicable	Not required because MBI-203 TGAI is not an emulsifiable form of microbial pesticide (refer to test note #2 of 40 CFR § 158.2120(d)).	Not applicable
830.6320	Corrosion Characteristics	Not applicable	Not corrosive to packaging materials in a one-year study.	479450-01 484406-01
830.7000	pH	4.1 (1% w/w)	Not applicable	479450-01
830.7100	Viscosity	Not applicable	5.4 cP	479450-01
830.7300	Density/Relative Density/Bulk Density (Specific Gravity)	1.01 g/mL	Not applicable	479450-01

TABLE 4. Physical and Chemical Characteristics for the End-Use Product (EP), MBI-203 EP Bioinsecticide (40 CFR § 158.2120)			
OCSPP Guideline Number	**Data Requirement**	**Results**	**MRID No.**
830.6302*	Color	Purple-blue	479450-02
830.6303*	Physical State	Liquid	479450-02
830.6304*	Odor	Herbaceous	479450-02
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	Not applicable	Not applicable
830.6317	Storage Stability	Expected to be stable for two years when stored per label instructions. **As a term of the MBI-203 EP Bioinsecticide registration, EPA is requiring the results of a two-year storage stability and corrosion characteristics study (ongoing) be submitted within one year.**	479450-02 484407-01
830.6319	Miscibility	Miscible with water	479450-02
830.6320	Corrosion Characteristics	Not expected to be corrosive to packaging materials. **As a term of the MBI-203 EP Bioinsecticide registration, EPA is requiring the results of a two-year storage stability and corrosion characteristics study (ongoing) be submitted within one year.**	479450-02 484407-01
830.7000*	pH	6.2	479450-02
830.7100	Viscosity	21.8 cP	479450-02
830.7300*	Density/Relative Density/Bulk Density (Specific Gravity)	1.02 g/mL	479450-02

* According to 40 CFR § 158.2120, these data are only required for the technical grade of the active ingredient. Since Marrone Bio Innovations included this information with its application for MBI-203 EP Bioinsecticide, it is summarized appropriately in this table.

TABLE 5. Toxicology Data Requirements for the Technical Grade of the Active Ingredient (TGAI)/Manufacturing-Use Product (MP), MBI-203 TGAI (40 CFR § 158.2140)

OCSPP Guideline Number	Data Requirement	Results		MRID No.
		TGAI	MP	
Tier I				
885.3050	Acute Oral Toxicity/Pathogenicity	Waived based on the results of MRID Nos. 479450-11 and 479450-03. **Classification: Acceptable**	Not applicable	479450-23
885.3150	Acute Pulmonary Toxicity/Pathogenicity	Waived based on the results of MRID Nos. 479450-11 and 479450-05. **Classification: Acceptable**	Not applicable	479450-23
885.3200	Acute Injection Toxicity/Pathogenicity (Intravenous)	Not toxic, infective, and/or pathogenic to rats when dosed intravenously at 3.1 x 10^6 cfu per animal. **Classification: Acceptable**	Not applicable	479450-11
885.3400	Hypersensitivity Incidents	No hypersensitivity incidents, including immediate-type or delayed-type reactions of humans and domestic animals that occurred during research, development, or testing of the TGAI/MP, were reported by the applicant. Any future hypersensitivity incidents must be reported to EPA (refer to test note #3 of 40 CFR § 158.2140(d)).		479450-23
885.3500	Cell Culture	Not required because *Chromobacterium subtsugae* strain PRAA4-1^T is not a virus (refer to test note #4 of 40 CFR § 158.2140(d)).	Not applicable	Not applicable
870.1100	Acute Oral Toxicity	Not applicable	Oral LD_{50} female rats > 5,000 mg/kg **Classification: Acceptable TOXICITY CATEGORY IV**	479450-03
870.1200	Acute Dermal Toxicity	Not applicable	Dermal LD_{50} combined (male and female) rats > 5,050 mg/kg **Classification: Acceptable TOXICITY CATEGORY IV**	479450-04
870.1300	Acute Inhalation Toxicity	Not applicable	Inhalation LC_{50} combined (male and female) rats > 2.12 mg/L **Classification: Acceptable TOXICITY CATEGORY IV**	479450-05
870.2400	Acute Eye Irritation	Not applicable	MBI-203 TGAI was minimally irritating to the eyes of rabbits. **Classification: Acceptable TOXICITY CATEGORY IV**	479450-06
870.2500	Primary Dermal Irritation	Not applicable	MBI-203 TGAI was slightly irritating to the skin of rabbits. **Classification: Acceptable TOXICITY CATEGORY IV**	479450-07
Tiers II and III				
Not required for *Chromobacterium subtsugae* strain PRAA4-1^T based on the lack of acute toxicity/pathogenicity in the Tier I studies.				

TABLE 5. Toxicology Data Requirements for the Technical Grade of the Active Ingredient (TGAI)/Manufacturing-Use Product (MP), MBI-203 TGAI (40 CFR § 158.2140)				
OCSPP Guideline Number	**Data Requirement**	**Results**		**MRID No.**
		TGAI	**MP**	
Additional Studies				
870.2600	Skin Sensitization	Not a dermal sensitizer **Classification: Acceptable**		479450-08
Not applicable	Safety Study (Subcutaneous Injection)	Not toxic or pathogenic at $\geq 10^6$ cfu/mouse subcutaneously **Classification: Supplemental – Not a required study**		479450-09
885.3200	Acute Injection Toxicity/Pathogenicity (Intravenous) Pilot Study	Provides no useful data as to the mechanism of toxicity observed **Classification: Supplemental – Not a required study**		479450-10

TABLE 6. Toxicology Data Requirements for the End-Use Product (EP), MBI-203 EP Bioinsecticide (40 CFR § 158.2140)			
OCSPP Guideline Number	**Data Requirement**	**Results**	**MRID No.**
885.3050	Acute Oral Toxicity/Pathogenicity	Not applicable	Not applicable
885.3150	Acute Pulmonary Toxicity/Pathogenicity	Not applicable	Not applicable
885.3200	Acute Injection Toxicity/Pathogenicity	Not applicable	Not applicable
885.3400	Hypersensitivity Incidents	No hypersensitivity incidents, including immediate-type or delayed-type reactions of humans and domestic animals that occurred during research, development, or testing of the EP, were reported by the applicant. Any future hypersensitivity incidents must be reported to EPA (refer to test note #3 of 40 CFR § 158.2140(d)).	Not applicable
885.3500	Cell Culture	Not applicable	Not applicable
870.1100	Acute Oral Toxicity	Waived based on the results of MRID No. 479450-03 and because this formulation contains inert ingredients that are present in small amounts, are not expected to be of toxicological concern, and are cleared for food use. **Classification: Acceptable TOXICITY CATEGORY III**	479450-24 481129-08
870.1200	Acute Dermal Toxicity	Waived based on the results of MRID No. 479450-04 and because this formulation contains inert ingredients that are present in small amounts, are not expected to be of toxicological concern, and are cleared for food use. **Classification: Acceptable TOXICITY CATEGORY III**	479450-24 481129-08
870.1300	Acute Inhalation Toxicity	Waived based on the results of MRID No. 479450-05 and because this formulation contains inert ingredients that are present in small amounts, are not expected to be of toxicological concern, and are cleared for food use. **Classification: Acceptable TOXICITY CATEGORY III**	479450-24 481129-08
870.2400	Acute Eye Irritation	Waived based on the results of MRID No. 479450-06 and because this formulation contains inert ingredients that are present in small amounts, are not expected to be of toxicological concern, and are cleared for food use. **Classification: Acceptable TOXICITY CATEGORY III**	479450-24 481129-08

TABLE 6. Toxicology Data Requirements for the End-Use Product (EP), MBI-203 EP Bioinsecticide (40 CFR § 158.2140)			
OCSPP Guideline Number	**Data Requirement**	**Results**	**MRID No.**
870.2500	Primary Dermal Irritation	Waived based on the results of MRID No. 479450-07 and because this formulation contains inert ingredients that are present in small amounts, are not expected to be of toxicological concern, and are cleared for food use. **Classification: Acceptable TOXICITY CATEGORY III**	479450-24 481129-08

TABLE 7. Nontarget Organism Toxicity and Environmental Fate Data Requirements for the Technical Grade of the Active Ingredient (TGAI), *Chromobacterium subtsugae* strain PRAA4-1^T (40 CFR § 158.2150)			
OCSPP Guideline Number	**Data Requirement**	**Results**	**MRID No.**
		Tier I	
885.4050	Avian Oral Toxicity	The no-observed-effect dosage of MBI-203 TGAI in this study was 4.0 x 10^{11} cfu/kg body weight/day for 5 days. **Classification: Acceptable**	479450-13
885.4100	Avian Inhalation Toxicity/Pathogenicity	Data waiver rationale provides sufficient information to determine that pathogenicity to birds is not expected. **Classification: Acceptable**	479450-23
885.4150	Wild Mammal Toxicity/Pathogenicity	Tests required by 40 CFR § 158.2140 are adequate and appropriate for assessment of hazards to wild mammals. Testing indicates no adverse effects to laboratory rats when dosed orally at 5,000 mg MBI-203 TGAI/kg body weight. **Classification: Acceptable**	479450-03
885.4200	Freshwater Fish Toxicity/Pathogenicity	The study indicates no adverse effects to fathead minnow (*Pimephales promelas*) when dosed with *Chromobacterium subtsugae* at a rate of 8.24 x 10^7 cfu/mL. **Classification: Acceptable**	479450-14
885.4240	Freshwater Invertebrate Toxicity/Pathogenicity	Tests indicate toxicity to *Daphnia magna*, and the addition of aquatic uses would require further testing. **Classification: Supplemental but acceptable for risk assessment**	479450-12 481129-04
		The following mitigating language is required in the Environmental Hazards section of the MBI-203 EP Bioinsecticide label: "This product is toxic to aquatic invertebrates. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas." Additionally, the MBI-203 EP Bioinsecticide label will (1) bear a maximum application rate of 12 quarts of product per acre, (2) include a restriction that aerial applications not occur within 75 feet of aquatic habitats, (3) require aerial applicators to use medium or coarser spray nozzles, and (4) list certain requirements and instructions to further reduce potential for spray drift to offsite areas.	

TABLE 7. Nontarget Organism Toxicity and Environmental Fate Data Requirements for the Technical Grade of the Active Ingredient (TGAI), *Chromobacterium subtsugae* strain PRAA4-1^T (40 CFR § 158.2150)			
OCSPP Guideline Number	**Data Requirement**	**Results**	**MRID No.**
885.4280	Estuarine/Marine Fish and Invertebrate Testing	Not required because *Chromobacterium subtsugae* strain PRAA4-1^T will not be applied to water and is not expected to enter marine/estuarine environments in amounts that are significantly higher than naturally occurring concentrations (refer to test note #6 of 40 CFR § 158.2150(e)).	Not applicable
885.4300	Nontarget Plant Testing	Effects of mild phytotoxicity were observed in cucumbers at 5X and 10X the field application rates and in chrysanthemum flowers at all application rates. **Classification: Supplemental but acceptable for risk assessment**	479450-15
		Even though effects in cucumbers and chrysanthemum flowers were mild, the MBI-203 EP Bioinsecticide label will still require all users to test for phytotoxicity prior to pesticide application.	
885.4340	Nontarget Insect Testing	Tests indicate toxicity to ladybird beetles. There were no observed effects to green lacewing larvae or parasitic wasps. The dosing and duration of the parasitic wasp study, however, were insufficient for a conclusive determination of no effects. **Classification: Supplemental but acceptable for risk assessment**	479450-16 479450-17 479450-18 481129-05
		The following mitigating language is required in the Environmental Hazards section of the MBI-203 EP Bioinsecticide label: "This product is toxic to certain nontarget terrestrial arthropods. Minimize spray drift away from target area to reduce effects to nontarget insects." Further testing would be required for the removal of this mitigating language from the MBI-203 EP Bioinsecticide label. Additionally, the MBI-203 EP Bioinsecticide label will list certain requirements and instructions to further reduce potential for spray drift to offsite areas.	
885.4380	Honey Bee Testing	Tests indicate toxicity to *Apis mellifera*. **Classification: Supplemental but acceptable for risk assessment**	479450-19 479450-20 479450-21
		The following mitigating language is required in the Environmental Hazards section of the MBI-203 EP Bioinsecticide label: "This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area." Further testing would be required for the removal of this mitigating language from the MBI-203 EP Bioinsecticide label. Additionally, the MBI-203 EP Bioinsecticide label will list certain requirements and instructions to further reduce potential for spray drift to offsite areas.	

TABLE 7. Nontarget Organism Toxicity and Environmental Fate Data Requirements for the Technical Grade of the Active Ingredient (TGAI), *Chromobacterium subtsugae* strain PRAA4-1^T (40 CFR § 158.2150)			
OCSPP Guideline Number	**Data Requirement**	**Results**	**MRID No.**
Tiers II, III, and IV			
Not required for *Chromobacterium subtsugae* strain PRAA4-1^T based on the current uses and application methods.			
Additional Studies			
Not applicable	Endangered Species Evaluation	Sufficient information was provided to determine that any potential risk from use of MBI-203 TGAI to endangered mammalian, avian, or fish species would likely be below the level of concern, and that adverse effects to endangered plant species are unlikely. Sufficient information was not provided to determine the potential risk to endangered nontarget insects or aquatic invertebrates. BPPD will make an independent endangered species determination. **Classification: Supplemental – not a required study**	479450-22

APPENDIX B. PESTICIDE PRODUCTS

EPA Registration Number	Registration Name	Percentage Active Ingredient	Formulation Type	Use Site(s)	Method(s) of Application	Application Rate	Target Pest
84059-9	MBI-203 TGAI	100.00%	Technical	N/A	N/A	N/A	N/A
84059-10	MBI-203 EP Bioinsecticide	94.50%	End Use – Liquid	Various agricultural and greenhouse crops (e.g., vegetables, ornamentals, and turf)	Standard ground or aerial spray application equipment and chemigation	2–12 quarts per acre	Various insects and mites