BIOPESTICIDES REGISTRATION ACTION DOCUMENT

Trichoderma virens strain G-41

Pesticide Chemical (PC) Code: 176604

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

February 6, 2012

TABLE OF CONTENTS

BIOPESTICIDES REGISTRATION ACTION DOCUMENT TEAM

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

Science Reviews

United States Environmental Protection Agency

Ibrahim S. Barsoum, Ph.D.	Product Analysis, Human Health
John L. Kough, Ph.D.	Product Analysis, Human Health
Shannon Borges	Environmental Effects

Health Canada Pest Management Regulatory Agency

Leila Heikkila	Human Health
James Elwin	Product Analysis, Environmental Effects

Regulations

United States Environmental Protection Agency

Sheryl K. Reilly, Ph.D.	Chief, Microbial Pesticides Branch
Jeannine Kausch	Regulatory Action Leader

I. EXECUTIVE SUMMARY

Background

In September 2009, BioWorks, Inc. submitted applications for a manufacturing-use pesticide product, G-41 Technical (EPA File Symbol 68539-I), and an end-use pesticide product, BW240 WP Biological Fungicide (EPA File Symbol 68539-O), to both the United States Environmental Protection Agency (EPA) and the Health Canada Pest Management Regulatory Agency (PMRA) and requested a North American Free Trade Agreement (NAFTA) Joint Review of these applications.[1] Concurrently with these applications, BioWorks, Inc. submitted an application for another end-use pesticide product, BW240 G Biological Fungicide (EPA File Symbol 68539-RN), and filed a petition for a tolerance exemption for residues of *Trichoderma virens* strain G-41, the new active ingredient contained in all three proposed pesticide products, with EPA only.

Trichoderma virens, including strain G-41, is a naturally occurring fungus that is native to the United States and is widely distributed throughout the world, inhabiting forest, agricultural, and orchard soils, as well as plant litter (Samuels 1996). *Trichoderma* virens strain G-41 was isolated from soil samples taken from *Aphanomyces*-suppressive fields in Livingston County, New York. Much like other *Trichoderma* species, *Trichoderma virens* strain G-41 inhibits or kills certain plant-pathogenic fungi (e.g., *Rhizoctonia* species and *Fusarium* species) through several mechanisms: (1) competition for food and space, (2) mycoparasitism, (3) antibiosis, and (4) induction of plant defense responses (Kenerley 2010, Samuels 1996). Given the fungicidal capabilities of *Trichoderma virens* strain G-41, BioWorks, Inc. proposed to register these pesticide products to control soilborne plant pathogens and plant root diseases that adversely affect agricultural, greenhouse, and nursery crops, as well as plants in residential settings (e.g., vegetables, fruit, and ornamentals).

EPA and/or PMRA 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 three proposed *Trichoderma virens* strain G-41 pesticide products. Overall, such data and information are adequate for risk assessment purposes, fulfill the current microbial pesticide data requirements, and allow for registration under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Product Analysis

Most of the product analysis data requirements for *Trichoderma virens* strain G-41, including product chemistry and composition, analysis of samples, and physical and chemical characteristics, were fulfilled by acceptable guideline studies. Although a one-year storage stability and corrosion characteristics study is outstanding, EPA reviewed an interim report of a storage stability and corrosion characteristics study and, as a term of registration, is requiring the final report of this study be submitted approximately one year from the date of registration.

Toxicology

Adequate mammalian toxicology data were submitted or cited to support the *Trichoderma virens* strain G-41 pesticide products. An acute injection toxicity/pathogenicity study showed that, at a single high dose, *Trichoderma virens* strain G-41 is not toxic, infective, and/or pathogenic via the

[1] See *http://www.epa.gov/oppfead1/international/naftatwg/guidance/jointreview-biope.pdf*.

intraperitoneal route of exposure, while two acute oral toxicity/pathogenicity studies (one conducted with *Trichoderma virens* strain G-41 and the other conducted with functionally similar *Trichoderma virens* strain GL-21 (formerly known as *Gliocladium virens* strain GL-21)) indicate that, at a single high dose, *Trichoderma virens* strain G-41 is not toxic and/or pathogenic via the oral route of exposure.[2] Acute pulmonary toxicity/pathogenicity testing demonstrated that *Trichoderma virens* strain GL-21, a functionally similar strain to *Trichoderma virens* strain G-41, was not toxic to, infective in, or pathogenic for rats when given a single intratracheal dose. Given the functional similarity of these two strains, EPA concluded that *Trichoderma virens* strain G-41 is also not likely to be toxic, infective, and/or pathogenic through the inhalation route. Moreover, no hypersensitivity incidents, occurring during research, development, or testing of *Trichoderma virens* strain G-41, were reported by the applicant. In light of the results of the injection, pulmonary, and oral toxicity/pathogenicity data, as well as the absence of hypersensitivity incidents, testing at higher tiers (i.e., Tiers II and III) was not required.

Tolerance Exemption

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 residues of *Trichoderma virens* strain G-41. No dietary risks are expected from use of *Trichoderma virens* strain G-41 as an active ingredient in pesticide products. Significant exposure to *Trichoderma virens* strain G-41—through food and drinking water and exceeding already present background levels—is not anticipated due to: (1) the proposed application methods of the end-use pesticide products (soil directed and soil incorporated; no aquatic applications); (2) the filtering effect of many particulate soil types; and (3) the conditions (e.g., filtration and pH adjustments) water is subjected to in wastewater treatment systems and drinking water facilities. Should this microbial pesticide be present on food or in drinking water, the acute oral toxicity and pathogenicity data available for *Trichoderma virens* strain G-41 and functionally similar *Trichoderma virens* strain GL-21 demonstrated that no toxicity, infectivity, and/or pathogenicity is likely to occur with any exposure level of *Trichoderma virens* strain G-41 resulting from application in accordance with good agricultural practices.

Occupational Exposure

Despite the low toxicological profile of *Trichoderma virens* strain G-41, 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 *Trichoderma virens* strain G-41 in agricultural settings are directed to wear a long-sleeved shirt, long pants, socks, shoes, protective eyewear, 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 different PPE, other than the standard described above, on a product-specific basis.

Nontarget Organisms

Data and other information (e.g., scientific literature) submitted by the applicant to support

[2] With its pesticide product applications, BioWorks, Inc. cited to toxicological data done with a similar, previously registered strain of *Trichoderma virens*, GL-21 (Kenerley 2010). Although GL-21 and G-41 are not identical, the two strains share many characteristics typical of *Trichoderma virens* (e.g., particular morphological features and weak growth at the temperature of the human body (37°C)), and thus are considered to be functionally similar. Based on these similarities, EPA concluded that data on *Trichoderma virens* strain GL-21 would be representative of the toxicological nature of *Trichoderma virens* strain G-41.

requests to waive nontarget organism testing for *Trichoderma virens* strain G-41 are sufficient to fulfill the relevant microbial pesticide 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. EPA performed an environmental risk assessment based on data and other information provided by the applicant, and determined that adverse effects to nontarget organisms are not anticipated from the proposed pesticidal uses of *Trichoderma virens* strain G-41. Moreover, EPA has made a "No Effect" determination for direct and indirect effects to listed species and their designated critical habitats resulting from these same proposed pesticidal uses.

Public Participation

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 proposed pesticide products containing *Trichoderma virens* strain G-41, a new active ingredient, and allowing for this active ingredient's first outdoor, food, and residential 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 *Trichoderma virens* strain G-41 pesticide products, G-41 Technical, BW240 WP Biological Fungicide, and BW240 G Biological Fungicide. Therefore, EPA maintained that, based upon the risk assessment and information submitted in support of registration of such pesticide products, it was appropriate to issue the G-41 Technical, BW240 WP Biological Fungicide, and BW240 G Biological Fungicide registrations under FIFRA section 3(c)(5). The basis for this decision can be found in the risk assessment for *Trichoderma virens* strain G-41, which is characterized throughout this Biopesticides Registration Action Document (BRAD).

II. ACTIVE INGREDIENT OVERVIEW

Biological Name:	*Trichoderma virens* strain G-41
Culture Deposit:	American Type Culture Collection in Manassas, Virginia under Accession Number ATCC 20906
OPP Chemical Code:	176604
Type of Pesticide:	Microbial Pesticide – Fungicide 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 September 18, 2009, Technology Sciences Group, Inc. (address: 1150 18th Street NW, Suite 1000; Washington, District of Columbia 20036), on behalf of BioWorks, Inc. (address: 100 Rawson Road, Suite 205; Victor, New York 14564), submitted applications to register a manufacturing-use pesticide product, G-41 Technical (EPA File Symbol 68539-I), and two end-use pesticide products, BW240 WP Biological Fungicide (EPA File Symbol 68539-O) and BW240 G Biological Fungicide (EPA File Symbol 68539-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. North American Free Trade Agreement Joint Review

Trichoderma virens strain G-41 was the subject of a NAFTA Joint Review conducted by EPA and PMRA.

C. Food Tolerance Exemption

Concurrent with its registration applications and under Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(d), Technology Sciences Group, Inc., on behalf of BioWorks, Inc., submitted a petition to establish an exemption from the requirement of a tolerance for *Trichoderma virens* strain G-41 (Pesticide Petition (PP) 9F7618). In the Federal Register of March 10, 2010 (75 FR 11171), EPA announced that Technology Sciences Group, Inc., on behalf of BioWorks, Inc., proposed to establish an exemption from the requirement of a tolerance for residues of the fungicide, *Trichoderma virens* strain G-41, in or on all food commodities and opened a 30-day comment period. No comments were received following this publication.

On February 1, 2012, EPA established an exemption from the requirement of a tolerance for residues of *Trichoderma virens* strain G-41, in or on all food commodities, when applied as a fungicide and used in accordance with good agricultural practices (40 CFR § 180.1310; 77 FR 4903).

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)

With the exception of a one-year storage stability and corrosion characteristics study, which EPA will require as a term of registration, all product analysis data requirements for *Trichoderma virens* strain G-41 have been fulfilled. Refer to Tables 1, 2, 3, and 4 in Appendix A for a 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 *Trichoderma virens* strain G-41 have been fulfilled. Acceptable Tier I mammalian toxicology data and information support registration of the *Trichoderma virens* strain G-41 pesticide products. Furthermore, Tier II and Tier III studies were not required for *Trichoderma virens* strain G-41, based on the lack of acute toxicity/pathogenicity in the Tier I studies.

For a 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 – Rat (Harmonized Guideline 885.3050; Master Record Identification Number (MRID No.) 483438-01): In an acute oral toxicity study, groups of young Sprague-Dawley albino rats (12 per sex) were given a single oral dose of G-41 technical grade of the active ingredient (TGAI) (1.5×10^9 colony-forming units per milliliter (cfu/mL)) in Phosphate Buffered Saline at doses of 1.5×10^8 colony-forming units (cfu) per animal. The animals were then observed for a period of up to 21 days with interim scheduled sacrifices on Days 3, 7, and 14. A group of animals (5 per sex) were also dosed with inactivated test substance. A group of control (untreated) animals (5 per sex) and a group of shelf control animals (2 per sex) were concurrently conducted. There were no treatment-related clinical signs, and no necropsy findings other than an empty digestive system in one animal from the test substance group. There were no changes in body weight, other than in one animal from the test substance group who lost weight on Day 3. The test substance had cleared from all tissues and organs by

Day 7; however, the sensitivity of detection indicated low recovery of the microbial pest control agent (MPCA) from tissues and fluids (0.5–9%). Clearance of the MPCA by Day 7 is uncertain. *Trichoderma virens* strain G-41 is not toxic to rats when administered by oral gavage in a single dose of 1.5 x 10^8 cfu per animal. This study was rated acceptable.

Acute Oral Toxicity/Pathogenicity – Rat (Harmonized Guideline 885.3050; MRID No. 407198-04): In a 14-day acute oral toxicity/pathogenicity study in Sprague-Dawley rats (13 per sex) with *Trichoderma virens* strain GL-21, there were no mortalities, and no signs of infectivity/pathogenicity were observed following oral administration at 10^8 cfu in 2.0% carboxymethyl cellulose per animal in a maximum dosing volume of 5 milliliters. General signs of toxicity (lethargy, rapid breathing) were observed 1 hour post treatment, but all signs had resolved by Day 1. There were no observable abnormalities upon necropsy, and all animals gained weight throughout the study. Interim sacrifices (Days 1, 7 and 14) were carried out to analyze for the presence of the microbe in kidney, lungs, liver, brain, spleen, mesenteric lymph nodes, and blood as a clearance assessment of the test organism. The test organism was detected in the feces on Day 1 and in low levels in the lungs (one animal) on Day 7 only; the test organism had cleared from all organs/tissue by Day 14. *Trichoderma virens* strain GL-21 is not toxic to, infective in, or pathogenic for rats when administered in a single oral dose at 10^8 cfu per animal. This study was originally rated acceptable but is supplemental in this situation (test organism is not the active ingredient proposed for registration).

Acute Pulmonary Toxicity/Pathogenicity (Harmonized Guideline 885.3150; MRID Nos. 407198-04 and 408640-02): In a 21-day acute pulmonary toxicity/pathogenicity study in rats with *Trichoderma virens* strain GL-21, no mortality, toxicity, or pathogenicity was observed following intratracheal administration at 10^8 cfu per animal. General signs of toxicity (poor weight gain; lethargy; rapid breathing; rough hair coat) were observed after dosing, but all signs had resolved by Day 4. Interim sacrifices (Days 1, 7 and 14) were carried out to analyze for the presence of the microbe in kidney, lungs, liver, brain, spleen, mesenteric lymph nodes, and blood as a clearance assessment of the test organism. The test organism was steadily cleared from the lungs of test animals after 2–3 weeks. For other organs/tissues, the test organism was detected on Day 1 in low numbers in the liver, blood, mesenteric lymph nodes, spleen, kidney, and brain. The test organism had cleared in all organs/tissues by Day 7, except for one animal that had low levels of the organism in the spleen on Day 14. Upon necropsy, treated animals appeared normal except for the appearance of grey spots in the lungs at each interim sacrifice. The peritracheal lymph nodes of dosed animals often appeared enlarged and pale. This can most likely be attributed to the administration of the test substance and probably represents the test material itself. *Trichoderma virens* strain GL-21 is not toxic to, infective in, or pathogenic for rats when administered in a single intratracheal dose at 10^8 cfu per animal. This study was originally rated acceptable but is supplemental in this situation (test organism is not the active ingredient proposed for registration).

Acute Injection Toxicity/Pathogenicity (Intraperitoneal) – Rat (Harmonized Guideline 885.3200; MRID Nos. 478651-02 and 482368-01): In an acute intraperitoneal infectivity study, young adult Wistar rats were injected with approximately 10^7 cfu of the G-41 TGAI in distilled water by intraperitoneal route (3 per sex; 1 milliliter per animal). A vehicle control group, which received sterile, distilled water, was also included. The animals were observed once daily for 21 days. The observation included changes in the skin and fur, eyes and mucous membrane, respiratory system, circulatory system, autonomic and central nervous system, somatomotor activity, and

behavior pattern. Particular attention was directed to observations of tremors, convulsions, diarrhea, lethargy, salivation, sleep and coma; all observed toxic signs were recorded. Clearance, however, was not unequivocally assessed as it is not specified as a requirement for infectivity testing by intraperitoneal injection. There were no mortalities, no toxic signs in any of the animals, no abnormal findings upon necropsy, and body weight gain was not affected. While clearance was not directly assessed in this study, the lack of clinical findings upon necropsy, in combination with the lack of mortality and signs of toxicity in the animals, strongly suggests that *Trichoderma virens* strain G-41 is also not pathogenic by intraperitoneal injection. *Trichoderma virens* strain G-41 is not toxic, infective, and/or pathogenic to rats when administered intraperitoneally in a single dose of 10^7 cfu per animal. This study was rated acceptable.

Hypersensitivity Incidents (Harmonized Guideline 885.3400; MRID No. 482526-01): No hypersensitivity incidents, including immediate-type or delayed-type reactions of humans and domestic animals that occurred during research, development, or testing of *Trichoderma virens* strain G-41, 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 (Harmonized Guideline 885.3500): This study is not required because *Trichoderma virens* strain G-41 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 *Trichoderma virens* strain G-41, 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.

Trichoderma virens strain G-41 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 exemption, 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 Tables 5 and 6 in Appendix A, the data required for a FFDCA risk assessment for *Trichoderma virens* strain G-41 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: All proposed *Trichoderma virens* strain G-41 applications are soil directed or soil incorporated because of the targeted soilborne pests (e.g., *Rhizoctonia* spp. and *Fusarium* spp.). Based on calculations made in EPA's environmental risk assessment, these applications are not expected to significantly increase the populations of this fungus above natural levels in the soil. No reports were available in the literature describing natural concentrations of *Trichoderma virens*; however, *Trichoderma* species have been reported in various types of soils at concentrations of 10^4 to 10^6 colony-forming units per gram (cfu/g) (Leandro *et al*. 2007, Liu *et al*. 2008). Based on the maximum application rate of the proposed end-use pesticide products containing *Trichoderma virens* strain G-41, the estimated amount of *Trichoderma virens* applied to the soil surface is approximately 6.7 x 10^3 colony-forming units per square centimeter (cfu/cm^2). Assuming a bulk density of 1 to 2 grams per cubic centimeter (g/cm^3), the maximum application rate will not result in soil concentrations that are substantially greater than concentrations of *Trichoderma virens* naturally found in the soil, and overall increased exposure to *Trichoderma virens* in the terrestrial environment, including on above-ground plant parts such as food commodities, is not expected. Work by Jackson *et al*. (1991) supports this conclusion given that, after *Trichoderma virens* and three other *Trichoderma* isolates were incorporated into soil, fungal numbers either transiently increased, remained stable, or declined. Should this microbial pesticide be present on food, the acute oral toxicity and pathogenicity data available for *Trichoderma virens* strain G-41 and functionally similar *Trichoderma virens* strain GL-21 demonstrated no toxicity, infectivity, and/or pathogenicity is likely to occur with any exposure level of *Trichoderma virens* strain G-41 resulting from application in accordance with good agricultural practices (see section IV(B)(1)(a) and Table 5 in Appendix A).

Drinking Water Exposure and Risk Characterization: Exposure to residues of *Trichoderma virens* strain G-41 in consumed drinking water is unlikely. The proposed use patterns for *Trichoderma virens* strain G-41 are soil directed and soil incorporated, thereby limiting contact with surface water by drift and runoff. Furthermore, ground water is not expected to have significant exposure to *Trichoderma virens* strain G-41 since, like other *Trichoderma* species, this fungus would likely be filtered out by the particulate nature of many soil types, and be concentrated in upper soil horizons (Longa *et al*. 2009, Sariah *et al*. 2005) near plant roots (USPTO 2010). If *Trichoderma virens* strain G-41 were to be transferred to surface or ground waters (e.g., through spray drift or runoff) that are intended for eventual human consumption 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 chlorination, pH adjustments, filtration, and occasionally high temperatures (Centers for Disease Control and Prevention 2009, U.S. EPA 2004). For instance, *Trichoderma virens* strain G-41 does not grow well at 37°C (Kenerley 2010, Lumsden *et al*. 1996), and test data has shown it to be unstable at elevated temperatures; therefore, any heat treatment applied to water containing *Trichoderma virens* strain G-41 would probably render the fungus non-viable. In the remote likelihood that this microbial pesticide is present in drinking water (e.g., water not subject to treatment systems or facilities), the acute oral toxicity and pathogenicity data available for *Trichoderma virens* strain G-41 and functionally similar *Trichoderma virens* strain GL-21 demonstrated no toxicity, infectivity, and/or pathogenicity is likely to occur with any exposure level of *Trichoderma virens* strain G-41 resulting from application in accordance with good agricultural practices (see section IV(B)(1)(a) and Table 5 in Appendix A).

Non-occupational, Residential Risk Characterization: Given *Trichoderma virens*' natural occurrence in soil (Samuels 1996), non-occupational exposure to the fungus is likely already occurring. Even with the proposed pesticide applications of *Trichoderma virens* strain G-41, it is not likely that there will be a significant increase in these exposures due to the relative stability of typical background levels in the soil (see calculations and information presented in the food exposure section above). If significant non-occupational exposures were to occur, such exposures would not exceed EPA's level of concern in light of test results that indicated *Trichoderma virens* strain G-41 is not toxic (acute pulmonary toxicity/pathogenicity, acute inhalation toxicity, and acute dermal toxicity), is non-irritating (primary dermal irritation), and is not pathogenic or infective (acute pulmonary toxicity/pathogenicity) (see section IV(B)(1)(a) and Tables 5 and 6 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."

There are several *Trichoderma* species used as active ingredients in registered pesticide products. While these different microbial pest control agents may produce similar metabolites, the likelihood of adverse cumulative effects via a common mechanism of toxicity is not anticipated, based on the lack of toxicity/pathogenicity potential of the active ingredients used on food and/or labeled for residential uses (U.S. EPA 2008, 2010a, 2010b, and 2010c). 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 Population, Infants and Children

FFDCA section 408(b)(2)(C) provides that, in considering the establishment of a tolerance or tolerance exemption for a pesticide chemical residue, 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 Tables 5 and 6 in Appendix A, as well as use of *Trichoderma* pesticide products since 1989 without reported adverse effects to humans, EPA concludes that there are no threshold effects of concern to infants, children, or adults when *Trichoderma virens* strain G-41 is used as labeled in accordance with good agricultural practices. As a result, EPA concludes that

no additional margin of exposure (safety) is necessary to protect infants and children and that not adding any additional margin of exposure (safety) will be safe for infants and children.

Moreover, based on the same data and EPA analysis as presented directly above, the Agency is able to conclude 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 *Trichoderma virens* strain G-41 when it is used as labeled and in accordance with good agricultural practices as a fungicide. 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 and information available on *Trichoderma virens* strain G-41, as well as data available on functionally similar *Trichoderma virens* strain GL-21, do not demonstrate toxic, pathogenic, and/or infective potential to mammals, including infants and children.

3. Occupational Exposure and Risk Characterization

Handler exposure to *Trichoderma virens* strain G-41 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 *Trichoderma virens* strain G-41 end-use pesticide products in agricultural settings must wear a long-sleeved shirt, long pants, socks, shoes, protective eyewear, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. EPA may require different PPE, other than the standard described above, on a product-specific basis.

4. Human Health Risk Characterization

EPA considered human exposure to *Trichoderma virens* strain G-41 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 United States population in general, and to infants and children in particular, will result when *Trichoderma virens* strain G-41 pesticide products are used in accordance with EPA-approved labeling.

C. Environmental Assessment (40 CFR § 158.2150)

Data and other information (e.g., scientific literature) submitted by the applicant to support requests to waive nontarget organism testing for *Trichoderma virens* strain G-41 are sufficient to fulfill the relevant microbial pesticide 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. EPA performed an environmental risk assessment based on data and other information provided by the applicant, and has determined that adverse effects to nontarget organisms are not anticipated from the proposed pesticidal uses of *Trichoderma virens* strain G-41. Moreover, EPA has made a “No Effect” determination for direct and indirect effects to listed species and their designated critical habitats resulting from these same proposed pesticidal uses.

For a 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

Birds (Harmonized Guideline 885.4050) and Wild Mammals (Harmonized Guideline 885.4150) (MRID Nos. 478651-03 and 482526-01): Data and other information submitted by BioWorks, Inc. to support its waiver requests showed that *Trichoderma virens* strain G-41 is not expected to be toxic or pathogenic to birds or mammals because (1) birds and mammals are commonly exposed to this fungus; (2) *Trichoderma virens* strain G-41 does not grow at mammalian or avian body temperatures; and (3) *Trichoderma virens* strain G-41 is similar to *Trichoderma virens* strain GL-21, which was previously determined to present minimal risk to birds and mammals. *Trichoderma virens* is a ubiquitous fungus in terrestrial environments, inhabiting soil of all types and plant litter (Samuels 1996). Therefore, wild mammals and birds are commonly exposed to this fungus. *Trichoderma virens* strain G-41 also does not grow at 39ºC or above (Kenerley 2010). Kenerley (2010) also provides data to show that *Trichoderma virens* strain G-41 is biologically similar to *Trichoderma virens* strain GL-21 and is expected to have a similar toxicity/pathogenicity profile. *Trichoderma virens* strain G-41 is not expected to adversely affect wild mammals, since no toxicity or pathogenicity was shown in laboratory rats exposed to G-41 Technical by injection at 10^7 units of MPCA per animal (submitted in MRID Nos. 478651-02 and 482368-01). Based on this information, adverse effects to wild mammals and birds are not anticipated to result from the proposed labeled uses of *Trichoderma virens* strain G-41.

Nontarget Insects (Harmonized Guideline 885.4340) and Honey Bees (Harmonized Guideline 885.4380) (MRID Nos.478651-03 and 482526-01): BioWorks, Inc. presented similar data and information to support waiver requests and a conclusion of minimal exposure and risk to nontarget insects and honey bees. *Trichoderma virens* strain G-41 is not expected to be toxic or pathogenic to honey bees and other insects, because it is a naturally occurring fungus that is not an insect pathogen, and it also has not been known to produce insect epizootics (i.e., widespread outbreaks of disease that spread quickly). It is also native to the United States and is widely distributed throughout the world, inhabiting forest, agricultural and orchard soils as well as plant litter (Samuels 1996). The end-use pesticide products are proposed for use in greenhouses, nurseries, and soil treatments, which will reduce exposure to honey bees and many other insects. Since *Trichoderma virens* is naturally found in soils and plant litter, soil- and ground-dwelling insects are commonly exposed to this fungus. As discussed below (see "nontarget plants" summary), the proposed applications of *Trichoderma virens* strain G-41 are not expected to increase the concentrations of this fungus above naturally occurring levels. Based on these lines of evidence, the proposed pesticidal uses of *Trichoderma virens* strain G-41 are not expected to result in adverse effects to honey bees and other nontarget insects.

Nontarget Plants (Harmonized Guideline 885.4300; MRID Nos. 478651-03 and 482526-01): BioWorks, Inc. presented data and other information to support waiver requests and show that *Trichoderma virens* strain G-41 will not cause adverse effects in nontarget plants. *Trichoderma virens* is a naturally occurring fungus that is native to the United States and is widely distributed throughout the world, inhabiting forest, agricultural and orchard soils, as well as plant litter (Samuels 1996). Therefore, nontarget terrestrial plants are commonly exposed to *Trichoderma virens*. The proposed applications are also not expected to significantly increase the populations of this fungus in soil above natural levels. No reports were available in the literature describing natural concentrations of *Trichoderma virens*; however, *Trichoderma* spp. have been reported in

various types of soils at concentrations of 10^4 to 10^6 cfu/g (Leandro *et al*. 2007, Liu *et al*. 2008). Based on the maximum application rate of the end-use pesticide products containing *Trichoderma virens* strain G-41, and its reported minimum viability in the end-use pesticide products (5 x 10^6 cfu/g), the estimated amount of *Trichoderma virens* applied to the soil surface is approximately 6.7 x 10^3 cfu/cm^2. Assuming a soil bulk density of 1 to 2 g/cm^3, the maximum application rate will not result in soil concentrations that are substantially greater than concentrations of *Trichoderma virens* naturally found in the soil, and increased exposure to *Trichoderma virens* in the terrestrial environment is not expected. *Trichoderma virens* is also not related to known plant pathogens. Therefore, based on the data and information presented, adverse effects to terrestrial nontarget plants resulting from the proposed pesticidal applications of *Trichoderma virens* strain G-41 are not expected.

b. Aquatic Animals and Plants

Freshwater Fish (Harmonized Guideline 885.4200), Freshwater Invertebrates (Harmonized Guideline 885.4240), Estuarine/Marine Fish and Invertebrates (Harmonized Guideline 885.4280), and Nontarget Plants (Harmonized Guideline 885.4300) (MRID Nos. 478651-03 and 482526-01): BioWorks, Inc. presented similar data and information to support waiver requests and show that adverse effects to freshwater and marine/estuarine fish and invertebrates will not occur as a result of the proposed applications of *Trichoderma virens* strain G-41. Similar data and information was also provided for aquatic plants. *Trichoderma virens* is native to the United States and is widely distributed, inhabiting forest, agricultural and orchard soils, as well as plant litter (Samuels 1996). Given the ubiquitous distribution of *Trichoderma virens* in soil, this microbe is very likely washed into freshwater and marine/estuarine systems in nature, and fish, invertebrates, and aquatic plants are commonly exposed to this fungus. As discussed above (see "nontarget plants" summary), the maximum proposed application rate is not expected to raise the concentration of *Trichoderma virens* in the soil above naturally occurring levels, so runoff from treated areas is expected to contain similar amounts of *Trichoderma virens* as would be expected in runoff from natural areas. *Trichoderma virens* is also not known to proliferate in water, so *Trichoderma virens* deposited in water from runoff would not become established in aquatic environments. Based on this data and information, the proposed pesticidal applications of *Trichoderma virens* strain G-41 are not expected to result in significant exposure of nontarget aquatic organisms to levels above those that occur naturally, and adverse effects to freshwater and marine/estuarine fish, invertebrates, and plants are not expected.

2. Environmental Fate Data

As the data and information provided are sufficient to fulfill the Tier I nontarget organism data requirements and allow for nontarget organism risk assessment for *Trichoderma virens* strain G-41, further testing at higher tier levels (i.e., Tiers II, III, and IV) is not required.

3. Threatened and Endangered Species Assessment

Since EPA has determined that no effects are anticipated for any nontarget species exposed to *Trichoderma virens* strain G-41 as a result of the proposed applications, effects to threatened and endangered species and their designated critical habitats are also not expected. Therefore, a "No Effect" determination is made for direct and indirect effects to listed species and their designated critical habitats resulting from the proposed pesticidal uses of *Trichoderma virens* strain G-41, as

labeled.

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 *Trichoderma virens* strain G-41, 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 *Trichoderma virens* strain G-41 pesticide products have well-known properties. EPA has no knowledge that would contradict the claims made on the G-41 Technical, BW240 WP Biological Fungicide, and BW240 G Biological Fungicide labels, and such pesticide products are not expected to cause unreasonable adverse effects on the environment when used according to their respective 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 *Trichoderma virens* strain G-41 pesticide products will not cause any unreasonable adverse effects on the environment, and BW240 WP Biological Fungicide and BW240 G Biological Fungicide (end-use pesticide products), in particular, are likely to provide protection against fungal pests as claimed, satisfying criterion 3. Criterion 4 is satisfied in that the *Trichoderma virens* strain G-41 pesticide products are not expected to cause unreasonable adverse effects when used according to label instructions. Therefore, G-41 Technical, BW240 WP Biological Fungicide, and BW240 G Biological Fungicide, containing *Trichoderma virens* strain G-41 as a new active ingredient, are eligible for registration under FIFRA section 3(c)(5) for the labeled uses.

VII. ACTIONS REQUIRED OF THE REGISTRANT

A. Final Printed Labeling

Before releasing pesticide products containing *Trichoderma virens* strain G-41 for shipment, the registrant is required to provide appropriate final printed labeling to EPA.

B. Terms of Registration

As terms of the G-41 Technical, BW240 WP Biological Fungicide, and BW240 G Biological Fungicide registrations, BioWorks, Inc. must submit the results of a one-year storage stability (Harmonized Guideline 830.6317) and corrosion characteristics (Harmonized Guideline 830.6320) study within one year of registration.

Additionally, as a term of the BW240 G Biological Fungicide registration, BioWorks, Inc. must submit additional information (confirmatory) on the discussion of formation of unintentional ingredients (Harmonized Guideline 885.1300) and analysis of samples (Harmonized Guideline 885.1400) data requirements within six months of registration.

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

BRAD	Biopesticides Registration Action Document
CFR	Code of Federal Regulations
cfu	colony-forming unit(s)
cfu/cm^2	colony-forming units per square centimeter
cfu/g	colony-forming units per gram
cfu/mL	colony-forming units per milliliter
EDSP	Endocrine Disruptor Screening Program
EP	end-use pesticide product
EPA	United States Environmental Protection Agency (the "Agency")
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FR	Federal Register
g	gram
g/cm^3	grams per cubic centimeter
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 pesticide product
MPCA	microbial pest control agent
MRID No.	Master Record Identification Number
NAFTA	North American Free Trade Agreement
NIOSH	National Institute for Occupational Safety and Health
OPP	Office of Pesticide Programs
PC Code	Pesticide Chemical Code
PMRA	Health Canada Pest Management Regulatory Agency
PP	Pesticide Petition
PPE	personal protective equipment
ppm	parts per million
TGAI	technical grade of the active ingredient
U.S.	United States
USPTO	United States Patent and Trademark Office

IX. BIBLIOGRAPHY

A. Studies Submitted or Cited to Support the *Trichoderma virens* strain G-41 Pesticide Product Registrations

MRID No.	Study Information
407198-04	David R. 1988. Acute Oral Toxicity/Pathogenicity Study of Alginate Prill of Strain GL21 in Rats – Final Report. Study Number: G-7131.222. Unpublished study prepared by Microbiological Associates, Inc., 22 pages.
407198-05	David R. 1988. Acute Pulmonary Toxicity/Pathogenicity Study of Spores of Strain GL21 in Rats – Interim Report. Study Number: G-7131.225. Unpublished study prepared by Microbiological Associates, Inc., 20 pages.
407198-06	David R. 1981. Acute Intravenous Toxicity/Pathogenicity Study of Mycelia of Strain GL21 in Rats – Interim Report. Study Number: G-7131.224. Unpublished study prepared by Microbiological Associates, Inc., 21 pages.
408640-01	David R. 1988. Acute Intravenous Toxicity/Pathogenicity Study of Mycelia of Strain GL21 in Rats – Final Report. MBA Study Number: G-7131.224. Unpublished study prepared by Microbiological Associates, Inc., 23 pages.
408640-02	David R. 1988. Acute Pulmonary Toxicity/Pathogenicity Study of Spores of Strain GL21 in Rats – Final Report. MBA Study Number: G-7131.225. Unpublished study prepared by Microbiological Associates, Inc., 23 pages.
478649-01	Brookman D. 2009. Product Chemistry of BW240 Granules. Project Number: BW240G/001. Unpublished study prepared by Technology Sciences Group, Inc., 57 pages.
478650-01	Brookman D. 2009. Product Chemistry of BW240 WP. Project Number: BW240/001. Unpublished study prepared by Technology Sciences Group, Inc., 79 pages.
478650-02	Kuhn J. 2009. BW240 WP: Acute Oral Toxicity Study (UDP) in Rats – Final Report. Project Number: 12982/09. Unpublished study prepared by Stillmeadow, Inc., 11 pages.
478650-03	Kuhn J. 2009. BW240 WP: Acute Dermal Toxicity Study in Rats – Final Report. Project Number: 12983/09. Unpublished study prepared by Stillmeadow, Inc., 12 pages.
478650-04	Younger C. 2009. BW240 WP: Acute Inhalation Toxicity Study in Rats – Final Report. Project Number: 12984/09. Unpublished study prepared by Stillmeadow, Inc., 18 pages.

MRID No.	Study Information
478650-05	Kuhn J. 2009. BW240 WP: Acute Eye Irritation Study in Rabbits – Final Report. Project Number: 12985/09. Unpublished study prepared by Stillmeadow, Inc., 17 pages.
478650-06	Kuhn J. 2009. BW240 WP: Acute Dermal Irritation Study in Rabbits – Final Report. Project Number: 12986/09. Unpublished study prepared by Stillmeadow, Inc., 12 pages.
478651-01	Brookman D. 2009. Product Chemistry of G-41 Technical. Project Number: BWG41/001, G6690/PHYCHEM, G6690. Unpublished study prepared by Technology Sciences Group, Inc., 95 pages.
478651-02	Prakash P. 2009. G41 Technical Grade Active Ingredient: Acute Injection Toxicity/Pathogenicity Study in Wistar Rats. Project Number: G6692/AP/R, G6692. Unpublished study prepared by Advinus Therapeutics Private Ltd., 28 pages.
478651-03	Mileson B. 2009. Response to Tier I Microbial Pesticide Data Requirements for G-41 Technical. Unpublished study prepared by Technology Sciences Group, Inc., 47 pages.
478708-01	Even M. 2009. Response to Tier I Microbial Pesticide Data Requirements for G-41 Technical. Unpublished study prepared by Technology Sciences Group. Inc., 32 pages.
481964-02	Even M. 2010. Response to Tier I Microbial Pesticide Data Requirements for BW240 G. Unpublished study prepared by Technology Sciences Group, Inc., 4 pages.
482104-01	Brookman D. 2010. Supplemental Product Chemistry of BW240 WP. Project Number: BW240WP/002. Unpublished study prepared by Technology Sciences Group, Inc., 22 pages.
482104-02	Even M. 2010. Response to Tier I Microbial Pesticide Data Requirements for BW240 WP. Unpublished study prepared by Technology Sciences Group, Inc., 4 pages.
482120-01	Brookman D, Bjornson H. 2010. Supplemental Product Chemistry of G-41 Technical. Project Number: BWG41/002. Unpublished study prepared by Technology Sciences Group, Inc., 57 pages.
482368-01	Prakash P. 2009. G41 Technical Grade Active Ingredient: Acute Injection Toxicity/Pathogenicity Study in Wistar Rats – Final Report. Project Number: G6692. Unpublished study prepared by Advinus Therapeutics Private Ltd., 7 pages.

MRID No. Study Information

482526-01 Mileson B, Even M. 2010. Response to Tier I Microbial Pesticide Data Requirements for G-41 Technical. Unpublished study prepared by BioWorks, Inc., 220 pages.

483438-01 Monds K. 2010. G41 TGAI: Acute Oral Toxicity/Pathogenicity Study in Rats – Final Report. Project Number: 14392/10. Unpublished study prepared by Stillmeadow, Inc., 28 pages.

B. Environmental Protection Agency Risk Assessment Memoranda

U.S. EPA. 2011a. Review of Product Chemistry, Manufacturing Process, Discussion of Formation of Unintentional Ingredients, Analysis of Samples, Certification of Limits, and Physical and Chemical Characteristics for Section 3 Registration of an End Use Product BW240 G (EPA Reg. No. 68539-RN). Memorandum from I.S. Barsoum, Ph.D. and J.L. Kough, Ph.D. to J. Kausch dated July 7, 2011.

U.S. EPA. 2011b. Environmental Risk Assessment of the FIFRA Section 3 registration of *Trichoderma virens* strain G-41 (PC Code 176604; EPA File Symbols 68539-I, -O, -RN). Memorandum from S. Borges to J. Kausch dated November 14, 2011.

U.S. EPA. 2011c. Review of Product Chemistry, Manufacturing Process, Discussion of Formation of Unintentional Ingredients, Analysis of Samples, Certification of Limits, Physical and Chemical Characteristics, and Acute Toxicity Studies for Section 3 Registration of an MUP G-41 Technical (EPA Reg. No. 68539-I) and an EP BW240 WP (EPA Reg. No. 68539-O). Memorandum from I.S. Barsoum, Ph.D. and J.L. Kough, Ph.D. to J. Kausch dated December 20, 2011.

C. Other References

Bjornsen HR. 2009. Cover Letter Accompanying Application for Pesticide Registration (re: Application to Register BW240 G). Letter from H.R. Bjornsen to S. Reilly dated September 18, 2009.

Brookman D. 2010. Supplement Product Chemistry of BW240 Granules. Unpublished study prepared by Technology Sciences Group, Inc., 16 pages (No MRID No.).

Centers for Disease Control and Prevention. 2009. Drinking Water - Water Treatment. Available from *http://www.cdc.gov/healthywater/drinking/public/water_treatment.html*.

Jackson AM, Whipps JM, Lynch JM. 1991. Production, delivery systems, and survival in soil of four fungi with biocontrol potential. *Enzyme Microb. Tech.* 13:636–642.

Kenerley CM. 2010. Report on studies comparing two strains of *Trichoderma virens*; GL21 and G41. Texas A&M University, Department of Plant Pathology and Microbiology. Unpublished report.

Leandro LFS, Guzman T, Ferguson LM, Fernandez GE, Louws FJ. 2007. Population dynamics of *Trichoderma* in fumigated and compost-amended soil and on strawberry roots. *Appl. Soil Ecol*. 35:237–246.

Liu B, Glenn D, Buckley K. 2008. *Trichoderma* communities in soils from organic, sustainable, and conventional farms, and their relation with Southern blight of tomato. *Soil Biol. Biochem*. 40:1124–1136.

Longa CMO, Savazzini F, Tosi S, Elad Y, Pertot I. 2009. Evaluating the survival and environmental fate of the Biocontrol agent *Trichoderma atroviride* SC1 in vineyards in northern Italy. *J. Appl. Microbiol*. 106:1549–1557.

Lumsden RD, Walter JF, Baker CP. 1996. Development of *Gliocladium virens* for damping-off disease control. *Can. J. Plant Pathol*. 18:463–468.

Samuels GJ. 1996. *Trichoderma*: A review of biology and systematics of the genus. *Mycol. Res*. 100:923–935.

Sariah M, Choo CW, Zakaria H, Norihan MS. 2005. Quantification and characterization of *Trichoderma* spp. from different ecosystems. *Mycopathologia* 159:113–117.

U.S. EPA. 2010a. *Trichoderma asperellum* strain ICC 012 Biopesticides Registration Action Document dated March 4, 2010 (available as "Supporting & Related Material" within docket ID number EPA-HQ-OPP-2009-1004 at *http://www.regulations.gov*).

U.S. EPA. 2010b. *Trichoderma gamsii* strain ICC 080 Biopesticides Registration Action Document dated March 4, 2010 (available as "Supporting & Related Material" within docket ID number EPA-HQ-OPP-2009-1003 at *http://www.regulations.gov*).

U.S. EPA. 2010c. *Trichoderma hamatum* isolate 382 Biopesticides Registration Action Document dated July 13, 2010 (available as "Supporting & Related Material" within docket ID number EPA-HQ-OPP-2010-0489 at *http://www.regulations.gov*).

U.S. EPA. 2008. *Trichoderma* Species Final Registration Review Decision (signed September 11, 2008). Available from *http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2006-0245-0008;oldLink=false*.

U.S. EPA. 2004. Primer for Municipal Wastewater Treatment Systems. EPA 832-R-04-001. Available from *http://www.epa.gov/npdes/pubs/primer.pdf*.

USPTO. 2010. Control of Plant Diseases and Enhancing Plant Growth Using a Combination of a *Trichoderma virens* Species and a Rhizosphere Competent *Trichoderma harzianum* Species (United States Patent Application – US 2010/0028303 A1). Available from *http://www.freepatentsonline.com/20100028303.pdf*.

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), *Trichoderma virens* strain G-41, and the Manufacturing-Use Pesticide Product (MP), G-41 Technical (40 CFR § 158.2120)

Harmonized Guideline Number	Data Requirement	Results		MRID No.
		***Trichoderma virens* strain G-41**	**G-41 Technical**	
885.1100	Product Identity	N/A	Submitted data fulfill the requirement for product identity. G-41 Technical contains 12.10% by weight *Trichoderma virens* strain G-41.	478651-01 482120-01
885.1200	Manufacturing Process	Submitted data fulfill the requirement for manufacturing process.		
Not applicable	Deposition of a Sample in a Nationally Recognized Culture Collection	*Trichoderma virens* strain G-41 is on deposit with the American Type Culture Collection in Manassas, Virginia under Accession Number ATCC 20906.	N/A	
885.1300	Discussion of Formation of Unintentional Ingredients	Submitted data fulfill the requirement for discussion of formation of unintentional ingredients.		
885.1400	Analysis of Samples	Submitted data fulfill the requirement for analysis of samples.		478651-01
885.1500	Certification of Limits	N/A	Limits listed on the confidential statement of formula are adequate/acceptable.	478651-01 482120-01

TABLE 2. Product Analysis Data Requirements for the End-Use Pesticide Product (EPs), BW240 WP Biological Fungicide and BW240 G Biological Fungicide (40 CFR § 158.2120)

Harmonized Guideline Number	Data Requirement	Results		MRID No.
		BW240 WP*	**BW240 G****	
885.1100	Product Identity	Submitted data fulfill the requirement for product identity. BW240 WP contains 1.15% by weight *Trichoderma harzianum* Rifai strain T-22 and 0.61% by weight *Trichoderma virens* strain G-41.	Submitted data fulfill the requirement for product identity. BW240 G contains 1.15% by weight *Trichoderma harzianum* Rifai strain T-22 and 0.61% by weight *Trichoderma virens* strain G-41.	478649-01** Brookman (2010)** 478650-01* 482104-01*
885.1200	Manufacturing Process	Submitted data fulfill the requirement for manufacturing process.		478649-01** 478650-01* 482104-01*
N/A	Deposition of a Sample in a Nationally Recognized Culture Collection	N/A		N/A
885.1300	Discussion of Formation of Unintentional Ingredients	Submitted data fulfill the requirement for discussion of formation of unintentional ingredients.	Submitted data fulfill the requirement for discussion of formation of unintentional ingredients for purposes of FIFRA section 3(c)(5) registration. **As a term of the BW240 G registration, EPA is requiring additional information (confirmatory) on this data requirement.**	478649-01** 478650-01*
885.1400	Analysis of Samples	Submitted date fulfill the requirement for analysis of samples.	Submitted data fulfill the requirement for discussion of formation of unintentional ingredients for purposes of FIFRA section 3(c)(5) registration. **As a term of the BW240 G registration, EPA is requiring additional information (confirmatory) on this data requirement.**	478649-01** 478650-01*
885.1500	Certification of Limits	Limits listed on the confidential statement of formula are adequate/acceptable.		478649-01** Brookman (2010)** 478650-01* 482104-01*

TABLE 3. Physical and Chemical Characteristics for the Technical Grade of the Active Ingredient (TGAI), *Trichoderma virens* strain G-41, and the Manufacturing-Use Pesticide Product (MP), G-41 Technical (40 CFR § 158.2120)

Harmonized Guideline Number	Data Requirement	Results		MRID No.
		***Trichoderma virens* strain G-41**	**G-41 Technical**	
830.6302[1]	Color	Gray-green		478651-01
830.6303[1]	Physical State	Solid		
830.6304[1]	Odor	Slight musty odor		
830.6313[1]	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	Unstable at elevated temperatures; stable to metals or metal ions (iron metal, aluminum metal, iron acetate, and aluminum acetate).		
830.6317	Storage Stability	Stable at 4°C and 21°C for 6 months. **As a term of the G-41 Technical registration, EPA is requiring the results of a one-year storage stability and corrosion characteristics study be submitted within one year of registration.**		
830.6319	Miscibility	N/A	Not required because G-41 Technical is not an emulsifiable liquid form of a microbial pesticide (refer to test note #2 of 40 CFR § 158.2120(d)).	N/A
830.6320	Corrosion Characteristics	Not corrosive to polyethylene bag in a six-month study. **As a term of the G-41 Technical registration, EPA is requiring the results of a one-year storage stability and corrosion characteristics study be submitted within one year of registration.**		478651-01
830.7000[1]	pH	5.6 (1% solution)		
830.7100	Viscosity	N/A	Not required because G-41 Technical is not a liquid form of a microbial pesticide (refer to test note #4 of 40 CFR § 158.2120(d)).	N/A
830.7300[1]	Density/Relative Density/Bulk Density (Specific Gravity)	0.178 g/cm^3		478651-01

[1] According to 40 CFR § 158.2120, these data are only required for the technical grade of the active ingredient. Since BioWorks, Inc. included this information with its application for G-41 Technical, it is summarized appropriately in this table.

TABLE 4. Physical and Chemical Characteristics for the End-Use Pesticide Products (EPs), BW240 WP Biological Fungicide and BW240 G Biological Fungicide (40 CFR § 158.2120)

Harmonized Guideline Number	Data Requirement	Results		MRID No.
		BW240 WP*	BW240 G**	
830.6302	Color	N/A		N/A
830.6303	Physical State	N/A		N/A
830.6304	Odor	N/A		N/A
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	N/A		N/A
830.6317	Storage Stability	Stable at 4°C and 21°C for 6 months. **As terms of the BW240 WP and BW240 G registrations, EPA is requiring the results of a one-year storage stability and corrosion characteristics study be submitted within one year of registration.**		478649-01** 478650-01*
830.6319	Miscibility	Not required because the end-use pesticide products, BW240 WP and BW240 G, are not emulsifiable liquid forms of microbial pesticides (refer to test note #2 of 40 CFR § 158.2120(d)).		N/A
830.6320	Corrosion Characteristics	Not corrosive to polyethylene bag in a six-month study. **As terms of the BW240 WP and BW240 G registrations, EPA is requiring the results of a one-year storage stability and corrosion characteristics study be submitted within one year of registration.**		478649-01** 478650-01*
830.7000[1]	pH	4.35 (1% solution)	N/A	482104-01*
830.7100	Viscosity	Not required because the end-use pesticide products, BW240 WP and BW240 G, are not liquid forms of microbial pesticides (refer to test note #4 of 40 CFR § 158.2120(d)).		N/A
830.7300[1]	Density/Relative Density/Bulk Density (Specific Gravity)	0.147 g/cm^3		N/A[2]

[1] According to 40 CFR § 158.2120, these data are only required for the technical grade of the active ingredient. Since BioWorks, Inc. included this information with its application for BW240 WP and/or BW240 G, it is summarized appropriately in this table.

[2] Obtained from the confidential statements of formula for the end-use pesticide products.

TABLE 5. Toxicology Data Requirements for the Technical Grade of the Active Ingredient (TGAI), *Trichoderma virens* strain G-41, and the Manufacturing-Use Pesticide Product (MP), G-41 Technical (40 CFR § 158.2140)

Harmonized Guideline Number	Data Requirement	Results		MRID No.
		***Trichoderma virens* strain G-41**	**G-41 Technical**	
		Tier I		
885.3050	Acute Oral Toxicity/Pathogenicity	Not toxic to rats when administered by oral gavage in a single dose of 1.5 x 10^8 cfu per animal. Although a pattern of pathogenicity was established, pathogenicity was not unequivocally assessed given a sensitivity of detection that demonstrated low recovery of the MPCA from tissues and fluid (0.5–9%). **Classification: Acceptable TOXICITY CATEGORY IV**	N/A	483438-01
885.3150	Acute Pulmonary Toxicity/Pathogenicity	Fulfilled based on the results of MRID Nos. 407198-05 and 408640-02 (acute pulmonary toxicity/pathogenicity study) and MRID No. 478650-04 (acute inhalation toxicity study).	N/A	478708-01 482526-01
885.3200	Acute Injection Toxicity/Pathogenicity (Intraperitoneal)	Not toxic, infective, and/or pathogenic to rats when administered intraperitoneally in a single dose of 10^7 cfu per animal. **Classification: Acceptable**	N/A	478651-02 482368-01
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 or 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)).		482526-01
885.3500	Cell Culture	Not required because *Trichoderma virens* strain G-41 is not a virus (refer to test note #4 of 40 CFR § 158.2140(d)).	N/A	N/A
870.1100	Acute Oral Toxicity	N/A	Waived based on the results of MRID No. 483438-01 and because this formulation contains inert ingredients that are not expected to be of toxicological concern. **Classification: Acceptable TOXICITY CATEGORY III**	478651-03
870.1200	Acute Dermal Toxicity	N/A	Waived because this formulation contains inert ingredients that are not expected to be of toxicological concern. **Classification: Acceptable TOXICITY CATEGORY III**	478651-03

TABLE 5. Toxicology Data Requirements for the Technical Grade of the Active Ingredient (TGAI), *Trichoderma virens* strain G-41, and the Manufacturing-Use Pesticide Product (MP), G-41 Technical (40 CFR § 158.2140)				
Harmonized Guideline Number	**Data Requirement**	**Results**		**MRID No.**
		***Trichoderma virens* strain G-41**	**G-41 Technical**	
870.1300	Acute Inhalation Toxicity	N/A	Waived based on the results of MRID Nos. 478650-04, 407198-05, and 408640-02 and because this formulation contains inert ingredients that are not expected to be of toxicological concern. **Classification: Acceptable TOXICITY CATEGORY III**	478651-03
870.2400	Acute Eye Irritation	N/A	Waived because this formulation contains inert ingredients that are not expected to be of toxicological concern. **Classification: Acceptable TOXICITY CATEGORY III**	478651-03
870.2500	Primary Dermal Irritation	N/A	Waived because this formulation contains inert ingredients that are not expected to be of toxicological concern. **Classification: Acceptable TOXICITY CATEGORY III**	478651-03
Tiers II and III				
Not required for *Trichoderma virens* strain G-41 based on the lack of acute toxicity/pathogenicity in the Tier I studies.				
Additional Studies				
885.3050	Acute Oral Toxicity/Pathogenicity	Not toxic to, infective in, or pathogenic for rats when given a single oral dose of 10^8 cfu/animal (*Trichoderma virens* strain GL-21). **Classification: Acceptable but supplemental in this situation (test organism is not the MPCA proposed for registration).**	N/A	407198-04
885.3150	Acute Pulmonary Toxicity/Pathogenicity	Not toxic to, infective in, or pathogenic for rats when given a single intratracheal dose of 10^8 cfu/animal (*Trichoderma virens* strain GL-21). **Classification: Acceptable but supplemental in this situation (test organism is not the MPCA proposed for registration).**	N/A	407198-05 408640-02

TABLE 5. Toxicology Data Requirements for the Technical Grade of the Active Ingredient (TGAI), *Trichoderma virens* strain G-41, and the Manufacturing-Use Pesticide Product (MP), G-41 Technical (40 CFR § 158.2140)

Harmonized Guideline Number	Data Requirement	Results		MRID No.
		***Trichoderma virens* strain G-41**	**G-41 Technical**	
885.3200	Acute Injection Toxicity/Pathogenicity (Intravenous)	Not infective in or pathogenic for rats when given a single intravenous dose of 0.1 gram (g)/animal (*Trichoderma virens* strain GL-21). The data supports the conclusion, however, that the test material is acutely toxic and lethal for test animals via mechanical clogging of capillaries. **Classification: Acceptable but supplemental in this situation (test organism is not the MPCA proposed for registration).**	N/A	407198-06 408640-01

TABLE 6. Toxicology Data Requirements for the End-Use Pesticide Products (EPs), BW240 WP Biological Fungicide and BW240 G Biological Fungicide (40 CFR § 158.2140)

Harmonized Guideline Number	Data Requirement	Results		MRID No.
		BW240 WP*	**BW240 G****	
885.3050	Acute Oral Toxicity/Pathogenicity	N/A		N/A
885.3150	Acute Pulmonary Toxicity/Pathogenicity	N/A		N/A
885.3200	Acute Injection Toxicity/Pathogenicity	N/A		N/A
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 EPs, 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)).		482104-02* 481964-02**
885.3500	Cell Culture	N/A		N/A
870.1100	Acute Oral Toxicity	Oral LD_{50} female rats > 5,000 mg/kg **Classification: Acceptable TOXICITY CATEGORY IV**	Waived based on the results of MRID No. 478650-02, which evaluated a substance with identical active ingredients (1.15% *Trichoderma harzianum* Rifai strain T-22 and 0.61% *Trichoderma virens* strain G-41) and nearly identical inert ingredients to BW240 G. **Classification: Acceptable TOXICITY CATEGORY IV**	478650-02* Bjornsen (2009)**
870.1200	Acute Dermal Toxicity	Dermal LD_{50} combined (male and female) rats > 5,050 mg/kg **Classification: Acceptable TOXICITY CATEGORY IV**	Waived based on the results of MRID No. 478650-03, which evaluated a substance with identical active ingredients (1.15% *Trichoderma harzianum* Rifai strain T-22 and 0.61% *Trichoderma virens* strain G-41) and nearly identical inert ingredients to BW240 G. **Classification: Acceptable TOXICITY CATEGORY IV**	478650-03* Bjornsen (2009)**

TABLE 6. Toxicology Data Requirements for the End-Use Pesticide Products (EPs), BW240 WP Biological Fungicide and BW240 G Biological Fungicide (40 CFR § 158.2140)

Harmonized Guideline Number	Data Requirement	Results		MRID No.
		BW240 WP*	**BW240 G****	
870.1300	Acute Inhalation Toxicity	4-Hour Inhalation LC_{50} combined (male and female) rats > 5.14 mg/L **Classification: Acceptable TOXICITY CATEGORY IV**	Waived based on the results of MRID No. 478650-04, which evaluated a substance with identical active ingredients (1.15% *Trichoderma harzianum* Rifai strain T-22 and 0.61% *Trichoderma virens* strain G-41) and nearly identical inert ingredients to BW240 G. **Classification: Acceptable TOXICITY CATEGORY IV**	478650-04* Bjornsen (2009)**
870.2400	Acute Eye Irritation	BW240 WP was minimally irritating to the eye of rabbits based on the maximum irritation score of 18 obtained 24 hours after treatment. Positive effects cleared by Day 4. **Classification: Acceptable TOXICITY CATEGORY III**	Waived based on the results of MRID No. 478650-05, which evaluated a substance with identical active ingredients (1.15% *Trichoderma harzianum* Rifai strain T-22 and 0.61% *Trichoderma virens* strain G-41) and nearly identical inert ingredients to BW240 G. **Classification: Acceptable TOXICITY CATEGORY III**	478650-05* Bjornsen (2009)**
870.2500	Primary Dermal Irritation	BW240 WP was non-irritating to the skin of rabbits. **Classification: Acceptable TOXICITY CATEGORY IV**	Waived based on the results of MRID No. 478650-06, which evaluated a substance with identical active ingredients (1.15% *Trichoderma harzianum* Rifai strain T-22 and 0.61% *Trichoderma virens* strain G-41) and nearly identical inert ingredients to BW240 G. **Classification: Acceptable TOXICITY CATEGORY IV**	478650-06* Bjornsen (2009)**

TABLE 7. Nontarget Organism Toxicity and Environmental Fate Data Requirements for the Technical Grade of the Active Ingredient (TGAI), *Trichoderma virens* strain G-41 (40 CFR § 158.2150)			
Harmonized Guideline Number	**Data Requirement**	**Results**	**MRID No.**
Tier I			
885.4050	Avian Oral Toxicity	Data and other information provide sufficient information to determine that toxicity/pathogenicity to avian wildlife is not expected as a result of the proposed pesticidal uses. **Classification: Acceptable**	478651-03 482526-01
885.4100	Avian Inhalation Toxicity/Pathogenicity	Not required as the nature of the microbial pesticide does not indicate potential pathogenicity to birds or relatedness to any known bird pathogens (refer to test note #3 of 40 CFR § 158.2150(e)).	N/A
885.4150	Wild Mammal Toxicity/Pathogenicity	Data and other information provide sufficient information to determine that toxicity/pathogenicity to wild mammals, freshwater and marine/estuarine fish and invertebrates, honey bees, nontarget insects, and nontarget plants is not expected as a result of the proposed pesticidal uses. **Classification: Acceptable**	478651-03 482526-01
885.4200	Freshwater Fish Toxicity/Pathogenicity		
885.4240	Freshwater Invertebrate Toxicity/Pathogenicity		
885.4280	Estuarine/Marine Fish and Invertebrate Testing		
885.4300	Nontarget Plant Testing		
885.4340	Nontarget Insect Testing		
885.4380	Honey Bee Testing		
Tiers II, III, and IV			
Not required for *Trichoderma virens* strain G-41 based on the acceptability of the data and other information provided for Tier I.			

APPENDIX B. PESTICIDE PRODUCTS

EPA Reg. Number	Registration Name	Percentage Active Ingredient	Formulation Type	Use Site(s)	Method(s) of Application	Application Rate(s)	Target Pest
68539-8	G-41 Technical	12.10%[3]	Technical	N/A	N/A	N/A	N/A
68539-9	BW240 WP Biological Fungicide	1.15%[2] 0.61%[3]	End Use – Wettable Powder	Various agricultural, greenhouse, and nursery crops, as well as residential plants (e.g., vegetables, ornamentals, and fruit)	Chemigation (agricultural and commercial applications)	1–32 ounces BW240 WP per 100 gallons of water	Various fungal pests
					Cutting or bare-rooted transplant dip (agricultural and commercial applications)	(1) 0.25–5 pounds of BW240 WP per 20 gallons of water (2) Direct dip into BW240 WP powder	
					Soil drench (agricultural and commercial applications)	(1) Shallow beds or pots (up to 4-inch depth) – 50–100 gallons of prepared mixture[1] per 800 square feet of beds or pots (2) Deep beds or pots (greater than 4-inch depth) – 100 gallons of prepared mixture[1] per 400 square feet of beds or pots, ½ cup of prepared mixture[1] per 3-inch diameter pot, or 1 cup of prepared mixture[1] per 6-inch diameter pot	
					In-furrow spray or transplant starter solution (agricultural and commercial applications)	1–32 ounces of BW240 WP per acre of soil	
					Bulb, tuber, or cut potato seed piece treatment (agricultural and commercial applications)	(1) 0.03–3 pounds of BW240 WP per 100 pounds of bulbs or cut potato seed pieces (2) Dip bulbs, tubers, or cut potato seed pieces into suspension of 0.25–5 pounds of BW240 WP per 20 gallons of water	
					Seed drench (residential applications)	Prepared mixture (1–3 tablespoons of BW240 WP per gallon of water) to 25 feet of planting furrow	
					Transplants or potted plants (residential applications)	1/2–1 cup of prepared mixture[1] per transplant or per 4–8 inch diameter pot	
					New and established plant beds (residential applications)	1 gallon of prepared mixture[1] per 25 square feet of plant bed	

EPA Reg. Number	Registration Name	Percentage Active Ingredient	Formulation Type	Use Site(s)	Method(s) of Application	Application Rate(s)	Target Pest
68539-10	BW240 G Biological Fungicide	1.15%[2] 0.61%[3]	End Use – Granular	Various agricultural, greenhouse, and nursery crops (e.g., vegetables, ornamentals, and fruit)	In-furrow soil treatment	2.5–6 pounds of BW240 G per ½ acre of soil	Various fungal pests
					Planting mix amendment (greenhouse and nursery applications)	1–3 pounds of BW240 G per cubic yard of planting mix	
					Bed incorporation (nursery applications)	0.5–7.5 pounds of BW240 G per 1,000 square feet of bed	
					Transplant	0.2–8 ounces of BW240 G per planting hole	
					Broadcast (turf only)	(1) New turf seedings – 1–4 pounds of BW240 G per 1,000 square feet of turf (2) Established turf (early spring) – 1–4 pounds of BW240 G per 1,000 square feet of turf (3) Established turf (late summer/early fall) - 1–2 pounds of BW240 G per 1,000 square feet of turf	

[1] Prepared mixture = BW240 WP + water
[2] *Trichoderma harzianum* Rifai strain T-22
[3] *Trichoderma virens* strain G-41