



## **BIOPESTICIDE REGISTRATION ACTION DOCUMENT**

*Ulocladium oudemansii* (U3 strain)

PC Code: 102111

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

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## I. EXECUTIVE SUMMARY

The active ingredient, *Ulocladium oudemansii* (U3 strain), is a naturally occurring soil fungus existing as a saprophyte of dead and decaying plant matter. As a biofungicide, it is intended to protect fruit and vegetable crops, and ornamental plants from plant pathogenic diseases by competing for the same ecological niches (senescent plant material) and nutrients. EPA has determined that *Ulocladium oudemansii* (U3 strain) presents no issues of toxicological, ecological, or environmental concern. Accordingly, EPA is granting a time-limited registration for *Ulocladium oudemansii* (U3 strain) under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Adequate mammalian toxicology data and other information were submitted to support the registration of *Ulocladium oudemansii* (U3 strain). Acceptable acute toxicity guideline studies were submitted, and data waivers were granted by the Agency to fulfill the remaining Tier I acute toxicity data requirements, based on the lack of toxicity and/or pathogenicity of *Ulocladium oudemansii* (U3 strain), because the manufacturing-use product is equivalent to the technical grade of the active ingredient, and/or the low potential for worker exposure attributed to appropriate precautionary statements and requirements for personal protective equipment on the label.

Based on studies evaluated by the Agency, the active ingredient demonstrates very low toxicity potential by neither damaging live plant tissue nor being able to grow on human serum or blood at 17<sup>o</sup>, 25<sup>o</sup> or 37<sup>o</sup>C. Thus, the application of *Ulocladium oudemansii* (U3 strain) as a fungicide on food crops, and ornamental plants is not expected to cause harm to exposed populations.

The toxicological data demonstrate that *Ulocladium oudemansii* (U3 strain) is not toxic, infective or pathogenic to mammals. No acute, sub-chronic, chronic, immune, endocrine, or non-dietary exposure issues indicating that fungicidal use of the active ingredient could be expected to cause no harm to infants, children, and the general U.S. population were identified. Because of the low toxicity profile, an exemption from the requirement of a tolerance is being established in 40 CFR 180 under Section 408 of the Federal Food, Drug, and Cosmetics Act (FFDCA).

Dietary exposure via drinking water is not expected to pose harm to populations because the biofungicide is not known to grow or thrive in aquatic environments and is not expected to survive municipal treatment of drinking water. Further, the intended uses of this microbial fungicide do not pose a dietary risk to the U.S. population in general, and to infants and children in particular. Even if humans were exposed to *Ulocladium oudemansii* (U3 strain) by this route, the results of acute oral toxicity testing suggest no adverse effect via drinking water.

The potential for aggregate, non-occupational exposure from agricultural applications is unlikely, because use sites identified for the subject active ingredient are not expected to be in close proximity to residential areas.

Data waiver rationales were submitted in response to data requirements for avian, freshwater fish and invertebrate, insect, and honey bee non-target organism testing requirements. The information provided is sufficient to satisfy the Tier I non-target organism data requirements for the technical product and proposed end-use products containing *Ulocladium oudemansii* (U3 strain) as an active ingredient, and further testing of non-target organisms at higher tier levels is not required. Based on the rationales submitted, adverse effects to terrestrial animals and plants or freshwater and marine/estuarine fish, invertebrates, and plants are not expected as a result of exposure to fungicidal applications of *Ulocladium oudemansii* (U3 strain). Furthermore, BPPD made “No Effect” (NE) determinations for direct and indirect effects to listed threatened and endangered species and their habitat as a result of the proposed uses of *Ulocladium oudemansii* (U3 strain).

Fungicidal applications of *Ulocladium oudemansii* (U3 strain) will not pose unreasonable adverse risks to non-target organisms, including endangered species or to the environment. The Agency does not require labeling, or data for endangered species, for the proposed fungicidal uses of *Ulocladium oudemansii* (U3 strain).

The Biopesticides and Pollution Prevention Division (BPPD) reviewed data requirements for granting registration under Section 3(c)(5) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). It was determined that the data/information submitted fulfilled current guideline requirements (refer to 40 CFR Subpart V § 158.2100).

On October 1, 2009, EPA announced a new policy to provide a more meaningful opportunity for the public to participate on major registration decisions before they occur. According to this new 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 use, first outdoor use, and first residential use.

Notwithstanding that the current action on *Ulocladium oudemansii* (U3 strain) qualifies as a “new active ingredient” under the new policy, EPA believes that it is in the best interests of the public and the environment to issue the registration for *Ulocladium oudemansii* (U3 strain) without delay. As discussed above, acute toxicity data for *Ulocladium oudemansii* (U3 strain) demonstrate that it is either toxicity category IV or III. *Ulocladium oudemansii* (U3 strain) does not demonstrate subchronic or developmental toxicity, and it is not mutagenic or genotoxic. EPA has no concerns for any non-target organisms exposed to *Ulocladium oudemansii* (U3 strain) in accordance with approved label directions. EPA has not identified any toxic endpoints for non-target mammals, birds, plants, aquatic, or soil organisms. Nor are there concerns for any threatened and endangered species. Thus, given that *Ulocladium oudemansii* (U3 strain) has very low toxicity and presents little if any risk to non-target organisms, EPA concludes that it is

in the best interests of the public and the environment to issue the registration for *Ulocladium oudemansii* (U3 strain) without delay. Consistent with the Agency's new policy for making these registration actions more transparent, however, EPA is issuing this registration with an initial period of one-year and, concurrent with its issuance, providing a 30-day public comment period on both the time-limited registration and the final rule establishing a tolerance exemption for *Ulocladium oudemansii* (U3 strain). EPA is registering this product as a time-limited registration, with the understanding that public comments could bring to light new information or concerns that could inform EPA's initial decision. Any subsequent action taken by EPA will be made in the context of information received during the public comment period.

All data requirements are fulfilled and EPA has determined that a time-limited, 12-month unconditional registration for *Ulocladium oudemansii* (U3 strain) is warranted under Section 3(c)(5) of FIFRA. If the Agency receives comments during the 30 day public comment period that inform EPA's initial decision, EPA will address such new information and take appropriate action.

## II. ACTIVE INGREDIENT OVERVIEW

**Biological Name:** *Ulocladium oudemansii* (U3 strain)

**Patent Number:** <http://www.patentstorm.us/patents/7407794/description.html>

**Culture Deposit:** Held at National Measurement Institute as NM 99/06216 in Australia

**Trade/Other Names:** BOTRY-Zen®

**OPP Chemical Code:** 102111

**Type of Pesticide:** Microbial Pesticide/Biofungicide

## III. REGULATORY BACKGROUND

EPA published in the Federal Register (FR) on October 29, 2008 (73 FR 64325) a notice announcing that Botry-Zen, Ltd., 21 Willis St., PO Box 5664, Dunedin, New Zealand, submitted applications to register pesticide products (EPA File Symbols 75747-R and 75747-E) containing a new active ingredient not included in any currently registered products. No comments were received following the publication of this notice

A pesticide petition (7F7269) seeking an exemption from the requirement of a tolerance for residues of the biofungicide, *Ulocladium oudemansii* (U3 Strain), when applied or used pre-harvest only, in/on all food commodities was filed by Botry-Zen, Ltd., and published in the FR on November 14, 2008 (73 FR 67512). One comment from an anonymous correspondent was received following this publication. A final rule establishing the exemption from tolerance was signed October 20, 2009, in which the commenter's concerns were addressed. The exemption from the requirement of a tolerance is codified under 40 CFR part 180.

Before issuing any tolerance exemption, the Agency examines the potential effects of the pesticide on humans and the environment. For this particular microbial pesticide, EPA conducted a comprehensive assessment of *Ulocladium oudemansii* (U3 Strain), including a review of the acceptable studies and other supporting information addressing the potential effects of this pesticide. EPA's review of these data and information indicated that the active ingredient is not toxic to test animals when administered via the oral, dermal, or intraperitoneal routes of exposure and is unlikely under the conditions of use to be a human health hazard by the pulmonary route because the large aggregated fungal spore material is not respirable. Also, there was no evidence that the active ingredient is a mutagen. In addition, the active ingredient was not infective or pathogenic to test animals when administered via the oral, dermal or intravenous routes. Moreover, growth temperature analysis has shown that *Ulocladium*

*oudemansii* (U3 strain) does not grow above 30°C, making infection of humans and other mammals having normal body temperatures above 37 °C unlikely. No reports of hypersensitivity have been recorded in personnel working with this organism. Based on these data, the Agency has concluded that there is a reasonable certainty that no harm will result from dietary exposure to residues of *Ulocladium oudemansii* (U3 Strain), when applied/used pre-harvest only in or on all food commodities (excluding applications made post-harvest or to processed commodities). Thus, under the standard in FFDC section 408(c)(2), an exemption from the requirement of a tolerance is appropriate.

The US representative for Botry-Zen, Ltd. is Technology Sciences Group, Inc., 1101 17<sup>th</sup> Street, N.W., Suite 500, Washington, D.C., 20036-4704, US.

#### **IV. RISK ASSESSMENT**

On October 26, 2007, the Agency issued a Final Rule in the Federal Register on the data requirements to support registration of biochemical and microbial pesticides, and updated the definitions for biochemical and microbial pesticides ([72 FR 61002](#)). The rule became effective on December 26, 2007. The data and information evaluated for this Biopesticides Registration Action Document (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: UPGRADABLE”). If a study is rated as “SUPPLEMENTAL: UPGRADABLE,” the Environmental Protection Agency 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 the current 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 need to 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 the Agency 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.



## **A. PRODUCT ANALYSIS ASSESSMENT**

### **1. Product Chemistry and Composition**

*Ulocladium oudemansii* is a common soil fungus, existing as a saprophyte of dead and decaying plant matter. Rapid growth on plant-based media occurs at 18-20°C, first appearing olive-green then darker to a velvety charcoal black. *Ulocladium oudemansii* (U3 strain) rapidly declines in viability at 30°C, and spores begin losing viability after 48 hours at 25°C. This strain is reported to not damage live plant tissues or grow on human serum or blood at 17, 25 or 37°C.

*Ulocladium oudemansii* Technical (100% w/w *Ulocladium oudemansii* (U3 strain)) is a technical grade of the active ingredient/manufacturing product (TGAI/MP) to be used to manufacture end-use products intended to control plant pathogenic diseases, such as *Botrytis cinerea* and *Sclerotinia sclerotiorum*, by competing for the same ecological niches and nutrients on degrading plant debris.

Master seed stock is stored (in 15% glycerol/water at -70°C) and maintained at the HortResearch Labs in New Zealand and at a culture collection (National Measurement Institute, as NM 99/06216) in Australia.

### **2. Analysis and Certification of Limits**

The submitted data satisfied the requirement for Analysis and Certification of Limits. Five batches tested by cultural methods showed a 98% viability of *Ulocladium oudemansii*, (U3 Strain) with no appreciable contaminants. The certified limits for the active and inert ingredients fall within the ranges specified by OPPTS Guideline 8850.1500.

### **3. Physical and Chemical Characteristics**

The Agency has determined that the submitted data adequately describe the physical and chemical characteristics, and the scientifically justified data waiver rationales are acceptable for color, physical state, odor, stability to normal and elevated temperatures, metals, and metal ions, corrosion characteristics, pH, viscosity, and density/relative density/bulk density (specific gravity).

## **B. HUMAN HEALTH ASSESSMENT**

### **1. Toxicological Hazard Assessment**

Acute toxicology studies have shown that *Ulocladium oudemansii* (U3 Strain) is not toxic, pathogenic, infective, or irritating to mammals. The intended use is on agricultural crops, and *Ulocladium oudemansii* (U3 Strain) has limited survivability once its carrier nutrient source is exhausted. The results of the toxicity testing indicate there is no risk to human health or the

environment, and there are no reports of ecological or human health hazards caused by *Ulocladium oudemansii* (U3 Strain). It does not produce any recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. There is a reasonable certainty of no harm to the general U.S. population, including infants and children, from exposure to this active ingredient from the proposed uses.

For a comprehensive guideline-by-guideline summary of the toxicology data requirements described in sections IV(B)(1)(a) and IV(B)(1)(b), refer to [Table 2](#) in Appendix A.

**a. Acute Toxicity/Pathogenicity – Tier I ([40 CFR § 158.2140](#))**

Acute Oral Toxicity and Pathogenicity – Rat [OPPTS Guideline 885.3050; Master Record Identification (MRID) Number (No.) 472465-03]: *Ulocladium oudemansii* Technical (purity  $5.7 \times 10^9$  cfu/g) does not appear to be toxic, infective, and/or pathogenic in rats, at a dose of  $1 \times 10^8$  CFU/animal in 0.9% sterile injectable saline. This study was rated “ACCEPTABLE” and *Ulocladium oudemansii* (U3 Strain) was classified as TOXICITY CATEGORY IV.

Acute Dermal Toxicity and Pathogenicity – Rat (OPPTS Guideline 885.3100; MRID No. 472465-04): Botry-Zen® does not appear to be toxic, infective, and/or pathogenic in rats, when treated at  $1 \times 10^8$  cfu/animal. There were no treatment related clinical signs, dermal irritation, necropsy findings, or changes in body weight. No test organism was recovered from blood, brain, kidney, liver, cervical lymph nodes, or spleen of any animal. This study was rated “ACCEPTABLE” and *Ulocladium oudemansii* (U3 Strain) was classified as TOXICITY CATEGORY III.

Acute Pulmonary Toxicity and Pathogenicity – Rat (OPPTS Guideline 885.3150; MRID No. 472465-05): Test material was a coarse suspension of particles in a liquid vehicle. Due to the rapid sedimentation of these particles, the suspension was unsuitable for aerosolization as supplied and efforts were made to reduce the larger particles using a homogenizer, using polyethylene glycol (PEG 400) to give a better suspension, and forcing the formulation through a 38 µm sieve to obtain particle size suitable for the purposes of an inhalation study. A representative portion of the sample was dried at 65°C for 2 days. The milled powder was passed through a Marple Cascade Impactor in order to investigate the relative proportion of material below 10 µm. The results of three runs showed that the percentages of material < 10 µm were 5.06, 2.98, and 3.44 with a mean of 3.83. The sponsor had provided the following data: *Ulocladium oudemansii*: Mycelium 3-6 micron diameter; conidiophores up to 250 x 5-8 micron; conidia dimensions are 18-34 micron x 11-17 micron with 1-3 transverse and 1 or more longitudinal or oblique septa. For rats, it is generally considered that a mass median aerodynamic diameter (MMAD) between 1-4 µm is required to ensure deposition throughout the respiratory tract. For humans, data on deposition are not so clear and it is generally considered that particles with an MMAD > 10 µm have a low probability of being inhaled and deposited in pulmonary region. Particles deposited in the naso-pharyngeal region are removed by coughing, sneezing, or physical wiping from the nasal regions. Particles deposited in the tracheobronchial

region are removed by the mucociliary escalator system. As for the particles swallowed, an oral study would determine the hazard represented by the material. BOTRY-Zen® is considered unlikely to represent a significant hazard to humans by the inhalation route due to the large particle sizes of the fungal spores.

CLASSIFICATION: This study does not satisfy the guideline requirement for an acute pulmonary toxicity and pathogenicity study (OPPTS 885.3150; PMRA DATA CODE M4.2.3 OECD IIIM 7.1.3) in rat. The study sponsor has submitted a formal waiver request for acute pulmonary toxicity and pathogenicity study.

Acute Injection Toxicity and Pathogenicity – Rat (OPPTS Guideline 885.3200; MRID No. 472465-02): *Ulocladium oudemansii* Technical did not appear to be toxic, infective, and/or pathogenic in rats, when dosed at  $>10^7$  cfu/animal. This study was rated “ACCEPTABLE”

Skin Sensitization (OPPTS Guideline 870.2600; MRID No. 472465-08) Based upon the submitted data, *Ulocladium oudemansii* Technical, purity not less than  $2 \times 10^8$  cfu/g and a minimum spore viability of 90% does not appear to be a dermal sensitizer. This study was classified as “ACCEPTABLE.”

Cell Culture (OPPTS Guideline 885.3500; MRID 472465-17): Cell culture testing is required if the active ingredient *Ulocladium oudemansii* (U3 Strain) is a naturally-occurring fungus. Cell culture testing is therefore not required.

Acute Oral Toxicity (OPPTS Guideline 870.1100; MRID No. 472482-02): Waiver request rationales offered by the registrant for acute oral toxicity/pathogenicity, for *Ulocladium oudemansii* Technical, is as follows: 1) The submitted studies MRIDs 47246502 to 09 did not show any pathogenicity in animals dosed/treated by oral gavage, dermal application, pulmonary instillation, or intravenous injection; 2) Based on the laboratory data and the ubiquitous nature of *Ulocladium oudemansii*, the end-use product BOTRY-Zen® is non-toxic and non-pathogenic. None of the inerts are known to cause any adverse effects or toxicity. This waiver request was rated “ACCEPTABLE” and *Ulocladium oudemansii* (U3 Strain) was classified as TOXICITY CATEGORY IV.

Acute Dermal Toxicity (OPPTS Guideline 870.1200; MRID No. 472482-02): Waiver request rationales offered by the registrant for acute dermal toxicity for *Ulocladium oudemansii* Technical is as follows: 1) The submitted studies MRIDs 47246502 to 09 did not show any pathogenicity in animals dosed/treated by oral gavage, dermal application, pulmonary instillation, or intravenous injection; 2) Based on the laboratory data and the ubiquitous nature of *Ulocladium oudemansii*, the end-use product BOTRY-Zen® is non-toxic and non-pathogenic. None of the inerts are known to cause any adverse effects or toxicity. This waiver request was rated “ACCEPTABLE” and *Ulocladium oudemansii* (U3 Strain) was classified as TOXICITY CATEGORY IV.

*Acute Inhalation Toxicity (OPPTS Guideline 870.1300; MRID No. 472482-02)*: Waiver request rationales offered by the registrant for acute inhalation toxicity for *Ulocladium oudemansii* Technical is as follows: 1) The submitted studies MRIDs 47246502 to 09 did not show any pathogenicity in animals dosed/treated by oral gavage, dermal application, pulmonary instillation, or intravenous injection; 2) Based on the laboratory data and the ubiquitous nature of *Ulocladium oudemansii*, the end-use product BOTRY-Zen® is non-toxic and non-pathogenic. None of the inerts are known to cause any adverse effects or toxicity. This waiver request was rated “ACCEPTABLE” and *Ulocladium oudemansii* (U3 Strain) was classified as TOXICITY CATEGORY IV.

*Acute Eye Irritation (OPPTS Guideline 870.2400; MRID No. 472482-02)*: Waiver request rationales offered by the registrant for acute eye irritation for *Ulocladium oudemansii* Technical is as follows: 1) The submitted studies MRIDs 47246502 to 09 did not show any pathogenicity in animals dosed/treated by oral gavage, dermal application, pulmonary instillation, or intravenous injection; 2) Based on the laboratory data and the ubiquitous nature of *Ulocladium oudemansii*, the end-use product BOTRY-Zen® is non-toxic and non-pathogenic. None of the inerts are known to cause any adverse effects or toxicity. This waiver request was rated “ACCEPTABLE” and *Ulocladium oudemansii* (U3 Strain) was classified as TOXICITY CATEGORY IV.

*Primary Dermal Irritation (OPPTS Guideline 870.2500; MRID No. 472482-02)*: Waiver request rationales offered by the registrant for primary dermal irritation for *Ulocladium oudemansii* Technical is as follows: 1) The submitted studies MRIDs 47246502 to 09 did not show any pathogenicity in animals dosed/treated by oral gavage, dermal application, pulmonary instillation, or intravenous injection; 2) Based on the laboratory data and the ubiquitous nature of *Ulocladium oudemansii*, the end-use product BOTRY-Zen® is non-toxic and non-pathogenic. None of the inerts are known to cause any adverse effects or toxicity. This waiver request was rated “ACCEPTABLE” and *Ulocladium oudemansii* (U3 Strain) was classified as TOXICITY CATEGORY IV.

**b. Acute Toxicology and Subchronic Toxicity/Pathogenicity – Tier II;  
Reproductive Fertility Effects, Carcinogenicity, Immunotoxicity, and  
Infectivity/Pathogenicity Analysis – Tier III ([40 CFR § 158.2140](#))**

Tier II and Tier III studies were not required for *Ulocladium oudemansii* (U3 Strain) based on the lack of acute toxicity/pathogenicity in the Tier I studies.

**c. Effects on the Endocrine System**

Section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) “may have an effect in humans that is similar to an effect produced by a

naturally occurring estrogen, or such other endocrine effect as the Administrator may designate.” Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of its program, androgen and thyroid hormone systems, in addition to the estrogen hormone system. The Environmental Protection Agency also adopted EDSTAC’s recommendation that the Program include evaluations of potential effects on wildlife.

*Ulocladium oudemansii* is a ubiquitous organism in the environment. The subject of this tolerance exemption, *Ulocladium oudemansii* (U3 Strain), is non-toxic to mammals. To date, there is no evidence to suggest that *Ulocladium oudemansii* (U3 Strain) affects the immune system, functions in a manner similar to any known hormone, or that it acts as an endocrine disruptor. Indeed, the submitted toxicity/pathogenicity studies in rodents indicate that, following several routes of exposure, the immune system is intact and able to process and clear the active ingredient. Therefore, it is unlikely that this organism will have estrogenic or endocrine effects.

## 2. Dietary Exposure and Risk Characterization

*Ulocladium oudemansii*, a common soil fungus, is ubiquitous in the environment and exists worldwide as a naturally occurring saprophyte, i.e., an organism that lives and feeds on dead and decaying plant matter. The subject of this tolerance exemption, *Ulocladium oudemansii* (U3 strain), was originally isolated from kiwifruit leaf litter. Spores of *Ulocladium oudemansii* (U3 strain), when deposited under the suitable environmental conditions on dead or decaying plant debris, will germinate and colonize the necrotic plant tissue. But if such decayed vegetative matter is not available, or becomes exhausted, the fungus cannot survive. Therefore, despite its presence in soils, dietary exposure from the proposed use of *Ulocladium oudemansii* (U3 strain) will be minimal on food due to its limited viability in the absence of a decayed plant material nutrient source. Also, there are no known mycotoxins associated with *Ulocladium species*, and the submitted toxicological studies indicate no risk to human health from dietary exposure to *Ulocladium oudemansii* (U3 strain). Furthermore, the fungus produces no recognized toxins, enzymes or virulence factors normally associated with mammalian invasiveness or toxicity. Additionally, growth temperature analysis has shown that *Ulocladium oudemansii* (U3 strain) does not grow above 30°C, making infection of humans and other mammals having normal body temperatures above 37 °C unlikely

*Ulocladium oudemansii* (U3 Strain) applied to food crops to control plant pathogens will not survive except on dead or decaying plant tissues. Food crops exhibiting such tissues are of poor quality, are not commonly consumed, and are not commercially marketed. Good quality food free of such decayed material will not support the fungus and so *Ulocladium oudemansii* (U3 Strain) residues would not be expected. Due to the limited survivability of *Ulocladium oudemansii* (U3 Strain) once its decayed plant material nutrient source is exhausted, dietary exposure to the naturally-occurring microbe from the proposed pre-harvest applications to food crops is unlikely. Even if oral exposure from ingestion of poor-quality treated crops should occur, the hazard posed to adults, infants and children from food-related exposures to

*Ulocladium oudemansii* (U3 Strain) will be minimal due to the demonstrated lack of acute oral toxicity/pathogenicity associated with the microbial pesticide. Based on the evaluation of the submitted data, there are no dietary risks that exceed the Agency's level of concern.

### **3. Drinking Water Exposure Risk Characterization**

Exposure of humans to residues of *Ulocladium oudemansii* (U3 Strain) in consumed drinking water would be unlikely. *Ulocladium oudemansii* (U3 Strain) is not known to grow or thrive in aquatic environments. Potential exposure via surface water would be negligible and exposure via drinking water would be impossible to measure. *Ulocladium oudemansii* (U3 Strain) is intended for use on agricultural and horticultural crops, and has limited survival potential once its carrier nutrient source is exhausted. The risk of the microorganism passing through soil to groundwater is minimal to unlikely. Additionally, the fungus would not tolerate municipal drinking water treatment processes, such as chlorination, pH adjustment, high temperature and/or anaerobic conditions. More importantly, even if oral exposure to this ubiquitous microbe should occur through drinking water, due to its demonstrated lack of acute oral toxicity/pathogenicity, the Agency concludes that there is a reasonable certainty that no harm will result from such exposure.

### **4. Acute and Chronic Dietary Exposure and Risks for Sensitive Subpopulations, Particularly Infants and Children**

Based on the toxicity information discussed above, EPA concludes 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 *Ulocladium oudemansii* (U3 Strain). This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because the data available on *Ulocladium oudemansii* (U3 Strain) demonstrate a lack of toxicity/pathogenicity potential. *Ulocladium oudemansii* (U3 Strain) is not known to produce any recognized toxins, virulence factors or enzymes normally associated with mammalian invasiveness or toxicity.

### **5. Occupational, Residential, School and Day Care Exposure and Risk Characterization**

Due to its use as an agricultural product, outdoors and in greenhouses, significant additional human exposure to *Ulocladium oudemansii* (U3 Strain) is not expected in occupational, residential, school, or daycare areas.

#### **a. Occupational Exposure and Risk Characterization**

In light of the Tier I acute toxicity/pathogenicity studies, which did not show any toxic and/or pathogenic effects to rats *via* oral, pulmonary, dermal, and intravenous routes of exposure ([see section IV\(B\)\(1\)\(a\)](#)), handler exposure to *Ulocladium oudemansii* (U3 Strain) is not expected to

pose any undue risk. Regardless, requirements for the use of appropriate personal protective equipment, and precautionary statements are required on the product label to mitigate any potential risks to pesticide handlers due to prolonged exposure. Handlers working with *Ulocladium oudemansii* (U3 Strain) in manufacturing facilities 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.

### **b. Residential, School, and Daycare Exposure and Risk Characterization**

According to the label, *Ulocladium oudemansii* (U3 Strain) is only to be used for agricultural areas, greenhouses and horticultural nurseries. No indoor residential, school, or daycare uses currently appear on the label; thus, human exposure to *Ulocladium oudemansii* (U3 Strain) should not occur in these areas.

### **6. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation**

Due to the inability of *Ulocladium oudemansii* (U3 Strain) to survive once its carrier nutrient source is exhausted, and the low to negligible toxicity and infectivity potential, non-occupational exposure through these uses is not likely to cause harm to the exposed population.

### **7. Cumulative Effects**

Section 408(b)(2)(D)(v) of FFDCA requires the Agency, when considering whether to establish, modify, or revoke a tolerance, to consider “available information” concerning the cumulative effects of pesticide residues and “other substances that have a common mechanism of toxicity.” These considerations include the cumulative effects of such residues on infants and children. Because, there is no indication of mammalian toxicity from *Ulocladium oudemansii* (U3 Strain), the Agency concludes that *Ulocladium oudemansii* (U3 Strain) does not share a common mechanism of toxicity with other substances. Therefore, section 408(b)(2)(D)(v) does not apply.

### **8. Risk Characterization**

The Agency considered human exposure to *Ulocladium oudemansii* (U3 Strain) in light of the standard for registration in FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996. 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 from *Ulocladium oudemansii* (U3 Strain), when used in accordance with the Agency’s accepted labeling.

## C. ENVIRONMENTAL ASSESSMENT

### 1. Summary of Non-target Organism Testing and Waiver Rationales

#### a. Avian Oral Toxicity/Pathogenicity (OPPTS Guideline 885.4050); Avian Inhalation Toxicity/Pathogenicity (OPPTS Guideline 885.4100)

Requests for waivers for these tests with avian species are based on the rationale that *Ulocladium oudemansii* is ubiquitous as a naturally occurring saprophyte found in soils worldwide, has a mode of action that are not consistent with those causing toxic or pathogenic effects in animals, and there is no literature documenting reports of animal pathogenicity or toxicity as a result of exposure to *Ulocladium oudemansii* (U3 Strain) (based on a search in the AGRICOLA, TOXLINE and NLM PubMed databases). *Ulocladium* spp. are typically associated with decaying plant material, and some are also associated with soil (Bokhary et al. 1995), and mycotoxins associated with this genus have not been found (Andersson et al. 1978, Nielsen et al. 1999). The mode of action exhibited by *Ulocladium oudemansii* is antagonistic competition with plant pathogenic fungi for physical space, and thus it does not have a toxic mode of action (Kohl et al. 1997). The rationale presented is acceptable and satisfies the data requirement. Based on this information, adverse effects to birds resulting from exposure to *Ulocladium oudemansii* (U3 Strain) are not anticipated.

#### b. Wild Mammal Toxicity/Pathogenicity (OPPTS 885.4150)

Similar rationale as presented above for birds is given in the waiver request for the wild mammal toxicity/pathogenicity data requirement. In addition to that rationale, *Ulocladium oudemansii* (U3 Strain) does not grow at normal mammalian body temperatures. Growth temperature range data for *Ulocladium oudemansii* (U3 Strain) shows that this strain does not grow at temperatures above 30°C and does not show mycelial growth of germ tube formation in human blood serum at 25°C or 37°C. The rationale presented is acceptable and satisfies the data requirement. Based on this information, adverse effects to wild mammals resulting from exposure to *Ulocladium oudemansii* (U3 Strain) are not anticipated.

#### c. Freshwater Fish Toxicity/Pathogenicity (OPPTS Guideline 885. 4200; MRID No. 472465-10)

In a 30-day toxicity/pathogenicity study, juvenile rainbow trout (*Oncorhynchus mykiss*) received an aqueous exposure to nominal concentrations of 9.4, 19, 38, 75, and 150 mg *Ulocladium oudemansii* Technical/L (corresponding to  $7.9 \times 10^6$ ,  $1.6 \times 10^7$ ,  $3.2 \times 10^7$ ,  $6.3 \times 10^7$ , and  $1.3 \times 10^8$  cfu/L, respectively) under static-renewal conditions. Accurate confirmation of the test material concentrations was not possible due to its hydrophobic nature and tendency to adhere to the surfaces of the test containers. The nominal



concentrations represented 11x, 22x, 44x, 86x, and 177x the estimated environmental concentration (EEC), of *U. oudemansii* in water expected from application of the product at the labeled rate. A dilution water control and an attenuated control were also included. The fish also received a daily oral exposure to the test material via its inclusion in commercial fish feed at a nominal concentration of 300 mg/kg of food (equivalent to 345x the EEC in water). There was no statistically significant difference in the mortality of any of the groups in the test, and there were no other compound-related toxic or pathogenic effects observed in examinations of fish at test termination. The 30-day LC<sub>50</sub> was empirically estimated to be greater than the highest nominal concentration tested ( $>1.3 \times 10^8$  cfu/L,  $>177x$  EEC). This test concentration is below the maximum hazard dosage recommendations in the OPPTS guideline. However, the difficulty of meeting this requirement due to the nature of the fungus preparations in water is recognized, and so the test concentrations are acceptable. Based on the results, this study indicates that adverse effects to freshwater fish are not expected as a result of exposure to *Ulocladium oudemansii*. This study was rated “ACCEPTABLE.”

**d. Freshwater Invertebrate Toxicity/Pathogenicity (OPPTS Guideline 885.4240; MRID No. 472465-11)**

In a 21-day static-renewal chronic toxicity/pathogenicity study (MRID 47246511), *Daphnia magna* neonates received an aqueous exposure to nominal concentrations of 9.4, 19, 38, 75, and 150 mg *Ulocladium oudemansii* Technical/L (corresponding to  $7.9 \times 10^6$ ,  $1.6 \times 10^7$ ,  $3.2 \times 10^7$ ,  $6.3 \times 10^7$ , and  $1.3 \times 10^8$  cfu/L, respectively). Accurate confirmation of the test material concentrations was not possible due to its hydrophobic nature and tendency to adhere to the surfaces of the test containers. The nominal concentrations represent 11x, 22x, 44x, 86x, and 177x the EEC, which is  $7.35 \times 10^5$  cfu/L (2.9 mg/L) based on a product application rate of 4 lbs/acre. An untreated control (dilution water only) and an attenuated control were also included. At the conclusion of the test, cumulative survival was 50%, 60%, 70%, 85%, and 75% in the 11x, 22x, 44x, 86x, and 177x EEC test groups, respectively. Survival in the untreated control was 100%, while survival in the attenuated control was 70%. There were no statistically significant differences ( $p \leq 0.05$ ) in cumulative mortality among any of the control or test groups. Since a similar level of mortality was observed in the attenuated control (assumed to be sufficiently killed), mortality on the *Daphnia* was apparently the result of other effects related to the presence of the test material and could have resulted from complications of maintaining the test substance in suspension at high concentrations. Based on the results, the EC<sub>50</sub> value was therefore empirically estimated to be  $>1.3 \times 10^8$ , or  $>177x$  the EEC. This test concentration is below the maximum hazard dosages recommended by the OPPTS guideline. However, the difficulty of meeting this requirement due to the nature of the fungus preparations in water is recognized and so the test concentrations are acceptable. Based on the results, the study indicates that adverse effects related to pathogenicity or toxicity of *Ulocladium oudemansii* in freshwater invertebrates are not anticipated. This study was classified as “ACCEPTABLE.”

**e. Estuarine/Marine Fish Testing and Estuarine/Marine Invertebrate Testing (OPPTS Guideline 885.4280)**

Similar rationale as presented above for birds is also given in the waiver request for the estuarine/marine fish and invertebrate testing data requirement. Documented cases of toxicity or pathogenicity to aquatic species were not found in the literature search in the AGRICOLA, TOXLINE, and NLM PubMed databases. Furthermore, the end use product is not intended for direct application to water, and *Ulocladium oudemansii* (U3 Strain) is not expected to enter estuarine or marine environments in significant concentrations. This rationale is acceptable and satisfies the data requirement. Based on the information provided, adverse effects to estuarine/marine fish and invertebrates resulting from exposure to *Ulocladium oudemansii* (U3 Strain) are not anticipated.

**f. Non-Target Plant Testing (OPPTS Guideline 885.4300; MRID No. 472465-16)**

The phytotoxic effect of Botry-Zen® on tomato, lettuce, cabbage, parsley, rose, rhododendron, azalea, and apple was studied at nominal concentrations of 1x, 2x, and 10x the normal commercial concentration of Botry-Zen®. The plants were observed for 21 days following application of the test material. A separate test was also performed in which the presence of *Ulocladium oudemansii* (U3 Strain) was examined in grapes following a spray program with a commercial batch of Botry-Zen®. No *Ulocladium oudemansii* (U3 strain) was detected on the grapes post-harvest, but other fungi (*Penicillium*, *Aspergillus*, *Alternaria* spp.) were detected. The study is deficient in that it does not include a positive control as required by the guideline for microbial pesticides that are closely related to plant pathogens (though one was included in the residue study with grapes), and the sample sizes were very small. There were no test material-related phytopathogenic effects seen in any of the plants in the test at the 10x concentration ( $2.7 \times 10^7$  cfu/mL). This study contains several deficiencies. Although the study was not performed according to the OPPTS Microbial Test Guidelines, it does demonstrate a lack of adverse effect of *Ulocladium oudemansii* (U3 strain) in plants. In addition, there are no published reports of *Ulocladium oudemansii* causing phytopathological effects. Therefore, adverse effects to non-target terrestrial plants are not anticipated from the proposed uses of Botry-Zen®. This study was classified as “SUPPLEMENTARY.”

**g. Non-Target Insect Testing (OPPTS Guideline 885.4340)**

In a 27-day dietary toxicity/pathogenicity study, green lacewing (*Chrysoperla rufilabris*) larvae were exposed to *Ulocladium oudemansii* Technical at nominal doses of 95,000 ppm, 47,900 ppm, or 19,200 ppm of the test material (equivalent to  $5.4 \times 10^7$ ,  $2.7 \times 10^7$  and  $1.1 \times 10^7$  cfu/mL, respectively) in accordance with OPPTS 885.4340 (MRID 472465-12). Test subjects were exposed via Mediterranean meal moth (*Ephesia kuehniella*) eggs sprayed with the test material suspended in water. Accurate confirmation of the test material concentrations was not possible

due to spore settling in the dose suspensions. The nominal concentrations represented 11.3x, 5.5x, and 2.2x the highest EP label recommended

concentration (based on the maximum application rate of 4 lbs/acre, mixed in the lowest reasonable spray volume of 25 gallons of water per acre). The test also included an untreated control, an adjuvant control (Tween 80, 0.3% v/v in sterile water), and a reference control (Dimilin 2L, 96 fl oz/A). Pre-emergence mortality in the test group exposed to the highest concentration was significantly higher than in the untreated control group, but was comparable to that of the adjuvant control group. Emergence of fully-formed adults in the groups exposed to the highest and lowest concentrations was significantly reduced compared to the untreated control group, but was comparable to that of the adjuvant control group. The adjuvant apparently contributed to the differences between the test material groups and the untreated control group seen in this study, which has been observed in other studies with nontarget insects (MRID 472465-13, 472465-14, and 472465-15). Based on comparable pre-emergence mortality and overall survival in the test material and adjuvant control groups, the test material did not produce any adverse effects on the test organisms. Therefore, the LC<sub>50</sub> for the test material is determined to be >95,000 ppm. Thus, adverse effects in green lacewing resulting from exposure to the tested levels of *Ulocladium oudemansii* (U3 strain) are not expected. This study was rated “ACCEPTABLE.”

In a 24-day dietary toxicity study, adult ladybird beetles (*Hippodamia convergens*; MRID 472465-13) were exposed to *Ulocladium oudemansii* Technical via a cotton wick soaked with the test material at nominal concentrations of 95,000 ppm, 47,900 ppm, or 19,200 ppm (equivalent to  $5.4 \times 10^7$ ,  $2.7 \times 10^7$ , and  $1.1 \times 10^7$  cfu/mL, respectively). The nominal concentrations were calculated to represent 11.3x, 5.5, and 2.2x the highest EP label application rate in the lowest reasonable spray volume (4 lbs EP in 25 gallons of water). Accurate confirmation of the test material concentrations was not possible due to spore settling in the dose suspensions. The test also included an untreated control (30% sucrose solution only), an adjuvant control (Tween 80, 0.3% v/v in sucrose solution), and a positive control (Dimethoate, 50 ppm). Percent mortality in the nominal high, middle, and low *U. oudemansii* test groups was 59.65%, 64.25%, and 67.96%, respectively. Mortality in the untreated control was 22.16% and in the adjuvant control was 59.05%. Mortality in all the *U. oudemansii* treatments was significantly higher than in the untreated control, but did not differ significantly from the adjuvant control, indicating that the adjuvant contributed to the increased mortality. This effect has also been observed in *U. oudemansii* studies with the honeybee (MRID 472465-15), green lacewing (MRID 472465-12), and a parasitic wasp (MRID 472465-14). No adverse effects were observed at the highest nominal concentration tested if compared to the adjuvant control, and it is concluded that the mortality resulted from the adjuvant. Therefore, the LC<sub>50</sub> for the test material is determined to be >95,900 ppm. Thus, adverse effects in ladybird beetle resulting from dietary exposure to the tested levels of *Ulocladium oudemansii* are not expected. This study was rated “ACCEPTABLE.”

In a nontarget insect dietary toxicity/pathogenicity test with the parasitic wasp (MRID 472465-14), *Ulocladium oudemansii* technical was administered for five days via a cotton wick soaked with the test material at nominal concentrations of 95,900 ppm, 47,900 ppm, and 19,200 ppm (equivalent to  $5.4 \times 10^7$ ,  $2.7 \times 10^7$ , and  $1.1 \times 10^7$  cfu/mL, respectively). The

nominal test concentrations represented, respectively, 11.3x, 5.5x, and 2.2x the pesticide concentration expected to result from the EP label application rate in the lowest reasonable spray volume (4 lbs EP in 25 gallons of water). Mortality in the test groups did not differ significantly from the untreated control (70% honey/sterile water solution) The  $LC_{50}$  of *Ulocladium oudemansii* technical for parasitic wasp was empirically determined to be greater than the highest test concentration of 95,900 ppm (>11.3x the maximum application rate of *Ulocladium oudemansii* EP). The results of this study demonstrate that exposure of the parasitic wasp, *Aphytis melinus*, to *U. oudemansii* at the concentrations tested is not expected to result in adverse effects. This study was rated “ACCEPTABLE.”

#### **h. Honey Bee Testing (OPPTS Guideline 885.4380; MRID No. 472465-15)**

In a honey bee dietary toxicity/pathogenicity test, larvae were treated with *Ulocladium oudemansii* (U3 strain) technical at two test concentrations. The “low” concentration represented 19,200 ppm or 2.2x the expected max spore concentration if the end use product (EP) is prepared according to the label directions (4 lbs EP in 25 gallons of water). The “high” concentration represented 95,900 ppm or 11.3x the maximum expected concentration. Both test substance concentrations were combined with Tween 80 in a 30% sucrose solution for dosing of larvae in brood frames. Control solutions administered to honey bee larvae were a positive control (potassium arsenate), negative control (30% sucrose only) and an adjuvant control (Tween 80, 0.3% v/v in 30% sucrose solution). Overall, survival in the *Ulocladium oudemansii* treatments did not differ significantly from the adjuvant control (ANOVA,  $p < 0.05$ ). These treatments and the adjuvant control also differed significantly from the untreated control. Thus, mortality observed in the *Ulocladium oudemansii* technical treatments appears to be an adverse effect of the adjuvant (Tween 80) and not the *Ulocladium oudemansii* technical. This was also documented in other studies with *U. oudemansii* and nontarget insects, including green lacewing (MRID 472465-12), ladybird beetle (MRID 472465-13) and a parasitic wasp (MRID 472465-14). Therefore, the  $LC_{50}$  is determined to be greater than the highest concentration of 95,900 ppm. The results indicate that exposure to *Ulocladium oudemansii* at the tested concentrations is not expected to result in adverse effects to honeybees. This study was rated “ACCEPTABLE.”

## **2. Environmental Effects Conclusions**

### **a. Terrestrial Animals and Plants**

Data waiver rationale provides sufficient information to conclude that adverse effects are not expected in birds and mammals as a result of exposure to *Ulocladium oudemansii*. *Ulocladium*

*oudemansii* is ubiquitous as a naturally-occurring saprophyte found in soils worldwide, does not have a toxic mode of action, and there is no literature documenting reports of animal pathogenicity or toxicity as a result of exposure to *Ulocladium oudemansii*.

Additionally, *Ulocladium oudemansii* does not grow at normal mammalian body temperatures.

Studies were submitted with three nontarget insect species, including the green lacewing (*Chrysoperla rufilabris*), ladybird beetle (*Hippodamia convergens*) and a parasitic wasp (*Aphytis melinus*). The parasitic wasp was used in place of the big-eyed bug due to limitations of the testing facility chosen to conduct these studies (rationale for use of this species was acceptable to BPPD). A honeybee (*Apis mellifera*) study was also submitted. The effects of dietary exposure to these four insect species was tested at nominal concentrations that were up to 11.3x the concentration of the EP expected if prepared according to labeled rates (i.e., 4 lbs EP in 25 gallons of water). Adverse effects were not observed in these species, and therefore the results of the studies indicate that adverse effects to nontarget insects and honey bees as a result of exposure to *Ulocladium oudemansii* are not anticipated.

A study with terrestrial nontarget plants (tomato, lettuce, cabbage, parsley, rose, rhododendron, azalea, and apple -scientific names not provided) demonstrated no adverse effects for 21 days following an application of the EP. An additional study on grapes demonstrated no post-harvest residues of *Ulocladium* spp. on grapes following a spray program of the EP. This study is classified as supplemental, but does provide data that demonstrate a lack of effects in nontarget plants. *Ulocladium oudemansii* is related to species that are known plant pathogens, but no reports of pathogenicity of *Ulocladium oudemansii* are documented. Therefore, based on this information adverse effects to terrestrial nontarget plants are not expected from applications of the EP.

#### **b. Aquatic Animals and Plants**

Studies with a freshwater fish species (rainbow trout [*Oncorhynchus mykiss*]) and a freshwater invertebrate (*Daphnia magna*) indicate no adverse effects in these animals at concentrations up to 177x the EEEEC of the EP in water. Data waiver rationale was provided to satisfy data requirements and support effects conclusions for marine and estuarine nontarget animals. *Ulocladium oudemansii* is ubiquitous as a naturally-occurring saprophyte found in soils worldwide, does not have a toxic mode of action, and there is no literature documenting reports of pathogenicity or toxicity to aquatic animals as a result of exposure to *Ulocladium oudemansii*. Based on the studies and rationale submitted, adverse effects to freshwater and marine/estuarine fish and invertebrates are not expected as a result of exposure to *Ulocladium oudemansii*. Furthermore, exposure in these environments is not expected to be significant, and the product is not intended for direct application to water. For this reason, aquatic plant testing is not necessary.

Based on the data and waiver rationale submitted, adverse effects to terrestrial and aquatic nontarget organisms are not anticipated as a result of the application of *Ulocladium oudemansii* as intended on the proposed EP label.

### **c. Threatened and Endangered Species Assessment**

As discussed above, *Ulocladium oudemansii* presents no toxicological concerns to any living organisms. *Ulocladium oudemansii* only survives and thrives on dead and decaying plant matter. Given EPA's determination that no effects are anticipated for any non-target species exposed to *Ulocladium oudemansii* (U3 strain) as a result of labeled applications, effects to listed species are also not expected. Therefore, a "No Effect" determination is made for direct and indirect effects to listed species resulting from the proposed use of *Ulocladium oudemansii* (U3 strain), 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, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to *Ulocladium oudemansii* (U3 strain), compared to the general population. Please comment if you are aware of any sub-populations that may have atypical, unusually high exposure compared to the general population.

For a comprehensive guideline-by-guideline summary of the non-target toxicity data requirements, refer to [Table 3](#) in Appendix A.

## **VI. RISK MANAGEMENT AND REGISTRATION DECISIONS**

### **A. Determination of Eligibility**

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

The four criteria of the Eligibility Determination for Pesticidal Active Ingredients are satisfied by the science assessments supporting products containing *Ulocladium oedemansii* (U3 Strain).

Such products are not expected to cause unreasonable adverse effects, and are likely to provide protection as claimed when used according to label instructions. Therefore, *Ulocladium oedemansii* (U3 Strain) is eligible for registration for the labeled uses.

## **B. Regulatory Decision**

As set forth above, EPA has determined that *Ulocladium oedemansii* (U3 Strain) presents no issues of toxicological, ecological, or environmental concern. Accordingly, EPA is granting a time-limited registration for *Ulocladium oedemansii* (U3 Strain) under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). On October 1, 2009, EPA announced a new policy to provide a more meaningful opportunity for the public to participate on major registration decisions before they occur. According to this new 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 use; first outdoor use; and first residential use.

Notwithstanding that the current action on *Ulocladium oedemansii* (U3 Strain) qualifies as a “new active ingredient” under the new policy, EPA believes that it is in the best interests of the public and the environment to issue the registration for *Ulocladium oedemansii* (U3 Strain) without delay. As discussed above, acute toxicity data for *Ulocladium oedemansii* (U3 Strain) demonstrate that it is either toxicity category IV or III. *Ulocladium oedemansii* (U3 Strain) does not demonstrate subchronic or developmental toxicity, and it is not mutagenic or genotoxic. EPA has no concerns for any non-target organisms exposed to *Ulocladium oedemansii* (U3 Strain) in accordance with approved label directions. EPA has not identified any toxic endpoints for non-target mammals, birds, plants, aquatic, or soil organisms. Nor are there concerns for any threatened and endangered species. Thus, given that *Ulocladium oedemansii* (U3 Strain) has very low toxicity and presents little if any risk to non-target organisms, EPA concludes that it is in the best interests of the public and the environment to issue the registration for *Ulocladium oedemansii* (U3 Strain) without delay. Consistent with the Agency’s new policy for making these registration actions more transparent, however, EPA is issuing this registration with an initial period of one-year and, concurrent with its issuance, providing a 30-day public comment period on both the time-limited registration and the final rule establishing a tolerance exemption for *Ulocladium oedemansii* (U3 Strain). EPA is registering this product as a time-limited registration, with the understanding that public comments could bring to light new information or concerns that could inform EPA’s initial decision. Any subsequent action taken by EPA, will be made in the context of information received during the public comment period.

The data submitted fulfill the requirements of registration of *Ulocladium oedemansii* (U3 Strain) for pre-harvest use as a biofungicide in on food commodities and ornamental plants. Refer to Appendix B for product-specific information.

## **1. Conditional/Unconditional Registration**

All data requirements are fulfilled and EPA has determined that a time-limited, 12-month unconditional registration for *Ulocladium oedemansii* (U3 Strain) is warranted under Section 3(c)(5) of FIFRA. If the Agency receives comments during the 30 day public comment period that inform EPA's initial decision, EPA will address such new information and take appropriate action.

### **C. Labeling**

Before releasing pesticide products containing *Ulocladium oedemansii* (U3 Strain) for shipment, the applicant is required to provide appropriate labels.

## **VII. ACTIONS REQUIRED BY THE REGISTRANT**

The Agency evaluated the data submitted in connection with the initial registration of *Ulocladium oedemansii* (U3 Strain) and determined that these data fulfill current registration guideline requirements. No additional data are required to be submitted to the Agency at this time. Additional data may be required for new uses and/or changes to existing uses.

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

### **A. Reporting of Adverse Effects and Hypersensitivity Incidents**

Reports of all incidents of adverse effects to the environment must be submitted to the Agency 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 the Agency under the provisions of 40 CFR Part 158.2140 OPPTS Guideline reference number 885.3400.



## VIII. GLOSSARY OF ACRONYMS AND ABBREVIATIONS

BPPD	Biopesticides and Pollution Prevention Division
BRAD	Biopesticide Registration Action Document
CFR	Code of Federal Regulations
cm <sup>3</sup>	cubic centimeter
CSF	Confidential Statement of Formula
°C	degrees Celsius
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
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	gram
kg	kilogram
L	liter
LD <sub>50</sub>	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).
MRID No.	Master Record Identification Number
mg	milligram
mL	milliliter
MP	manufacturing-use product
MPCA	microbial pest control agent
NE	“No Effect”
NIOSH	National Institute for Occupational Safety and Health
OPP	Office of Pesticide Programs
OPPTS	Office of Prevention, Pesticides, and Toxic Substances
PCR	polymerase chain reaction
PPE	personal protective equipment
TGAI	technical grade of the active ingredient

## IX. BIBLIOGRAPHY STUDIES SUBMITTED IN SUPPORT OF THIS REGISTRATION

### A. Studies Submitted in Support of this Registration.

47246500	Botry-Zen Limited (2007) Submission of Product Chemistry and Toxicity Data in Support of the Application for Registration of <i>Ulocladium oudemansii</i> Technical and the Petition for Tolerance of <i>Ulocladium oudemansii</i> in/on All Agricultural Commodities. Transmittal of 17 Studies.	28-Sep-2007
47246501	Roberts, A. (2007) Product Chemistry for <i>Ulocladium oudemansii</i> Technical. Project Number: VP/BOT/001, VP/BOT/002, BZWG2. Unpublished study prepared by Technology Science Group, Inc. 145 p.	28-Sep-2007
47246502	Crutchfield, V. (2007) <i>Ulocladium oudemansii</i> Technical: Acute IP Injection Toxicity/Pathogenicity Study in Rats with Microbial Pest Control Agents (MPCA): Final Report. Project Number: 10073/06. Unpublished study prepared by Stillmeadow, Inc. 35 p.	28-Sep-2007
47246503	Dreher, D. (2002) Acute Oral Toxicity / Infectivity Study in the Rat ( <i>Ulocladium oudemansii</i> Technical). Project Number: 1638/001. Unpublished study prepared by Safepharm Laboratories, Ltd. 30 p.	28-Sep-2007
47246504	Dreher, D. (2002) Acute Dermal Toxicity / Infectivity Study in the Rat ( <i>Ulocladium oudemansii</i> Technical). Project Number: 1638/002. Unpublished study prepared by Safepharm Laboratories, Ltd. 31 p.	28-Sep-2007
47246505	Wesson, C. (2002) Acute Inhalation (Nose Only) Toxicity / Infectivity Study in the Rat ( <i>Ulocladium oudemansii</i> Technical). Project Number: 1638/003. Unpublished study prepared by Safepharm Laboratories, Ltd. 17 p.	28-Sep-2007
47246506	Dreher, D. (2002) Acute Eye Irritation / Infectivity Study in the Rabbit ( <i>Ulocladium oudemansii</i> Technical). Project Number: 1638/005. Unpublished study prepared by Safepharm Laboratories, Ltd. 23 p.	28-Sep-2007
47246507	Dreher, D. (2002) Acute Dermal Irritation Study in the Rabbit ( <i>Ulocladium oudemansii</i> Technical). Project Number: 1638/004. Unpublished study prepared by Safepharm Laboratories, Ltd. 17 p.	28-Sep-2007
47246508	Dreher, D. (2002) Skin Sensitisation in the Guinea Pig - Magnusson and Kligman Maximisation Method ( <i>Ulocladium oudemansii</i> Technical). Project Number: 1638/008. Unpublished study prepared by Safepharm Laboratories, Ltd. 28 p.	28-Sep-2007
47246509	Thompson, P. (2002) Reverse Mutation Assay "Ames Test" Using <i>Salmonella typhimurium</i> ( <i>Ulocladium oudemansii</i> Technical). Project Number: 1638/007. Unpublished study prepared by Safepharm Laboratories, Ltd. 25 p.	28-Sep-2007
47246510	Putt, A. (2007) <i>Ulocladium oudemansii</i> Technical - Toxicity, Infectivity and Pathogenicity to Rainbow Trout ( <i>Oncorhynchus mykiss</i> ) During a 30-Day Static-Renewal Test. Project Number: 13881/6100, 020606/OPPTS/RBT/STR/MCPA. Unpublished study prepared by Springborn Smithers Laboratories. 53 p.	28-Sep-2007

47246511	Putt, A. (2007) <i>Ulocladium oudemansii</i> Technical - Toxicity, Infectivity and Pathogenicity to Daphnids ( <i>Daphnia magna</i> ) During a 21-Day Static-Renewal Test. Project Number: 13881/6101, 020606/OPPTS/DAPHNID/STR/MPCA. Unpublished study prepared by Springborn Smithers Laboratories. 48 p.	28-Sep-2007
47246512	Richards, K. (2007) <i>Ulocladium oudemansii</i> Technical: A Dietary Study with Green Lacewing Larvae ( <i>Chrysoperla rufilabris</i> ). Project Number: CAR/106/06, 10428/06. Unpublished study prepared by California Agricultural Research Inc. and Stillmeadow, Inc. 76 p.	28-Sep-2007
47246513	Richards, K. (2007) <i>Ulocladium oudemansii</i> Technical: A Dietary Toxicity Study with the Ladybird Beetle ( <i>Hippodamia convergens</i> ). Project Number: CAR/105/06, 10410/06. Unpublished study prepared by California Agricultural Research Inc. and Stillmeadow, Inc. 58 p.	28-Sep-2007
47246514	Richards, K. (2007) <i>Ulocladium oudemansii</i> Technical: A Dietary Study with Parasitic Wasp ( <i>Aphytis melinus</i> ). Project Number: CAR/107/06, 10431/06. Unpublished study prepared by California Agricultural Research Inc. and Stillmeadow, Inc. 96 p.	28-Sep-2007
47246515	Richards, K. (2007) Evaluation of the Dietary Effect(s) of <i>Ulocladium oudemansii</i> Technical on Larval Honeybee Development. Project Number: CAR/111/06, 10141/06. Unpublished study prepared by California Agricultural Research Inc. and Stillmeadow, Inc. 54 p.	28-Sep-2007
47246516	Burgess, I. (2001) Non-Target Plant Testing with <i>Ulocladium oudemansii</i> (U3 Strain). Project Number: VP/BOT/005, VP/BOT/006. Unpublished study prepared by Botry-Zen Limited. 18 p.	28-Sep-2007
47246517	Milesen, B. (2007) Response to Tier 1 Microbial Pesticide Data Requirements for <i>Ulocladium oudemansii</i> Technical. Unpublished study prepared by Technology Sciences Group. 47 p.	28-Sep-2007
47340701	Roberts, A. (2008) Supplemental Product Chemistry for <i>Ulocladium oudemansii</i> Technical. Unpublished study prepared by Technology Sciences Group, Inc. 14 p.	06-Feb-2008
47445501	Roberts, A. (2008) Supplemental Product Chemistry for <i>Ulocladium oudemansii</i> Technical. Project Number: SOP/BQA/001/1. Unpublished study prepared by Technology Sciences Group, Inc. 12 p.	13-Jun-2008
47638901	Milesen, B. (2008) Supplemental Product Chemistry for <i>Ulocladium oudemansii</i> Technical - Product Identity. Unpublished study prepared by Technology Sciences Group, Inc. 39 p.	08-Jan-2009
47638902	Roberts, A. (2009) Supplemental Product Chemistry for <i>Ulocladium oudemansii</i> Technical and BOTRY-Zen - Analysis of Samples and Manufacturing Process Description. Unpublished study prepared by Technology Sciences Group, Inc. 24 p.	08-Jan-2009
47639301	Roberts, A. (2008) Supplemental Product Chemistry for <i>Ulocladium Oudemansii</i> Technical. Unpublished study prepared by Botry-Zen Limited. 12 p.	22-Sep-2008

**B. EPA Risk Assessment Memoranda**

Borges, S. Amended: September 25, 2008 Environmental Risk Assessment of *Ulocladium oudemansii* (U3 Strain). Undated memorandum received via an email dated October 2, 2008.

Etsitty, C. and J. Gagliardi. BPPD Review of Pathogenicity and Toxicity Data Submitted by BOTRY-ZEN Limited, for Registration of BOTRY-Zen® Containing *Ulocladium oudemansii* (U3 Strain). Memorandum dated December 9, 2008.

Gagliardi, J. Review of Product Characterization Data for a Technical and an End-use Product; BOTRY-Zen® Containing *Ulocladium oudemansii* (U3 Strain). Memorandum dated January 27, 2009.

**APPENDIX A – MICROBIAL PESTICIDE DATA REQUIREMENTS**

**TABLE 1. Product Analysis Data Requirements for the Technical Grade of the Active Ingredient (TGAI)/ Manufacturing-Use Product (MP), *Ulocladium oudemansii* (U3 Strain) (40 CFR § 158.2120)**

Data Requirement (OPPTS Guideline)	Results		MRID Number
	TGAI	MP	
<i>Product Chemistry and Composition</i>			
Product Identity (885.1100)		<i>Ulocladium oudemansii</i> , a soil saprophytic fungus, grows rapidly at 18-20°C first appearing olive-green then darker to a velvety charcoal black. The registrant has described characteristics on several different media and incubation conditions, some listed in Table 1, useful in characterizing the a.i. Spore production is high on oatmeal agar. “Conidiophores are abundant, erect or ascending, simple or branched, golden brown, smooth, septate, bearing solitary conidia at 1-5 uniporate geniculations. Conidia are initially narrowly obovoid, hyaline, smooth, becoming yellowish brown, and inconspicuously roughened; finally broadly obovoid or ellipsoidal, dark olivaceous-charcoal 21.6-30.8 by 10.8-16.9 microns with 3-5 transverse and one or two longitudinal or oblique septa, base broadly conical to rounded, apex broadly rounded and often more conspicuously varicose (warted) than remainder of conidium. Conidia germinate readily on moist substrates producing one or more rapidly growing hyphae per conidium.”	473407-01
Manufacturing Process (885.1200)	Submitted data satisfy the requirements of manufacturing process for the TGAI/MP for the purposes of a conditional, time-limited FIFRA section 3(c)(7)(C) registration only.		
Deposition of a Sample in a	<i>Ulocladium oudemansii</i> is	Not applicable	Not applicable

Data Requirement (OPPTS Guideline)	Results		MRID Number
	TGAI	MP	
Nationally Recognized Culture Collection (Not applicable)	stored in 15% glycerol/water at -70°C at the HortResearch Labs in New Zealand and at the National Measurement Institute as NM 99/06216 in Australia		
Discussion of Formation of Unintentional Ingredients (885.1300)	Submitted data satisfy the requirements of discussion of formation of unintentional ingredients for the TGAI/MP. <b>Classification: Acceptable</b>		476389-01 476389-02
<b>Analysis and Certified Limits</b>			
Analysis of Samples (885.1400)	Submitted data satisfy the requirements of manufacturing process for the TGAI/MP for the purposes of a conditional, time-limited FIFRA section 3(c)(7)(C) registration only. <b>Classification: Acceptable</b>		476389-01 476389-02
Certification of Limits (885.1500)	Not applicable	The certified limits for the active and inert ingredients fall within the OPPTS Guideline 830.1750 specified ranges. <b>Classification: Acceptable</b>	
<b>Physical and Chemical Characteristics</b>			
Color (830.6302)	Black	Not applicable	472465-01
Physical State (830.6303)	Solid	Not applicable	472465
Odor (830.6304)	Not stated	Not applicable	472465
Stability to Normal and Elevated Temperatures, Metals, and Metal Ions (830.6313)	Used immediately to make EP in an integrated process	Not applicable	472465
Storage Stability (830.6317)	Not required for TGAI [OPPTS 830.1000 (e)(2)]		
Miscibility (830.6319)	Not required for TGAI [OPPTS 830.1000 (e)(2)]	Not applicable	472465
Corrosion Characteristics (830.6320)	Not required for TGAI [OPPTS 830.1000 (e)(2)]	Not applicable	472465
pH (830.7000)	6.6	Not applicable	472465
Viscosity (830.7100)	Not applicable, product is not a liquid [40 CFR 158.190 (b)(8)]	Not applicable	472465
Density/Relative Density/Bulk Density (Specific Gravity) (830.7300)	0.7g/mL	Not applicable	472465

**TABLE 2. Toxicology Data Requirements for the Technical Grade of the Active Ingredient (TGAI)/  
Manufacturing-Use Product (MP), *Ulocladium oudemansii* (U3 Strain) (40 CFR § 158.2140)**

Data Requirement (OPPTS Guideline)	Results		MRID Number
	TGAI	MP	
<i>Tier I</i>			
Acute Oral Toxicity/Pathogenicity (885.3050)	Technical (purity $5.7 \times 10^9$ cfu/g) does not appear to be toxic, infective, and/or pathogenic in rats, at a dose of $1 \times 10^8$ CFU/animal in 0.9% sterile injectable saline. <b>Classification: Acceptable TOXICITY CATEGORY IV</b>	Not applicable	472465-03
Acute Dermal Toxicity/Pathogenicity (885.3100)	Botry-Zen® does not appear to be toxic, infective, and/or pathogenic in rats, when treated at $1 \times 10^8$ cfu/animal. <b>Classification: Acceptable TOXICITY CATEGORY III</b>	Not applicable	472465-04
Acute Pulmonary Toxicity/Pathogenicity (885.3150)	Waived based on the results of MRID Number 472482-02	Not applicable	472482-02
Acute Injection Toxicity/Pathogenicity (885.3200)	Technical did not appear to be toxic, infective, and/or pathogenic in rats, when dosed at $>10^7$ cfu/animal. <b>Classification: Acceptable</b>	Not applicable	472465-02
Skin Sensitization (870.2600)	Based upon the submitted data, <i>Ulocladium oudemansii</i> Technical, purity not less than $2 \times 10^8$ cfu/g and a minimum spore viability of 90% does not appear to be a dermal sensitizer. Any hypersensitivity incidents must be reported per OPPTS Guideline 885.3400.		
Cell Culture (885.3500)	Not required because <i>Ulocladium oudemansii</i> (U3 Strain) is not a virus (refer to test note #4 of 40 CFR § 158.2140(d)).	Not applicable	472465-17
Acute Oral Toxicity (870.1100)	Not applicable	Waived based on the results of MRID Number 472465-03 and because the MP is equivalent to the TGAI. <b>Classification: Acceptable TOXICITY CATEGORY IV</b>	472482-02
Acute Dermal Toxicity (870.1200)	Not applicable	Waived based on the results of MRID Number 472465-04 and because the MP is equivalent to the TGAI. <b>Classification: Acceptable TOXICITY CATEGORY</b>	472482-02

Data Requirement (OPPTS Guideline)	Results		MRID Number
	TGAI	MP	
		<b>IV</b>	
Acute Inhalation Toxicity (870.1300)	Not applicable	Waived based on the results of MRID Number 472482-02 and because the MP is equivalent to the TGAI. <b>Classification: Acceptable TOXICITY CATEGORY IV</b>	472482-02
Acute Eye Irritation (870.2400)	When dosed with <i>Ulocladium oudemansii</i> Technical, purity not less than $2 \times 10^8$ cfu/g and a minimum spore viability of 90% at 0.1 mL/animal, <i>Ulocladium oudemansii</i> Technical is non-irritating. <b>Classification: Acceptable TOXICITY CATEGORY IV</b>	Not Applicable	472465-06
Primary Dermal Irritation (870.2500)	When dosed with <i>Ulocladium oudemansii</i> Technical, purity not less than $2 \times 10^8$ cfu/g and a minimum spore viability of 90% at 0.5 mL/animal, Botry-Zen® is non-irritating. <b>Classification: Acceptable TOXICITY CATEGORY IV</b>	Not Applicable	472465-07
<b>Tiers II and III</b>			
Not required for <i>Ulocladium oudemansii</i> (U3 Strain) based on the lack of acute toxicity/pathogenicity in the Tier I studies.			

**TABLE 3. Non-Target Organisms and Environmental Fate Data Requirements for the Technical Grade of the Active Ingredient (TGAI), *Ulocladium oudemansii* (U3 Strain) (40 CFR § 158.2150)**

Data Requirement (OPPTS Guideline)	Results	MRID Number
<b>Tier I</b>		
Avian Oral Toxicity (885.4050)	Data waiver rationale provides sufficient information to satisfy this data requirement. <b>Classification: Acceptable</b>	472465-17
Avian Inhalation Toxicity/Pathogenicity (885.4100)	Data waiver rationale provides sufficient information to satisfy this data requirement. <b>Classification: Acceptable</b>	472465-17
Wild Mammal Toxicity/Pathogenicity (885.4150)	Data waiver rationale provides sufficient information to satisfy this data requirement. <b>Classification: Acceptable</b>	472465-17
Freshwater Fish Toxicity/Pathogenicity (885.4200)	Based on a 30-day toxicity study of rainbow trout, receiving an aqueous exposure up to $1.3 \times 10^8$ cfu/L, it was determined that adverse effects to freshwater fish are not expected.	472465-10

Data Requirement (OPPTS Guideline)	Results	MRID Number
	<b>Classification: Acceptable</b>	
Freshwater Invertebrate Toxicity/Pathogenicity (885.4240)	Based on a 21-day static renewal chronic toxicity/pathogenicity study, receiving an aqueous exposure up to $1.3 \times 10^8$ cfu/L, adverse effects in freshwater invertebrates are not anticipated. <b>Classification: Acceptable</b>	472465-11
Estuarine/Marine Fish Testing Estuarine and Marine Invertebrate Testing (885.4280)	Data waiver rationale provides sufficient information to satisfy this data requirement. <b>Classification: Acceptable</b>	472465-17
Non-Target Plant Testing (885.4300)	Various vegetables were treated with concentrations 10x stronger than the end product. This test had several deficiencies, but due to no published reports of phytophthological effects no adverse effects to nontarget terrestrial plants are anticipated. <b>Classification: Supplementary</b>	472465-16
Non-Target Insect Testing (885.4340)	A 27-day dietary toxicity/pathogenicity study exposed Green lacewings, ladybird beetles, and parasitic wasps to concentrations of $1.1 \times 10^7$ cfu/mL, determined that adverse effects are not expected <b>Classification: Acceptable</b>	472465-12 472465-13 472465-14
Honey Bee Testing (885.4380)	Honey bees larvae were treated with doses 2.2x the expected maximum concentration of the end use product. The test indicated that no adverse effects is expected in honey bees. <b>Classification: Acceptable</b>	472465-15



**APPENDIX B – *Ulocladium oudemansii* (U3 Strain) MANUFACTURING-USE AND END-USE PRODUCTS**

<b>EPA Registration Number</b>	<b>Registration Name</b>	<b>Percentage Active Ingredient</b>	<b>Formulation Type</b>	<b>Use Site</b>	<b>Method of Application</b>	<b>Application Rate</b>	<b>Target Pests</b>
75747-R	<i>Ulocladium oudemansii</i> (U3 Strain)	100.0%	Technical	N/A	N/A	N/A	N/A
75747-E	<i>Ulocladium oudemansii</i> (U3 Strain)	45.0%	End Use Product	Agricultural, Horticultural	Spray	4 pounds/acre	<i>Botrytis cinerea</i> and <i>Sclerotinia sclerotiorum</i>