BIOPESTICIDE REGISTRATION ACTION DOCUMENT

Alternaria destruens Strain 059

(PC Code 028301)

U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
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I. EXECUTIVE SUMMARY/FACT SHEET

Active Ingredient and Proposed Use

The active ingredient, *Alternaria destruens* Strain 059 (PC Code 028301, ATCC No. 20831[1]) (also referred to in this document as *A. destruens*), was initially isolated from swamp dodder (*Cuscuta gronovii*) in 1986. This colonist of *Cuscuta* spp., is a ubiquitous, naturally occurring fungus that is indigenous to the United States. *Alternaria destruens* has been formulated into two herbicidal end-use products, Smolder G (a soil applied granular product containing 4.4 % *A. destruens*) and Smolder WP (a spray formulation containing 41.3 % *A. destruens*), which are to be used as herbicidal agents in certain agricultural fields and dry bogs.

Alternaria destruens Strain 059 acts by infecting and suppressing dodder at early and late stages of growth. To function effectively, the active ingredient requires a moist environment and adequate temperature during the infection period, which can last for three to four hours. Under dry conditions, the onset of infection may be delayed until increased moisture is available. *Alternaria destruens* Strain 059 can feed on live or dead host plant tissue and demonstrates poor survival in the absence of a dodder species.

Toxicology, Human Exposure and Risks

Evaluations of mammalian toxicology data comply with the Food Quality Protection Act (FQPA) of 1996, and are sufficient to support the unconditional registration of this microbial pesticide for the proposed uses. The technical grade active ingredient (TGAI) was classified as Toxicity Category IV for acute oral toxicity and primary dermal irritation, and as Toxicity Category III for primary eye irritation.

The Agency accepted requests to waive hypersensitivity and immune response studies. The rationale for granting waivers was based on the following: a) the low toxicity and irritation potential as demonstrated by acute oral, acute dermal, acute pulmonary, acute injection toxicity/pathogenicity, and primary dermal irritation studies; b) minimal opportunity for exposure via dermal and inhalation routes; and c) no documented reports of hypersensitivity incidents during production and testing of the active ingredient and end use products [Table 3b and discussion in Section III.B.2].

Food Tolerances

For this section 3(c)(5) unconditional registration, a permanent tolerance exemption is being established in 40 CFR Part 180. for residues of *A. destruens* on all agricultural commodities when used/applied in accordance with label directions.

[1] The American Type Culture Collection (ATCC) acts as a central collection point for microorganisms.

FQPA Considerations

The Agency has considered *A. destruens* in light of the safety factors identified in the Food Quality Protection Act (FQPA) of 1996 and has made a determination of reasonable certainty of no harm to the U.S. population in general, and to infants and children in particular. The ubiquitous occurrence of *A. destruens* suggests that humans are exposed to the microbe under natural conditions. Thus, application of *A. destruens* for agricultural purposes is not expected to increase exposure above normal background levels [Section III.B.3].

Toxicity endpoints which justify setting numerical tolerances for a pesticide product were not identified for *A. destruens*. Submitted studies indicate that the active ingredient demonstrates low acute oral toxicity potential (Toxicity Category IV), showing no incremental dietary risk [Section III.B.3]. In this assessment, no acute, subchronic, chronic, immune, endocrine, or non-dietary exposure issues were identified which may impose any incremental adverse effects on infants, children, and the general U.S. population. Based on the classification of Toxicity Category IV for acute oral toxicity effects, a safety factor is not required for residues of *A. destruens* Strain 059. Potential risks via exposure to drinking water or runoff are not expected, because the fungal agent does not thrive in aquatic environments [Section III.B.5].

The potential for aggregate non-occupational exposure is unlikely, because use sites identified for the subject active ingredient are agricultural and horticultural. If such exposure was to occur, risk concerns would be negligible, because the fungus is non-pathogenic and minimally toxic to mammals.

Occupational and Residential Exposure and Risk

Potential worker and pesticide handler exposure to *A. destruens* is not expected to pose any undue risk. Appropriate Personal Protective Equipment (PPE) and a Restricted Entry Interval (REI) of 4 hours for agricultural field/dry bog applications are required to mitigate potential risks to workers and pesticide handlers. Residential exposure is not expected because the end use products will be used in agricultural settings. Risk to workers, pesticide handlers, and residential communities are further reduced because the TGAI is minimally toxic and non-pathogenic to mammals.

Ecological and Environmental Exposure and Risks

The submitted non-target avian, freshwater fish, and aquatic invertebrate studies fulfill the respective OPPTS guidelines for ecological assessment of microbial herbicides and are considered acceptable. No adverse effects to non-target populations of avian, freshwater fish, aquatic invertebrates, nor their respective endangered taxa, are expected to result from intended uses of *A. destruens*.

It was concluded that intended uses of *A. destruens* will not pose incremental hazards to the tested crop plants of economic importance, nor to plants related to target weeds. In the unlikely

event that some non-target plants are affected during the commercial application of this product, such incidents should immediately be reported to the EPA, as required under FIFRA Section 6(a)(2), so that the Agency may take appropriate action.

Non-target toxicity tests were waived for wild mammal, estuarine and marine animals, honeybee, and insects [Section III.C.1.f.].

Data Gaps and Requirements/Labeling
There are no data deficiencies for *A. destruens*. However, if more extensive use patterns are sought for treatment of other agricultural terrestrial sites or crops, additional information and data may be required on a case-by-case basis.

II. OVERVIEW

A. Product Overview

Biological Name:	*Alternaria destruens* Strain 059
ATCC Number:	20831
Trade/Other Names:	Smolder G and Smolder WP
OPP Chemical Code:	028301
Basic Manufacturer:	Loveland Products, Inc. 7251 West 4th Street Greeley, CO 80634

B. Use Profile

Type of Pesticide:	Herbicide
Use Sites:	Alfalfa, cranberries (dry bogs only), carrots, peppers, tomatoes, eggplant, blueberries, nursery-grown woody ornamentals.
Target Pests:	*Cuscuta* spp., known as dodder, swamp dodder, largeseed dodder, smallseed dodder, and field dodder.
Formulation Types:	Solid granular (Smolder G) and liquid sprayable (Smolder WP) products.
Method/Rate of Application:	Smolder G: Granules are applied to a moist surface at a rate of 50 pounds (1 bag) per acre at, or immediately prior to, dodder emergence. Smolder WP: This product consists of Component A, a water-soluble packet of active ingredient, co-packaged with Component B, a liquid adjuvant. One water-soluble packet and one container of adjuvant are combined with sufficient water to bring the final mix volume to 30 gallons. The product should be applied when dodder vines are beginning to reach the top of the crop canopy.
Limitations of Use:	Not for use with irrigation systems.

C. Estimated Usage

An estimate of usage, based on existing commercial use patterns of similar products, cannot be made since these are the first pesticide registrations containing *A. destruens* as the active ingredient.

D. Data Requirements

Data and accompanying information, submitted under section 3(c)(5) of FIFRA in support of this unconditional registration, have been reviewed by the BPPD. Product identity and analysis data, as well as documents submitted for acute mammalian toxicity and ecological effects, meet the requirements set forth for the proposed use patterns. If label instructions are followed, the Agency foresees no unreasonable adverse affects to human health and the environment from use of *A. destruens*.

E. Regulatory History

1. Experimental Use and Temporary Tolerance Exemption

No EUPs or temporary tolerance exemptions have been issued for *A. destruens*.

2. Section 3 Registration and Exemption from tolerance

EPA received an application from Loveland Products, Inc., 7251 West 4th Street, Greeley, CO 80634 on July 7, 2000 to register the active ingredient *A. destruens* Strain 059. When the application package was deemed complete, the receipt of the application for the new active ingredient was published in the Federal Register [FR: February 7, 2001, Vol. 66, No. 26, pp. 9318- 9319]. The Agency received no comments on the FR announcement.

Concomitant with the application for the Section 3(c) registration, the registrant filed a petition (PP 0F6191) requesting a permanent exemption from the requirement of a tolerance for the active ingredient, *A. destruens* Strain 059, on all agricultural commodities. A notice of filing of this petition was published in the Federal Register [FR: January 17, 2001, Vol. 66, No. 11, pp. 4017- 4020]. No comments to the FR announcement were received by the Agency. An exemption from the requirement of a tolerance for residues of *A. destruens* on all agricultural commodities is being processed in connection with this petition and the final rule will be published in the Federal Register (40 CFR Part 180), concurrent with the unconditional registration.

III. SCIENCE ASSESSMENT

A. Physical and Chemical Properties Assessment

The data submitted in support of product identity requirements for *A. destruens* Strain 059 are sufficient for the proposed use patterns of the microbial pesticide.

1. Product Identity and Mode of Action (MRID 451664-01; OPPTS 885.1100, 885.1200, 885.1300, 885.1400, 885.1500; Gdln. 151-10)

The active ingredient, *A. destruens* Strain 059, was initially isolated from swamp dodder (*Cuscuta gronovii*) in 1986. The fungus colonizes several *Cuscuta* species (dodder, swamp dodder, largeseed dodder, field dodder, smallseed dodder, etc.) and survives only on the live or dead tissue of host plants. *Alternaria destruens* is indigenous to the United States and has been isolated from natural populations in Wisconsin and Massachusetts.

This fungal pathogen has been formulated into two herbicidal end-use products. Smolder G, a soil applied granular product, acts by infecting and suppressing dodder at early stages of growth. The granular formulation is applied in the late spring to suppress dodder at plant emergence. Smolder WP, a spray formulation, is applied in late summer to suppress dodder vines that have reached, or are close to reaching, the top of the cash crop canopy.

To function effectively, the fungal pathogen requires a moist environment and adequate temperature during the infection period. Under dry conditions, the onset of infection may be delayed until increased moisture is available.

There are no impurities of toxicological significance associated with *A. destruens* and human/animal pathogens are not expected due to sterile manufacturing processes (BPPD Review - October 25, 2002).

Table 1: Product Identity & Manufacturing Process for *A. destruens* (MRID 451664-01)

Guideline	Study	Result
151-10 *885.1100	Product Identity	ACCEPTABLE. The active ingredient is a naturally-occurring fungal pathogen that colonizes *Cuscuta* spp.
151-11 885.1200	Manufacturing Process	ACCEPTABLE. Products are produced by an integrated system. Description of production process is sufficient.
151-12 885.1300	Discussion of Formation of Unintentional Ingredients	ACCEPTABLE. No toxicological impurities are associated with the active ingredient.
151-13 885.1400	Analysis of Samples	ACCEPTABLE. Samples were analyzed prior to mixing with final inert ingredients. Quantification of bacterial counts was done by scoring five different colonies after incubation.
151-15 885.1500	Certification of limits	ACCEPTABLE. Certified limits are within OPPTS guidelines.
151-16	Analytical Method	ACCEPTABLE. Serial dilutions of *A. destruens* are plated and incubated. Fungal counts are determined by scoring colonies after incubation.

*OPPTS Guidelines

2. Physical and Chemical Properties Assessment (MRID 462778-01; OPPTS 830.6302, 830.6303, 830.7000, 830.7300, 830.6320, 830.6317; Gdln. 151-17)

The color, physical state, pH, bulk density, corrosion characteristics, and storage stability of the end use products are described below (Table 2). Guideline data requirements (40 CFR Part §158.740(a)) for melting point, boiling point, solubility, vapor pressure, dissociation constant, octanol/water partition coefficient, stability, oxidizing or reducing potential, flammability/flash point, explodability, viscosity, miscibility, and dielectric breakdown voltage were waived due to the nature of the microbial pesticide (BPPD Review - October 25, 2002).

Table 2: Physical & Chemical Properties of *A. destruens* Product Formulations (MRID 462778-01)

Physical/Chemical Properties			
Guideline	**Study**	**Result**	
		Smolder G	**Smolder WP**
151-17 *830.6302	Color	Grey/black	
151-17 830.6303	Physical state	Granule	Solid (powder)
151-17 830.7000	pH	6.7	6.2
151-17 830.7300	Bulk density	36.1 lbs/f^3	51.2 lbs/f^3
151-17 830.6320	Corrosion characteristics	Not corrosive in original packaging	
151-17 830.6317	Storage stability	Stable for up to six months when stored in original packaging at 40-80ºF	

*OPPTS Guidelines

B. Human Health Assessment

Submitted mammalian toxicology studies are sufficient to support the unconditional registration of *A. destruens* Strain 059 for the proposed use patterns.

1. Food Clearances/Tolerances

This is the first proposed Section 3(c)(5) unconditional registration of *A. destruens*. There is a reasonable certainty that no harm is likely to result from exposure to the active ingredient. This includes all anticipated dietary exposures for which there is reliable information. As such, an exemption from the requirement of a food tolerance for residues of *A. destruens* Strain 059 is being established concomitant with the unconditional registration (40 CFR Part 180). Below is the toxicology assessment, and discussion of other factors covered under the Food Quality Protection Act (1996), which led to the decision to grant an exemption from tolerance.

2. Toxicology Assessment

Summaries of acute toxicology studies (Table 3a) and rationales for certain waiver requests (Table 3b) are discussed below.

a. Acute Oral Toxicity (MRID 451664-02; OPPTS 885.3050; Gdln. 152-30)

Twenty seven male and 27 female Sprague-Dawley rats were dosed with formulated (end use product) *A. destruens* via oral gavage. During the observation period, no rats died, one male showed hair loss for 3 days following dosage, another male displayed colored material around the nose for up to 4 hours after dosing, and one animal produced few or no feces until day 7 following exposure. All rats gained weight during the study and no rats had observable abnormalities during gross necropsy examinations. The pesticide was classified as **Toxicity Category IV** for acute oral toxicity (BPPD Review - October 25, 2002).

b. Acute Pulmonary Toxicity/Pathogenicity (MRIDs 451664-03, 462778-03, data submission with no accompanying MRID; OPPTS 885.3150; Gdln. 152-32)

Alternaria destruens was shown to be non-toxic, infective, or pathogenic to rats when administered intratracheally at 5.0×10^5 CFU/animal. Thirty-five male and 37 female Sprague-Dawley rats were included in the study. Four rats died or were moribund, and therefore humanely sacrificed, within 3 days of test material administration. With the exception of 3 animals that lost weight on day 7, all treated rats gained weight during the study. Clinical signs that followed test material administration were described as rales, colored material around nose/eyes, anogenital staining, few feces, labored breathing, and/or rough hair coat after dosing; full recovery was seen within 6 days of test administration. Necropsy showed no significant signs of abnormality. Test animals which died following exposure, or were sacrificed on days 3, 7, or 14, exhibited lungs with multifocal areas of congestion and consolidation, mottled colored areas, and enlargement. These symptoms are characteristic of an immune response and are considered normal when test material is

delivered using this vehicle of exposure. The test organism was detected in the lung tissues of all treated rats until day 3, with clearance established by day 14. Deficiencies were noted in the original submission, and addressed in MRID 462778-03 and in a subsequent submission with no MRID assigned (BPPD Reviews - October 25, 2002, September 10, 2004 and December 14, 2004).

c. Acute Injection Toxicity/Pathogenicity (MRID 451664-04, 462778-03, data submission with no accompanying MRID; OPPTS 885.3200; Gdln. 152-33)
Five male and 5 female Sprague-Dawley rats were included in the study. There were no mortalities following intraperitoneal injection of 9.6×10^6 CFU test material/animal. All but one rat gained weight. Rats exhibited soiled hair coat, emission of colored material around the nose, anogenital staining, and soft/few/no feces for up to 8 days following test material administration. Gross necropsy provided evidence of an inflammatory response to the test substance in the form of multiple adhesions associated with liver, spleen, diaphragm, stomach, and/or testes/ovaries. Some males exhibited one or more of the following: enlarged testis, small testis, lump in the scrotum, subcutaneous lump, multiple adhesions and nodular masses associated with the testes. Subcutaneous lumps and/or multiple nodules in the abdominal cavity were noted in some females. Adhesions and lumps identified in the abdominal and peritoneal area are indicative of an inflammatory response to administration of the test material and are considered normal. Deficiencies were noted in the original submission, and addressed in MRID 462778-03 and in a subsequent submission with no MRID assigned (BPPD Reviews - October 25, 2002, September 10, 2004 and December 14, 2004).

d. Acute Dermal Toxicity (MRID 451664-05; OPPTS 870.1200; Gdln. 152-31)
Five male and 5 female Sprague-Dawley rats were given a single dose of 5000 mg/kg of formulated *A. destruens* applied under a gauze pad. No mortality occurred and no observable abnormalities were seen on necropsy. The pesticide is considered non-toxic and is therefore classified as **Toxicity Category IV** for acute dermal toxicity (BPPD Review - October 25, 2002).

e. Acute Inhalation Toxicity (MRID 451664-06; OPPTS 870.1300; Gdln. 152-32)
Five male and 5 female Sprague-Dawley rats were exposed to a test concentration of 2.03 mg/L of formulated *A. destruens* by inhalation. No mortality resulted from exposure to the formulated end-use product. Ocular and nasal discharge, hunched posture, and hypoactivity were noted during exposure. Ocular and/or nasal discharge continued upon removal from the exposure chamber. Full recovery was noted within 17 hours of test completion. The acute lethal dose (LC_{50}) was greater than 2.03 mg/L. The pesticide is considered non-irritating and is therefore classified as **Toxic Category IV** for acute inhalation (BPPD Review - October 25, 2002).

f. Primary Eye Irritation (MRID 451664-07; OPPTS 870.2400; Gdln. 152-35)
Three male rabbits were given a single dose of 0.1 g of formulated *A. destruents* applied to the right eye. There was no resulting mortality, corneal opacity, or iritis following test material administration. All rabbits exhibited positive conjunctival irritation. Full resolution was seen within 48 hours of test material administration. The pesticide is considered to be minimally irritating and is therefore classified as **Toxicity Category III** for primary eye irritation (BPPD Review - October 25, 2002).

g. Primary Dermal Irritation (MRID 451664-08; OPPTS 870.2500; Gldn. 152-34)
Three male 3 female rabbits were given a single dose of 0.5 g of formulated *A. destruens* applied under a gauze pad. None of the rabbits died during the study and no dermal irritation was noted. The pesticide is considered non-irritating and is therefore classified as **Toxicity Category IV** for primary dermal irritation (BPPD Review - October 25, 2002).

Table 3a: Tier I - Acute Mammalian Toxicity of *A. destruens*

Guideline	Study	Toxicity Category	Results	MRID #
152-30 *870.1100	Acute oral toxicity	IV	ACCEPTABLE. No mortality. No observable abnormalities. Hair loss, colored material around nose, and reduced fecal production noted. Signs cleared by day 7.	451664-02
152-32 885.3150	Acute pulmonary toxicity/ pathogenicity	N/A	ACCEPTABLE. The active ingredient was not toxic, infective, or pathogenic to rats. Clearance from lungs was seen by day 14.	451664-04, 462778-03, and data submission with no MRID
152-33 885.3200	Acute injection toxicity/ pathogenicity	N/A	ACCEPTABLE. The active ingredient was not toxic, infective, or pathogenic to rats. Adhesions and lumps identified in the abdominal and peritoneal area are indicative of a normal inflammatory response to administration of the test material.	451664-04, 462778-03,and data submission with no MRID
152-31 870.1200	Acute dermal toxicity	N/A	ACCEPTABLE. No mortality. No observable abnormalities on necropsy.	451664-05
152-32 870.1300	Acute inhalation toxicity	N/A	ACCEPTABLE. Inhalation exposure resulted in ocular and nasal discharge, hunched posture, and hypoactivity. Following exposure, ocular and/or nasal discharge were noted. Full recovery was seen within 17 hours of test completion.	451664-06
152-35 870.2400	Primary eye irritation	III	ACCEPTABLE. No corneal opacity or iritis. All test animals showed an initial positive conjunctival irritation response, with full resolution within 48 hours of test administration.	451664-07

152-34 870.2500	Primary dermal irritation	IV	ACCEPTABLE. No dermal irritation. The test substance was found to be nonirritating.	451664-08

* OPPTS Guidelines

h. Waiver Requests: Health Effects

The Agency approved waivers for the Tier I studies listed below. Waiver justifications are provided beneath each subheading (BPPD Review – September 10, 2004):

i) Hypersensitivity Study (OPPTS 870.2600; Gdln. 152-36)

A waiver was granted due to the following considerations: a) the low toxicity and irritation potential of the test substance, as demonstrated by acute oral, acute dermal, acute pulmonary, injection toxicity/pathogenicity, and dermal irritation studies; b) few opportunities for exposure via dermal and inhalation routes; and c) no documented reports of hypersensitivity incidents during production and testing of the active ingredient and end-use product.

ii) Immune response (OPPTS 885.3800; Gdln. 152-38)

The submitted acute toxicity and pathogenicity studies (discussed above) demonstrated that *A. destruens* is not toxic, infective, or pathogenic to test animals. This finding justifies the waiver request for immune response testing.

Table 3b: Tier I - Waivers: Acute Mammalian Toxicity of *A. destruens*

Guideline	Study	Toxicity Category	Comments
152-36 *870.2600	Hypersensitivity	N/A	WAIVER GRANTED. The test substance has a low toxicity and irritation potential, there is minimal opportunity for exposure via dermal and inhalation routes, and there are no documented reports of hypersensitivity incidents.
152-38 870.2500	Immune Response	N/A	WAIVER GRANTED. The submitted acute toxicity and pathogenicity studies (discussed above) demonstrated that *A. destruens* is nontoxic, infective, or pathogenic to test animals.

*OPPTS Guidelines

i. Subchronic, Chronic Toxicity and Oncogenicity

Based on the data generated in accordance with Tier I data requirements (40 CFR Part §158.740(c)), Tier II tests (Guidelines 152B-40 through 152B-49), which include acute oral, acute inhalation, subchronic oral, acute intraperitoneal/intracerebral, primary dermal, primary eye, immune response, teratogenicity, virulence enhancement, and mammalian mutagenicity, were not required. Tier III tests (Guidelines 152-50 through 53), which include chronic testing, oncogenicity testing, mutagenicity, and teratogenicity, were also not required.

j. Effects on the Immune and Endocrine Systems
EPA is required under section 408(p) of the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." *Alternaria destruens* is not a known endocrine disruptor nor is it related to any class of known endocrine disruptors. Consequently, endocrine-related concerns did not adversely impact the Agency's safety finding for *A. destruens*.

3. Dietary Exposure and Risk Characterization
Due to the proposed use of *A. destruens* on food crops, fungal residues may be present on agricultural commodities. However, negligible to no risk is expected for the general population, including infants and children, because *A. destruens* demonstrated no pathogenicity or oral toxicity at the maximum doses tested (BPPD Review - October 25, 2002).

4. Occupational and Residential Exposure and Risk Characterization

a. Non-occupational Residential, School and Day Care Exposure, and Risk Characterization
Alternaria destruens will be applied to agricultural fields and dry bogs. Since these application sites are not generally located near residential areas, there will be little opportunity for non-occupational exposures to *A. destruens*. Moreover, in the unlikely event of such exposure, no harm would be expected due to the active ingredient's low toxicity classification (see Section III.B.2 above).

b. Occupational Exposure and Risk
Potential worker and pesticide handler exposure to *A. destruens* Strain 059 to is not expected to pose any undue risk. Appropriate Personal Protective Equipment (PPE) and a Restricted Entry Interval (REI) of 4 hours are required to mitigate any potential risks to workers and pesticide handlers. PPE for workers and handlers consists of long-sleeved shirt, long pants, shoes, socks, waterproof gloves, and a filtering respirator. To perform post-application activities, early entry workers must wear coveralls in addition to the PPE described above.

The primary routes of exposure for mixer/loaders and applicators would be dermal and/or inhalation exposure. The acute pulmonary toxicity/pathogenicity study submitted in support of the registration demonstrated that *A. destruens* Strain 059 is minimally toxic and non-pathogenic. As such, the risks anticipated for occupational exposure are considered minimal (Section III.B.2 above).

5. Drinking Water Exposure and Risk Characterization
Alternaria destruens does not thrive in aquatic environments and there are no aquatic use sites for the pesticide. Although cranberry is listed as a use site, the product may only be applied to dry bogs. Accordingly, application of this pesticide to agricultural crops is not expected to increase drinking water exposure to *A. destruens*. Furthermore, any material that is consumed through drinking water would pose negligible to no risk for the general population, including infants and children, due to the pesticide's low toxicity classification (see Section III.B.2 above).

6. Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children
There is a reasonable certainty that no harm to the U.S. population, including infants and children, will result from aggregate exposure to residues of *A. destruens* due to its use as a microbial pest control agent. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed in Section III.B.2 above, *A. destruens* is minimally toxic, non-pathogenic, and non-infective to mammals. Accordingly, exempting *A. destruens* from the requirement of a tolerance is considered safe and poses no significant risks.

7. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation
The potential for aggregate exposure should be adequately mitigated if label instructions are followed.

a. Dermal
Non-occupational exposure should be minimal due to limited to use sites (agricultural fields/dry bogs) and minimal potential for wind dispersal of soil applied granular and foliar applied spray products.

Occupational dermal exposure is limited by use of the required PPE and REI (see Section III.B.4).

b. Oral
Oral exposure would occur primarily from eating treated produce. However, negligible to no risk is expected, because *A. destruens* Strain 059 demonstrated no pathogenicity or toxicity potential at the maximum doses tested. Based on the acute oral toxicity study, the pesticide is classified as Toxicity Category IV for oral exposure (BPPD Review - October 25, 2002; for more discussion, see Section III.B.3).

c. Inhalation
The potential for non-occupational inhalation exposure to *A. destruens* pesticide residues is unlikely, because the potential use sites are agricultural. The greatest likelihood of inhalation exposure would occur in an occupational setting, among mixers/loaders and

applicators. However, as demonstrated in the acute pulmonary toxicity/pathogenicity test, *A. destruens* is non-infective, pathogenic, or toxic. Despite the benign nature of the active ingredient, the Agency requires that all workers exposed to microbial pesticides must wear a dust/mist filtering respirator. As such, the risks anticipated for inhalation exposure are considered minimal.

8. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effect of exposure to *A. destruens* and to other substances that have a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. As demonstrated in Section III.B.2 above, *A. destruens* is minimally toxic and non-pathogenic to mammals. Consequently, no cumulative effects from the residues of this product with other related microbial pesticides are anticipated.

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

There is a reasonable certainty that no harm to the U.S. population, including infants and children, will result from aggregate exposure to residues of *A. destruens* due to its use as a microbial pest control agent. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed in Section III.B.2 above, *A. destruens* is minimally toxic, non-pathogenic, and non-infective to mammals. Accordingly, exempting *A. destruens* from the requirement of a tolerance is considered safe and poses no significant risks.

FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold margin of exposure (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 exposure (safety) will be safe for infants and children. Margins of exposure (safety), which often are referred to as uncertainty factors, are incorporated into EPA risk assessment either directly or through the use of a margin of exposure analysis or by using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk. Actual exposures to adults and children through diet are expected to be several orders of magnitude less than the doses used in the toxicity and pathogenicity tests referenced in Section III above. Thus, the Agency has determined that an additional margin of safety for infants and children is unnecessary.

C. Environmental Assessment

1. Ecological Effects Hazard Assessment

Below is a summary of the ecological effects data evaluated in support of this action. Studies and information submitted for evaluation of toxicity to non-target organisms are sufficient to allow unconditional registration of *A. destruens* Strain 059 as a microbial pesticide for dodder control on fruit and vegetable field crops and nursery-grown woody ornamentals.

a. Avian Oral Toxicity (MRID 451664-09; OPPTS 885.4050; Gdln. 154-16)
Alternaria destruens was shown to be non-toxic to the Northern Bobwhite. The acute oral toxicity of the test substance was evaluated by syringe insertion of the test substance directly into the crop or the proventriculus of 21-day old bobwhite for 5 days, with a dosage of 6.0×10^8 CFU/kg/day, followed by a 30 day observation period. There were no treatment related mortalities, toxicity, pathogenicity or other adverse effects noted in the 30-day study (BPPD Review-August 21, 2002).

b. Freshwater Fish Testing (MRID 451664-10; OPPTS 885.4200; Gdln. 154-19)
The toxicity and pathogenicity of *A. destruens* Strain 059 to juvenile Rainbow Trout (*Oncorhynchus mykiss*) was evaluated in a 30-day static/renewal study. There were no treatment related mortalities or adverse effects noted at 167 mg PCC578/L (highest nominal concentration tested); the LC 50 is > 167 mg PCC578/L (measured activity> 3.00×10^4 CFU/ml). Although testing may not have been conducted at the maximum EEC (since it was noted that the measured viability levels in the renewal solutions were 10^3-fold lower than the nominal concentrations), the study is acceptable for the intended outdoor terrestrial applications. If exposures to freshwater aquatic ecosystems increase, the study may have to be supplemented with additional data, in which test substance activity (viability) is shown to decrease to the same extent under experimental and "normal usage conditions" (BPPD Review - August 21, 2002).

c. Freshwater Fish Testing (MRID 451664-11; OPPTS 885.4200; Gdln. 154-19)
The toxicity and pathogenicity of the MPCA to juvenile bluegill (*Lepomis macrochirus*) was evaluated in a 30-day static/renewal study. There were no treatment related mortalities or adverse effects noted at 167 mg *A. destruens*/L (highest nominal concentration tested); the LC_{50} is > 167 mg *A. destruens*/L (measured activity > 3.04×10^4 CFU/ml). Although testing may not have been conducted at the maximum hazard dose (since it was noted that the measured viability levels in the renewal solutions were 10^3-fold lower than the nominal concentrations), the study is acceptable for the intended outdoor terrestrial applications. If exposures to freshwater aquatic ecosystems increase, the study may have to be supplemented with additional data, in which MPCA activity (viability) is shown to decrease to the same extent under test and "normal usage conditions" (BPPD Review - August 21, 2002).

d. Freshwater Aquatic Invertebrate Testing (MRID 451664-12; OPPTS 885.4240; Gdln. 154-20)
Cladoceran (*Daphnia magna*) were exposed to a range of 5 concentrations of *A. destruens* under static renewal conditions for 21 days. The 21-day NOEC for the sublethal effects of decreased reproduction and decreased growth (length and weight of 1st generation) was 84 mg/L or 1.5 x 10^4 CFU/mL. The LOEC for reproduction was 167 mg/L or 2.8 x 10^4 CFU/mL. The 21-day LC_{50} based on mortality or immobility could not be calculated because these parameters were similar among control and MPCA-treated groups (e.g., survival $\geq$30%). Decreased reproduction and decreased growth of the first generation were sensitive at a concentration of 118 mg/L (2.06 x 10^4 CFU/mL). These sublethal effects may have been attributable to the physical presence of the excess *A. destruens* in the test containers. Since the proposed uses are not for aquatic environments, the aquatic concentrations of the active ingredient from agricultural run-off are expected to be below the levels that showed adverse effects in this study (BPPD Review - August 21, 2002).

e. Non-target Plant studies (MRID #451664-13; OPPTS 885.4300; Gdln. 154-22)
Results from a small-scale definitive study, performed under controlled conditions, demonstrated that treatment with laboratory-grade *A. destruens* significantly affected the height and weight of several crop plants, particularly *Lupinus polyphyllus*, an ornamental legume. Data also suggested that crop plants including potato, alfalfa, carrot, cranberry, celery, spearmint, maize, cucumber, tomato, squash, pumpkin, beet, spinach, turnip, broccoli, radish, pepper, tobacco, and lettuce are not hosts of *A. destruens* and consequently, would not be affected by the fungal pesticide.

These data were gathered over a limited period under controlled conditions and did not fulfill the guideline for assessing risks to non-target plants (OPPTS 885.4300). Consequently, the study was rated supplemental. However, these data present sufficient information to conclude that it is unlikely that intended applications of *A. destruens* will pose incremental hazards to crop plants of economic importance, or to plants related to the target weed. No further studies are required at this time. In the unlikely event that some non-target plants are affected during the commercial application of this product, such incidents should be immediately reported to the EPA as required under FIFRA Section 6(a)(2) so that the Agency may take appropriate action. (BPPD Review August 21, 2002 and December 22, 2004).

Table 4a: Eco-Toxicology Summary/Studies Evaluated

Guideline	Study	Status, Classification & Comments	MRID No.
154-16 *885.4050	Avian oral	ACCEPTABLE. No treatment related mortality, toxicity, pathogenicity or other adverse effects were noted following administration of 6.0 x 10^8 CFU/kg/day *A. destruens*, for 5 consecutive days, to the Northern Bobwhite.	451664-09
154-19 885.4200	Freshwater fish testing	ACCEPTABLE. No treatment related mortality, toxicity, pathogenicity or other adverse effects were noted following administration of 167 mg *A. destruens*/L (LC_{50} is > 167 mg *A. destruens*/L) to Rainbow Trout.	451664-10
154-19 885.4200	Freshwater fish testing	ACCEPTABLE. No treatment related mortality, toxicity, pathogenicity or other adverse effects were noted following administration of 167 mg *A. destruens*/L (LC_{50} is > 167 mg *A. destruens*/L) to juvenile Bluegill.	451664-11
154-20 885.4240	Freshwater aquatic invertebrate testing	ACCEPTABLE. Daphnia were exposed to a range of 5 concentrations of *A. destruens* under static renewal conditions for 21 days. The 21-day NOEC for the sublethal effects of decreased reproduction and decreased growth (length and weight of 1st generation) was 84 mg/L or 1.5 x 10^4 CFU/mL. The LOEC for reproduction was 167 mg/L or 2.8 x 10^4 CFU/mL.	451664-12
154-22 885.4300	Non-target plant studies	SUPPLEMENTAL. Treatment with *A. destruens* significantly affected the height and weight of several crop plants, particularly *Lupinus polyphyllus*, an ornamental legume. Data suggested that crop plants including potato, alfalfa, carrot, cranberry, celery, spearmint, maize, cucumber, tomato, squash, pumpkin, beet, spinach, turnip, broccoli, radish, pepper, tobacco, and lettuce are not hosts of *A. destruens*. Data were of limited duration and were rated supplemental, as they did not fulfill the guideline for assessing risks to non-target plants. However, it was concluded that *A. destruens* will not likely pose a hazard to the tested crop plants of economic importance, nor to plants related to the target weed.	451664-13

*OPPTS Guidelines.

f. Waivers: Ecological Effects

The Agency approved waivers for the Tier I studies listed below. Waiver justifications are provided beneath each subheading (BPPD Review – December 22, 2004).

i) Wild Mammal Testing (OPPTS 885.4150; 154-18)

Results from studies conducted for a human health assessment of *A. destruens* demonstrated a lack of oral, dermal and inhalation toxicity to mammals. The test substance occurs naturally and is a known colonizer of dodder spp. Population levels of *A. destruens* temporarily increase when used as a pesticide, and no other host or habitat has been identified in studies conducted on related and unrelated non-target organisms. Online literature searches through the TOXLINE and AGRICOLA databases yielded no reports of adverse exposures of *A. destruens* to mammals. Finally, extensive environmental exposures of the test substance are precluded by the limited number of intended uses.

ii) Estuarine and Marine Animal Testing (OPPTS 885.4280; Gdln. 154-21)
Products containing *A. destruens* are not intended for direct application to estuarine/marine environments, nor is it anticipated that they will enter these environments in large concentrations.

The ecological risk assessment (BPPD Review – August 21, 2002) determined that exposure of freshwater fish to *A. destruens* resulted in no adverse effects to test species, yet that the test material may impart sublethal effects on aquatic invertebrates (*Daphnia magna*). Since exposure levels in freshwater aquatic ecosystems are not expected to exceed the NOEC, further evaluation is not required at this time. However, if exposures increase, further testing might be necessary to evaluate test material activity (viability) under normal usage conditions (not test conditions)**.**

iii) Non-target Insect testing (**OPPTS 885.4340; Gdln. 154-23)**
Alternaria destruens is a naturally occurring colonist of *Cuscuta* species. Following pesticide application, test material concentration increases temporarily at the use site. Although exposures to insects are likely, such temporary increases are not anticipated to adversely affect non-target species.

vii) Honey Bee Testing (OPPTS 885.4380; Gdln. 154-24)
Alternaria destruens is a naturally occurring colonist of *Cuscuta* species. Following pesticide application, test material concentration increases temporarily at the use site. Although exposures to honeybees are likely, such temporary increases are not anticipated to adversely affect the non-target species.

Table 4b: Eco-Toxicology Summary – Waivers

Guideline	Study	Status, Classification & Comments	MRID Nos. Reviewed
154-18 *885.4150	Wild mammal testing	WAIVED. No toxic, infective, or pathogenic effects were observed in the mammalian toxicity tests and the active ingredient is not known to infect animals.	N/A
154-21 885.4280	Estuarine and marine animal testing	WAIVED. No exposures to estuarine or marine organisms are anticipated as a result of intended terrestrial uses as an agricultural pesticide. There was a lack of toxicity in freshwater fish and aquatic invertebrate testing.	N/A
154-23 885.4340	Non-target insect testing	WAIVED. Following pesticide application, test material concentration increases temporarily at the use site. Although exposures to insects are likely, such temporary increases are not anticipated to have an adverse effect on honey bees.	N/A
154-24 885.4380	Honey bee testing		N/A

* OPPTS Guidelines

2. Environmental Fate, Ecological Exposure, and Environmental Expression Risk Characterization

Alternaria destruens is a naturally-occurring microorganism that is readily isolated from live or dead host plant tissue. Population levels of the subject fungus temporarily increase when it is applied as a pesticide, and dodder spp. are the only known hosts. Online literature searches through the TOXLINE and AGRICOLA databases yielded no reports of adverse exposures of *A. destruens* to mammals. Extensive environmental exposures of the MPCA are precluded by the limited number of intended uses**.**

The Agency finds little opportunity for broad exposure of non-target organisms to *A. destruens*. Incremental exposures to the environment and to non-target organisms, that inhabit or pass through treated areas, do not present an adverse concern due to the limited proposed uses of the microbial pesticide. The ecological data and waiver discussions (as summarized above in Section III.C.1) support a conclusion of reasonable certainty that no incremental hazards to non-target organisms or to the environment are expected to result from the intended uses of *A. destruens*.

D. Efficacy Data

Efficacy data were not reviewed by the Agency because the end use product is not labeled for public health pests.

IV. RISK MANAGEMENT AND REGISTRATION DECISION

A. Determination of Eligibility

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

To satisfy Criterion "A" above, *A. destruens* Strain 059 has well known properties. The Agency has no knowledge that would contradict the claims made on the label of this product and the active ingredient is not expected to cause unreasonable adverse effects when used according to label instructions. Criterion "B" is satisfied by the current label and by the data presented in this document. It is believed that this new pesticidal active ingredient will not cause any unreasonable adverse effects, and is likely to provide protection as claimed, satisfying Criterion "C". Criterion "D" is satisfied in that *A. destruens* is not expected to cause unreasonable adverse effects when used according to label instructions. Therefore, *A. destruens* Strain 059 is eligible for registration.

B. Regulatory Position

1. Unconditional Registration

The data requirements are fulfilled. Consequently, the BPPD recommends unconditional registration of products that contain *A. destruens* Strain 059 as a new active ingredient (Smolder G and Smolder WP).

2. Tolerances for Food Uses and /or Exemptions

EPA received a pesticide petition (PP 0F6191) from Loveland Products Inc., which proposed [pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. section 346a(d)] to amend 40 CFR Part 180 by establishing an exemption from the requirement of a tolerance for residues of the microbial pesticide, *A. destruens* Strain 059, on growing crops.

EPA is issuing a notice establishing an exemption from the requirement of a tolerance for residues of *A. destruens* Strain 059 in or on all food commodities (40 CFR Part 180).

3. CODEX Harmonization

There are no Codex harmonization considerations since there is no Codex Maximum Residue Limits set for food use of this active ingredient.

4. Non-food Reregistrations
This is a new active ingredient and, therefore, not the subject of reregistration at this time.

5. Risk Mitigation
There is minimal or negligible potential risk to non-target organisms (plants and wildlife), and to ground and surface water contamination through the proposed use of products containing *A. destruens* as discussed in this document. No mitigation measures are required at this time for dietary risk, including risk due to exposure via drinking water. Appropriate PPE is required for pesticide handlers. These include long-sleeved shirt, long pants, shoes plus socks, and a dust/mist filtering respirator. The product label will also bear Environmental Hazards text to mitigate any potential risk as determined by reviewed data and use sites.

6. Endangered Species Statement
Based on the submitted data (as discussed in section III), *A. destruens* Strain 059 is not known to be toxic or pathogenic to animals or to cause plant diseases under natural environmental conditions, except in the targeted *Cuscuta* spp. The limited plant effects on *Lupinus* species that were seen during testing, conducted under controlled conditions with laboratory formulations of the MPCA (as summarized in section III), may be an anomaly and are unlikely to be observed in the natural environment. The Agency, therefore, concluded that intended applications of *A. destruens* are unlikely to pose incremental hazards to crop plants of economic importance, or to plants related to the target weed.

Currently, there are four Federally listed species of *Lupinus*, all of which occur in the sandy, coastal areas of Florida's Orange county (*L. aridorum*), California's Monterey, Madera, and San Luis Obispo counties, and Oregon's Polk county (*L. nipomensis, L. sulphureus*, and *L. tidestromii*). This habitat lies further than the acceptable ¼ mile limit from the intended *A. destruens* application sites (fruit and vegetable field crops, alfalfa, and nursery-grown woody deciduous ornamentals); consequently, exposure to *Lupinus* is not expected.

In addition, *Lupinus perrenis* populations, which are critical for the endangered *Lycaeides melissa samuelis* (Karner blue butterfly), should not be exposed to the intended applications of *A. destruens*. Suitable habitats of the Karner blue butterfly are limited to sandy savannas and barrens, and partially shaded dry sandy soils that support wild lupine (*Lupinus perrenis*). These early successional landscapes are ecologically distinct and unlikely to overlap with fruit and vegetable field crops, alfalfa, and nursery-grown woody deciduous ornamentals.

As a result of the above findings, the Agency has determined that the intended pesticidal applications of *A. destruens* are not likely to adversely affect endangered fauna and flora.

C. Use Sites

Use of *A. destruens* has been approved for use sites listed in Table

Table 5: Approved Use Sites for *A. destruens* Pesticide Products.

End-use Product	Use Sites	Date of Registration
Smolder G	Alfalfa, cranberries (dry bogs only), carrots, peppers, tomatoes, eggplant, blueberries, nursery-grown woody ornamentals.	May 5, 2005
Smolder WP		

D. Labeling

There is no separate manufacturing use product (MP) registered at this time. The following information describes labeling and rationale for approved end-use products.

It is the Agency's position that the labeling for end-use products containing *A. destruens* must comply with the pesticide labeling requirements in existence when such products are registered.

1. Human Health Hazards

a. Worker Protection Standard

Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with PR Notice 93-7, "Labeling Revisions required by the Worker Protection Standard (WPS), and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7", which reflect the WPS (40 CFR Part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR Part 170). Unless specifically directed otherwise, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those Notices.

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR Part 156.10 and other applicable notices, such as, and including the WPS labeling. *Alternaria destruens* products with commercial use sites are subject to the Worker Protection Standard. Because of the low toxicity of *A. destruens*, the Restricted Entry Interval (REI) for greenhouse foliar applications within the scope of WPS is 4 hours. For use as a soil amendment (incorporation into soil mixes), the REI is 0 hours due to the low likelihood of contact with treatment residues. Precautionary statements and personal protective equipment (PPE) as specified below are required based on the acute toxicity categories of this organism.

Workers and handlers (including mixer/loaders and applicators) applying this product must wear long-sleeved shirt, long pants, shoes plus socks, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Post application agricultural workers and early-entry workers must wear coveralls in addition to the PPE above when entering treated areas during the REI period of four hours.

b. Non-Worker Protection Standard
For non-WPS uses of *A. destruens*, unprotected persons must stay out of treated areas until the sprays have dried or the dusts have settled.

c. Other Precautionary Labeling
The Agency has examined the toxicological data base for *A. destruens* and concluded that the precautionary labeling required (*i.e.* Signal Word, First Aid Statements, WPS statements for pesticide handlers, and other label statements) adequately mitigates the risks associated with the proposed uses. Additional labeling may be required for other uses of products containing *A. destruens* on a case-by-case basis.

2. Environmental Hazards
The risk of non-target organism/endangered species exposure to *A. destruens* is minimal to nonexistent trovided the following statements are placed in the environmental hazards statement:

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

3. Application Rate
It is the Agency's position that the labeling for the pesticide products containing *A. destruens* must comply with the current pesticide labeling requirements.

Smolder G: The granular product is to be applied at a rate of 50 pounds of product per acre, at or immediately prior to, dodder emergence. Apply granules to a moist soil surface to activate. Efficacy is enhanced by daily moisture.

Smolder WP: The spray formulation is packaged as Component A, a water-soluble packet of active ingredient, and Component B, a liquid adjuvant. Apply at a rate of one water-soluble packet, with one container of adjuvant, per acre. The Agency has not set a maximum number of applications per a season for this active ingredient.

4. Ingredient Statement

Smolder G

Alternaria destruens Strain 059*	4.40 %
Inert Ingredients	95.60 %
Total	100.00 %

* Contains a minimum of 1 x 10^7 CFU/g product

Smolder WP

Alternaria destruens Strain 059*	41.30 %
Inert Ingredients	58.70 %
Total	100.00 %

* Contains a minimum of 1 x 10^7 CFU/g product

V. ACTIONS REQUIRED BY REGISTRANTS

Reports of incidents of adverse effects to humans or domestic animals are required under FIFRA, Section 6(a)(2) and incidents of hypersensitivity under 40 CFR Part 158.690(c), guideline reference number 152-16. There are no data requirements, label changes and other responses necessary for the reregistration of the end-use product since the product is being registered after November 1984 and is, therefore, not subject to reregistration. For the same reason, there are also no existing stocks provisions at this time. Before releasing these products for shipment, the registrant is required to provide appropriate labels and other Agency requirements as discussed in this Biopesticide Registration Action Document.

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