US Environmental Protection Agency
Office of Pesticide Programs

BIOPESTICIDES REGISTRATION ACTION DOCUMENT

Colletotrichum gloeosporioides f.sp. aeschynomene

(PC Code 226300)

March 26, 2006

BIOPESTICIDES REGISTRATION ACTION DOCUMENT

Colletotrichum gloeosporioides f.sp. *aeschynomene*
(PC Code 226300)

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

3/29/06

TABLE OF CONTENTS

I. EXECUTIVE SUMMARY

A. Characteristics of *Colletotrichum gloeosporioides* f.sp. *aeschynomene* (Cga)

Colletotrichum gloeosporioides f.sp. *aeschynomene* (Cga), a fungus with herbicidal activity against certain members of the legume family, was initially approved as an active ingredient in 1982 for use against Northern jointvetch (NJV), an economically important weed in mid-South rice fields. When Cga is applied to emerged NJV plants, the fungus causes disease lesions that completely encircle the stems of the NJV plants. The fungus primarily infects the stems, but also infects leaf stems and leaflets. Diseased plants wilt, but even if they do not die, they no longer compete with the rice crop or produce seeds that can lower the value of harvested rice grains.

B. History

The sole pesticidal product containing Cga, Collego™ , was registered to various companies between 1982 and 2003, and was in use for more than 20 years. During the mid-1990's, EPA reviewed old and new data related to the toxicity and ecological effects of Cga. In the resulting report, EPA concluded that products containing Cga were eligible for continued registration with some minor limitations (see "Reregistration Eligibility Decision" document for *Colletotrichum gloeosporioides* f.sp. *aeschynomene*; EPA-738-F-96-026, April 1997) (RED 1997).

When the Collego™ registration lapsed in 2003 for non-payment of maintenance fees, Cga lost its status as an active ingredient. Therefore, EPA was required to treat Cga as a new active ingredient for subsequent product submissions. The RED (1997) provides complete justifications for registration and reregistration decisions for products containing Cga.

NJV decreases rice yield between 5 and 17%. More relevant to farmers, the value of the harvested rice decreases substantially when it is contaminated by NJV seeds. Several factors have recently led to the weed's resurgence. One factor is the introduction of an herbicide-resistant rice strain, where chemical herbicide use is limited during the time NJV would be susceptible. In addition, Cga products or substitutes have not been available to control this weed during the past few years.

NOTE: To avoid redundancy, this BRAD refers extensively to the RED (1997), and should be read in conjunction with that 1997 document.

C. Toxicology, Human Exposure, and Risks

EPA issued a RED (1997) that reviewed these data in detail. This active ingredient showed no harmful endpoints when tested in laboratory rodents for toxicity and pathogenicity by the oral, dermal, and pulmonary routes. It induced slight eye irritation.

Food Tolerances

Cga is exempt from the requirement of a tolerance at 40 CFR 180.1075 when used on rice grain and soy. EPA reassessed this tolerance exemption, finding that the exemption met all requirements and therefore could be maintained.

FQPA Considerations

The Agency has considered Cga in light of the safety factors of the Food Quality Protection Act (FQPA) of 1996 (RED, 1997), 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 fungus is found in the rice-growing areas of Arkansas, Louisiana, and Mississippi. Its pesticidal use in those areas is not expected to increase exposure above background levels. Based on minimal expected exposure and virtually no toxicity of Cga, a safety factor is not required to protect the U.S. population. No incremental risk to infants, children, or adults is expected.

D. Ecological and Environmental Exposure and Risks

No adverse ecological and environmental effects are expected at field concentrations of the active ingredient (RED 1997).

Endangered Species

Because information related to endangered species can change over time, a new assessment was performed for Cga. The findings were identical to those in the 1997 RED, which found that certain legumes are the only organisms potentially susceptible to this fungus. Price's potato bean (*Apios priceana*) is the only endangered legume in the three states where Cga is approved for use, but it requires different habitat than does rice. Therefore, EPA does not foresee any adverse effects on threatened or endangered species from use of Cga as a pesticide active ingredient.

E. Data Requirements

All data requirements have been fulfilled for registering pesticide products containing Cga as the active ingredient under FIFRA 3(c)5.

II. OVERVIEW

A. Product Overview

!	**Microbial Pesticide Name:**	*Colletotrichum gloeosporioides* f.sp. *aeschynomene* (Cga)
!	**Depository Number**:	ATCC strain 20358
!	**Trade Name(s):**	LockDown™ *retro*; LockDown™ *XL*
!	**OPP Chemical Code**:	PC Code 226300
!	**Basic Manufacturer:**	Agricultural Research Initiatives, Inc. 700 Research Center Blvd. Fayetteville, AR 72701 dkellyc@alltel.net

B. Use Profile

Type of Pesticide: Microbial Herbicide

Mechanism of action: Cga is applied to NJV when the weed is 8 to 24 inches high. The resulting infection prevents the weed from growing and producing seeds.

Use Sites: Flooded rice fields in Arkansas, Louisiana, and Mississippi

Target Pest for Active Ingredient: Northern jointvetch (curly indigo) (*Aeschynomene virginica* (L.) B.S.P.

Formulation Type: Pressed powder or granules subsequently mixed with water

Rate and Method of Application:

Timing: When NJV is 8 to 24 inches high, but before rice heads appear

Rate of Application: Approximately 75g of product (32g of active ingredient) per acre per application. One to two applications per year.

Method of Application: Aerial spraying with fixed-wing or helicopter aircraft.

C. Estimated Usage

Because rice-growing conditions have changed in the past 5 to 10 years, future usage cannot be estimated.

D. Data Requirements

All data requirements for a 3(c)(5) registration have been fulfilled

E. Regulatory History

Cga was an active ingredient between 1982 and 2003, when the registration of the only product lapsed because of non-payment of maintenance fees. In an effort to bring back this active ingredient, ARI, Inc. applied for EUPs to test three LockDown products each on 5000 acres of rice in Arkansas, Louisiana, and Mississippi. In February, 2006, EPA awarded the company three EUPs, each for one year (Reg # 82681-EUP-1; 2; 3). **Add FR citation when available**.

III. SCIENCE ASSESSMENT

A. Toxicity

Except for slight eye irritation, no toxic endpoints were found when acute toxicity studies were carried out on rodents. (See RED 1997 for details)

1. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effects of exposure to Cga and to any other substances that may share a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. Cga is not toxic or pathogenic to mammals, based on rodent laboratory tests that showed no adverse effects. Thus, there is no indication that Cga shares any common mechanisms of toxicity with other substances.

2. Risk Characterization

The Agency has considered human exposure to the mycoherbicide Cga in light of the relevant safety factors in FQPA and FIFRA. It has also considered the lack of toxicity and pathogenicity in laboratory studies by various routes of exposure. Based on these considerations, no unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, are expected from approved uses of products containing Cga.

B. ENVIRONMENTAL ASSESSMENT

1. Ecological Effects Hazard Assessment

No adverse ecological effects are expected (See RED 1997)

2. Endangered Species

The RED (1997) concluded that no threatened or endangered species would be at risk if users followed label directions on Cga products. EPA updated its endangered species assessment to be sure that no additional species had been listed since 1997. The updated

assessment agrees with the RED; both documents conclude that there is no "may affect" finding if users follow label directions.

IV. RISK MANAGEMENT AND REGISTRATION DECISION

All conditions for registration of this product under FIFRA 3(c)(5) have been met.

A. Exemption from the Requirement of a Tolerance

Cga is exempt from the requirement of a tolerance according to 40 CFR 180.1075.

V. LABELING ACTIONS REQUIRED BY REGISTRANTS

A. Precautionary Labeling

Cga products must follow the labeling instructions found in RED (1997) as updated in the Label Review Manual (2003)**.** In addition to other Precautionary Statements, the following must appear on the label:

"Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization."

Under **Directions for Use:**

"This product may only be applied in the states of Arkansas, Louisiana and Mississippi."

Under **Crop Rotation:**

"Any food, feed, or forage crops ***except peas,*** may be sown in *LockDown*-treated fields immediately after harvest of rice. Peas may be planted following the harvesting of a non-*LockDown*-treated crop."

B. Environmental Hazards Labeling

1. End Product Environmental Hazards Labeling

Labeling must meet the requirements of the Label Review Manual and RED (1997).

C. Labeling Requirements

1. The label will include all information required in the OPP Label Review Manual (2003).
2. Below are the ingredient statements for the two end products:
   LockDown *retro* (82681-1);
   LockDown *XL* (82681-2)

LockDown retro

Active Ingredient : *Colletotrichum gloeosporioides* f.sp. *aeschynomene*.....45%
Other Ingredients 55%

Total . . . . . 100.0 %
Contains a minimum of 1 x 10^9 cfu/g product

Product Use Sites.

Terrestrial Food: Rice grain; soybeans (Only in Arkansas, Louisiana, Mississippi)	**Date Registered:** March 28, 2006

****

LockDown *XL*

Active Ingredient : *Colletotrichum gloeosporioides* f.sp. *aeschynomene*.....30%
Other Ingredients 70%

Total . . . . . 100.0 %
Contains a minimum of 7 x 10^8 cfu/g product

Product Use Sites.

Terrestrial Food: Rice grain; soybeans (Only in Arkansas, Louisiana, Mississippi)	**Date Registered:** March 28, 2006

BIBLIOGRAPHY

Reregistration Eligibility Decision document for *Colletotrichum gloeosporioides* f.sp. *aeschynomene*; EPA-738-F-96-026, April 1997. (RED 1997)

Label Review Manual, 3rd Edition (EPA 735-B-03-001 August 2003)

MRID	Citation Reference
48741701	Volume 1. Product Identity of *Colletotrichum gloeosporioides* f. sp. *aeschynomene.* Guideline Number OPPTS 885.1100/Group A Product Analysis Test Guidelines. Prepared and submitted by Kelly Cartwright, Agricultural Research Initiatives, Inc., Fayetteville, AR. 2005
48741702	Volume 2. Manufacturing Process for Production of *Colletotrichum gloeosporioides* f. sp. *aeschynomene.* Guideline Number OPPTS 885.1200/Group A Product Analysis Test Guidelines. Prepared and submitted by Kelly Cartwright, Agricultural Research Initiatives, Inc., Fayetteville, AR. 2005
48741703	Volume 3. Discussion of Unintentional Ingredients in Production of *Colletotrichum gloeosporioides* f. sp. *aeschynomene.* Guideline Number OPPTS 885.1300/Group A Product Analysis Test Guidelines. Prepared and submitted by Kelly Cartwright, Agricultural Research Initiatives, Inc., Fayetteville, AR. 2005
48741704	Volume 4. Analysis of Samples of *Colletotrichum gloeosporioides* f. sp. *aeschynomene.* Guideline Number OPPTS 885.1400/Group A Product Analysis Test Guidelines. Prepared and submitted by Kelly Cartwright, Agricultural Research Initiatives, Inc., Fayetteville, AR. 2005
48741705	Volume 5. Certification of Limits of *Colletotrichum gloeosporioides* f. sp. *aeschynomene.* Guideline Number OPPTS 885.1500/Group A Product Analysis Test Guidelines. Prepared and submitted by Kelly Cartwright, Agricultural Research Initiatives, Inc., Fayetteville, AR. 2005