



R.E.D. FACTS

Colletotrichum gloeosporioides f.sp. aeschynomene

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 4103, *Colletotrichum gloeosporioides f.sp. aeschynomene* (C.g.a.) ATCC strain 20358.

Use Profile

Colletotrichum gloeosporioides f.sp. aeschynomene (C.g.a.) ATCC strain 20358 is a mycoherbicide used to control Northern Jointvetch (NJV)

The sole registered product is *Collego*™

Colletotrichum gloeosporioides f. sp. aeschynomene ATCC 20358 is applied by air and ground equipment.

Use practice limitations include: no applications to be made

(a) after rice heads emerge from the boot or after pods form on the lower nodes of soybeans.

(b) when rice and soybeans are under stress for moisture or when drying conditions are likely to occur.

(c) to NJV previously treated with phenoxy herbicides.

Do not apply fungicides for at least three weeks following application of *C.g.a.* ATCC 20358.

Regulatory History

C.g.a. ATCC 20358 was first registered as a pesticide in the U.S. in 1982. A September 1993 Data Call-In (DCI) required additional product chemistry, acute mammalian, avian and freshwater fish and invertebrate toxicity/pathogenicity data as well as some information to assess the effects of its use on some non-target plants and insects. The sole registered product, *Collego*TM, has been mainly used for control of NJV on rice in Arkansas.

Human Health Assessment

Toxicity

No unreasonable adverse effects to human health are expected from the use of *Colletotrichum gloeosporioides* f. sp. *aeschynomene* ATCC 20358. Adequate mammalian toxicology data on *C.g.a.* ATCC 20358 are available and will support a Reregistration Eligibility Decision (RED). In studies using laboratory animals, *C.g.a.* ATCC 20358 generally has been shown to be of low acute toxicity. On the basis of acute oral, acute dermal, and acute pulmonary toxicity/pathogenicity tests, it was rated as a Toxicity Category IV mycoherbicide. It is neither a dermal irritant, nor a dermal sensitizer and is considered a Toxicity Category III primary eye irritant. These tests demonstrate that the active ingredient is practically non-toxic to mammalian species.

Dietary Exposure and Risk

The RED document permits limited use of the pesticide on two crops, rice and soybeans, in three states, Arkansas (AR), Louisiana (LA) and Mississippi. Currently available data demonstrate the use of the mycoherbicide on less than 0.1 percent of acreage of rice under cultivation in Arkansas. Potential residues of the mycoherbicide are likely to be removed from treated raw agricultural commodities by processing. Therefore, exposure and risk of human infants, children and adults to residues of *C.g.a.* ATCC strain 20358 through the diet is expected to be minimal.

Exemptions from tolerances were established for the microbial pesticide on rice grain and soybeans in 40 CFR 180.1075. EPA has reassessed these exemptions from tolerances and found that there is no need

to change them at this time. If data become available to necessitate any changes to these exemptions from tolerances, the Agency will take appropriate regulatory action.

Acute and Chronic Dietary Risks for Sensitive Subpopulations, Particularly Infants and Children

The general population may be exposed to naturally occurring *C.g.a* ATCC 20358, as a plant pathogenic fungus, with low or no specificity for animals and human beings. The pesticidal use is not expected to increase exposure to this microorganism above the natural levels of the fungus. The Agency considers the toxicity database, together with the low volume use and the removal of the pesticide during processing, sufficient to perform a risk assessment for this mycoherbicide. To date, none of the active ingredients of the microbial pesticides registered by the Agency have required subchronic or chronic exposure studies. Also, for food uses of the microbial pesticides, the acute toxicity/pathogenicity studies have allowed for the conclusion that an exemption from the requirement of a tolerance is appropriate and adequate to protect human health, including that of infants and children. The results of testing done with *Colletotrichum gloeosporioides* f.sp. *aeschynomene* ATCC 20358 agree with this conclusion.

Effects on the Immune and Endocrine Systems

The active ingredient is a plant pathogenic fungus. No known metabolite that acts as an "endocrine disrupter" is produced by this microorganism. The submitted toxicity/pathogenicity studies in the rodent indicated that the intact immune system was able to process and clear the active microbial ingredient, as is expected of challenge from non-pathogenic micro-organisms.

Potential for the Transfer of the Pesticide to Drinking Water

C.g.a ATCC 20358 is a naturally occurring plant pathogen. Although the potential exists for some minimal amount of the applied microorganism to enter ground water or other drinking water sources, the amounts present would in all probability be undetectable or at least several orders of magnitude lower than those levels tested for safety. Also, drinking water is not screened for this fungus as a potential indicator of microbial contamination or as a direct pathogenic contaminant. Both percolation through soil and municipal treatment of drinking water would reduce the possibility of exposure to the microbe through drinking water. Therefore, the Agency considers the potential of significant transfer of *Colletotrichum gloeosporioides* f.sp. *aeschynomene* ATCC 20358 to drinking water is minimal to nonexistent.

Cumulative Exposure From Multiple Routes Including Oral and Inhalation

Skin would primarily be a route of exposure for mixer/loader applicators. Unbroken skin is a natural barrier to microbial invasion of the human body. The only way in which skin could be a significant route for exposure would be if the skin were cut, or the microbe were a pathogen with mechanisms for entry through or infection in the skin, or if metabolites were produced that could not be absorbed dermally. Since the submitted toxicology studies demonstrated no adverse effects in animals, even cut skin should not pose a risk to health via entry of *Colletotrichum gloeosporioides* f.sp. *aeschynomene* ATCC 20358 into the body.

Inhalation would also be a route of exposure for mixer/loader applicators. Because the pulmonary study showed no adverse effects, the risks anticipated for this route of exposure are considered minimal.

Oral exposure would occur primarily from eating treated produce but minimal risk is expected because of the active ingredient's exemption from the requirement of a tolerance.

Occupational and Residential Exposure

This is a low toxicity category III or IV mycoherbicide, which is to be applied in three states by ground and air at low rates to the raw agricultural commodities, rice and soybeans. Based on current use patterns, the exposure and risk to handlers (mixers, loaders, and applicators) using this pesticide is likely to be minimal.

The Agency recommends that handlers wear long-sleeved shirts, long pants, socks, and shoes. Post-application reentry workers will be required to observe a 4-hour Restricted-entry Interval (REI). During this REI, the Agency recommends that the reentry workers wear long-sleeved shirts, long pants, socks, and shoes and a dust/mist filtering respirator MSHA/NIOSH approval number prefix TC-21C.

Environmental Assessment

The database in support of the ecological effects of this mycoherbicide establishes that *Colletotrichum gloeosporioides* f.sp. *aeschynomene* (C.g.a.) ATCC strain 20358 is a plant pathogen with a great degree of host specificity for the Northern Joint Vetch (NJV), the target pest.

Risks Posed by Potential Residential, School or Daycare Exposure

No residential, school or daycare uses currently appear on the label. Both use sites, rice and soybeans, are agricultural for control of the northern jointvetch weed. Therefore, under current agricultural practice, nondietary exposure to sites where children are present is minimal to nonexistent.

Environmental Effects and Risk Assessment

After application to soybeans and rice, no spores were isolated from either raw agricultural commodity. Infested host plant debris, buried in the soil for more than 8 weeks under field conditions did not yield any colony forming units. After application, fungus spores remain airborne for a period of less than 5 minutes. Laboratory tests indicate that the fungus can survive in field water for at least 90 days, but its population gradually declines due to either microbial degradation/predation. Irrigation water, assayed after aerial application of the fungus at label rates contained less than 1 colony forming unit. Further studies demonstrated a short half-life of the fungal spores in the aquatic system. Thus appreciable build-up of the fungal spores in the air, soil and water is not anticipated.

Ecological Effects and Risk Assessment

Studies were submitted and reviewed to establish the effects of the mycoherbicide on the required invertebrates, vertebrates, and non-target plants. Adverse effects on non-target insects, mammals and other aquatic and terrestrial vertebrates and invertebrates are not expected. There is some potential for phytopathogenicity to sweet peas and to NJV, which is an endangered species in the Northeastern United States. However, peas are not grown as an agricultural crop in Louisiana, Arkansas and Mississippi, where NJV is the target pest.

Risk Mitigation

To lessen the risks of potential phytopathogenicity to peas posed by *C.g.a.* ATCC 20358, EPA is requiring the following risk mitigation measures.

1. Peas are not to be planted in rotation to crops treated with the mycoherbicide.
2. This microbial pesticide is to be applied only to rice and soybeans in Arkansas, Louisiana and Mississippi.

Additional Data Required

EPA is requiring revised Confidential Statements of Formula (CSFs), certification of nominal limits and revised labeling for reregistration.

Product Labeling Changes Required

All end-use products containing *Colletotrichum gloeosporioides* f.sp. *aeschynomene* (C.g.a.) ATCC strain 20358 must comply with EPA's current pesticide product labeling requirements and with the following. For a comprehensive list of labeling requirements, please see the RED document.

For products containing *Colletotrichum gloeosporioides* f.sp. *aeschynomene* (C.g.a.) ATCC strain 20358, the Personal Protective Equipment (PPE) recommended by the WPS are: long sleeved shirt, long pants, socks, and shoes for the mixer/loader and applicator. In addition the mixer/loaders should wear a dust/mist filtering respirator MSHA/NIOSH approval number prefix TC-21C. Early entry workers should wear long sleeved shirt, long pants, shoes and socks for postapplication activities during the four (4) hour Restricted-entry Interval (REI).

Products containing *Colletotrichum gloeosporioides* f.sp. *aeschynomene* (C.g.a.) ATCC strain 20358 may not be applied to peas, nor should peas be planted in rotation to crops treated with this mycoherbicide. Use is restricted to Arkansas, Louisiana, and Mississippi.

Regulatory Conclusion

The use of currently registered products containing *Colletotrichum gloeosporioides* f.sp. *aeschynomene* (C.g.a.) ATCC strain 20358 in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products as specified in the RED document are eligible for reregistration.

Products containing *Colletotrichum gloeosporioides* f.sp. *aeschynomene* (C.g.a.) ATCC strain 20358 will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for *Colletotrichum gloeosporioides* f.sp. *aeschynomene* (C.g.a.) ATCC strain 20358 during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, *GOPHER.EPA.GOV*, or using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the *Colletotrichum gloeosporioides* f.sp. *aeschynomene* (C.g.a.) ATCC strain 20358 RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the *Colletotrichum gloeosporioides* f.sp. *aeschynomene* (C.g.a.) ATCC strain 20358 RED, or reregistration of individual products containing *Colletotrichum gloeosporioides* f.sp. *aeschynomene* (C.g.a.) ATCC strain 20358, please contact the Biopesticides and Pollution Prevention Division (7501W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8712.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 9:30 am and 7:30 pm Eastern Standard Time, Monday through Friday.