

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

PM 92 63950-6

9/23/98

PM 1/7

SEP 23 1998

144 300
37

49258 200
17

Mr. Vernon L. Illum
6613 Haskins
Shawnee, KS 66216

Dear Mr. Illum:

Subject: Blue Circle Liquid Biological Fungicide
EPA Reg. No. 63950-6
Correspondence of June 11, 1998, and August 17, 1998

The Biopesticides and Pollution Prevention Division (BPPD) issued a letter on May 19, 1998, requesting voluntary revisions of the cited pesticide product label. A representative of your client, Stine Microbial Products (Stine), responded on June 11, 1998 (J. Reichling to J. Andersen), by agreeing to work with BPPD to amend the label and requesting a meeting on the issues. You and Dr. Dick Ridgeway represented Stine at the resulting July 22, 1998, meeting. A revised label was submitted for review on August 17, 1998.

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable subject to the comments listed below. A stamped copy is enclosed for your records. One copy of the printed labeling must be submitted prior to releasing the product for shipment.

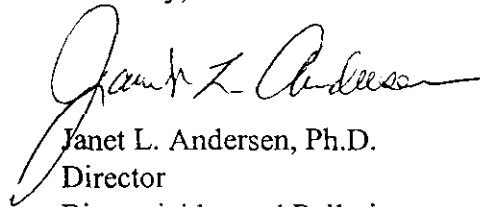
- 1) On page one of both the label and the labeling booklet, and in the text immediately below the heading "Application," replace the period following "Ornamentals" with a comma.
- 2) On page one of the labeling booklet, the location of the "Directions for Use" and "Precautionary Statements" sections must be reversed. Doing so will also correct the "Storage and Disposal" section location by placing it at the beginning of the "Direction for Use" section.
- 3) Under the "Application" subheading "Banded into Seed Furrow at Planting," insert "per acre" between "Blue Circle Liquid" and "directly."

CONCURRENCES							
SYMBOL	7511C	7511C					
SURNAME	Greenway	Huxton					
DATE	9/21/98	9/21/98					

Thank you for the July 15, 1998 report from Dr. Pamela A. Sokol of PathoProbe, Inc. It was included with the August 1998, submission of the subject revised label. During the July 22, 1998, meeting, BPPD was advised that Stine's three strains of the active ingredient, *Burkholderia cepacia*, had also been placed with additional laboratories for similar analyses. Please provide BPPD with the test results from the other laboratories when that data become available. It is required that any adverse effects be promptly reported to the Agency, as per section 6(a)(2) of FIFRA.

We appreciate the professional responsiveness and cooperation with which our requests for the voluntary label revisions were met by you and your client. Should you have any questions or concerns, please contact me, or telephone Denise Greenway, of my staff, on (703) 308-8263.

Sincerely,



Janet L. Andersen, Ph.D.

Director

Biopesticides and Pollution

Prevention Division (7511C)

Enclosure

DGreenway/308-8263/9-17-98/63930-6revised.wpd/Bcepacia

BLUE CIRCLE®

LIQUID BIOLOGICAL FUNGICIDE

Use this product to protect plant roots from soil borne disease pathogens (such as *Pythium*, *Rhizoctonia*, *Fusarium*) in greenhouse or field grown crops such as: Vegetables, Fruits and Berries, Nut Crops, Vine Crops, Herbs and Spices, Ornamentals, Flowers and Ornamental Bulbs, Trees and Shrubs, Field Crops and Grain Crops.

Some *Burkholderia cepacia* strains have been linked to cepacia syndrome. Persons and family members of persons with cystic fibrosis or immune system-compromising illnesses should not use this product.

Active Ingredient:

Burkholderia (Pseudomonas) cepacia type Wisconsin Isolate B82 2.0% (by weight)

Inert Ingredients: 98.0% (by weight)

Total 100.0% (by weight)

Contains at least 8.3×10^9 viable cells of Isolate B82/fluid oz. of product at expiration

Expiration Date:

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

DIRECTIONS FOR USE

See additional Labeling Booklet

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. Refer to additional labeling under "Agricultural Use Requirements" in the Directions for Use section in the Labeling Booklet for information about this standard.

Manufactured for
Stine Microbial Products
2225 Laredo Trail
Adel, IA 50003

LOT NUMBER:

NET CONTENTS: 1 GAL. (3.785 liters)

EPA Reg. No.: 63951-1

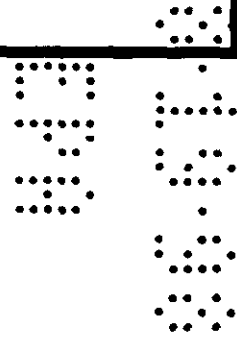
EPA Est. No.: 71173-WI-003

U.S. Patent: 4,798,723

**PERISHABLE
KEEP FROM HEAT AND SUN**

ACCEPTED
with COMMENTS
In IPA Letter Dated

SEP 23 1998
Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
63950-6



BLUE CIRCLE®

LIQUID BIOLOGICAL FUNGICIDE

Use this product to protect plant roots from soil borne disease pathogens (such as *Pythium*, *Rhizoctonia*, *Fusarium*) in greenhouse or field grown crops such as: Vegetables, Fruits and Berries, Nut Crops, Vine Crops, Herbs and Spices, Ornamentals, Flowers and Ornamental Bulbs, Trees and Shrubs, Field Crops and Grain Crops.

LABELING BOOKLET

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

➤ Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

➤ Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

➤ PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- 1) Coveralls
- 2) Waterproof gloves
- 3) Shoes plus socks

Do not apply via any method that will result in the production of an inhalable aerosol.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals: CAUTION

Personal Protective Equipment (PPE) - Applicators and other handlers must wear...1) long sleeved shirt and long pants, 2) shoes plus socks, 3) protective eyewear and 4) dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE filter.

Follow manufacturers instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to inter-tidal areas below the mean highwater mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL

Pesticide Storage: BLUE CIRCLE LIQUID should be stored in the original container until used. Container should be kept in a cool place at a temperature between 35°F-75°F. This product contains live rhizobacteria. AVOID heat and sun.

Pesticide Disposal: Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Do not re-use empty container. Rinse thoroughly with a 10% solution of household bleach for 15 minutes. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

APPLICATION

Use this product to protect plant roots from soil borne disease pathogens (such as *Pythium*, *Rhizoctonia*, *Fusarium*) in greenhouse or field grown crops such as: **Vegetables, Fruits and Berries, Nut Crops, Vine Crops, Herbs and Spices, Ornamentals, Flowers and Ornamental Bulbs, Trees and Shrubs, Field Crops and Grain Crops.**

Application Site: Plant or seedling roots.

Target Crops:

Vegetables (field and greenhouse) including but not limited to: tomatoes, peppers, cucumbers, carrots, potatoes and lettuce.

Fruits and Berries including but not limited to: apple, peach, tropical, cherry and brambles.

Nut Crops including but not limited to: walnut, pistachio and pecan.

Vine Crops including but not limited to: melons and grapes.

Herbs and Spices (field and greenhouse) including but not limited to: basil, sage, marjoram, oregano, cinnamon and nutmeg.

Ornamentals (field and greenhouse) including but not limited to: philodendron, dieffenbachia, dracaena and ficus.

Flowers and Ornamental Bulbs (field and greenhouse) including but not limited to: impatiens, petunias, geraniums, roses, chrysanthemums, violets, azaleas, kalanchoes, begonias, gloxinias, cyclamen, lilies and exacum.

Trees and Shrubs (field and greenhouse) including but not limited to: barberry, cotoneaster, euonymus, holly, ivy, ilex, rhododendron, rose, spirea, viburnum, juniper, pine, spruce, yew, oak, maple and birch.

Field and Grain Crops including but not limited to: corn, soybeans, dry beans, cotton, canola, sunflower, peanut and wheat.

Dosage Rates:

- For chemigation - 1 pint (0.5 liter) per acre
- For seedling transplant drenches - 1 pint (0.5 liter) per 100 gallons (400 liters) of water
- For In-furrow placement - 6 fluid ounces (175 ml) to 1 pint (0.5 liter) per acre

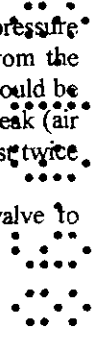
Frequency of Application: Early root colonization by **BLUE CIRCLE LIQUID** is important. Initial applications at seeding or transplant followed by 2 to 6 subsequent applications at 2 week intervals will provide the best results.

Types of Application:

CHEMIGATION - Apply this product only through drip (trickle), flood (basin), furrow or border irrigation systems. Do not apply this product through any other type of irrigation system. Crop injury, lack of effectiveness, or illegal pesticide residues in the crop can result from non-uniform distribution of treated water. If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers or other experts. Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system, unless the pesticide label-prescribed safety devices for public water systems are in place. A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

For Chemigation Systems Connected to Public Water Systems -

1. Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.
2. Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone, backflow preventer (RPZ) or the functional equivalent in the water supply line, upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.
3. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.



4. The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
5. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump, such as a positive displacement injection pump (e.g. diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Do not apply when wind speed favors drift beyond the area intended for treatment.

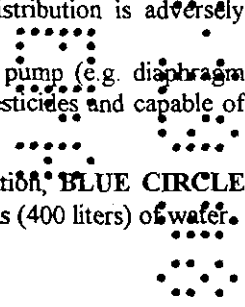
For Flood (Basin), Furrow and Border Chemigation -

1. Systems using a gravity flow pesticide dispensing system must meter the pesticide into the water at the head of the field and downstream of a hydraulic discontinuity such as a drop structure or weir box to decrease potential for water source contamination from backflow if water flow stops.
2. Systems utilizing a pressurized water and pesticide injection system must meet the following requirements -
 - a) The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
 - b) The pesticide injection pipeline must contain a functional, automatic, quick closing check valve to prevent the flow of fluid back toward the injection pump.
 - c) The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
 - d) The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
 - e) The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
 - f) Systems must use a metering pump, such as a positive displacement injection pump (e.g. diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

For Drip (Trickle) Chemigation -

1. The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump, such as a positive displacement injection pump (e.g. diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

If a pesticide supply tank is used, agitation in the tank is recommended. For this application, BLUE CIRCLE LIQUID should be diluted just prior to application at the rate of 1 pint (0.5 liter) in 100 gallons (400 liters) of water.



7/7

DRIP IRRIGATION - Inject undiluted **BLUE CIRCLE LIQUID** at the rate of 1 pint (0.5 liter) per acre or the supply tank mixture at the rate of 100 gallons (400 liters) per acre during the first half of the irrigation cycle.

BANDED INTO SEED FURROW AT PLANTING - Using precision placement technology apply 6 fluid ounces (175 ml) to 1 pint (0.5 liter) **BLUE CIRCLE LIQUID** directly into the seed furrow at planting.

SEEDLING TRANSPLANT DRENCH - Inject undiluted **BLUE CIRCLE LIQUID** into the drench water at the rate of 1 pint (0.5 liter) per 100 gallons (400 liters) of water, or prepare drench water by mixing 1 pint (0.5 liter) **BLUE CIRCLE LIQUID** per 100 gallons (400 liters) of water. Drench root ball thoroughly just after seeding to just prior to transplanting and/or just after transplanting.

WARRANTIES AND LIABILITIES: The manufacturer guaranties that the contents and total amount are as stated within lawful limits. Due to conditions beyond the control of Stine Microbial Products, such as the time, place and rate of application; weather conditions; dispensing equipment; storage facilities, etc.; the warranty shall be limited to refund of purchase price or replacement product. Such is expressly agreed to by the Buyer as the exclusive sole remedy. In no event shall Stine Microbial Products be liable for indirect or consequential damages. The manufacturer warrants that this product consists of the specified ingredients listed on the label and is reasonably fit for the purpose stated when used in accordance with the directions under normal conditions of use. No one other than an officer of Stine Microbial Products is authorized to make any other warranty or guarantee regarding this product.

Manufactured for:
Stine Microbial Products
2225 Laredo Trz
Adel, IA 50003

BLUE CIRCLE® is a registered trademark of Stine Microbial Products
EPA Registration Number: 63950-6
EPA Establishment Number: 7173-WI-003
U.S. Patent: 4,798,723

NET CONTENTS: 1 GAL. (3.785 liters)

**ACCEPTED
with COMMENTS
in EPA Letter Dated**

SEP 23 1998

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
63950-6**

