

67 986-6

9/30/2011

1/10

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Biopesticides and Pollution
Prevention Division (7511P)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

EPA Reg. Number:

67986-6

Date of Issuance:

SEP 30 2011

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance: Unconditional

Name of Pesticide Product:

Agriphage - CMM

Name and Address of Registrant (include ZIP Code):

OmniLytics, Inc.
9100 South 500 West
Sandy, UT 84070

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This registration does not eliminate the need for continual reassessment of the pesticide. If EPA determines, at any time, that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under section 3(c)(2)(B) of FIFRA.

This product is registered in accordance with FIFRA section 3(c)(5) and is subject to the following terms and conditions:

- 1) Submit/cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
- 2) The subject registration is limited to lytic bacteriophage active against *Clavibacter michiganensis* subspecies *michiganensis* produced in *Clavibacter michiganensis* subspecies *michiganensis*.
- 3) Change the EPA File Symbol Number entry to "EPA Registration Number 67986-6" on the final printed label.

Signature of Approving Official:

Date:

30 September 2011

W. Michael McDavit, Associate Director

CONCURRENCES

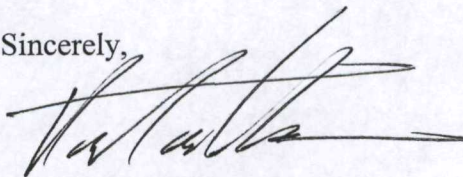
SYMBOL	7511P	2011P			
Biopesticides and Pollution Prevention Division	Greenway	Marking			
EPA Form 8570-6	9/30/2011	25/09/11			
SURNAME					
DATE					

- 4) The subject registration is subject to the following terms:
- a. A new 5-batch analysis (OCSPP 830.1400) to support a change in the manufacturing site must be submitted within one (1) year of registration to ensure the integrity of pesticide products produced at a new facility.
 - b. A new storage stability study (OCSPP 830.6317) must be submitted within one (1) year of registration to verify viability claims for the product.
- 5) Submit two (2) copies of the revised final printed labeling before releasing the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

Failure to comply with these conditions will subject the registration to cancellation, in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,



W. Michael McDavit
Associate Director
Biopesticides and Pollution
Prevention Division (7511P)

Enclosures (2)

DGreenway/308-8263/9-30-11/67986-6 reg not uncond w terms 2011.doc

3/10

US Label

AGRIPHAGE – CMM

Bactericide for use on tomato plants
[Biological control for bacterial canker disease on tomatoes]

Active Ingredient:

Bacteriophage active against *Clavibacter michiganensis*
subsp. *michiganensis**

0.0005%

Other Ingredients:

99.9995%

Total:

100.0000%

*Contains at least 3.8×10^{12} PFU per gallon

*Contains at least 9.46×10^{11} PFU per quart

*(Contains at least 1.0×10^{12} PFU per liter)

Keep Out of Reach of Children

CAUTION

See side panel for additional precautionary statements

EPA Reg. No. 67986-~~2~~6

EPA Est. No. 067986-UT-001

Manufactured by: OmniLytics, Inc.
9100 South 500 West
Sandy, UT 84070
801-746-3600
www.omnilytics.com

ACCEPTED

SEP 30 2011

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

67986-6

Net Contents: 1 qt., 2.5 gal.

Expiration Date:

Batch Code:

First Aid

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

Call a poison control center or doctor for treatment advice

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the National Pesticide Information Center (NPIC) 1-800-858-7378. NPIC operates seven days a week from 7:30 a.m. to 3:30 p.m. (Pacific Time)

Precautionary Statements

CAUTION

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. .

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long Sleeved Shirt
- Long Pants
- Waterproof Gloves
- Shoes plus socks

Mixers/loaders and applicators must wear a dust/mist filtering respirator that meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

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

User Safety Recommendations

User should:

Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet

Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Environmental Hazards

For Terrestrial Uses: Do not apply directly to water, or to areas where surface water is present or to inter-tidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

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 State or Tribal 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 green houses, 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 (REI). 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:

- Coveralls
- Chemical resistant gloves (made of any waterproof material)
- Shoes plus socks

6/10

Product Information

AgriPhage-CMM is a bactericide, comprised of a formulation of bacteriophages to be used as a preventive and curative product for the control of bacterial canker, caused by the bacterium *Clavibacter michiganensis* subsp. *michiganensis*. Apply AgriPhage-CMM as a preventive to protect growing leaf tissue, as a curative when the first disease symptoms are visible, or when conditions are conducive to heavy disease pressure. In the greenhouse apply AgriPhage-CMM as a foliar spray or by fogging. Apply AgriPhage-CMM in the field with conventional ground or aerial spray equipment immediately after planting and as the plant matures. (see MIXING AND APPLICATION INSTRUCTIONS) .

Mixing and Application Instructions

- MIX WELL PRIOR TO USE -

Do not apply this product through any type of irrigation system.

Compatibility: Do not combine AgriPhage-CMM in the spray tank with denaturing agents or copper salts. Apply AgriPhage-CMM in approved tank mixes or with an alternating spray program, applying denaturing agents or copper salts 4 days after AgriPhage-CMM application, as copper salts and denaturing agents compromise bacteriophage survival. AgriPhage-CMM is compatible with several commonly used fungicides, liquid fertilizers, herbicides, and insecticides, but has not been fully evaluated with all of these. To ensure compatibility of tank-mix combinations, please consult with an OmniLytics representative prior to tank mixing. AgriPhage-CMM cannot be mixed with another product with a prohibition against mixing. Use of the tank mix must be in accordance with the more restrictive label limitations and precautions.

Seedling Treatment

RATE	Pre-Harvest Interval(PHI)	APPLICATION	NOTES
1 pint of AgriPhage-CMM per 12-25 gallons of water per 9600 sq ft. of greenhouse space	AgriPhage-CMM may be applied up to and including the day of harvest	<p>Apply to foliage by spraying or fogging.</p> <p>Begin applications to seedlings (at the 4 leaf stage) immediately after planting or grafting, prior as a preventive to protect the growing leaf tissue, or as a curative when the first disease symptoms are visible</p>	<p>Apply treatments daily.</p> <p>Use sufficient spray solution to ensure complete coverage. Avoid excessive amounts of spray solution that result in the runoff of spray material.</p>

7/10

Hydroponic Greenhouse Treatment

RATE	Pre-Harvest Interval (PHI)	APPLICATION	NOTES
½ to 1 quart of AgriPhage-CMM per 12-25 gallons of water per 9600sq. ft. of greenhouse space.	AgriPhage-CMM may be applied up to and including the day of harvest	<p>Apply to foliage by spraying or fogging.</p> <p>Begin applications for foliar applications as a preventive to protect the growing leaf tissue, or as a curative when the first disease symptoms are visible. Continue throughout the growing season.</p> <p>Begin at the lower rate of 1/2 quart when plants are small. As plants increase in size and foliage, increase rate to 1 quart per 9600 sq. ft of greenhouse space to ensure adequate coverage.</p> <p>Repeat application 1-3 times per week.</p>	<p>Use sufficient spray solution to ensure complete coverage. Avoid excessive amounts of spray solution that result in the runoff of spray material.</p> <p>Under severe disease conditions, use 1 qt. per acre.</p>

Field Treatment

RATE	Pre-Harvest Interval (PHI)	APPLICATION	NOTES
Ground Application: 1 to 2 pints of AgriPhage-CMM per 50-100 gallons of water per acre (See directions below for aerial application)	AgriPhage-CMM may be applied up to and including the day of harvest	<p>Begin applications as a preventive to protect the growing leaf tissue or as a curative when the first disease symptoms are visible. Continue throughout the growing season.</p> <p>Begin at the lower rate of 1 pint per acre at planting (below second tie). As plants increase in size and foliage (above second tie) increase rate to 2 pints per acre to ensure adequate coverage.</p> <p>Repeat application 1-3 times per week.</p>	<p>Use sufficient tank mix solution to ensure complete coverage. Avoid excessive amounts of spray solution that result in the runoff of spray material.</p> <p>Under severe disease conditions and periods of heavy rain, apply immediately after rainfall and use the higher dilution rate of 2 pints per acre.</p>

AERIAL APPLICATION INSTRUCTIONS: Apply Agriphage-CMM by aerial application to field grown tomato only at the rate of 1 – 2 pints per acre in a minimum of 5 gallons of water per acre. Increasing the amount of water applied per acre may improve product performance. Follow all instructions to reduce aerial drift.

AERIAL DRIFT REDUCTION ADVISORY INFORMATION

GENERAL: Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment and weather related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions. Where states have more stringent regulations, they should be observed. Note: This section is advisory in nature and does not supersede the mandatory label requirements.

INFORMATION ON DROPLET SIZE: The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply droplets large enough to provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions).

CONTROLLING DROPLET SIZE: Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets. Pressure – Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types, lower pressure produces larger droplets. When high flow rates are needed, use higher flow rate nozzles instead of increasing pressure. Number of Nozzles – Use the minimum number of nozzles that provide uniform coverage. Nozzle Orientation – Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential. Nozzle Type – Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift.

BOOM WIDTH: For aerial applications, the boom width must not exceed 75% of the wingspan or 90% of the rotary blade. Use upwind swath displacement and apply only when wind speed is 3-10 mph as measured by an anemometer. Use medium or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles.

APPLICATION HEIGHT: Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

SWATH ADJUSTMENT: When applications are made with a crosswind, the swath will be displaced downward. Therefore, on the up and downwind edges of the field, the applicator must

compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase with increasing drift potential (higher wind, smaller drops, etc.).

WIND: Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

TEMPERATURE AND HUMIDITY: When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.

TEMPERATURE INVERSIONS: Do not apply during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small, suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

SENSITIVE AREAS: Apply when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas). Do not allow spray to drift from the application site and contact people, structures people occupy at any time and the associated property, parks and recreation areas, non-target crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product at 39.2°F (4°C).

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

Container Handling: Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or reconditioning if appropriate, 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.

Warranty Statement

OmniLytics, Inc. warrants that this material conforms to the description on the label and is reasonably fit for the purposes referred to in the Directions for Use. To the extent consistent with applicable law OmniLytics, Inc. makes no other express or implied warranty of fitness or merchantability or any other express or implied warranty. To the extent consistent with applicable law, in no case or circumstance shall OmniLytics, Inc. or seller be liable for consequential, special or indirect damages resulting from the use or handling of this product including but not limited to, loss of profits, business reputations, or customers; labor cost; or any other expenses incurred in planting, cultivating or harvesting.