



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

October 23, 2018

Tyler Homer  
Director of Regulatory Affairs  
OmniLytics, Inc.  
9075 South Sandy Parkway  
Sandy, UT 84070

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling and Formulation  
Amendment – Adding National Organic Program Text and Logo, Adding “Not for Sale  
or Use After” Date, Adding Supplemental Labeling for Chemigation, Addressing the  
Storage Stability Term of Registration, and Making Requested Updates to the Label and  
the Confidential Statement of Formula  
Product Name: AgriPhage-CMM  
EPA Registration Number: 67986-6  
Application Date: 11/28/2017  
OPP Decision Number: 536269

Dear Mr. Homer:

The amended labeling and Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

The supplemental labeling contains some new and/or revised uses and/or directions that may be additional to the uses and/or directions found on the label on or attached to the container, but the supplemental labeling does not by itself constitute the complete set of use directions. The complete set of use directions is set forth on the container label as combined with the supplemental labeling.

Please note that the record for this product currently contains the following acceptable CSF:

- Basic CSF dated 10/19/2018

Any CSFs other than that listed above are superseded/no longer valid.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

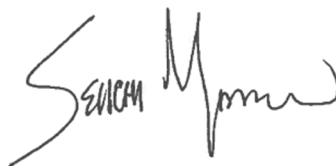
Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains statements or claims substantially differing from statements or claims made in connection with obtaining a FIFRA section 3 registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

Additionally, as requested by the EPA in a letter dated November 6, 2017, you have replaced "Expiration Date:" with "Not for sale or use after: [Date stamped/placed on labeling will be 18 months after the date of manufacture]" on the label. Thus, you have fulfilled term #4 of the September 30, 2011, AgriPhage-CMM Registration Notice.

If you have any questions, please contact Alex Boukedes by phone at (703) 347-0305 or via email at [boukedes.alexandra@epa.gov](mailto:boukedes.alexandra@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "SEIICHI MURASAKI", with a stylized flourish at the end.

Seiichi Murasaki, Senior Regulatory Advisor  
Microbial Pesticides Branch  
Biopesticides and Pollution Prevention Division (7511P)  
Office of Pesticide Programs

Enclosure: Stamped Label

US Label

# AGRIPHAGE – CMM



FOR ORGANIC PRODUCTION

## Bactericide for use on tomatoes

[Biological control for bacterial canker on tomatoes]

### Active Ingredient:

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

0.0005%

### Other Ingredients:

99.9995%

### Total:

100.0000%

\*Contains at least  $3.8 \times 10^{12}$  plaque-forming units (PFU) per gallon of product  
(Contains at least  $9.46 \times 10^{11}$  PFU per quart of product,  
Contains at least  $1.0 \times 10^{12}$  PFU per liter of product)

**Keep Out of Reach of Children**

## CAUTION

See side panel for first aid and additional precautionary statements

EPA Reg. No. 67986-6

EPA Est. No. 67986-UT-001

**Manufactured by:** OmniLytics, Inc.  
9075 South Sandy Parkway  
Sandy, Utah 84070  
801-746-3600  
[www.omnilytics.com](http://www.omnilytics.com)

**ACCEPTED**

Oct 23, 2018

Under the Federal Insecticide, Fungicide  
and Rodenticide Act as amended, for the  
pesticide registered under  
EPA Reg. No. 67986-6

**Net Contents:** 1 qt. or 2.5 gal.

**Not for sale or use after:** [Date stamped/placed on labeling will be 18 months after the date of manufacture]

**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.
<b>Hotline Number</b> Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For non-emergency information concerning this product, call the National Pesticide Information Center (NPIC) at 1-800-858-7378, Monday through Friday, 8:00 a.m. to 12:00 p.m. Pacific Time (NPIC Web site: <a href="http://www.npic.orst.edu">www.npic.orst.edu</a> ). For emergencies, call your poison control center at 1-800-222-1222.	

## PRECAUTIONARY STATEMENTS

### Hazards to Humans and Domestic Animals

**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
- Protective eyewear

Mixers/loaders and applicators must wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N, R, or P filter; OR a NIOSH-approved elastomeric particulate respirator with any N, R, or P filter; OR a NIOSH-approved powered air-purifying respirator with an HE filter. Repeated exposures 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:

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, to areas where surface water is present or to intertidal 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.

CHEMIGATION: Refer to supplemental labeling entitled "AGRIPHAGE-CMM CHEMIGATION" for use directions for chemigation. Do not apply this product through any irrigation system unless the supplemental labeling on chemigation is followed.

### **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 (REI). The requirements in this box apply to uses of this product that are covered by the Worker Protection Standard.

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

Do not enter or allow workers to enter the treated greenhouse or enclosed space until the ventilation requirements in 40 CFR 170.405(b)(3) have been met and the REI of 4 hours has expired. Until then, only handlers wearing the appropriate personal protective equipment can

enter the greenhouse or enclosed space.

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
- Waterproof gloves
- Shoes plus socks
- Protective eyewear

### **Product Information**

AgriPhage-CMM is a bactericide that is comprised of a formulation of bacteriophage to be used as a preventive and curative product for the control of bacterial canker (caused by the bacterium *Clavibacter michiganensis* subsp. *michiganensis*) on tomatoes. 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. In the field, apply AgriPhage-CMM with conventional ground spray equipment or via aerial application immediately after planting and as the plants mature. See the Mixing and Application Instructions section of this label for additional details.

### **Mixing and Application Instructions**

**- MIX WELL PRIOR TO USE -**

**COMPATIBILITY:** Do not combine AgriPhage-CMM in the spray tank with denaturing agents or copper salts. Apply AgriPhage-CMM in approved tank mixes or in 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.

## Greenhouse Seedling Treatment

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

## Greenhouse Treatment – For Tomatoes Grown Hydroponically

RATE	PRE-HARVEST INTERVAL (PHI)	APPLICATION NOTES
½ to 1 quart of AgriPhage-CMM per 12-25 gallons of water per 9600 square feet 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 application rate of ½ quart of AgriPhage-CMM per 9600 square feet of greenhouse space when plants are small. As plants increase in size and foliage, increase application rate to 1 quart of AgriPhage-CMM per 9600 square feet 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 runoff.</p> <p>Under severe disease conditions, use the higher application rate of 1 quart of AgriPhage-CMM per 9600 square feet of greenhouse space.</p>

## Field Treatment – Ground Application

RATE	PRE-HARVEST INTERVAL (PHI)	APPLICATION NOTES
1 to 2 pints of AgriPhage-CMM per 50-100 gallons of water per acre	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 application rate of 1 pint of AgriPhage-CMM per acre at planting (below the second tie). As plants increase in size and foliage (at or above the second tie), increase application rate to 2 pints of AgriPhage-CMM per acre 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 runoff.</p> <p>Under severe disease conditions and periods of heavy rain, apply immediately after rainfall, and use the higher application rate of 2 pints of AgriPhage-CMM per acre.</p>

## Field Treatment – Aerial Application

Apply AgriPhage-CMM by aerial application to field-grown tomato crops 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 the Application Notes in the Field Treatment – Ground Application section for information on items like application timing and the instructions in the Aerial Drift Reduction Information section to reduce aerial drift.

## Aerial Drift Reduction Information

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.



## **Storage and Disposal**

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

**Pesticide Storage:** Store this product at 39.2°F (4°C). Direct sunlight and/or extreme heat will cause degradation of the product and decrease product efficacy.

**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:** Nonrefillable 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.

# **AGRIPHAGE-CMM CHEMIGATION**

**Instructions for the Application of AgriPhage-CMM by Chemigation to Tomatoes**

## **AGRIPHAGE-CMM**

**Bactericide for use on tomatoes**

[Biological control for bacterial canker on tomatoes]

**It is a violation of Federal law to use this product in a manner inconsistent with its labeling.**

**The labeling must be in possession of the user at the time of application.**

**Read the label affixed to the container for AgriPhage-CMM before applying.**

**Use of AgriPhage-CMM according to this labeling is subject to the use precautions and limitations imposed by the label affixed to the container for AgriPhage-CMM.**

OmniLytics, Inc.  
9075 South Sandy Parkway  
Sandy, Utah 84070  
801-746-3600  
www.omnilytics.com  
EPA Reg. No. 67986-6

**ACCEPTED**

**Oct 23, 2018**

Under the Federal Insecticide, Fungicide  
and Rodenticide Act as amended, for the  
pesticide registered under  
EPA Reg. No. 67986-6

## **Instructions Applicable to All Chemigation Types**

- 1) Apply this product only through drip (trickle) or sprinkler (including center pivot, lateral move, end tow, side (wheel) roll, traveler, big gun, solid set, or hand move) irrigation systems. Do not apply this product through any other type of irrigation system.
- 2) Crop injury, lack of effectiveness, or illegal pesticide residues in the crop can result from non-uniform distribution of treated water.
- 3) If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers or other experts.
- 4) 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.
- 5) 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.

## **Instructions 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 flow 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.
- 8) Agitate the supply tank immediately after adding AgriPhage-CMM.
- 9) AgriPhage-CMM is to be applied continuously for the duration of the water application.
- 10) Apply AgriPhage-CMM at a rate of 1 to 2 pints per acre. Repeat application 1-3 times per week.

### **Instructions for Sprinkler 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.
- 7) Do not apply when wind speed favors drift beyond the area intended for treatment.
- 8) Agitate the supply tank immediately after adding AgriPhage-CMM.
- 9) AgriPhage-CMM is to be applied continuously for the duration of the water application.
- 10) Apply AgriPhage-CMM at a rate of 1 to 2 pints per acre. Repeat application 1-3 times per week.

### **Instructions 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.
- 7) Agitate the supply tank immediately after adding AgriPhage-CMM.
- 8) AgriPhage-CMM is to be applied continuously for the duration of the water application.
- 9) Apply AgriPhage-CMM at a rate of 1 to 2 pints per acre. Repeat application 1-3 times per week.