



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 18, 2018

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

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – To Update Application Instructions, Update Formatting, Add Supplemental Labeling for Chemigation, and Make Changes Requested by the EPA
Product Name: AgriPhage
EPA Registration Number: 67986-1
Application Date: 07/29/2015
OPP Decision Number: 541876

Dear Mr. Homer:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is 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.

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

Page 2 of 2

EPA Reg. No. 67986-1

OPP Decision No. 541876

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.

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

Sincerely,

A handwritten signature in black ink, appearing to read "SEIICHI MURASAKI". The signature is written in a cursive style with a large initial "S" and "M".

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

Enclosure: Stamped Label

US Label

AGRIPHAGE



FOR ORGANIC PRODUCTION

Bactericide for use on tomatoes and peppers

[Biological control for bacterial spot and bacterial speck on tomatoes and peppers]

Active Ingredients:

Bacteriophage active against *Xanthomonas campestris* pv. *vesicatoria* and
Pseudomonas syringae pv. *tomato** 0.000046%

Other Ingredients:

99.999954%

Total:

100.000000%

*(Contains at least 1.55×10^{13} plaque-forming units (PFU) per gallon of product)

*(Contains at least 3.9×10^{12} plaque-forming units (PFU) per quart of product)

*(Contains at least 4.1×10^{12} plaque-forming units (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. 67986-1
EPA Est. No. 67986-UT-001

Manufactured by: OmniLytics, Inc.
9075 South Sandy Parkway
Sandy, Utah 84070
801-746-3600
www.omnilytics.com



Net Contents: 1 qt. or 2.5 gal.

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.

Hotline Number

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: www.npic.orst.edu). 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 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. The requirements in this box 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.

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 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 spot (caused by the bacterium *Xanthomonas campestris* pv. *vesicatoria*) and bacterial speck (caused by the bacterium *Pseudomonas syringae* pv. *tomato*) on tomatoes and peppers. Apply AgriPhage 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 as a foliar spray or by fogging. In the field, apply AgriPhage with conventional ground spray equipment or via aerial application immediately after planting and as the plants mature. See the Mixing Instructions and Compatibility Information and Applications Instructions sections of this label for additional details.

Mixing Instructions and Compatibility Information

- MIX WELL PRIOR TO USE -

GROUND TANK MIX INSTRUCTIONS: Mix 1-2 pints of AgriPhage in 50-100 gallons of water. If mechanical mixing is available when preparing the spray solution, agitation ensures proper blending.

AERIAL TANK MIX INSTRUCTIONS: Mix 1-2 pints of AgriPhage in a minimum of 5 gallons of water. If mechanical mixing is available when preparing the spray solution, agitation ensures proper blending.

COMPATIBILITY: Do not combine AgriPhage in the spray tank with denaturing agents or copper salts. Apply AgriPhage in approved tank mixes or in an alternating spray program, applying denaturing agents or copper salts 4 days after AgriPhage application, as copper salts and denaturing agents compromise bacteriophage survival. AgriPhage 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 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.

Application Instructions

Greenhouse Seedling Treatment

CROP	PEST	RATE	PRE-HARVEST INTERVAL (PHI)	APPLICATION NOTES
Tomato & Pepper	Tomato & Pepper Spot (<i>Xanthomonas campestris</i> pv. <i>vesicatoria</i>) Tomato Speck (<i>Pseudomonas syringae</i> pv. <i>tomato</i>)	1 pint of AgriPhage per 50-100 gallons of water per 9600 square feet of greenhouse space	AgriPhage may be applied up to and including the day of harvest.	Apply daily treatments to foliage by spraying or fogging. 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. Use sufficient spray solution to ensure complete coverage. Avoid excessive amounts of spray solution that result in runoff.

Field Treatment – Ground Application

CROP	PEST	RATE	PRE-HARVEST INTERVAL (PHI)	APPLICATION NOTES
Tomato & Pepper	Tomato & Pepper Spot (<i>Xanthomonas campestris</i> pv. <i>vesicatoria</i>) Tomato Speck (<i>Pseudomonas syringae</i> pv. <i>tomato</i>)	1 to 2 pints of AgriPhage per 50-100 gallons of water per acre	AgriPhage may be applied up to and including the day of harvest.	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. Begin at the lower application rate of 1 pint of AgriPhage 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 per acre to ensure adequate coverage. Repeat application 1-3 times per week.

CROP	PEST	RATE	PRE-HARVEST INTERVAL (PHI)	APPLICATION NOTES
				<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 per acre.</p>

Field Treatment – Aerial Application

Apply AgriPhage by aerial application to field-grown tomato and pepper 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 determines 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 in a cool, dry area, away from direct sunlight and extreme heat. Direct sunlight and/or extreme heat may 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 $\frac{1}{4}$ 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 this 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 CHEMIGATION

Instructions for the Application of AgriPhage by Chemigation to Tomatoes and Peppers

AGRIPHAGE

Bactericide for use on tomatoes and peppers

[Biological control for bacterial spot and bacterial speck on tomatoes and peppers]

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 before applying.

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

OmniLytics, Inc.
9075 South Sandy Parkway
Sandy, Utah 84070
801-746-3600
www.omnilytics.com
EPA Reg. No. 67986-1

A C C E P T E D

Oct 18, 2018

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 67986-1

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.
- 9) AgriPhage is to be applied continuously for the duration of the water application.
- 10) Apply AgriPhage 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.
- 9) AgriPhage is to be applied continuously for the duration of the water application.
- 10) Apply AgriPhage 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.
- 8) AgriPhage is to be applied continuously for the duration of the water application.
- 9) Apply AgriPhage at a rate of 1 to 2 pints per acre. Repeat application 1-3 times per week.