

67986-1

10/17/2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 17 2011

Kristine Blum
OmniLytics, Inc.
9100 South 500 West
Sandy, Utah 84070

Re: Agriphage
EPA Reg. No. 67986-1
Submission dated May 28, 2010 and subsequent revisions
Decision No. 434829, and
Submission dated June 6, 2006
Decision No. 369365

Dear Ms Blum:

The Agency has completed its review of two amendments to this registration submitted in connection with registration under FIFRA Sec. 3(c)(7)(C): the submission dated May 28, 2010 and subsequent revisions related to this submission (Decision No. 434829) and the submission dated June 6, 2006 (Decision No. 369365). The Agency's conclusions are set forth below:

Submission dated May 28, 2010 and subsequent revisions

The subject product registration includes changes to the product label, an update to the basic confidential statement of formula (CSF), a submission of a new five batch analysis data and a request to waive the requirement at 40 CFR 158.2120 that a sample of each bacteriophage be deposited in a nationally recognized culture collection. Changes to the product label include the following:

1. Addition of the statement "For Use in Organic Production".
2. Revision of the ingredient statement to take account of new information on the weight of a phage.
3. Addition to the label of greenhouse use.
4. Revision of the Precautionary Statements in accordance with the Label Review Manual.
5. Revision of the Re-entry Interval (REI) in accordance with PR Notice 95-3.
6. Revision of the personal protective equipment (PPE) in accordance with the WPS.
7. Revision of Container Handling statements in accordance with PR Notices 2007-4 and 83-3.
8. Update of the address of registrant.
9. Update of the Directions for Use in accordance with the Label Review Manual.

CONCURRENCES

SYMBOL	▶ 7511P	7511P						
SURNAME	▶ Schold	Reilly						
DATE	▶ 10/17/11	10/17/11						

Submission dated June 6, 2006

The registrant submitted Product Identity and Characterization data (MRID 46887301), dated June 6, 2006, to address the following condition of registration: "Submit a PCR based screen with 6 months of this registration."

Decision on amendments

The PCR based screen to address a condition of registration was submitted before the due date of June 9, 2006. The Agency has reviewed it and found it acceptable.

The five batch analysis shows that all products meet the pfu/ml requirement but does not demonstrate that the product is sterile. The five batch analysis will be acceptable if OmniLytics submits data to show that the product is sterile.

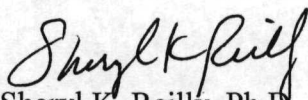
The waiver of the requirement at 40 CFR 158.2120 to deposit a sample of each bacteriophage active against *Xanthomonas campestris* pv. *vesicatoria* and *Pseudomonas syringae* pv. *tomato* in a nationally recognized culture collection is acceptable, subject to a provision which is discussed in the confidential attachment to this amendment letter.

The amendment to the label and the revised basic CSF dated 9/15/2011, referred to above, are acceptable. A stamped copy of the label is enclosed for your records. Submit two (2) copies of the revised final printed labeling before you release the product for shipment.

A copy of the updated basic CSF dated 9/15/2011, which supersedes all previous basic CSFs, has been placed in the file jacket for this registration.

If you have questions, please contact Ann Sibold by phone at 703 305-6502 or by email at sibold.ann@epa.gov.

Sincerely,



Sheryl K. Reilly, Ph.D.
Chief, Microbial Pesticides Branch
Biopesticides and Pollution Prevention
Division (Mail Code 7511P)

Enclosures (4):
A-79
Stamped Label
Reviews

3/10

US Label

AGRIPHAGE

Bactericide for use on tomatoes and peppers

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

Active Ingredient:

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 x 10¹³ PFU per gallon)

*(Contains at least 3.9 x 10¹² PFU per quart)

*(Contains at least 4.1 x 10¹² PFU per liter)

Keep Out of Reach of Children

CAUTION

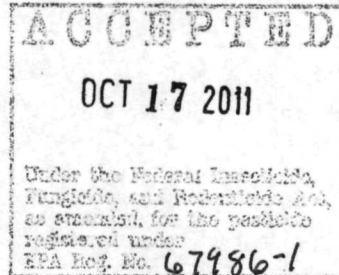
See side panel for additional precautionary statements

For Use in Organic Production

EPA Reg. No. 67986-1

EPA Est. No. 67986-UT-001

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



Net Contents: 1 qt, 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.

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

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.

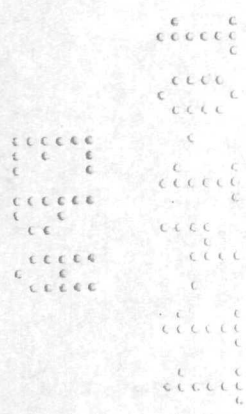
PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long sleeved shirt
- Long Pants
- Waterproof Gloves
- Shoes plus socks

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 intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or 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 requirement 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), notification to workers, 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 workers entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE for early entry into 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

Product Information

AgriPhage is a bactericide, comprised of a formulation of bacteriophages 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. Apply AgriPhage in the field with conventional ground spray equipment or via aerial application 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.

Ground Tank Mix Instructions: Apply AgriPhage 1-2 pints of AgriPhage per acre in 50-100 gallons of water. If mechanical mixing is available when preparing the spray solution, agitation ensures proper blending.

Aerial Tank Mix Instructions: Apply AgriPhage 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. If mechanical mixing is available when preparing the spray solution, agitation ensures proper blending. Follow all instructions to reduce aerial drift.

Compatibility: Do not combine AgriPhage in the spray tank with denaturing agents or copper salts. Apply AgriPhage in approved tank mixes or with 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. 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 Rates

Greenhouse Seedling Treatment

RATE	Pre-Harvest Interval (PHI)	APPLICATION	NOTES
1 pint of AgriPhage per 50-100 gallons of water per 9600 sq ft. of greenhouse space	AgriPhage 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, 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>

Field Treatment

RATE	Pre-Harvest Interval (PHI)	APPLICATION	NOTES
Ground Application: 1 to 2 pints of AgriPhage per 50-100 gallons of water per acre (see directions below for aerial application)	AgriPhage 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 of AgriPhage per acre at planting (below second tie), as plants increase in size and foliage (above second tie), increase rate to 2 pints of AgriPhage 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 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 of AgriPhage per acre.</p>

AERIAL APPLICATION INSTRUCTIONS: Apply AgriPhage 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 in a cool dry area, away from direct sunlight and extreme heat. This may cause degradation of the product which will 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: Non-refillable containers. 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 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.