

72898-4

11/2/2011

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FEDERAL STATES ENVIRONMENTAL PROTECTION AGENCY

Washington, D.C. 20460



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Ms. Kathy Bolan
Registration Consultant/
Agent for BioTepp Inc.
575 Viewridge Dr.
Angwin, CA 94508

NOV 02 2011

Re: Virosoft CP4
EPA Reg. No. 72898-4
Submission dated 8/4/2011
Decision No. 453833

Dear Ms. Bolan:

The Agency has reviewed your request to amend the subject product registration, which includes the following changes to the product's label in accordance with the Label Review Manual (LRM).

- 1. Addition of sublabel for residential uses.
2. Expanded crop uses.
3. National Organic Program (NOP) labeling and OMRI logo.
4. Updated First Aid statement.
5. Addition of Warranty statement.
6. Modified Directions for Use.

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(A), is acceptable provided that you:

- 1. Submit and/or 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. Submit two (2) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of a final printed label.

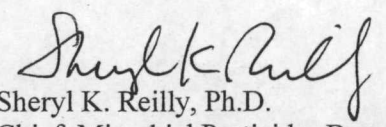
If these conditions are not complied with, then the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

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

Table with columns for SYMBOL, SURNAME, and DATE, containing handwritten entries: 7511P, Glikes, 10/14/11; 7511P, Reynolds, 11/1/11; 7511P, Rulf, 11/2/11.

If you have questions, please contact Michael Glikes by phone at (703)305-6231 or by email at glikes.michael@epa.gov.

Sincerely,



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

Enclosures (2):
A-79
Stamped Label

MASTER LABEL

This master label bears directions for agricultural and homeowner use with various application rates specific to the container size.

VIROSOFT^{CP4}

Sublabel A: Agricultural Use
Sublabel B: Homeowner's Use

<i>Cydia pomonella</i> Granulovirus.....	0.07%
<u>OTHER INGREDIENTS:</u>	<u>99.93%</u>
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA Reg. No. 72898-4
EPA Est. No. 72898-CAN-001

BIOTEPP INC.

895, chemin Benoit
Mont-Saint-Hilaire (Québec) Canada J3G 4S6
Tel.: (418) 659-4446 – Email: bioteppinfo@globetrotter.net

ACCEPTED

NOV 02 2011

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

72898-4

Sublabel A: Agricultural Use

VIROSOFT^{CP4}



Bio-insecticide for control of Codling Moth Larvae of Pome Fruits such as Apple, Pear; Tree Nuts such as Walnuts and Stonefruits such as Plums and Prunes

For Organic Production



ACTIVE INGREDIENT*:

<i>Cydia pomonella</i> Granulovirus.....	0.07%
OTHER INGREDIENTS:.....	99.03%
Total	100.00%

* Contains 4x10¹³ viral occlusion bodies (Obs.) per Quart

KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID

IF IN EYES: Immediately hold eyes open, slowly and gently rinse with water for 15-20 minutes. If wearing contact lenses, rinse eyes for 5 minutes, remove contact lenses, and continue rinsing.

IF ON SKIN OR CLOTHING: Remove contaminated clothing. Immediately rinse skin for 15-20 minutes using plenty of water.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.

Contact a poison control center or doctor for treatment advice. Have the product container or label with you when contacting a poison control center or doctor, or going for treatment. HOT LINE NUMBER: 1-800-255-3924

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EPA Reg. No. 72898-4
 EPA Est. No. 72898-CAN-001

Net Contents: 1 Quart

Lot No. _____

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Harmful if absorbed through skin or inhaled. Avoid contact with skin, eyes or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Protective eyewear: goggles, face shield, or shielded safety glasses
- Waterproof gloves
- Long-sleeved shirt and long pants
- Shoes and socks

Mixers/loaders and applicators must wear a dust/mist filtering respirator 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 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.

Engineering Controls

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR § 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down.

USER SAFETY RECOMMENDATIONS

Users 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 the gloves before removing them. As soon as possible, wash thoroughly and change into clean clothing.

Environmental Hazards

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 cleaning equipment or disposing of equipment washwater or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in any 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. Do not apply this product through any type of irrigation system.

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:

- Protective eyewear: goggles, face shield, or shielded safety glasses
- Waterproof gloves
- Coveralls
- Shoes plus socks

Application Instructions

Mixing Instructions:

VIROSOFT^{CP4} is to be used at the rate of 1.6 to 3.2 fluid ounces per acre. Fill your sprayer partially with water. Next add **VIROSOFT^{CP4}** to the sprayer while vigorously agitating and or recirculating the spray solution to ensure a uniform dispersion of the **VIROSOFT^{CP4}** in the solution. Apply in sufficient water to thoroughly wet the tree canopy while avoiding excessive spray runoff. **VIROSOFT^{CP4}** may be used in tank mixes with other products as long as prior use or experience has demonstrated physical and biological compatibility. Spray tank pH should be maintained near neutral.

Application Rates:

Apply diluted **VIROSOFT^{CP4}** with orchard sprayers prior to egg hatching and thereafter every 7 to 14 days. In orchards with high codling moth populations, apply **VIROSOFT^{CP4}** at 3.2 fluid ounces per acre every 7 days. To avoid direct exposure to sunlight, apply this product in late afternoon or on a cloudy day. Make two (2) or more applications per codling moth larvae generation. Repeat as often as necessary to maintain control through the season. Consult with local crop specialists or the cooperative extension service to access information related to predictive models, which predict the best timing of applications against codling moth larvae.

Tree Fruits & Nut Crops	Target Insect Pests	Rates in fl. oz./Acre
Pome Fruits: Apple; azarole; crabapple; loquat; mayhaw; medlar; pear; Asian pear; quince; Chinese quince; Japanese quince; tejocote; cultivars, varieties, and/or hybrids of these	Codling Moth larvae (<i>Cydia pomonella</i>)	1.6 to 3.2 fl. Oz.
Tree Nuts: Almond; beech nut; Brazil nut; butternut; cashew; chestnut; chinquapin; filbert (hazelnut); hickory nut; macadamia nut; pecan; black and English walnut	Codling Moth larvae (<i>Cydia pomonella</i>)	1.6 to 3.2 fl. Oz.
Stonefruits: Plum, prune, peach, nectarine, apricot, pluot and cherry	Codling Moth larvae (<i>Cydia pomonella</i>)	1.6 to 3.2 fl. Oz.

Spray Drift 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 of these factors when making decisions.

Product Information

VIROSOFT^{CP4} is a biological insecticide containing *Cydia pomonella* granulovirus. Virus particles must be ingested by larvae to be effective. Timing applications, so that early-instar larvae exiting the eggs or on the surface of the leaf, bark or fruit come in contact with the virus before entering the fruit, will ensure maximum effectiveness. **VIROSOFT^{CP4}** may be used in integrated pest management (IPM) programs.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store unused product in original container away from children and direct sunlight. For long-term storage, product is best kept frozen. For short-term storage (up to 4 months), product can be stored at room temperature. Keep open container refrigerated or frozen.

PESTICIDE DISPOSAL: To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

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 puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances.

WARRANTY:

To the extent consistent with applicable law, BioTEPP Inc. warrants that the material herein conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the insect problem, condition of the crop, incompatibility with other chemicals not specifically recommended and other influencing factors in the use of this product are beyond the control of the seller. Buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

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Sublabel B: Homeowner Use

VIROSOFT^{CP4}



BIO-Insecticide for Control of Codling Moth Larvae in Home Garden or Orchard Settings

For Organic Gardening



ACTIVE INGREDIENT*:

Cydia pomonella Granulovirus.....0.07%

OTHER INGREDIENTS:.....99.93%

Total.....100.00%

* Contains 4x10¹³ viral occlusion bodies (OBs.) per Quart

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

IF IN EYES: Immediately hold eyes open, slowly and gently rinse with water for 15-20 minutes. If wearing contact lenses, rinse eyes for 5 minutes, remove contact lenses, and continue rinsing.

IF ON SKIN OR CLOTHING: Remove contaminated clothing. Immediately rinse skin for 15-20 minutes using plenty of water.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.

Contact a poison control center or doctor for treatment advice. Have the product container or label with you when contacting a poison control center or doctor, or going for treatment. HOT LINE NUMBER: 1-800-255-3924

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EPA Reg. No. 72898-4
EPA Est. No. 72898-CAN-001

Net Contents: 0.5 fl. oz., 1.0 fl. oz., and 1.5 fl. oz. (16 ml, 32 ml and 48 ml)

Lot No. _____

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Harmful if absorbed through skin or inhaled. Avoid contact with skin, eyes or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Environmental Hazards

To protect the environment, do not allow pesticides to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help insure that wind or rain does not blow or wash pesticide off the treatment area. Rinsing application equipment over the treated area will help avoid run off to water bodies or drainage systems.

DIRECTIONS FOR USE

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

VIROSOFT^{CP4} is a biological insecticide (containing *Cydia pomonella* Granulovirus) that is specific for the control of the codling moth. To be effective, the virus particles must be ingested by larvae. Applications should be timed, so that early-instar larvae exiting the eggs or on the surface of the leaf or fruit come in contact with the virus before entering the fruit.

Application rate: Mix 0.064 fl. oz. or 2 ml for each gallon of spray water.

Instructions:

1. Add water to a clean hand pump or other suitable sprayer until partially full.
2. Add **VIROSOFT^{CP4}** to the water in the sprayer and add additional water.
3. Close the sprayer and shake well.
4. Pump and spray fruit or nut trees until leaves, bark and fruit are completely covered with spray solution.
5. Repeat every 7-14 days as needed until codling moth larvae are no longer a threat to your crop.
6. **VIROSOFT^{CP4}** may lose effectiveness with extended exposure to direct sunlight. Therefore, reapply after 7-8 sunny days.

When to spray:

Begin **VIROSOFT^{CP4}** applications in late spring or early summer when 1st generation codling moth eggs begin to hatch. This normally occurs about 2 weeks after the petals fall from the tree. Repeat as needed every 7-14 days but at least twice during each larval generation. Some regions have 2 or more generations of codling moth larva per season. Effective control of codling moth larvae may require additional treatments for each generation through mid to late summer. Consult your local Master Gardener or Cooperative Extension Service for more information about the best timing of codling moth larva sprays.

VIROSOFT^{CP4} can be applied up to and including the day the fruit or nuts are picked and stored.

Tree Fruits & Nut Crops	Target Insect Pests
Pome Fruits: Apple; azarole; crabapple; loquat; mayhaw; medlar; pear; Asian pear; quince; Chinese quince; Japanese quince; tejocote; cultivars, varieties, and/or hybrids of these	Codling Moth larvae (<i>Cydia pomonella</i>)
Tree Nuts: Almond; beech nut; Brazil nut; butternut; cashew; chestnut; chinquapin; filbert (hazelnut); hickory nut; macadamia nut; pecan; black and English walnut	Codling Moth larvae (<i>Cydia pomonella</i>)
Stonefruits: Plum, prune, peach, nectarine, apricot, pluot and cherry	Codling Moth larvae (<i>Cydia pomonella</i>)

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store unused product in original container away from children and direct sunlight. For long-term storage, product is best kept frozen. For short-term storage (up to 4 months), product can be stored at room temperature. Keep open container refrigerated or frozen.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container.

IF EMPTY: Place in trash or offer for recycling, if available.

IF PARTIALLY FULL: Store in cool place. Call your local solid waste agency or 1-800-CLEAN-UP for disposal instructions. Never place unused product down any indoor or outdoor drain.

WARRANTY:

To the extent consistent with applicable law, BioTEPP Inc. warrants that the material herein conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the insect problem, condition of the crop, incompatibility with other chemicals not specifically recommended and other influencing factors in the use of this product are beyond the control of the seller. Buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.