

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

May 23, 2019

Kathy A. Bolan Authorized Agent for BioTEPP, Inc. 575 Viewridge Dr. Angwin, CA 94508

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – Add New

Pest (Oriental Fruit Moth), Resistance Management Language, Update Personal Protective Equipment Language, and Make Other Agency-Initiated Changes.

Product Name: VIROSOFT CP4 EPA Registration Number: 72898-4 Application Date: 11/29/2018 OPP Decision Number: 547149

Dear Ms. Bolan:

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.

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 false

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or misleading statements or claims substantially differing from the EPA-approved 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,

Seiichi Murasaki, Senior Regulatory Advisor

Microbial Pesticides Branch

Biopesticides and Pollution Prevention Division (7511P)

Office of Pesticide Programs

Enclosure: Stamped Label

MASTER LABEL

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

VIROSOFT™ CP4

Sublabel A: Agricultural Use Sublabel B: Residential Use

Cydia pomonella Granulovirus	0.07%	
OTHER INGREDIENTS:	99.03%	
Total	100.00%	

^{*} Contains 4x10¹³ viral occlusion bodies (Obs.) per Quart of Product

KEEP OUT OF REACH OF CHILDREN CAUTION

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

BioTEPP Inc.

201, Mgr Bourget Lévis (Québec) Canada G6V 6Z3 Tel.: (514) 893 2044

ACCEPTED

May 23, 2019

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 72898-4

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Sublabel A: Agricultural Use

VIROSOFT™ CP4

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

▽FOR ORGANIC PRODUCTION

ACTIVE INGREDIENT*:

Cydia pomonella Granulovirus	0.07%
OTHER INGREDIENTS:	99.03%
Total	100.00%

^{*} Contains 4x10¹³ viral occlusion bodies (Obs.) per Quart of Product

CAUTION CAUTION

FIRST AID		
IF ON SKIN OR CLOTHING:	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. 	
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. 	
Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.		
HOT LINE NUMBER		

Have the product container or label with you when calling a poison control center or doctor, or when going for treatment. For non-emergency information concerning this product, call the National Pesticide Information Center (NPIC) at 1-800-858-7378 (NPIC Web site: www.npic.orst.edu). For emergencies, call the poison control center at 1-800-222-1222.

BioTEPP Inc.

201, Mgr Bourget Lévis (Québec) Canada G6V 6Z3 Tel.: (514) 893 2044

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

Net Contents: 1 Quart, and 10 fluid ounces	Lot No.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. 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. Causes moderate eye irritation. Harmful if inhaled. Avoid breathing spray mist.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Protective eyewear
- Waterproof gloves
- Long-sleeved shirt and long pants
- Shoes and socks

Wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N, R, or P filter; <u>OR</u> a NIOSH-approved elastomeric particulate respirator with any N, R, or P filter; <u>OR</u> a NIOSH-approved powered air- purifying respirator with HE filters. (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.

ENGINEERING CONTROLS

When handlers use closed systems, enclosed cabs, or aircraft 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 spiil 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. As soon as
 possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

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 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.

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.

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, wear:

- Protective eyewear
- · Waterproof gloves
- Coveralis
- · Shoes plus socks

APPLICATION INSTRUCTIONS

Mixing Instructions:

Use VIROSOFT™ CP4 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 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 before the larvae feed their way into the fruit and thereafter every 7 to 10 days. In orchards with high codling moth and oriental fruit 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 and oriental fruit moth larvae generation. In general, one to two sprays per generation are generally sufficient. Due to unfavorable weather conditions, flight, egg laying, and hatching may extend over a longer period of time and up to 6 applications may be needed. Frequent applications at low rates and shorter interval may be more effective than one or two applications at high rates. 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 or oriental fruit moth larvae. Do not apply this product through any type of irrigation system.

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</i> pomonella) and Oriental Fruit Moth larvae (Grapholita molesta)	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 (Cydia pomonella) and Oriental Fruit Moth larvae (Grapholita molesta)	1.6 to 3.2 fl. oz.
Stonefruits: Plum, prune, peach, nectarine, apricot, pluot and cherry	Codling Moth larvae (<i>Cydia</i> pomonella) and Oriental Fruit Moth larvae (Grapholita molesta)	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 determines 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. Do not apply directly to aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds).

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.

RESISTANCE MANAGEMENT RECOMMENDATIONS

For resistance management, VIROSOFT™ CP4 contains a Group 31 insecticide. Any insect population may contain individuals naturally resistant to VIROSOFT™ CP4 and other Group 31 insecticides. The resistant individuals may dominate the insect population if this group of insecticides are used repeatedly in the same fields. Appropriate resistance-management strategies should be followed.

To delay insecticide resistance, take the following steps:

- Rotate the use of VIROSOFT™ CP4 or other Group 31 insecticides within a growing season, or among growing seasons, with different groups that control the same pests.
- Avoid application of more than 6 consecutive sprays of VIROSOFT™ CP4 or other insecticides in the same group
 in a season.
- Use tank mixtures with insecticides from a different group that are equally effective on codling moth and oriental
 fruit moth when such use is permitted. Do not rely on the same mixture repeatedly for the same pest populations.
 Consider any known cross-resistance issues for codling moth and oriental fruit moth between the individual
 components of a mixture. In addition, consider the following recommendations provided by the Insecticide
 Resistance Action Committee (IRAC):
 - Individual insecticides selected for use in mixtures should be highly effective and be applied at the rates at which they are individually registered for use against codling moth and oriental fruit moth.
 - Mixtures with components having the same IRAC mode of action classification are not recommended for insect resistance management.
 - When using mixtures, consider any known cross-resistance issues between the individual components for the codling moth and oriental fruit moth.
 - Mixtures become less effective if resistance is already developing to the active ingredient, but they may still
 provide pest management benefits.
 - The insect resistance management benefits of an insecticide mixture are greatest if the components have similar periods of residual insecticidal activity. Mixtures of insecticides with unequal periods of residual insecticide activity may offer an insect resistance management benefit only for the period where both insecticides are active.
- Adopt an integrated pest management program for insecticide use that includes scouting, use historical information related to pesticide use, crop rotation, record keeping, and which considers cultural, biological and other chemical control practices.
- Monitor after application for unexpected target pest survival. If the level of survival suggests the presence of resistance, consult with your local university specialist or certified pest control advisor.
- Contact your local extension specialist or certified crop advisors for any additional pesticide resistancemanagement and/or IPM recommendations for the specific site and pest problems in your area.
- For further information or to report suspected resistance contact BioTEPP Inc at www.BioTEPP.com.

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 waste, 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 ½ 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. If burned, stay out of smoke.

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.

Also, to the extent consistent with applicable law, BioTEPP Inc. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of BioTEPP Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, BioTEPP Inc. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at BioTEPP Inc.'s election, the replacement of product.

VIROSOFT™ is a trademark of BioTEPP Inc.

Sublabel B: Residential Use

VIROSOFT™ CP4

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

FOR ORGANIC GARDENING



^{*} Contains 4x10¹³ viral occlusion bodies (OBs.) per Quart of Product

CAUTION

FIRST AID		
IF ON SKIN OR	Take off contaminated clothing.	
CLOTHING:	Rinse skin immediately with plenty of water for 15-20 minutes.	
CLOTTING.	Call a poison control center or doctor for treatment advice.	
	Hold eye open and rinse slowly and gently with water for 15-20 minutes.	
IF IN EYES:	Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.	
	Call a poison control center or doctor for treatment advice.	
Call a poison control center or doctor immediately for treatment advice.		
IF SWALLOWED:	Have person sip a glass of water if able to swallow.	
IF SWALLOWED.	Do not induce vomiting unless told to by a poison control center or doctor.	
	Do not give anything by mouth to an unconscious person.	
HAT I ME MUMBER		

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or when going for treatment. For non-emergency information concerning this product, call the National Pesticide Information Center (NPIC) at 1-800-858-7378 (NPIC Web site: www.npic.orst.edu). For emergencies, call the poison control center at 1-800-222-1222.

BioTEPP Inc.

201, Mgr Bourget Lévis (Québec) Canada G6V 6Z3 Tel.: (514) 893 2044

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
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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. 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. Causes moderate eye irritation. Harmful if inhaled. Avoid breathing spray mist.

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 and oriental fruit 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.

Application 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.
- Repeat every 7-14 days as needed until codling moth larvae and oriental fruit moth larvae are no longer a threat to your crop.
- 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 and oriental fruit moth eggs begin to hatch. This normally occurs about 2 weeks after the petals fall from the tree. Repeat as needed every 7-10 days but at least twice during each larval generation. Some regions have 2 or more generations of codling moth and oriental fruit moth larva per season. Due to unfavorable weather conditions, flight, egg laying, and hatching may extend over a longer period of time so control of codling moth larvae and oriental fruit 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 and oriental fruit moth larva sprays.

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

Best Timing of Applications against Codling Moth larvae or Oriental Fruit Moth larvae.

Tree Fruits & Nut Crops	Target Insect Pests	Rates per gallon of water
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 (Cydia pomonella) and Oriental Fruit Moth larvae (Grapholita molesta)	Mix 0.064 fl. oz. or 2 ml for each gallon of spray water
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</i> pomonella) and Oriental Fruit Moth larvae (Grapholita molesta)	Mix 0.064 fl. oz. or 2 ml for each gailon of spray water
Stonefruits: Plum, prune, peach, nectarine, apricot, pluot and cherry	Codling Moth larvae (<i>Cydia</i> pomonella) and Oriental Fruit Moth larvae (Grapholita molesta)	Mix 0.064 fl. oz. or 2 ml for each gatlon of spray water

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: Nonrefiliable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling, if available. **If partly filled:** Call your local solid waste agency 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.

Also, to the extent consistent with applicable law, BioTEPP Inc. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of BioTEPP Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, BioTEPP Inc. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at BioTEPP Inc.'s election, the replacement of product.

VIROSOFT™ is a trademark of BioTEPP Inc.