72898-2 7/17/2000 1/4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
7511C, 401 M St., S.W.
Washington, D.C. 20460

Number:	Date of Issuance:
72898-2	JUL 17 2000

NOTICE OF PESTICIDE:
__X__ Registration
____ Reregistration

(under FIFRA, as amended)

Term of Issuance:
Conditional
Time-Limited

Name of Pesticide Product:
VIROSOFT^{CP4}

Name and Address of Registrant (include ZIP Code):
BIOTEPP, INC.
177, 71eme rue Est
Charlesbourg, Quebec G1H 1L4

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The registration application referred to above, submitted in connection with registration under § 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you do the following terms and conditions.

1. Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

2. The manufacturing process submitted did not sufficiently address the QA/QC procedures as required. Rather, the data as reviewed by the Agency describes the criteria used for determining the quality of the product for bacterial contamination (i.e. virus:bacteria ratio) but does not further these tests, because of a relatively small amount of the starting material, to include testing for the presence of human pathogens. Therefore, the need for confirmatory data was triggered as a result of a manufacturing process that is atypical of most reviewed by the Agency. These data are being required as a term and/or condition of the registration and must be submitted to the Agency within two years from the date of registration. Confirmatory data will consist of: (1) Product identity to include a repeated gel analysis in order to provide better separation of the DNA fragments thus resulting in a gel figure with more clarity; (2) Analysis of samples and acute toxicity data to include an Intraperitoneal batch analysis on each full production lot which is to be incorporated into the manufacturing process in order to insure that the end-use product is free of microbial contaminants in addition to the incorporation of microbe-specific media tests as part of the normal quality control process to detect human pathogens (if any) found in the present formulaton.

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CONCURRENCES

SYMBOL	7511C	7511C						
SURNAME	Hollis L	Hutton						
DATE								

EPA Form 1320-1A (1/90) *Printed on Recycled Paper* OFFICIAL FILE COPY

Signature of Approving Official:	Date:
JZA see next page	7-17-2000

EPA Form 8570-6

3. This registration will automatically expire on midnight July 21, 2002. EPA will reevaluate this registration before July 1, 2002 to determine whether to convert the registration to a non-expiring registration.

4. This registration is registered under FIFRA § 3(c)(7)(C) because of the outstanding product chemistry and toxicity data . Submit the following data within the specified time frames:

TABLE 1: SUMMARY OF CONDITIONAL REGISTRATION DATA REQUIREMENTS
Product Chemistry Data Required

Guideline	Study	*Data Required*	*Date Required*
885.1100	*Product Identity*	Digestion of the *Cydia pomonella* Granulosis Virus with Bam HI and EcoRI resulted in similar number of DNA fragments but distinct restriction patterns. While the restriction patterns were distinct, the resolution of the gel figure was not clear and the DNA fragments could not be visualized. CLASSIFICATION: Acceptable. Confirmatory data are required which consists of the submission of clarification of the sizes of the DNA fragments and a new gel figure.449696-01	2 years from the date of registration
885.1200	Manufacturing Process	An Additional quality control step should be incorporated to better address the issue of bacterial pathogens and clarification regarding the use of any new isolates. A complete description on handling methods and procedures for a new virus isolate. An IP batch analysis was not performed and should be performed on each production batch. CLASSIFICATION: Acceptable. Confirmatory data is required which consists of the submission of an IP batch analysis performed on each production lot, assurance that both microbe specific media tests to detect human pathogens present in the formulation and insect bioassays will be performed on each production batch.449696-01	2 years from the date of registration
885.1400	Analysis of Samples	The method for selecting the NaCl concentration the final product and tests used to control product purity were described CLASSIFICATION: Acceptable. Confirmatory data is required which consists of the submission of tests to be performed to insure that no primary pathogenic bacteria are present in the product.449696-01	2 years from the date of registration

Guideline	Study	*Data Required*	*Date Required*
885.1500	Certification of Limits	Limits as listed on CSF are adequate. Five batch analysis will be submitted as a condition of the registration.449696-01	2 years from the date of registration
885.3200	Acute Intraperitoneal Toxicity	Toxicity study performed only. Test animals were discarded after sacrifice without a necrospy evaluation. The 22 day observation period revealed moderate clinical effects (e.g. scabs on sacrum and scrotum, thin yellow stained fur) to the male test animals. Cause of effects by CpGV or an unidentified organism were not attainable because a gross necrospy was not performed. CLASSIFICATION: Acceptable: Confirmatory data is required which consists of the submission of a full one batch analysis on each end-use product. Analyze microbial contamination. Should clinical signs as noted above appear, perform a gross necrospy. 440051-05	2 years from the date of registration

*885-xxxx = OPPTS Microbial Pesticide Test Guideline Numbers.

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

5. Submit five(5) copies of the revised final printed labeling before you release the product for shipment.

Sincerely,

Janet L. Andersen, Ph.D.
Director
Biopesticides and Pollution
Prevention Division (7511C)

Enclosure

VIROSOFT CP4

BIO-Insecticide for Codling Moth on apple trees

ACTIVE INGREDIENT: *Cydia pomonella* Granulovirus .....0.07% (4x10''OBs)
INNERT INGREDIENT: 99.93%

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals. Avoid contact with skin, eyes, and clothing.

FIRST AID: If on skin or clothing: Take off affected clothing, rinse skin immediately with plenty of water for 15-20 minutes. Call a doctor for treatment advice if needed. 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 doctor for treatment advice if needed.

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. Keep out of lakes, ponds, or streams. Do not contaminate water by cleaning equipment or disposing of equipment washwaters.

BIOTEPP

177, 71ième rue Est - Charlesbourg, Québec G1H 1L4
Tel.: (418) 626 7628 - Email: biotepp@mediom.qc.ca

EPA Reg. No.: 72898 - 2
EPA Est. No.: 72898 - CAN - 001

NET CONTENTS: 32 Fl.oz.

DIRECTION 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 Agency responsible for pesticide regulation. Do not appy this product through any types of irrigation system.

VIROSOFT CP4 is biological insecticide containing *Cydia pomonella* Granulovirus. Virus particles must be ingested by larvae to be effective. Applications should be timed so that early-instar larvae on the surface of the leaf or fruit come in contact with the virus before entering the fruit.

Dilute 8 fl.oz. of VIROSOFT CP4 in the amount of water needed to treat 1 hectare (2.47-2.5 acres). Apply diluted VIROSOFT CP4, with jet or conventional sprayers prior to egg hatching and thereafter another 3 times in 2-week intervals for a total of 2 applications per generation. It is recommended to apply this product in late afternoon or on a cloudy day to avoid direct exposure to sunlight.

STORAGE AND DISPOSAL: Do not contaminate water, food or feed by storage or disposal. STORAGE: Store unused product in original container away from children and direct sunlight. Store refrigerated at 4oC. Keep open bottle refrigerated. PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. CONTAINER DISPOSAL: Triple rinse (or equivalent). Offer for recycling or reconditioning, or by incineration. PRECAUTION: Keep away from children, food and animal feedstuffs. Applicators and other handlers must wear: long-sleeved shirt and long pants, waterproof gloves, shoes and socks, protective eyewear, goggles or protective shield, dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with any N, P, R, or HE filter. Follow the manufacturer's instructions for cleaning/maintaining PPE. If there are no such instructions furnished, wash PPE clothing with detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS: User should (1) wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. (2) Remove clothing immediately if pesticide gets inside, then wash thoroughly and put on clean clothing. (3) Remove PPE immediately after handling this product. Wash the outside of the gloves before removing them. As soon as possible, wash thorougly and change into clean clothing.

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), notification to the workers 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. 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: overalls, waterproof gloves, shoes plus socks, and protective eyewear.

ACCEPTED
with COMMENTS
In EPA Letter Dated

7-7-2000

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

72898-2

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