



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

FEB 09 2011

Mr. Jeff Jones
Agent, Tree Care Innovations LLC
Delta Analytical Corporation
12510 Prosperity Drive, Suite 160
Silver Spring, MD 20904

Re: Dutch Trig
EPA Reg. No. 83170-1
Submission dated 1/7/2011
Decision No. 444572

Dear Mr. Jones:

The Agency has reviewed your request to amend the subject product registration, which includes the following changes to the product's label:

1. Label format revised in accordance with the Label Review Manual (LRM).
2. Restoring the phrase, "This label must be in the possession of the user at the time of application," to the front panel.
3. Adding a "Manufactured for" statement on the bottom of the middle panel.
4. Adding the phrase "Injector sold separately" below "Net Contents" on the bottom of the middle panel.
5. Updating the storage and disposal statements, which EPA approved on June 1, 2010.
6. Updating the label text for a small container label to be in full compliance with requirements for small containers.
7. Packaging the product in 40 ml vials, each labeled with the new small container label, in a sealed plastic bag with a paper copy of the full label.
8. Updating the names of the registrant and the producer on the Confidential Statement of Formula (CSF).

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.

Type Size Requirements for 3 Front Panel Headings

Size of front panel square inches	Minimum type size for "RESTRICTED USE PESTICIDE" (if required) and Signal Word in capital letters	Minimum type for "Storage and Disposal" heading & "Keep Out of Reach of Children" warning
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

DUTCH TRIG®

Biological vaccination for American elms to prevent Dutch elm disease

For use by Professional Arborists/Applicators

This label must be in the possession of the user at the time of application

Under the Federal Insecticide, Fungicide, and Plant Disease Act, as amended, for the pesticide registered under EPA Reg. No. 83170-1

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. If in eyes, flush eyes with plenty of water. Get medical attention if irritation occurs or persists.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear: long sleeved shirt and long pants, waterproof gloves, shoes plus socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing. Remove PPE immediately if pesticide gets inside then wash thoroughly and put on 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 water high-water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. **PESTICIDE STORAGE:** Dutch Trig® vials, which contain live *Verticillium* spores, must be kept refrigerated at 33° to 40° F from receipt until shortly before use. Use Dutch Trig® before the expiration date. Prevent freezing of the product. Store vials lying down. **PESTICIDE DISPOSAL:** To avoid wastes, use all material in this container by application according to label directions. 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. Offer for recycling, if available 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.

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. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.
- Both Dutch Trig® and Tree Inoculation tool to be used for inoculation of American elms only!
- Keep product and inoculation tool out of reach of children. The inoculation tool is NOT a toy.
- Avoid treating trees in the proximity of crops susceptible to *Verticillium* without the consent of the grower due to the unknown possibility that treated trees may produce infectious inoculum.

(Continued on opposite panel)

ACTIVE INGREDIENT:
Verticillium isolate WCS850* 1.0%

OTHER INGREDIENT:
Distilled water** 99.0%

TOTAL 100.0%

*Product contains at least 8.0 x 10⁶ conidia per ml of formulated product
**H₂O only, distilled, inert, non-reactive, and free of other bacterial or fungal microbes until seal is broken

EPA Reg. No. 83170-1 EPA Est. No. 83793-NLD-001

STOP-READ THE LABEL BEFORE USE

KEEP OUT OF REACH OF CHILDREN CAUTION - AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

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.
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.
Important: Have the product container or label with you when calling a doctor or going for treatment.

Read directions for use and additional precautionary statements before use.

Manufactured for:

Tree Care Innovations LLC
12510 Prosperity Drive., Suite 160
Silver Spring, MD 20904

Net Contents per vial: 40 ml

Injector sold separately.

(Directions for Use Cont.) GENERAL INFORMATION

- Dutch Trig® contains conidiospores of the hyaline form of *Verticillium* isolate WCS 850. Dutch Trig® is a biological treatment used to prevent Dutch elm disease based on the process of optimizing the tree's natural mechanisms to stop a Dutch elm disease (DED) infection, called induced resistance.
- Dutch Trig® is injected in the trunk of the elm in the early spring after bud break with the Tree Care Innovations gouge pistol. The Tree Care Innovations gouge pistol is the closed system in which spores of *Verticillium* - isolate WCS 850 are injected from the sealed vial into the trunk of an elm. The vaccine induces the tree's immune system to respond; there is no direct interaction between the DED fungus and Dutch Trig® of any kind.

APPLICATION INSTRUCTIONS

GENERAL: • Keep Dutch Trig® refrigerated at 33° to 40° F from receipt until shortly before use. • Transport Dutch Trig® in a portable refrigerator to the treatment location. • Application of Dutch Trig® may only be executed with Tree Care Innovations gouge pistol. • Only inject healthy elm trees which show no signs of Dutch elm disease for Dutch Trig® has no curative properties.

TREATMENT: • Remove the plastic cap of the vial. • Place aluminum cap with silicone membrane on the vial. Shake vial gently before use. • Load the vial containing Dutch Trig® into the injector. • Place one injection every 10 cm (approximately 4 inches) of tree circumference. Make injections in the bark fissures. • Make the injections at a comfortable waist height. • Push the chisel through the bark with the tip pointing downwards under a slight angle (see picture) up to the point where resistance is encountered (xylem tissue). Do not push the chisel further into the tree. • Inject one drop of product with one slow and full pull of the trigger. The total volume depends on tree size. • Twist the gun slightly sideways to create an opening. The vaccine will be sucked into the tree through the xylem tissue. • Clean the chisel with rubbing alcohol when moving from site to site to prevent the possible spread of other diseases.

TIMING: • Injections must be made after bud break but before full leaf. • Only inject if there is uptake of the liquid into the tree. • Inject during daytime. • Do not inject when it is raining.

STORAGE STABILITY: • Do not use Dutch Trig® after the expiration date (see exp. date on vial). • When a vial has been opened for use, continue to keep cool between treatments and during storage. Once opened, use all product within 24 hours. If opened vial is not refrigerated, use contents within 8 hours. • The contents of the vial should appear clear. If a whitish growth or other discoloration appears, do not use.

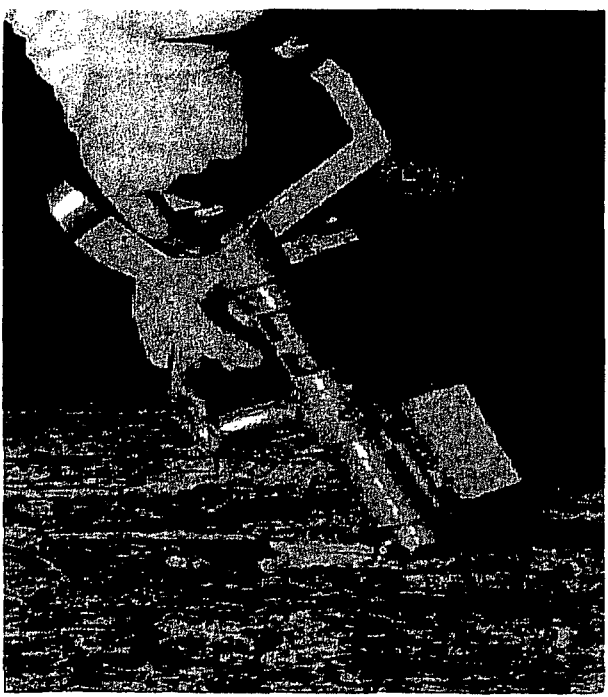
NOTES: • Dutch elm disease control is most effective when Dutch Trig® is used in conjunction with other cultural practices recommended for prevention (checking trees for symptoms during the growing season, removal of dead and diseased elm trees and severing of root grafts between healthy and infected trees). • The Dutch Trig® treatment provides protection against Dutch elm disease for the current year only. • To ensure ongoing protection, repeat application every year. • Dutch Trig® has no curative properties and will not cure trees that are already infected.

WARRANTY - Seller makes no warranty, express or implied, of merchantability, fitness or otherwise concerning the use of this product other than indicated on the label. User assumes all risks of use, storage, or handling not in strict accordance with label instructions.

83170-1315A

SECRETARY OF DEFENSE
WASHINGTON, D.C. 20301
OFFICE OF THE SECRETARY
ATTENTION: [illegible]

DATE: [illegible]



[Small container label]

Dutch Trig®

ACTIVE INGREDIENT:
Verticillium isolate WCS850* 1.0%
OTHER INGREDIENT
Distilled water 99.0%
TOTAL 100.0%
*Product contains at least 8.0×10^8 conidia per ml of formulated product

CAUTION

Keep Out of Reach of Children

EPA Reg. No. 83170-1
EPA Est. No. 83793-NLD-001

See Box Label for Precautionary Statements and Complete Directions for Use

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