

83170-1

6/1/2010

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

JUN 01 2010

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

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

RE: Product Name: Dutch Trig®  
EPA Reg. No: 83170-1  
Application for Notification Dated: March 18, 2010 to update the Storage and  
and Disposal container statement as per PRN 98-10 and PR Notice 2007-4.

Dear Mr. Jones,

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticides Registration Notice (PRN) 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PRN 98-10 and it has been determined that the action(s) requested falls within the scope of PRN 98-10. Our records have been duly noted, and the label submitted with this application has been stamped as "Notification, received and accepted" and will be placed accordingly in our records.

Questions concerning this action should be directed to Mary Paden (703) 308-0411 or email at [paden.mary@epa.gov](mailto:paden.mary@epa.gov).

Sincerely,

*Sheryl K. Reilly*

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

CONCURRENCES

SYMBOL	7511(P)						
SURNAME	Paden						
DATE	01 JUN 10						

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United States Environmental Protection Agency Washington, DC 20460

Registration Amendment Other

OPP Identifier Number NOTIF

Application for Pesticide - Section I

1. Company/Product Number 83170-1
2. EPA Product Manager Sheryl Reilly
3. Proposed Classification
4. Company/Product (Name) Tree Care Innovations LLC / Dutch Trig
5. Name and Address of Applicant Tree Care Innovations LLC c/o Delta Analytical Corp.
6. Expedited Review Notification Accepted Date: 06/01/2010 Reviewer: Mary Baker

Section - II

Amendment - Explain below
Resubmission in response to Agency letter dated
Notification - Explain below
Final printed labels in response to Agency letter dated
Me Too Application
Other - explain below

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification per PR Notice 2007-4 to update the Storage and Disposal language.

Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156.

Section - III

1. Material this Product will be Packaged in:
Child-Resistant Packaging
Unit Packaging
Water Soluble Packaging
2. Type of Container
3. Location of Net Contents Information
4. Size(s) of Retail Container
5. Location of Label Direction
6. Manner In Which Label Is Affixed to Product

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)
Name: Jeff Jones
Title: Agent
Tree Care Innovations LLC
Telephone No.: 301-680-7971

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any kind of knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature: Jeff Jones
3. Title: Agent Tree Care Innovations LLC
4. Typed Name: Jeff Jones
5. Date: March 18, 2010
6. Date Application Received (Stamped)

3015



March 18, 2010

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7511P)  
Environmental Protection Agency  
One Potomac Yard  
2777 S. Crystal Drive, Room S-4900  
Arlington, VA 22202

Attn: Sheryl Reilly, BPPD

**Re: Notification per PR Notice 2007-4 to update Storage and Disposal statement**  
**Product: Dutch Trig**  
**EPA Reg. No.: 83170-1**  
**Company: Tree Care Innovations LLC**

Dear Ms. Reilly:

On behalf of Tree Care Innovations LLC, I am submitting a notification per PR Notice 2007-4 to update the Storage and Disposal language for the product Dutch Trig, EPA Reg. No. 83170-1.

Revisions to the label include the addition of pesticide product disposal statements taken from the Label Review Manual, Chapter 13 - Storage and Disposal, section V, C, 1, page 17; the addition of container type and reuse statements from PR Notice 2007-4, Appendix B; and a label note regarding the batch code. Since this is a ready to use product, a residue removal statement is not required as indicated in PR Notice 2007-4, section III, B, ii. No other changes have been made to this label.

Enclosures

- EPA form 8570-1
- 1 copy of the label highlighted to show changes

If you have any questions regarding this submission, please contact me at 301-680-7971 or jjones@delta-ac.com.

Sincerely,

Jeff Jones, Agent  
Tree Care Innovations LLC

# DUTCH TRIG®

Notification Accepted

Date: 06/01/2010

Reviewer: Mary Paden

## Biological vaccination for American elms to prevent Dutch elm disease

### For use by Professional Arborists/Applicators

(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.

[label note, not a part of labeling: Product must bear a batch code]

#### 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.

##### Use and 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)

<b>ACTIVE INGREDIENT:</b>	
Verticillium isolate WCS850*	1.0%
<b>OTHER INGREDIENT:</b>	
Distilled water**	99.0%
<b>TOTAL</b>	<b>100.0%</b>

\*Product contains at least 8.0 x 10<sup>6</sup> conidia per ml of formulated product  
 \*\*H<sub>2</sub>O 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.

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

Net Contents per vial: 40 ml

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