

DOCUMENT SCAN CONTROL SHEET

Document ID 514347

DAY AFTER APPLICATION SWIMMING  
RESTRICTION

**PLEASE REFER TO LETTERS THAT  
FOLLOW LABEL IMAGE**

EPA # SLN NY-080003

EPA #  
For SLN 70506-175

Product HYDROTHOL 191 AQUATIC ALGICIDE AND HERBICIDE (DAY AFTER  
Name APPLICATION SWIMMING RESTRICTION) (EPA REG. NO. 70506-175)

Accepted  
Date 3/28/2008

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# Special Local Need

FOR DISTRIBUTION AND USE ONLY WITHIN THE STATE OF NEW YORK

## HYDROTHOL<sup>®</sup> 191 Aquatic Algicide and Herbicide

EPA Registration Number 70506-175

EPA SLN No. NY-080003

### *"Day After Application" Swimming Restriction*

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Use HYDROTHOL 191 to control submersed aquatic weeds named on the label in irrigation and drainage canals, ponds and lakes.

**In order to allow for sufficient mixing of this product after application to bodies of water, swimming in the treated area is restricted until the day after application.**

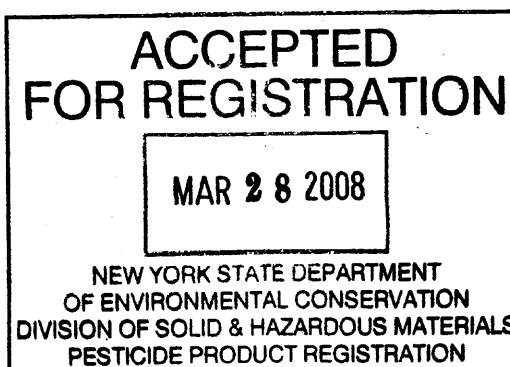
For First Aid and other Precautionary Statements, see the label attached to the container.

All applicable directions, restrictions and precautions on the EPA-registered label are to be followed.

NOTE: This labeling must be in the possession of the user at the time of application.

Rev. 3/19/08

**CLASSIFIED FOR  
"RESTRICTED USE"  
IN NEW YORK STATE  
UNDER 6NYCRR PART 326**



United Phosphorus, Inc.  
630 Freedom Business Center, Suite 402  
King of Prussia, PA 19406  
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1-800-438-6071

Doc ID  
514347

# New York State Department of Environmental Conservation

## Division of Solid & Hazardous Materials

Bureau of Pesticides Management

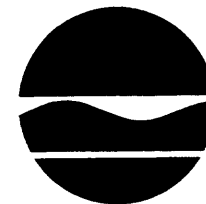
Pesticide Product Registration Section

625 Broadway, Albany, New York 12233-7257

Phone: 518-402-8768 FAX: 518-402-9024

Website: <http://www.dec.ny.gov>

E-Mail: [ppr@gw.dec.state.ny.us](mailto:ppr@gw.dec.state.ny.us)



Alexander B. Grannis  
Commissioner

March 28, 2008

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Ms. Melissa DePro  
Registration Specialist  
United Phosphorus, Inc.  
630 Freedom Business Center, Suite 402  
King of Prussia, Pennsylvania 19406

Dear Ms. DePro:

Re: **Registration of Two New Products Hydrothol 191 Granular Aquatic Algicide and Herbicide (EPA Reg. No. 70506-174) and Hydrothol 191 Aquatic Algicide and Herbicide (EPA Reg. No. 70506-175) Which Represent a Major Change in Labeling for the Active Ingredient Endothall**

The New York State Department of Environmental Conservation (Department) has reviewed your application, received May 22, 2007, and addition information, received September 25, 2007, to register supplemental labels for the currently registered products **Hydrothol 191 Granular** (EPA Reg. No. 4581-172-82695) and **Hydrothol 191** (EPA Reg. No. 4581-174-82695) in New York State. The supplemental labels contain a revised Environmental Hazards Section with the "Do not use fish from treated areas for food or feed within three days after treatment." statement removed. The supplemental labeling represents a major change in labeling for the active ingredient **endothall** (mono(N,N-dimethylalkylamine) salt of endothall) in New York State.

During the course of the review, the products were transferred from Cerexagri-Nisso LLC to United Phosphorus, Inc. and the products were assigned new EPA Registration Numbers. **Hydrothol 191 Granular** is now (EPA Reg. No. 70506-174) and **Hydrothol 191** is now (EPA Reg. No. 70506-175).

The application was deemed complete for purposes of review on November 5, 2007 and the registration decision is due by April 3, 2008.

The New York State Department of Health (DOH) stated that these pesticide products contain the active ingredient endothall and are currently labeled as aquatic herbicides and algicides for use in irrigation and drainage canals, lakes and ponds. The labels contain a revised Environmental Hazards section with the "Do not use fish from treated areas for food or feed within three days after treatment" statement removed.

To support removal of the "Do not use fish..." statement, the registrant submitted a review from the United States Environmental Protection Agency (U.S. EPA) on a magnitude of residue study conducted in finfish, crustaceans and mollusks. In this study, seven replicate tanks containing 19 bluegill sunfish, 28 catfish, 25 crayfish and 10 freshwater clams each were treated with endothall at a target concentration of 5.0 parts per million (ppm). The maximum label treatment rate for lakes and ponds is 3.0 parts per million. Sample organisms were taken from the tanks 2 hours, 12 hours and 1, 2, 3, 5 and 7 days after treatment, and were analyzed for endothall residues. The maximum residue concentrations in these samples were 0.035 ppm in sunfish, 0.23 ppm in crayfish and 0.96 ppm in clams. The concentration in catfish was less than the level of quantification (0.02 ppm). In a separate study, endothall did not show evidence of bioaccumulation in bluegill sunfish kept for a period of 28 days in endothall-treated water.

The U.S. EPA established a tolerance for endothall in fish tissues at 0.1 ppm. The concentration of endothall residues in the fish tested in the magnitude of residue study were lower than this tolerance. The U.S. EPA also developed an acute population adjusted dose (aPAD) and a chronic population adjusted dose (cPAD) to evaluate dietary exposures to endothall residues. The aPAD is 0.05 milligrams per kilogram body weight per day (mg/kg/day) and is based on a no-observed-effect level (NOEL) of 5 mg/kg/day for maternal effects (mortality) in a mouse developmental toxicity study and an uncertainty factor of 100. The more recent, final tolerance announcement for endothall in fish tissues indicates that no aPAD was developed because there were no available appropriate single dose endpoints to serve as a basis. Nevertheless, the DOH used this aPAD to evaluate the risks from a single exposure. The cPAD is 0.007 mg/kg/day and is based on a lowest-observed-effect level (LOEL) of 2.0 mg/kg/day from a rat two-generation reproduction toxicity study (proliferative lesions of gastric epithelium) and an uncertainty factor of 300.

A risk assessment for consumption of endothall residues in fish from treated water bodies was not provided in the registration package. However, dietary risks can be estimated using the maximum tissue concentration from the magnitude of residue study (0.035 ppm) and assuming consumption rates of either a 227-gram (one-half pound) meal for the acute exposures or 33 grams per day for the chronic exposure. For acute exposures, endothall residue ingestion for a 60-kilogram person would be about 380-fold lower than the aPAD. For chronic exposures, endothall residue ingestion for a 70-kilogram person, would be about 420-fold lower than the cPAD.

Consumption of crayfish and freshwater clams from Hydrothol 191 treated water bodies is not likely to be prevalent in New York State. Nevertheless, using the same risk assessment methods as described above for finfish, exposures to endothall from consuming crayfish and clams would range from about 14- to 65-fold lower than the aPAD or cPAD.

According to the registrant, the original fish consumption restriction on endothall-containing product labels was based on study data that demonstrated non-detectable levels of endothall in fish three days after exposure. The study that was used to remove the fish consumption prohibition from the Hydrothol 191 product labels now under consideration provides endothall residue data in fish for time points ranging from 2 hours to 7 days post-exposure. A risk assessment conducted using these residue data indicates that the consumption of fish from treated water bodies is not likely to exceed levels (the aPAD and cPAD) developed to be protective of dietary exposure to endothall. Given the above, the DOH does not object to removal of the label statement prohibiting fish consumption for a period of three days after

treatment of a water body with Hydrothol 191. However, the labels for the Hydrothol 191 products do not contain a swimming restriction, which is required for all Aquathol products (which also contain endothall as an active ingredient and are labeled as aquatic herbicides). The DOH recommends that the "day after application" swimming restriction be required in conjunction with the Hydrothol 191 products as well, in order to reduce the likelihood of eye irritation among swimmers in areas that were recently treated.

In response to the DOH's concerns, United Phosphorus, Inc. has submitted Special Local Need (SLN) labeling which specifies a "Day After Application" swimming restriction in New York State for **Hydrothol 191 Granular Aquatic Algicide and Herbicide** (EPA Reg. No. 70506-174) and **Hydrothol 191 Aquatic Algicide and Herbicide** (EPA Reg. No. 70506-175).

The Department concludes that the use of Hydrothol 191 Granular Aquatic Algicide and Herbicide and Hydrothol 191 Aquatic Algicide and Herbicide should not have an adverse effect on the health of users or the general public of New York State when used in conjunction with the Special Local Need labeling.

Therefore, under the authority of Section 24(c) of FIFRA, the Department hereby grants Special Local Need registrations for **Hydrothol 191 Granular Aquatic Algicide and Herbicide** (EPA Reg. No. 70506-174), assigned the registration number **SLN No. NY-080002**, and **Hydrothol 191 Aquatic Algicide and Herbicide** (EPA Reg. No. 70506-175) assigned the registration number **SLN No. NY-080003**.

The products are registered only in conjunction with the supplemental SLN labeling in New York State. All precautionary statements, applicable use directions, use precautions and limitations of the labeling affixed to the Hydrothol 191 Granular Aquatic Algicide and Herbicide and Hydrothol 191 Aquatic Algicide and Herbicide containers must be followed.

The products, Hydrothol 191 Granular Aquatic Algicide and Herbicide (SLN No. NY-080002) and Hydrothol 191 Aquatic Algicide and Herbicide (SLN No. NY-080003), as noted on the "restriction" column on the certificate, are classified as "restricted use" in New York State under rules and regulations 6NYCRR 326.2(h). As such, these products are restricted in their purchase, distribution, sale, use, and possession in New York State.

According to New York State Department of Environmental Conservation Regulations 6NYCRR 326.3(a): "It shall be unlawful for any person to distribute, sell, offer for sale, purchase for the purpose of resale, or possess for the purpose of resale, any restricted pesticide unless said person shall have applied for, and been issued a commercial permit."

Should you require information to obtain a commercial permit, please contact the Pesticide Reporting & Certification Section, at (518) 402-8748.

The Pesticide Reporting Law (PRL) in the Environmental Conservation Law Article 33 Title 12 requires all certified commercial pesticide applicators to report information annually to the Department regarding each pesticide application they make. **Commercial pesticide retailers are required to report all sales of restricted pesticide products and sales of general use pesticide products to private applicators for use in agricultural crop production.** If no sales are made within New York State, a report still must be filed with the Department indicating this is the case.

If you need information relating to the Pesticide Reporting Law, or annual report forms, please visit the Department's website at <http://www.dec.ny.gov/chemical/27506.html> or call (518) 402-8748.

The Certificate of Pesticide Registration and a copy of the New York State stamped "ACCEPTED" SLN labeling for Hydrothol 191 Granular Aquatic Algicide and Herbicide and Hydrothol 191 Aquatic Algicide and Herbicide are enclosed for your records.

Please be reminded that a copy of the accepted SLN label **must** be distributed with all product sold in New York State and be in the possession of the user at the time of pesticide application.

United Phosphorus, Inc. is reminded that if New York State registration is requested for Hydrothol or for any other product which contains endothall with an increased application rate, different application method and/or expanded use sites, the product will be considered a **Major Change in Labeling and the Department will require an extensive review.**

If you have any questions, please contact Mr. Samuel Jackling, Chief of our Pesticide Product Registration Section, at (518) 402-8768.

Sincerely,



Maureen P. Serafini  
Director  
Bureau of Pesticides Management

Enclosures

cc: w/enc. - R. Mungari - NYS Dept. of Ag. & Markets  
W. Smith - Cornell University, PMEP