

55146-99

12/02/2011

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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
WASHINGTON, DC 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

Christie Hitchcock  
Nufarm Americas, Inc.  
4020 Aerial Center Parkway, Suite 101  
Morrisville, NC 27560

DEC 02 2011

Product Name: Oxytetracycline Calcium Technical  
EPA Reg. No.: 55146-99  
Subject: Application for Pesticide Notification (PRN 98-10) dated 11/1/11  
EPA Decision Number: 457515

Dear Ms. Hitchcock:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10.

The Agency acknowledges the revision of the Storage and Disposal language per PRN 2007-4.

The label submitted with the application has been stamped "Notification" and will be placed in our records. If you have questions concerning this letter, please contact Heather Garvie at 703-308-0034 or me at 703-308-3194.

Sincerely,

A handwritten signature in cursive script, reading "Shaja B. Joyner", is positioned above the typed name.

Shaja B. Joyner  
Product Manager 20  
Fungicide Branch  
Registration Division (7505P)

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United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other:

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number <b>55146-99</b>	2. EPA Product Manager <b>Mary Waller</b>	3. Proposed Classification  <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>Oxytetracline Calcium Technical</b>	PM# <b>21</b>	
5. Name and Address of Applicant (Include ZIP Code) <b>Nufarm Americas Inc. AGT Division</b> <b>4020 Aerial Center Parkway, Suite 101</b> <b>Morrisville, NC 27560</b> <input type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below

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

Notification per PRN 98-10: This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make false statements to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

## Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
*Certification must be submitted			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container Greater than 50 pounds	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other Self-Adhesive label _____	

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name <b>Christie Hitchcock</b>	Title <b>Regulatory Specialist</b>	Telephone No. (Include Area Code) <b>919-379-2534</b>
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Christie Hitchcock</i>	3. Title <b>Regulatory Specialist</b>	
4. Typed Name <b>Christie Hitchcock</b>	4. Date <b>November 1, 2011</b>	



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**NUFARM AMERICAS, INC.**  
4020 Aerial Center Parkway, Suites 101/103  
Morrisville, NC 27560  
Phone: 919-379-2510 ■ Fax: 919-467-5923

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**VIA FEDEX**

November 1, 2011

Document Processing Desk (NOTIF)  
Registration Division (7504P)  
OPP, USEPA  
2777 S. Crystal Drive  
Room S-4900  
Arlington, VA 22202

Attn: Mary Waller, PM 21  
Fungicide Branch

Re: Oxytetracycline Calcium Technical, EPA Reg. No. 55146-99  
Notification per PRN 2007-4

Dear Ms. Waller:

We are notifying the Agency of a label update as allowed in PR Notice 98-10 and PR Notice 2007-4. The changes are the final printed label from the transfer of this product from EPA Reg. No. 100-1176 to EPA Reg. No. 55146-99 on March 3, 2004 and the updated container handling instructions.

In support of this submission, the following documents are attached:

- Application for Pesticide Registration (EPA Form 8570-1)
- One copy of final printed labeling
- One copy of the transfer document dated March 3, 2004.

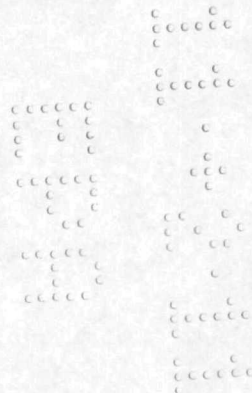
If you have any questions regarding this submission, please contact me at (919) 379-2531 or [Christie.hitchcock@us.nufarm.com](mailto:Christie.hitchcock@us.nufarm.com)

Sincerely,

*Christie Hitchcock*

Christie Hitchcock  
Regulatory Specialist

enclosures





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# OXYTETRACYCLINE CALCIUM TECHNICAL ANTIBIOTIC

## FOR MANUFACTURING USE ONLY

A non-sterile, non-pharmaceutical grade technical antibiotic product intended for formulation into EPA-registered end-use pesticide products.

### ACTIVE INGREDIENT

Oxytetracycline Calcium\* ..... 50.0%

OTHER INGREDIENTS ..... 50.0%

TOTAL..... 100.0%

\*(Equivalent to 96.0% oxytetracycline)

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

SEE BELOW FOR FIRST AID AND ADDITIONAL PRECAUTIONARY STATEMENTS

For Chemical Spill, Leak, Fire, or Exposure, Call CHEMTREC (800) 424-9300  
For Medical Emergencies Only, Call (877) 325-1840

EPA REG. NO. 55146-99  
EPA EST. NO.

MANUFACTURED FOR:  
Nufarm Americas Inc. AGT Division  
150 Harvester Drive  
Burr Ridge, IL 60527

NET CONTENTS: \_\_\_\_\_ Pounds  
[Designation as "NONREFILLABLE" or "REFILLABLE" for containers >5 gals]

**NOTIFICATION**

**DEC 02 2011**

055146-00099.20110111.MASTER (RV011111)

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS  
CAUTION**

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Do not breathe dust. Wear an MSHA/NIOSH approved TC-21C dust filtering respirator, long-sleeved shirt, pants, shoes and chemical resistant gloves while handling this product. Remove contaminated clothing and wash before reuse. Harmful if swallowed or absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

<b>FIRST AID</b>	
<b>IF ON SKIN OR CLOTHING</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>IF SWALLOWED</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>IF IN EYES</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>IF INHALED</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferable mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>HOT LINE NUMBER</b>	
Have the product container or label with you when you call a poison control center, or going for treatment. You may contact 1-877-325-1840 for emergency medical treatment information.	

**ENVIRONMENTAL HAZARDS**

This product may be hazardous to aquatic plants. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters, unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into fungicides for the following crops or uses:

- Pear, peach, nectarine.
- Uses for which US EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration.
- Uses for experimental purposes that are in compliance with US EPA requirements.

Each formulator is responsible for obtaining the EPA registration of his formulated product(s).

For specific information relating to composition, toxicity, methods of formulation and the product's effectiveness, please contact your Nufarm representative.

**STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage, disposal or cleaning of equipment.

**PESTICIDE STORAGE:** Keep container tightly closed and in a dry place. Product is temperature sensitive. Store below 77° F (25° C) with minimum exposure to the atmosphere.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.



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**CONTAINER HANDLING:** [Note to Reviewer: The following statement will be included on all Final Printed Labels bearing multiple Container Disposal (Container Handling) statements] **"NOTE:** This product is available in multiple containers. Refer to the Net Contents section of this products labeling for the applicable "Nonrefillable" or "Refillable" designation. Follow the container handling instructions below that apply to your container type/size."

**Nonrefillable Containers:**

**For Paper and Plastic Bags:** Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling, if available, or dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

**For Fiber Drums with Liners:** Nonrefillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into manufacturing or application equipment. Then offer for recycling, if available, or dispose of liner in a sanitary landfill or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

**Refillable container greater than 50 pounds:** Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10% full with water. Agitate vigorously or recirculate water with the pump for two minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling if available, or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

**WARRANTY DISCLAIMER**

The directions for use of this product must be followed carefully. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, (1) THE GOODS DELIVERED TO YOU ARE FURNISHED "AS IS" BY MANUFACTURER OR SELLER AND (2) MANUFACTURER AND SELLER MAKE NO WARRANTIES, GUARANTEES, OR REPRESENTATIONS OF ANY KIND TO BUYER OR USER, EITHER EXPRESS OR IMPLIED, OR BY USAGE OF TRADE, STATUTORY OR OTHERWISE, WITH REGARD TO THE PRODUCT SOLD, INCLUDING, BUT NOT LIMITED TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, USE, OR ELIGIBILITY OF THE PRODUCT FOR ANY PARTICULAR TRADE USAGE. UNINTENDED CONSEQUENCES, INCLUDING BUT NOT LIMITED TO INEFFECTIVENESS, MAY RESULT BECAUSE OF SUCH FACTORS AS THE PRESENCE OR ABSENCE OF OTHER MATERIALS USED IN COMBINATION WITH THE GOODS, OR THE MANNER OF USE OR APPLICATION, INCLUDING WEATHER, ALL OF WHICH ARE BEYOND THE CONTROL OF MANUFACTURER OR SELLER AND ASSUMED BY BUYER OR USER. THIS WRITING CONTAINS ALL OF THE REPRESENTATIONS AND AGREEMENTS BETWEEN BUYER, MANUFACTURER AND SELLER, AND NO PERSON OR AGENT OF MANUFACTURER OR SELLER HAS ANY AUTHORITY TO MAKE ANY REPRESENTATION OR WARRANTY OR AGREEMENT RELATING IN ANY WAY TO THESE GOODS.

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If you do not agree with or do not accept any of directions for use, the warranty disclaimers, or limitations on liability, do not use the product, and return it unopened to the Seller, and the purchase price will be refunded.

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