



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 3, 2022

Danielle Larochelle
Regulatory Manager
Nufarm Limited
c/o Nufarm Americas, Inc., Agent
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560

Subject: PRIA Label Amendment: Oxytetracycline- Additional Time-limited Use on
Citrus Crop Group 10-10 expiring 12/4/2025; PRIA Category R352
Product Name: Calcium Oxytetracycline Technical (86%)
EPA Registration Number: 35935-113
Application Date: April 15, 2021
Decision Number: 573376

Dear Danielle Larochelle:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable under FIFRA sec 3(c)(5) for a limited period of time. The citrus uses being granted in this amendment will automatically expire 12/4/2025. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

- 1) Resistance Management Plan implementation (e.g. education/training and stewardship plan). A yearly summary report describing the Resistance Management Plan implementation details must be submitted to the Registration Division by December 31st of each year for confirmatory purposes.
- 2) Annual sales reports listed by state, submitted by Nufarm Limited to the Registration Division by December 31st of each year.
- 3) Any end-use products formulated from this technical product will also be subject to the following terms:
 - a. You must submit protocol submissions describing how you plan to monitor both soil and citrus foliage for incidences of antibiotic resistance on a yearly basis for 3 years of this new use amendment on Citrus Crop Group 10-10. The protocol submission to the Registration Division must be made 3 months prior to each use season to allow for Agency review prior to start of monitoring. The first protocol submission is due by September 30, 2022.
 - b. Annual monitoring report submissions by December 31st of each year starting in 2022.
- 4) One year prior to expiration, if you choose to seek an extension or remove the time limitation for the Citrus Crop Group 10-10 use, you are required to submit an application for amendment along with a revised assessment on the development of oxytetracycline

resistance in human pathogens addressing release, exposure, consequence assessments and overall risk estimation with regard to public health effects resulting from cumulative usage of oxytetracycline on all citrus crops in all states where it is registered and used. The Agency will consult with the federal partners to reevaluate the current risk picture for oxytetracycline prior to extending or removing the time limitation on citrus, or allowing the use to expire.

- 5) If the Agency determines it will not be able to grant an extension or remove the time-limitation, the Agency will notify you by 2 months prior to the use expiring. Upon notification, you must submit revised labeling with the Citrus Crop Group 10-10 use removed by 1 month prior to expiration.
- 6) You must submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these terms. If you have any questions, please contact Stephanie Suarez by phone at 202-566-2918, or via email at Suarez.Stephanie@epa.gov.



Nathan Mellor, Product Manager 21
Fungicide Branch
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

Calcium Oxytetracycline Technical (86%)

AGRICULTURAL ANTIBIOTIC/BACTERICIDE - FOR MANUFACTURING USE ONLY

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

ACTIVE INGREDIENT

Calcium Oxytetracycline* 86.0%

OTHER INGREDIENTS 14.0%

TOTAL..... 100.0%

*Equivalent to 82.6% Oxytetracycline

KEEP OUT OF REACH OF CHILDREN

CAUTION

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

EPA Reg. No. 35935-113

EPA Est. No. _____

Manufactured for
NUFARM LIMITED
4020 Aerial Center Parkway
Morrisville, NC 27560



NET WEIGHT: _____ LB (_____ KG)

035935-00113.20210415.Add Use_Citrus

ACCEPTED

06/03/2022

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under

EPA Reg. No. 35935-113

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

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if absorbed through skin or swallowed. Avoid contact with skin, eyes, or clothing. Do not breathe dust. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wear a NIOSH approved particulate respirator with any N, R or P filter with NIOSH approval number prefix TC-84A or a NIOSH approved powered air purifying respirator with HE filter with NIOSH approval number prefix TC-21C, long-sleeved shirt, pants, shoes and chemical resistant gloves while handling this product. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling.

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.

For formulating only into antibiotic/bactericide end-use products for the following uses:

- Apple;
- Citrus Fruit Crop Group 10-10;
- Pear;
- Peach, Nectarine.
- Uses for which the U.S. 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 U.S. 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 or disposal.

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.

CONTAINER HANDLING:

[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.

[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.

[Plastic Drums with capacities equal to or less than 50 lb:] Nonrefillable Container. Do not reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. **Triple rinse as follows:** Empty the remaining contents in manufacturing equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into manufacturing equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. **Pressure rinse as follows:** Empty the remaining contents into manufacturing equipment and drain for 10 seconds after the flow begins to drip. Hold container upside down over manufacturing equipment or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip. Then offer for recycling, if available, or puncture and dispose of in an approved sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

[Plastic Drums with capacities greater than 50 lb:] Nonrefillable Container. Do not reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. **Triple rinse as follows:** Empty the remaining contents into manufacturing equipment. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into manufacturing equipment, or store rinsate for later use or disposal. Repeat this procedure two more times. **Pressure rinse as follows:** Empty the remaining contents into manufacturing equipment and drain for 10 seconds after the flow begins to drip. Hold container upside down over manufacturing equipment or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip. Then offer for recycling, if available, or puncture and dispose of in an approved sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke..

WARRANTY DISCLAIMER AND LIMITATION OF LIABILITY

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. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BUYER'S OR USER'S EXCLUSIVE REMEDY, AND MANUFACTURER'S OR SELLER'S TOTAL LIABILITY SHALL BE FOR DAMAGES NOT EXCEEDING THE COST OF THE PRODUCT.

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

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