

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 4, 2018

James Messina Agent for Geologic Corporation C/O Exponent LLC 1150 Connecticut Ave., NW Suite 1100 Washington, DC 20036

Subject: PRIA Label Amendment – Oxytetracycline- New Time-Limited Uses on Citrus Crop Group 10-10 expiring 12/4/2025 Product Name: EAC Oxytetracycline Manufacturing Use Product EPA Registration Number: 71185-5 Application Date: 10/23/2015 Decision Number: 510560

Dear Mr. Messina:

The application referred to above, submitted 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 new uses being granted in this amendment will automatically expire 12/4/2025. The following terms apply:

- 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.
- 2) If the Agency determines it will not be able to grant an extension or remove the timelimitation, 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.
- 3) You must submit and/or cite all data required for registration/registration/registration review of your product when the Agency requires all registrants of similar products to submit such data.

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A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) 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 Hope Johnson by phone at 703-305-5410, or via email at johnson.hope@epa.gov.

Sincerely,

Cynthia Giles-Parker, Chief Fungicide Branch Registration Division (7505P) Office of Pesticide Programs

Enclosure

# EAC<sup>™</sup> Oxytetracycline Manufacturing Use Product

This material is a non-sterile, nonpharmaceutical grade, manufacturing use antibiotic/fungicide/bactericide product for formulation into EPA-registered end-use pesticide products.

#### Not for Resale Under This Label

#### **Active Ingredient:**

Oxytetracycline Hydrochloride*	98.30%
Related Compounds	0.92%
Other Ingredients:	<u>0.78</u> %
-	100.00%
* Equivalent to a minimum of 83.5% oxy	/tetracycline

### EPA Reg. No. 71185-5 EPA Est. No. xxxxxxxx

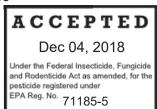
medical treatment information.

# KEEP OUT OF THE REACH OF CHILDREN DANGER

FIRST AID		
If In Eyes:	<ul> <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.</li> <li>Call a poison control center or doctor immediately for treatment advice.</li> </ul>	
If On Skin or Clothing:	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> </ul>	
	<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> </ul>	
HOT LINE NUMBER		
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact InfoTrac at 1-800-535-5053 for emergency		

#### NET CONTENT: XXXX

Geo Logic Corporation P. O. Box 3091 Tequesta, FL 33469



### PRECAUTIONARY STATEMENTS Hazards to Humans & Domestic Animals

**DANGER:** Corrosive. Causes irreversible eye damage. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield or safety glasses). May cause allergic skin reactions. Do not breathe dust. Wear dust mask and rubber gloves. Wash thoroughly with soap and water after handling and before eating drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. This material is not to be used for medical, veterinary or human purposes.

#### **Environmental Hazards**

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.

This manufacturing use product is for use as an active ingredient to be formulated into end-use antibiotic/fungicide/bactericide products. The manufacturer of such products shall be responsible for registering its product with EPA as a pesticide for acceptable use patterns.

Only for formulation into an antibiotic/fungicide/bactericide for the following uses:

Terrestrial Crops – Nectarine, Peach, Pear, Apple, Citrus Crop Group 10-10 (Australian desert lime; Australian finger-lime; Australian round lime; Brown River finger lime; calamondin; citron; citrus hybrids; grapefruit; Japanese summer grapefruit; kumquat; lemon; lime; Mediterranean mandarin; mount white lime; New Guinea wild lime; sour orange; sweet orange; pummelo; Russell River lime; satsuma mandarin; sweet lime; tachibana orange; Tahiti lime; tangelo; tangerine (mandarin); tangor; trifoliate orange; uniq fruit; cultivars, varieties, and/or hybrids of these).

Terrestrial Non-Food Non-Agricultural Uses – Ornamentals non-crop bearing trees, woody shrubs and palms

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product.

#### Storage & Disposal

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

**Storage:** Keep container tightly closed and sealed. Product is moisture, temperature and light sensitive. Product is hygroscopic so protect from moisture. Store in a cool (<77°F, 25°C), dry place away from heat and open flames with minimum exposure to the atmosphere. Avoid extremes in temperature.

**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: Nonrefillable Container. Fiber Drums with Liners – DO NOT reuse or refill this container. Completely empty paper or plastic bag, fiber sack or drum liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulating manufacturing or equipment. Then offer for recycling if available or dispose of empty paper or plastic bag, fiber sack or fiber drum and liner in a sanitary landfill, or by incineration. DO NOT burn, unless allowed by State and local ordinances.

**Container Handling: Refillable Container.** Refill this container with pesticide only. Do not reuse the 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 completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into the formulation equipment. Return to supplier when empty.

#### Conditions of Sale and Limitation of Warranty and Liability

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials, resistant strains or other influencing factors in the use of the product, which are beyond the control of GEO LOGIC CORP. or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold GEO LOGIC CORP. and Seller harmless for any claims relating to such factors.

GEO LOGIC CORP. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or GEO LOGIC CORP., and Buyer and User assume the risk of any such use. GEO LOGIC CORP. MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

In no event shall GEO LOGIC CORP. or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF GEO LOGIC CORP. AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF GEO LOGIC CORP. OR SELLER, THE REPLACEMENT OF THE PRODUCT.

GEO LOGIC CORP. and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of GEO LOGIC CORP.