



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 30, 2020

Danielle A. Larochelle
Regulatory Manager
Nufarm Americas Inc.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560

Subject: Label Amendment – revised supplemental label extending the expiration date to 6/15/21
Product Name: Mycoshield®
EPA Registration Number: 55146-97
Application Date: 11/16/20
Decision Number: 568120

Dear Ms. Larochelle:

The amended supplemental label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your supplemental labeling is enclosed for your records. This supplemental labeling supersedes all previously accepted supplemental 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.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Heather A. Garvie by phone at 703-308-0034, or via email at garvie.heather@epa.gov.

Sincerely,



Sandip Chattopadhyay, Ph.D.
Acting Product Manager 21, Fungicide Branch (7505P)
Office of Pesticide Programs

Enclosure - stamped "accepted" label



Supplemental Label

ACCEPTED

11/30/2020

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 55146-97

Mycoshield®

Agricultural Antibiotic/Bactericide

EPA Reg. No.: 55146-97

OXYTETRACYCLINE

GROUP

41

FUNGICIDE

This supplemental label expires June 15, 2021, and must not be used or distributed after this date

SUPPLEMENTAL LABEL TO ADD DIRECTIONS FOR USE

Use on Citrus Fruit Crop Group 10-10
for Suppression of Huanglongbing (HLB) and Citrus Canker

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING. THIS LABELING MUST BE IN THE POSSESSION OF THE USER AT THE TIME OF APPLICATION. READ THE LABEL AFFIXED TO THE CONTAINER FOR MYCOSHIELD BEFORE APPLYING. CAREFULLY FOLLOW ALL PRECAUTIONS, LIMITATIONS, AND APPLICABLE USE DIRECTIONS.

ACTIVE INGREDIENT:

Calcium Oxytetracycline † 17.7%

OTHER INGREDIENTS: 82.3%

TOTAL: 100.0%

† Equivalent to 17% Oxytetracycline

KEEP OUT OF REACH OF CHILDREN WARNING / 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.)

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

PRECAUTIONARY STATEMENTS

The following PPE information supersedes the PPE on the label affixed to the container.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

All applicators and other handlers must wear a minimum of:

- Coveralls over short-sleeved shirt and short pants
- Chemical-resistant gloves
- Shoes and socks
- Protective eyewear (goggles, safety glasses, or face shield)
- NIOSH approved particulate filtering facepiece respirator with any N, R or P filter (TC-84A); OR an elastomeric NIOSH approved particulate respirator with any N, R or P filter (TC-84A); OR a NIOSH approved powered air purifying respirator with an HE filter (TC-21C). Higher level respirators that are NIOSH approved for particulates that contain oil may also be used.

Applicators must also wear:

- Chemical-resistant headgear ensuring full coverage of the neck.

PERSONAL PROTECTIVE EQUIPMENT (PPE) (Continued)

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables are available, use detergent and hot water. Keep and wash PPE separately from other laundry.

Applicators do not have to wear the protective eyewear, chemical-resistant gloves, chemical-resistant headgear, or a respirator when using closed cab systems that meet the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.607(e)].

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the WPS for agricultural pesticides [40 CFR 170.607(d) and (e)], the handler PPE requirements may be reduced or modified as specified in the WPS.

DIRECTIONS FOR USE

RESISTANCE MANAGEMENT

Mycoshield contains oxytetracycline, a Group 41 antibiotic/bactericide/fungicide. Bacterial strains/fungal isolates with acquired resistance to Group 41 may eventually dominate the bacterial/fungal population if Group 41 bactericides/fungicides are used repeatedly in the same field or in successive years as the primary method of control for targeted species. This may result in partial or total loss of control of those species by Mycoshield or other Group 41 products.

To delay antibiotic/fungicide/bactericide resistance, take one or more of the following steps:

- Use only the specified and full-strength application rates.
- The mode of action for oxytetracycline is the inhibition of protein synthesis. This product should be used to treat or prevent infections that are proven or strongly suspected to be caused by the indicated target bacteria. To reduce likelihood of bacteria developing resistance to oxytetracycline, follow the crop specific resistance management and use direction information present on this labeling. Use of this product should conform to resistance management practices/strategies established for the crop and use area (for example, the use of IPM, disease forecasting models, resistant crop varieties, etc.). Consult your local extension/crop consultant or state agricultural authority if reduced efficacy is suspected.
- Adopt an integrated disease management program that includes scouting, uses historical information related to pesticide use, and crop rotation, and which considers host plant resistance, impact of environmental conditions on disease development, disease thresholds, as well as cultural, biological and other chemical control practices.
- Where possible, make use of predictive disease models to effectively time applications.
- Avoid the consecutive use of Mycoshield or other target site of action Group 41 products that have a similar target site of action, on the same pathogens.
- Use tank-mixtures or premixes with products from different target site of action Groups as long as the involved products are all registered for the same use and are both effective at the tank mix or prepack rate on the pathogen(s) of concern. Do not use any product that has a prohibition on tank mixing and follow the more restrictive use directions.
- When feasible, Mycoshield should be alternated with a comparable bactericide with a different mode of action.
- Base use on a comprehensive IPM program.
- Monitor treated bacterial/fungal populations for loss of field efficacy.
- Contact your local extension specialist, certified crop advisors, and/or manufacturer for fungicide/bactericide resistance management and/or IPM recommendations for specific crops and resistant pathogens.
- For further information or to report suspected resistance contact Nufarm Americas Inc. at (855) 280-6609.

SPRAY DRIFT PRECAUTION - ALL USES

- To help reduce off-target drift, direct spray into the canopy, and turn off outward pointing nozzles at row ends and when spraying outer rows.

APPLICATION RESTRICTIONS – ALL USES

- Not to be used for medical, veterinary, or human purposes.
- Not for residential use.
- Animal grazing in treated areas is prohibited. The public must be notified by posting restriction signs along the perimeter of the treatment area.
- Do not apply oxytetracycline in orchards in which the soil has been fertilized with animal waste/manure or human biosolids.
- When alternatives are available, do not apply more than two consecutive applications before alternating with another fungicide/bactericide of a different mode of action.
- Do not apply this product by aerial application.
- Do not apply this product through any type of irrigation system, including chemigation.
- Use only the specified and full-strength application rates.

APPLICATION INFORMATION

For best results, apply this product using an airblast sprayer with enough water to provide full coverage. Thorough coverage is essential.

CROP USE DIRECTIONS

CITRUS FRUIT, 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; orange, sour; orange, sweet; pummelo; Russell River lime; satsuma mandarin; sweet lime; tachibana orange; Tahiti lime; tangelo; tangerine (mandarin); tangor; trifoliolate orange; uniq fruit; cultivars, varieties, and/or hybrids of these

DISEASE	PRODUCT USE RATE PER ACRE	APPLICATION INSTRUCTIONS
<p>Huanglongbing (HLB) (<i>Candidatus Liberibacter asiaticus</i> or CLas)</p> <p>Also known as “citrus greening” or “greening disease”</p> <p>(Suppression of foliar infections)</p>	<p>1.5 lb (equivalent to 0.255 lb oxytetracycline free base)</p>	<p>Apply as a foliar spray using sufficient carrier volume to ensure complete coverage. Use with spray adjuvant, spreader sticking agent, or horticultural oil.</p> <p><u>Make first application</u> at initiation of spring flush to suppress HLB titer and disease symptoms.</p> <p><u>Make a second application</u> mid-summer (not less than 21 days after first application).</p> <p><u>Make a third application</u> in late summer to reduce the incidence of HLB-induced fruit drop and to further suppress HLB titer and disease symptoms (not less than 21 days after second application).</p>
<p>Citrus Canker (<i>Xanthomonas citri</i> pv. <i>citri</i>)</p>	<p>1.5 lb (equivalent to 0.255 lb oxytetracycline free base)</p>	<p>Apply as a foliar spray using sufficient carrier volume to ensure complete coverage. Use with spray adjuvant, spreader sticking agent, or horticultural oil.</p> <p><u>Make first application</u> when spring flush is approximately 75% expanded to protect new growth from canker infection.</p> <p><u>Make a second application</u> in summer when weather conditions warrant during periods of high citrus canker risk (not less than 21 days after first application).</p> <p><u>Make a third application</u> in late summer to reduce the incidence of canker-induced fruit drop (not less than 21 days after first application).</p>

RESTRICTIONS

- Do not apply more than 1.5 lb of product (0.255 lb oxytetracycline free base) per acre per application.
- Do not apply more than 4.5 lb of product (0.77 lb oxytetracycline free base) per acre per year.
- Maximum number of applications per year: 3
- Minimum retreatment interval: 21 days
- Do not apply within 40 days of harvest.
- Use only the full-strength application rate.
- Follow Application Restrictions – All Uses.

NOTICE

Read the "WARRANTY DISCLAIMER" and "LIMITATION OF LIABILITY" in the label booklet for this product before using this product. Those terms apply to this supplemental labeling and if those terms are not acceptable, return the product unopened at once.

**Manufactured for NUFARM AMERICAS INC. AGT DIVISION
11901 S. Austin Avenue, Alsip, IL 60803**