



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Ted Head
Product Registration Manager
NUFARM Americas Inc.
AGT Division
133 Burr Ridge Parkway, Suite 125A
Burr Ridge, IL 60527

OCT 30 2007

Subject: Mycoshield
EPA Registration No. 55146-97
Your Amendment dated June 2, 2004: Adding the new use for apples
PRIA Decision No. 346137

Dear Mr. Head:

The labeling referred to above, submitted in connection with registration under section under 3(c)(7)(b) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) is acceptable provided the following conditions are met:

Label Revisions:

1. Within the "Directions For Use" section add the following sentences: "This product contains the antibiotic oxytetracycline. To reduce the development of drug-resistant bacteria and maintain the effectiveness of this and other antibacterial products, this product should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria."

"This material is not to be used for medical or veterinary purposes."

Data Requirements:

1. You must satisfy all data requirements identified in the June 2006 Tolerance Reassessment Decision (TRED).
2. Pursuant to section 408(f)(1) of FFDCA within 5 years, you must provide data demonstrating that the anticipated residues used for risk assessment purposes did not underestimate the residue levels found in food. This data must be submitted by no later than 5 years from the date of registration.

One copy of the label stamped "Accepted with comments" is enclosed for your records. Please submit one copy of the final printed label that incorporates the required changes before the product is released for shipment. If you have any questions, please contact Tamue L. Gibson by phone at (703) 305-9096 or via email at gibson.tamue@epa.gov

Sincerely,



Mary L. Waller
Product Manager (21)
Fungicide Branch
Registration Division (7505P)

Enclosure

Mycoshield®

FOR THE CONTROL OF FIRE BLIGHT OF PEAR AND APPLE AND
BACTERIAL SPOT OF PEACH AND NECTARINE

ACTIVE INGREDIENT:

Oxytetracycline Calcium complex:
(Equivalent to 17% oxytetracycline)

31.5%

OTHER INGREDIENTS:

68.5%

TOTAL: 100.0%

**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.)

SEE INSIDE BOOKLET 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. 55146-97
EPA EST. NO. 67545-AZ-1

MANUFACTURED FOR
NUFARM AMERICAS INC.
AGT DIVISION
150 HARVESTER DRIVE
BURR RIDGE, IL 60527



NET WEIGHT: 2.0 POUNDS

055146-00097.20071026.apples

**ACCEPTED
with COMMENTS
In EPA Letter Dated:**

10/30/07

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

55146-97

FIRST AID	
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 eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • 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.
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 do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
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 1-877-325-1840 for emergency medical treatment information.	

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING / AVISO**

Causes substantial but temporary eye injury. Harmful if absorbed through skin. Do not get in eyes, on skin, or on clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material
- Shoes plus socks
- Protective eyewear.

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, use detergent and hot water. Keep and wash PPE separately from other laundry.

Engineering Controls Statement

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d) (4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users Should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the high water mark. Do not contaminate water when disposing of equipment washwater.

DIRECTIONS FOR USE

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

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves made of any waterproof material
- Shoes plus socks
- Protective eyewear

CHEMIGATION

Do not apply this product through any type of irrigation system.

APPLICATION PROCEDURES

The recommended method of application of Mycoshield is by airblast sprayer with enough water to provide full coverage. Thorough coverage is essential.

MIXING PROCEDURES

MIXING:

To avoid possible pesticide contamination use only clean metal or plastic containers in preparing all solutions.

CONCENTRATION DESIRED	QUANTITY MYCOSHIELD PER VOLUME OF WATER		
	50 gals.	100 gals.	500 gals.
ppm*			
150	6 oz.	12 oz.	3-3/4 lbs.
200	8 oz. (1/2 lb.)	16 oz. (1 lb.)	5 lbs.

*ppm = parts per million oxytetracycline base in prepared solution.

CROP USE DIRECTIONS

Use of predictive models for fire blight threshold treatment conditions is recommended and encouraged to minimize the number of applications of this product. Thorough spray coverage is essential.

CROP	DISEASES CONTROLLED	USE RATE	COMMENTS
Pears	Fire Blight (<i>Erwinia amylovora</i>)	200 ppm per acre in 50 - 150 gals. solution per acre which is equivalent to: • 0.50 lb. Mycoshield/ 50 gals. water or • 1.0 lb. Mycoshield/ 100 gals. water	Begin applications at 10% bloom and repeat on 4-6 day interval. Use of this product may cause phytotoxicity to the fruit and/or foliage or sensitive varieties, especially Asian varieties. Do not apply more than 10 applications per year. Do not apply more than 1.0 lb. Mycoshield per acre. Do not apply within 60 days of harvest.
Peaches and Nectarines	Bacterial Spot (<i>Xanthomonas campestris pv. pruni</i>)	• 0.75-1.5 lbs. per 50-200 gals. water per acre	Apply on a weekly application schedule beginning at petal fall (<5% shuck split) through first cover. After first cover, interval can be extended 7-10 days depending on weather conditions. The higher rate is recommended early in the season and during periods conducive for disease. Use a pressure sprayer capable of delivering the spray at least 250 lbs. pressure per square inch through a hand-held single nozzle gun, or 150 lbs. pressure per square inch using an airblast sprayer. For best results with airblast sprayer, do not exceed 3 miles per hour ground speed or 100 miles per hour spray velocity. Do not apply within 3 weeks of harvest. Do not apply more than 12 lbs. product per acre per year.
Apples	Fire Blight (<i>Erwinia amylovora</i>)	Ground Application: Apply a 200 ppm solution per acre which is equivalent to: • 0.50 lb. Mycoshield/ 50 gals. water Aerial Application: • 1.0 lb. Mycoshield/ 100 gals. water	Ground Application: Apply using air-blast sprayer. Ensure good coverage of plant parts. A maximum of 5 applications may be made. Apply beginning with 10% bloom and continue at 3-6 day intervals, or apply when blight favorable weather is expected during apple bloom. Aerial Application: Application by air is not a direct replacement for applications by ground. Begin spray application at 10% bloom and continue at 3-6 day intervals, or apply when blight favorable weather is expected during apple bloom. Spray coverage of blossoms is essential. Restrictions: DO NOT apply more than a total of 5 applications of oxytetracycline per acre per year using either ground or aerial methods of application. DO NOT apply within 60 days of harvest. DO NOT apply more than 1.0 lb. of product per acre per application. DO NOT use treated crop or by products for feed. DO NOT allow livestock to graze on treated orchards.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited.

PESTICIDE STORAGE: Store in original containers in a cool, dry place. Keep container closed when not in use. Do not store near food or feed. In case of spill on floor or paved surfaces, mop and remove to chemical waste storage area until proper disposal can be made if product cannot be used according to the label.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative of the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL:

Plastic Containers: Triple rinse (or equivalent); then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or alternatives allowed by State and local authorities.

Paper Bags: Completely empty bags into application equipment. Then dispose of empty bag in a sanitary landfill or alternatives allowed by state and local authorities.

Fiber Drums with Liners: Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or alternatives allowed by State and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

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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