



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 26, 2016

Nathan P. Ehresman
Nufarm Americas Inc.
4020 Aerial Center Parkway
Morrisville, NC 27560

Subject: Label Amendment – Addition of optional statement and seed bag language revisions
Product Name: SPIRATO M 185 FS
EPA Registration Number: 55146-118
Application Date: 01/26/2016
Decision Number: 513511

Dear Mr. Ehresman:

The amended 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 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.

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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 Maryam K. Muhammad by phone at 703-347-0301, or via email at Muhammad.maryam@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to be 'HJ', written in a cursive style.

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

Enclosure

SPIRATO[®]M 185 FS

For use as a seed treatment for protection of seed and seedlings
against listed diseases

ACTIVE INGREDIENT:

Metalaxyl 15.00%
Fludioxonil..... 2.36%

OTHER INGREDIENTS: 82.64%
TOTAL: 100.00%

Contains 1.34 lbs metalaxyl and 0.21 lbs fludioxonil per gallon.

KEEP OUT OF REACH OF CHILDREN

CAUTION

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. 55146-118
EPA EST. NO. _____

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



ACCEPTED

Apr 26, 2016

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 55146-118

NET CONTENTS _____ GAL. (_____ Liters)
[Designation as "NONREFILLABLE" or "REFILLABLE" for containers > 5 GAL]

FIRST AID

IF SWALLOWED

- 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.

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

CAUTION: Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

Engineering Controls Statement

When handlers use closed systems 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 / PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

ENVIRONMENTAL HAZARDS

This product is toxic to fish and aquatic invertebrates. For terrestrial use, **DO NOT** apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. **DO NOT** contaminate water when disposing of equipment wash water or rinsate. Cover or incorporate spilled treated seeds.

Groundwater Advisory: Metalaxyl is known to leach through soil into groundwater under certain conditions as a result of agricultural use. Use of this chemical where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.

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.

[OPTIONAL STATEMENT: The SPIRATO M 185 FS in this container must be used in the use season immediately following purchase from Nufarm.]

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 of this product 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 24 hours.

Exception: If the seed is treated with the product and the treated seed is soil-injected or soil -incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated. 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
- Shoes plus socks

PRODUCT INFORMATION

SPIRATO M 185 FS is a seed treatment fungicide for use on soybeans, legumes, rice, and cotton to protect against damping-off and seed rots due to *Pythium*, *Phytophthora*, *Fusarium*, *Rhizoctonia* spp., and *Phytophthora* root rot. SPIRATO M 185 FS also suppresses seed-borne *Sclerotinia* and *Phomopsis* spp. particularly in soybeans.

Mix thoroughly before use or use entire container at one time.

SPIRATO M 185 FS contains an EPA approved dye/colorant that imparts an unnatural color to the seed.

SPIRATO M 185 FS is formulated for on-farm or commercial seed treatment.

Planter Box Treatment: Apply at the specified rate and premix with the seed directly in the planter box at planting. Place half the amount of seed into the planter box and apply half the required amount of pesticide to the seed. Stir the seed thoroughly with a paddle until the seed is uniformly coated. Place the remaining half of the seed into the planter box and add the remaining half of the pesticide. Again stir the seed with the paddle until all seed is thoroughly coated.

Tank Mixing: All tank mixes should be pre-tested to determine physical compatibility between formulations. When tank mixing, follow the most restrictive label instructions for any tank mix partner. **DO NOT** tank mix with any product that bears a label prohibition against tank mixing.

MIXING INSTRUCTIONS FOR SOYBEANS

SPIRATO M 185 FS may be used with liquid rhizobia products that are resistant to fungicides; using standard mechanical slurry or mist-type seed treatment equipment which accurately measures and mixes a flowable seed treatment. The equipment must provide uniform coverage of SPIRATO M 185 FS on the seed. Uneven seed coverage may not give the desired level of disease control. SPIRATO M 185 FS must be diluted with either water or liquid inoculants prior to application to soybeans. Consult the manufacturer of the application equipment you plan to use for suitability for this application and for instructions on operation and calibration of the equipment.

In a clean container large enough to contain the entire mixture add the desired amount of SPIRATO M 185 FS. Add half of the required water or liquid inoculant and mix thoroughly. Add the remaining amount of water or liquid inoculant and mix again. The slurry is ready for application to the soybeans. Mix as needed and do not store diluted mixture.

Additional or continuous agitation or mixing of the slurry mixture may be necessary to prevent the SPIRATO M 185 FS from settling out of solution when using water or liquid inoculants. SPIRATO M 185 FS has been found to be compatible with some liquid inoculant products. SPIRATO M 185 FS may be mixed or applied sequentially with approved liquid inoculants. Consult the maker of the liquid inoculants and a Nufarm Americas representative for directions before applying SPIRATO M 185 FS with liquid inoculants.

Special Precaution: SPIRATO M 185 FS is specially formulated to be compatible with some liquid inoculants. If water is used to further dilute SPIRATO M 185 FS when rhizobia are present, use only nonchlorinated water. Chlorinated water will kill the live rhizobia contained in the inoculant.

MIXING INSTRUCTIONS FOR SEED AND POD VEGETABLES, RICE, AND COTTON

Apply SPIRATO M 185 FS as a water based slurry utilizing standard slurry seed treatment equipment which provides uniform seed coverage. Uneven or incomplete seed coverage may not give the desired level of disease protection. Thoroughly mix the labeled amount of SPIRATO M 185 FS into the required amount of water for the slurry treater and dilution rate to be used.

Follow the manufacturer application instructions for the seed treatment equipment being used. Maintain constant agitation of the slurry during the treatment. Allow seed to dry before bagging.

RESTRICTIONS:

DO NOT use treated seed for feed, food, or oil purposes.

USE SPECIFICATIONS

SOYBEANS				
DISEASE	USE RATE (based on 3,000 seeds / lb)			
Protection against damping-off and seed rots caused by <i>Pythium</i> , <i>Phytophthora</i> , <i>Fusarium</i> , <i>Rhizoctonia</i> spp, and <i>Phytophthora</i> root rot. Suppresses seed-borne <i>Sclerotinia</i> and <i>Phomopsis</i> spp.	fl.oz. / 100 lb. of seed**	fl.oz / 1,000 seed	fl.oz / 140,000 seed	mg AI / seed
	1.5	0.005	0.7	0.0037 (fludioxonil) 0.0237 (metalaxyl)
**Contains 15.6 g of metalaxyl and 2.5 g of fludioxonil / 100 kg of seed.				
REMARKS				
Apply SPIRATO M 185 FS at the rate specified in the rate table, plus water at 3.5 fl. oz. per 100 lbs seed to obtain adequate coverage. Alternatively, approved liquid rhizobia inoculants at rates specified by manufacturer to achieve proper total slurry volumes can be used.				
An additional 0.75 fl oz./100 lbs seed of SEBRING 318 FS* may be used if targeting fields with high <i>Phytophthora</i> pressure.				

SEED AND POD VEGETABLES: Black-Eyed Peas, Chickpeas, Garbanzos, Cowpeas, Field Beans, Field Peas, Garden Peas, Green Beans, Kidney Beans, Lima Beans, Lupines, Navy Beans, Okra, Peas, Pole Beans, Snap Beans, String Beans, Wax Beans, and Lentils	
DISEASE	USE RATE (fl.oz / cwt. seed)
Protection against damping-off and seed rots caused by <i>Pythium</i> , <i>Phytophthora</i> , <i>Fusarium</i> , <i>Rhizoctonia</i> spp, and <i>Phytophthora</i> root rot. Suppresses seed-borne <i>Sclerotinia</i> and <i>Phomopsis</i> spp.	1.5

RICE		
DISEASE	USE RATE (based on 21,000 seeds / lb)	
Protection against early season soil and seed-borne fungi which cause decay, damping off, and seedling blights including <i>Pythium</i> , <i>Rhizoctonia</i> , <i>Fusarium</i> .	fl.oz. / 100 lb. of seed**	mg AI / seed
	1.5	0.00053 (fludioxonil) 0.00338 (metalaxyl)
	3.0	0.00106 (fludioxonil) 0.00677 (metalaxyl)
REMARKS		
**SPIRATO M 185 FS contains 0.74 grams fludioxonil and 4.72 grams metalaxyl per fl.oz.		
RESTRICTIONS		
<p>Not registered for use on Rice in California</p> <p>DO NOT use treated seed for feed, food, or oil.</p> <p>Forage must not be grazed until 30 days after planting.</p> <p>Bags or containers of Spirato M treated rice must be labeled with the restriction: “DO NOT use metalaxyl or mefenoxam to control <i>Pythium</i> in water-seeded rice”.</p>		

COTTON	
DISEASE	USE RATE (fl.oz / 100 lb. of seed)
Protection against seed and soil borne fungi such as <i>Pythium</i> , <i>Rhizoctonia</i> , and <i>Fusarium</i> that cause decay, damping-off, and seedling blights.	1.5 – 3.0
REMARKS	
For protection against black rot, use SPIRATO M 185 FS in combination with SPERA 240 FS (myclobutanil) or other seed treatment fungicide containing myclobutanil that is labeled for use on cotton seed.	
RESTRICTIONS	
DO NOT use treated seed for feed, food, or oil.	

*Use Sebring 318 FS or an equivalent rate of an appropriate metalaxyl or mefenoxam formulation.

SEED BAG LABELING REQUIREMENTS

Seed commercially treated with this product must be labeled in accordance with all applicable requirements of the Federal Seed Act. The user of this product is responsible for ensuring that the seed bag meets all requirements under the Federal Seed Act.

THE FEDERAL SEED ACT REQUIRES THAT BAGS CONTAINING TREATED SEED BE LABELED WITH THE FOLLOWING INFORMATION:

- This seed has been treated with (metalaxyl and fludioxonil) seed treatment.
- **DO NOT** use for food, feed, or oil purposes. Store away from feeds and other foodstuffs.

US EPA REQUIRES THAT BAGS OF TREATED RICE SHALL BE LABELED WITH THE FOLLOWING INFORMATION:

- *“Forage must not be grazed until 30 days after planting”*

THE U.S. ENVIRONMENTAL PROTECTION AGENCY REQUIRES THE FOLLOWING STATEMENTS ON CONTAINERS CONTAINING TREATED SEED:

- **Groundwater Advisory:** Metalaxyl is known to leach through soil into groundwater under certain conditions as a result of agricultural use. Use of this chemical where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.
- Store treated seed away from food and feedstuffs.
- Wear long pants, long-sleeved shirt, and protective gloves when handling treated seed.
- Cover or collect treated seeds spilled during loading and planting.
- Treated seed exposed on soil surface may be hazardous to wildlife.
- Dispose of all excess treated seed by burying seed away from bodies of water. **DO NOT** contaminate bodies of water when disposing of planting equipment wash water.
- Dispose of seed packaging or containers in accordance with local requirements.
- **DO NOT** contaminate water bodies when disposing of planting equipment wash water.
- **DO NOT** allow children, pets, or livestock to have access to treated seed.
- **DO NOT** graze or feed livestock on treated areas for 30 days after planting.
- After the seeds have been planted, do not enter or allow worker entry into treated areas during the **restricted-entry interval (REI) of 24 hours**. Exception: If the treated seed is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated. 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, and chemical-resistant footwear.
- Excess treated seed may be used for ethanol production only if (1) by-products are not used for livestock feed and (2) no measurable residues of pesticides remain in the ethanol by-products that are used in agronomic practice.

STORAGE AND DISPOSAL

DO NOT contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in a cool place, **DO NOT** store in direct sunlight. Protect from freezing temperatures.

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

CONTAINER DISPOSAL [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 disposal [handling] instructions below that apply to your container type / size.”

[Nonrefillable Containers 5 Gallons or Less]

Nonrefillable container. DO NOT reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. **Triple rinse as follows:** Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application 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. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities. Plastic containers are also disposable by incineration, or, if allowed by State and local authorities, by burning. If burned stay out of smoke.

[Nonrefillable containers larger than 5 gallons]

Nonrefillable container. DO NOT reuse or refill this container. Offer for recycling if available. Triple rinse or pressure rinse container (or equivalent) promptly after emptying.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 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. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. **Pressure rinse as follows:** Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank 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.

[Refillable containers larger than 5 gallons]

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.

[Refillable containers for return to Nufarm]

Refillable container. Refill this container with pesticide only. **DO NOT** reuse this container for any other purpose. Close all openings and replace all caps. Contact Nufarm’s Customer Service Department at 1-800-345-3330 to arrange for return of the empty refillable container.

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.

LIMITATION OF LIABILITY

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL MANUFACTURER OR SELLER BE LIABLE FOR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, OR FOR DAMAGES IN THEIR NATURE OF PENALTIES RELATING TO THE GOODS SOLD, INCLUDING USE, APPLICATION, HANDLING, AND DISPOSAL. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, MANUFACTURER OR SELLER SHALL NOT BE LIABLE TO BUYER OR USER BYWAY OF INDEMNIFICATION TO BUYER OR TO CUSTOMERS OF BUYER, IF ANY, OR FOR ANY DAMAGES OR SUMS OF MONEY, CLAIMS OR DEMANDS WHATSOEVER, RESULTING FROM OR BY REASON OF, OR ARISING OUT OF THE MISUSE, OR FAILURE TO FOLLOW LABEL WARNINGS OR INSTRUCTIONS FOR USE, OF THE GOODS SOLD BY MANUFACTURER OR SELLER TO BUYER. ALL SUCH RISKS SHALL BE ASSUMED BYTHE BUYER, USER, OR ITS CUSTOMERS.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 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.

(RV042216)

Spirato is a registered trademark of Nufarm Americas Inc.

All other trademarks are the property of their respective owners.

LABEL HISTORY

File Name	Revision Mark	Comment
055146-00xxx.20110808.SPIRATO_M_185_FS	RV080811	Draft Label
055146-00RRI.20120202.SPIRATO_M_185_FS	RV020212	Revised Draft
055146-00RRI.20120221.SPIRATO_M_185_FS	RV022112	Revised Draft
055146-00118.20120228.MASTER	RV022812	SECTION 3 APPROVAL
055146-00118.20160126.DRAFT	RV012616	Addition of optional label statement, updated seed tag statements
055146-00118.20160422.DRAFT	RV042216	Additional revisions prior to approval