

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

August 28, 2017

Heidi Irrig Syngenta Crop Protection. LLC P.O. Box 18300 Greensboro, NC 27419

Subject: Label Amendment – Adds "This product is toxic to aquatic invertebrates" to the "Environmental Hazards" section Product Name: Plenaris 200FS EPA Registration Number: 100-1590 Application Date: April 17, 2017 Decision Number: 528856

Dear Ms. Irrig:

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.

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

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with FIFRA section 6. If you have any questions, please contact me by phone at 703-308-9443, or via email at <u>kish.tony@epa.gov</u>.

Sincerely,

Tomfish

Tony Kish, Product Manager 22 Fungicide Branch Registration Division (7505P) Office of Pesticide Programs

Enclosure

[Master Label]

GROUP U15 FUNGICIDE



Fungicide Seed Treatment

PLENARIS® 200FS

A fungicide seed treatment product for early season protection against Oomycete pathogens in sunflowers. PLENARIS[®] 200FS is a flowable suspension

Active Ingredient	By Weight
Oxathiapiprolin*	18.7%
Other Ingredients	81.3%
TOTAL	100.0%
*CAS No. 1003318-67-9	

Contains 1.67 pounds of oxathiapiprolin per gallon of product.

KEEP OUT OF REACH OF CHILDREN

Si usted no entiende la etiquete, 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 additional precautionary statements and directions for use inside booklet.

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EPA Est. No.

SCP

Net Contents

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

HOT LINE NUMBER

For 24-Hour Medical Emergency Assistance (Human or Animal) Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident)

Call

1-800-888-8372

PRECAUTIONARY STATEMENTS

Personal Protective Equipment (PPE)

Mixers, loaders, applicators, and other handlers must wear:

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

USER SAFETY REQUIREMENTS

Follow the 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.

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.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Environmental Hazards

This product is toxic to aquatic invertebrates. For terrestrial uses: Do not apply directly to water, or 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 washwater or rinsate.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

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 or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, LLC or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA 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. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and (2) Buyer and User assume the risk of any such use. TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA 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 SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE

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

PLENARIS 200FS fungicide seed treatment must be used only in accordance with instructions on this label, in separately issued labeling or exemptions under FIFRA (Supplemental labels, Special Local Needs Registrations, FIFRA Section 18), or as otherwise permitted by FIFRA. Always read the entire label including the Limitation of Warranty and Liability.

PLENARIS 200FS is a fungicide seed treatment for sunflower seed for use by a Syngenta-authorized seed company or a commercial seed treatment facility. Do not use on agricultural establishments in hopper-box, planter box, slurry box or other seed treatment applications at time of planting.

Do not use treated seed for food or animal feed, mix with food or animal feed, or process for oil.

This product contains no colorant. An EPA-approved colorant must be added when this product is applied to seed. Seed must be conspicuously colored at the time of treatment.

When applied according to this label, PLENARIS 200FS will provide early season protection against selected Oomycete pathogens including *Plasmopara halstedii* causing downy mildew in sunflowers. Use tank mixtures with other appropriate fungicides to control these diseases or to otherwise extend the control spectrum (see Tank Mixing). Consult your local Syngenta company representative or agricultural advisor for guidance on predicted disease pressure based on historical data for these diseases in your area.

PLENARIS 200FS treated seed may be replanted immediately if an emergency replanting is required due to an early season crop failure.

Treating significantly damaged seed or seed that is low vigor or overall poor quality may result in reduced germination, seedling vigor and plant stand. Before treating an entire seed lot with the proposed seed treatment, treat a small portion of the seed lot and conduct subsequent germination tests. Syngenta makes no guarantee regarding the germination of damaged or carry-over treated seed, since seed quality and storage conditions are beyond the control of Syngenta.

PRODUCT INFORMATION

PLENARIS 200FS fungicide is a flowable suspension containing oxathiapiprolin and is recommended for use as a seed treatment product, for early season protection from selected Oomycete pathogens including *Plasmopara halstedii* causing downy mildew in sunflowers.

PLENARIS 200FS has preventive, residual, curative, eradicative, and antisporulant activity against selective Oomycete pathogens listed in this label.

Mode-of-action

Oxathiapiprolin, the active ingredient in PLENARIS 200FS, acts as an oxysterol binding protein (OSBP) modulator in fungal cells and protects against sensitive Oomycete diseases by inhibiting OSBP.

Cultivar/Varietal Seed Safety

Not all varieties, cultivars or hybrids of crops have been individually tested for seed safety. It is not possible to evaluate all applications of PLENARIS 200FS for seed safety on all varieties, cultivars, or hybrids of those crops, or under all environmental conditions and growing circumstances. To test for seed safety, apply the product in accordance with the label instructions to a small amount of target seed and confirm acceptable germination to ensure that a phytotoxic response will not occur, especially where the application is a new use of the product by the applicator.

Resistance

PLENARIS 200FS fungicide contains the active ingredient oxathiapiprolin, which is novel and currently assigned the code U15 based on the mode of action classification system of the Fungicide

Resistance Action Committee (FRAC). Oxathiapiprolin inhibits the oxysterol-binding protein (OSBP).

A disease management program that includes rotation and/or mixing with fungicides that have a different mode of action is essential to reduce the risk of fungicide resistance development.

APPLICATION INFORMATION

Mixing Procedures

PLENARIS 200FS is for use in commercial seed treaters only, operating standard, calibrated seed treatment equipment. Do not use this product on agricultural establishments in hopper-box, planter-box, slurry-box or other seed treatment applications at or immediately before planting. Treatment equipment must be clean and free of previous pesticide deposits before applying PLENARIS 200FS. Before transferring PLENARIS 200FS from its container, thoroughly mix the contents to ensure the product is homogenous. Add PLENARIS 200FS directly to the mixing tank. Mix thoroughly the recommended amount of PLENARIS 200FS with the required amount of water. If available on the application equipment, PLENARIS 200FS can be applied directly through dedicated application modules in place of a mixing tank.

Add an EPA approved colorant to treat the seeds per 40 CFR 153.155(b)(1) during the seed treatment process. Ensure that all treated seeds are dyed an unnatural color.

Mixing Tank and Equipment Cleanout

Prior to application, start with clean, well maintained application equipment. Immediately following application, thoroughly clean all mixing equipment to reduce the risk of forming hardened deposits, which might become difficult to remove.

Drain mixing equipment. Thoroughly rinse mixing equipment and flush with clean water.

Clean all other associated application equipment. Take all necessary safety precautions when cleaning equipment. Do not clean near wells, water sources or desirable vegetation. Dispose of waste rinse water in accordance with local regulations.

Tank Mixtures

PLENARIS 200FS may be applied as a water-based slurry with other registered seed treatment products including fungicides, insecticides, nematicides or micronutrients. Potential mixing partners should be tested for physical compatibility with PLENARIS 200FS including added colorants or polymers before mixing in a large tank for seed treatment. Follow the most restrictive labeling limitations and precautions of all products used in mixtures. Do not mix this product with any product that prohibits such mixing.

Use Rate

For protection against soil-borne *Plasmopara halstedii*, that cause sunflower downy mildew, apply 0.0094 to 0.0188 mg ai/seed following the specific instructions in the Sunflower table below. Use the higher rate in areas with a history of high disease pressure, or where extended early-season protection is required and/or field conditions favor seed and soil-borne pathogens.

PLENARIS 200FS Use Rate for Sunflowers

Сгор	Target diseases (pathogen)	Rate mg ai/seed	Rate lb ai/100 lbs seed	Rate fl oz/ seed unit	Rate fl oz/100 lbs seed	Specific Directions
Sunflower	Downy mildew (Plasmopara halstedii)	0.0094 to 0.0188	0.0135 to 0.0269	0.318 to 0.636 fl. oz /200,000 seeds (based on an average of 6,500 seeds per pound)	2.066	Use the higher rate in areas with a history of high disease pressure, or where extended early season protection is required and/or field conditions favor development of seed and soil- borne pathogens

CROP ROTATION

The following list of crops and crop groups may be planted immediately after harvest of crops grown from PLENARIS 200FS-treated seed, or following a PLENARIS 200FS-treated seed crop failure: tuberous and corm vegetables (Subgroup 1C), bulb vegetables (Group 3-07), leafy greens (Subgroup 4A), brassica, head and stem (Subgroup 5A), peas, succulent shelled, peas, edible-podded, fruiting vegetables (Group 8-10), cucurbit vegetables (Group 9), strawberries, herbs and spices (Group 19), oilseed (Group 20), ginseng, and tobacco.

The following crops and crop groups may be planted immediately after harvest of crops grown from PLENARIS 200FS-treated seeds, or in the case of crop failure, 30 days after the planting of PLENARIS 200FS-treated seeds: cereals (Group 15 and 16) and grass animal feeds (Group 17).

All other crops cannot be planted until 180 days after the planting of PLENARIS 200FS-treated seeds.

SEED STORAGE

Field and laboratory tests have demonstrated that an application of PLENARIS 200FS to sunflowers will not negatively affect germination. Due to seed quality and seed storage conditions beyond the control of Syngenta, no claims are made to guarantee the germination of carry-over seed.

COMMERCIAL SEED BAG LABELING

In accordance with the Federal Seed Act and the US Environmental Protection Agency recommendations, seeds commercially treated with PLENARIS 200FS must include the following on its labeling:

- Treated seed. Do not use for food, feed or oil purposes.
- This seed has been treated with PLENARIS 200FS fungicide which contains oxathiapiprolin.
- Store away from food or feed.
- Dispose of all obsolete treated seed away from bodies of water and according to federal and state regulations.
- Do not allow children, pets, or livestock to have access to treated seed.
- Dispose of seed packaging in accordance with local requirements.
- Wear long pants, long-sleeved shirt, shoes, and socks when handling treated seed.

Crop Rotation

- The following list of crops and crop groups may be planted immediately after harvest of crops grown from PLENARIS 200FS-treated seed, or following a PLENARIS 200FS-treated seed crop failure: tuberous and corm vegetables (Subgroup 1C), bulb vegetables (Group 3-07), leafy greens (Subgroup 4A), brassica, head and stem (Subgroup 5A), peas, succulent shelled, peas, edible-podded, fruiting vegetables (Group 8-10), cucurbit vegetables (Group 9), strawberries, herbs and spices (Group 19), oilseed (Group 20), ginseng, and tobacco.
- The following crops and crop groups may be planted immediately after harvest of crops grown from PLENARIS 200FS-treated seeds, or in the case of crop failure, 30 days after the planting of PLENARIS 200FS-treated seeds: cereals (Group 15 and 16 and grass animal feeds (Group 17).
- All other crops cannot be planted until 180 days after the planting of PLENARIS 200FS-treated seed.

RESISTANCE MANAGEMENT RECOMMENDATIONS:

For resistance management, please note that PLENARIS 200FS contains the active ingredient oxathiapiprolin which is novel and is currently assigned the Code U15 by the Fungicide Resistance Action Committee (FRAC). Oxathiapiprolin inhibits the oxysterol-binding protein (OSBP). A disease management program that includes rotation and/or mixing with fungicides that have a different mode of action is essential to reduce the risk of fungicide resistance development. Any pathogen population may contain individuals naturally resistant to PLENARIS 200FS and other OSBP-inhibiting fungicide. The resistant individuals may dominate the pathogen population if these groups of fungicides are used repeatedly in the same fields. Appropriate resistance-management strategies should be followed.

- GENERAL GUIDANCE: Seed treatment applications of oxathiapiprolin in mixture with a different mode of action fungicide active against the target oomycete disease are encouraged whenever feasible.
- No foliar or soil fungicide application of an OSBP-inhibiting fungicide should be made following a seed treatment application of oxathiapiprolin or other OSBP-inhibiting fungicides.
- For resistance management, do not make more than one seed treatment application of oxathiapiprolin per year on the same acreage, targeting the same pathogen, except in the case of crop failure.

To delay fungicide resistance:

- Where possible, rotate the use of PLENARIS 200FS with fungicides with a different FRAC group that control the same pathogen.
- Use tank mixtures with fungicides from a different FRAC group when such use is permitted.
- Fungicide use should be based on an IPM program that includes scouting, record keeping and considers cultural, biological and other chemical control practices.
- Monitor treated pathogen populations for resistance development.
- Contact your local extension specialist or certified crop advisors for any additional pesticide resistance-management and/or IPM recommendations for the specific site and pest problems in your area.

STORAGE AND DISPOSAL

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

Pesticide Storage

Keep container closed when not in use. Always store pesticides in the original container only, away from food, pet food, feed, seed, fertilizers, and veterinary supplies. If a leaky container must be contained within another, mark the outer container to identify the contents. Storage areas must be locked and secure from vandalism, with precautionary signs posted. The storage area must be dry, well-lit, and well-ventilated. Keep pesticide storage areas clean. Clean up any spills promptly. Protect pesticide containers from extreme heat and cold. Store herbicides, insecticides and fungicides in separate areas within the storage unit. Place liquid formulations on lower shelves and dry formulations above. Maintaining a spill kit and fire extinguisher on hand and having emergency phone numbers posted will allow you to be prepared for emergencies. If spill cleanup PPE is stored nearby, but outside the pesticide storage area, it will be accessible when needed.

Pesticide Disposal

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

Container Handling [less than or equal to 5 gallons]

Non-refillable container. Do not reuse or refill this container. 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 if available or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures approved by state and local authorities.

Container Handling [greater than 5 gallons – mini-bulk]

Non-refillable container. Do not reuse or refill this container. Triple 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. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures approved by state and local authorities.

Container Handling [greater than 5 gallons – bulk]

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 person refilling. To clean the container before final disposal, empty the remaining contents from this container into application or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this pressure rinsing procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures approved by state and local authorities.

CONTAINER IS NOT SAFE FOR FOOD, FEED, OR DRINKING WATER.

PLENARIS[®], the ALLIANCE FRAME the SYNGENTA Logo and the PURPOSE ICON are Trademarks of a Syngenta Group Company

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For non-emergency (e.g., current product information), call Syngenta Crop Protection at 1-800-334-9481.

Manufactured for: Syngenta Crop Protection, LLC P.O. Box 18300 Greensboro, North Carolina 27419-8300

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