

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

August 11, 2022

Christine Villegas Senior Regulatory Affairs Manager Bayer U.S.- Crop Science 700 Chesterfield Pkwy W Chesterfield, MO 63017

Subject: Registration Review Label Mitigation for METALAXYL and

PROTHIOCONAZOLE

Product Name: PROCEED CONCENTRATE FUNGICIDE

EPA Registration Number: 264-1102 Application Dates: 06/28/2018, 12/10/2021

Decision Number: 580960, 586194

Dear Christine Villegas:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all the information submitted with your application to support the Registration Review of the above referenced product in connection with the Metalaxyl and Prothioconazole Interim Decisions, and has concluded that your submission is acceptable. The label referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable.

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.

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 12 months from the date of this letter. After 12 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.

Page 2 of 2 EPA Reg. No. 264-1102 Decision No. 580960, 586194

If you have any questions about this letter, please contact Srijana Shrestha by phone at 202-566-2329, or via email at <a hrestha.srijana@epa.gov.

Sincerely,

Linda Arrington, Branch Chief

Risk Management and Implementation Branch 4

Pesticide Re-Evaluation Division

Office of Pesticide Programs

Enclosure: Stamped Label

PROTHIOCONAZOLE	GROUP	3	FUNGICIDE
TEBUCONAZOLE	GROUP	3	FUNGICIDE
METALAXYL	GROUP	4	FUNGICIDE

PROCEED™ CONCENTRATE

Fungicide

ACTIVE INGREDIENTS:

Prothioconazole: 2-[2-(1- Chlorocylocpropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]- 1,2- dihydro-3H-1,2,4-triazole-3-thione...6.88% OTHER INGREDIENTS: 88.99% TOTAL: 100.00%

Contains 0.643 pound prothioconazole, 0.129 pound tebuconazole and 0.257 pound metalaxyl per U.S. gallon.

EPA Reg. No. 264-1102

EPA Est.

KEEP OUT OF REACH OF CHILDREN CAUTION

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577 For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

Please refer to [back panel] [booklet] for additional precautionary statements and directions for use. [Note to reviewer: Location of additional precautionary statements and directions for use will vary between those listed, depending on container type/size.]

FIRST AID

IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 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 SWALLOWED:	Immediately call a poison control center or doctor for treatment advice.		
	Have person sip a glass of water if able to swallow.		
	Do not induce vomiting unless told to do so by a poison control center or doctor.		
	Do not give anything by mouth to an unconscious person.		
IF INHALED:	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 ON SKIN OR	Take off contaminated clothing.		
CLOTHING:	Rinse skin immediately with plenty of water for 15-20 minutes.		
	Call a poison control center or doctor for treatment advice.		
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For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.

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

NOTE TO PHYSICIAN: No specific antidote. Treat symptomatically.

ACCEPTED

Aug 11, 2022

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 264-1102

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Harmful if swallowed, inhaled, or absorbed through skin. Causes moderate eye irritation. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield or safety glasses). Avoid contact with skin, eyes, or clothing and breathing vapor or spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

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 (goggles, face shield or safety glasses)

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 Control Statements

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.607 (d)(e) and (f)], 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.

Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothes.

Users should 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 pesticide is toxic to mammals, fish, aquatic invertebrates, and freshwater/estuarines/marine aquatic plants. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate.

Cover or incorporate spilled treated seed.

Surface Water Advisory

This product may impact surface water quality due to runoff of rainwater. This is especially true for poorly draining soils and soils with shallow ground water. This product is classified as having high potential for reaching surface water via runoff for several months or more after application. A level, well-maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential loading of prothioconazole and degradates from runoff water and sediment. Runoff of this product will be reduced by avoiding applications when rainfall or irrigation is expected to occur within 48 hours.

Ground Water Advisory

Metalaxyl, tebuconazole and degradates of prothioconazole are known to leach through soil into groundwater under certain conditions as a result of label use. These chemicals may leach into groundwater if used in areas where soils are permeable, particularly where the water table is shallow.

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.

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.

RESTRICTIONS

Maximum usage when applying both metalaxyl- and mefenoxam-containing products to the same crop within the same season: Do not apply more than the maximum yearly total application rate for the active ingredient as stated on the label of the product containing the lowest yearly total on that crop.

Resistance-Management Recommendations

For resistance management, please note that Proceed Concentrate Fungicide contains both Group 3 (Prothioconazole and Tebuconazole) and Group 4 (Metalaxyl) fungicides. Any fungal population may contain individuals naturally resistant to Proceed Concentrate Fungicide and other Group 3 or Group 4 fungicides. A gradual or total loss of pest control may occur over time if these fungicides are used repeatedly in the same fields. Appropriate resistance-management strategies should be followed.

To delay fungicide resistance, take the following steps:

- Rotate the use of Proceed Concentrate Fungicide or other Group 3 and Group 4 fungicides within a growing season sequence with different groups that control the same pathogens.
- Use tank mixtures with fungicides from a different group that are equally effective on the target pest when such use is permitted. Use at least the minimum application rate as labeled by the manufacturer.
- Adopt an integrated pest management program for fungicide use 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 fungicide applications. Note that using predictive models alone is not sufficient to manage resistance.
- Monitor treated fungal populations for resistance development.
- Contact your local extension specialist or certified crop advisor for any additional pesticide resistance-management and/or IPM recommendations for specific crops and pathogens.
- For further information or to report suspected resistance contact Bayer CropScience at 1-866-99BAYER (1-866-992-2937).

You can also contact your pesticide distributor or university extension specialist to report resistance.

APPLICATION DIRECTIONS

Apply this product only as specified on this label. This product is for commercial or on-farm application. Applications must be made using standard slurry or mist-type seed treatment equipment. Do not apply this product with a hopper box, planter box, slurry box, or any other at-plant methods. Dilute with a sufficient amount of water to achieve uniform application to seed which is necessary to ensure seed safety and best disease control. Only use seed that is sound and well cured prior to treatment.

Crop	Disease	Rate Proceed Concentrate Fungicide fl oz/100 lbs of seed
Barley, Triticale and Wheat	Aids in the control or suppression of the following seed, seedling and soilborne diseases: stinking smut, flag smut, loose smut, covered smut (common bunt), early season Septoria disease complex, general seed rots, Pythium damping-off, early season Rhizoctonia root rot, early season common root rot, seedborne Fusarium scab (barley stripe), early season Fusarium foot rot.	1 – 1.5
	Early season suppression of powdery mildew and rust.	

In California - Registered only for use in commercial seed treating establishments. Not allowed for "on-farm" use.

Seed Bag Label Requirements

The Federal Seed Act requires that containers containing treated seeds shall be labeled with the following statements:

- This seed has been treated with PROCEED CONCENTRATE Fungicide, which contains Prothioconazole, Tebuconazole, and Metalaxyl.
- Do not use treated seed for food, feed, or oil purposes.

The U.S. Environmental Protection Agency requires the following statements on containers containing seed treated with prothioconazole:

- Store treated seed away from food and feedstuffs.
- Do not allow children, pets, or livestock to have access to treated seeds.
- When opening this bag or loading/pouring the treated seed/seed-pieces, wear long sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves.
- Treated seeds exposed on the soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading and planting (such as in row ends).
- 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.
- Plant treated seed into the soil to the recommended minimum depth or greater to minimize exposure.
- DO NOT plant treated seed by broadcasting to the soil surface. Ensure that all planted seeds are thoroughly incorporated by the planter during planting, additional incorporation may be required to thoroughly cover exposed seeds.
- Dispose of seed packaging or containers in accordance with local requirements.
- Excess treated seed may be used for ethanol production if (1) by-products are not used for livestock feed and (2) no measurable residues of pesticide remain in ethanol by-products that are used in agronomic practice.
- Barley, wheat and triticale green forage may be grazed or harvested for hay 31 days after seeding.

Seed treated with this product must be visually identifiable from untreated seed by the use of an approved colorant or dye to prevent accidental use of treated seed as food for humans or feed for animals. Refer to 21 CFR, § 2.25. Any colorant or dye added to treated seed must be cleared for use in accordance with 40 CFR, § 153.155(c).

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Keep out of reach of children and animals. Store in original containers only. Store in a cool, dry place and avoid excess heat

PESTICIDE DISPOSAL

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 at the nearest EPA Regional Office for guidance

CONTAINER DISPOSAL

Rigid, Non-refillable containers small enough to shake (i.e., with capacities equal to or less than 5 gallons).

Non-refillable 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 and drain for 10 seconds after the flow begins to drip. Fill the container ¼ 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.

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 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.

Once container is rinsed, offer for recycling if available, or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned stay out of smoke.

Rigid Non-refillable containers that are too large to shake (i.e., with capacities greater than 5 gallons or 50 lbs)

Non-refillable Containers

Non-refillable containers - Do not reuse or refill this container. After emptying product from container, either return container to Bayer CropScience per instructions from Bayer CropScience Customer Service Center (1-800-527-4781), or rinse and either recycle or dispose of the container as follows:

Bottom Discharge IBC (e.g. - Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Top Discharge IBC, Drums, Kegs (e.g.- Snyder 120 Next Gen, Bonar B120, Drums, and Kegs).

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. To triple rinse the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill.

Refillable Containers

Refillable container. Refill this container with pesticide only. Do not reuse this container for any

other purpose. After emptying product from container, either return container to Bayer CropScience per instructions from Bayer CropScience Customer Service Center (1-800-527-4781) or rinse and either recycle or dispose of the container as follows:

Bottom Discharge IBC (e.g. – Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing 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 pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Top Discharge IBC, Drums, Kegs (e.g. – Snyder 120 Next Gen, Bonar B120, Drums, and Kegs).

Triple rinsing 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 triple rinse the containers before final disposal, empty the remaining contents from this container into

application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill.

Refillable Containers

End users are authorized to remove tamper evident cables as required to remove the product from the container unless the container is equipped with one way valves and refilling or returning is planned. If this is the case, end users are not authorized to remove tamper evident cables, one way valves or clean container. See Container Disposal instructions under Storage and Disposal.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, disclaimer of Warranties and Limitations of Liability.

Treatment of highly mechanically damaged seed, or seed of known low vigor and poor quality, may result in reduced germination and/or reduction of seed and seedling vigor. Treat and conduct germination tests on a small portion of seed before committing the total seed lot to a selected chemical treatment. Due to seed quality conditions beyond the control of Bayer CropScience, no claims are made to guarantee germination of carry-over seed.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, all such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

NET CONTENTS:

PROCEED is a trademark of Bayer Group.

PRODUCED FOR



Bayer CropScience LP 800 N. Lindbergh Blvd. St. Louis, MO 63167 1-866-99BAYER (1-866-992-2937)

PROCEED CONCENTRATE Fungicide (PENDING) 06/04/2018, 06/30/2021, 12/10/2021, 03/09/2022, 03/11/2022, 05/31/2022, 06/01/2022, 06/01/2022, 06/13/2022