

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

May 20, 2021

Cinda Bell Regulatory Agent Ceradis B.V. Agrobusiness Park 10 6708 PW Wageningen The Netherlands

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – Addition of Treatment of Rhizoctonia to Wheat and Addition of Supplemental Label Product Name: CeraMax EPA Registration Number: 92311-2 Application Date: 3/3/21 Salesforce Case Number: 293380

Dear Ms. Bell:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or 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 (1) copy of the final printed labeling before you release this 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 your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims

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made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA 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 Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Chris Pfeifer of my team by phone at (703) 308-0031 or via email at pfeifer.chris@epa.gov.

Sincerely,

andrew E. kuycelow

Andrew Bryceland, Team Leader Biochemical Pesticides Branch Biopesticides and Pollution Prevention Division (7511P) Office of Pesticide Programs

Enclosure

CERAMAX

Seed treatment for the protection against Fusarium and Rhizoctonia on soybean, corn, and wheat seeds

ACTIVE INGREDIENT:

Natamycin	13.459%
OTHER INGREDIENTS:	
TOTAL	1 <u>00.000</u> %



Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 92311-2

Contains 1.25 lbs Natamycin per gallon (150 grams Natamycin per Liter)

KEEP OUT OF REACH OF CHILDREN CAUTION

See [back][side] panel for additional Precautionary Statements

FIRST AID					
lf	• Call a poison control center or doctor immediately for treatment advice.				
swallowed	 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 by mouth to an unconscious person. 				
If in eyes	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Demove contact longer, if present, offer the first 5 minutes.				
	minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.				
	Call a poison control center or doctor for treatment advice.				
If on skin	 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	 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. 				
Have the product container or label with you when calling a poison control center,					
doctor, or going for treatment. For non-emergency information concerning this					
product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378					
(NPIC Web site: www.npic.orst.edu). For emergencies, call the poison control center					
1-800-222-1222, 24 hours a day, 7 days a week.					

EPA Reg. No. 92311-2 EPA Est. No. Batch Code: Net Contents: 2.5 gallons

PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals

CAUTION. Harmful if swallowed, absorbed through skin, or inhaled. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Avoid breathing vapor. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Protective eyewear
- Shoes plus socks

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

USER SAFETY RECOMMENDATIONS

Users should:

- 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

[Container sizes less than 5 gallons] 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.

[Container sizes equal to or greater than 5 gallons] 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.

For use only in commercial seed treatment equipment. Not for use in hopper box, planter box, slurry box, or other on-farm seed treatment applications.

Product Description

CeraMax is highly active against true fungi. CeraMax contains the biological molecule, Natamycin. Natamycin is a natural fermentation product of soil bacteria as a defense mechanism against fungi. The mode of action of Natamycin is unique and does not affect any other type of microorganism. CeraMax is a stable liquid fungicide seed treatment that provides protection against all Fusarium and Rhizoctonia diseases. On soybean seeds, it provides protection against *Fusarium* spp. such as *Fusarium virguliforme*, the causal agent of Sudden Death Syndrome.

Application Information

Use Information

Apply CeraMax as a water-based slurry either alone or with registered seed treatments using standard slurry or mist-type seed treatment application equipment.

CeraMax may be used in combination with other registered seed treatment products. Check for compatibility with other seed treatment products before use.

Dilute with sufficient amount of water to achieve uniform application. Use high quality, properly cleaned seed.

All seed treated commercially with this product must be adequately dyed with a suitable color to prevent accidental use as food for humans or feed for animals. Use an EPA-approved dye or colorant that imparts an unnatural color to the seed. Any dye or colorant added to treated seed must be cleared for use pursuant to 40 CFR 153.155.

Mixing Instructions

Add 1/2 to 2/3 of the required water to the treatment slurry tank followed by any accompanying seed treatment products and CeraMax (see application rate table below). The order of product addition is dependent on the accompanying seed treatment products and application equipment used. Allow each slurry component to disperse completely prior to the next addition until a uniform suspension is obtained. After all slurry components have been added and dispersed completely, add the remaining 1/2 to 1/3 of required water for proper slurry volume and mix until uniform.

Maintain adequate agitation until treatment slurry is applied. Ensure that seed is dry prior to packaging.

Application Rate

Crop	Diseases	Product Use Rate (mL/kg seed)	Product Use Rate (fl. oz. per 100 lbs. seed)
Soybean	<i>Fusarium</i> spp., such as <i>Fusarium virguliforme</i>	0.8 – 1.6	1.23 – 2.46
	<i>Rhizoctonia</i> spp.	0.8	1.23
Corn	<i>Fusarium</i> spp.	0.8	1.23
	<i>Rhizoctonia</i> spp.	0.8	1.23
Wheat	<i>Fusarium</i> spp.	0.8	1.23
	Rhizoctonia spp.	0.8	1.23

Seed Labeling

Seed treated with CeraMax that is then packaged for future use must contain the following labeling on the outside of the seed package.

- This seed has been treated with CeraMax.
- Do not use this treated seed for food, feed, or oil production.
- Wear long-sleeved shirt, long pants, shoes, socks, and gloves when handling treated seed.
- Store treated seed away from food and feed.
- Do not allow access by children, pets, or livestock.
- Do not reuse empty seed containers.
- Store or dispose of surplus treated seed or empty seed containers according to local requirements.
- Do not contaminate bodies of water when disposing of excess treated seed or wash waters from planting equipment.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. **PESTICIDE STORAGE**: Keep pesticide in original container. Store product away from direct sunlight between 40°F and 90°F.

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: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment, then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration. If burned, stay out of smoke.

Conditions of Sale and Warranty

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 due to such factors as weather or crop conditions, manner of use or application, presence of other material or other influencing factors in the use of the product, which are beyond the control of Ceradis B.V., the manufacturer or the seller. Buyer and User agree to hold Ceradis B.V. and Seller harmless for any claims relating to such factors, to the extent permitted by applicable law.

To the extent consistent with the applicable law, Ceradis B.V. makes no other warranties of merchantability or fitness for a particular purpose.

To the extent consistent with the applicable law, the exclusive remedy of the User or Buyer for any and all claims, losses, injuries or damage resulting from the use or handling of this product (including claims based on contract, warranty, negligence, strict liability, tort or otherwise) shall not exceed the purchase price paid by the User or Buyer for the quantity of this product involved.

To the extent consistent with the applicable law, in no event shall Ceradis B.V. or the Seller be liable for special, incidental or consequential damages resulting from the use, handling, application, storage or disposal of this product.

No agent or employee at Ceradis B.V. or seller is authorized to modify the terms of the warranty disclaimer or the product's label. Buyer and User accept the Conditions of Sale and Warranty by opening and using the product.

Ceradis B.V. Agrobusiness Park 10 6708 PW Wageningen The Netherlands

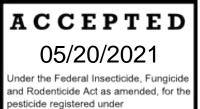
Supplemental Label

This supplemental label expires on [date to be added: 18 months after EPA approval of this label] and must not be used or distributed after this date.

CERAMAX

For control of Rhizoctonia on wheat seeds

KEEP OUT OF REACH OF CHILDREN CAUTION



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DIRECTIONS FOR USE

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Application Rate

Crop	Diseases	Product Use Rate (mL/kg seed)	Product Use Rate (fl. oz. per 100 lbs. seed)
Wheat	<i>Rhizoctonia</i> spp.	0.8	1.23

Have the product container or label with you when calling a poison control center, doctor, or going for treatment. For non-emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 (NPIC Web site: www.npic.orst.edu). For emergencies, call the poison control center 1-800-222-1222, 24 hours a day, 7 days a week.