

264-985

10/02/2008

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OCT 02 2008

Dr. Jamin Huang  
Product Registration Manager  
Bayer Cropscience  
2 T.W. Alexander Drive  
Research Triangle Park, NC 27709

Re: Bayer Cropscience, GB34 Concentrate Biological Fungicide  
EPA Registration No. 264-985  
Minor Label ("Fast Track") Amendment  
Original Application Dated 08/21/2008

Dear Dr. Huang:

The Agency has reviewed your request to amend the subject product registration, which included the following changes to the product label:

- 1) Presentation of both the primary brand name (GB34 Concentrate Biological Fungicide) and the alternate brand name (Yield Shield Biological Fungicide),
- 2) Conversion of "Inert Ingredients" to "Other Ingredients" per Pesticide Registration (PR) Notice 97-6,
- 3) Structural and clarity adjustments to the Precautionary Statements and the Directions for Use,
- 4) Modification of the "dust/mist filtering respirator" statement and addition of the "sensitization" statement in the Hazards to Humans and Domestic Animals section,
- 5) Insertion of the statement, "For indoor commercial seed treatment use only," in the Directions for Use to account for the reduction of statements in the Environmental Hazards section,
- 6) Insertion of the statement, "Treated seed must be labeled in accordance with the requirements of the Federal Seed Act," to the Directions for Use per Policy and Criteria Notice 2170.1,
- 7) Insertion of the statement, "Observe the most restrictive of the labeling limitations and precautions of all products used in mixtures," to the Directions for Use per Chapter 8 of the Label Review Manual,
- 8) Revision of the Mixing Instructions,
- 9) Revision of the Warranty per Chapter 12 of the Label Review Manual, and
- 10) Revision of the Storage and Disposal statements in accordance with PR Notice 2007-4.

CONCURRENCES

SYMBOL	7511P	7511P	7511P					
SURNAME	KAUSCH	Byrne/nd	Curly					
DATE	10/01/2008	10/1/08	10/2/08					

Jamin Huang  
EPA Registration No. 264-985


The changes referred to on the previous page, submitted in connection with registration under FIFRA section 3(c)(5), are acceptable provided that you:

- 1) Submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
- 2) Submit two (2) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of a final printed label.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. If you have any questions contact Jeannine Kausch at 703-347-8920 or by email at: [kausch.jeannine@epa.gov](mailto:kausch.jeannine@epa.gov).

A stamped copy of the label is enclosed for your records.

Sincerely,

  
Sheryl Reilly, Ph.D., Chief  
Microbial Pesticides Branch  
Biopesticides and Pollution  
Prevention Division (7511P)

Enclosures (2):  
- A-79 Enclosure  
- Accepted Label

OCT 02 2008

Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended, for  
the pesticide registered under  
EPA Reg. No. 264-985

# GB34 Concentrate Biological Fungicide

{Alternate Brand Name: Yield Shield Biological Fungicide}

## FOR USE AS A SEED TREATMENT

### ACTIVE INGREDIENT:

*Bacillus pumilus* GB34† ..... 0.28%

OTHER INGREDIENTS: ..... 99.72%

TOTAL 100.00%

†Contains  $1.0 \times 10^{10}$  CFU per gram

EPA Reg. No. 264-985

EPA Est.

## KEEP OUT OF REACH OF CHILDREN

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)

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

NET CONTENTS: 2 x 2 lbs

{Batch code: inkjetted onto product container at production facility}

## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Mixers/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95 or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

Wash face, hands and arms thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

For emergency information concerning this product, call the National Pesticides Information Center (NPIC), at 1-800-858-7378 seven days a week, 6:30 to 4:30 pm Pacific time (PT), or visit the NPIC website at npic.orst.edu. At other times, call the poison control center at 1-800-222-1222. Have the product container or label with you when calling the NPIC, a poison control center or doctor, or when going for treatment.

### ENVIRONMENTAL HAZARDS

Do not contaminate water when cleaning equipment or disposing of equipment washwaters or rinsate.

## DIRECTIONS FOR USE

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

Not for use on agricultural establishments in hopper-box, planter-box, slurry-box, or other seed treatment applications at or immediately before planting.

For indoor commercial seed treatment use only.

## GENERAL INFORMATION

GB34 Concentrate Biological Fungicide is a biological fungicide that, when applied to seed, colonizes the developing root system and provides protection against disease organisms such as *Rhizoctonia* and *Fusarium* that attack the root system. Through a mode of action in which the plant's own host resistance is activated, biological protection is achieved which frequently results in improved plant stand, plant health and yield.

## FOR USE AS A SEED TREATMENT

Apply GB34 Concentrate Biological Fungicide as a water-based slurry either alone or with other registered seed treatment insecticides and fungicides through standard slurry or mist commercial seed treatment equipment. Coloring is not required for seed treated with GB34 Concentrate Biological Fungicide alone. However, when using GB34 Concentrate Biological Fungicide in conjunction with registered fungicides or other seed protectant products, the treated seed may be required to be colored. Treated seed must be labeled

in accordance with the requirements of the Federal Seed Act. Observe the most restrictive of the labeling limitations and precautions of all products used in mixtures.

**MIXING INSTRUCTIONS**

To mix, either add water to the container to pre-slurry GB34 Concentrate Biological Fungicide prior to adding to the treatment slurry tank or add 1/2 of the required water to the treatment slurry tank prior to adding GB34 Concentrate Biological Fungicide to the slurry until a uniform suspension is obtained. If applying with other registered seed treatment products, contact your Bayer CropScience representative for further guidelines for mixing and slurry storage instructions.

**APPLICATION RATES**

May be used alone or in combination with other registered Bayer CropScience seed treatment fungicides and insecticides. Pre-test for compatibility with other seed treatment products.

**Carrot, Corn, Cotton, Cucumber, Peanut, Radish, Squash, Sugar Beet, Barley, Oat, Wheat, Triticale, and Legume Vegetables [Adzuki, Bean, Asparagus Bean, Broad Bean (Succulent or Dry), Catjang Bean, Chinese Longbean, Field Bean, Guar Bean, Jackbean, Kidney Bean, Lablab Bean, Lima Bean (Succulent or Dry), Moth Bean (Succulent or Dry), Mung Bean, Navy Bean, Pinto Bean, Rice Bean, Runner Bean, Snap Bean, Sword Bean, Tepary Bean, Urd Bean, Wax Bean, Yardlong Bean, Blackeyed Pea (Succulent or Dry), Chickpea, Cowpea (Succulent or Dry), Crowder Pea, Dwarf Pea, Edible-Pod Pea, English Pea, Field Pea, Garden Pea, Green Pea, Pigeon Pea (Succulent or Dry), Snow Pea, Southern Pea (Succulent or Dry), Sugar Snap Pea, Grain Lupin, Sweet Lupin, White Lupin, White Sweet Lupin, Lentil, and Soybean]:**

For suppression of root diseases caused by *Rhizoctonia* and *Fusarium*, apply 0.1 ounces of GB34 Concentrate Biological Fungicide per 100 pounds of seed.

**STORAGE AND DISPOSAL**

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

**PESTICIDE STORAGE**

Store in a dry place.

**PESTICIDE DISPOSAL**

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

**CONTAINER DISPOSAL**

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 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. Do not burn, unless allowed by State and local ordinances.

**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 the user must follow directions. 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. 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.

**NOTICE TO BUYER**

Purchase of this material does not confer any rights under patents governing this product or the use thereof in countries outside of the United States.



Listed by the Organic Materials Review Institute (OMRI) for use in organic production

Produced for



Bayer CropScience

Bayer CropScience LP  
P.O. Box 12014, 2 T.W. Alexander Drive  
Research Triangle Park, North Carolina 27709  
1-866-99BAYER (1-866-992-2937)

GB34 Concentrate Biological Fungicide (PENDING) 08/21/08, resubmit09/26/08, 9/30/08