

264-970

12/7/2007

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DEC 07 2007

Dr. Jamin Huang
Bayer CropScience
2 T.W. Alexander Drive
P.O. Box 12014
Research Triangle Park, NC 27709

Subject: Bayer CropSciences' Kodiak Flowable Biological Fungicide
EPA Reg. No. 264-970
Label Resubmission Amendment
Application Dated: June 13, 2007
(EPA Submission No.: 812396)

Dear Mr. Kellogg:

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(5) is acceptable provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Submit five (5) copies of your final printed labeling before you release the product for shipment. Final printed labeling means the label or labeling of the product when distributed or sold. Clearly legible reproductions or photo reductions will be accepted for unusual labels, such as those silk-screened directly onto glass or metal containers or large bags or drum labels.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

If you have any questions contact Ms. Linda Roberts at 703-308-0045 or by e-mail at Roberts.Linda@epa.gov

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

Sincerely,

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

		CONCURRENCES						
SYMBOL	Enclosure: Stamped Label							
SURNAME	7511P 7511P							
DATE	Roberts Reilly							
	12/7/07 12/7/07							

ACCEPTED
 DEC 07 2007
 Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 264-970

KODIAK® Flowable Biological Fungicide

FOR USE AS A SEED TREATMENT

ACTIVE INGREDIENT:

Bacillus subtilis GB03 (not less than of 5.0 X 10¹⁰ viable spores per milliliter)..... 1.37%

INERT INGREDIENTS: 98.63%

TOTAL 100.00%

EPA Reg. No. 264-970

EPA Est.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Additional Precautionary Statements

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)

FIRST AID

IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • 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 IN EYES:	<ul style="list-style-type: none"> • 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.
<p>In case of emergency call toll free the Bayer CropScience Emergency Response Telephone No. 1-800-334-7577. Have a product container or label with you when calling a poison control center or doctor, or going for treatment.</p>	

PRECAUTIONARY STATEMENTS

CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- long sleeved shirt and long pants
- waterproof gloves
- shoes plus socks
- protective eyewear
- 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.

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

USER SAFETY REQUIREMENTS

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

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ENVIRONMENTAL HAZARDS

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. Cover or incorporate spilled seed or seed on soil surface.

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 State or Tribal agency responsible for pesticide regulation.

Federal law requires that bags containing treated seed shall be labeled with the following information: This seed has been treated with *Bacillus subtilis* GB03. Do not use for food, feed, or oil purposes. Store away from feeds and foodstuffs.

STORAGE AND DISPOSAL

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

STORAGE

Store in a cool, dry place.

PRODUCT DISPOSAL

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

CONTAINER DISPOSAL

Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

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 4 hours. Exception: If the product 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, waterproof gloves, and shoes plus socks and protective eyewear.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses.

Keep unprotected persons out of the treated areas until sprays have dried.

KODIAK Flowable Biological Fungicide contains bacteria which colonize the developing root system, suppressing disease organisms such as *Fusarium*, *Rhizoctonia*, *Alternaria* and *Aspergillus* that attack root systems. When used with a chemical seed treatment, the combination of chemicals and KODIAK Flowable provides protection to the root for a much longer time than with chemicals alone. As the root system develops, the bacteria grow with the roots extending the protection throughout the growing season. As a result of this biological protection, a vigorous root system is established by the plant, which often results in more uniform stands and greater yields.

In addition, KODIAK Flowable has been shown to increase the amount of nodulation by nitrogen-fixing bacteria when used on many legumes. This improvement in nodulation is a result of a healthier root system allowing more sites for nodules to form from naturally-occurring soilborne nitrogen-fixing bacteria.

FOR USE AS A SEED TREATMENT

KODIAK Flowable Biological Fungicide may be applied as a water-based slurry with other registered seed treatment insecticides and fungicides through standard slurry or mist commercial seed treatment equipment. Note: This product does not contain colorant. To comply with 40 CFR 153.155; all seed treated commercially with this product must be colored with an EPA approved dye or colorant of a suitable color to prevent accidental use as food for man or feed for animals. To mix, first add the chemical insecticides and/or fungicides to the slurry mix with approximately 1/2 of the required water. Slowly add the KODIAK Flowable Biological Fungicide to the slurry until a uniform suspension is obtained. Add the remainder of the required water and maintain continuous agitation. Do not store mixed slurries for longer than 72 hours.

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APPLICATION RATES

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

COTTON:

For treating of cotton seed destined for planting in states other than California. Treated seed is not to be planted in California.

For suppression of *Rhizoctonia* and *Fusarium* seedling diseases, apply 0.5 fl.oz. per 100 lbs. of seed.

SEED AND POD VEGETABLES (such as) green beans, snap beans, lima beans, kidney beans, navy beans, pinto beans, wax beans pole beans, garden peas, peas and field beans:

For treating of seed and pod vegetable seed destined for planting in states other than California. Treated seed is not to be planted in California.

For suppression of root diseases caused by *Rhizoctonia* and *Fusarium*, apply 0.25 fl.oz. per 100 lbs. of seed. For improvement of nodulation by *Rhizobium* in fields where appropriate strains are detectable, apply at 0.25 fl.oz. per 100 lbs. of seed.

SOYBEANS:

For treating of soybean seed destined for planting in states other than California. Treated seed is not to be planted in California.

For suppression of root diseases caused by *Rhizoctonia* and *Fusarium* and for improvement of nodulation by *Bradyrhizobium*, apply 0.25 fl.oz. per 100 lbs. of seed.

WHEAT AND BARLEY:

For treating of wheat and barley seed destined for planting in states other than California. Treated seed is not to be planted in California.

For suppression of root diseases caused by *Rhizoctonia* and *Fusarium*, apply 0.1 – 0.2 fl.oz. per 100 lbs. of seed.

CORN (field and sweet)

For treating of corn (field and sweet) seed destined for planting in states other than California. Treated seed is not to be planted in California.

For suppression of root diseases caused by *Rhizoctonia* and *Fusarium*, apply 0.2 – 1.0 fl.oz. per 100 lbs. of seed.

ALL OTHER AGRICULTURAL SEEDS:

For treating of all other agricultural seed destined for planting in states other than California. Treated seed is not to be planted in California.

For suppression of root diseases caused by *Rhizoctonia* and *Fusarium*, apply 0.2 – 1.0 fl.oz. per 100 lbs. of seed. Adjust rate accordingly to provide good coverage. Larger seed, because of reduced surface area, requires less product per 100 pounds than smaller seed.

FOR APPLICATIONS OF KODIAK Flowable Biological Fungicide IN THE FIELD BY THE GROWER:

KODIAK Flowable Biological Fungicide when packaged in 32 fl. oz. (one-quart) 'Tip-and-Pour' containers are filled to a 16 fl. oz. volume. Prior to applying KODIAK Flowable Biological Fungicide to cottonseed in a "downstream" application, KODIAK Flowable Biological Fungicide must be mixed thoroughly with an equal volume (16 fl. oz) of clean tap or well water. Mixing must be done directly in the Tip-and-Pour container. The 50/50 mixture of the KODIAK Flowable Biological Fungicide and water (now a total of 32 fl.oz.) will treat a total of 64 bags (32 cwt.) of cottonseed per container. Each time the 'Tip-and-Pour' is inverted, the pouring chamber will have 2.0 fl.oz. of the mixture. To obtain an appropriate amount of KODIAK Flowable Biological Fungicide to treat 8 bags of cottonseed, two 'tips' must be made to measure the correct amount of KODIAK Flowable Biological Fungicide. Do not use treated seed for food or feed purposes or process for oil. Treat only those seeds needed for immediate use, minimizing the interval between treatment and planting.

FOR APPLICATIONS OF KODIAK Flowable Biological Fungicide TO SEED AND POD VEGETABLES:

KODIAK Flowable Biological Fungicide when packaged in 32 fl. oz. (one-quart) 'Tip-and-Pour' containers are filled to a 16 fl. oz. volume. Prior to applying KODIAK Flowable Biological Fungicide to seed and pod vegetables, KODIAK Flowable Biological Fungicide must be mixed thoroughly with an equal volume (16 fl. oz) of clean tap or well water. Mixing must be done directly in the Tip-and-Pour container. The 50/50 mixture of the KODIAK Flowable Biological Fungicide and water (now a total of 32 fl.oz.) will treat a total of 64 cwt. of seed and pod vegetables. One tip of the bottle after mixing with water will provide 2 fl.oz. (a diluted 1 fl.oz. of KODIAK Flowable Biological Fungicide) that will treat 4 cwt. of seed and pod vegetables. Do not use treated seed for food or feed purposes or process for oil. Treat only those seeds needed for immediate use, minimizing the interval between treatment and planting.

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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. 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.

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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.

NET CONTENTS:

KODIAK is a registered trademark of Bayer



Bayer CropScience

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