

71840-4

04-13-2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 13 2004

Catherine B. Rice
Regulatory Specialist, Becker Underwood, Inc.
801 Dayton Avenue
P.O. Box 667
Ames, IA 50010

Dear Ms. Rice:

Subject: Application dated September 26, 2003 for product Subtilex HB Biological Fungicide
EPA Reg. No. 71840-4

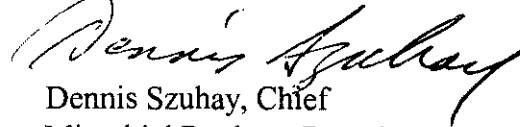
Your application for amendment of the label amendment for the subject product is acceptable under the Federal Insecticide and Rodenticide Act, as amended (FIFRA). The revisions to the label are as follows:

- The FIRST AID section is revised as follows:
 - The section "If in eyes" is deleted, as it is not required.
 - The statement is added: "Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals."
- In the PRECAUTIONARY STATEMENTS section, the first paragraph after the word CAUTION is deleted and the following statement is inserted: "Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals."
- In the DIRECTIONS FOR USE section under FOR USE AS A HOPPER BOX TREATMENT FOR COTTON SEED the reference to "inoculants" is made in the first and second sentences.

Please send to the Agency three (3) final printed labels before shipment.

A stamped accepted label is enclosed.

Sincerely,



Dennis Szuhay, Chief
Microbial Products Branch
Biopesticides and Pollution Prevention Division (7511C)

Enclosure		CONCURRENCES					
SYMBOL	7511C	7511C					
SURNAME	BALL	Szuhay					
DATE	4-13-04	4-13-04					

SUBTILEX™ HB

Biological Fungicide

HOPPER BOX SEED TREATMENT FOR COTTON

ACTIVE INGREDIENT:

Bacillus subtilis, MBI 600 (not less than 3.12 X 10⁹ viable spores per gram).....0.17%

INERT INGREDIENTS:.....99.83%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Additional Precautionary Statements on Side (Back) Panel

EPA Reg. No. 71840-4

EPA Establishment No. _____

U.S. Patent No. 5,061,495

U.S. Patent No. 5,344,647

Canada Patent No. 1,324,099

Another quality biological product from:

Becker Underwood, Inc.

801 Dayton Avenue

PO Box 667

Ames, IA 50010

Tel. (515) 232 5907 (800) 232 5907

www.beckerunderwood.com

Net Contents: _____

Batch Code: _____

SUBTILEX is a Reg. TM of The MicroBio Group Ltd.
Bacillus subtilis, MBI 600 strain is a product of MicroBio Ltd., England.

FIRST AID

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

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: 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 and shoes plus socks. As a general precaution when exposed to concentrations of living microbial products such as this, all mixers / loaders and applicators must wear a dust / mist filtering respirator meeting NIOSH standards of at least N-95, R-95 or P-95. Follow manufacturer's instructions for cleaning / maintaining PPE. Keep and wash PPE separately from other laundry.

User Safety Requirements:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove PPE immediately after handling this product. If gloves are worn, wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Environmental Hazards:

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public water unless this product is specifically identified and addressed in a NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment authority. For guidance, contact your state water Board or Regional Office of the EPA.

For Seed Treatment: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean highwater mark. Do not contaminate water when disposing of equipment washwater. Do not apply this product while bees are actively visiting the area.

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.

AGRICULTURAL USE REQUIREMENTS

Use this product 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 for exceptions pertaining to the statements in this labeling about PPE, restricted-entry intervals, and notification to workers. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard (WPS).

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

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.

ACCEPTED
APR 13 2004
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 71840-4

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SUBTILEX™ contains bacteria, which colonize on 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 SUBTILEX™ 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.

FOR USE AS A HOPPER BOX TREATMENT FOR COTTON SEED

SUBTILEX™ may be applied to dry seed or as a water-based slurry with other inoculants and registered seed treatment insecticides and fungicides. To mix, first add the inoculant / chemical insecticides and / or fungicides to the slurry mix with approximately ½ of the required water. Slowly add the SUBTILEX™ 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.

APPLICATION RATE:

For suppression of *Rhizoctonia* and *Fusarium* seedling diseases, and *Fusarium* wilt, apply 4 ounces per 50 lbs. of seed.

CHEMIGATION

Do not apply this product through any type of irrigation system.

STORAGE AND DISPOSAL

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

STORAGE: Store in a dry place.

PRODUCT DISPOSAL: Wastes resulting from the use of this product may be disposed on site, or at an approved waste disposal facility.

CONTAINER DISPOSAL: Completely empty package by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into mixing equipment. Then dispose of package in a sanitary landfill or by incineration if allowed by State and local authorities. Dispose of box in the same manner. Do not reuse package or box.

NOTICE – READ CAREFULLY CONDITIONS OF SALE AND LIMITED WARRANTY STATEMENT

Becker-Underwood, Inc. warrants that this product conforms to the specifications on the label and is reasonably fit for the purposes stated on the label when used in strict accordance with the directions, subject to the inherent risks set forth below. Becker-Underwood, Inc. MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

Inherent Risks of Use: It is impossible to eliminate all risks associated with use of this product. Lack of performance, injury, or other unintended consequences may result because of such factors as use of the product contrary to strict label instructions and established safe practice, abnormal conditions (such as excessive rainfall, drought, and Acts of God), presence of other materials, use in combination with other materials, the manner of application, or other factors, all of which are beyond the control of Becker-Underwood, Inc. or the seller. All such risks shall be assumed by the buyer.

Limitation of Remedies: The exclusive remedy for losses or damages resulting from this product (including claims based on contract, negligence, strict liability, or other legal theories), shall be limited to, at Becker-Underwood, Inc.'s election, one of the following: (1) replacement of the amount of product used; or (2) refund of the purchase price paid for the product. Becker-

Underwood, Inc. shall not be liable for losses or damages resulting from handling, storage, or use of this product unless Becker-Underwood, Inc. is promptly notified of such loss or damage in writing. In no case shall Becker-Underwood, Inc. be liable for consequential or incidental damages or losses. Becker-Underwood, Inc. neither assumes, nor authorizes any person to assume for it, any other liability in connection with the sale, storage, use, or handling of this product other than expressly set forth herein.