

71840-1

1045

JUL 18 2011

Gordon Sargent
Becker Underwood
801 Dayton Avenue, P.O. Box 667
Ames, Iowa 50010

D 445989 | B680
5 891283 | 1155
DP 390053

Re: *Bacillus subtilis*, strain MBI 600
SUBTILIX® MUP
EPA Reg. No. 71840-1
Your Correspondence of February 25, 2011

Dear Mr. Sargent:

On February 25, 2011, you wrote to request amendment of the referenced pesticide product registration to a) reflect its formulation from a recently registered source product, b) become solely a manufacturing-use product though removal of end-use product use directions (per the Agency's letter of November 29, 2007; S. K. Reilly to G. Sargent), and c) change the product name from SUBTILIX® Biological Fungicide to SUBTILIX® MUP. In support of the requests, you submitted a new Confidential Statement of Formula (CSF, EPA Form 8570-4) and a draft product label. On July 8, 2011, an updated draft label for EPA Reg. No. 71840-1 was provided in response our July 1, 2011 email request. The Biopesticides and Pollution Prevention Division (BPPD) reviewed the submission and update, and a summary of our conclusions is presented below. Please also consult the enclosed memorandum (J. L. Kough to D. Greenway; June 24, 2011).

The product name has been changed, as requested, to become SUBTILIX® MUP.

The February 25, 2011 CSF for EPA Reg. No. 71840-1, showing a registered source for the active ingredient, is acceptable.

The label revision referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you submit two copies of your final printed labeling before releasing the product for shipment. Refer to the A-79 enclosure for further description of final printed labeling.

CONCURRENCES

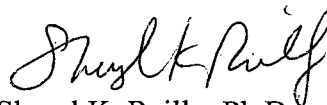
SYMBOL	7511P	7511P	7511P				
SURNAME	Greenway	Reynolds	Rully				
DATE	7/13/2011	7/14/11	7/18/11				

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

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

Should you have questions or concerns regarding this letter, please contact me or Ms. Denise Greenway, of my staff, via greenway.denise@epa.gov or (703) 308-8263.

Sincerely,



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

Enclosures (3)

DGreenway/308-8263/7-11-2011/71840-1MUPamendment.docx

SUBTILEX® MUP

FOR FORMULATING INTO REGISTERED END-USE PRODUCTS

ACTIVE INGREDIENT:

Bacillus subtilis, strain MBI 600* 9.9%

OTHER INGREDIENTS 90.1%

Total: 100.0%

* Contains not less than 5.5 x 10¹⁰ viable spores per gram

KEEP OUT OF REACH OF CHILDREN

CAUTION

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.

HOTLINE NUMBER

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

For emergency information on SUBTILEX® MUP, call 1-800-232-5907, Monday through Friday, 8 a.m. to 5 p.m. CST. After 5 p.m. call your poison control center at 1-800-222-1222.

EPA Reg. No. 71840-1
EPA Est. No. 67064-IA-001

ACCEPTED

JUL 18 2011

Net Contents: 14.1 ounces (400 grams) Batch Code: _____

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

71840-1

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Personal Protective Equipment (PPE)

Individuals handling this material 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.

ENVIRONMENTAL HAZARDS

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 MANUFACTURING OR FORMULATING USE ONLY. This product may be used only for formulating end-use pesticide products for the control of specific fungal plant pathogens. Not for direct treatment of pests. Do not use from damaged, punctured or unsealed containers. End-use products formulated from this product must be in compliance with FIFRA.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry place until used. Do not store this product near food, feed, seed, fertilizers or other pesticides.

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. Triple rinse as follows: Empty the remaining contents into manufacturing equipment. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into manufacturing equipment or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. 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.

NOTICE- READ CAREFULLY
CONDITIONS OF SALE AND LIMITED WARRANTY STATEMENT

NOTICE: 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.

To the extent permitted by applicable law, 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.

Limitations of Remedies: To the extent permitted by applicable law, 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 the 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 contrary to label instructions unless Becker Underwood Inc. is promptly notified of such loss and damage in writing. To the extent permitted by applicable law, Becker Underwood Inc. shall not 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.

Manufactured by:
Becker Underwood Inc.
801 Dayton Avenue, PO Box 667
Ames, IA 50010
Tel. 800-232-5907 Fax 515-232-5961
www.beckerunderwood.com

SUBTILEX is a registered trademark of Becker Underwood Inc.