

71840-5

11/13/2008

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Mr. Gordon Sargent
Regulatory and Compliance Manager
Becker Underwood, Incorporated
801 Dayton Avenue, P.O. Box 667
Ames, IA 50010

NOV 13 2008

Re: Becker Underwood, Incorporated; Integral®
EPA Registration No. 71840-5
Minor Label ("Fast Track") Amendment
Original Application Dated 10/20/2008

Dear Mr. Sargent:

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

- 1) Addition of an 818 mL package size,
- 2) Addition of the indicator, "Batch Code:," in accordance with PR Notice 2007-4, and
- 3) Combination of Sub-labels A and B so that all approved uses (in-furrow treatment, peat moss or growing media incorporation, commercial seed treatment, and pre-plant seed treatment) are on the same label.

The changes referred to above, 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.

CONCURRENCES

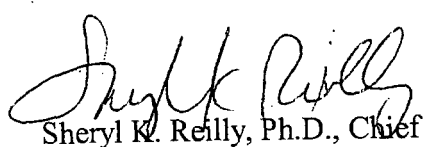
SYMBOL	7511P	7511 P	7511P				
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Gordon Sargent
EPA Registration No. 71840-5

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.

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

Sincerely,



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

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

INTEGRAL®

Liquid Biological Fungicide
{Alternate Brand Name: SUBTILEX® L}

MASTER LABEL

ACTIVE INGREDIENT:

<i>Bacillus subtilis</i> , MBI 600*	0.18%
OTHER INGREDIENTS	99.82%
TOTAL:	100.00%

* Contains not less than 2.2×10^{10} viable spores per mL

Batch code: Located on physical container.

EPA Registration No. 71840-5
EPA Est. No. 67064-IA-001

Becker Underwood
801 Dayton Avenue
P.O. Box 667
Ames, IA 50010

ACCEPTED

NOV 13 2008

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 71840-5

INTEGRAL®

A Liquid Biological Fungicide

**FOR USE AS AN IN-FURROW TREATMENT APPLICATION; OR
INCORPORATION INTO PEAT MOSS OR GROWING MEDIA;
OR FOR USE AS A SEED TREATMENT**

ACTIVE INGREDIENT:

Bacillus subtilis, MBI 600*0.18%

OTHER INGREDIENTS 99.82%

TOTAL: 100.00%

* Contains not less than 2.2×10^{10} viable spores per mL

KEEP OUT OF REACH OF CHILDREN

See Additional Precautionary Statements on Label

EPA Reg. No. 71840-5

EPA Est. No. 67064-IA-001

U.S. Patent No. 5,061,495 • U.S. Patent No. 5,344,647 • Canada Patent No. 1,324,099

NET CONTENTS:

PRECAUTIONARY STATEMENTS

FIRST AID

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- 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. 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 are provided, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- 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

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 cleaning equipment or disposing of equipment wash waters or rinsate. 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 State or Tribal agency responsible for pesticide regulation.

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 apply to uses of this product that are covered by the Worker Protection Standard.

No restricted-entry interval (REI) is required for this product.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses 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.

GENERAL INFORMATION

INTEGRAL® contains bacteria, which colonize on the developing root system, suppressing disease organisms such as *Fusarium*, *Rhizoctonia*, and *Alternaria* that attack root systems. 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, INTEGRAL® 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 inoculated or naturally occurring soil borne nitrogen-fixing bacteria.

USE RESTRICTIONS

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

FOR USE AS AN IN-FURROW TREATMENT

Apply INTEGRAL® as a water-based suspension with other in-furrow treatments (including Becker Underwood liquid inoculants such as VAULT®, *Rhizobium* inoculants, etc.) via standard application equipment.

To mix, first add the in-furrow treatment(s) and/or the *Rhizobium* liquid inoculant to the mix tank with approximately ½ of the required water. Slowly add INTEGRAL® to the slurry until a uniform suspension is obtained. Add the remainder of the water and maintain constant agitation throughout the application. Do not mix INTEGRAL® with any product containing a label prohibition against such mixing. When tank-mixing INTEGRAL® with any other registered in-furrow treatment insecticide and/or fungicide, always read and follow all use directions, restrictions, and precautions of both INTEGRAL® and the tank mix partner(s). The resulting tank mix must be in accordance with the more restrictive label limitations and precautions. Do not exceed label dosage rates.

Apply the slurry at 5-20 gallons (19-76 L) per acre. Do not store mixed slurries for longer than 4 hours.

ATTENTION: If *Rhizobium* inoculants are to be used in the tank mix with other in-furrow treatments (fungicides, insecticides, nematicides, fertilizers, etc.), make sure that they are compatible (not harmful) to the *Rhizobium*. Use only chlorine-free water in the tank mix. If one or more treatments are not compatible (harmful), mix the products in and apply them from a separate mix tank.

PEANUTS

Apply INTEGRAL® concentrate at 0.1-1.2 fl. oz. (3-35 mL) per acre following the application procedures listed above.

When INTEGRAL® is co-packed with VAULT® Liquid Peanut Inoculant, you will also find a bottle labeled Natural Growth Promoter plus a bladder of liquid *Rhizobium* inoculant in the same box. Note that the Natural Growth Promoter, which is packaged with INTEGRAL®, is designed to work with the *Rhizobium* inoculant. Neither the Natural Growth Promoter nor the *Rhizobium* inoculant affects the activity of INTEGRAL®. Combine INTEGRAL®, *Rhizobium* inoculant, and the Natural Growth

Promoter, plus a sufficient quantity of de-chlorinated water, into a homogeneous mixture prior to application to the seed furrow. Apply 1.2 fl. oz. (35 mL) of concentrate per 1000 linear feet of row.

COTTON AND POD VEGETABLES, SOYBEANS AND CORN

Apply INTEGRAL® concentrate at 0.1-1.2 fl. oz. (3-35 mL) per acre following the application procedures listed above.

FOR INCORPORATION INTO PEAT MOSS OR GROWING MEDIA

INTEGRAL® may be applied as a water-based slurry with/without other registered insecticide, fungicides or fertilizers. Pretest for compatibility.

APPLICATION RATES: Add INTEGRAL® to peat moss or soil-based growing media at a rate of 1.3-13 fl. oz. per 100 cubic yards (50-500 mL per 100 cubic meters) of loose growing media.

First mix the required amount of INTEGRAL® with water at the equivalent rate of 1.3-13 fl. oz. per 131 gallons (77-770 mL per 1000 liters). Agitate continuously and then apply evenly with conventional spray equipment to the growing media.

IMPORTANT: Treated peat moss or growing media is only for non-bearing, non-fruiting plant use in protected growing environments (e.g., glasshouse or greenhouse), and is not for use in non-protected environments (e.g. non-contained nurseries or slat houses).

FOR USE AS A PRE-PLANT SEED TREATMENT

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. Do not store excess treated seeds beyond planting time.

Dilute INTEGRAL® with water and apply directly to dry seed or mix INTEGRAL® with liquid *Rhizobium* inoculants and/or other registered seed treatment insecticides and fungicides. Do not mix INTEGRAL® with any product containing a label prohibition against such mixing. When tank-mixing INTEGRAL® with any other registered seed treatment insecticide and/or fungicide, always read and follow all use directions, restrictions, and precautions of both INTEGRAL® and the tank mix partner(s). The resulting tank mix must be in accordance with the more restrictive label limitations and precautions. Do not exceed label dosage rates.

ATTENTION: If *Rhizobium* inoculants are to be used in the tank mix with other seed treatments (fungicides, insecticides, nematicides, fertilizers, etc.), make sure that they are compatible (not harmful) to the *Rhizobium*. Use only chlorine-free water in the tank mix. If one or more treatments are not compatible (harmful), mix the products in and apply them from a separate mix tank.

COTTON

For suppression of root diseases caused by *Rhizoctonia* and *Fusarium* seedling diseases, and *Fusarium* wilt, apply at 0.6-2.4 fl. oz. of INTEGRAL® per 100 lbs (18-72 mL per 45 kg) of delinted cotton seed. Dilute with water to achieve improved application coverage to the seed. Please consult manufacturer for additional information.

SOYBEANS

For suppression of root diseases caused by *Rhizoctonia* and *Fusarium*, and for improvement of nodulation by *Bradyrhizobium japonicum*, combine with inoculant products (i.e., Becker Underwood's VAULT®). Apply 0.136 fl. oz. (4 mL) of INTEGRAL® per 100 lbs (45 kg) of soybeans or in combination with *Bradyrhizobium japonicum* inoculant to improve nodule formation.

When INTEGRAL® is co-packed with VAULT® LVL Soybean Inoculant, you will also find a bottle labeled Liquid Conditioner/Natural Growth Promoter plus a bladder of liquid *Rhizobium* inoculant in the same box. Note that the Liquid Conditioner/Natural Growth Promoter, which is packaged with INTEGRAL®, is designed to work with the *Rhizobium* inoculant. Neither the Liquid Conditioner/Natural Growth Promoter nor the *Rhizobium* inoculant affects the activity of INTEGRAL®. Combine contents of all three containers together and mix into a homogeneous mixture prior to application to the soybean seed. The final mixture will result in the following rates per 100 lbs (45 kg) of seed:

- 0.136 fl. oz. (4 mL) INTEGRAL®
- 0.40 fl. oz. (12 mL) Liquid Conditioner/Natural Growth Promoter
- 2.60 fl. oz. (75 mL) *Rhizobium* inoculant

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 suppression of root diseases caused by *Rhizoctonia* and *Fusarium*, apply 0.6-2.4 fl. oz. of INTEGRAL® per 100 lbs (18-72 mL per 45 kg) of seed. For improvement of nodulation by *Rhizobium* in fields where appropriate strains are detectable, apply 0.6-1.2 fl. oz. of INTEGRAL® per 100 lbs (18-36 mL per 45 kg) of seed.

ALFALFA, FORAGE AND TURF GRASSES

For suppression of root diseases caused by *Rhizoctonia* and *Fusarium*, and for stimulation of germination and plant vigor, apply 0.2-12 fl. oz. of INTEGRAL® per 100 lbs (6-354 mL per 45 kg) (large – small seed varieties respectively) of seed as a blend, or mixed with other registered seed treatments or liquid seed coating agents.

WHEAT AND BARLEY

For suppression of root diseases caused by *Rhizoctonia* and *Fusarium*, apply 0.1-0.6 fl. oz. of INTEGRAL® per 100 lbs (3-18 mL per 45 kg) of seed.

CORN (Field and Sweet)

For suppression of root disease caused by *Fusarium*, apply 0.6-2.4 fl. oz. of INTEGRAL® per 100 lbs (18-72 mL per 45 kg) of seed.

CANOLA

For suppression of root diseases caused by *Rhizoctonia* and *Fusarium*, apply 1.6-38 fl. oz. of INTEGRAL® per 100 lbs (47-1125 mL per 45 kg) of seed.

FOR USE AS A COMMERCIAL SEED TREATMENT

Dilute INTEGRAL® with water and apply directly to dry seed or mix INTEGRAL® with liquid *Rhizobium* inoculants and/or other registered seed treatment insecticides and fungicides. Do not mix INTEGRAL® with any product containing a label prohibition against such mixing. When tank-mixing INTEGRAL® with any other registered seed treatment insecticide and/or fungicide, always read and follow all use directions, restrictions, and precautions of both INTEGRAL® and the tank mix partner(s). The resulting tank mix must be in accordance with the more restrictive label limitations and precautions. Do not exceed label dosage rates.

ATTENTION: If *Rhizobium* inoculants are to be used in the tank mix with other seed treatments (fungicides, insecticides, nematicides, fertilizers, etc.), make sure that they are compatible (not harmful) to the *Rhizobium*. Use only chlorine-free water in the tank mix. If one or more treatments are not compatible (harmful), mix the products in and apply them from a separate mix tank.

Note: This product does not contain dye. 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.

The Federal Seed Act requires that bags containing treated seed shall be labeled with the following information: "This seed has been treated with *Bacillus subtilis*, MBI 600. Do not use for food, feed or oil purposes."

COTTON

For suppression of root diseases caused by *Rhizoctonia* and *Fusarium* seedling diseases, and *Fusarium* wilt, apply at 0.6-2.4 fl. oz. of INTEGRAL® per 100 lbs (18-72 mL per 45 kg) of delinted cotton seed. Dilute with water to achieve improved application coverage to the seed. Please consult manufacturer for additional information.

SOYBEANS

For suppression of root diseases caused by *Rhizoctonia* and *Fusarium*, and for improvement of nodulation by *Bradyrhizobium japonicum*, combine with inoculant

products (i.e., Becker Underwood's VAULT®). Apply 0.136 fl. oz. (4 mL) of INTEGRAL® per 100 lbs (45 kg) of soybeans or in combination with *Bradyrhizobium japonicum* inoculant to improve nodule formation.

When INTEGRAL® is co-packed with VAULT® LVL Soybean Inoculant, you will also find a bottle labeled Liquid Conditioner/Natural Growth Promoter plus a bladder of liquid *Rhizobium* inoculant in the same box. Note that the Liquid Conditioner/Natural Growth Promoter, which is packaged with INTEGRAL®, is designed to work with the *Rhizobium* inoculant. Neither the Liquid Conditioner/Natural Growth Promoter nor the *Rhizobium* inoculant affects the activity of INTEGRAL®. Combine contents of all three containers together and mix into a homogeneous mixture prior to application to the soybean seed. The final mixture will result in the following rates per 100 lbs (45 kg) of seed:

- 0.136 fl. oz. (4 mL) INTEGRAL®
- 0.40 fl. oz. (12 mL) Liquid Conditioner/Natural Growth Promoter
- 2.60 fl. oz. (75 mL) *Rhizobium* inoculant

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 suppression of root diseases caused by *Rhizoctonia* and *Fusarium*, apply 0.6-2.4 fl. oz. of INTEGRAL® per 100 lbs (18-72 mL per 45 kg) of seed. For improvement of nodulation by *Rhizobium* in fields where appropriate strains are detectable, apply 0.6-1.2 fl. oz. of INTEGRAL® per 100 lbs (18-36 mL per 45 kg) of seed.

ALFALFA, FORAGE AND TURF GRASSES

For suppression of root diseases caused by *Rhizoctonia* and *Fusarium*, and for stimulation of germination and plant vigor, apply 0.2-12 fl. oz. of INTEGRAL® per 100 lbs (6-354 mL per 45 kg) (large – small seed varieties respectively) of seed as a blend, or mixed with other registered seed treatments or liquid seed coating agents.

WHEAT AND BARLEY

For suppression of root diseases caused by *Rhizoctonia* and *Fusarium*, apply 0.1-0.6 fl. oz. of INTEGRAL® per 100 lbs (3-18 mL per 45 kg) of seed.

CORN (Field and Sweet)

For suppression of root disease caused by *Fusarium*, apply 0.6-2.4 fl. oz. of INTEGRAL® per 100 lbs (18-72 mL per 45 kg) of seed.

CANOLA

For suppression of root diseases caused by *Rhizoctonia* and *Fusarium*, apply 1.6-38 fl. oz. of INTEGRAL® per 100 lbs (47-1125 mL per 45 kg) of seed.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE:

Store in a dry place.

PESTICIDE DISPOSAL:

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by stated or local governments or by industry).

CONTAINER DISPOSAL:

Nonrefillable 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 and drain for 10 seconds after flow begins to drip. Fill the container ¼ 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.

NOTICE – READ CAREFULLY BEFORE USING

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.

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.

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 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.

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. 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.

Another quality biological product from:

Becker Underwood
801 Dayton Avenue
PO Box 667
Ames, IA 50010
Tel. 515-232-5907 • 800-232-5907
www.beckerunderwood.com

INTEGRAL is a Reg. TM of Becker Underwood, Inc.
Bacillus subtilis, MBI 600 strain is a product of Becker Underwood, Inc.