

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

AUG 20 2002

Dr. Sarah Hinz-Bridger SHB Scientific Enterprises P.O. Box 7012 Chandler, AZ 85246-7012

Subject:

Label Amendment Application Dated July 25, 2002

EPA Registration No. 53871-9

Naturalis Products

Dear Dr. Hinz-Bridger:

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(A), is acceptable provided that you:

- 1. Use Naturalis L only as the registered stamped label.
- 2. Do not use the Naturalis H&G (Home and Garden) sublabel as part of this master label. You must revise the Naturalis H&G sublabel to reflect the proposed uses on home and garden sites. For example, golf courses, pastureland, tobacco, athletic fields, sod farms, etc., do not relate to home and garden types of application. You must also include appropriate (a) warranty statements; and (b) application rates and Worker Protection Standards statements on the Naturalis H&G labels to suit the sites to be treated. Should you wish to add any sublabels to the Naturalis L label, you must submit an amendment to revise the entire label.
- Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data.
- 3. 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.

A stamped copy of the Naturalis L label is enclosed for your records. If you have any

questions regarding this matter, do not hesitate to email Shanaz Bacchus at bacchus.shanaz@epa.gov or call her on 703-308-8097.

Sincerely,

Janet L. Andersen, Ph.D., Director Biopesticides and Pollution Prevention Division

Enclosure

Troy biosciences Inc. (53871-9) Page 2 of 19

NATURALIS

Biological insecticide for use on field crops; vegetables; and fruit, nut & vine crops, turfgrasses and ornamentals. Including golf courses, home lawns, athletic fields, sod farms, nurseries, greenhouses, landscape plantings and all other areas where turfgrasses and ornamentals are grown.

ACTIVE INGREDIENTS: Beauveria bassiana ATCC 74040 7.16% (contains no less than 2.3 x 10⁷ viable spores per milliliter of product) INERT INGREDIENTS: ________92.84% TOTAL:......100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

SHAKE WELL BEFORE USING

EPA REG. NO. 53871-9 EPA EST. 53871-AZ-01 PATENT NO. 5,413,784 and 5,516,513

Manufactured By: TROY BIOSCIENCES INC., 113 S. 47th AVENUE, PHOENIX, AZ 85043

Beauveria bassiana Manufactured for Troy Biosciences Inc. by JABB of the Carolinas (EPA Est. 70787-NC-1), P.O. Box 310, Pine Level, NC 27568

NOT FOR SALE OR USE AFTER:

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

This is a potential sensitizing agent via inhalation. Spray mist may cause respiratory irritation. Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling. Avoid eye and skin contact. Avoid breathing vapors.

STATEMENT OF PRACTICAL TREATMENT FIRST AID

If swallowed: Drink 1 or 2 glasses of water, then induce vomiting by touching fingers to the back of the throat. Do not induce vomiting or give anything by mouth to an unconscious person. Consult a physician.

If inhaled: Potential sensitizing agent. If inhaled, move to fresh air. In case of acute allergic reactions or respiratory irritation, consult a

If on Skin: Remove contaminated clothing and wash affected areas with soap and water. Consult a physician if irritation persists.

If in Eyes: Flush eyes with copious amounts of water. If irritation persists, consult a physician.

ENVIRONMENTAL HAZARDS

Do not apply when weather conditions favor drift from the target area. Beauveria bassiana is an insect specific fungus and exposure to non-target insects should be avoided. Avoid applying to areas where honeybees are actively foraging or around bee hives because this product is pathogenic to honeybees. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not discharge into lakes, streams, ponds or public waterways.

PERSONAL PROTECTIVE EQUIPMENT (PPE):

Some materials that are chemical resistant to this product are listed below. If you want more options follow the instructions for category C on the EPA chemical resistance chart. Applicator, mixer loaders, applicators, early entry workers as well as other handlers must wear:

- A. Long sleeved shirt and long pants.
- B. Chemical resistant gloves.
- C. Mist filtering respirators with NIOSH standards of at least N-95, R-95, P-95.
- D. Shoes plus socks must be worn.

Follow manufacturer's instructions for washables, 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 immediately if pesticide gets inside. Then clean thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing

ACCEPTED COMMENTS AUG 2 0 2002

d Redenticide Act for the pesticide registered under EPA Reg. No.

03/2002

53871-

Page 3 of 19

The following requirements or. ∍ply to use of this product on sod farms, in gree Juses, or in production nurseries.

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). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard. 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 requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

Do not enter or allow worker re-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 involves contact with anything that has been treated, such as plants,

- Coveralls over long sleeve shirt
- Long pants
- Shoes plus socks

STORAGE AND DISPOSAL

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

STORAGE: Store in a cool, dry place away from direct sunlight or excessive heat. Optimum storage temperatures are 4° C to 27° C

(39° F to 80° F). Do not allow spray solution to stand more than 4 hours before use. Avoid contamination and loss of potency of opened containers by closing containers tightly after use. It is suggested that opened containers be used in their entirety when possible.

CONTAINER DISPOSAL: Do not reuse empty container. Rinse thoroughly before discarding. Triple rinse (or equivalent), puncture and dispose of in a sanitary landfill, or incinerate if allowed by authorities, or by burning. If burned, stay out of smoke.

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

PHYSICAL AND CHEMICAL HAZARDS

Do not use near heat or open flame.

NON AGRICULTURAL USES

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.

- Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.
- Keep unprotected persons, children and pets out of treated areas until sprays have dried.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. For end use only **GENERAL DIRECTIONS:**

Naturalis L works primarily through contact action, so good spray coverage is essential. Treat when pest populations are manageable and before extensive damage occurs to crops. Naturalis L contains an insect specific fungus. Time must be allowed to achieve pest population suppression. Climatic conditions and pest pressures will determine pretreatment needs. Do not tank mix with fungicides.

The addition of sticking agents, insecticidal soaps or emulsifiable oils may improve control of insects in conditions of high insect pressure. Wait a minimum of 48 hours after application before applying fungicides. If fungicides are on a set schedule, i.e. 10 to 14 day intervals, apply Naturalis Lat midpoint. Do not mix with fungicides. Slotted screens may be used. Do not use nozzles with screens finer than 25 mesh to avoid clogging.

Naturalis L is a unique biological product. Consult local Pest Management authorities, extension agents or Troy Biosciences Inc. representative for guidance in selecting rates and timing schedules of application.

APPLICATION

SHAKE WELL BEFORE USING

Mix recommended quantity with water. Triple rinse container shaking each time, and empty contents into partially filled spray tank free of fungicide residues. Complete filling the tank and mix well. For best results, spray immediately. Use best possible spray coverage techniques. For ornamental use, applications may be necessary every 3 to 5 days and 3 to 5 applications may be necessary before pests are adequately under control. In turf and lawns, reapply only when pest populations are above tolerable levels.

| CROP | PEST | NATURALIS COVERAGE | SPECIAL DIRECTIONS |
|--|--|--|--|
| ALFALFA, CEREAL CROPS (WHEAT, OATS, AND BARLEY), BERRY AND SMALL FRUIT CROPS (BLACKBERRY, BLUEBERRY, CRANBERRY, AND STRAWBERRY), CANOLA, CITRUS (GRAPEFRUIT, ORANGES AND TANGERINES), CORN, COTTON, HOPS, PASTURE LAND, PEANUTS, PINEAPPLE, SAFFLOWER, SUNFLOWERS, AND TOBACCO, BULB VEGETABLES ONIONS (GREEN AND BULB) AND GARLIC, CUCURBIT VEGETABLES (CUCUMBERS, MELONS AND SOUASH), FRUITING VEGETABLES (EGPLANT, PEPPER AND TOMATO), LEAFY AND COLE CROPS, (LETTUCE (HEAD AND LEAF), KALE, CELERY, SPINACH, BROCCOLI, CABBAGE AND PARSLEY), LEGUME VEGETABLES (BEANS, LENTIL, PEAS AND SOYBEAN), ROOT AND TUBER VEGETABLES (CARROTS, POTATOES, BEETS AND SUGARBEETS). | ANTS. APHIDS, ARMYWORMS, BUDWORM AND BOLLWORM, CITRUS BLACKFLY, COLORADO POTATO BEETLE, CORN BORERS, FLEAHOPPERS, JAPANESE BEETLES, LEAFROLLERS, LOOPERS, LYGUS BUG, MEALYBUGS, TETRANYCHID MITES, PEAR PSYLLA, TARNISHED PLANT BUG, THRIPS, TOMATO FRUITWORM, WEEVILS, AND WHITEFLIES EGGS OF LEPIDOPTERAN PESTS | OUTDOORS 10 TO 15 FLUID OUNCES PER ACRE. | A STICKER OR SURFACTANT, WHICH HAS BEEN APPROVED FOR USE ON GROWING AND HARVESTED CROPS, SHOULD BE ADDED FOR USE ON HARD-TO-WET CROPS, SUCH AS COLE CROPS. FOR ALL CROPS, APPLY AT THE UNSET OF INFESTATION. REPEAT AT 3 TO 5 DAY INTERVALS AS NEEDED. AT LEAST 3 TO 5 APPLICATIONS MAY BE NECESSARY BEFORE PESTS ARE ADEQUATELY UNDER CONTROL. |
| HERBS, SPICES AND MINT (BASIL, CHIVES, DILL, LEEK AND PEPPERMINT). | | | **** |
| POME FRUIT (APPLE AND PEAR), STONE FRUIT (CHERRY, NECTARINE, PEACH, PLUM AND PRUNE), TREE NUTS (ALMOND, FILBERT, PECAN AND WALNUT), AND VINES (GRAPES, HOPS AND KIWI FRUIT). | | | |
| AVOCADO AND TROPICAL FRUITS (BANANAS. MANGO, PAPAYA, AND SAPODILLA). | | | |

| CROP | PEST | NATURALIS COVERAGE | SPECIAL DIRECTIONS |
|---|---|---|---|
| ORNAMENTALS: FOLIAGE PLANTS, FLOWERING PLANTS, WOODY AND HERBACEOUS ORNAMENTALS, CONIFERS (INCLUDING CHRISTMAS TREES) AND NON-FOOD BEDDING PLANTS AND TREES. INCLUDING GREENHOUSE AND OUTDOOR ORNAMENTAL PLANTINGS, PLANTSCAPES, TREES, SHRUBS, FLOWER, FOLIAGE CUTTINGS, AND GROUNDCOVERS, | APHIDS, THRIPS, MITES, WHITEFLIES, LEAF-FEEDING CATERPILLARS, LYGUS BUGS, BEETLES- FLEA CUCUMBER, ELM LEAF, ELM LEAF LEAFHOPPERS, ROOT WEEVILS, PSYLLIDS, FUNGUS GNATS, SHORE FLIES, MEALYBUGS | 100 GALLONS: USE 30 TO 100 FLUID OZ. 1 GALLON: 0.3 TO 1 FL. OZ. | USE SUFFICIENT WATER TO ENSURE THOROUGH COVERAGE OF UPPER AND LOWER LEAF SURFACES. USE LOWER RATES FOR LIGHT TO MODERATE PRESSURE, HIGHER RATES FOR HEAVY INFESTATION. CAN BE MIXED WITH STICKING AGENTS, INSECTICIDAL SOAPS AND EMULSIFIABLE OILS. SPRAY IMMEDIATELY AFTER MIXING, FOR FUNGUS GNAT AND SHOREFLY CONTROL TREAT MEDIA AND UNDER BENCHES WITH A COARSE SPRAY. |
| TURFGRASSES: LAWNS. GOLF COURSES (ALL AREAS), SOD FARMS, ATHLETIC FIELDS. | MOLE CRICKETS, CHINCH BUGS, SOD WEBWORMS, ARMYWORMS, CUTWORMS, GRASSHOPPERS, BILLBUGS, SPITTLEBUGS, BERMUDA GRASS MITES, ANTS, MILLIPEDES, SOWBUGS. LARVAE OF THE FOLLOWING PESTS: WHITE GRUBS, ANNUAL WHITE GRUB, BLACK TURFGRASS ATAENIUS, EUROPEAN CHAFER, GREEN JUNE BEETLE, JAPANESE BEETLE, NORTHERN MASKED CHAFER, EUROPEAN CRANEFLY LARVAE. | 1 OZ. PER 1,000 SQ. FEET OR 1 OZ. IN 2 GALLONS OF WATER. | USE SUFFICIENT WATER TO ENSURE COVERAGE. CAN BE MIXED WITH SURFACTANTS & INSECTICIDAL SOAPS, THE ADDITION OF A WETTING AGENT HELPS INSURE PENETRATION THROUGH TURE TO SOIL. WATERING IN IS ESSENTIAL FOR SUBSURFACE FEEDING INSECTS. DO NOT IRRIGATE FOR SEVERAL HOURS WHEN TREATING FOR SURFACE FEEDING INSECTS. NOT RECOMMENDED FOR APPLICATION TO HOT, DRY TURF. PREFER EVENING OR EARLY AM APPLICATION. PRE-IRRIGATE IF TURF IS VERY DRY AND TEMPERATURES ARE OVER 80° F. APPLICATION BY INJECTION INTO TURFGRASS IRRIGATION SYSTEMS. |

NOTICE: It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness, or other unintended consequences may result due to factors which are beyond the control of Troy Biosciences Inc. or Seller. All such risks shall be assumed by Buyer or User.

To the extent required by law, Troy Biosciences Incorporated warrants this product conforms to the chemical description on its label and is reasonably fit for the purposes stated on the Directions for Use, under normal conditions, subject to risks described above. Troy Biosciences Incorporated makes no other warranty, expressed or implied.

NATURALIS IS A REGISTERED TRADEMARK OF TROY BIOSCIENCES INCORPORATED.

