



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 27 2013

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

Mr. Matthew Feinberg
c/o Ms. Carrie Daniels (Agent for Novozymes Biologicals, Inc.)
Exponent
1150 Connecticut Ave., N.W.
Suite 1100
Washington D.C. 20036

Re: Novozymes Biologicals - *Metarhizium anisopliae* Strain F52 Pesticide Product
Registration Label Amendment Request Dated February 11, 2013
Tick-EX EC BIOINSECTICIDE (EPA Reg. No. 70127-10)

Dear Mr. Feinberg:

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.

This approval does not eliminate the need for continual reassessment of the pesticide. If EPA determines at any time that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act.

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.

If you have any questions regarding this pesticide, please email Shanaz Bacchus at bacchus.shanaz@epa.gov or call her at 703-308-8097.

Sincerely,

A handwritten signature in blue ink, appearing to read "Kimberly Nesci for".

Kimberly Nesci, Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division.

Encl: Approved label

[Text in brackets is optional]

(Note: The following information will be presented as a booklet on the front of the product container. Page 1 and 2 are the primary display panel of the booklet.)

(Front Panel)

TICK-EX EC BIOINSECTICIDE

[ABN: MET52[®] EC]

| | |
|---|--------|
| ACTIVE INGREDIENT – <i>Metarhizium anisopliae</i> Strain 52* | % w/w |
| OTHER INGREDIENTS** | 11.0% |
| Total | 89.0% |
| | 100.0% |

* Contains 5.5 x 10⁹ Colony Forming Units (CFU)/gram of Tick-EX EC based on 5x10¹⁰ viable conidia per gram of active ingredient.

** Contains petroleum distillates

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

ACCEPTED
NOV 27 2013

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 70127-10

Causes moderate eye irritation. Harmful if inhaled, absorbed through skin, or swallowed. Avoid contact with skin, eyes, or clothing. Avoid breathing dust. Wash thoroughly with soap and water after handling, and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

[REFER TO DIRECTIONS OF USE WITHIN THIS BOOKLET]

| 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. |
| IF INHALED: | Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice. |
| IF ON SKIN OR CLOTHING: | 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 SWALLOWED: | Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person. |
| HOT LINE 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 this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Information Center at 1-800-368-7378, 6:30 AM to 4:30 PM Pacific Time (PT), seven days a week. During other times, call the poison control center at 1-800-222-1222. | |
| NOTE TO PHYSICIAN | |
| Contains petroleum distillate. Vomiting may cause aspiration pneumonia. | |

Batch Code/Expiry Date: _____

Net Contents: [1 gallon] [1 quart] [1.06 quarts] [1 pint] [½ pint] [XX L]

[Produced For:]
Novozymes Biologicals, Inc.
5400 Corporate Circle
Salem, VA 24153
1-888-744-5662 [1-800-245-4104]

EPA Establishment Number: [070127-VA-001]
[085238-CAN-001]
EPA Registration Number: 70127-10
Made in [USA] [Canada]
[www.bioag.novozymes.com]

[NOVOZYMES RETHINK TOMORROW] [LOGO]

PERSONAL PROTECTIVE EQUIPMENT

Mixer/loaders, applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes and socks
- Protective eyewear
- Dust-mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N-95, R-95, P-95 or HE filter.
- 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 RECOMMENDATIONS

- Users should remove clothing immediately if pesticide gets inside, then wash thoroughly and put on clean clothing.
- Remove personal protection equipment 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

This product is approved for residential (urban and suburban) outdoor terrestrial non-food and agricultural food uses. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. 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.

PHYSICAL OR CHEMICAL HAZARDS

For spill, leak, fire, exposure, or accident, call CHEMTREC at 1-800-424-9300, day or night.

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

For uses that are soil incorporated mechanically, there is a 0 hour Restricted Entry Interval (REI) - the Worker Protection Standard allows workers to enter the treated area if there will be no contact with anything that has been treated. For all other uses, do not enter or allow worker entry into treated areas during the REI of four hours.

PPE required for early entry to treated areas requiring a REI that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, plants, soil, or water are:

- Coveralls
- Waterproof gloves
- Shoes plus socks
- Protective eyewear
- Dust-mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N-95, R-95, P-95 or HE filter.

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.

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

GENERAL

Tick-EX EC is composed of spores of the insect pathogenic fungus *Metarhizium anisopliae* strain F52. Once the product is sprayed onto the foliage or drenched into the soil, insects that come into contact with the fungus will become infected. The spores of *Metarhizium anisopliae* attach to the surface of the insect, germinate and begin to grow. It will penetrate the exoskeleton of the insect and grow inside the insect, causing the insect to die. Under moderate temperatures it usually takes 3 to 7 days, once the insect is exposed for death to occur. At very cold or hot temperatures death may occur more slowly. The fungal spores will be more persistent when incorporated in the soil, especially in potting media, than when applied to foliage.

Note: Tick-EX EC contains live spores that may be harmed by storage at high temperatures or held as a water suspension for more than 24 hours. See storage and disposal section for more information.

MODE OF ACTION AND APPLICATION TIMING: Application frequency will depend on the environment to which Tick-EX EC is applied and the target insects' life cycle. Persistence of Tick-EX EC will generally be higher when incorporated into soil and higher in foliar applications in greenhouses than outdoor foliar.

Tick-EX EC may be used for foliar applications to control insects with a high reproductive potential. It is best to begin applying Tick-EX EC at early stages of population development. Repeat applications at 5-10 day intervals, matching application interval to insect and population. High insect populations of whiteflies may require 2-5 day intervals. Applications to leaf litter and turf may be done on a four to six week interval with an expected residual efficacy of a few months.

Applications of drenches to potting media may be done as appropriate to standard pest management practices and the product may remain efficacious for up to one year. When possible, application to soil should be done in advance of a target insect's life stage that will be passing through the first six inches of soil, with an expected residual efficacy of a few months. Although the penetration of Tick-EX EC into soil will vary greatly with soil type and level of irrigation it is best to target populations as close to the surface as possible or time application of Tick-EX EC with a soil incorporation event

PRE-HARVEST INTERVAL: Pre-harvest interval for Tick-EX EC is zero (0) days. Tick-EX EC may be applied up to the day of harvest.

SITES FOR USE

TERRESTRIAL NON-FOOD: Tick-EX EC can be used on the crops listed in Table 1 (greenhouse, nursery and outdoor sites including urban and suburban turf). Do not apply on poinsettias after bract formation. Tick-EX EC has shown plant safety but has not been tested on all varieties. Test Tick-EX EC on a small number of plants to check for potential damage before applying to a large number of plants.

FOOD CROPS: Tick-EX EC can be used on the crops listed in Table 1 (including greenhouse, nursery and outdoor agricultural sites). Tick-EX EC has shown plant safety but has not been tested on all varieties. Test Tick-EX EC on a small number of plants to check for potential damage before applying to a large number of plants.

APPLICATION INSTRUCTIONS

MIXING INSTRUCTIONS: Shake well before using. Tick-EX EC may be applied using hand-held, ground and/or aerial spray equipment. Tick-EX EC contains emulsifiers and mixes readily in water. Fill spray tank with half of the desired amount of water and start agitation. Slowly add desired amount of Tick-EX EC to spray tank. Add remaining desired amount of water. Triple rinse empty Tick-EX EC container with water and add rinse water to spray tank. Continue agitation throughout spraying. Do not mix more Tick-EX EC than can be applied within six hours of mixing.

PLANT SAFETY: Tick-EX EC has been determined to be safe and efficacious for the uses described on this label but not been tested on all varieties of listed plant species. Test Tick-EX EC on a small number of plants to check for potential damage before applying to a large number of plants.

FOLIAR APPLICATION, HIGH VOLUME: Apply at a rate of 8 – 32 fl oz (½ pint to 1 quart) per 100 gallons in high volume sprays (0.5 to 2.5 teaspoons per gallon). Mix well by external mixing, in-tank mixing, or pump circulation to form emulsion. [Do not apply at pressures above [200] [400] [600] PSI.]
Spray to wet all foliage, but avoid runoff.

FOLIAR APPLICATION, LOW VOLUME: Apply 8 -64 fl oz (½ pint to 2 quarts) of Tick-EX EC to one (1) acre. Follow spray equipment manufacturer's instructions for final spray volume to obtain adequate coverage. [Do not apply at pressures above [200] [400] [600] PSI.] **Do not apply through a thermal pulse fogger.**

DRENCH: Add from 40 to 80 fluid ounces of Tick-EX EC to 100 gallons of drench solution. **For pots:** drench application should be thoroughly watered-in without causing water to come out of the bottom of the pots – depending on the soil type and moisture this will be around 8 ounces per gallon pot. **For soil applications:** drench application should be thoroughly watered-in without causing water to move laterally – this will vary by soil type and moisture holding capacity at time of application. Applications should be targeted to move Tick-EX EC into the top 2 inches of soil.

FOLIAGE AND ROOT PLANT DIP: To prepare dip solution, thoroughly mix ½ to 1 fluid ounce of Tick-EX EC per gallon of water. Prepare only as much dip solution as can be used in 6 hours. When treating plants by the dip method, thoroughly wet all plant surfaces to be treated. Allow treated plant foliage to dry prior to potting and watering.

APPLICATION TO TURF: Apply 2 to 3 fluid ounces of Tick EX EC to 1000 square feet in residential and institutional lawns and landscape perimeters. Applications for blacklegged ticks should focus on the border of manicured lawns and paths creating a minimum of a 9 foot border. Applications for more mobile ticks such as lonestar tick should cover a wider area and include the entire lawn. Apply using a minimum of 4 gallons of water per 1000 square feet. Initial applications should begin in the spring before ticks become active and continue at 4 to 8 week intervals throughout their active season.

TANK MIX COMPATIBILITY: Tick EX EC contains a fungal active. Do not mix Tick-EX EC with fungicides. Tick-EX EC is physically and biologically compatible with a wide range of pesticides and spray adjuvants. If adjuvants are required when applying Tick-EX EC in combination with other pesticides, contact your dealer or Novozymes Biologicals for specific recommendations.

Observe the most restrictive of the labeling limitations and precautions of all products used in mixtures.

CONTROLLING PESTICIDE DRIFT: Do not allow spray to drift from the application site and contact people, nontarget crops, aquatic and wetland areas, or animals.

For ground boom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy and when wind speed is 10 mph or less at the application site as measured by an anemometer. Use a fine or medium spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles.

For orchard/vineyard airblast applications, do not direct spray above trees/vines and turn off outward pointing nozzles at row ends and outer rows. Apply only when wind speed is 3 -10 mph at the application site as measured by an anemometer outside of the orchard/vineyard on the upwind side.

For aerial applications, the boom width must not exceed 75% of the wingspan or 90% of the rotary blade. Use upwind swath displacement and apply only when wind speed is 3 -- 10 mph as measured by an anemometer. Use medium or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles. If application includes a no-spray zone, do not release spray at a height greater than 10 feet above the ground or the crop canopy.

The applicator also must use all other measures necessary to control drift.

TABLE 1: CROPS ON WHICH TICK-EX EC MAY BE USED:

| CROP | PEST | APPLICATION | RATE |
|---|------------------------------------|-------------|--|
| Cucurbits | thrips, whiteflies, mites | drench | 40-80 fl. oz./100 gal. |
| | | foliar | 8 – 64 fl.oz. [0.5 pt.- 2 qt]/acre |
| Onions | thrips | drench | 40-80 fl. oz./100 gal. |
| | | foliar | 8 – 64 fl.oz. [0.5 pt.- 2 qt]/acre |
| Celery, lettuce, spinach | thrips, whiteflies, mites | drench | 40-80 fl. oz./100 gal. |
| | | foliar | 8 – 64 fl.oz. [0.5 pt.- 2 qt]/acre |
| Peppers, tomatoes | thrips, whiteflies, mites | drench | 40-80 fl. oz./100 gal. |
| | | foliar | 8 – 64 fl.oz. [0.5 pt.- 2 qt]/acre |
| Grape, strawberry, cranberry, raspberry, blackberry | thrips, whiteflies, mites, weevils | drench | 40-80 fl. oz./100 gal. |
| | | foliar | 8 – 64 fl.oz. [0.5 pt.- 2 qt]/acre |
| Ornamental plants and grasses: shrubs, vines, trees, lawn, bedding plants, poinsettia, etc. | thrips, weevils, mites, whiteflies | drench | 40-80 fl. oz./100 gal. |
| | | foliar | 8 – 32 fl. oz. [0.5 pt.-1 qt.]/100 gallons, spray to wet but avoid runoff. |
| Turf: institutional, residential lawns (urban and suburban) | ticks | drench | 40-80 fl. oz./100 gal. |
| | | foliar | 2 to 3 fl. oz./ 1000 ft ² |

Applicators other than homeowners

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Store TICK-EX EC in its original container below 73°F (23°C) in a dry, locked place, out of the reach of children and out of direct sunlight. Do not use or store near heat or open flame. Use product within one year and by the expiry date noted on the label.

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 state or local governments or by industry).

CONTAINER HANDLING

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 the 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.

Homeowners

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Store TICK-EX EC in its original container below 73°F (23°C) in a dry, locked place, out of the reach of children and out of direct sunlight. Do not use or store near heat or open flame. Use product within one year and by the expiry date noted on the label.

PESTICIDE DISPOSAL AND CONTAINER HANDLING

Nonrefillable container. Do not reuse or refill container.

If empty:

Place container in trash or offer for recycling, if available.

If partly filled:

Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

WARRANTY

The Directions for Use of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and must be followed carefully.

Novozymes Biologicals warrants that at the time of the first sale of this product it conforms to the chemical description on the label and when used according to the label directions under normal growing conditions is reasonably fit for the purposes referred to above. To the extent consistent with applicable law, buyers/users of this product assume full risk for any use contrary to the specified directions. If this product does not perform as warranted above, customer's sole remedy for breach of warranty, to the extent consistent with applicable law, shall be replacement of the product or refund of the purchase price paid, at the option of Novozymes Biologicals.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, EXCEPT AS PROVIDED ELSEWHERE IN WRITING CONTAINING AN EXPRESS REFERENCE TO THIS WARRANTY AND LIMITATION OF DAMAGES, SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTEE, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO.

(Note: The following information will affixed to the unit package)

TICK-EX EC BIOINSECTICIDE

[ABN: MET52[®] EC]

| | |
|---|----------------|
| ACTIVE INGREDIENT – <i>Metarhizium anisopliae</i> Strain 52* | % w/w 11.0% |
| OTHER INGREDIENTS** | 89.0% |
| Total | 100.0% |

* Contains 5.5 x 10⁹ Colony Forming Units (CFU)/gram of Tick-EX EC based on 5x10¹⁰ viable conidia per gram of active ingredient.

** Contains petroleum distillates

KEEP OUT OF REACH OF CHILDREN CAUTION

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Causes moderate eye irritation. Harmful if inhaled, absorbed through skin, or swallowed. Avoid contact with skin, eyes, or clothing. Avoid breathing dust. Wash thoroughly with soap and water after handling, and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

[REFER TO DIRECTIONS OF USE WITHIN THE BOOKLET]

See booklet for additional precautionary statements, directions for use, application instructions and warranty.

| 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. |
| IF INHALED: | Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice. |
| IF ON SKIN OR CLOTHING: | 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 SWALLOWED: | Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person. |
| HOT LINE 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 this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific Time (PT), seven days a week. During other times, call the poison control center at 1-800-222-1222. | |
| NOTE TO PHYSICIAN | |
| Contains petroleum distillate. Vomiting may cause aspiration pneumonia. | |

Batch Code/Expiry Date: _____
 Net Contents: [1 gallon] [1 quart] [1.06 quarts] [1 pint] [½ pint] [XX L]

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Store TICK-EX EC in its original container below 73°F (23°C) in a dry, locked place, out of the reach of children and out of direct sunlight. Do not use or store near heat or open flame. Use product within one year and by the expiry date noted on the label.

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