

#### U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

**EPA Reg. Number:** 

Date of Issuance:

4/2

4/28/21

	NOTICE OF PESTICID	ძ:
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X Registration
Reregistration
(under FIFRA, as amended)

Term of Issuance: Conditional

Name of Pesticide Product:

BioTX

Name and Address of Registrant (include ZIP Code):

Jennifer Tillman Agent for Intelligent Fabric Technologies, Inc. 16441 Space Center Blvd, Suite D100 Houston, TX 77058

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/registration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:	Date:
Alm slifferm	4/28/21
Aline Heffernan	4/20/21
Acting Product Manager Team 31	
Regulatory Management Branch I	
Antimicrobials Division (7510P)	
Office of Pesticide Programs	

- 2. You are required to comply with the data requirements described in the DCI identified below:
  - a. 3-trimethoxysilyl propyldimethyloctadecyl ammonium chloride GDCI-107401-1635

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Reevaluation Team Leader (Team 36): <a href="http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division">http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division</a>

- 3. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, "EPA Reg. No. 87246-10."
- 4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process, FIFRA section 12(a)(1)(B). Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Assurance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

• Basic CSF dated 12/15/2020

If you have any questions, please contact Tara Flint via email at <a href="mailto:flint.tara@epa.gov">flint.tara@epa.gov</a> or John Hebert at hebert.john@epa.gov.

**Enclosure: Stamped Label** 

[Note to reviewer: In accordance with 40 CFR 156.68(d), all first aid statements, as prescribed, will appear on the front panel of the product label.]

### BioTX EPA Reg. No. 87246-X EPA Est.

ACTIVE INGREDIENT: 3-(trimethoxysilyl) propyldimethyloctadecyl ammoniu	um chloride42%
INERT INGREDIENTS	
TOTAL	100%

**CONTAINS OVER 50% METHANOL** 

# **KEEP OUT OF REACH OF CHILDREN DANGER! POISON FIRST AID**

## ACCEPTED

Apr 28, 2021

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 87246-10

Have product container or label with you when calling Poison Control Center or doctor, or going for treatment.

If inhaled:	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 91 or ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>Call a Poison Control Center or doctor for treatment advice.</li> </ul>
If in eyes:	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after first 5 minutes, then continue rinsing.</li> <li>Call a Poison Control Center or doctor for treatment advice.</li> </ul>
If on skin or clothing:	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a Poison Control Center or doctor for treatment advice.</li> </ul>
If swallowed:	<ul> <li>Call a Poison Control Center or doctor for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by a Poison Control Center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>

#### PRODUCT FEATURES AND BENEFITS

- BioTX imparts durable bacteriostatic activity to the surface of a wide variety of substrates.
- This product does not protect users or others against food-borne or disease-causing mircoorganisms.

- BioTX is effective against mold, mildew and algae as a static agent.
- Increased efficiency through proper application, durable bacteriostatic, fungistatic and algistatic surfaces can be attained with BioTX.
- Provides freshness and combats deterioration and discoloration caused by bacteria, fungi and algae.

Lot No. Net Contents:

Intelligent Fabric Technologies North America Inc. (IFTNA) 66 South West 12th Avenue Deerfield Beach, Florida 33442 USA

#### PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS DANGER! CORROSIVE CONTAINS 50% METHANOL.

#### CAUSES IRREVERSIBLE EYE DAMAGE AND SKIN IRRITATION. MAY BE FATAL IF INHALED.

Methanol may cause blindness. May be harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, rubber gloves, and protective clothing. Do not breathe vapor. Wear a NIOSH approved respirator with ant N, R, P, or HE filter. Appropriate measures should be taken to prevent the accumulation of hazardous concentrations of methanol vapors in the work area. 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.

#### **Environmental Hazards:**

This pesticide is toxic to fish and aquatic invertebrates. 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.

Every effort should be made to contain accidental spills of concentrate to the immediate area. This may be accomplished by the use of sandbags or barrier material to confine the spill to facilitate cleanup and disposal. Contaminated sand or barrier material may then be disposed of by burial in an approved landfill. Many spills may be cleaned up with rags or other absorbent materials by wiping, soaking and/or mopping and allowing the liquid to absorb onto the material. The absorbent material may then be disposed of by incineration or landfill. Floor drains in areas of material use should be protected with absorbent material or barrier material to contain accidental spills.

Inactivation of solutions containing BioTX may be accomplished by addition of an anionic surfactant, or detergent in quantity equivalent to that of BioTX in solution.

#### PHYSICAL OR CHEMICAL HAZARDS

Flammable. Keep away from heat and open flame.

#### **DIRECTIONS FOR USE:**

It is a violation of Federal Law to use this product in a manner inconsistent with its label.

**FOR INDUSTRIAL USE.** This product is registered for formulation into Antimicrobial Products or as a microbiostatic agent for material preservation.

- Antimicrobial product formulations containing BioTX require approval by the US EPA for antimicrobial claims made. Formulators are responsible for satisfying registration requirements for their formulated products.
- For use as a bacteriostatic agent for material preservation, neither this product nor the articles treated
  with this product may state or imply any public health claims. Articles or substances treated with this
  product will be exempt from FIFRA regulation pursuant to 40 CFR 152.25(a) if the intended use for
  incorporating this material into a treated article or substance is for the protection of the article or
  substance itself.
- Finished products containing this product may not make claims of antimicrobial activity other than
  protection of the article itself against growth of bacteria, mold, mildew and fungus in the treated article. If
  growth of bacteria, mold, mildew or fungus in the treated article would lead to unpleasant odors and
  discoloration of the treated article, then such a claim may be made.

**APPROVED USES:** BioTX may be applied to or incorporated into manufactured products listed below for use in industrial, Institutional, commercial or residential locations for non-food contact uses.

<u>Plastics, fiberglass, metals, glass, wood, ceramics, stone, natural materials, composites:</u> Including air filters for furnaces, air conditioners, air purification devices, automobiles, and recirculating air handling systems; aquarium filters; automotive and vehicular parts; roofing materials (tiles, shakes, shingles, granules, stone, membranes, felt, underlayment and synthetic overcoats); building materials and components (including siding, wallboard, wood and wood composites, polymer composites, insulation and non-food contact cabinetry); ceiling tiles; concrete products; paints and coatings; mastics and sealants; cementitious materials (including caulk, grout and cement and grout premixes); non-food contact conveyor and humidifier belts; non-food contact countertops; fiberglass ductboard for air handling systems; floor covering, flooring, general purpose (non-food contact) containers; furniture; bathroom and non-food contact kitchen hardware; mats; plumbing supplies and fixtures; sheet and formed glass; non-food contact sponges and mops; vacuum cleaner bags and filters; foam and packaging and cushioning in non-food contact applications.

Fibers, fabrics (natural and synthetic, woven and non-woven), leather and household materials (natural and synthetic): Including buffer pads (abrasive and polishing): mattress cover pads, filling and ticking; threads; pillow covers; sheets; blankets; bedspreads; fiber for upholstery, recreational gear, quilts and pillows; curtains; draperies; carpet and carpet underlay; rugs; upholstery; towels; shower curtains; toilet tank and seat covers; wall covering fabrics and wallpaper (including vinyl) for non-food contact surfaces; umbrellas; fire hose fabric; non-woven disposable diapers; wiping cloths; pre-moistened towelettes and tissue wipes for non-food contact surface uses (these do not impart pesticidal properties); apparel, including outerwear, sportswear, sleepwear, socks, hosiery, undergarments, gloves and uniforms; footwear (boots, shoes and components); sports equipment and athletic gear; cloth for sails, ropes, tents, and other outdoor equipment; sand bags; tarps; awnings; file folders and binder covers; book covers; pictures.

<u>Miscellaneous Manufactured Products</u>: disposable foam cushions for Lapidus Airfloat Systems; foam used as a growth medium for non-food crops and plants.

#### **HOW TO USE**

**SDS INFORMATION**: BEFORE HANDLING, READ PRODUCT AND SAFETY DATA SHEETS AND CONTAINER LABELS FOR SAFE USE, PHYSICAL AND HEALTH HAZARD INFORMATION. THE SAFETY DATA SHEET CAN BE OBTAINED BY WRITING TO INTELLIGENT FABRIC TECHNOLOGIES (NORTH AMERICA), INC. OR BY CALLING (905) 752-0566. A SAFETY DATA SHEET FOR A TYPICAL USE DILUTION AQUEOUS SOLUTION IS ALSO AVAILABLE.

Use with proper ventilation. Undiluted BioTX contains 50 percent methanol. Do not breathe vapors. Keep away from heat and open flame. Methanol is released during mixing, application and drying. If desired, methanol removal may be accelerated by heating dilute solution before treatment of substrate. Appropriate measures should be taken to prevent the accumulation of hazardous concentrations of methanol vapors in the work area. BioTX can be applied to organic and inorganic surfaces as a dilute aqueous solution to give 0.1 to 1.0 percent by weight of active ingredients. Aqueous solutions can be prepared by simply adding the antimicrobial agent to water with stirring.

NOTICE: Poor agitation when adding this silane to water can result in locally high concentrations, which may form gel particles. Surfaces can be treated with the aqueous solution by brushing, dipping, padding, soaking, spraying or fogging until adequately wet, or applying by foaming techniques. After applying treatment, the surface should be allowed to dry at temperatures from ambient to a maximum of 160° C (320° F) to effect complete curing of silanol groups and remove water, solvents and/or traces of methanol from hydrolysis. Curing of polymer may be accelerated or enhanced with heat or catalysis. For each application, determine optimum application and drying conditions, such as time and temperature before use. If desired, reapply BioTX if odor, staining and discoloration due to bacteria, mold or mildew occur.

Incorporate BioTX directly into formulations used to make end-use products, or dilute with water or with organic solvents such as alcohols, ketones, esters, hydrocarbons and chlorinated hydrocarbons and the apply it to the organic and inorganic surfaces to give 0.1 to 1.0 percent by weight of active ingredient.

#### TREATED INTERMEDIATES/CONCENTRATES1

This product is a pesticidal additive that protects treated intermediate manufacturing/industrial products and treated manufacturing/industrial products from the growth of bacteria, mold, mildew and fungus.

MAXIMUM CONCENTRATION: For use in manufacturing/industrial intermediates at active ingredient levels up to 50% on a weight basis for further processing in an industrial environment into finished products. This dosage applies only to intermediate manufacturing/industrial uses. It does not apply to active ingredient concentrations in consumer finished products. The intermediate treated concentrate must be used in proportion to other inputs in the manufacture of treated articles entering commerce so that the final concentration of this product does not exceed the application rate of 1.0% on a weight basis in the consumer finished product articles to be preserved.

Specific materials: Polyester, silicones, polyethyleneimine, epoxy, emulsifiers, polyamides, ethoxylates, polyacrylic polymers, plasticizers (including epoxidized soybean oil, phthalate and non-phthalate plasticizers), latex, polyurea, polyurethane, polyaspartic, surfactants, quaternary ammonium compounds, stain release, stain repellents, water repellents, soil releasing agents, softeners, antistatic agents, moisture management agents, viscosity modifiers, film builders, sealants, antirust agents, flame retardants, lubricants, UV curable coatings, metal oxides, stabilizers.

<sup>1</sup>Not approved for use in California

**FOR COMMERCIAL APPLICATIONS IN HOMES, OFFICES, AUTOMOBILES AND INSTUTIONS**. This product is registered as a microbiostatic agent for material preservation only; neither this product not the articles treated with this product may state or imply any public health claims. Articles or substances treated with this product will be exempt from FIFRA regulation pursuant to 40 CFR 152.25(a) if the intended use for incorporating this material into a treated article or substance is for the protection of the article or substance itself.

APPROVED USES: BioTX is effective against odor causing bacteria which causes staining and discoloration, fungi (mold and mildew) and algae as a static agent. BioTX can be used as a final bacteriostatic finish on the following items to impart bacteriostatic/fungistatic (mold and mildew) activity:

- Carpet, Draperies and Upholstery, Furniture, Book Covers, and Pictures;
- Plastics, fiberglass, metals, glass, wood, ceramics, stone, natural materials, composites: including air filters
  for furnaces; air conditioners, air purification devices, automobiles, and recirculating air handling systems;
  automotive and vehicular parts; concrete products, roofing materials (tiles, shakes, shingles, granules,
  stone, membranes, felt, underlayment and synthetic overcoats); building materials and components
  including siding, wallboard, wood and wood composites, and insulation; Interior non-food contact hard
  surfaces including floors and floor covering, walls, ceilings, ceiling tiles, ceramic tile, non-food contact
  countertops, concrete, chrome, stainless steel, fiberglass, vinyl, porcelain, fabric and paper wall covering,
  wood and glass fixtures, marble, aluminum, and non-food contact cabinetry.

#### **HOW TO USE:**

**SDS INFORMATION:** BEFORE HANDLING, READ PRODUCT AND SAFETY DATA SHEETS AND CONTAINER LABELS FOR SAFE USE, PHYSICAL AND HEALTH HAZARD INFORMATION. THE SAFETY DATA SHEET CAN BE OBTAINED BY WRITING TO INTELLIGENT FABRIC TECHNOLOGIES (NORTH AMERICA), INC. OR BY CALLING (905) 752-0566. A SAFETY DATA SHEET FOR A TYPICAL USE DILUTION AQUEOUS SOLUTION IS ALSO AVAILABLE.

Wear goggles or face shield, protective clothing, rubber gloves and respirator when handling the concentrated material. Use with proper ventilation. Undiluted BioTX contains 50 percent methanol. Do not breathe vapors. Keep away from heat and open flame. Methanol is released during mixing, application and drying. If desired, methanol removal may be accelerated by heating dilute solution before treatment of substrate. Appropriate measures

should be taken to prevent the accumulation of hazardous concentrations of methanol vapors in the work area. Dry treated areas and articles such as clothing before use. Remove children and pets from treated area until completely dry.

BioTX can be applied to organic and inorganic surfaces as a dilute aqueous solution to give 0.1 to 1.0 percent by weight of active ingredients (suggested starting level is 2.5 ounces of BioTX to one gallon of water). Aqueous solutions can be prepared by simply adding the antimicrobial agent to water with stirring. NOTICE: Poor agitation when adding this silane to water can result in locally high concentrations, which may form gel particles. Surfaces can be treated with the aqueous solution by brushing, dipping, padding, soaking, spraying or fogging until adequately wet, or applying by foaming techniques. After applying treatment, the surface should be allowed to dry at temperatures from ambient to a maximum of 160° C (320° F) to effect complete condensation of silanol groups and to remove water, solvents and/or traces of methanol from hydrolysis. Open windows and use a fan or other active means of ventilation to remove ant methanol vapors from the room.

**For Pump Spray Application**: Dilute 2.5 ounces of BioTX per gallon of water. Using pump sprayer, spray entire area 4-6 inches from the surface making sure the surface is completely covered. Apply and the let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test for staining and colorfastness of fabrics and carpets by treating and drying a small, concealed area prior to application. When treating coarser substrates, more BioTX may be required due to absorption.

**For Spray Application**: For commercial application equipment, dilute 2.5 ounces of BioTX per gallon of water; mix well. Apply then let stand until dry or let stand 3 minutes and wipe dry with cloth or sponge. If spotting occurs, wipe with moist cloth or sponge. Test for staining and color-fastness of fabrics and carpets by treating and drying a small, concealed area prior to application. When treating coarser substrates, more BioTX may be required due to absorption. Dry carpet areas and surfaces before re-entry and dry articles before use.

**For Dipping/Soaking Application**: Use appropriately sized washbasin or tub for dipping/soaking the item you are treating. Use enough BioTX solution to completely submerge item. Dilute 2.5 ounces of BioTX per gallon of water; mix well. Completely submerge item in solution for 3 minutes. Remove item and dry. Test for staining and color-fastness of fabrics by treating and drying a small, concealed area prior to application. Do not reuse solution after dipping/soaking. The substrate can be dried at room temperatures or at temperatures to a maximum of 160° C (320° F).

For each application, determine optimum application and drying conditions, such as time and temperature before use. If desired, reapply BioTX if odor, staining and discoloration due to bacteria, mold or mildew occur.

#### TREATED INTERMEDIATES/CONCENTRATES<sup>1</sup>

This product is a pesticidal additive that protects treated intermediate manufacturing/industrial products and treated manufacturing/industrial products from the growth of bacteria, mold, mildew and fungus.

MAXIMUM CONCENTRATION: For use in manufacturing/industrial intermediates at active ingredient levels up to 50% on a weight basis for further processing in an industrial environment into finished products. This dosage applies only to intermediate manufacturing/industrial uses. It does not apply to active ingredient concentrations in consumer finished products. The intermediate treated concentrate must be used in proportion to other inputs in the manufacture of treated articles entering commerce so that the final concentration of this product does not exceed the application rate of 1.0% on a weight basis in the consumer finished product articles to be preserved.

Specific materials: Polyester, silicones, polyethyleneimine, epoxy, emulsifiers, polyamides, ethoxylates, polyacrylic polymers, plasticizers (including epoxidized soybean oil, phthalate and non-phthalate plasticizers), latex, polyurea, polyurethane, polyaspartic, surfactants, quaternary ammonium compounds, stain release, stain repellents, water repellents, soil releasing agents, softeners, antistatic agents, moisture management agents, viscosity modifiers, film builders, sealants, antirust agents, flame retardants, lubricants, UV curable coatings, metal oxides, stabilizers.

<sup>1</sup>Not approved for use in California

#### STORAGE AND DISPOSAL:

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

**PESTICIDE STORAGE**: Store in original, tightly closed container in an area inaccessible to children and away from food or feed. Moisture sensitive. Keep tightly closed until ready to use. Reclose tightly after each use. When stored in original, unopened containers at or below 25° C (77° F), AEM 5700 Antimicrobial has a minimum shelf life of 12 months from date of shipment.

**PESTICIDE DISPOSAL**: Pesticide is acutely hazardous. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER HANDLING: NONREFILLABLE CONTAINER.** Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide related materials in the container. Contact your state regulatory agency to determine allowable practices in your state. Offer for recycling, if available, or puncture and dispose of in sanitary landfill, or by incineration, or by other procedures approved by state and local authorities.

#### Triple rinse container promptly after emptying.

**For pails**: 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.

**For drums:** Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

**NOTICE:** Intelligent Fabric Technologies (North America), Inc. warrants that the product conforms to its chemical description and is reasonable fit for the purposes stated in the labeling when used in accordance with directions under normal conditions of use; but this warranty of fitness for a particular purpose does not extend to the use of this product contrary to written instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use. **Intelligent Fabric Technologies (North America)**, **specifically disclaims any other express or implied warranty, including the warranty of merchantability**.