

81446-2

12/3/2010

1 of 15



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

DEC - 3 2010

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

R. Bruce Jaeger
Agent for Chem-Tex Laboratories
Health & Environmental Horizons, Ltd
2851 South Haven Road
Annapolis, MD 21401

Subject: ChitoSante' [BacShield] RTU
EPA Registration No.81446-2,
Amendment Date: October 26, 2010
EPA Receipt Date: October 28, 2010

Dear Mr. Jaeger:

The following amendment, submitted in connection with registration under section the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with conditions.

Proposed Amendment:

- Revised labeling per October 20, 2010 Meeting with the Agency

Conditions

Revise the label as follows:

- 1.) Revise the 3rd statement under the "Precautionary Statements" on page 1 to read "Wash thoroughly with soap and water after handling and before eating drinking, chewing gum, using tobacco, or using the toilet."
- 2.) Revise the 2nd claim on page 3 by deleting the phrase, "non-health related organisms" to read to read "*non-public health* organisms."
- 3.) Delete the 10th claim on page 11 because it is misleading to have endorsement from a Federal Agency.
- 4.) Revise the 12th and 13th claims on page 11 to read "Protect treated article from *odor, stains, decay, deterioration, or discoloration* bacteria/fungi."
- 5.) Revise the 16th, 17th, 20th, 21st, 23rd, and 24th claims on page 11 by indicating "*odor, stains, decay, deterioration, or discoloration* bacteria/fungi inhibitor" and "inhibits the growth of *odor, stains, decay, deterioration, or discoloration* bacteria [in/on treated article]."

7.) Delete the 18th claim, "Fills the gap between laundering, cleaning, and disinfecting," on page 11 because it is misleading.

8.) Revise the 25th claim on page 11 and 1st claim on page 12 by stating "*prevents the growth of odor, stains, decay, deterioration, or discoloration bacteria.*"

9.) Delete the 8th claim on page 12 because this product does not support directions as a Plant defense booster.

10.) Delete the 23rd claim on page 12, "Bac-Shield is one aspect of a hygienic cleaning program."

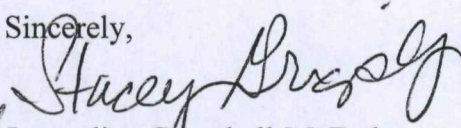
11.) Revise the last claim on page 13 to read "Please refer to www.bacshield.com to obtain more information regarding our corporate commitment to sustainability and comprehensive evaluation of Chitin and Chitosan." You need to provide a link on your website that will direct consumers to the appropriate site for the comprehensive evaluation of the active ingredient.

Please Note: The Agency considers a website as labeling under the Federal Insecticide, Fungicide, and Rodenticide Act and is subject to review by the Agency. 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) list 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. 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 Compliance Assurance.

General Comments

A stamped label with conditions is enclosed for your records. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6416 or by e-mail at Campbell-mcfarlane.jacqueline@epa.gov or Jaclyn Carl by telephone at (703) 347-0213 or by e-mail at carl.jaclyn@epa.gov.

Sincerely,

/s/ Jacqueline Campbell-McFarlane
Product Manager
Regulatory Management Branch II
Antimicrobials Division (7510P)

30f 15

ChitoSante' [BacShield] RTU™

Ready-to-Use

Antimicrobial for Textiles and Surfaces
Inhibits Growth and Odor from Bacteria, Mold, Mildew and Fungi

ACTIVE INGREDIENT:	% w/w
Chitosan	0.3%
OTHER INGREDIENTS:	<u>99.7%</u>
Total	100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling.

FIRST AID STATEMENTS

IF IN EYES	<ul style="list-style-type: none"> • 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.
-------------------	---

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

EPA Reg. No. 81446-2
EPA Est. No. 081446-NC-001

Net Contents: 1 Qt [32 Fl Oz] 1 Gal. [128 Fl. Oz] 5 gal.

Chem-Tex Laboratories, Inc.
2725 Armentrout Dr
Concord, NC 28025

ACCEPTED
with COMMENTS
EPA Letter Dated:

DEC - 3 2010
**Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
81446-2**

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless in accordance with the requirements of 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 into sewer without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or regional Office of the EPA.

NOTICE OF WARRANTY

Chem-Tex Laboratories, Inc. warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label only when used in accordance with the label directions under normal conditions of use. Chem-Tex Laboratories, Inc. makes no other express or implied warranties either of merchantability or fitness for a particular use. Handling, storage and use of the product by Buyer or User are beyond the control of Chem-Tex Laboratories, Inc. and Seller. Risks such as ineffectiveness or other unintended consequences resulting from, but not limited to, failure to follow label directions will be assumed by the Buyer or User. In no case will Chem-Tex Laboratories, Inc. or Seller be held liable for consequential, special or indirect damages resulting from the handling, storage or use of this product.

The terms of this Limited Warranty and Disclaimer cannot be varied by any written or verbal statements or agreements. No employee or agent of the seller is authorized to vary or exceed the terms of this Limited Warranty and Disclaimer in any manner.

Produced by:
Chem-Tex Laboratories, Inc.
2725 Armentrout Dr
Concord, NC 28025

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. ChitoSante' is intended as a treatment in order to give antimicrobial and antifungal activity to the treated materials.

ChitoSante' [BacShield] RTU inhibits the growth of non-health related organisms such as bacteria, mold, mildew and fungus that cause odor, stains, discoloration, decay and deterioration of the treated materials.

Distributors of products containing ChitoSante' [BacShield] RTU may not make claims of antimicrobial activity other than the protection of the treated material against the growth of bacteria, mold, mildew and fungi that cause odor, stains, discoloration, decay, and deterioration in or on the treated product.

See 40 C.F.R.152.25 (a) for further guidance about treated article claims.

DOMESTIC USES

As a cleaner:

ChitoSante' [BacShield] RTU may be used as a cleaner to remove [odor-causing bacteria], [mold], [mildew], and [other organic matter] from surfaces [materials] prior to subsequent [treatment] [application] to inhibit [prevent] bacterial and [or] fungal [mold] growth on those surfaces [and] [or] [materials]. [Thoroughly clean the material to be treated by spraying this product and letting it sit for 1-2 minutes. Wipe or scrub clean.]

Note: Always test for staining in an inconspicuous area. ChitoSante' [BacShield] RTU should not stain articles not stained by water alone.

Laundry:

As an after-wash treatment for clothing, linens, uniforms, textiles in general:

Remove laundry from washer after final spin cycle.
Spray each article with ChitoSante' [BacShield] RTU solution.
ChitoSante' [BacShield] RTU may also be applied to articles which have been previously washed and dried.
Dry treated articles thoroughly before use.
Apply to each load.

Other Uses:

Porous Surfaces:

As a spray for textiles, paper and other porous surfaces such as but not limited to: awnings, bedding, car covers, boat covers, ceilings, curtains, drapes, linens, mattresses, pet bedding, pillows, shoes, umbrellas, upholstery, vehicle interiors, leather, textile wall partitions, wallboard liner, wallboard and other household or construction materials.

Areas to be treated with ChitoSante' [BacShield] RTU must be thoroughly cleaned to remove dirt, mold, mildew, fungi, or other organic matter. ChitoSante' [BacShield] RTU

can be used as a cleaner prior to subsequent treatment [application] with [of] ChitoSante' [BacShield] RTU.

See section titled "Cleaning with ChitoSante' [BacShield] RTU" for instructions in using ChitoSante' [BacShield] RTU as a cleaner

Apply ChitoSante' [BacShield] RTU until the surface is thoroughly damp. One gallon of solution covers approximately 270 sq. ft. Allow to dry before use.

Non-Food Hard Contact Surfaces:

As a spray or mist for non-food hard contact surfaces, such as, but not limited to: fiberglass, masonry, metal, particle board, vinyl, wood, garbage cans, laminated surfaces, desks, window sills and other interior and exterior surfaces:

Areas to be treated with ChitoSante' [BacShield] RTU must be thoroughly cleaned to remove dirt, mold, mildew, fungi, or other organic matter. ChitoSante' [BacShield] RTU can be used as a cleaner prior to subsequent treatment [application] with [of] ChitoSante' [BacShield] RTU. [Thoroughly clean the material to be treated by spraying this product and letting it sit for 1-2 minutes. Wipe or scrub clean.] **See section titled "Cleaning with ChitoSante' [BacShield] RTU" for instructions in using ChitoSante' [BacShield] RTU as a cleaner**

After all foreign matter is removed from surface, apply ChitoSante' [BacShield] RTU to surfaces until thoroughly wet.

Allow to dry before use.

To treat surfaces, apply ChitoSante' [BacShield] RTU using a hand held spray bottle or other suitable sprayer.

Apply ChitoSante' [BacShield] RTU to surfaces until thoroughly wet. [Apply ChitoSante' BacShield RTU evenly to surfaces.] Avoid runoff.

Allow to dry before use. [Allow sprayed surfaces to dry completely before re-use.]

PROFESSIONAL APPLICATORS – DIRECTIONS FOR USE

Professional Mold Remediators Refer to Section Titled "Mold/Mildew Remediation and Prevention" or call Chemtex Laboratories @ 800-532-5361 for specific questions.

ChitoSante' [BacShield] RTU may be applied by hand sprayer, garden sprayer, airless/compression sprayer, cold-fogger, brush, roller, cloth, or immersion

Carpet: Apply to clean carpet as a spray or mist. One gallon of solution covers approximately 270 square feet of surface area. Allow to dry before use.

In homes, offices, commercial, industrial and hospitality settings apply ChitoSante' [BacShield] RTU each time carpet is cleaned or as needed for odors due to mold, mildew, fungi, or bacteria.

Re-apply ChitoSante' [BacShield] RTU after each carpet cleaning.

In athletic facilities, carpet must be cleaned regularly and ChitoSante' [BacShield] RTU applied weekly.

Synthetic Turf: Apply ChitoSante' [BacShield] RTU as a spray at a rate of 1 gallon of solution per 270 square feet of synthetic turf. Allow to dry before use. Apply every three months.

Vehicle interiors: Spray 3 fl. oz. of ChitoSante' [BacShield] RTU [solution] per average size car. Use more solution to cover larger vehicles.

Mold /Mildew Remediation and Prevention

Note: The information contained in this section is not intended to provide comprehensive instructions for mold removal and remediation, but is intended as a general guide for mold removal and prevention and to provide sources for additional information pertaining to mold, mold removal, and prevention. Mold can have serious health consequences in certain individuals. Consult a certified professional mold remediator for areas larger than 30 square feet.

"A Brief Guide to Mold, Moisture and Your Home"
<http://www.epa.gov/mold/moldcleanup.html>

Mold Cleanup Guidelines
<http://www.epa.gov/mold/cleanupguidelines.html>

Institute of Inspection, Cleaning and Restoration Certification (IICRC)
(360) 693-5675
www.iicrc.org EXIT Disclaimer
Information on and standards for the inspection, cleaning, and restoration industry

Centers for Disease Control and Prevention (CDC)
(800) 311-3435
www.cdc.gov EXIT Disclaimer

The New York City Department of Health and Mental Hygiene (212) 788-4290 / 4288.
[Guidelines on Assessment and Remediation of Fungi in Indoor Environments](#) EXIT Disclaimer

What to Wear When Cleaning Moldy Areas <http://www.epa.gov/mold/whattowear.html>

Please note that the Occupational Safety and Health Administration (OSHA) requires that respirators fit properly (fit testing) when used in an occupational setting; consult OSHA for more information (800-321-OSHA or www.osha.gov).

Hidden Mold

<http://www.epa.gov/mold/hiddenmold.html#CleanupandBiocides>

Recommended Web Sites for Mold Removal/Remediation Information:

NORMI – National Organization for Remediators and Mold Inspectors
www.normi.org

Indoor Air Quality Association Inc
www.iaqa.org

Chemtex Laboratories Inc
www.bacshield.com

EPA – Environmental protection Agency
www.epa.gov

IICRC – Institute of Inspection, Cleaning and Restoration Certification
www.iicrc.org

Mold [Removal] [and] [or] [Prevention]

If mold is present refer to recommended web sites for accepted remediation practices. Refer to section titled "PPE- Personal Protection Equipment for Applicators" for appropriate protective equipment to wear.

ChitoSante' [BacShield] RTU may be applied by hand sprayer, garden sprayer, airless/compression sprayer, cold-fogger, brush, roller, cloth, or immersion.

Small Areas - Affected surface areas less than 30 square feet

If the affected area is easily replaceable, such as ceiling tiles, remove the [panel] [area], place in a trash bag, seal, and dispose of in normal trash. Area to be removed can be sprayed with ChitoSante' [BacShield] RTU prior to removal to reduce likelihood of airborne spores. If the affected area cannot be easily removed, follow these steps.

[1] Eliminate [correct] any sources of water [moisture] that may be causing mold growth.

[2] Remove excess water from area and dry affected area thoroughly

[3] Clean affected area with ChitoSante' [BacShield] RTU or other appropriate cleaner [procedure] to remove mold, soil and any other organic matter from surface. In many instances, ChitoSante' [BacShield] RTU will not remove mold stains. Aggressive scrubbing, up to and including partial substrate removal may be required to remove stains.

[4] Apply ChitoSante' [BacShield] RTU until surface is evenly wet. If area was wet for more than 24 hours prior to removal of mold, allow area to dry thoroughly following first

application, and then make a second application.
[5] Allow treated surfaces to dry completely before covering.

Large Areas – Affected surfaces area larger than 30 square feet

Areas larger than 30 square feet require specific procedures performed by professionals properly trained in mold remediation.
Refer to the recommended web sites for assistance in locating a certified mold inspector and/ or remediator or call Chemtex Laboratories @ 800-532-5361 for assistance.

If you are properly trained in mold remediation, develop a complete assessment and remediation plan incorporating ChitoSante' [BacShield] RTU to [prevent] inhibit future mold [fungal] [and] [or] [bacterial] growth.

Once the water source has been eliminated [corrected] and the surfaces properly cleaned and prepared, apply ChitoSante' [BacShield] RTU until the surface is evenly wet. When properly applied, one gallon of ChitoSante' [BacShield] RTU solution will cover 270-1000 square feet of surface area, depending upon the surface texture and absorbency of the substrate. Extremely porous substrates such as carpet and heavy textiles require more product per square foot and one gallon of solution would be expected to cover approximately 270 square feet. Substrates such as unpainted wood will require approximately one gallon per 600 -800 square feet of surface area. Painted wood, vinyl, fiberglass and similar substrates will require approximately one gallon per 1000 -1500 square feet of surface area.

For substrates that are prone to beading and significant run-off, such as vinyl, painted surfaces and [or] unpainted wood with high resin content, the use of a product such as BacCote (Chemtex Labs 800-532-5361) in combination with ChitoSante' [BacShield] RTU will improve coverage and reduce runoff.
Very small droplets such as in fine sprays, mists and fog will minimize run-off.
Several light applications rather than one heavy application will reduce run-off.

If affected area was wet for more than 24 hours prior to removal of mold, allow area to dry thoroughly following first application of ChitoSante' [BacShield] RTU, and then make a second application. Allow treated surfaces to dry completely before covering.

Cleaning [Preparing the Surface] with ChitoSante' [BacShield] RTU

- [1] Apply ChitoSante' [BacShield] RTU until area to be cleaned is thoroughly wet.
- [2] Wipe or scrub area to loosen mold [dirt] [soil] [organic matter]
- [3] Wipe with rag [cloth] to remove mold [dirt] [soil] [organic matter] from surface and dispose of rag [cloth]

Protecting the Surface with ChitoSante' [BacShield] RTU

- [1] Apply ChitoSante' [BacShield] RTU to cleaned area until surface is thoroughly wet.
- [2] Allow area to dry completely to inhibit [prevent] future growth of mold [and] [or] [odor-causing bacteria].

100415

Prevention of Future Growth

- [1] Monitor and maintain moisture levels at or below 17% in wood and other cellulosic materials
- [2] Minimize [reduce] high humidity levels in areas such as crawl spaces. De-humidifiers may be beneficial in high humidity areas. If de-humidifiers are used, make certain drain lines are piped to the outside.
- [3] Correct [Eliminate] source [sources] of water intrusion[s].
- [4] Keep surfaces free of dust, dirt and other organic matter where feasible.

PPE – Personal Protection Equipment Requirements for Applicators

Small Areas - Less than 30 square feet: Gloves, protective eye wear [goggles] and a NIOSH approved N-95 respirator to prevent exposure to mold [and] [or] [mold spores].

Large Areas – more than 30 square feet: Gloves, protective eye wear [goggles], disposable protective suit [coveralls], NIOSH approved N-95 respirator or half-face respirator with HEPA filter as specified by mold remediation certification training.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE:

Store in original container in a cool, dry place, away from sunlight and out of the reach of children and pets.

PESTICIDE DISPOSAL:

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

CONTAINER DISPOSAL:

Non-refillable container. Do not reuse or refill this container.
Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

BULK CONTAINERS:

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

MARKETING BULLETS:**Use On:**

Apparel:

- Athletic uniforms
- Uniforms: military; law enforcement; nursing
- Work attire
- Athletic clothing
- Body Armour (bullet proof vests)
- Soles/insoles

Athletic/Sports Equipment/Locker Rooms/Training Facilities:

- Exercise equipment
- Exercise mats
- Wrestling mats/protective headgear
- Blocking pads/dummies
- Playing surfaces: wood, plastic, vinyl, carpet

All Athletic Equipment, head to toe

Sports equipment

Vehicle Interiors: all automobiles

- Cars, trucks, busses, trains, airplanes

Boat interiors

Boat covers

Synthetic Turf

Synthetic Putting Greens

Indoor/outdoor carpet

Non-food hard contact surfaces

Carpets

Use Outdoors

Vinyl siding

Vinyl fencing

Awnings

Outdoor Upholstery

Outdoor Furniture

Masonry

Wood: painted and unpainted

Exterior Fabric Protectors

Carpets

Use Indoors:

- Curtains, Drapes
- Mattresses
- Bedding Products
- Leather
- Wall Board
- Upholstery
- Carpet
- Locker rooms
- Easy to use in laundry and a convenient spray bottle
- ~~Approved for use by D.O.D. and/or the Service Branches~~
- Odor causing bacteria anti-microbial
- Protects treated article from bacterial growth.
- Protects treated article from fungal growth.
- Protects treated article from mold.
- Protects treated article from mildew.
- Inhibits bacterial growth in/on treated article
- Inhibits fungal growth in/on treated article
- ~~Fills the gap between laundrings, cleaning and disinfecting~~
- Bac-Shield RTU makes your cleaning program more effective.
- Bacteria Inhibitor
- Fungi Inhibitor
- Mold/Mildew Inhibitor
- Inhibits growth from bacteria
- Bacteria growth inhibitor
- Prevents bacterial growth
- Inhibits the growth of mold and mildew
- Dries on the surface to create an invisible antimicrobial shield
- Acts as an invisible barrier to mold and mildew growth
- Creates a shield against mold and mildew
- Water resistant when dry
- Contains No Phosphates
- Ammonia free
- Bleach free
- Low Vocs
- Contains No Ammonia
- Contains No Butyl
- No fumes
- No dilution! Ready-To-Use!
- Indoor and Outdoor Use!
- Cleans and protects!
- Derived from crab shells
- Mold Cleaner and Protectant
- Reduces Mold Spores that could cause musty, mold and mildew related odors
- Provides long lasting protection

Prevent bacterial growth.
Easy to use in laundry and a convenient spray bottle.
By-product of the fishing/crabbing industry
Chitosan is commercially available for use in antimicrobial products from recycled crab shells.
Chitosan, the active ingredient in Bac-Shield RTU, is commercially produced from recycled crab shell waste.
Chitosan, the active ingredient in Bac-Shield RTU is derived from waste snow crab shells.
Chitosan (Poly-D-Glucosamine) is a polysaccharide, a long chain of glucose molecules.

~~Active ingredient is chitosan (registered as a Fungicide, Bactericide, and Insecticide)~~

Bac-Shield RTU is formulated with chitosan, a glucose polymer.
Bac-Shield RTU is formulated with chitosan, a crab shell constituent.
Crab shell waste is the commercial source of Chitosan.
Bac-Shield RTU is formulated with chitosan, a structural component of crab shells.

- Active ingredient is chitosan
- Antimicrobial made from chitosan.
- Chitosan-based antimicrobial.
- Antimicrobial made from chitin.
- Chitin-based antimicrobial.
- Antimicrobial for odor-causing fungi.
- Antimicrobial for mold.
- Antimicrobial for mildew.
- Antimicrobial for odor-causing mold.
- Antimicrobial for odor-causing mildew.

~~Chitosan is a natural polysaccharide derived from the shells of crustaceans.~~

Bac-Shield RTU is not phytotoxic to plants.
Chitosan is a plentiful resource.

May also be used on outdoor surfaces such as concrete, masonry, cinder blocks, construction materials in buildings, stucco, awnings, decks, fences, vinyl and wood siding, patios, patio furniture, and shingles (asphalt and shake).

Use in boats, cruise ships, homes, attics, basements, laundry rooms, closets, institutions, business, schools, health clubs, transportation terminals, and recreational vehicles (RVs), apartments, workshops, trailers, carports, porches, camping equipment and other household areas.

Thoroughly clean the material to be treated by spraying this product and letting it sit for 1-2 minutes. Apply ChitoSante' [Bac-Shield] RTU evenly to surfaces. Hold spray 6 to 8 inches away from surface and spray until damp. Wipe or scrub clean. Allow sprayed surfaces to dry completely before reuse.

Please refer to www.bacshield.com for a comprehensive evaluation of the active ingredient, chitosan, with regards to sustainability, biodegradation, ecological effects, environmental contributions and other biological effects. For a comprehensive evaluation of Chitin and Chitosan, additional documents can be found in EPA's public docket (Docket #EPA-HQ-2007-0566, Chitin Case 6063) at www.regulations.gov.