

81446-1

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 7, 2008

R. Bruce Jaeger
President, Health & Environmental Horizons, Ltd.
Chem-Tex Laboratories, Inc.
c/o Health & Environmental Horizons, Ltd.
2851 South Haven Road
Annapolis, MD 21401

Subject: **ChitoSante™**
EPA Registration No. 81446-1
Application Dated: August 14, 2008
Receipt Date: August 18, 2008

Dear Mr. Jaeger:

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

Proposed Amendment:

- Updated labeling

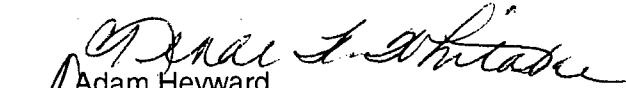
Other comments:

A stamped copy of the accepted labeling is enclosed.

The Agency is moving away from review of paper submitted registration applications to electronic review of applications. Therefore, we need your help to make this an efficient and convenient process for both you and the Antimicrobials Division. Accordingly, we are asking you to submit future labeling amendments for this product via the electronic labeling process. Refer to the following website for guidance on electronic submissions, including label: http://www.epa.gov/opfead1/eds/esr_guidance.htm#overallsub. If you have questions concerning electronic labeling, a list of contacts is available at the following site: <http://www.epa.gov/opfead1/eds/edsgoals.htm#contacts>

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6422 or email address at: heyward.adam@epa.gov, or Renae Whitaker telephone at (703) 308-7003 or email address at: whitaker.renae@epa.gov during the hours of 8:00 am to 3:30 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,


Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: EPA stamped approved labeling

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

ACTIVE INGREDIENT:	% w/w
Chitosan	6.00%
OTHER INGREDIENTS:	<u>94.00%</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

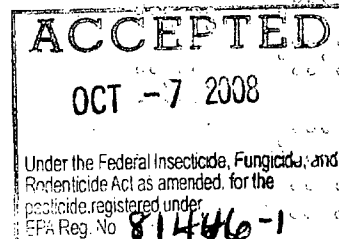
- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

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

EPA Reg. No. 81446-1
EPA Est. No. 081446-NC-001

Net Contents:

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



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.

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' 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' may not make claims of antimicrobial activity other than the protection of the treated material against the growth of bacteria, mold, mildew and fungi in or on the treated product. See 40 C.F.R.152.25(a) for further guidance about treated article claims.

COMMERCIAL/INDUSTRIAL USE

ChitoSante' is used in the finishing process of manufacturing textiles. It is generally applied during or after the dyeing process, at a rate of 0.1- 4.0% owg ("on weight of goods") or, relative to the dry weight of the textiles. The textile materials should be soaked in this ChitoSante' solution to achieve good saturation and penetration of fibers. After soaking, textile materials should be dried at a temperature of 150-338 degrees F, depending upon the fiber content of the textile material.

Manufacturing of carpet: ChitoSante' can be applied to the face or the back of the carpet after the drying process. Apply by spray, foam, kiss roll, or flooded nip. Apply at a rate of 1-2% on the face weight or 0.3 to 0.6 grams per square foot.

For surface applications to textiles, paper, leather, textile wall partitions, wallboard liner and other construction materials, apply as a spray, direct surface application (kiss roll, flooded nip) or foam at a rate of 3-12 fluid ounces of ChitoSante' per gallon of water, depending upon surface texture and absorption qualities of textile.

APPLICATOR USES

Carpet: Apply to clean carpet. Add 12 ounces ChitoSante' to one gallon of water. Apply as a spray or mist. One gallon of solution covers 540 square feet of surface area. Allow to dry before use. In homes, offices, industrial settings apply each time carpet is cleaned or as needed for odors due to mold, mildew, fungi, or bacteria. In athletic facilities, carpet should be cleaned regularly and ChitoSante' applied weekly.

Synthetic Turf: Mix 6 fluid ounces ChitoSante' per gallon of water. Apply as a spray at a rate of 1 gallon of solution per 270 square feet of synthetic turf. If less water is desired in/on turf mix at a rate of 12 fluid ounces ChitoSante' per gallon of water and apply at a rate of one gallon of solution per 540 square feet of synthetic turf. Allow to dry before use. Apply every three months.

Vehicle interiors: Dilute 6 fl. oz. ChitoSante' with 1 gallon of water, spray 3 fl. oz. of solution per average size car. Use more solution to cover larger vehicles.

DOMESTIC INDOOR USES

Home use/Laundry: Run laundry through entire rinse cycle. Re-set washer to rinse cycle. Add ChitoSante' to fabric softener receptacle or directly onto laundry. Repeat rinse cycle. Dry laundry thoroughly. Apply to each load. NOTE: Always test for staining in an inconspicuous area. ChitoSante' should not stain articles not stained by water alone.

Washer Type: Domestic/Coin Operated (less than 30 lb machines)

	<u>Front Load</u>	<u>Top Load</u>
Cotton/Cotton blends	1.75 oz/load	4 oz/load
Nylon, polyester & Other synthetics	6.5 oz/load	15 oz/load

As an after-wash treatment for clothing, linens, uniforms, textiles in general: Remove laundry from washer after final spin cycle. Mix 6 ounces of ChitoSante' per gallon of water and apply to damp or dry articles. Spray each article with ChitoSante' solution. Dry thoroughly before use. Apply to each load.

Home use/Other: As a spray for textiles, paper and other porous surfaces such as but not limited to: awnings, bedding, car and boat covers, ceilings, curtains/drapes, linens, mattresses, pet bedding, pillows, shoes, umbrellas, upholstery, vehicle interiors, and wallboard. Clean areas or articles to be treated to remove dirt, mold or mildew. Add 6 ounces of ChitoSante' per gallon of water. Apply until thoroughly damp. Allow to dry before use.

Table: Amount of ChitoSante' for Spray Applications

<u>Textile</u>	<u>Absorption</u>	<u>Solution</u> fl. oz/gal	<u>Light Material</u> fl. oz/sq yd	<u>Heavy Material</u> fl. oz/sq yd
Nylon	Low	12	0.06	0.25
Polyester	Moderate	6	0.12	0.50
Cotton	High	3	0.25	1.00

As a spray or mist for non-food hard contact surfaces, such as, but not limited to: fiberglass, masonry, metal, particle board, vinyl, wood, other interior and exterior surfaces. Clean areas to be treated with appropriate cleaner to remove dirt, mold, mildew, fungi from the surface. Mix 3-12 ounces of ChitoSante' per gallon of water. Apply to surfaces until thoroughly wet. Allow to dry before use.

ATHLETIC/SPORTS EQUIPMENT/FACILITIES:

Laundry: Run laundry through entire rinse cycle. Re-set washer to rinse cycle. Add ChitoSante' to fabric softener receptacle or directly onto laundry. Repeat rinse cycle. Dry laundry thoroughly. Apply to each load.

Washer Type: Domestic/Coin Operated (less than 30 lb machines)

	<u>Front Load</u>	<u>Top Load</u>
Cotton/Cotton blends	1.75 oz/load	4 oz/load
Nylon, polyester & Other synthetics	6.5 oz/load	15 oz/load

Large Capacity Washers (30 lb and greater)

Cotton/cotton blends 0.125- 1.0 oz/gal of water in final rinse cycle

Nylon, polyester & Other synthetics 0.5- 4.0 oz / gal of water in final rinse cycle

ChitoSante' should be added to the final rinse cycle, along with fabric softener, if used. Use the lowest water level setting. Apply to each load. Dry thoroughly before use. Laundry may be air-dried if desired.

As an after-wash treatment for clothing, linens, uniforms, textiles in general: Remove laundry from washer after final spin cycle or drying. Mix 6 ounces of ChitoSante' per gallon of water and apply to damp articles. Spray each article with ChitoSante' solution. Dry thoroughly before use. Apply to each load.

Athletic equipment, including but not limited to: protective helmets, pads, blocking dummies: First, clean or disinfect articles to be treated with an approved disinfectant. Mix 6 ounces of ChitoSante' per gallon of water. Apply as a spray or mist until surface is completely moist. Apply weekly. Allow to dry thoroughly before use.

Exercise equipment/surfaces/lockers/mats: First, clean or disinfect articles to be treated with an approved disinfectant. Mix 6 ounces of ChitoSante' per gallon of water and apply as a spray, mist or wipe with soaked cloth until surface is thoroughly damp. Allow to dry thoroughly before use. Apply daily to exercise equipment, surfaces and mats. Apply weekly to lockers.

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:

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.

For consultation on specific manufacturing directions for a given application, contact Chem-Tex Laboratories, Inc.

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

ADDITIONAL MARKETING BULLETS AND DIRECTIONS FOR USE:

USE ON:

Wearing Apparel:

- 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

Vehicle Interiors: all automobiles

- Cars, trucks, busses, trains, airplanes

Boat interiors

Boat covers

Synthetic Turf

Synthetic Putting Greens

In-door/outdoor carpet

Non-food hard contact surfaces

Use Outdoors

- Vinyl siding
- Vinyl fencing
- Awnings
- Outdoor Upholstery
- Outdoor Furniture
- Masonry
- Wood: painted and unpainted
- Exterior Fabric Protectors

Use Indoors:

- Curtains, Drapes
- Mattresses
- Bedding Products
- Leather
- Wall Board
- Upholstery
- Carpet

MARKETING BULLETS:

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 launderings, cleaning and disinfecting.

ChitoSante' is one aspect of a hygienic cleaning program.

ChitoSante' makes your cleaning program more effective.

Active ingredient is derived from a replenishable natural resource.

Active ingredient has a long history of a safe effective application.

Bacteria Inhibitor

Fungi Inhibitor

Mold/Mildew Inhibitor

Inhibits growth from bacteria

Bacteria growth inhibitor

Prevents bacterial growth

ADDITIONAL MARKETING BULLETS AND DIRECTIONS FOR USE:

Use On:

- Uniforms
- Sports Equipment
- Locker Rooms
- Carpets
- All Equipment Head to Toe
- Easy to use in laundry and a convenient spray bottle

Home Use/Other (spray): Add 3-12 ounces of ChitoSante' per gallon of water. Apply until thoroughly damp. Allow to dry before use. [See table under Domestic Indoor Uses/Home Use/Other].

CALIFORNIA

The following label language is restricted to the State of California and will replace the labeling under the same headings, for shipment of this product to, and use, in California.

DIRECTIONS FOR USE

COMMERCIAL/INDUSTRIAL USE

ChitoSante' [Bac-Shield] is used in the finishing process of manufacturing paper and textiles, including carpet. ChitoSante' [Bac-Shield] should always be applied to textiles during or after the dyeing process, at a ratio of 1 part ChitoSante' [Bac-Shield] to 50 – 100 parts soft water. Apply approximately 1-2% ChitoSante' [Bac-Shield] relative to the dry weight of the textiles. The textile materials should be soaked in this bath solution to achieve good saturation and penetration of fibers. After soaking, textile materials should be dried at a temperature of 70-170 degrees C (150-338 degrees F).

Table 1. Mixing instructions for 1% application rate. Fabric weight of 10 oz/sq. yd. used in the example below.

<u>Textile</u>	<u>Absorption</u>	<u>ChitoSante' [Bac-Shield] / gal water</u>	<u>Amount of ChitoSante' [Bac-Shield] Solution/ sq yd fabric</u>
Nylon	Low	12 fl. oz	0.12 fl. oz
Polyester	Moderate	6 fl. oz	0.25 fl. oz
Cotton	High	3 fl. oz	0.50 fl. oz

PROFESSIONAL APPLICATOR USES

Dilute ChitoSante' [Bac-Shield] with water at a ratio suitable for spray equipment and surface to be treated. Apply at a rate of 1-2% ChitoSante' [Bac-Shield] per weight of the material to be treated.

For vehicle interiors, dilute 6 fl. oz. ChitoSante' [Bac-Shield] with 1 gallon of water, spray 3 fl. oz. of solution per average size car. Use more solution to cover larger vehicles.

For carpet cleaners, dilute 6 fl. oz. ChitoSante' [Bac-Shield] per gallon of water. One gallon of solution treats 30 sq. yds of 20 oz/sq. yd. weight carpet at 1%.

DOMESTIC INDOOR USES

Home use (washing machine): Add ChitoSante' [Bac-Shield] to the fabric softener dispenser or directly onto laundry in washer. Dry laundry in dryer or allow to air-dry before use. [See Table 2]:

Table 2. Mixing Instructions for a 1% Application Rate

<u>Textile</u>	<u>Absorption</u>	8 Gallons	12 Gallons	15 Gallons
		<u>Small Load</u>	<u>Medium Load</u>	<u>Large Load</u>
Nylon	Low	5 cups	7.5 cups	9.5 cups
Polyester	Moderate	2 cups	3 cups	4 cups
Cotton	High	1 cups	1.5 cups	1.75 cups

Home use (as an after-wash spray for laundry): Add 3-12 ounces ChitoSante' [Bac-Shield] per gallon of water. Spray articles to be treated until thoroughly soaked. Dry article in dryer or allow to air-dry before use. [See Table 3].

Table 3. Amount of ChitoSante' [Bac-Shield] for Spray Applications (1% application rate)

<u>Textile</u>	<u>Absorption</u>	ChitoSante'
		<u>[Bac-Shield]/gal water</u>
Nylon	Low	12 fl. oz/gal
Polyester	Moderate	6 fl. oz/gal
Cotton	High	3 fl. oz/gal

To spray textile covers (boat, car seat/cover, sofa): add 6 ounces ChitoSante' [Bac-Shield] per gallon of water. One gallon of solution covers 270 sq ft. Dry thoroughly before use.

To spray textile surfaces (carpet): add 6 ounces ChitoSante' [Bac-Shield] per gallon of water. One gallon of solution covers 270 sq ft of carpet. Dry thoroughly before use.

End of California Instructions.