



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number: 83019-2

Date of Issuance: JUL 15 2010

Term of Issuance:

Conditional

Name of Pesticide Product: HM 4001 RTU Antimicrobial

NOTICE OF PESTICIDE:
[X] Registration
Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Biosafe, Inc.
100 Technology Drive, Suite 400
Pittsburgh, PA 15219

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration 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/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

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 sec 3(c)(7)(A) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Make the labeling changes listed below before you release the product for shipment:
a. Revise the EPA Registration Number to read, "EPA Reg. No. 83019-2".

Signature of Approving Official:

Date:

Velma Noble
Product Manager Team-31

JUL 15 2010

Regulatory Management Branch I

CONCURRENCES

Table with columns for SYMBOL, SURNAME, and DATE. Includes handwritten entries: 7510P, J. Lee, 7/15/10.

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b. Repeat the signal word "Caution" immediately proceeding the Precautionary Statements as follows: "CAUTION: Causes substantial but temporary..."

c. Revise your directions for use to include mandatory language as per PR Notice 2000-5 as follows: "Approved uses: HM 4001 RTU Antimicrobial is applied to or incorporated..." "...HM 4001 RTU Antimicrobial is incorporated into or applied onto organic and inorganic substances. HM 4001 RTU Antimicrobial is used to give a treatment..." and "...After applying treatment, the surface *must* be allowed..."

d. Delete the following statement which is not supported by the submitted data: "HM 4001 RTU Antimicrobial has a minimum shelf life of 24 months from the date of shipment."

e. Revise the Container Handling section by deleting the current information and adding the following text to bring this label into agreement with PR Notice 2007-4:

Non-Refillable Metal Containers: "Nonrefillable container. Do not reuse or refill this container. Triple rinse (or equivalent). Then offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities."

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

Non-Refillable Glass Containers: "Nonrefillable container. Do not reuse or refill this container. Triple rinse (or equivalent). Then offer for recycling if available or dispose of in a sanitary landfill, or by other procedures approved by state and local authorities."

f. Upon completion, submit 1 year Storage Stability and Corrosion Characteristics study for review.

General Comments

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

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A stamped copy of the label is enclosed for your records. Submit one (1) copy of your final printed labeling prior to release of this product for shipment. If you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

Tracy Lantz

for

Velma Noble
Product Manager 31
Regulatory Branch I
Antimicrobials Division (7510P)

Enclosures: Stamped Label, DER D375050
7510P:T. Lantz:7/15/2010:83019-2 reg notice

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HM 4001 RTU Antimicrobial

PRECAUTIONARY STATEMENTS

A SILANE QUATERNARY AMMONIUM SALT

EPA Reg. No. 83019-2

EPA Est. 072899-VA-001

ACTIVE INGREDIENT: 3-(trihydroxysilyl) propyldimethyloctadecyl ammonium chloride:..... 0.75%
INERT INGREDIENTS: 99.25%
TOTAL: 100%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID	
Have product container or label with you when calling Poison Control Center or doctor, or going for treatment.	
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 first 5 minutes, then continue rinsing. Call a Poison Control Center or doctor for treatment advice.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS.

CAUSES MODERATE EYE IRRITATION; Do not get in eyes. Wear protective eyewear, rubber gloves, and protective clothing.

PRODUCT FEATURES AND BENEFITS

HM 4001 Antimicrobial imparts durable biostatic activity to the surface of a wide variety of substrates. HM 4001 Antimicrobial 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 a minimum amount of HM 4001 Antimicrobial. Provides freshness and combats deterioration and discoloration caused by bacteria, fungi and algae.

LOT NO. _____

NET CONTENTS _____



Sold by:

BIOSAFE, INC.
100 Technology Drive, Suite 400, Plymouth, MA 01969
1-412-770-1302

ACCEPTED
with COMMENTS
in EPA Letter Dated:
JUL 15 2010

MADE IN U.S.A.

December 15, 2009

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 83019-2

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 powder to the immediate area. Many spills may be cleaned up alone or with sand or absorbent materials by sweeping and collection in a waste bin. The material may then be disposed of by incineration or landfill.

Inactivation of solutions containing HM 4001 Antimicrobial may be accomplished by addition of an anionic surfactant, or detergent in quantity equivalent to that of HM 4001 Antimicrobial in solution.

DIRECTIONS FOR USE

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

FOR COMMERCIAL APPLICATIONS IN HOMES, OFFICES, AUTOMOBILES AND INSTITUTIONS AND FOR INDUSTRIAL USE ONLY. This product is registered as a microbistatic 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.

APPROVED USES: HM 4001 Antimicrobial 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

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; 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, insulation and non-food contact cabinetry); ceiling tiles; concrete products; 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.

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; pillow covers; sheets; blankets; bedspreads; fiberfill for upholstery, apparel, 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 toweltetes and tissue wipes (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; book covers; pictures.

HOW TO USE:

MSDS INFORMATION: BEFORE HANDLING, READ PRODUCT AND MATERIAL SAFETY DATA SHEETS AND CONTAINER LABELS FOR SAFE USE; PHYSICAL AND HEALTH HAZARD INFORMATION. THE MATERIAL SAFETY DATA SHEET CAN BE OBTAINED BY WRITING TO BIOSAFE INC. OR BY CALLING (412) 770-1302. A MATERIAL SAFETY DATA SHEET FOR A TYPICAL USE DILUTION AQUEOUS SOLUTION IS ALSO AVAILABLE.

Wear goggles or face shield, protective clothing, and rubber gloves when handling the material. Use with proper ventilation.

HM 4001 Antimicrobial can be incorporated into or applied onto organic and inorganic substrates. HM 4001 Antimicrobial can be used to give a treatment 0.01 to 1.0 percent by weight of active ingredients. Common polymer processes such as compounding will disperse HM 4001 Antimicrobial throughout the bulk product. Aqueous solutions for surface treatment 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. When in water, particles of HM 4001 will swell and become dispersed in water. This process can be sped up by increasing the temperature of the water to 160-190° F. 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 to remove water or solvents. 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 BIOSAFE Antimicrobial if odor, staining and discoloration due to bacteria, mold or mildew occur.

Incorporate HM4001 Antimicrobial directly into formulations used to make end-use products, or dilute with water or alcohol and then apply it to the organic and inorganic surfaces to give 0.01 to 1.0 percent by weight of active ingredient.

STORAGE AND DISPOSAL

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

STORAGE: Store in original, tightly closed container in an area inaccessible to children and away from food or feed. HM 4001 is 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), HM 4001 Antimicrobial has a minimum shelf life of 24 months from date of shipment.

PESTICIDE DISPOSAL: 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 DISPOSAL: Do not reuse containers. Do not cut or weld containers. Triple rinse (or equivalent) empty containers. 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. This container will have product residues when emptied. All hazard precautions on label must be observed when handling emptied container.

NOTICE: BIOSAFE warrants that the product conforms to its chemical description and is reasonably 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. BIOSAFE, INC. SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY.

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