UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 28, 2017

Bob MacDonald
Agent for Gelest Biosystems, LLC
11 East Steel Road
Morrisville, PA 19067

Subject: Notification per PRN 98-10 – To add NSF logos to the Master label as optional text
Product Name: HM 4100 Antimicrobial
EPA Registration Number: 83019-1
Application Date: November 6, 2017
Decision Number: 535828

Dear Mr. MacDonald:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

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 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.

If you have any questions, please contact Emilia Oiguenblik by phone at 703 347 0199, or via email at Oiguenblik.emilia@epa.gov or Eric Miederhoff by phone at 703 347 8028, or via email at Miederhoff.eric@epa.gov

Sincerely,

Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

NOTIFICATION

83019-1

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

11/28/2017

November 6, 2017

HM 4100 Antimicrobial

A SILANE QUATERNARY AMMONIUM SALT

For use as an antimicrobial preservative under EPA and FDA Regulations to preserve finished food contact articles* (Food Preparation Surfaces, Polymeric Tubing for Beverages, Activated Carbon Water Filters) subject to FDA Regulations.

EPA Reg. No. 83019-1 EPA Est.No. 83019-PA-001

ACTIVE INGREDIENT: 3-(trihydroxysilyl) propyldimethyloctadecyl ammonium chloride:…….. 84%
OTHER INGREDIENTS……...……..……..…….. 16%
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:	• 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

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear goggles or safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

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 4100 Antimicrobial may be accomplished by addition of an anionic surfactant, or detergent in quantity equivalent to that of HM 4100 Antimicrobial in solution.

LOT NO. _____ NET CONTENTS _____

{deleted and moved logo and address}

Note to reviewer: All text in brackets […] is optional and may or may not be included on a final label. All text in braces {…} is administrative and will not appear on a final label.

PRODUCT FEATURES AND BENEFITS

HM 4100 Antimicrobial imparts durable biostatic activity to the surface of a wide variety of substrates.
HM 4100 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 4100 Antimicrobial.
Provides freshness and combats deterioration and discoloration caused by bacteria, fungi and algae.

DIRECTIONS FOR USE

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

FOR USE AS AN ANTIMICROBIAL UNDER EPA REGULATIONS

FOR COMMERCIAL APPLICATIONS IN HOMES, OFFICES, AUTOMOBILES AND INSTITUTIONS AND FOR INDUSTRIAL USE ONLY, This product is registered as a microbiostatic 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 4100 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, sand, 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; paints and coatings, thin films, 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; silica sand (for use in swimming pool filters)

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; nonwoven disposable diapers; wiping cloths; pre-moistened towelettes 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.

Note to reviewer: All text in brackets […] is optional and may or may not be included on a final label. All text in braces {…} is administrative and will not appear on a final label.

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 SAFETY DATA SHEET CAN BE OBTAINED BY WRITING TO GELEST BIOSYSTEMS, LLC OR BY CALLING (215) 547-1015. A 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 4100 Antimicrobial can be applied to organic and inorganic surfaces as a dilute aqueous solution to give 0.01 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. When in water, particles of HM 4100 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, soaking, or spraying until adequately wet. After applying treatment, the surface should be allowed to dry at temperatures from ambient to a maximum of 160ºC (320º 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 antimicrobial if odor, staining and discoloration due to bacteria, mold or mildew occur.

Incorporate HM4100 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.

HM4100 Antimicrobial can be diluted in industrial, institutional or commercial water based formulas used to treat clean items. Concentrate may not be used in Residential locations. Only manufactured product treated with the antimicrobial concentrate to deliver 0.01% to 1.0% by weight of dry fabric may be used in residential locations.

Washable Linens, Draperies, Fabric, Bedding and Apparel:

Always treat only clean items and use only fresh rinse water.

Wash Tub: HM4100 Antimicrobial can be diluted in water based formulas used to treat clean items. Use wash basin or tub big enough to completely soak the item you are treating. Add an appropriate amount of solution to treat the textile or apparel with 0.01%-1.0% by weight of dry fabric. Completely submerge items in solution for 3 minutes. Remove items 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 temperature or in clothes dryer at the appropriate setting for the items.

Washing Machine: HM4100 Antimicrobial can be diluted in water based formulas used to treat clean items during the softening/rinse cycle. Solution should be optimized to achieve between 0.01-1.0% of active ingredient by weight of dry fabric. Run the full softening/rinse cycle to treat the fabrics, then allow to dry overnight or use a dryer under the appropriate heat setting for the fabrics being treated. Test for staining and color-fastness of fabrics by treating and drying a small, concealed area prior to application.

For treating silica sand: Treat by spraying sand with dilute solution of product, or immersing sand into dilute solution of product (to provide up to 0.1% active ingredient by weight). After applying treatment, allow sand to cure at temperatures from ambient to a maximum of 160ºC (320º F) to effect complete curing of silanol groups and to remove water or solvents.

*__FOR USE AS AN ANTIMICROBIAL TO PRESERVE FINISHED FOOD CONTACT ARTICLES SUBJECT TO FDA REGULATIONS__

Incorporate HM4100 Antimicrobial as an antimicrobial additive at or below the indicated maximum concentration into the polymeric manufactured products listed below that are used for manufacturing, packing, packaging, transporting, handling and/or holding food if such use is not intended to have any antimicrobial effect in the food itself. Do not

Note to reviewer: All text in brackets […] is optional and may or may not be included on a final label. All text in braces {…} is administrative and will not appear on a final label.

incorporate HM4100 Antimicrobial into any food or drinking water contact application listed on this label unless the substance is approved, with associated use conditions, for food contact in **21 CFR 174-186** (inclusive) as amended, or in the United States Food and Drug Administration's Food Contact Substance Notification System, as amended.

This Food Contact Substance (FCS) can be used as an additive without food type or temperature limitation in food preparation surfaces (where the FCS is either incorporated into the resin, a food contact laminated layer, or applied to the surface as part of a coating). The FCS may be used at a maximum use level of 1 weight percent of the resin, laminate, or coating.
Use: Food contact coatings, films and laminates
Products: Appliances and equipment, barrier fabrics, building materials and components, collection and storage equipment (such as conveyor belts, piping systems, silos, tanks and process vessels), cookware, countertops, food wrap (including coated deli paper, coated meat interleavers and plastic wrap), general purpose containers, glazing for cement tile, glazing for vitreous china used in plumbing fixtures (such as sinks and countertops), industrial equipment, natural and synthetic fibers and fabrics, packaging, paper products (such as wipes, tissues, wall coverings, towels), plastic film, sinks
Maximum Concentration*:* 1% weight percent of the resin, laminate, or coating.

Polymeric tubing for the transfer of beverages. The FCS may be used at a maximum use level of 1 percent of the finished tubing.
Use: Food contact molded plastic parts
Products: Beverage dispensing equipment tubing, beverage processing equipment tubing
Maximum Concentration: 1% weight percent of the finished tubing

Repeat use activated carbon water filters. The FCS may be used at a maximum use level of 0.25 weight percent of the carbon block.
Use: Water filter
Products: Activated carbon water filters
Maximum Concentration*:* 0.25% weight percent of the carbon block

STORAGE AND DISPOSAL

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

STORAGE*:* Store in original, tightly closed container in an area inaccessible to children and away from food or feed. HM 4100 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 4100 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.

{*The appropriate container handling statement below will be selected*}

CONTAINER HANDLING:

[For containers less than or equal to 5 gallons:] 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.

[For containers greater than 5 gallons:] 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. Fill the container ¼ full with water. Recap 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. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

{*Lot code may appear on either the container or label*}

BIOSAFE®

GELEST BIOSYSTEMS, LLC
11 East Steel Road, Morrisville, PA 19067
215-547-1015

MADE IN U.S.A.

NOTICE: GELEST BIOSYSTEMS, LLC warrant 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. GELEST BIOSYSTEMS, LLC **SPECIFICALLY DISCLAIM ANY OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING THE WARRANTY OF MERCHANTABILITY**.

[Optional Graphic – following graphic may or may not appear on label]

NSF®

NSF
X000000

Note to reviewer: All text in brackets […] is optional and may or may not be included on a final label. All text in braces {…} is administrative and will not appear on a final label.