

### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 17, 2018

Matthew Brooks Lotte Advanced Materials c/o Ag-Chem Consulting 12644 Chapel Road Clifton, VA 20124

Subject: Label Amendment – Minor Labeling Updates: Adding additional nonfood articles for integration of product Product Name: Defensin EPA Registration Number: 89854-1 Application Date: January 16, 2018 Decision Number: 537921

Dear Dr. Brooks:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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

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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.

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

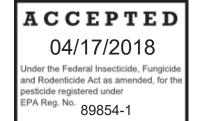
If you have any questions, please contact me by phone at 703.305.6440, or via email at <u>grigsby.stacey@epa.gov</u>.

Sincerely,

Stacey Grigoly

Stacey Grigsby Registration Risk Manager, 34 Regulatory Management Branch II Antimicrobials Division (7510P)

Enclosure: 04/17/18 Stamped Label



# Defensin

Defensin is an antimicrobial additive that effectively inhibits the growth of stain and odor causing bacteria, mold, and mildew on the product to which it is applied. It is intended for use in the manufacturing of commercial and consumer products to impart antimicrobial properties.

Active Ingredient:	
Zinc Oxide	
Other Ingredients	60%
TOTAL	

## **KEEP OUT OF REACH OF CHILDREN**

CAUTION ------ PRECAUCION Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand this label, find someone to explain it to you in detail.) See Below For Other Precautions.

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### FIRST AID

**IF SWALLOWED**: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**IF INHALED**: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Poison Control Center at 1-800-222-1222.

### PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS

Caution. Harmful if swallowed or inhaled. Avoid breathing dust or vapor. 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 wildlife. Do not apply directly to water, or to areas where surface water is present or to inter-tidal areas below the mean high water mark. Runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wash waters. 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.

#### **DIRECTIONS FOR USE**

#### It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Defensin is an antimicrobial additive to be used by compounding for manufacturing use. The master batch is to be incorporated into polymeric materials during the manufacturing process to impart antimicrobial activity to the manufactured products. The polymeric materials are to be used in the manufacturing process as final articles or as a material incorporated into final articles. Defensin suppresses the growth of algae, mold, mildew, fungi and bacteria which causes unpleasant odors, discoloration, staining, deterioration or corrosion. Defensin provides antimicrobial protection to the final articles identified on this label. Manufactured products using Defensin may not make any public health claims relating to antimicrobial activity without first obtaining an EPA registration for the manufactured product. When incorporated into treated articles, this product does not protect users of any such treated article or others against food borne or disease causing bacteria, viruses, germs or other disease causing organisms.

**IMPORTANT!** Read precautionary statements before using this product.

**MAXIMUM CONCENTRATION:** Defensin may be incorporated into the types of products listed below at a maximum concentration (on a weight basis of the finished products) of no more than as specified below for the following types of products:

Ceramics, ceramic glazes, porcelain enamels, and other glasses: 37.5% Plastics and plastic composite materials: 37.5% Coatings: 25% Fibers: 37.5% Adhesives and sealants: 25% This product is for use in materials that are incorporated into manufactured products listed below. This product may not be used for any applications involving food contact or food packaging.

TYPES OF PRODUCTS - Defensin may be incorporated into the following types of products:

# 1) Ceramics, ceramic glazes, porcelain enamels, and other glasses: <u>The final article may contain up to</u> 37.5% Defensin by weight. Final concentration up to 15% Active Ingredient.

Specific materials: ceramics, glazes, dental glasses, borosilicate glasses, lead glasses, soda lime glasses, special glasses, porcelains, porcelain enamels, clays, concretes, and grouts.

<u>Applications</u>: Applications include toilets, sinks, urinals, bidets, lavatories, bathtubs, tile, flooring, windows, shower doors, shower walls, shower trays, bath accessories, bathroom countertops, handles, and knobs, artificial marble except kitchen countertop, engineered stone except kitchen countertop.

# 2) Plastics and plastic composite materials: <u>The final article may contain up to 37.5% Defensin by</u> weight. Final concentration up to 15% Active Ingredient.

Specific materials: Resins including alkyds, amino resins, (melamine formaldehyde and urea formaldehyde), polyester (PET, PBT, and PEN), polyamide (Nylon), polyimide, polypropylene (PP), polyethylene (PE), polybutylene, polymethylpentene (PMP), polysiloxane, polyvinyl alcohol (PVOH), polyvinyl acetate (PVA), ethylene vinyl acetate (EVA), polyethylene copolymer, polyvinyl chloride (PVC), epoxies, phenolic, polycarbonate, cellulosics, cellulose acetate, polystyrene, styrene acrylonitrile (SAN), polyeurethane, acrylic, polymethyl methacrylate, acrylonitrile-butadiene-styrene copolymer (ABS), acrylonitrilestyrene-acrylic copolymer (ASA), acetals, polyketones, polyphelylene, polyphenylene sulfide, polyphenylene oxide, polysulfones, liquid crystal polymer and fluoropolymers, amino resins, thermoplastic elastomer, rubber (including styrene, butadiene, common acrylonitrile rubber, CR) polyacetal (polyoxymethylene), and blends and copolymers thereof.

Applications: This product may not be used for any applications involving food contact, food packaging, or storage of human drinking water. Applications include air purifier; air conditioner; dehumidifier; interior shell of refrigerator (nonfood contact); handle and door of refrigerator, nonfood contact portions (i.e. housing) of food processor, coffeemaker; TV; monitor; washing machine; dryer; spin-dryer; vacuum cleaner; computer; keyboard; mouse; computer accessory; printer; multifunction printer; grinder; telephone; set-top box; copy machine; fax machine; beam projector; electric pen; stylus; speaker; camera; camera accessories; laptop; laptop accessories; tablet PC; tablet PC accessories; cellphone; cellphone accessories; bidet; iron; fan; hair dryer; speaker; charger; antenna; router; electronic shelf label; switch box; switch; fire alarm; electric lamp; multi plug; bathroom countertop; sink; sink drain trap; building materials and components; cabinet; flushing system; furniture; pipes; pipe fittings; tubing; housing of water heater; boiler; ceiling sheet; lighting equipment; wallpaper; wallboard; wall; flooring; floor covering; embedded building materials; blind; dressing table; tatami; door; stair; railing; canopy; window; window frame; roof tile; roof; vinyl siding; rain gutter; elevator; escalator; vehicle part; roof rack carrier of vehicle; vehicle accessory; handle; handle of vehicle; car navigation; black box; air filter; filter of vehicle; car seat; seat of vehicle; console of vehicle; baby seat; caravan; ventilation system in vehicle; helmet; indoor sports equipment; outdoor sports equipment; flippers; fin; mask; scuba diving

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equipment; skateboard equipment; rollerblade equipment; snowboard equipment; surfing board equipment; bicycle; bicycle accessories; ski; jet ski; camping gear; canoe; buoy; footwear; shoes; frame; picture frame; stationery; pen; glasses; toy; lego; earphones; headphones; video game console; game controller; hanger; clothes hanger; instrument; musical instrument; credit card; suitcase; paper dispenser; door lock; padlock; comb; brush; hairclip; mats; mop; dustpan; plunger; broom; broom handle; toilet; bath accessories; drying rack; nail dryer; toilet seat; toilet and toilet lid; bidet; urinal; floor tile; ceiling tile; bathtub; spa; shower heads; shower hose; shower booth; shower curtain; washstand; bathtub drain stopper; toothbrush holder; button, switch; bath cover; towel rack; soap case; soap dispenser; trash can; toilet paper holder; razor; dryer; clothes horse; washing ball; medical bed; hospital supplies; housing of medical analysis equipment; hearing aid; wheelchair; device housing; table; chair; microphone; mic; battery; cart; calculator; display shelf; grip; knob; hilt; strap; baby carriage; pushchair; dog bed; bags; shopping basket; plastic bag; packaging; box; pallet; cosmetic cases; cosmetic housing; airplane table; train table; tray, nonfood contact portions (i.e. housing) of water dispenser, nonfood contact portions (i.e. housing) of water purifier, box of first aid kit, socket, watch, watchband, goggles, swimming goggles, life vest, sun lounger, shoehorn, umbrellas, scraper, gloves, fitness equipment, pet cage, pet bed, wardrobe, rail of stairs, deck, toilet diaper change table, artificial marble except kitchen countertop, engineered stone except kitchen countertop, hand dryer, water softener, POS (Point of Sales) terminals, scanner, hand held scanner, personal identification security system, remote controller, virtual reality equipment, control panel of electric equipment, knob of electric equipment, handle of electric equipment, button of electric equipment, display window, display protection film, key holder, card, casino token.

# 3) Coatings: The final article may contain up to 25% Defensin by weight. Final concentration up to 10% Active Ingredient.

Types of coatings: All application methods.including water borne, nonaqueous solvent borne, 100% solids, physical vapor deposition, radiation cure, thermal cure, liquid, slurry, and powder coatings. Specific materials: Resins including alkyds, amino resins, (melamine formaldehyde and urea formaldehyde), polyester (PET, PBT, and PEN), polyamide (Nylon), polyimide, polypropylene (PP), polyethylene (PE), polybutylene, polymethylpentene (PMP), polysiloxane, polyvinyl alcohol (PVOH), polyvinyl acetate (PVA), ethylene vinyl acetate (EVA), polyethylene copolymer, polyvinyl chloride (PVC), epoxies, phenolic, polycarbonate, cellulosics, cellulose acetate, polystyrene, polyeurethane, acrylic, polymethyl methacrylate, acrylonitrile-butadiene-styrene copolymer (ABS), acrylonitrile - styrene-acrylic copolymer (ASA), acetals, polyketones, polyphelylene, polyphenylene sulfide, polyphenylene oxide, polysulfones, liquid crystal polymer and fluoropolymers, amino resins, thermoplastic elastomer, rubber (including styrene, butadyene, common acrylonitrile rubber, CR) polyacetal (polyoxymethylene), and blends and copolymers thereof.

<u>Applications</u>: This product may not be used for any applications involving food contact, food packaging, or storage of human drinking water. Applications include toilet seats, toilets, sinks, urinals, bidets, lavatories, bathtubs, spas, tile, flooring, shower doors, shower walls, shower trays, bath and kitchen' accessories, plumbing supplies and fixtures, bathroom countertops, handles, knobs, automobile parts,

shower curtains, mats, protective covers, waste containers, general purpose containers, shower heads, mops, brooms, tapes, packaging, gaskets, pipes, tubing, pipe fittings, whirlpool tub and spa

components, structural reinforcement composites (e.g., fiber reinforced resin backings), furniture, window blinds, tools, keyboards, personal grooming equipment, footwear including boots, sports equipment, telephones, and computer equipment, carpets, rugs, mats, and broadloom and tile carpeting.

# 4) Fibers: The final article may contain up to 37.5% Defensin by weight. Final concentration up to 15% Active Ingredient.

Specific materials: Resins including polyester ("Dacron" PET, and PTT), acetate, polyolefins, polyamides (Nylon), polypropylene (PP), polyethylene (PE), acrylics, viscose, polyurethane, "Rayon," polyvinyl alcohol (PVOH), polyvinyl Chloride (PVC), polyvinylidene chloride, polysaccharides, and blends and copolymers thereof.

<u>Applications:</u> This product may not be used for any applications involving food contact, food packaging, or storage of human drinking water. Applications include fabrics for household applications, home furnishings, automotive fabrics, apparel, bedding, mattress cover pads and filling, pillow covers, sheets, blankets, fiberfill for quilts and pillows, table cloths, napkins, wiping cloths, mops, towels, vacuum cleaner bags, cushion pads, sleeping bags, brush bristles, air and dust filters, book covers, curtains, draperies, upholstery, wall covering fabrics, carpet underlay, carpet backing, conveyor belts that do not come in contact with any type of food, automotive and truck upholstery, automotive and truck carpeting and interior liners, apparel, outerwear, uniforms, coats, aprons, sportswear, sleepwear, stockings, socks, hosiery, caps, undergarments (undershirts, underwear, bras, thermal underwear), inner liners for jackets, shoes, gloves and helmets, sails, ropes, canvas, ducking, awnings, and umbrellas, shower ball, shower scraper, life vest, vertical blind, horizontal blind, window shade.

# 5) Adhesives and Sealants: The final article may contain up to 25% Defensin by weight. Final concentration up to 10% Active Ingredient.

Specific materials: Resins including alkyds, amino resins, (melamine formaldehyde and urea formaldehyde), polyester (PET, PBT, and PEN), polyamide (Nylon), polyimide, polypropylene (PP), polyethylene (PE), polybutylene, polymethylpentene (PMP), polysiloxane, polyvinyl alcohol (PVOH) polyvinyl acetate (PVA), ethylene vinyl acetate (EVA), polyethylene copolymer, polyvinyl chloride (PVC), epoxies, phenolic, polycarbonate, cellulosics, cellulose acetate, polystyrene, polyeurethane, acrylic, polymethyl methacrylate, acrylonitrile-butadiene-styrene copolymer (ABS), acrylonitrile - styrene-acrylic copolymer (ASA), acetals, polyketones, polyphelylene, polyphenylene sulfide, polyphenylene oxide, polysulfones, liquid crystal polymer and fluoropolymers, amino resins, thermoplastic elastomer, rubber (including styrene, butadyene, common acrylonitrile rubber, CR) polyacetal (polyoxymethylene), and blends and copolymers thereof.

<u>Applications:</u> This product may not be used for any applications involving food contact, food packaging, or storage of human drinking water. Applications include adhesives used in the manufacture of toilet seats, toilets, sinks, urinals, bidets, lavatories, bathtubs, spas, tile, flooring, shower doors, shower walls, shower trays, bath accessories, plumbing supplies and fixtures, countertops, handles, knobs, automobile parts, shower curtains, mats, protective covers, waste containers, general purpose containers, shower heads, mops, brooms, tapes, packaging, gaskets, pipes, tubing, pipe fittings, whirlpool tub and spa components, structural reinforcement composites (e.g., fiber reinforced resin backings), furniture, window blinds, keyboards, personal

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grooming equipment, footwear including boots, sports equipment, telephones, and computer equipment.

#### STORAGE AND DISPOSAL

**PESTICIDE STORAGE**: Store in safe manner. Store in original container only. Store in cool, dry place. Storing product at temperatures below -30 °F and above 200 °F is not recommended. Keep container tightly closed when not in use. Reduce stacking height where local conditions, such as humidity or pallet overhang, can affect package strength. Do not store under conditions which might adversely affect the container or its ability to function properly. Such conditions include, but are not limited to, positioning of the container in storage, storage temperature, potential for crushing or damage due to stacking, and penetration of moisture.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. 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. Open dumping is prohibited.

**CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follow: Empty the remaining contents into application equipment or a mix tank. 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. Offer for recycling if possible. If recycling is not possible, dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

#### WARRANTY

To the extent consistent with applicable Law, Lotte makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Lotte is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Lotte disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

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