UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460



September 4, 2019

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Abigail T.D. Wacek Senior Regulatory Consultant Packers Sanitation Services, Inc., Ltd. D/B/A Packers Chemical 3729 Peddle Hollow Road, PO Box 338 Kieler, WI 53812

Subject: Notification per PRN 98-10 – To update label for Kosher, Halal and SQF symbols Product Name: KC-644 EPA Registration 63679-2 Application Date: August 8, 2019 Decision Number: 554725

Dear Ms. Wacek:

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, you may contact Emilia Oiguenblik by phone at 703 347 0199, or via email at <u>Oiguenblik.emilia@epa.gov</u> or Eric Miederhoff by phone at 703 347 8028, or via email at <u>Miederhoff.eric@epa.gov</u>.

Sincerely,

E. Miderhoff

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

DISINFECTION PERFORMANCE IN NON-MEDICAL FACILITIES (Food Services, Beverage, Food Processing Plants and Other Non-Medical Facilities): This product kills the following bacteria in 10 minutes at 6 oz. per 4 gal. of 500 ppm hard water (1,200 ppm active) and 5% soil on hard, non-porous surfaces against: Salmonella enterica (ATCC 10708) and Staphylococcus aureus (ATCC 6538).

VIRUCIDAL* PERFORMANCE: This product kills the following viruses in 10 minutes at 10 oz. per 4 gal. of 500 ppm hard water (2,000 ppm active) and 5% soil on hard, non-porous surfaces: Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Herpes Simplex Type 1 Virus, Human Immunodeficiency Virus Type 1 (HIV-1).

MILDEWSTATIC PERFORMANCE: This product controls the following mold at 6 oz. per 4 gal. of water (1,200 ppm active) and 5% soil on hard, nonporous surfaces for up to 7 days: Aspergillus niger (ATCC 6275)

NON-FOOD CONTACT SANITIZING PERFORMANCE: This product is an effective one step nonfood contact sanitizer in 3 minutes at 1 oz. per 4 gal. of 500 ppm hard water (200 ppm active) and 5% soil on hard, non-porous surfaces against: Staphylococcus aureus (ATCC 6538), Enterobacter aerogenes (ATCC 13048).

FOOD CONTACT SANITIZING PERFORMANCE: This product is an effective f ood contact sanitizer in 1 minute at 1 oz. per 4 gal. of 500 ppm hard water (200 ppm active quat) on hard, non- ACTIVE INGREDIENTS: porous surfaces: Campylobacter jejuni (ATCC 29428), Escherichia coli (ATCC 11229), Escherichia coli O157:H7 (ATCC 35150), Cronobacter sakazakii (ATCC 29544), Listeria monocytogenes (ATCC 19117), Salmonella enterica (ATCC 10708), Salmonella enteritidis (ATCC 4931), Salmonella enterica subspecies enterica serovar Paratyphi B (ATCC 10719), Staphylococcus aureus (ATCC 6538). This product is an effective food contact sanitizer in 1 minute at 2 oz, per 4 gal, of 500 ppm hard water (400 ppm active quat) on hard, non-porous surfaces: Pseudomonas aeruginosa (ATCC 15442).

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Before using this product, food products and packaging materials must be removed from the room or carefully protected. This product is not for use on medical device surfaces.

FOR USE AS A GENERAL DISINFECTANT, VIRUCIDE*, CLEANER: 1. Pre-clean visibly soiled areas. 2. Apply use solution of 10-15 oz. of this product per 4 gal. of water (2,000-3,000 ppm active quat) (or equivalent use dilution) to disinfect hard, non-porous surfaces with a sponge, brush, cloth, mop, by immersion, auto scrubber, mechanical spray device, hand pump, coarse pump or trigger spray device. For spray applications, spray 6-8 inches from surface. Do not breathe spray. 3. Treated surfaces must remain wet for 10 minutes. 4. Rinse food contact surfaces with potable water following the application. 5. Prepare inhaled or absorbed through the skin. Avoid breathing spray mist. Do not get in eyes, on skin or on a fresh solution daily or when visibly dirty.

*KILLS HIV, HBV and HCV ON PRE-CLEANED HARD, NON-POROUS SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of hard, non-porous surfaces/objects with blood or body fluids and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1. HBV and HCV ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS. Personal Protection: Wear protective latex gloves, gowns, masks and eye protection. Cleaning Procedure: Blood and other body fluids containing HIV-1, HBV & HCV must be thoroughly cleaned from hard, non-porous surfaces and objects before application of this product. Disposal of Infectious Materials: Blood and other body fluids, cleaning materials and clothing must be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal. Contact Time: Allow hard, non-porous surfaces to remain wet for 10 minutes to kill all viruses and bacteria listed on the label.

FOR USE AS A GENERAL DISINFECTANT, CLEANER ON HARD, NON-POROUS SURFACES: Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Pre-clean surfaces. Apply use solution of 6-15 oz. of this product per 4 gal. of water (1,200-3,000 ppm active) (or equivalent use dilution) to hard, nonporous surfaces with a sponge, brush, cloth, mop, by immersion, auto scrubber, mechanical spray device, hand pump, coarse pump or trigger spray device. For spray applications, spray 6-8 inches from surface. Do not breathe spray. Treated surfaces must remain wet for 10 minutes. Rinse food contact surfaces with potable water following the application. Prepare a fresh solution daily or when visibly dirty.

NON-FOOD CONTACT SANITIZING DIRECTIONS

NON-FOOD CONTACT SANITIZING: Pre-clean visibly soiled surfaces. Add 1 oz. of this product per 4 gal. of water (200 ppm active) (or equivalent use dilution). Apply solution to hard, non-porous surfaces with a sponge, brush, cloth, mop, by immersion, auto scrubber, mechanical spray device, hand pump, coarse pump or trigger spray device. For spray applications, spray 6-8 inches from surface. Do not breathe spray. Treated surfaces must remain wet for 3 minutes. Prepare a fresh solution daily or when visibly dirty.

ENTRYWAY SANITIZING SYSTEMS: To reduce cross contamination from area to area, set the system to deliver 6 to 15 oz. of this product per 4 gallons of water (1,200-3,000 ppm active) of sanitizing solution. The foam must cover the entire path of the doorway. Set the system so that a continuous wet blanket of sanitizer solution is delivered to the floor. Do not mix other foam additives to the sanitizing solution.

FOOD CONTACT SANITIZING DIRECTIONS

Prior to application, remove visible food particles and soil by a pre-flush or pre-scrape and when necessary, presoak. Then thoroughly wash or flush objects with a good detergent or a cleaner compatible with surfaces to be cleaned, followed by a potable water rinse before applications of the sanitizing solution.

FOOD CONTACT SANITIZING DILUTION TABLE: To prepare a 200, 300 or 400 ppm active solution use the following dilution table. Prepare the correct dilution rate based upon the appropriate use site.

FOOD CONTACT SANITIZING DILUTION TABLE

Active solution	1 gallon	4 gallons	10 gallons	20 gallons	
200 ppm	0.25 ounce	1.0 ounce	2.5 ounces	5.0 ounces	
300 ppm	0.375 ounce	1.5 ounces	3.75 ounces	7.5 ounces	
400 ppm	0.50 ounce	2.0 ounces	5.0 ounces	10.0 ounces	
DIRECTIONS FOR USE CONTINUED ON RIGHT PANEL					

Packers Chemical KC-644

Cleaner - Disinfectant - Sanitizer - Mildewstat - Virucide*

Alkyl (50% C14, 40% C12, 10% C16) Dimethyl Benzyl Ammonium Chloride	4.0%
Octyl Decyl Dimethyl Ammonium Chloride	3.0%
Didecyl Dimethyl Ammonium Chloride	1.5%
Dioctyl Dimethyl Ammonium Chloride	1.5%
OTHER INGREDIENTS:	<u>90.0%</u>
TOTAL:	100.0%

KEEP OUT OF REACH OF CHILDREN DANGER PELIGRO

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS DANGER. Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed, clothing. Wear goggles or face shield and rubber gloves and protective clothing when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS

This product 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 into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

FIRST AID

In case of emergency, 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 IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes.

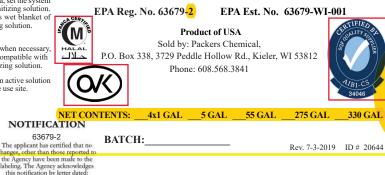
IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

IF SWALLOWED: 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. Call a poison control center or doctor immediately for treatment advice.

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.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

FOR MEDICAL EMERGENCIES, CALL 1-800-424-9300



09/04/2019

FOOD CONTACT SANITIZING PERFORMANCE FOR DAIRY PROCESSING EOUIPMENT AND FOOD PROCESSING EQUIPMENT, UTENSILS AND OTHER HARD, NON-POROUS FOOD CONTACT SURFACES IN FOOD PROCESSING LOCATIONS, MEAT PLANTS AND DAIRIES DIRECTIONS (REGULATED BY 40 CFR sec 180.940(a)(c): Immerse pre-cleaned glassware, dishes, silverware, cooking utensils and other similar size food processing equipment in a solution of 1-2 oz. of this product per 4 gal. of water (200-400 ppm active quat) (or equivalent use dilution) for at least 1 minute. Allow sanitized surfaces to adequately drain before contact with food so that little or no residue remains. Do not rinse.

For articles too large for immersing, apply a use solution of 1-2 oz. of this product per 4 gal. of water (200-400 ppm active quat) (or equivalent use dilution) to sanitize hard, non-porous food contact surfaces with a brush, cloth, mop, sponge, auto scrubber, mechanical spray device, hand pump, coarse pump or trigger spray device. For spray applications, spray 6-8 inches from surface. Do not breathe spray. Surfaces must remain wet for at least 1 minute. Allow sanitized surfaces to adequately drain before contact with food so that little or no residue remains. Do not rinse. Prepare a fresh solution daily or when visibly dirty. For mechanical application, use solution must not be reused for sanitizing applications.

CLEAN-IN-PLACE (CIP) METHOD FOR DAIRY AND FOOD PROCESSING FACILITIES: 1. Thoroughly flush, clean and potable water rinse the system. 2. Prepare required volume of sanitizer solution needed by diluting 1-2 oz. of this product per 4 gal. of water (200-400 ppm active quat) (or equivalent use dilution) of this product. 3. To sanitize entire system by circulation methods, run pumps

for at least 2 minutes to thoroughly wet and sanitize all parts of the system. SANITIZING OF FOOD PROCESSING EQUIPMENT AND OTHER HARD, NON-POROUS SURFACES IN FOOD CONTACT LOCATIONS: For sanitizing food processing equipment, dairy equipment and other hard, non-porous food contact surfaces, surfaces must be thoroughly pre-flushed or pre-scraped and, when necessary, presoaked to remove visible food particles. 1. Turn off refrigeration. (Note: Use this direction only if applicable.) 2. Unit must be washed with a detergent compatible with surfaces to be cleaned and rinsed with potable water before sanitizing. (Note: Use this direction only if applicable.) 3. Apply a solution of 1-2 oz. of this product per 4 gal. of water (200-400 ppm active quat) (or equivalent use dilution) of this product by coarse pump or trigger spray device, direct pouring or by recirculating through the system. For spray applications, spray 6-8 inches from surface. Do not breathe spray. Surfaces must remain wet for at least 1 minute. 4. Drain thoroughly before reuse before contact with food/liquid. Do not rinse. Return machine to service. 5. Prepare a fresh solution daily or when visibly dirty.

FOR TREATMENT OF MEAT AND POULTRY OR FRUIT AND VEGETABLE CONVEYOR BELTS: Remove gross food particles and excess soil by a pre-flush or pre-scrape. Wash with a good detergent or compatible cleaner. Rinse equipment thoroughly with potable water and then rinse equipment with a sanitizing solution. During processing apply 1-2 oz. of this product per 4 gal. of water (200-400 ppm active quat) (or equivalent use dilution) of this product to conveyors with suitable feeding equipment. Do not allow this solution to be sprayed directly on food. Controlled volumes of sanitizer are applied to return portion of conveyor through nozzles so located as to permit maximum drainage of sanitizer from equipment and to prevent puddles on top of belt. During interruptions in operation, apply solution using coarse spray equipment to peelers, collators, slicers and saws, and other non-porous conveyor equipment. Allow surfaces to remain wet for at least 1 minute. Conveyors and other equipment must be free of product when applying this coarse spray.

GLOVE DIP/SPRAY SANITIZER DIRECTIONS: To reduce cross contamination from area to area in animals areas and the packaging and storage areas of food plants, dip, soak or spray prewashed plastic, latex or other synthetic rubber gloves thoroughly to ensure sanitizing solution covers the exterior surfaces of the gloves prior to usage. For spray applications, use a coarse spray device. Do not let sanitizing solution come into contact with exposed skin. After applying solution, allow gloves to remain wet for at least 1 minute. Let air dry thoroughly before wearing gloves. Do not rinse. Prepare sanitizing solution by adding 0.25-0.5 oz. of this product per gal. of water (200-400 ppm active) (or equivalent use dilution). Prepare a fresh solution daily or when visibly dirty.

TO CONTROL MOLD/MILDEW: Prepare use solution by adding 6 oz. of this product per 4 gal. of water (or equivalent use dilution). Apply use solution to hard, non-porous surfaces and allow to dry to effectively inhibit the growth of mold and mildew and their odors. Repeat treatment every seven days, or more often if new growth appears.

STORAGE AND DISPOSAL

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

UN1903

n.o.s.

Liquid, Corrosive,

Compound) 8, PG II

STORAGE: Store only in original container. Keep this product under locked storage sufficient to make it inaccessible to children or persons unfamiliar with its proper use.

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.

CONTAINER HANDLING: Non-Refillable Container. Do not reuse or refill this container. Triple rinse container promptly after emptying. Triple rinse as follows: Fill the container 1/4 full with water. Replace 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 back and forth several times. Turn the container over onto its other end and tip back and forth several times. Follow Pesticide Disposal instructions for rinsate 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.

(**Ouaternary**

Disinfectant

Ammonium