

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 5, 2017

Kimberly Hensley Senior Regulatory Specialist Heritage Systems, Inc. 2471 Solano Ave., Suite 141 Napa, CA 94558

Subject: Notification per PRN 98-10 – Add Alternate brand name

Product Name: LANCER 5%

EPA Registration Number: 81456-2 Application Date: October 17, 2017

Decision Number: 536048

Dear Ms. Hensley:

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 alternate brand name "Lancer 5% Antimicrobial Solution" have been added to the product record.

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 Zebora Johnson at (703) 308-7080 or via email at johnson.zebora@epa.gov.

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Sincerely,

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Zeno Bain, Product Manager Regulatory Management Branch I Antimicrobials Division (7510P)

Office of Pesticide Programs

LANCER 5% (ANTIMICROBIAL SOLUTION)

LANCER 5% is a peroxyacetic acid-based sanitizer/disinfectant developed for the following uses:

Institutional/Industrial Sanitizer and Disinfectant for Previously Cleaned Hard, Non-Porous Food Contact Surfaces in:

Dairies, Wineries, Breweries, Food and Beverage Plants, Poultry and Egg Facilities, and Animal Housing. **Hard Non-Porous Surface Disinfection in:** Hospitals, Schools, Industrial Facilities, Office Buildings, & Veterinary Clinics. **Bacteria, Slime, Odor and Algae Control in:** Recirculating Cooling Water and Evaporative Coolers, Reverse Osmosis, Nano and Ultra Filtration, and Agricultural Waters.

ACTIVE INGREDIENTS:

Peroxyacetic Acid 5.6% Hydrogen Peroxide 26.5%

INERT INGREDIENTS: 67.9%

TOTAL 100.0%

EPA Registration No.: 81456-2 EPA Establishment Nos.: 87736-CA-001

Before Using This Product, Please Read This Entire Label Carefully. Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.

KEEP OUT OF REACH OF CHILDREN DANGER PELIGRO

NOTIFICATION

81456-2

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:

12/05/17

FIRST AID

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.

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 ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor 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 by mouth-to-mouth, if possible. 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. NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER CORROSIVE: Do not enter an enclosed area without proper respiratory protection. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through skin. Harmful if swallowed. Do not breathe vapors or spray mist. Do not get in eyes, on skin, or on clothing. Wear goggles and face shield and rubber gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash before reuse.

Physical or Chemical Hazards

STRONG OXIDIZING AGENT. CORROSIVE. Mix only with potable water below 140°F. Product must be diluted in accordance with label directions prior to use. **LANCER 5%** is not combustible; however, at temperatures exceeding 156°F, decomposition occurs releasing oxygen. The oxygen released could initiate combustion.

Environmental Hazards

This pesticide is toxic to birds, fish and aquatic invertebrates. Caution must be used when applying indoors because pets may be at risk. Do not discharge effluent containing Lancer 5% into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of the National Pollution Discharge System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing Lancer 5% into sewer systems without previously notifying the local sewage plant authority.

Storage and Disposal

Storage: Never return Lancer 5% to the original container after it has been removed. Avoid all contaminants, especially dirt, caustic, reducing agents, and metals. Contamination and impurities will reduce shelf life and can induce decomposition. In case of decomposition, isolate container, spray container with cool water and dilute LANCER 5% with large volumes of water. Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store at temperatures below 86°F.

Procedure for Leak or Spill: Stop leak if this can be done without risk. Shut off ignition sources: no flames, smoking, flares, or spark producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water. Undiluted material must not enter confined spaces.

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 Hazardous Waste representative at the nearest EPA Regional Office for guidance. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all Local, State and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods of disposal may vary by location, regulatory agencies must be contacted prior to disposal. LANCER 5%, which is to be discarded, must be disposed of as hazardous waste after contacting the appropriate Local, State or Federal agency to determine proper procedures.

Disposal: Refillable container. Refill this container with Lancer 5% only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal - empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with a pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times.

DOT: UN3098, Oxidizing liquid, corrosive, n.o.s. (contains hydrogen peroxide and peroxyacetic acid mixture, stabilized), 5.1(8), PGII

Directions for Use

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

NOTE: All volumes given in ounces are fluid ounces.

SANITIZATION

LANCER 5%, a peroxyacetic acid sanitizer, is recommended for use on precleaned surfaces such as equipment, pipelines, tanks, vats, filters, evaporators, pasteurizers, and aseptic equipment in dairies, breweries, wineries, beverage and food processing/packing plants, egg processing/packing equipment surfaces, and eating establishments. Lancer 5% is effective as a sanitizer when solution is prepared in water of up to 400 ppm hardness as CaCO₃. Lancer 5% has demonstrated greater than 99.999% reduction of organisms after 60 seconds exposure period in the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants study.

NOTE: For MECHANICAL OPERATIONS prepared use solution may not be reused for sanitizing but may be reused for other purposes such as cleaning. For MANUAL OPERATIONS fresh sanitizing solutions must be prepared daily or more often if the solution becomes diluted or soiled.

Sanitizing Food Contact Surfaces: Lancer 5% can be used in Federally inspected Meat and Poultry facilities as a sanitizer. Prior to sanitizing remove gross food particles, then wash with a detergent solution, followed by a potable water rinse. Sanitize with a concentration of 1.0-6.1 oz. LANCER 5% diluted in 6 gallons of water (0.13-0.79% v/v concentration, or 82-500 ppm active peroxyacetic acid). At this dilution, LANCER 5% is effective against Staphylococcus aureus, Escherichia coli, Salmonella enterica, and Listeria monocytogenes. Use immersion, spray or circulation techniques as appropriate to the equipment. All surfaces must be exposed to sanitizing solution for a period of at least 60 seconds or more if specified by a governing code. Drain any excess solution. Do not rinse.

<u>Sanitization of Conveyors and Equipment for Meat, Poultry, Seafood, Fruit, Nuts and Vegetables:</u> <u>LANCER 5%</u> is effective against the gram positive organisms Staphylococcus aureus and Listeria monocytogenes and gram negative organisms Salmonella enterica and Escherichia coli. For use in the static or continuous sanitizing, washing or rinsing of conveyors, slicers, saws, and equipment, apply a solution of Lancer 5% using 1.0 to 6.1 oz. per 6 gallons of water (82 to 500 ppm active peroxyacetic acid). Apply sanitizer solution to the return portion of the conveyor or equipment using spray or similar means of wetting surfaces, so as to affect draining and prevent puddling. Allow sanitizer to thoroughly wet surface for a minimum 60 seconds contact time. **No rinse is needed.**

Sanitizing of Casing, Shell or Hatching Eggs: To sanitize clean shell eggs intended for food or food products, spray with a solution of LANCER 5% by diluting 1.0-2.4 oz. product with 6 gallons of potable water (providing 82-197 ppm peroxyacetic acid). The solution must be equal to or warmer than the eggs, but not to exceed 130°F. Wet eggs thoroughly and allow to drain. Eggs that have been sanitized with Lancer 5% may be broken for use in the manufacture of egg products without a prior potable water rinse. Eggs must be reasonably dry before casing or breaking. The sanitizing solution must not be reused for sanitizing eggs. For hatching eggs, apply the sanitizing solution as eggs are gathered, or prior to setting, using a spray or flood so as to lightly wet egg shell surfaces. Allow to drain dry.

<u>Sanitizing Eating, Drinking, and Food Prep Utensils:</u> Remove gross food particles by a prescrape, a preflush and when necessary, a presoak treatment. Wash with a recommended detergent. Rinse with clean water. Sanitize using a solution of 1.0 oz. of Lancer 5% diluted in 6 gallons of water. Immerse all utensils for at least 60 seconds or contact time specified by a governing sanitary code. Drain excess solution.

Sanitizing Tableware: For sanitizing tableware in low temperature warewashing machines, inject Lancer 5% into the final rinse water at a concentration of 1.0 oz. Lancer 5% diluted in 6 gallons of water. Do not exceed 0.13% v/v. Air dry. To insure that this sanitizer concentration does not fall below 0.1%, periodically test the rinse solution with a suitable test kit and adjust the dispensing rate accordingly. Consult your technical service representative for assistance and further information on sanitizing tableware in warewashing machines.

<u>Final Sanitizing Bottle Rinse:</u> <u>LANCER 5%</u> may be used as a final sanitizer rinse, followed by adequate draining for returnable and non-returnable bottles at a 0.13-0.79% dilution (1.0-6.1 oz. <u>LANCER 5%</u> in 6 gallons of water), which yields 82-500 ppm active peroxyacetic acid.

Antimicrobial Rinse of Precleaned or New Returnable or Non-Returnable Containers: To reduce the number of beverage spoilage organisms, including Byssochlamys fulva, Aspergillus niger, and Bacillus subtilis use a 2% to 3% v/v solution, which equals 1120-1700 ppm peroxyacetic acid (2.5-3.8 oz. to 1 gallon of water) of LANCER 5% at a temperature range of 46-60°C for 15 seconds. Higher dilutions of 1 oz. per gallon of water is effective against Aspergillus niger and Byssochlamys fulva at 60°C. After adequate draining, rinse interior container surfaces with sterile or potable water.

Foam Cleaning of Food and Non-Food Contact Surfaces: As an adjunct to cleaning and sanitizing procedures, LANCER 5% may be added to PERAFOAM_{TM} (a foam additive) and foamed onto environmental or equipment surfaces using conventional foam-generating equipment. The resultant foam blend can be used on equipment, floors, walls, ceilings, drains, etc. and must be left on the surface for a minimum of 1 minute or longer. On food contact surfaces do not exceed 6.1 oz. of LANCER 5% per 6 gallons of water. Directions for mixing: Manually or mechanically blend 1.0-6.1 fl. oz. of Lancer 5% and 6-12 fl. oz. of PERAFOAM_{TM} per 6 gallons of water. The dilution water must not exceed 150°F.

Alkaline Detergent Cleaning Adjunct (Booster) to Clean Food Processing Equipment Lancer 5% is an effective cleaning booster (hypochlorite alternative) for use with alkaline detergents. It may be used as a cleaning additive for Clean-In-Place (CIP) operations involving the circulation cleaning of pipelines, tanks, vessels, evaporators, HTSTs, and other food processing equipment. For cleaning applications as a detergent booster, use 1–6 oz. per gallon of water, to assist in the removal of organic soils. All hard nonporous food contact surfaces treated with this boosted detergent must be thoroughly rinsed with potable water followed by sanitizing with an approved food contact surface sanitizer (such as Lancer 5%).

NON-FOOD CONTACT HARD SURFACE DISINFECTION

Combination Disinfection and Cleaning: Lancer 5% disinfects as it cleans in one operation. Lancer 5% can be used to disinfect floors, walls and other hard nonporous surfaces such as tables, chairs, countertops, bathroom fixtures, sinks, bed frames, shelves, racks, carts, refrigerators, coolers, tile, linoleum, vinyl, glazed porcelain, and use sites on this label made of plastic, stainless steel, or glass. For areas of use in hospitals, use Lancer 5% for surgical and obstetrical suites, housekeeping services, physical therapy departments, nursing services, autopsy facilities. Also use Lancer 5% in nursing homes, other health-care facilities, schools, colleges, veterinary clinics, animal life science laboratories, industrial facilities, dietary areas, office buildings, recreational facilities, retail and wholesale establishments.

Lancer 5% is effective against Staphylococcus aureus, Salmonella enterica, Pseudomonas aeruginosa, Trichophyton mentagrophytes and Escherichia coli O157:H7 at 0.38-3.0% v/v (2.5-20 oz. per 5 gal) in hard water (400 ppm as CaCO3) and 5% organic soil loading on hard nonporous surfaces. For heavily soiled areas a pre-cleaning step is required, followed by a potable water rinse. Apply solution with a mop, cloth, sponge, brush, etc. or by soaking or immersion so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, then remove solution and entrapped soil with a clean wet mop, cloth, wet vacuum pickup, or by draining. Surfaces that may directly or indirectly contact food must be rinsed with potable water before operations resume. A rinse for non-food contact surfaces is optional. Prepare a fresh solution daily or when it becomes soiled or diluted.

DISINFECTION OF ANIMAL AND POULTRY PREMISES, TRUCKS, COOPS AND CRATES

Lancer 5% is designed for use in animal hospitals, animal laboratories, kennels, pet shops, zoos, pet animal quarters, poultry premises, poultry hatcheries, and livestock quarters. When used as directed, Lancer 5% is specifically designed to disinfect, deodorize and clean inanimate, hard surfaces such as walls, floors, sink tops, furniture, operating tables, kennel runs, cages and feeding equipment. In addition, Lancer 5% will deodorize those areas which are generally hard to keep smelling fresh, such as garbage storage areas, empty garbage bins and cans, and any other areas which are prone to odors caused by microorganisms.

Disinfection of Poultry Premises: For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use. Remove all poultry and feeds from premises, trucks, coops and crates. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with a detergent and rinse with water. Saturate surfaces with a 0.38-1.25% v/v (2.5-8.0 fl. oz. per 5 gal) solution of Lancer 5% for a period of 10 minutes. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with a detergent and rinse with potable water before reuse. Ventilate buildings, coops and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set or dried. All treated equipment that will contact food, feed, or drinking water must be rinsed with potable water before reuse. See your technical representative for specific recommendations for all cleaning and rinsing requirements.

Disinfection and Deodorizing of Animal Housing Facilities (Barns, Kennels, Hutches, Etc.): Remove animals and feed from premises, vehicles, and enclosures. Remove litter, waste matter from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering equipment. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces by applying a 0.38% (2.5 fl. oz. per 5 gal) solution of Lancer 5% with a mop, brush or spray. Wet all surfaces and allow to remain wet for 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing litter and manure. Ventilate buildings and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

Control of Slime Forming Bacteria in Recirculating and Cooling Water Systems (Cooling Towers, Evaporative Condensers, Pasteurizers, and Air Washers): Severely fouled systems must be cleaned before adding the LANCER 5% solution. LANCER 5% must be added to the system directly and not mixed with any other chemicals or additives. Discontinue the use of chlorine or bromine products prior to using Lancer 5%. Contamination with other chemicals could result in product decomposition. Add LANCER 5% at a point in the system where uniform mixing and even distribution will occur. For slug treatment add 20 oz. of product per 1000 gallons of process water. Repeat as necessary until microbiological control is evident. Thereafter, to maintain control, use 0.3-1.5 lbs. (4.0-17.5 fl. oz.) of LANCER 5% per 1000 gallons of process water (2-9 ppm active peroxyacetic acid) as a continuous or intermittent slug treatment. Continuous dosing methods usually require 2-5 ppm active peroxyacetic acid (4.0-10.2 fl. oz. per 1000 gallons of process water) to achieve adequate control.

Air Washers: Lancer 5% may be used to control bacteria and biofouling in industrial air washing/scrubbing systems. The air washer must have operational and effective mist elimination systems. Prior to use of Lancer 5%, heavily fouled systems must be pre-cleaned using the appropriate cleaner. Continuous dosing methods will require 2-7 ppm and intermittent dosing methods require 7-14 ppm (as peroxyacetic acid), as described in the previous paragraph, depending on the type of system and the level of microbiological control desired.

Evaporated or Condensed Water: Lancer 5% may be used to treat SWEET or COW water (e.g. condensate of whey) collected from evaporated or condensing water systems in food or dairy plants. Typically, the dosing regime would be using intermittent or continuous methods at 2-14 ppm as peroxyacetic acid.

Reverse Osmosis (RO), Ultra Filtration (UF), and Other Membrane Cleaning-Sanitizing: LANCER 5% may be used in the sanitization of Ultra Filtration (UF) and Reverse Osmosis (RO) membranes and other similar type membranes and their associated piping systems. Lancer 5% may be added continuously in food, beverage, and drinking water systems for RO (reverse osmosis) systems only and in accordance with the instructions below. Lancer 5% is not for use in kidney dialysis equipment. Lancer 5% may not totally eliminate all vegetative microorganisms in RO, Nano Filtration (NF) or UF membranes and their associated piping systems due to their construction or assembly, but can be relied upon to reduce the number of microorganisms to acceptable levels when used as directed. Prior to using Lancer 5%, check with the membrane manufacturer to confirm compatibility of membranes with various types or concentrations of peroxyacetic acid solutions.

Batch Sanitation of NF, UF and RO Systems: Isolate incompatible equipment, such as carbon filters and ion exchangers. Clean system with an appropriate cleaner and follow with RO permeate water or potable water. Remove mineral deposits if necessary with an acidic cleaner, and rinse as before. Fill entire system with water and add up to 1% of Lancer 5% by volume (620 ppm peroxyacetic acid) for heavily fouled systems. The typical sanitation use solution dosing of Lancer 5% is 1-2 oz. per 5 gallons of water (98-195 ppm peroxyacetic acid). Recirculate the sanitizing solution through the piping and membrane system at 20°C for 10 minutes minimum, or up to 4 hours, depending on the severity of cleaning to be done. Open and close process valves and solenoids to be sure all parts are in contact with the solution. For occasional intermittent feed, do not exceed 98 ppm active peroxyacetic acid, which equals 1 oz. of Lancer 5% per 5 gallons of feed water. Do not use the intermittent feed method for on-line use for potable water or direct food contact systems. Rinse the system with RO permeate or potable water until residual peroxygen concentration is below 1 ppm.

RO Continuous or Intermittent Addition: For continuous addition methods for RO systems, use 2-5 ppm active peroxyacetic acid (36-90 ppm as product), which equals 1.8-4.5 oz. LANCER 5% per 430 gallons of process water. For occasional intermittent feed, do not exceed 98 ppm active peroxyacetic acid, which equals 1 oz. of Lancer 5% per 5 gallons of feed water. Do not use the intermittent feed method for on-line use in potable water or direct food contact systems.

<u>Fruit and Vegetable Water Treatment:</u> Lancer 5% may be used to help control spoilage or decay-causing bacteria and fungi in water or ice that contacts raw, unprocessed fruits and vegetables in commercial operations and packing houses. For the target commodity, use continuous spray or submerge using a solution containing 4 oz. <u>LANCER 5%</u> per 20 gallons of water (100 ppm peroxyacetic acid). Adjust dose as necessary to obtain satisfactory efficacy. Remove excess water or allow to drain. If using the submersion method, replace with a fresh solution as necessary or when it becomes visibly soiled. A final potable water rinse is not necessary.

Manufactured By: HERITAGE SYSTEMS, INC. - 2471 Solano Ave., Suite 14 24 hr. Emergency InfoTrac Number: 800-535-5053	1 - NAPA, CA 94558	VER 101717
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