| U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Antimicrobials Division (7510P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460 | EPA Reg. Number: 95984-1 | Date of Issuance: 11/09/2020 | | |
|--|-----------------------------|---------------------------------|--|--|
| NOTICE OF PESTICIDE: | Term of Issuance: | | | |
| <u>X</u> Registration | | | | |
| Reregistration (under FIFRA, as amended) | Unconditional | | | |
| (under Fill KA, as antended) | Name of Pesticide Product: | | | |
| | The KleanTek Sanis 275 | | | |
| Name and Address of Registrant (include ZIP Code): The KleanTek, LLC 14246 80 th Avenue NE Kirkland, WA 98034 | | | | |
| Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials 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 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 unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you: 1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data. | | | | |
| Signature of Approving Official: for Demson Fuller, Product Manager 32 Regulatory Management Branch I Antimicrobials Division (7510P) EPA Form 8570-6 | Date: 11/09/20 | 020 | | |

Page 2 of 2 EPA Reg. No. 95984-1 Decision No. 563913

- 2. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 95984-1."
- 3. Submit one copy of the revised final printed label for the record before you release the product for shipment.

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) lists 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 Assurance.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

• Basic CSF dated 04/30/2020

If you have any questions, please contact Jack Hall by phone at 703-347-8647, or via email at hall.john.j@epa.gov

Enclosure

The KleanTek Sanis 275

Hypochlorous Acid Solution Generated Electrochemically from Sodium Chloride

ACTIVE INGREDIENT: Hypochlorous Acid OTHER INGREDIENTS: TOTAL:

0.0275% 99.9725% 100.0000%

Contains > 275 ppm Free Available Chlorine (FAC)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Label for Precautionary Statements

EPA Reg. No. 95984-R

EPA Est. No. XXXXX-XX-XXX

Manufactured for:

The KleanTek, LLC 14246 80th Avenue NE Kirkland, WA 98034

The KleanTek Sanis 275 must be used within 30 days after production OR Product must be tested with chlorine test kit provided by The KleanTek, LLC. DO NOT USE PRODUCT when chlorine concentration is below 248 ppm.

DATE PRODUCED: _____

Container size: 2 oz., 3.4 oz., 4 oz., 8 oz., 16 oz., 1 gallon, 5 gallon, 30 gallon, 55 gallon, 275 gallon, 330 gallon, 660 gallon



and Rodenticide Act as amended, for pesticide registered under EPA Reg. No.

95984-1

The KleanTek Sanis 275 is a Hypochlorous Acid solution produced by passing an aqueous saline solution (brine) through 1 or more electrolytic cells. The current within the electrolytic cell(s) splits the sodium chloride compound into two separate fluids. One fluid is Hypochlorous Acid, a powerful oxidizing agent exhibiting antimicrobial properties.

The KleanTek Sanis 275 is produced at a near neutral pH, (approximately pH 6.5) where the predominant antimicrobial agent is Hypochlorous Acid, an efficient and efficacious species of chlorine. Hypochlorous Acid kills bacteria, fungi, molds, viruses and spores.

The KleanTek Sanis 275 properties are closely controlled by controlling the voltage and the current to the electrolytic cell(s), brine conductivity, temperature and flow rate through the cells as well as the pH of the Hypochlorous Acid generated in the cell(s).

The KleanTek Sanis 275 freezes at 32°F and boils at 212°F. it is a colorless and aqueous solution with a slight chlorine or ozone odor.

After production, **The KleanTek Sanis 275** must be stored in a closed plastic container in a cool and dark area away from direct sunlight.

The KleanTek Sanis 275 is intended to be used soon after being produced.

Optional Marketing Statements:

- Directions Spray cleaned surfaces and allow to air dry
- No wiping needed
- See attached insert for precautionary statements, directions for use, storage and disposal statements
- A cost-effective disinfecting solution
- Produced with low energy and low costs from water and salt
- Produced in a single-stage process by simple electrolytic cell
- Produced for use in medical, institutional, industrial and commercial applications
- Produced with a controlled pH and controlled concentration of Free Available Chlorine (FAC)
- The KleanTek Sanis 275 leaves no residue
- The KleanTek Sanis 275 is made from salt and water
- The KleanTek Sanis 275 will eventually degrade back to salt and water

DIRECTIONS FOR USE

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

Hard, Non-Porous Surface Disinfection

To *[Clean and]* **Disinfect** *[and Deodorize]* **Hard, Non-Porous Surfaces:** For heavily soiled areas, a preliminary cleaning is required. Apply *[Wipe, Spray or Dip]* **The KleanTek Sanis 275** to hard, non-porous surfaces with a cloth, wipe, mop, sprayer, sponge or a spray applicator. Treated surfaces must remain wet for 10 minutes. Allow surfaces to air dry. Do not use on utensils, glasses or dishes.

(OPTIONAL – Follow the instructions below when applying with a spray applicator for hard, nonporous surface disinfection): (1) Remove disinfectant liquid at or over 1-week-old from the liquid storage tank; (2) Fill the empty liquid storage tank with fresh **The KleanTek Sanis 275** liquid; (3) Turn on the power on the main electrical switch; (4) Pull out the spray gun and point towards the target area to be sprayed; (5) Press the sprayer button and start spraying at a recommended distance of between 1 $\frac{1}{2}$ - 4 ft. from the target area; (6) When applying to a large, hard, nonporous surface, use a recommended motion of a 3-ft., side-by-side motion. Allow an overlap of 50% of the sprayed area when spraying from the top to the bottom, and an overlap of 10% when spraying adjacent areas; (7) Sprayed surfaces must remain wet for 10 minutes. Allow surfaces to air dry. Do not use on utensils, glasses or dishes.)

This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, or (2) contacts intact mucous membranes but which do not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to <u>pre-clean or decontaminate critical or semi-critical devices prior to sterilization or high-level disinfection.</u>

| Pathogen | Strain | Contact Time |
|------------------------------|-------------|--------------|
| Pseudomonas aeruginosa | ATCC 15442 | 10 minutes |
| Staphylococcus aureus | ATCC 6538 | 10 minutes |
| Swine Influenza Virus (H1N1) | ATCC VR-333 | 10 minutes |
| Salmonella enterica | ATCC 10708 | 10 minutes |

CLAIMS

- Broad Spectrum Disinfectant
- One-Step Cleaner / Disinfectant when Disinfection Directions are followed
- Aids in the Reduction of Cross-Contamination between Treated Surfaces
- This Disinfection Process assures Proper Strength, Product Effectiveness and Standardizes
 Technique
- Formulated for Bacteria Fighting
- Bactericide or Bactericidal
- Bathroom Disinfectant
- Nursery Disinfectant
- Athletic Facility Disinfectant
- Cleans and Disinfects Site(s) on Tables 1 4 below
- Cleans and Disinfects Hard, Non-Porous Surfaces

- Cleans, Deodorizes and Disinfects
- Deodorizes by Killing Odor-Causing Bacteria
- Disinfecting Formula
- Disinfects and Deodorizes by Killing Bacteria and their Odors
- Eliminates or Reduces Odors caused by Bacteria
- Eliminates odors at their source; bacteria
- Disinfects Hard, Non-Porous Surfaces on Site(s) on Tables 1 4 below
- Easy and Convenient Disinfecting on Site(s) on Tables 1 4 below
- Easy One-Step Cleaning and Disinfecting when Disinfection Directions are followed
- Effective against or Kills Organism(s) mentioned in Table on Page 2 above
- Effective against or Kills H1N1 Swine Influenza virus
- Effectively Disinfects Hard, Non-Porous, Environmental Surfaces
- Fight(s) and/or Kill(s) and/or Effective against Salmonella enterica
- Fight(s) and/or Kill(s) and/or Effective against Staphylococcus aureus
- Fight(s) and/or Kill(s) and/or Effective against Pseudomonas aeruginosa
- Fight(s) and/or Stopes and/or Prevent(s) Cross-Contamination on Hard, Non-Porous Surfaces on Tables 1 – 4 below
- Kills Odor-Causing Bacteria mentioned in Table on Page 2 above
- Kills or Effective against Bacteria mentioned in Table on Page 2 above
- Multi-Purpose Disinfectant
- One-Step Cleaner and Disinfectant when Disinfection Directions are followed
- One-Step Cleaner and Disinfectant (when Disinfection Directions are followed) designed for General Cleaning and Disinfecting Hard, Non-Porous Environmental Surfaces in Health Care Facilities and on Sites listed on Tables 1 – 4 below
- Pseudomonocidal
- Staphylocidal
- Ready-to-Use Hospital Disinfectant
- The Answer to your Disinfecting Needs
- The Easy and/or Convenient way to Disinfect
- This Product controls Cross-Contamination on most Hard, Non-Porous Surfaces
- This Product meets AOAC Efficacy Testing Requirements or Standards for Hospital Disinfection
- Use in Public or Common Places where Bacteria may be of concern on Hard, Non-Porous Surfaces
- Use where Control of the Hazards of Cross-Contamination between Treated Hard Non-Porous Surfaces is of importance

GENERAL CLAIMS

-Convenient -For General Use -For Use on Nursery Surfaces -Suitable for Hospital Use -Will not Harm Surfaces listed on Tables 1 – 4 -Will not Harm Hard, Non-Porous Inanimate Environmental Surfaces -Will not Harm Titanium-Coated, Medical Grade Stainless Steel -Easy to Handle -For Use on Bathroom Surfaces -For Use in Athletic Facilities -For Use on Athletic Equipment

TABLE ONE: Medical Environments

USE SITES

-Ambulances - or - Emergency Medical Transport Vehicles -Anesthesia Rooms – or – Areas -Assisted Living – or – Full Care Nursing Homes -CAT Laboratories -Central Service Areas -Central Supply Rooms - or - Areas Critical Care Units - or - CCUs -Dialysis Clinics -Emergency Rooms – or – RS (Registered Sanitarian) Health Care Settings – or – Facilities -Home Health Care Settings -Hospitals -Intensive Care Units – or – ICU Laboratories -Medical - or - Physician's - or - Doctor's Offices Newborn - or - Neonatal Nurseries -Medical Clinics -Medical Facilities -Nursing – or – Nurses' Stations -Orthopedics -Outpatient Clinics -Patient Restrooms -Patient Rooms -Pediatric Examination Rooms – or – Areas -Pharmacies -Physical Therapy Rooms – or – Areas -Radiology – or – X-Ray Rooms – or – Areas -Surgery Rooms – or – Operating Rooms – or – ORs -CPAP Medical Equipment

SURFACES (Applicable to Surface materials listed on Page 9)

-Bed pans -Exam – or – Examination Table -External Surfaces of Medical Equipment – or – Medical Equipment Surfaces -External Surfaces of Ultrasound Transducers -Gurneys -Hard, Non-Porous Environmental Hospital – or – Medical Surfaces -Hospital – or – Patient Bed Railings – or – Linings – or – Frames -IV Poles -Patient Chairs -Plastic Mattress Covers -Reception Counters – or – Desks – or – Areas -Stretchers -Wash Basins -Wheelchairs

TABLE TWO: Dental Environment

USE SITES

-Dental – or – Dentist's Offices -Dental Operatory rooms

SURFACES (Applicable to Surface Materials listed on Page 9)

-Dental Countertops -Dental Operatory Surfaces -Dentist – or – Dental Chairs -Hard, Non-Porous Environmental Dental Surfaces -Light Lens Covers -Reception Counters – or – Desks – or – Areas

TABLE THREE: Veterinary Environments

Animal Premises: Remove all animals and feed from the premises, vehicles and enclosures. Remove all litter, droppings and manure from the 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 appliances. Thoroughly clean all surfaces with soap and/or detergent and rinse with water.

Apply **The KleanTek Sanis 275** and saturate surfaces with solution 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.

After application, ventilate buildings, coops and other closed spaces. Do not house animals or employ equipment until treatment has be 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.

USE SITES

-Animal – or – Pet Grooming Facilities Kennels
-Animal Housing Facilities
-Animal Life Science Laboratories
-Livestock – and/or – Swine – and/or – Poultry Facilities
-Pet Areas
-Pest Shops – or- Stores
-Small Animal Facilities
-Veterinary – or – Animal Hospitals
-Veterinary Clinics – or – Facilities
-Veterinary Offices

-Animal Equipment Automatic Feeders

-Cages

-External Surfaces of Veterinary Equipment

-Food Racks

-Fountains

-Hard, Non-Porous Environmental Veterinary Surfaces

-Pens

-Reception Counters - or - Desks - or - Areas Stalls

-Troughs

-Veterinary Care Surfaces

-Water Appliances

TABLE FOUR: Miscellaneous / General Environments

USE SITES

-Airplanes -Blood Banks -Boats -Bowling Alleys -Chillers -Churches -Colleges -Correctional Facilities -Cruise Lines -Day Care Centers -Dormitories -Factories -Funeral Homes -Grocery Stores -Gymnasiums - or - Gyms -Health Club Facilities -Hotels -Industrial Facilities -Laundromats -Laundry Rooms -Locker Rooms -Manufacturing Facilities -Manufacturing Plants - or - Facilities -Military Installations -Motels -Preschool Facilities -Public Areas -Recreational Centers - or - Facilities -Restrooms - or - Restroom Areas -School Buses -Schools -Shelters -Shower Rooms -Storage Rooms – or – Areas -Supermarkets -Trains -Universities -Wineries -Yachts

SURFACES (Applicable to Surface Materials listed on Page 9) -Bathroom fixtures -Bath Tubs -Behind and under Counters -Behind and under Sinks -Booster Chairs -Cabinets -Ceilings -Cellular – or – Wireless – or – Mobile – or – Digital Phones -Chairs -Computer Keyboards -Computer Monitors -Counters – or – Countertops -Cribs -Desks -Diaper – or – Infant Changing Tables -Diaper Pails -Dictating Equipment Surfaces -Doorknobs -Exterior – or – External Toilet Surfaces -Exterior – or – External Urinal Surfaces -Faucets -Floors -Garbage – or – Trash Cans -Grocery Store - or - Supermarket Carts -Hampers -Hand Railings -Headsets -Highchairs -Lamps -Linoleum -Playpens -Shelves -Showers - or - Shower Stalls -Sinks -Stall Doors -Tables -Telephones -Tiled Walls -Toilet Rims -Toilet Seats -Towel Dispensers -Toys -Vanity Tops - or - Vanities -Other Telecommunications Equipment Surfaces

SURFACE MATERIALS

-Baked enamel

-Chrome -Common Hard, Non-Porous Household – or – Environmental Surfaces

-Formica

-Glass

-Glazed Ceramic Tile

-Glazed Porcelain

-Glazed Porcelain Enamel

-Laminated Surfaces

-Plastic Laminate

-Stainless Steel

-Synthetic Marble

-Vinyl Tile

-Similar Hard, Non-Porous Surfaces except those excluded by the label

Not Recommended for Use On – or – Avoid Contact With

-Aluminum -Brass -Chipped enamel -Clear plastic -Clothes -Copper -Fabrics -Gold -Natural marble -Natural rubber -Painted surfaces -Paper surfaces -Sealed granite -Silver -Unfinished wood -Wood

STORAGE AND DISPOSAL

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

For Industrial and Commercial Use Packages:

Pesticide Storage: Store in a closed dark plastic container in a cool, dry area away from heat and sunlight. Do not store near easily oxidizable materials, acids and reducers. In case of spill, isolate container (if possible) and flood area with water to dissolve all material before discarding this container in trash.

Emergency Handling: In case of contamination or decomposition. Do not reseal container. Isolate in open, well-ventilated area. Flood with large amounts of water. Cool unopened containers in vicinity by water spray.

Pesticide Disposal: Pesticide wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. 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 EPA Regional Office for guidance.

Small packages (5 gallons or less):

Container Handling: Non-refillable rigid container. Do not reuse or refill this container. Triplerinse container (or equivalent) promptly after emptying. Triple-rinse as follows: Empty the remaining contents into the application equipment or a mix tank and drain for 10 seconds. Pour rinsate contents into the 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 2 more times. Then offer for recycling or reconditioning if available or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay clear of smoke.

Container Handling: Refillable container. Refill this container with The KleanTek Sanis 275 only. Do not reuse this container for any other purpose. Cleaning before refilling is the responsibility of the refiller. Cleaning the container before final disposal is the responsibility of the person disposing the container. To clean the container before final disposal, empty the remaining contents into the application equipment or a mix tank. Agitate vigorously or recirculate water with the pump for 2 minutes. Dispose of rinsate as pesticide waste. Repeat the rinsing procedure two more times. Then offer for recycling if available and puncture and dispose of in a sanitary landfill, or by incineration, or by procedures allowed by state and local authorities.

Large packages (Greater than 5 Gallons)

Container Handling: Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ 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 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.

PRECAUTIONARY STATEMENTS

Physical or Chemical Hazards: **The KleanTek Sanis 275** is not compatible with other chemicals such as acids and hydrogen peroxide.

Hazards to Humans and Domestic Animals

CAUTION

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

FIRST AID

 Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center, doctor or going for treatment. You may also contact the National Pesticide Information Center (NPIC) 1-800-858-7378 for emergency medical treatment information.

 If in eyes

 Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.
 Demons contact lenges if present offer the first 5 minutes, then

| • | Remove contact lenses, if present, after the first 5 minutes, then |
|---|--|
| | continue rinsing eye. |