UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 24, 2021

Brian Hogan
Authorized Representative
Innovacyn, Inc.
3546 N. Riverside Ave.
Rialto, CA 92377

Subject: Notification per PRN 98-10 – Addition of note regarding chlorine test strips
Product Name: 275 TBD
EPA Registration Number: 88373-1
Received Date: 1/13/2021
Action Case Number: 00216667

Dear Mr. Hogan:

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) 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 you have any questions, you may contact Melanie Bolden at (703) 347-0165 or via email at Bolden.Melanie@epa.gov.

Sincerely,

Melanie Bolden for

Demson Fuller, Product Manager 32
Antimicrobials Division (7510P)
Regulatory Management Branch I
Office of Pesticide Programs

# 275 TBD

*{Alternate Brand Names: Sanacyn DX; Vetericyn Surface DX; SKV Disinfectant; SKV DX}*

## Hypochlorous Acid Solution Generated Electrochemically from Sodium Chloride

**275 TBD** is:

- a cost-effective disinfecting solution;
- produced with low energy and low costs from water and salt;
- produced in a single-stage process by a simple electrolytic cell;
- produced for use in medical, institutional, industrial and commercial applications and
- produced with a controlled pH and controlled concentration of Free Available Chlorine (FAC).

| | |
|---|---|
| **ACTIVE INGREDIENT:** | |
| Hypochlorous Acid | 0.0275% |
| **OTHER INGREDIENTS:** | 99.9725% |
| **TOTAL:** | 100.0000% |

Contains 275ppm Free Available Chlorine (FAC)

NOTIFICATION

88373-1

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:

06/24/2021

**KEEP OUT OF REACH OF CHILDREN**

See Back Panel for Precautionary Statements

EPA Reg. No. 88373-1 Est. No. xxxxx-xx-x

Manufactured by:

Innovacyn, Inc.
3546 North Riverside Avenue, Rialto, CA 92377
Phone No: +1.888.592.7844

***30 days after production,* test with a chlorine test strip. DO NOT USE PRODUCT when chlorine concentration is below 248ppm.**

DATE PRODUCED: _____

Net Contents: _____

**275 TBD** 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.

**275 TBD** 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.

**275 TBD** 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).

**275 TBD** 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, **275 TBD** must be stored in a closed plastic container in a cool and dark area away from direct sunlight.

**275 TBD** is intended to be used soon after being produced.

## 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 visibly soiled areas, a preliminary cleaning is required. Apply 275 TBD to hard, non-porous surfaces using a cloth, sponge, wipe, mop, sprayer or by dipping. Treated 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 pre-clean or decontaminate critical or semi-critical devices prior to sterilization or high-level disinfection.

| Pathogen | Strain | Contact Time |
|---|---|---|
| *Pseudomonas aeruginosa* | ATCC 15442 | 10 minutes |
| *Staphylococcus aureus* | ATCC 6538 | 10 minutes |
| *Salmonella enterica* | ATCC 10708 | 10 minutes |
| *Human Coronavirus* | ATCC VR-740, Strain 229E | 10 minutes |
| *Norovirus (as Feline Calicivirus)* | ATCC VR-782, Strain F-9 | 10 Minutes |

## EMERGING VIRAL PATHOGENS CLAIMS

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This Product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large Non-Enveloped Viruses

| For an emerging viral pathogen that is a/an… | …follow the directions for use for the following organisms on the label: |
|---|---|
| Enveloped Virus | Norovirus (as Feline Calicivirus) |
| Large, non-enveloped virus | Norovirus (as Feline Calicivirus) |

275 TBD has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, nonporous surfaces. Therefore, 275 TBD can be used against [name of emerging virus] when used in accordance with the directions for use against Norovirus on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. 275 TBD kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against Norovirus on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.

## DISINFECTION & ANTIMICROBIAL 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
+ 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 - Prevent(s) Cross-Contamination between treated 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**
+ Virucidal[1]
+ Kill -or- eliminate -or- destroy -or- remove 99.9% of viruses[1] -and/or- bacteria on Use Site(s) -and/or- Surface(s) in Tables 1 – 4 below
+ Ready-to-Use Hospital Disinfectant
+ The Answer to your Disinfecting Needs
+ The Easy - and/or - Convenient way to Disinfect
+ This Product controls Cross-Contamination between treated ~~on most~~ Hard, Non-Porous Surfaces
+ This Product was tested according to AOAC Test Methods
+ Use in Public - or - Common Places where Bacteria may be of concern on Hard, Non-Porous Surfaces
+ Use in Public - or - Common Places where Bacteria may be of concern on Hard, Non-Porous Surfaces
+ Use where Control of the Cross-Contamination between Treated Hard Non-Porous Surfaces is of Importance
+ Reduces Allergens[2]
+ Reduces allergens[2] -and/or- dust mite matter -and/or- pet dander
+ Reduces dust mite matter -or- particles, cockroach matter -or- particles, and pet dander allergens[2] [found in dust]

**Footnotes:**

* Pseudomonas aeruginosa (ATCC 15442)

** Staphylococcus aureus (ATCC 6538)
[1] [Human] Coronavirus, Norovirus
[2] Allergens: Cockroach matter -or- particles, Dust mite matter -or particles, Pet dander -or- dog and cat dander

## GENERAL CLAIMS

+ Convenient
+ For General Use
+ For Use on Nursery Surfaces
+ Suitable for Hospital Use
+ For Use on Bathroom Surfaces
+ For Use in Athletic Facilities
+ Easy to Handle
+ For Use on Athletic Equipment
+ 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

## 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

**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

*SURFACES* (Applicable to materials listed under **Surface Materials**)

+ 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 materials listed under **Surface Materials**)

+ 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 **275 TBD** 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 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.

*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
+ Pet Shops - or - Stores
+ Small Animal Facilities
+ Veterinary - or - Animal Hospitals
+ Veterinary Clinics - or - Facilities
+ Veterinary Offices

*SURFACES* (Applicable to materials listed under **Surface Materials**)

+ Animal Equipment Automatic Feeders
+ Cages
+ External Surfaces of Veterinary Equipment
+ Feed Racks
+ Fountains
+ Hard, Non-Porous Environmental Veterinary Surfaces
+ Pens
+ Reception Counters - or - Desks - or - Areas Stalls
+ Troughs
+ Veterinary Care Surfaces
+ Watering 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 materials listed under **Surface Materials**)

+ 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

## 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 Environment Control Agency, or the Hazardous Waste Representative at the EPA Regional Office for guidance.

**(For non-refillable containers 5 gallons or less):**
**Container Handling:** Non-refillable 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 the application equipment or a mix tank. Fill the container ¼ with water and recap. Shake for 10 seconds. Pour rinsate 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 out of smoke.

**(For non-refillable containers larger than 5 gallons):**
**Container Handling:** Non-refillable 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 the application equipment or a mix tank. Fill the container ¼ 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 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 out of smoke.

**(For refillable containers):**
**Container Handling:** Refillable container. Refill this container with **275 TBD** 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 of the container. To clean the container before final disposal, empty the remaining contents into the application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Dispose of rinsate as pesticide waste. Repeat this rinsing procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by procedures allowed by state and local authorities.

## PRECAUTIONARY STATEMENTS

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