| U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Antimicrobials Division (7510P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460 | EPA Reg. Number: 100798-1 | Date of Issuance: 4/20/22 |
|---|--|--|
| NOTICE OF PESTICIDE: <u>X</u> Registration Reregistration | Term of Issuance: Unconditional | |
| (under FIFRA, as amended) | Name of Pesticide Produ Nanocyn | ict: |
| Name and Address of Registrant (include ZIP Code): | | |
| Brian Hogan Agent, KRK Consulting, LLC MicroSafe Group DMCC Liwa Heights, 3908 Jumeirah Lake Towers, Dubai, UAE | | |
| 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 na under the Federal Insecticide, Fungicide and Rodenticide Act (FIFR Registration is in no way to be construed as an endorsement or reco Agency. In order to protect health and the environment, the Admini time suspend or cancel the registration of a pesticide in accordance name in connection with the registration of a product under this Act registrant a right to exclusive use of the name or to its use if it has b This product is unconditionally registered in accordance with FIFR. 1. Submit and/or cite all data required for registration/reregistra- product when the Agency requires all registrants of similar p | A). mmendation of thi strator, on his mot with the Act. The is not to be constr een covered by oth A section 3(c)(5) p ation/registration r | as product by the ion, may at any acceptance of any rued as giving the hers. |
| | Date: | |
| Demson Fuller, Product Manager 32 Regulatory Management Branch I Antimicrobials Division (7510M) | 4/20/22 | |
| EPA Form 8570-6 | | |

- 2. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 100798-1."
- 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 FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). 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, FIFRA section 12(a)(1)(B). 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 08/16/2021

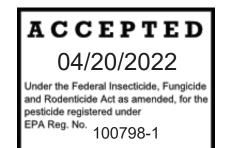
If you have any questions, please contact Michael Varco by phone at 202-566-0667, or via email at Varco.Michael@epa.gov.

Sincerely,

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

Enclosure

{Text that appears in {braces} are notes to reviewer. Text that appears in [brackets] is optional. Text that appears in (parenthesis) are required clarifiers or acronyms. X is a placeholder for any number.}



Nanocyn®

[Alternate Brand Names: Nanocyn Disinfectant, Nanocyn Hospital Disinfectant]

[Hospital] [healthcare] disinfectant for hard non-porous surfaces

ACTIVE INGREDIENT:

| Hypochlorous Acid: | 0.026% |
|--------------------|--------|
| OTHER INGREDIENTS: | |
| [Water] | |
| TOTAL: | |
| | |

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS: X [L] [mL] [gal] [oz] [fl oz]

EPA Reg. No. 100798-1

EPA Est No. ____-__-

MANUFACTURED FOR:

MicroSafe Group DMCC Liwa Heights, 3908 Jumeirah Lake Towers, Dubai United Arab Emirates

Manufactured by Oculus Technologies of Mexico, a subsidiary of Sonoma Pharmaceuticals

PRECAUTIONARY STATEMENTS

Physical or Chemical Hazards: [This product] [Nanocyn®] is an oxidizer. Do not use with or store near any reducing agents. Do not mix with other chemicals.

MARKETING CLAIMS {These can appear anywhere on the label}:

[This product] [Nanocyn®] is a disinfectant solution for use on hard non-porous inanimate surfaces.

[This product] [Nanocyn®] is a super-oxidized, pH-neutral, water-based [Hospital] [healthcare] disinfectant for hard for non-porous surfaces.

[This product] [Nanocyn®] is a ready-to-use product that is especially useful in hospitals, patient care areas, and dental offices.

When used according to the direction for use, [this product] [Nanocyn®] disinfects hard non-porous surfaces including: stainless steel, chrome, glass, vinyl, glazed porcelain, non-porous plastics, baked enamel and glazed tile in the below application areas.

| [Cleans] [and] [or] [kills] | For healthcare use |
|--|--|
| [disinfects] [removes] [attacks] [gets rid of] bacteria | • For hospital use |
| [Cleans] [and] [or] [kills] [disinfects] [removes] [attacks] [gets rid of] viruses** | Formulated –or- super- oxidized water-based disinfectant |
| Deodorizes by disinfecting | Formulated with patented hypochlorousacid technology |
| Designed for healthcare | Helps reduce cross |
| Disinfecting formula | contamination on treated hard, non-porous |
| Disinfection technology | surfaces |
| Disinfects odor causing bacteria | Hospital disinfectant |
| Easy - and or - convenient way to disinfect | Oxidizing agent to provide disinfection |
| | |
| | |
| | |

| [Antimicrobial] [and] [or] [antibacterial] [virucidal**] | Easy and convenient disinfecting |
|--|--|
| • [Bacteria] [and] [or] [virus*] | Effective against the tough non-enveloped Norovirus |
| • [Bactericide] [Bactericidal] | [Effective against] [Kills] Bacteria |
| [Hospital] [Healthcare] disinfectant | [Effective against] [Kills] Virus** |
| Can help reduce the risk of cross-contamination on treated, non-porous surfaces. | For hospital [&] [veterinary] hard nonporous surfaces |
| Cleans and disinfects treated hard non-porous surfaces | |
| [Clean] [and] [or] [disinfect] on the go | |
| | |

| • | Powered by Microcyn® technology | • | One step virucide** |
|---|--|---|--|
| • | Ready to use disinfectant | • | Tough on germs*, easy to use around patient areas on hard non-porous |
| • | Ready to use formula | | surfaces |
| • | Real world contact times on pathogens* | • | Tough on germs*, easy enough for everyday use on hard non-porous surfaces |
| • | Super-oxidized water works by oxidizing microorganisms for broad spectrum disinfection | • | Use on hard non-porous surfaces that you are concerned about [bacteria] |
| • | Tough on germs*, easy on hard, non-porous surfaces | | [and] [or] [viruses**] |
| • | Kills Staphylococcus aureus (ATCC 6538) [in 8 minutes] | • | Use on hard, non-porous surface where hazards of cross- contamination between treated surfaces is of primary importance at different sites |
| | | • | disinfects on hard non-porous healthcare surfaces |
| | | • | [Virucide**] [Virucidal**] |
| | | • | When used according to the directions foruse, this product disinfects hard non- porous surfaces including in a healthcare environment |

Water based, Proven disinfection technology

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•

One step virus** [antiviral] disinfectant

aces d nce

- healthcare environment
- Kills Viruses** [in 30 seconds] ٠

- No rinsing
- Non-abrasive
- Non-corrosive
- Non-flammable
- Packaging made with [x%] recycled -or-recyclable plastic
- Ready to use
- [The] Smell of clean

- No fragrance added
- No [smell] [odor] [and] [or] [buildup] [residue]
- No [mixing] [diluting] [required]
- [Non-corrosive] [non-staining] [of surfaces]
- No special handling or disposal requirements
- No Personal Protective Equipment (PPE) required

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 | follow the directions for use for the |
|--------------------------------|---------------------------------------|
| that is a/an… | following organisms on the label: |
| Enveloped Virus | Norovirus |
| Large, non-enveloped virus | Norovirus |

Nanocyn has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, nonporous surfaces. Therefore, Nanocyn 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]. Nanocyn 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.

DIRECTIONS FOR USE

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

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, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does 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 medical devices prior to sterilization or high-level disinfection.

To Disinfect Hard, Non-Porous Surfaces:

All surfaces must be pre-cleaned/cleaned before disinfection. Apply [this product] [Nanocyn®] with a cloth, wipe, mop, sponge, or spray. Allow to remain visibly wet for 30 seconds for viruses** and 8 minutes for bacteria.

* ORGANISM LIST

| Bacteria | | |
|--------------------------------------|-------------|--------------|
| Pathogen | Strain | Contact Time |
| Staphylococcus aureus | ATCC 6538 | 8 Minutes |
| Pseudomonas aeruginosa | ATCC 15442 | 8 Minutes |
| | | |
| ** Viruses | | |
| Pathogen | Strain | Contact Time |
| Norovirus (as Feline Calicivirus) | ATCC VR-782 | 30 seconds |

USE SITES [AREAS]: MEDICAL

| For Use on Hard, Non-Porous Surfaces at the Following Medical Sites: | | |
|---|---|--|
| Hospitals [including] [emergency rooms] [critical] [and] [intensive] [care] [units] [neonatal units] [isolation areas] [and] [quarantine rooms] [Ambulances] [Emergency Medical] [Transport vehicles] Ambulatory Surgical Centers (ASC) Anesthesia [Rooms] [Areas] [Assisted Living] [Full Care] Nursing Homes Carts CAT Lab[oratories] Central Service Areas Central Supply [Rooms] [Areas] Cleanrooms Compounding pharmacies [Critical Care Units] [CCUs] Dialysis [Clinics] [Facilities] Doctors' Offices Donation Centers [blood] [plasma] [Emergency Rooms] [ERs] Eye Surgical Centers Health Care [Settings] [Facilities] Home Health Care [Settings] | Hospital Kitchens Hospices Hospitals [Intensive Care Units] [ICU[s]] Isolation Areas Laundry Rooms Laboratories Long Term Care Facilities [Medical] Clinics Medical] Clinics Medical Facilities [Medical] [Physician's] [Doctor's] Offices [Newborn] [Neonatal] [Nurseries] [Intensive Care] Units [NICU] Nursing Homes [Nursing] [Nurses'] Stations Operating Rooms Ophthalmic Offices Orthopedics | |

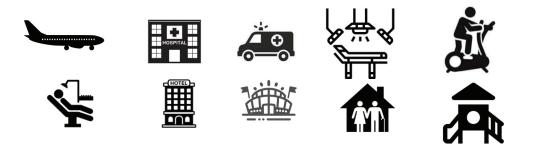
| Out-Patient [Surgical] [Centers] | Physical Therapy [Rooms] [Areas] |
|--|-------------------------------------|
| [(OPSC)] | Physicians' Offices |
| [Clinics] [Facilities] | Psychiatric Facilities |
| [Nursing] [retirement] homes | Public [Care] Areas |
| Operating rooms, patient rooms, | [Radiology] [X-Ray] [Rooms] [Areas] |
| Veterinary [clinics] [offices] [animal | Recovery Rooms |
| hospitals] [animal housing | Rehabilitation Centers |
| and grooming facilities] | Respiratory Therapy [Rooms] [Areas] |
| Pharmacies | Restrooms |
| [Laboratories] [animal life science | [Surgery] [Operating] [Rooms] [ORs] |
| laboratories] | Waiting [Rooms] [Areas] |
| Patient Areas | recycled –or- [%x] |
| Patient Restrooms | recyclable plastic |
| Patient Rooms | pH neutral |
| [Pediatric] Examination [Rooms] [| Ready to use |
| Areas] | VOC compliant |
| Pediatric Intensive Care Units [PICU] | VOC free |

USE SURFACES:

| [Ceramic] [Glazed] Tile | Glazed Porcelain |
|-------------------------|---------------------------|
| Chrome | Sealed Granite |
| Corian | Sealed Marble |
| Formica | Marble |
| Glass | Stainless Steel |
| Linoleum | Vinyl |
| Metal | [Finished] [Painted] Wood |
| Non-Porous Plastic | |
| | |

OPTIONAL GRAPHICS:





STORAGE AND DISPOSAL:

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

Storage: Store this product in its original sealed container at room temperature, away from direct sunlight and heat. Do not allow product to freeze.

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

Container Handling: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available.