



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 27, 2020

Simone Miller
PS & Regulatory Affairs Manager
NeoSan Labs, Inc.
1925 Aspen Drive, # 702
Santa Fe, NM 87505

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: Neosan Labs Part B
EPA Registration Number: 93672-2
Application Date: March 23, 2020
Decision Number: 561036

Dear Ms. Miller:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroups are large non-enveloped and enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Norovirus is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,



Steven Snyderman, Acting Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: stamped label

NeoSan Labs Part B
Antibacterial · Cleaner · Mildewstat · Decontaminant
Disinfectant · Deodorizer · Fungicide · Algacide · Virucide

Part B - Active Ingredient:

Hydrogen Peroxide	7.9%
Inert Ingredients:	92.1%
Total 100.0%	

KEEP OUT OF REACH OF CHILDREN
DANGER

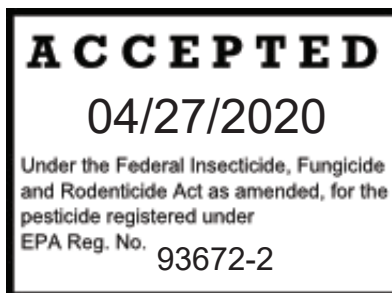
Corrosive. Causes irreversible eye damage.
See Back Panel for Additional Precautionary Statements

NeoSan Labs Part B is part of a two-part system and when Part A and Part B are combined creates a proven disinfectant, cleaner, fungicide, mildewstat and virucide (including Norovirus and H1N1). This product has been shown to control and inhibit mold and mildew on porous and nonporous surfaces.

NET CONTENTS: (1 gallon, 5 gallons, 250 gallons)

EPA REG. NO. 93672-2 (Part B)
EPA EST. NO. 80346-CO-01

Manufactured by NeoSan Labs Inc.
1925 Aspen Dr. #702A Santa Fe NM 87505



First Aid	
IF IN EYES:	<ul style="list-style-type: none"> • 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. • Call a poison control center or doctor for further treatment advice.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment.
IF SWALLOWED:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have a 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 INHALED:	<ul style="list-style-type: none"> • 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.
<p>NOTE TO PHYSICIAN Probable mucosal damage may contraindicate the use of gastric lavage. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also call 1-800-222-1222 for emergency medical treatment information.</p>	

PRECAUTIONARY STATEMENTS

Hazards To Humans And Domestic Animals

CORROSIVE. Causes irreversible eye damage. Causes skin irritation. Harmful if inhaled. Do not get in eyes, on skin, or on clothing. Avoid breathing vapor or spray mist. Wear protective eyewear such as goggles, face shield or safety glasses. Wear coveralls over short-sleeved shirt and short pant, socks, chemical-resistant footwear and chemical resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

[]-Denotes sections of optional language or instruction

[The following statements may or may not appear on some labels]

For Professional Use Only: For use by Mold Remediation Workers, Mold Remediation Contractors, Certified Mold Remediators, Certified Mold Contractors, Certified Mold Remediation Contractors, Applied Microbial Remediation Technicians, Certified Mold Professional, Certified Restorers, and Mold Remediation Companies.

Technology originally developed and patented by Sandia National Laboratories.

Technology originally developed and patented by Sandia National Laboratories.

NeoSan is Produced Commercially using the Formula Licensed by Sandia National Laboratories

Broad spectrum biocidal activity

Foaming Action

- Inhibits and Retards Growth of Mold, Mildew and Fungus on Porous and hard nonporous Surfaces.
- Shown to be effective against the pathogenic bacteria Staphylococcus aureus, (including MRSA Staphylococcus) Salmonella enterica, and Pseudomonas aeruginosa
- Proven to be effective against Norovirus
- Cleans & Controls Mold Growth on Porous and hard Non-Porous Surfaces as listed on the label
- Cleaner, Mildewstat, Fungicide, Disinfectant, Virucide and Deodorizer
- Used in Schools, Hospitals, Homes, and Commercial Facilities

NeoSan Labs Part B is a breakthrough product based on technology originally developed and patented by Sandia National Laboratories.

NeoSan Labs Part B is commercially manufactured under a license from Sandia National Laboratories. Modec MDF-200 prevents mildew & fungus (the causative agent for Athletes's Foot, Trichophyton mentagrophytes) on hard non porous surfaces and inhibits the growth of mold, mildew and fungal spores on stained wooden decks, aluminum siding, wood siding and other porous and non-porous surfaces.

NeoSan Labs Part B effectively cleans and disinfects all hard nonporous surfaces including those in basements and bathrooms as well as metal, plastic and glazed ceramic tile.

NeoSan Labs Part B cleans and inhibits the growth of mold and mildew on painted fences, aluminum siding, painted and stained wood, painted walls, metal, plastic, planters boxes, and ceramic tile.

- Foaming Action
- Coverage up to 200 sq. ft.
- Inhibits and Retards Growth of Mold, Mildew and Fungus
- Shown to be effective against the pathogenic bacteria Staphylococcus aureus, Salmonella enterica, and Pseudomonas aeruginosa
- Cleans & Controls Mold Growth on Porous and hard Non-Porous Surfaces
- Cleaner, Mildewstat, Fungicide, Disinfectant and Deodorizer
- This technology is Used by professionals for remediation in Schools, Hospitals, Homes, and Commercial Facilities
- Used by Professionals in Schools, Hospitals, Homes & Commercial Facilities
- Professionals recommend appropriate eye and respiratory equipment be worn when undertaking mold abatement procedures

- Propellant Cartridge: Aerosol Container, Spray-bridge & Dip Tube
- Part A
- Part B
- Mixing Bottle
- Insert
- **{Pictures of each of the five named components}**
- A Serious Product for a Serious Problem
- Mix, Spray and Wipe Away
- STOPS MOLD COLD!
- Kills Mildew and Fungus
- Kills Mildew and Fungus, such as those that cause Athlete's Foot, on hard non porous surfaces
- Inhibits Mold and Fungal Spores
- Disinfects & Deodorizes
- For Indoors and Outdoors
- Inhibits the growth of mold, and mildew, on wooden decks, cement, aluminum, and wood siding and other porous and non-porous surfaces.
- Effectively cleans and disinfects all hard, nonporous surfaces including those in basements and bathrooms as well as metal, plastic and ceramic tile.
- Contents: Propellant Cartridge: Aerosol Container Net Wt. 1 oz (28 g)
- Spray Bridge & Dip Tube
- Part A: 5 oz. (147 ml)
- Part B: 5 oz. (147 ml)
- Mixing Bottle
- Cleans and inhibits the growth of mold and mildew on porous surfaces of fences, cement walkways, siding, wood, painted walls, stucco, planters boxes, and terracotta.
- Remove Stains from surfaces prior to mold and mildew treatment. May be used to clean surfaces. Spray liberally to coat surfaces and allow to remain wet for 30 minutes. Scrub surface with sponge to remove stains.

[ATCC Numbers May not appear on labels]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. The product is designed specifically as a general cleaner and disinfectant for use in homes, hospitals, and commercial facilities. It is formulated to disinfect hard, non-porous, inanimate environmental surfaces such as floors, walls, metal surfaces, stainless steel, porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs, hard nonporous cabinets, and walls of swimming pools. May be used in the kitchen on non-food contact surfaces. If used on food contact surfaces, rinse with potable water prior to food contact. In addition, this product deodorizes areas that are hard to keep fresh smelling including garbage cans, basements, restrooms and areas prone to odors caused by microorganisms.

MIXING DIRECTIONS FOR ACTIVATION

NeoSan Labs Part B is formulated as one component of a two-part system and therefore must not be used alone as a disinfectant without activating. Activate by mixing equal amounts of NeoSan Labs Part A with equal amount of NeoSan Labs Part B as described below.

[The following directions apply only to aerosol product applicators and appear only on labels equipped with such:

TO ASSEMBLE: –

1. Fill empty mixing container with equal portions of Part A and Part B.
2. Securely screw mixing container onto the spray-bridge (dip-tube side).
3. Snap aerosol container onto the small end of spray-bridge, making sure container is firmly seated.

TO USE: - Depress round actuator tab of spray-bridge to dispense newly mixed solution.

Note: - To prevent the possibility of spraying pure propellant from the aerosol container, do not allow liquid in mixing bottle to become empty during use. The combined liquid from Parts A & B remains active for 12 hours after mixing. Product must remain in contact with surface area for a minimum of 10 minutes.

Contents of aerosol container are under pressure. Do not puncture or incinerate container. Do not expose to heat, fire, sparks or flame. Do not store at temperatures above 120F.

Intentional misuse by intentionally or deliberately concentrating and inhaling contents can be harmful or fatal.]

USE DIRECTIONS – NeoSan Labs Part B is to be used in a binary (two part) system. Part A is a surfactant formulation; Part B is a hydrogen peroxide based formulation. Thoroughly mix EQUAL VOLUMES of PART A and PART B. Apply the solution as a spray onto surfaces as directed below. Allow the product to remain on the surface for 10 minutes. The mixed solution has an efficacious pot life of 8 hours.

PRE-CLEANING - Prior to use on surfaces, remove gross filth, spray the mixture (Part A and Part B) onto the surface and allow to penetrate (about 2 minutes), and then clean thoroughly.

DISINFECTION – Follow Pre-Cleaning instructions listed above. To disinfect surfaces, apply the mixture and allow to remain wet with product for 10 minutes. No scrubbing is necessary. The product will not leave grit. The product exhibits disinfectant activity against *Staphylococcus aureus*, *Salmonella enterica*, *Pseudomonas aeruginosa* and *Listeria monocytogenes* and meets the requirements for hospital use. When used as directed, NeoSan Labs Part A and Part B mixture has been demonstrated to provide disinfection efficacy on hard non porous surfaces against the following organisms;

Organism	ATCC #
<i>Staphylococcus aureus</i>	6538
Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA <i>Staphylococcus aureus</i>)	33592
<i>Staphylococcus epidermidis</i>	12228
<i>Salmonella enterica</i>	10708
<i>Pseudomonas aeruginosa</i>	15442
<i>Klebsiella pneumoniae</i>	4352
<i>Proteus mirabilis</i>	9240
Vancomycin-Resistant <i>Enterococcus faecalis</i>	51299
<i>Enterobacter aerogenes</i>	15038
<i>Escherichia coli</i> (0157:H7)	43888
<i>Escherichia coli</i> (ESBL)	BAA-196
<i>Listeria monocytogenes</i>	19117

VIRUCIDAL ACTIVITY – Follow Pre-Cleaning instructions listed above. To eliminate viruses on hard non-porous surfaces, apply the mixture and allow to remain wet for 10 minutes. This product is virucidal against Influenza Type A (including H1N1), Influenza Type B and Norovirus (Feline Calicivirus Surrogate). When used as directed, NeoSan Labs Part A and Part B mixture has been demonstrated to provide disinfection efficacy on hard non porous surfaces against the following viruses;

Virus	ATCC #
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Influenza A	VR-544
Influenza B	VR-823
Norovirus (Feline Calicivirus Surrogate)	VR-782

FUNGICIDAL ACTIVITY – NeoSan Part A and Part B mixture has been demonstrated to be fungicidal on hard non porous surfaces against *Trichophyton mentagrophytes* (ATCC 9533), *Aspergillus niger* (ATCC 6275 and 1015) and *Penicillium variable* (ATCC 52262). Follow Pre-Cleaning instructions listed above and remove any mold that can be removed by hand. Apply a blended mixture of equal parts Part A and Part B as a spray onto a mold afflicted surface and allow to remain wet with product for 10 minutes.

Fungi	ATCC #
Trichophyton mentagrophytes	9533
Aspergillus niger	1644
Penicillium variable	522620

FUNGISTATIC ACTIVITY – NeoSan Labs Part A and Part B mixture has been demonstrated to be fungistatic on porous and non-porous surfaces. Follow Pre-Cleaning instructions listed above and remove any mold that can be removed by hand. Apply a blended mixture of equal volumes of Part A and Part B to the affected surface until thoroughly wet. Allow surface to remain wet for at least 10 minutes. Let dry.

MOLD & MILDEW CONTROL – This product controls mold and mildew on porous and hard non-porous surfaces. Follow Pre-Cleaning instructions listed above, then spray with the product, making sure to wet completely. Let the surface air dry but the surface must remain wet for at least 10 minutes. Reapply as necessary.

DEODORIZING – NeoSan Labs Part A and Part B mixture is an effective deodorizer when applied to areas affected with:

- Pet odors
- Food odors
- Putrefying odors
- Smoke odors

Always check fabric surfaces for colorfastness before applying. Remove gross filth. Mix equal parts of PART A and PART B and apply to surfaces until they appear wet to eliminate odors. Allow product to air dry or surface to remain wet for at least 10 minutes.

SWIMMING POOL APPLICATIONS - When used as directed, this product may be used as an algaecide to treat walls of swimming pools.

ALGAECIDE USE - After draining or before filling pool, spray and scrub walls with product. Allow to remain on surface for 30 minutes prior to rinsing.

TO CLEAN BY SPRAY APPLICATIONS - For outdoor use on cement, aluminum and wood siding, wood decks and metal roofs to inhibit the growth of mold and mildew.

REMOVES STAINS FROM SURFACES – NeoSan Labs Part A and Part B mixture may be used to clean surfaces. Mix 4 ounces of PART A and Part B into one gallon of water. Apply liberally to coat surfaces and allow to remain wet for 30 minutes. Scrub surface with sponge to remove stains.

SPRAYING – Mix equal parts of PART A and PART B directly into ULV spray equipment. Apply mixed product at a rate of no less than 1 ounce to 100-sq. ft. of surface area. Allow surface to air dry or remain wet for at least 30 minutes.

STORAGE AND DISPOSAL - Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE – Store in a dry place no lower in temperature than 50°F or higher than 120°F.

CONTAINER DISPOSAL – Nonrefillable container. Do not reuse or refill this container. Wrap container and put in trash.

PESTICIDE DISPOSAL – Pesticide wastes are acutely hazardous. Triple rinse or pressure rinse (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after flow begins to drip. Repeat this procedure two or more times.

<< APPENDIX 1 >>

<< **EMERGING VIRAL PATHOGENS CLAIMS – Hard, nonporous surface** >>

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 when combined with equal parts of NeoSan Labs Part A meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large Non-Enveloped Viruses

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label</i>
Enveloped Virus	Norovirus (Feline Calicivirus ATCC VR-782)
Large Non-Enveloped virus	Norovirus (Feline Calicivirus ATCC VR-782)

NeoSan Labs Part A & Part B combination has demonstrated effectiveness against viruses similar to **[name of emerging virus]** on **hard, non-porous surfaces**. Therefore, **NeoSan Labs Part A & Part B combination** can be used against **[name of emerging virus]** when used in accordance with the directions for use **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]**. **NeoSan Labs Part A & Part B combination** 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.