



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

September 5, 2019

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Kathryn Rosario
Regulatory Assurance Specialist
Lonza Inc.
412 Mount Kemble Avenue, Suite 200S
Morristown, NJ 07960

Subject: Notification per PRN 98-10 – Minor Label Changes
Product Name: NUGEN IID-64
EPA Registration Number: 6836-387
Application Date: August 21, 2019
Decision Number: 554755

Dear Ms. Rosario:

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) 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 Joseph Daniels at (703) 347-8669 or via email at Daniels.joseph@epa.gov

Sincerely,

A handwritten signature in blue ink that reads "E. Miederhoff".

Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

{Note to reviewer:

Items in brackets [AAA] are optional and may/may not be included on final label.

Items in braces {AAA} are for information purposes and will not appear on final label}

NUGEN® 1ID-64

NOTIFICATION

6836-387

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:

09/05/2019

One-Step Germicidal† Cleaner and Deodorant

DISINFECTANT
STAPHYLOCIDAL¹
FUNGICIDAL
*VIRUCIDAL

PSEUDOMONACIDAL²
BACTERICIDAL
MILDEWSTATIC

[FLORAL] / [CITRUS] / [FRESH] / [CLEAN] / [LEMON] / [PINE] / [MINT]
[scent] [fragrance] [odor] [scented]

Active Ingredients:

Didecyl dimethyl ammonium carbonate and Didecyl dimethyl ammonium bicarbonate.....	3.03%
Other Ingredients:	96.97%
Total	100.00%

DANGER [PELIGRO]

KEEP OUT OF REACH OF CHILDREN

See [left] [side] [right] [back] panel for Precautionary Statements

EPA Reg. No. 6836-387

EPA Est. No. (as indicated on container)

Net Contents (as indicated on container)

[DOT symbols]

[Country of origin (insert country)]

[Manufactured in (insert country)]

[BARCODE]

Manufactured by:

LONZA Inc.

412 Mount Kemble Avenue

Suite 200S

Morristown, NJ 07960

¹staphylococcus aureus and staphylococcus epidermis

²pseudomonas aeruginosa

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin, or on clothing. Do not breathe spray mist. Wear protective eyewear such as goggles, face shield, or safety glasses. Wear coveralls worn over long-sleeved shirt and long pants, socks and chemical-resistant boots, and waterproof gloves (Barrier Laminate, or Butyl Rubber, or Nitrile Rubber, or Neoprene Rubber, or Natural Rubber, or Poly-ethylene, or Polyvinyl Chloride (PVC), or Viton, selection Category A). Wear a minimum NIOSH-approved particulate filtering facepiece respirator with any N, R, or P filter; or a NIOSH-approved elastomeric particulate respirator with any N, R, or P filter; or a NIOSH-approved powered air purifying respirator with HE filters. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

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 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 SWALLOWED: Call 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 INHALED: 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.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For general information on product use, etc., call the National Pesticides Information Center at 1-800-858-7378. You may also contact 1-800-222-1222, the poison control center, for emergency medical treatment information.

NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage.

{If container size is 5 gallons or larger, use the following Environmental Hazards statement:}

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

{Note to reviewer: the following is considered optional marketing language:}

A multi-purpose, germicidal[†] detergent effective in the presence of a moderate amount of organic soil (5% serum).

Bleach-free

Cleans, disinfects, and eliminates odors.

Continuous Odor Removal

[Deodorizes and] has a clean, fresh scent

Destroys [mold] odors at the source.

Disinfecting [Multi-Purpose] Cleaner

Disinfects [and / or] cleans [and / or] deodorizes in one [labor saving] step when used according to the directions for disinfection.

Doesn't just mask odors, it eliminates them.

Eliminates [smoke] [pet] [mold] odors.

Eliminates tough [floor] dirt and germs[†]

[Good for] [use on] finished wood surfaces

Help is on the way

Makes 65 gallons *{on the 1 gallon label}*

Meets OSHA Bloodborne Pathogen standard for HIV

Mold Odor Destroyer

Multi-purpose –or- Floor cleaner –and/or- disinfectant

No smeary residue

Odor counteractant

[†]Note to reviewer: *If a supplemental label is using the “Germs” claim, per the EPA Guidance on use of the term “Germs” in order to make an unqualified “germ” claim the supplemental label must list all 3 of the major classes of organisms: Virus, Bacteria, Fungi and label must bear disinfectant directions. In order to make a qualified “germ” claim the supplemental label must be a broad spectrum disinfectant and list additional claims against one of the following two major classes of organisms: Fungi or Viruses and must bear disinfectant directions. The front panel of the label for a qualified claim must contain a designator [such as **] that refers the user to the qualified statements that describes the type of germ the product is efficacious against. An unqualified claim can appear on front or back panel and does not require a designator.*

{Note to reviewer: the following is considered optional marketing language:}

Use **NUGEN® 1ID-64** in:

{Note to reviewer: Each entry below also represents a graphic depicting the corresponding area of use. The graphics will only represent individual objects or outsides or insides of buildings as described below. No people animal or food will be depicted in graphics. Toy graphics will be submitted to Agency for review.}

Bathrooms

Homes [households]

Kitchens

Dental offices

Hospitals

Medical Offices [Clinics]

Nursing homes

Day care centers

Nurseries

Bars

Cafeterias

Convenience stores

Federally inspected meat and poultry plants,

Food processing plants

Food storage areas

Institutional kitchens

Restaurants

[USDA] [Federally] inspected food processing facilities

Athletic facilities

Barber shops

Business and office buildings

Colleges

Correctional facilities

Dressing rooms

Exercise facilities

Factories

Hotels

Institutional facilities

Institutions

Locker rooms

Motels

Prisons

Public facilities

Public rest rooms

Schools

Shower and bath areas

Salons [Beauty]

Universities

Camp grounds

Play ground equipment

Animal laboratories

Dairy farms

Farms [Farm premises]

Hog farms

Kennels

Pet animal quarters

Pet shops

Poultry farms

Poultry houses

Turkey farms

Veterinary clinics

Zoos

Airplanes

Airports

Boats

Buses

Campers

Cars

Emergency vehicles

Mobile homes

Ships

Taxis

Trailers

Trains

Transportation terminals

{Note to reviewer: the following is considered optional marketing language:}

ITYPES OF SURFACES:

Use **NUGEN® 1ID-64** on washable hard, nonporous surfaces of:

{Note to reviewer: Each entry below also represents a graphic depicting the corresponding type of surface. No people, animal or food will be depicted in the graphics. Only exteriors of microwaves and refrigerators will be depicted.}

Appliances, exterior surfaces
Basins [empty]
Bathroom [lavatory] fixtures
Bathtubs
Cabinets
Cages
Chairs
Coils and drain pans of air conditioning and refrigeration equipment and heat pumps
Conductive flooring
Counters [countertops]
Desks
Doorknobs
Floors
Garbage cans
Highchairs
Kennel runs

Microwave ovens, exterior surfaces
Outdoor furniture
Refrigerators, exterior surfaces
Refrigerated storage and display equipment
Showers
Shower stalls
Sinks [bathroom, kitchen]
Stoves [stovetops]
Tables, [picnic tables]
Telephones
Toilets
Toilet bowls
Toilet bowl surfaces
Tubs
Tiles, glazed
Urinals
Walls

Other hard nonporous surfaces made of:

Formica®
Glazed ceramic
Glazed enameled surfaces
Glazed porcelain
Metal
Painted surfaces
Plastic (such as polystyrene or polypropylene)
Sealed stone
Stainless steel
Upholstery, vinyl and plastic
Woodwork, finished

Note to reviewer: The following is an optional graphic that will be used to illustrate the scent.}



* Formica® is a registered trademark of The Diller Corporation

{Note to reviewer: The following are optional graphics that will be used to illustrate possible use sites.}



toilet
baño



garbage area
área de basura

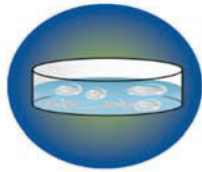


shower
ducha

{Note to reviewer: The following are optional graphics that will be used to illustrate odors to be controlled.}



smoke
humo



mold & mildew
moho y hongos



pet carrier
portador del
animal doméstico

{Note to reviewer: the following is considered optional marketing language:}

Effective [as a disinfectant] against the following pathogens:

[Bacteria:]

Enterobacter aerogenes (ATCC 13048)

Escherichia coli (ATCC 11229)

Klebsiella pneumonia (ATCC 4352)

Pseudomonas aeruginosa (ATCC 15442)

Salmonella enterica (ATCC 10708)

Serratia marcescens (ATCC 14756)

Shigella flexneri (ATCC 12022)

Shigella sonnei (ATCC 11060)

Staphylococcus aureus (ATCC 6538)

Staphylococcus aureus - Methicillin-Resistant [MRSA] (ATCC 700699)

Staphylococcus epidermidis (ATCC 12228)

Streptococcus pyogenes [Strep] (ATCC 19615)

[Viruses:]

*Herpes simplex Type 1 Virus [Herpes]

*Influenza A Virus [Influenza]

*HIV-1 [AIDS virus]

[Fungi:]

Trichophyton interdigitale [Athlete's Foot Fungus] [A Cause of ringworm]

DILUTION: 1:64 2 fl. oz. per gallon of water [474 ppm Active Quat]

{If the following Spanish statement is used, it must appear directly above DIRECTIONS FOR USE.}

[AVISO: SI NO PUEDE LEER EN INGLES, PREGUNTE A SU SUPERVISOR SOBRE LAS INSTRUCCIONES DE USO APROPIADAS ANTES DE TRABAJAR CON ESTE PRODUCTO.]

DIRECTIONS FOR USE

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

GENERAL USE DIRECTIONS

APPLICATION: For disinfection, remove heavy soil deposits from surface. Then thoroughly wet surface with a solution of 2 fl. oz. [1/4 cup] of the concentrate per 1 gallon of water. Apply with a cloth, mop, sponge, or coarse sprayer, or by soaking. For sprayer applications, use a coarse spray device. Spray 6-8-inches from surface, rub with a brush, cloth or sponge. Do not breathe spray. Let solution remain on surface for a minimum of 10 minutes. Rinse or wipe dry with a clean cloth or sponge or allow to air dry.

Rinse all surfaces that come in contact with food such as countertops, exterior surfaces of appliances, tables and stovetops with potable water before reuse. Do not use on utensils, glassware and dishes or appliance interior surfaces as a disinfectant.

Prepare a fresh solution daily or more often if the solution becomes diluted or visibly soiled.

Rinsing of floors is not necessary unless they are to be waxed or polished.

{Note for reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, one of the following statements must be used:}

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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

{or}

This product is not for use on medical device surfaces.

{Note to reviewer: Alternate Directions for use:}

General Cleaning:

Mix 2 fl. oz. [1/4 cup] per 1 gallon of water.

To Disinfect and Clean [throughout your home]:

Mix 2 fl. oz. [1/4 cup] per 1 gallon of water. Let stand for a minimum of 10 minutes before wiping. For heavily soiled surfaces, a precleaning step is required.

For tough jobs:

Pour directly on sponge or soil. Let stand for a minimum of (contact time) before wiping. Rinse thoroughly with clean water.

For surfaces that may come in contact with food potable water rinse is required.

USDA: Use in federally inspected meat and poultry plants on all hard, nonporous surfaces in inedible product processing areas, non-processing areas, and / or exterior areas.

USDA: For use in federally inspected meat and poultry plants as a floor and wall cleaner for use in all departments. Food products and packaging materials must be removed from the room or carefully protected. All surfaces must be thoroughly rinsed with potable water.

TOILET BOWLS: To clean, apply diluted solution around the bowl and up under the rim. Stubborn stains may require brushing.

To disinfect, first preclean to remove heavy soil, then [remove or expel over the inner trap the residual bowl water] or [empty bowl]. Pour in 3 fl. oz. of the diluted solution. [Swab the bowl completely using a scrub brush or mop] [Brush bowl completely], making sure to get under the rim. Let stand for 10 minutes [or overnight], then flush.

DISINFECTION OF BARBER / BEAUTY / SALON INSTRUMENTS AND TOOLS: Tools (such as combs, brushes, razors, scissors, and other shop tools) can be disinfected by immersing in a 2 fl. oz. [1/4 cup] per 1 gallon solution for a contact time of at least 10 minutes. Prepare a fresh solution daily or more often if the solution becomes diluted or visibly soiled.

FUNGICIDAL DIRECTIONS: NUGEN® 1ID-64 is an effective fungicide against Trichophyton interdigitale [the athlete's foot fungus] [a cause of ringworm] in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities. **Preclean hard, non-porous surfaces prior to treatment with the use-solution.** Follow disinfection directions.

MILDEWSTATIC DIRECTIONS:

[Will effectively control the growth of mold and mildew plus the odors caused by them when applied to hard, nonporous surfaces such as walls, floors, and table tops.] **Preclean hard, non-porous surfaces prior to treatment with the use-solution.** Apply solution [2 fl. oz. [1/4 cup] per 1 gallon of water] with a cloth, mop, sponge, or coarse sprayer, making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application weekly or when growth reappears.

***KILLS HIV-1 [AIDS VIRUS] ON PRECLEANED, ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BLOOD / BODY FLUIDS** in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces / objects with blood / body fluids, and in which the surfaces / objects likely to be soiled with blood / body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 [HIV1] [associated with AIDS].

Special Instructions for Cleaning and Decontamination Against *HIV-1 [*AIDS Virus] of Surfaces / Objects Soiled With Blood / Body Fluids.

Personal Protection: Clean-up must always be done wearing protective gloves, gowns, masks and eye protection.

Cleaning Procedures: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of NUGEN® 1ID-64.

Contact Time: Leave surface wet for **5 10** minutes [at 25°C] [77°F] [room temperature]. **Use a 10-minute contact time for disinfection against all other viruses, fungi, and bacteria claimed.**

Disposal of Infectious Materials: Blood, body fluids, cleaning materials and clothing must be disposed of according to federal, state, and local regulations for infectious waste disposal.

FARM PREMISE, LIVESTOCK, TURKEY AND POULTRY HOUSE DISINFECTANT:

1. Remove all animals and feeds from premises, trucks, coops, crates, and enclosures.
2. Remove all litter and manure from floors, walls, and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent, and rinse with water.
5. Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. 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.
7. Ventilate buildings, coops, cars, boats, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried.
8. After treatment with disinfectant, thoroughly scrub feed racks, troughs, automated feeders, fountains, and waterers with soap and detergent, and rinse with potable water before reuse.

**VETERINARY PRACTICE / ANIMAL CARE / ANIMAL LABORATORY / ZOOS / PET SHOP / KENNELS
DISINFECTION DIRECTIONS:**

For cleaning and disinfecting hard, nonporous surfaces: equipment used for feeding or watering animals, utensils, instruments, cages, kennels, stables, catteries. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 2 oz. of **NUGEN[®] 1ID-64** per 1 gallon of water *[or equivalent dilution]* for a period of 10 minutes. Wipe or allow to air dry. Immerse all animal handling and restraining equipment as well as forks, shovels, and scrapers used to remove litter and manure. Rinse all surfaces that come in contact with food, including equipment used for feeding or watering, with potable water before reuse. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

HEAVY-DUTY CLEANING INSTRUCTIONS:

Use [1 fl. oz. of **NUGEN[®] 1ID-64** per 24 fl. oz. of water] [4 to 6 fl. oz. of **NUGEN[®] 1ID-64** per 1 gallon of water] to clean heavily soiled areas.

{Note to reviewer: For Nonrefillable Containers, Label has Household and Residential Uses}

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children.

Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for recycling if available.

{or}

Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for reconditioning if appropriate.

{Note to reviewer: For Nonrefillable Containers for commercial, industrial, and institutional uses – all sizes – No Reuse Rinsate Statement for Public Health Use products. Chapter 13, Table 6 of the Label Review Manual states that for “All products in containers that could be burned,” the registrant has the option to “Remain silent on burning;” therefore, no incineration language is provided for plastic containers.}

STORAGE AND DISPOSAL

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

Pesticide Storage: Open dumping is prohibited. Store in original container in areas inaccessible to children.

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 the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal:

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying.

{Plastic and Metal Containers:} Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Follow pesticide disposal instructions for rinsate. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

{For metal containers only:} DO NOT cut or weld metal containers.

{For Bag in Box Containers:} Completely empty bag into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

{Note to reviewer: For Nonrefillable Sealed Containers: Packaging options can be in sealed containers or bottles designed for use dilution systems to reduce worker exposure to the concentrate. None of these can be triple rinsed because they are closed sealed containers. The following text will be used on these sealed container types:}

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Store in original container in areas inaccessible to children.

Pesticide Storage: Open dumping is prohibited. Store in original container in areas inaccessible to children.

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 the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Wrap empty container and put in trash.