



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

6836-446

Date of Issuance:

02/08/2021

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Nugen® NR-128

Name and Address of Registrant (include ZIP Code):

Lonza, LLC
412 Mt. Kemble Avenue, Suite 200S
Morristown, NJ 07960

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 conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Jacqueline Hardy, Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Date:

02/08/2021

2. You are required to comply with the data requirements described in the DCI identified below:

- a. PHMB GDCI-111801-1519
- b. DDACB GDCI-069208-1718

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>

3. Be aware that proposed data requirements for PHMB and DDACB, have been identified in a Work Plan. For more information on these proposed data requirements, you may obtain copies in the docket EPA-HQ-OPP-2012-0341 and EPA-HQ-OPP-2012-0651 at www.regulations.gov or contact the contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>

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:

4. 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.
5. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
6. 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 OIE, the pathogen's viral subgroup is small non-enveloped, 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.

7. 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.
8. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against *Clostridioides difficile* (ATCC 43598) 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.
9. Submit one copy of the final printed label for the record before you release the product for shipment.
 - Revise the EPA Registration Number to read, “EPA Reg. No. 6836-446.”

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 fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). 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 Confidential Statement of Formula dated 06/12/2020

If you have any questions, please contact Lorena Rivas by phone at (703) 305-5027, or via email at rivas.lorena@epa.gov.

Enclose: Stamped Label
 Product Chemistry Review dated 11/13/2020

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® NR-128

[Sanitizer] / [Disinfectant] / [Deodorizer] / [Virucide*]

For Home, Commercial, Institutional and Industrial Use

For Food, Dairy, Beverage, Meat, Poultry, Egg and Seafood Processing and Farm Use

For Farm, School, Dairy, Restaurant, Food Handling and Processing Areas, Bar and Institutional Kitchen Use

For use in federally inspected meat and poultry plants

An effective sanitizer for use on food contact surfaces

Active Ingredients:

Poly(hexamethylenebiguanide) hydrochloride 6.830%

Didecyl dimethyl ammonium carbonate and didecyl dimethyl ammonium bicarbonate..... 5.010%

Other Ingredients:..... 88.160%

Total..... 100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

Manufactured by:

Lonza, LLC

412 Mt. Kemble Ave

Suite 200S

Morristown, NJ 07960

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

EPA Reg. No. 6836-XXX

EPA Est. No. (as indicated on container)

Net [Contents] [Wt.] [Weight]: (expressed as avoirdupois pounds and ounces)

[Barcode]

[QR Code]

[Country of Origin (insert country name)]

[Manufactured in (insert country name)]

ACCEPTED**02/08/2021**

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No.

6836-446**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 first 5 minutes, then continue rinsing. 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 INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a 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.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

NUGEN® NR-128

EPA Reg. No. 6836-XXX

EPA Registration Submission 2021-02-04

{Note To Reviewer: Language in [] is considered optional or interchangeable.}

Have the product container or label with you when calling poison control center or doctor or going for treatment.

{Optional Emergency contact information}

[For emergency information on [product, usage, etc.], call [1-XXX-XXX-XXXX], Monday through Friday, 9 a.m. to 5 p.m. After 5 p.m. call your poison control center at 1-800-222-1222.]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin, or clothing. Do not breathe spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

{Note to reviewer: If container size is 5 gallons or larger, the following Environmental Hazards statements will be used:}

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. 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: Pages 3-11 are considered optional marketing language. All designators (i.e. asterisks and numbers) used throughout the label may be interchanged as needed on final printed label.}

{Note to reviewer: The following claims containing "New" may only be used for a period of six months after EPA's approval of a revised or alternate formula, beginning when the product is first sold or distributed.}

- Introducing [new]
- New and Improved [formula] [disinfecting no-rinse formula]!
- New [no-rinse disinfecting formula] [disinfecting no-rinse formula]!
- New [no-rinse disinfectant][!] [and] [food surface sanitizer][!]
- New [multifunctional][dual use] food surface antimicrobial
- New [Convenient] Package
- New Larger Size
- New Bigger Bottle

MARKETING CLAIMS:

- Dilutable concentrated disinfectant [and sanitizer]
- 4-minute disinfection
- [With] 4 minute contact times

CLEANING CLAIMS:

- [A] chemically balanced disinfectant [and sanitizer] [that provides clear use solutions even in the presence of hard water].
- Can help reduce cross-contamination between treated surfaces
- Cleans [and] [disinfects] in one step ²
- Cleans and disinfects hard, non-porous surfaces²
- [Cleans [and disinfects] everyday kitchen messes ^{1, 2}
- Cleans [away] [up] dirt, dust and hair
- Cleans [breaks] through [everyday] [messes]
- Cleans to a [Sparkle] [Shine]
- Cuts through [dirt] [stains] [grime] [soils]
- Delivers non-acid disinfectant and cleaning performance in an economical concentrate.
- Deodorizes by killing microorganisms that cause offensive odors.
- [Everyday] [Regular] Cleaning
- For commercial use
- For [light touch ups] [quick clean-ups]
- For everyday messes
- Formulated for effective farm, poultry, and swine premise and veterinary practice.
- Gets up stuck-on messes
- For cleaning [(insert from list of any approved use site)]
- For cleaning your home [home][kitchen][bathroom][room][dorm][office][cart][car][classroom][gym]
- Helps reduce risk of cross contamination between treated surfaces
- Multi-purpose kitchen [everyday] [daily] [touch-up] [cleaning]
- One step [disinfectant ²] [sanitizer ⁵]

CLEANING CLAIMS (Cont.):

- For [spring] [home] [kitchen] [bathroom] [dorm] [office] [cart] [car] cleaning
- For cleaning your [home] [kitchen] [bathroom] [room] [dorm] [office] [cart] [car]
- Leaves your [house] [bathroom] [kitchen] fresh and clean
- Great on [glass] [mirrors] [[stainless] steel]
- Is a no-rinse sanitizer formula.
- Is a no-rinse food contact surface sanitizer [concentrate] ¹
- Is an economical concentrate.
- Leaves no harsh chemical residue
- Low odor
- Low streak formula
- Tested according to AOAC Germicidal & Detergent standards for sanitizing previously cleaned food-contact surfaces.
- No rinsing required
- No rinse required [even on] [food contact surfaces]
- No rinse needed
- No-rinse disinfectant formula
- No need to rinse
- No potable water rinse required on [disinfected] [sanitized] hard, non-porous surfaces
- Rinse free [formula]
- No rinse [disinfecting] [sanitizing] formula
- Now cleaning is [easier] than [ever] [before]
- Quick easy clean-ups.
- The convenient way to keep your home looking “just cleaned”
- Worry free cleaning

ANTIBACTERIAL CLAIMS:

- 4 Minute broad pathogen kill claims including Norovirus
- 4 minute acting [disinfectant] [antimicrobial] ¹
- 60 second [sanitizer] [sanitization]
- All around the house [disinfecting] [cleaning formula] ¹
- A no-rinse formula that cleans [and] [disinfects] ^{1, 2}
- Antibacterial
- Antibacterial Formula
- [Antimicrobial] [antibacterial] [disinfecting] ¹
- [Clean and] [disinfect] in just [4] [four] minutes ^{1, 2}
- [Clean] [sanitize] and [disinfect] [commonly touched] [household] hard, non-porous surfaces in [just] minutes[!] ²
- Cleans and [disinfects] [sanitizes] ^{1, 2}
- Cleans and [disinfects] in one step ^{1, 2}
- Convenient 4 minute hospital disinfection ¹
- Kills bacteria
- Daily [Surface] [Disinfector] [Sanitizer] [Cleaner] ¹
- [Designed] [Built] [Developed] [Formulated] [Engineered] for [disinfecting] [sanitizing] and [cleaning] everyday messes ¹
- [Designed] [Built] [Developed] [Formulated] [Engineered] for Everyday [disinfecting] [sanitizing] [cleaning] messes ¹
- [Disinfect] [Surfaces] ¹ [Your House] [Your Kitchen] [Your Bathroom] [Daily] [Everyday]
- [Disinfect] [Your Desk] [Your Office] [Your Room] [Daily] [Everyday]
- [Disinfecting] Formula
- Disinfect Hassle-free
- Disinfects ¹
- Disinfect [household] surfaces in [just] 4 minutes[!] ¹
- [Disinfect] [airplane] [airliner] [tray[s]] [tray table[s]]

ANTIBACTERIAL CLAIMS (Cont.):

- [Disinfect] any room in the house¹
- Disinfects [without [a] [the] [that] disinfectant smell]
- [Clean] [Sanitize] and disinfect [in one step]
- Effective in [disinfecting] [sanitizing] [your] [household] [kitchen] [bathroom] [surfaces]¹
- Effectively disinfects common household hard, non-porous surfaces
- [Kills] [Destroys 99.9%] bacteria in [just] 4 minutes[!]¹
- [Kills] [Destroys 99.9%] [[Pseudomonas aeruginosa] [Escherichia coli] [Salmonella enterica] in [just] 4 minutes[!]¹
- Everyday [surface¹] [disinfectant] [sanitizer] [cleaner]
- Great for everyday [disinfecting] [sanitizing] [cleaning] [wiping] [messes]
- Hassle-free [disinfection] [sanitization]
- Kills harmful bacteria that grows in the shower/bathroom
- [Kills] [Removes] [Destroys 99.9%] (*Insert pathogen or pathogens from lists on page 11* [on [pre-cleaned] environmental surfaces]¹
- [Kills] [Removes] [Destroys] 99.9% of bacteria¹
- [Kills] [Removes] [Destroys] 99.9% of bacteria, leaves [leaving] hard, non-porous surfaces [clean and] disinfected
- [Kills] [Removes] [Destroys] 99.9% of foodservice bacteria¹
- [Kills] [Removes] [Destroys] 99.9% of Foodservice Germs [Escherichia coli [E. coli], Salmonella enterica [Salmonella], and Listeria monocytogenes [Listeria]¹
- Kills [Salmonella enterica] & [Flu Virus]¹!²
- Kills the Flu Virus¹
- Kills [99.9%] [of] Listeria monocytogenes
- Kills Norovirus [in] [just] 4 minutes [!]¹
- Leaves hard, non-porous surfaces clean and disinfected²
- Reduce risk of cross contamination on hard non-porous surfaces
- Remove 99.9% of bacteria [from your] [surfaces¹] [home] [kitchen] [bathroom] [office]
- Use as a [disinfectant] [sanitizer] on [dishes] [glassware] [utensils] [cutting boards] [without rinsing] [with no rinse required]
- Disinfect [food contact] [kitchen] hard, non-porous surfaces without a [potable] water rinse
- Dual food surface antibacterial claims [food] [surface][sanitization][and][no-rinse][disinfection][viral efficacy][norovirus efficacy] ¹
- Provides food surface [contact] sanitization and no-rinse disinfection¹
- Disinfect [and] [kill viruses] [kill norovirus] while you sanitize [food contact][kitchen] [surfaces] ¹
- [Multi-functional] antimicrobial for [food contact][kitchen] hard, non-porous surfaces
- [Disinfect] [Sanitize] [baby] [children's] toys
- [Disinfect] [Sanitize] [bathroom] [kitchen] [sink[s]] [faucet[s]] [flush handle] [seat] [light switch] [door] [handle] [knob]
- [Disinfect] [Sanitize] [camping] [hiking] [boating] equipment
- [Disinfect] [Sanitize] [cell] [mobile] phones
- [Disinfect] [Sanitize] [computers[s]] [keyboards] [touchpads] [mouse]
- [Disinfect] [Sanitize] [daycare] [childcare] facilities
- [Disinfect] [Sanitize] [desk tops] [work tables] [work areas] [school desks] [shared equipment]
- [Disinfect] [Sanitize] [hotel] [motel] [public] [shared] [TV] [television[s]] [remote control[s]] [remote[s]] [telephone[s]] [phone[s]] [computer[s]] [keyboard[s]] [fax machine[s]]
- [Disinfect] [Sanitize] [shopping] [grocery] cart[s] [handle[s]]
- [Disinfect] [Sanitize] [cabinets], [chairs], [counter[s]top[s]], [shower] [door[s]] [stalls], [bathtub[s]], [sink[s]], [vanities], [vanity] [top[s]], [bathroom] [fixture[s]] [faucet[s]]
- [Disinfect] [Sanitize] the hard, non-porous surfaces of [personal protective equipment] [PPE] [respirators] [full face breathing apparatus] [gas masks] [goggles] [face shields] [hearing protection] [ear covers] [safety ear muffs] [helmets] [protective head gear] [hard hats]
- [Disinfect] [Sanitize] the hard, non-porous surfaces of [sports] [sporting] [gym] [athletic] [workout] [equipment] [machines]

ANTIBACTERIAL CLAIMS (Cont.):

- [Disinfect] [Sanitize] the hard, non-porous surfaces of [wrestling] [gymnastic] [gym] [athletic] [yoga] [tumbling] [mats] [pads]
- [Disinfect] [Sanitize] the [interior] [exterior] of [household] [kitchen] appliances³
- [Disinfect] [Sanitize] [waiting rooms] [public areas]
- [Disinfect] [Sanitize] [your] [household] [surfaces¹] [items] [:] [such as] [high chairs] [booster seats] [strollers] [car seats] [cribs] [tables] [tabletops] [counters] [countertops] [appliances] [sinks] [glazed tiles] [light switches] [door handles] [railings] [telephones] [trash] [garbage] [can[s]] [receptacle[s]] [bin[s]]
- [Disinfect] [Sanitize] [your] [dishes] [glassware] [utensils] [plastic cutting boards] [without rinsing] [with no rinse required]
- [Disinfect] [Sanitize] [your] bottling and beverage dispensing equipment [without rinsing] [with no rinse required]
- Disinfects (*insert from approved list of pathogens*) in [just] 4 minutes
- Sanitizes (*insert from approved list of pathogens*) in [just] [1 minute] [60 seconds]
- The convenient way to disinfect your household hard, non-porous surfaces
- The smart [way to] clean [and disinfect]
- Use NUGEN® NR-128 to disinfect sinks and tubs.
- [This product or product name] is an effective disinfectant against [Staphylococcus aureus] [*Klebsiella pneumoniae*]
- This product will clean and disinfect hard, non-porous surfaces.
- Two in one action [cleans and [disinfects] in one step]²
- [With proven] antibacterial action

USAGE CLAIMS:

- For Homes
- For Homes & Institutional Use
- For Commercial Use
- For household surfaces [all around the house] indoor and outdoor¹
- Use NUGEN® NR-128 in kitchens, bathrooms and other household areas.
- For cleaning of showers and tubs, shower doors and curtains, fixtures and toilet bowls.
- For restaurants [Front of House] [Back of House]
- May be used on plastic cutting boards [without rinsing]
- May be used on dishes [without rinsing]
- May be used on eating utensils [without rinsing]
- May be used on [Household] kitchen surfaces [without rinsing]¹
- Multi-purpose¹
- Multi-surface¹
- Specially formulated for use in the [kitchen] [bathroom]

SURFACE SAFETY CLAIMS:

- This formula will not harm [most] surfaces.

VALUE CLAIMS:

- Saves [Labor] time [with 4 minute disinfection] [with 1 minute sanitization]
- Is effective and economical.
- Is an economical concentrate
- Concentrated to produce less waste
- Concentrated to avoid shipping water
- XX% More [Free] Bonus Size, [Bonus] [Free] [XX-oz] [XX-Ounces] XX for the Price of YY.

PACKAGING CLAIMS:

- Easy to use
- Only use approved refill packs.
- Package breakthrough
- Package is XX% recyclable

PACKAGING CLAIMS (Cont.):

- Portable
- Recyclable [packaging] [bottle]
- Refill [size] [bottle]
- Refillable [size] [bottle]
- [Bottle] [Packaging] composed of [x%] recycled materials
- [Bottle] [Packaging] composed of [x%] renewable materials
- Converted with [x%] [wind] [solar] energy
- Less [Oil Consumption], [Landfill Waste], [Production Energy], [and] [Freight Energy]
- [Made with] X% less plastic
- [Made with] X% less plastic [than similar size containers] [than previous[ly] used container[s]]
- Package contains xx% recycled materials
- Package contains xx% post-consumer waste
- Packaged with [x%] [wind] [solar] energy
- Packaging contains XX% [post-consumer waste] [recycled materials]
- Produced with [Wind] [Solar] Energy
- The product was manufactured with X% [Wind] [Solar] Energy
- [This product was] [Produced] [Manufactured] with [x%] [wind] [solar] energy

OTHER CLAIMS:

- Ammonia Free [formula]
- Bleach Free [formula]
- Call (*Insert phone number*)
- Cleaning Advice? Visit [insert webpage address]
- Clear drying formula
- Comments?
- Contains No Phosphate
- Do not use for personal cleansing.
- Does not contain [chlorine] bleach or ammonia.
- Fragrance-free
- If you are not completely satisfied with this product, return it for a refund or replacement.
- No harsh chemical residue
- No harsh scent
- Phosphate free
- Quality Guaranteed
- Questions?
- Save time with [this product or product name] [!]
- Saves steps
- Saves Time
- This product contains no [phosphates or] phosphorous [compounds].
- No [need to] rinse

NUGEN® NR-128 [Brand Name] [This Product]:

- Delivers non-acid disinfecting, sanitizing and cleaning performance
- [Is] A [disinfectant] [sanitizer] that [disinfects] [sanitizes] and deodorizes in one labor saving step.²
- When used as directed, NUGEN® NR-128 will deodorize surfaces in toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause malodors.
- Deodorizes by killing microorganisms that cause offensive odors.
- Is a chemically balanced disinfectant
- Will not leave grit or soap scum.
- Is a [one-step] disinfectant cleaner that is effective against a broad spectrum of bacteria when used as directed.
- Is a proven "one-step" disinfectant - which is effective in the presence of 5% serum contamination.
- [Kills] [kitchen¹] [bathroom¹] [household¹] bacteria.

- Kills bacteria
- Use it on bathroom and kitchen surfaces like countertops, appliances, door handles, light switches, sinks, and tubs.

Cross-contamination is of major [housekeeping] concern. **NUGEN® NR-128** has been formulated to aid in the reduction of cross-contamination between treated surfaces in the home, schools, institutions and industry.

Use NUGEN® NR-128:

- as a disinfectant on hard, nonporous surfaces.
- as a [food contact surface] sanitizer on hard, non-porous surfaces.
- in kitchens, bathrooms and other household areas. ¹
- to clean and disinfect finished floors, sinks and tubs.
- for cleaning of showers and tubs, shower doors and curtains, fixtures and exterior toilet bowl surfaces.
- to clean and disinfect non-porous personal [safety] [protection] equipment, protective headgear, hard hats, half mask respirators, full face breathing apparatus, gas masks, goggles, spectacles, face shields, silicone rubber or PVC hearing protectors and vinyl covered ear muffs. [Precaution: Cleaning at 120°F temperature will avoid overheating and distortion of the personal [safety] [protection] equipment that would necessitate replacement.
- to clean and disinfect hard non-porous surfaces of gym equipment, exercise machines, wrestling mats and gymnastic equipment.
- in [front of house] restaurant [dining] [eating] areas. ¹
- in [back of house] restaurant [food preparation] [operating] areas. ¹
- to [disinfect] [sanitize] dishes, glassware, plastic cutting boards, cookware and utensils.

May be used on dishes [without rinsing]

May be used on plastic cutting boards [without rinsing]

Can help reduce the risk of cross-contamination from treated surfaces

Cleaning [and] [or] [disinfecting] [sanitizing] to go

Cleaning [and] [or] [disinfecting] [sanitizing] on the go

May be used on eating utensils [without rinsing]

No harsh chemical residue

[Insert Brand name] is registered in the United States and Trademark Office to [Insert Company name].

[Insert Brand name] is [a] registered trademark of [Insert Company name].

{Note to reviewer: The following is considered optional marketing language. Each item 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.}

[AREAS OF USE:]

Use **NUGEN® NR-128** to disinfect and sanitize:

Bathrooms	Athletic facilities
Children's rooms	Banks
Dens	Banquet Halls
Family rooms	Barber / Beauty shops
Homes [households]	Beverage processing facilities
Kitchens	Business and office buildings
Living room	Caterers / Catering facilities
Dental offices	Colleges
Hospitals	Correctional facilities
Medical Offices	Dairy processing plants
Nursing homes	Day care centers
Bars	Delicatessens
Breakrooms	Dressing rooms
Cafeterias	Exercise facilities
Convenience stores	Factories
Dining halls	Fitness centers
	Food manufacturing facilities
Food storage areas	Food packaging facilities
Restaurants [Front of House] [Dining & Eating Areas]	Food processing facilities
Restaurants [back of house] [kitchen]	Food service facilities
	Grocery
Airplanes	Gyms
Airports	Health clubs
Ambulance(s)	Hospitals
Automobiles	Hotels
Boats	Institutional facilities
Boxcars	Institutions
Buses	Laundry rooms
Campers	Locker rooms
Cars	Motels
Cruise ships	Nurseries
Delivery trucks	Nursing homes
Emergency [Police] [EMS] [Fire] [Rescue] vehicles	Playrooms
Food trucks	[Poultry][Meat/Seafood Packing]
Mobile food establishments	Facilities
Mobile homes	Prisons
Ships	Public facilities
Taxis	Public rest rooms
Trailers	Salons
Trains	Schools
Transportation terminals	Shower and bath areas
	Sick rooms
	Temporary Food Establishments
	Transportation Centers
	Camp grounds
	Playground equipment

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

[TYPES OF SURFACES:]

[Use **NUGEN® NR-128** on washable hard, non-porous surfaces of:]

{or}

[This product] will clean and disinfect washable hard, non-porous surfaces of:

All washable food contact surfaces

Appliances

Bar tops

Bathroom fixtures

Bathtubs [Fiberglass]

Beverage [machine or dispensers]³

Booster seats[Dining] Booths

Broilers³

Cabinets

Cafeteria trays

Cages

Car seat

Cash registers

Chairs

Changing tables

Coffee machines

Computer keyboards

Cooking surfaces³

Coolers

Condiment containers

Cribs

Counters [countertops]

Bathrooms] [Kitchen] [Restaurant]

Cupboards

Desks

Diaper changing [tables] [counters]

Diaper pails

Digital devices

Dining tables

Dish racks

Doorknobs

Door handles

Drain boards

Equipment tables

Faucets

Faucet Handles

Floors

Finished floors

Food mixers

Garbage cans

Glass

Griddles³

Grills³

Gym mats

Hampers

Headsets

Highchairs

Ice machines [doors][tracks][ice chutes][ice bins][ceiling][wall][ice scoop][ice cube tray]³

Self-service condiment areas

Self-service service ware areas

Showers

Shopping cart handles

Shopping carts / baskets

Shower [stalls] [walls]

Sinks [bathroom, kitchen]

Slicers

Storage areas

Stoves [stovetops]³

Strollers

Tables, [picnic tables] [Dining Tables]

Tanning Beds

Telephones

Toasters³

Exterior Toilet bowl surfaces

Toilet seats

Touchscreens

Toys

Trays [high chair] [hospital]

Tub walls

Tubs

Tiles, glazed

Walls

Trashcans

Food Trays

Self-service condiment areas

Self-service serviceware areas

Host/Hostess Stations

Laminated Menus

Lawn chairs

Beverage Dispensers

Other hard non-porous surfaces made of:

Acrylic

Finished woodwork

Formica®

Glass

Glazed ceramic

Glazed enameled surfaces

Glazed porcelain

Metal

Plastic [such as polystyrene or polypropylene]

Sealed granite

Sealed marble

Sealed quartz

Sealed stone

Stainless steel

Upholstery- vinyl and plastic

NUGEN® NR-128

EPA Reg. No. 6836-XXX

EPA Registration Submission 2021-02-04

{Note To Reviewer: Language in [] is considered optional or interchangeable.}

Lab benches
Linoleum
Light switches
Lunch boxes
Microwave ovens [exteriors]
Mixers
Non-wooden cutting boards
Non-Wooden Outdoor [patio] furniture except
cushions and wood frames
Ovens³
Pet [bowls or dishes]
Plastic cutting Board[s]
Refrigerators [exteriors]³
Refrigerated storage and display equipment³
Restaurant tables

Note: Do not use on unpainted wood, natural marble or brass.

{Note to reviewer: ATCC numbers are listed on the data matrix.}

NUGEN® NR-128 [Brand Name] [This Product] is a [one-step] disinfectant, sanitizer, and cleaner tested according to the AOAC Modified Germicidal Spray Test Method modified in 375 ppm hard water in the presence of 5% organic serum against:

{or}

NUGEN® NR-128 [Brand Name] [This Product] is effective against [Kills] [Removes] [Destroys 99.9%]:

[Bacteria:]

Pseudomonas aeruginosa [ATCC 15442]
Salmonella enterica [Salmonella] [ATCC 10708]
Staphylococcus aureus [ATCC 6538]

Campylobacter jejuni [ATCC 29428]
Escherichia coli [ATCC 11229]
Escherichia coli O157:H7 [ATCC 35150]
Klebsiella pneumoniae [ATCC 4352]
Listeria monocytogenes [ATCC 19117]
Shigella sonnei [ATCC 25931]
Yersinia enterocolitica [ATCC 23715]
Vibrio cholera [ATCC 14035]

[Viruses*:]

*HIV-1 [AIDS Virus] [HTLV-IIIb]
*Human Norovirus [ATCC VR-782]

{Note to Reviewer: This product qualifies for the following emerging pathogen claims against large non-enveloped or enveloped viruses. The claims shall not appear on marketed (final print) product labels.}

EMERGING VIRAL PATHOGEN STATEMENT

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 category[ies]:

- Enveloped Viruses
- Large Non-Enveloped Viruses

For an emerging viral pathogen that is a/an...	...follow the direction for use for the following organisms on the label:
Enveloped Viruses	Norovirus [ATCC VR-782]
Large Non-Enveloped Viruses	Norovirus [ATCC VR-782]

[Nugen NR-128] [Brand Name] [This Product] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, **[Nugen NR-128] [Brand Name] [This Product]** can be used against [name of emerging virus] when used in accordance with the directions for use against [Norovirus (ATCC VR-782)] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

OR

[Name of illness/outbreak] is caused by [name of emerging virus]. **[Nugen NR-128] [Brand Name] [This Product]** kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against [Norovirus (ATCC VR-782)] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.

FOOD CONTACT SANITIZATION CLAIMS:

NUGEN® NR-128 is an effective sanitizer for use on food contact surfaces¹ in 30 seconds against:

Escherichia coli [ATCC 11229]
Staphylococcus aureus [ATCC 6538]

NON-FOOD CONTACT SANITIZATION CLAIMS:

NUGEN NR-128 is an effective sanitizer for use on non-food contact surfaces¹ in 15 seconds in 375 ppm hard water against:

Enterobacter aerogenes [ATCC 13048]
Staphylococcus aureus [ATCC 6538]

DIRECTIONS FOR USE

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

Preparation of Disinfectant Use-Solution:

[Add] [mix] 1 oz. per gallon of water [1:128]

DISINFECTION / VIRUCIDAL:

Apply use-solution with a coarse spray device by spraying 6 – 8 inches from the surface. Do not breathe spray. Treated surfaces must remain wet for 4 minutes. Wipe dry with a cloth, sponge or mop or allow to air dry. For visibly soiled areas, a preliminary cleaning is required.

To disinfect food processing facilities: Spray surfaces with solution and allow to remain wet for 4 minutes.

{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 pre-clean 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.

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

Special Instructions for Cleaning and Decontamination against HIV-1 On Surfaces / Objects Soiled With Blood / Body Fluids.

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

Cleaning procedure: Blood and other body fluids containing HIV must be thoroughly cleaned from surfaces and objects before application of **NUGEN® NR-128 [Brand Name]** [this product] [spray] can be used for this purpose.

Contact time: Leave surface wet for 4 minutes.

Disposal of infectious material: Blood, body fluids, cleaning materials and clothing must be autoclaved and disposed of according to local regulations for infectious waste disposal.

TO SANITIZE FOOD CONTACT SURFACES¹:

{or}

TO SANITIZE FOOD PROCESSING EQUIPMENT AND OTHER HARD SURFACES IN FOOD PROCESSING LOCATIONS, DAIRIES, RESTAURANTS AND BARS:

1. Prior to application, remove gross food particles and soil by a pre-flush, or pre-scrape and, when necessary, pre-soak.
2. Apply use-solution thoroughly wetting surfaces with a coarse spray device by spraying 6 – 8 inches from the surface. Do not breathe spray.
3. Treated surfaces must remain wet for at least 60 seconds [one minute] followed by adequate draining and air drying. Do not rinse.

[Apply to sink tops, countertops, refrigerated³ storage and display equipment and other stationary hard nonporous surfaces by coarse spray.]

TO SANITIZE NON-FOOD CONTACT SURFACES:

To sanitize hard non-porous surfaces, spray 6 – 8 inches from the surface. Treated surfaces must remain **visibly** wet for 60 seconds. Wipe dry with a sponge, mop, or cloth or allow to air dry. Do not use in food preparation, food handling and food storage areas. This product is not to be used on glassware, dishware, cookware or utensils.

[NUGEN® NR-128 can be used in accordance with the U.S. Public Health Service food service sanitization recommendations.]

U.S. PUBLIC HEALTH SERVICE FOOD SERVICE SANITIZATION RECOMMENDATIONS

CLEANING AND SANITIZING: Equipment and utensils shall be thoroughly pre-flushed or pre-scraped and when necessary, pre-soaked to remove gross food particles and soil.

1. Thoroughly wash equipment and utensils in hot detergent solution.
2. Rinse utensils and equipment thoroughly with clean water.
3. Apply use-solution thoroughly wetting surfaces with a coarse spray device by spraying 6 – 8 inches from the surface. Do not breathe spray.
4. Treated surfaces must remain wet for at least 60 seconds [one minute] followed by adequate draining and air drying. Do not rinse.

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.

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

Footnotes:

¹ On hard non-porous surfaces

² When used according to the directions for disinfection

³ Surfaces must be allowed to come to room temperature prior to application of product

⁴ Products with grease claims may not make one-step cleaning claims

⁵ When used according to the directions for sanitization

{SECONDARY CONTAINER LABEL}

NUGEN® NR-128

EPA. Reg. No. 6836-XXX
EPA. Est. No. *(insert EPA Est. No. here)*
Net Contents:
Net Weight:

Active Ingredients:
Poly(hexamethylenebiguanide) hydrochloride6.830%
Didecyl dimethyl ammonium carbonate and didecyl dimethyl ammonium bicarbonate.....5.010%
Other Ingredients:.....88.160%
Total.....100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER

See outer container for Directions for Use

Lonza, LLC
412 Mt. Kemble Avenue
Suite 200S
Morristown, NJ 07960