



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 7, 2023

Desiree Valentin
Regulatory Assurance Specialist
Arxada, LLC
412 Mount Kemble Avenue, Suite 200S
Morristown, NJ 07960
desiree.valentin@Arxada.com

Subject: PRIA Label Amendment – Adding Efficacy Claims
Product Name: Nugen NR-RTU
EPA Registration Number: 6836-445
Received Date: 07/01/2022
Action Case Number: 00376999

Dear Ms. Valentin:

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.

Pursuant to 40 CFR 156.10(a)(6), 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.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process, FIFRA section 12(a)(1)(B). Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Assurance.

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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, please contact Terria Northern by email at northern.terria@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Marcel Howard", written in a cursive style.

Marcel Howard, Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Accepted Label

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 RTU

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

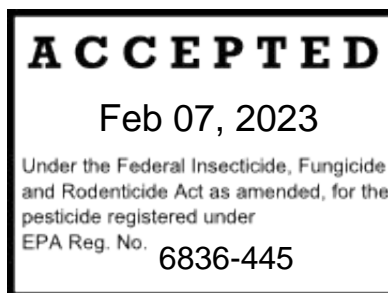
For Home, Commercial, Institutional and Industrial Use
For Food, Dairy, Beverage, Meat, Poultry, Egg and Seafood Processing and Farm Use
For Farm, School, Dairy, Restaurant, Food Handling and Processing Areas, Bar and Institutional Kitchen Use
For use in federally inspected meat and poultry plants
An effective sanitizer for use on food contact surfaces

Active Ingredients:

Poly(hexamethyleneguanide) hydrochloride 0.0534%
Didecyl dimethyl ammonium carbonate and didecyl dimethyl ammonium bicarbonate..... 0.0392%
Other Ingredients:..... 99.9074%
Total..... 100.0000%

KEEP OUT OF REACH OF CHILDREN

Manufactured by:
Arxada, LLC
412 Mt. Kemble Ave
Suite 200S
Morristown, NJ 07960



EPA Reg. No. 6836-445
EPA Est. No. (as indicated on container)
Net Contents: *insert # [disinfecting] [antibacterial] [cleaning] [wet] [multi-purpose] [touch-up]*
Net [Contents] [Wt.] [Weight]: (expressed as avoirdupois pounds and ounces)
[Barcode]
[QR Code]
[Country of Origin (insert country name)]
[Manufactured in (insert country name)]

{Note to reviewer: Pages 2-10 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
- Introducing new
- New
- New and Improved [formula] [disinfecting no-rinse formula]!
- New [disinfecting] [no-rinse [disinfecting] formula]!
- New [no-rinse disinfectant] [and] [food surface sanitizer]!
- New [multifunctional] [dual use] [Complete] food surface antimicrobial
- New [Convenient] [no-leak] [leak-free] Package
- New [Package] [Packaging] [sprayer]
- New EZ [start package] [sprayer]
- New Larger Size
- New Bigger Bottle

MARKETING CLAIMS:

- Ready-to-use disinfectant [and sanitizer]
- 4-minute disinfection
- [With] 4 minute contact times

CLEANING CLAIMS:

- [A] disinfectant [/] [and] sanitizer]
- 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] every day 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 a ready to use liquid.
- 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 sanitizer¹
- Low odor
- Low streak formula
- Tested according to AOAC Germicidal & Detergent test methods for sanitizing previously cleaned food-contact surfaces.
- No rinsing required
- No rinse required [even on] [food contact surfaces]
- No rinse needed
- No-rinse disinfectant formula¹
- No need to rinse
- No sticky residue
- No potable water rinse required on [disinfected] [sanitized] hard, non-porous surfaces
- Rinse free [formula]
- No rinse [disinfecting] [sanitizing] formula¹
- Now cleaning is [easier] than [ever] [before]
- Quick clean-ups.
- The convenient way to keep your home looking “just cleaned”
- Worry free cleaning

ANTIBACTERIAL CLAIMS:

- 4 Minute broad pathogen kill claims including Norovirus¹
- 4 minute acting [disinfectant] [antimicrobial]¹
- 60 second [sanitizer] [sanitization]¹
- 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 one step]
- [Clean and] [disinfect] in just [4] [four] minutes^{1, 2}
- [Clean] [sanitize] and [disinfect] [commonly touched] [household] hard, non-porous surfaces in [just] minutes^{1, 2}
- Cleans and [disinfects¹] [sanitizes⁵]¹,
- Cleans and [disinfects] in one step^{1, 2}
- Convenient 4 minute hospital disinfection¹
- Kills bacteria
- Daily [Surface] [Disinfection] [Sanitizer] [Cleaner]¹
- [Designed] [Built] [Developed] [Formulated] [Engineered] for [disinfecting] [sanitizing] and [cleaning]
- [Designed] [Built] [Developed] [Formulated] [Engineered] for Everyday [disinfecting] [sanitizing] [cleaning]
- [Disinfects] [Can be used][on][in] areas where you prepare food [without needing to rinse][without rinsing]
- [Disinfect] [Surfaces¹] [Your House¹] [Your Kitchen¹] [Your Bathroom¹] [Daily] [Everyday]
- Disinfects surfaces¹ by killing [99.9%] SARS-Related Coronavirus 2 [SARS-CoV-2] [USA-WA1/2020] [in one step]
- Disinfect[s][insert areas of use][insert types of surfaces]

- [Disinfect hard, non-porous surfaces][Can be used on hard, non-porous surfaces] [all around the house] [daily]
- Disinfect areas where food is prepared [or eaten] [without needing to rinse][without rinsing]
- [Disinfect] [Your Desk] [Your Office] [Your Room] [Daily] [Everyday]
- [Disinfecting] Formula
- Disinfect Hassle-free
- Disinfects¹
- Disinfect [commonly touched] [household] hard, non-porous surfaces in [just] 4 minutes[!]¹
- [Disinfect] [airplane] [airliner] [tray[s]] [tray table[s]]
- [Disinfect] any room in the house¹

ANTIBACTERIAL CLAIMS (Cont.):

- Disinfects [without [a] [the] [that] disinfectant smell
- [Disinfectant] [Spray] [Fine] [Mist] [is] gentle on hard, non-porous surfaces, not on germs⁷
- Effective against SARS-CoV-2 [USA-WA1/2020] [in 1 minute]¹
- [Effective against] [Disinfects] [Kills] [99.9%] SARS-CoV-2 virus¹, the cause of COVID-19
- [Effective against] [Disinfects] [Kills] [99.9%] SARS-CoV-2 [virus]¹
- EPA approved for use on food contact surfaces, without requiring [a potable water] rinsing
- [Even] Disinfect[s] areas where you prepare and eat food
- [Everyday] [disinfectant] [disinfecting]
- Everyday [surface¹] [disinfectant] [sanitizer] [cleaner]
- Effective in [disinfecting] [sanitizing] [your] [household] [kitchen] [bathroom] [surfaces¹]
- Effectively disinfects household hard, non-porous surfaces
- Fights the Flu Virus*^{1,9}
- Kills antibiotic resistant bacteria⁸
- Kills the Flu Virus*^{1,9}
- Kills [Community Associated] [Methicillin Resistant Staphylococcus aureus] [CA-MRSA]
- Kill[s] viruses*¹ including the following listed [organisms]: [Coronavirus SARS-CoV-2] [and] [Influenza A Virus [H1N1]] [and] [Hepatitis B] [and] [Hepatitis C]
- [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
- Kills [99.9% of] SARS-CoV-2¹, which causes COVID-19
- Kills 99.9% of [germs⁷] [viruses*] [and] [bacteria] [bacteria and viruses*]
- Kills 99.9% of viruses including SARS-CoV-2 [2019 Novel Coronavirus] on hard, non-porous surfaces
- Great for everyday [disinfecting] [sanitizing] [cleaning]
- Kills bacteria [while it cleans]
- Kills coronavirus⁶ that causes COVID-19
- Kills the coronavirus⁶ that causes COVID-19
- [Kills] [Effective against] the virus⁶ that causes COVID-19
- [Kills] [Eliminates] 99.9% SARS-Related Coronavirus [SARS-CoV-2] [USA-WA1/2020] [causative agent of COVID-19] [the virus that causes COVID-19]¹
- Kills harmful bacteria that grows in the shower/bathroom
- [Kills] [Removes] [Destroys] 99.9%-(*Insert pathogen or pathogens from lists on page 10*) [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] disinfected²
- [Kills] [Removes] [Destroys] 99.999% of [Escherichia coli [E. coli], Salmonella enterica [Salmonella], and Listeria monocytogenes [Listeria] [on food contact surfaces]^{1,5}
- Kills Salmonella enterica²
- Kills the virus⁶ that causes COVID-19
- Kills [the] COVID-19 causing virus^{6,2}

- Kills the virus that can cause COVID-19 [SARS-CoV-2]¹
- [Kills] [Tested and proven effective against] COVID-19 causing Virus⁶ on hard, non-porous surfaces
- Kills [99.9%] [of] *Listeria monocytogenes*
- Kills Norovirus [in] [just] 4 minutes [!]¹
- Leaves hard, non-porous surfaces clean and disinfected²
- Meets EPA criteria for use on food contact surfaces, without requiring [potable water] rinsing
- Reduce risk of cross contamination between treated surfaces 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 boards¹] [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]
- Provides food [contact] surface sanitization and no-rinse disinfection¹
- [Multi-functional] antimicrobial for [food contact][kitchen] hard, non-porous surfaces
- [Disinfect] [Sanitize] [bathroom] [kitchen] [sink[s]] [faucet[s]] [toilet[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] [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] the hard, non-porous surfaces of [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] [car seats] [tables] [tabletops] [counters] [countertops] [appliances] [sinks] [glazed tiles] [light switches] [door handles] [railings] [telephones] [trash] [garbage] [can[s]] [receptacle[s]] [bin[s]]
- [Disinfect] [Sanitize] [sanitize] [your] [dishes] [glassware] [utensils] [plastic cutting boards¹] [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 minutes¹
- [Proven to] kill[s] coronavirus⁶
- [Proven to] kill[s] the virus⁶ that causes COVID-19
- [Proven to] wipe out² 99.9% coronavirus⁶
- Sanitizes (*insert from approved list of pathogens*) in [just] [1 minute] [60 seconds]¹
- The convenient way to disinfect your household hard, non-porous surfaces
- The smart [way to] clean [and disinfect]
- Use NUGEN[®] NR RTU 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 step²
- [With proven] antibacterial action

- Wipes out² 99.9% of COVID-19-causing coronavirus^{1,6}
- Wipes out² 99.9% of [the] COVID-19-causing virus^{1,6}

USAGE CLAIMS:

- For Homes
- For Homes & Institutional Use
- For Commercial Use
- For household surfaces [all around the house] indoor and outdoor¹
- Use NUGEN NR RTU in kitchens, bathrooms and other household areas.
- For [non-scratch] 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 boards¹ [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]
- Multi-purpose¹
- Multi-surface¹
- Specially formulated for use in the [kitchen] [bathroom]

SURFACE SAFETY CLAIMS:

- [Gentle on] hard non-porous surfaces, tough on germs⁷
- [Safe to][Safe for] use on household surfaces¹ such as: *{Must insert specific surface types. See pages 10-11 of master label.}*
- [Safe for] use on [high traffic] [high touch][commonly touched] surfaces¹ such as: *{Must insert specific surface types. See pages 10-11 of master label.}*
- [Safe for] use on surfaces¹ where you prepare [and][or] [eat] food such as: *{Must insert specific surface type. See pages 10-11 of master label.}*
- This formula will not harm [most] surfaces.

VALUE CLAIMS:

- Guaranteed [longer lasting clean] [long lasting clean with fewer sprays] [clean more with less spraying needed] [you'll use fewer sprays to clean more]
- Saves [Labor] time [with 4 minute disinfection] [with 1 minute sanitization]¹
- One spray will get it done
- XX% More [Free] Bonus Size, [Bonus] [Free] [XX-oz] [XX-Ounces] XX for the Price of YY.
- Wide angle [spray][mist] [for efficient coverage] [for effective coverage]

PACKAGING CLAIMS:

- 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:

- Call (*Insert phone number*)
- Cleaning Advice? Visit [insert webpage address]
- Clear drying formula
- Comments?
- Contains No Phosphate
- Convenient
- Do not use for personal cleansing.
- Easy¹⁰ and convenient to store
- Fragrance-free
- If you are not completely satisfied with this product, return it for a refund or replacement.
- [No dyes][,] [No Harsh Fragrances][,][No need to rinse][No rinse]
- No harsh scent
- No [need to] rinse
- Phosphate free
- Quality Guaranteed
- Questions?
- Ready to Use
- Save time with [this product or product name] [!]
- Saves steps
- Saves Time
- This product contains no [phosphates or] phosphorous [compounds].

NUGEN® NR Disinfectant RTU [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 RTU 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 - cleaner which is effective in the presence of 5% serum contamination.
- [Kills] [kitchen¹] [bathroom¹] bacteria.
- Use it on bathroom and kitchen surfaces like countertops, appliances, door handles, light switches, toilets, sinks, and tubs.

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

Use **NUGEN® NR RTU**:

- as a disinfectant on hard, non-porous 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.
- 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] areas¹
- to [disinfect] [sanitize] dishes, glassware, plastic cutting boards¹, cookware and utensils.

May be used on dishes [without rinsing]

May be used on plastic cutting boards¹ [without rinsing]

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

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

Cleaning [and] [or] disinfecting on the go

May be used on eating utensils [without rinsing]

[*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 RTU**:

- | | |
|--|--|
| Bathrooms | Athletic facilities |
| Dens | Banks |
| Family rooms | Banquet Halls |
| Homes [households] | Barber / Beauty shops |
| Kitchens | Beverage processing facilities |
| Living room | Business and office buildings |
| Dental offices | Caterers / Catering facilities |
| Hospitals | Colleges |
| Medical Offices | Correctional facilities |
| Nursing homes | Dairy processing plants |
| 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 | Nursing homes |
| Delivery trucks | [Poultry][Meat/Seafood Packing] Facilities |
| Emergency [Police] [EMS] [Fire] [Rescue] vehicles | Prisons |
| Food trucks | Public facilities |
| Mobile food establishments | Public rest rooms |
| Mobile homes | Salons |
| Ships | Schools |
| Taxis | Shower and bath areas |
| Trailers | Sick rooms |
| Trains | Temporary Food Establishments |
| Transportation terminals | Transportation Centers |
| | |
| | Camp grounds |

{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 RTU** 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	Self-service condiment areas
Appliances	Self-service service ware areas
Bar tops	Showers
Bathroom fixtures	Shopping cart handles
Bathtubs [Fiberglass]	Shopping carts / baskets
Beverage [machine or dispensers] ³	Shower [stalls] [walls]
Booster seats[Dining] Booths	Sinks [bathroom, kitchen]
Broilers ³	Slicers
Cabinets	Storage areas
Cafeteria trays	Stoves [stovetops] ³
Cages	Strollers
Car seat	Tables, [picnic tables] [Dining Tables]
Cash registers	Tanning Beds ³
Chairs	Telephones
Changing tables	Toasters ³
Coffee machines	Exterior Toilet bowl surfaces
Computer keyboards	Toilet seats
Cooking surfaces ³	Touchscreens
Coolers ³	Trays [hospital]
Condiment containers	Tub walls
Counters [countertops]	Tubs
[Bathrooms] [Kitchen] [Restaurant]	Tiles, glazed
Cupboards	Walls
Desks	Trashcans
Diaper changing [tables] [counters]	Trays
Diaper pails	Food Trays
Digital devices	Host/Hostess Stations
Dining tables	Laminated Menus
Dish racks	Lawn chairs
Doorknobs	Beverage Dispensers
Door handles	
Drain boards	Other hard non-porous surfaces made of:
Equipment tables	Acrylic
Faucets	Finished woodwork
Faucet Handles	Formica®
Floors	Glass
Finished floors	Glazed ceramic
Food mixers	Glazed enameled surfaces
Garbage cans	Glazed porcelain
Glass	Metal
Griddles ³	Plastic [such as polystyrene or polypropylene]
Grills ³	Sealed granite
Gym mats	Sealed marble
Hampers	Sealed quartz
Headsets	Sealed stone
Highchairs	Stainless steel
Ice machines [doors][tracks][ice chutes][ice bins][ceiling][wall][ice scoop][ice cube tray] ³	Upholstery- vinyl and plastic
Lab benches	

Linoleum
Light switches
Lunch boxes
Microwave ovens [exteriors]
Mixers
Non-wooden cutting boards¹
Non-Wooden Outdoor [patio] furniture except
cushions and wood frames
Ovens³
Plastic cutting Board[s] ¹
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 RTU [Brand Name] [This Product] is a [one-step] disinfectant, sanitizer, and cleaner tested according to the AOAC Modified Germicidal Spray Test Method
{or}

NUGEN® NR RTU [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]
Staphylococcus aureus - Community Associated Methicillin-Resistant [CA-MRSA] (NRS123) (USA400)
Shigella sonnei [ATCC 25931]
Yersinia enterocolitica [ATCC 23715]
Vibrio cholerae [ATCC 14035]

[Viruses*:]

*Hepatitis B Virus [HBV] [Grimaud Strain]
*Hepatitis C Virus [HCV] [NADL Strain]
*HIV-1 [AIDS Virus] [HTLV-III_B]
*Human Norovirus [ATCC VR-782]
*Influenza A Virus [Influenza] [Influenza Virus] [A/8/68]
*SARS-Related Coronavirus 2 [SARS-CoV-2] [cause of COVID-19]

{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 RTU] [Brand Name] [This Product] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, **[Nugen NR RTU] [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 RTU] [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 RTU is an effective sanitizer for use on food contact, non-hard porous surfaces in 60 seconds against:

Escherichia coli [ATCC 11229]
Staphylococcus aureus [ATCC 6538]
Campylobacter jejuni [ATCC 29428]
Escherichia coli 01 57:H7 [ATCC 35150]
Listeria monocytogenes [ATCC 19117]
Shigella dysenteriae [ATCC 11835]
Salmonella enterica [ATCC 10708]

NON-FOOD CONTACT SANITIZATION CLAIMS:

NUGEN® NR RTU is an effective sanitizer for use on non-food contact, hard-non porous surfaces in 15 seconds against:

Klebsiella 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.

Before use in federally inspected meat and poultry food processing plants and dairies, food products and packaging materials must be removed from the room or carefully protected.

DISINFECTION / VIRUCIDAL*:

Remove visible soil prior to treatment. Use a coarse spray device. Spray 6 - 8 inches from hard, non-porous surface. Allow to remain visibly wet for 4 minutes. Wipe dry with a sponge, mop, or cloth or allow to air dry. Do not breathe spray.

To disinfect food processing facilities: Spray surfaces with solution and allow to remain visibly 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 AND HBV AND HCV 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] or Hepatitis B Virus [HBV] or Hepatitis C Virus [HCV].

Special Instructions for Cleaning and Decontamination against HIV-1 or HBV or HCV 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 or HBV or HCV 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 visibly 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 SURFACES:

{or}

TO SANITIZE FOOD PROCESSING EQUIPMENT AND OTHER HARD, NON-POROUS 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. A pre-clean step is required for food contact sanitization.
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 visibly 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 non-porous 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 15 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 RTU 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.

NUGEN® NR Disinfectant RTU

EPA Reg. No. 6836-445

Submission EPA Label Amendment 2022-07-01

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

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 visibly 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.

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 Handling:

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.

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 Handling: 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

⁶ SARS-CoV-2

⁷ Kills *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and Norovirus

⁸ [Community associated methicillin-resistant *Staphylococcus aureus* [CA-MRSA]]

⁹ Influenza A Virus

¹⁰ See directions for use



Nonfood Compounds
D2

{**Note to reviewer:** The following are optional graphics. Similar representative graphics (for example, different colors) may be added for the final printed label.}



**THE FOLLOWING SECTIONS CONTAIN PROPRIETARY
LANGUAGE AND GRAPHICS.**

**THESE SECTIONS ARE ONLY AVAILABLE FOR
SUPPLEMENTAL REGISTRANTS APPROVED FOR ITS USE.**

{Note to reviewer: Optional proprietary graphics depicting areas for use will require qualified statement " 1 On hard non-porous surfaces"}



{Note to reviewer: The following is an optional, proprietary claim and graphic}

{Section 1}

To Disinfect on hard, non-porous surfaces including food contact surfaces:

Spray 6-8 inches from pre-cleaned surface until visibly wet. Allow product to remain visibly wet on the surface for 4 minutes. If desired, wipe with a clean cloth or paper towel or allow to air dry. No need to rinse.

To Sanitize hard, non-porous surfaces including food contact surfaces:

Spray 6-8 inches from pre-cleaned surface until visibly wet. Allow product to remain visibly wet on the surface for 60 seconds. If desired, wipe with a clean cloth or paper towel or allow to air dry. No need to rinse.

NUGEN® NR Disinfectant RTU:

- No rinse[,] [no sticky residue][,] [No worries]
- [No rinse,] no dyes, no fragrance [, no worries]
- [Thoughtfully] [Expertly] formulated for food contact surfaces
- [Thoughtfully] [Expertly] formulated without dyes [or fragrance]
- [Expertly][Thoughtfully] formulated for use in homes
- Use [with confidence] to kill 99.9% of germs⁷ on hard, non-porous surfaces
- Use [with confidence] for everyday disinfecting²
- Use with confidence [in][on][your] {insert approved areas or surfaces listed on pages 10-11 of master label}
- Use with confidence for everyday germ¹ mess rescue
- Use with confidence to disinfect² the hard non-porous surfaces you touch
- Use [with confidence] on [food contact] surfaces¹
- Tough on germs⁷, but gentle on your hard, non-porous surfaces
- Gentle on hard surfaces, not on germs⁷

Note to reviewer: {Optional proprietary graphics depicting areas for use will require qualified statement " 1 On hard non-porous surfaces"}



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